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Content

EDITORIAL MESSAGE

Pharmaceutical Sciences have witnessed an enormous growth in diverse fields. It is the need of the hour for pharmacists to keep abreast of the current trends, research and practices with respect to the diversities. Nirma University Journal of Pharmaceutical Sciences (NUJPS) aims to publish research in basic as well as applied pharmaceutical science topics; case studies related to Pharmaceutical management, Regulatory affairs, clinical reports and review articles. The major emphasis will be given to publish high quality research papers that follows blind review process. Review process will be transparent and will acknowledge all the beneficiaries involved.

We are glad to launch the first issue of NUJPS. In this issue we have tried to bring forth a blend from different areas of Pharmaceutical Sciences to keep the readers updated about the ongoing research in academia at national and international level as well as opinions & trends from pharmaceutical industries. We are thankful to all the members of national and international advisory board foraccepting our invitation and timely advised in this new initiative of Nirma University.

In this issue we have received two research articles from prestigious US universities namely: 'Strategies to Improve Plasma Circulation of Nanoparticals' by Ameya R. Kirtane, University of Minnesota, Minneapolis and 'Blood-Brain Barrier Permeation of Paclitaxel' by Dr. Vijaykumar Sutariya, University of South Florida. We have also received articles from reputed Indian Pharmaceutical Industries namely: 'Microdosing: A Phase 0 Clinical Trial' by Dr. Jignesh. Patel from Sun Pharmaceutical Industries Ltd, Vadodara; 'Compulsory License in Light of Indian Patent Perspective' by Mr. Sanjaykumar Patel from M/s. Alembic Pharmaceuticals Ltd., Vadodara; 'Identification of a Biomarker: a Necessary Approach in Herbal Industry' by Mr. R. Rajendran, CEO, Green Chem, Bangalore. We have also received articles from prestigious Indian Universities namely: 'Chemometric Assisted Spectrophotometric and HPLC method for the Estimation of Amlodipine Besylate and Telmisartan Marketed Formulations' by Prof. Sadhna Rajput, Dept of Pharmacy, M.S.University of Baroda and 'Holistic Application of Quality by Design (QbD) for Pharma Product Development Excellence and Regulatory Compliance' by Prof. Bhupindersingh Bhoop, Department of Pharmaceutics, Punjab University, Chandigarh.

We are adorably thankful to all invited authors for timely support and valuable scientific contribution in this first issue of NUJPS and also expecting similar contributions in future issues.

We are thankful to all faculty members, Heads of Department and Director, Institute of Pharmacy, Nirma University for support and help rendered to shape this new endeavors.

We are specially thankful to Dr. Anup Singh, Director General, Nirma University for sharing his views and experience, which greatly helped us to reach to present form of NUJPS.

We would also like to express deep sense of gratitude to Management Authorities of Nirma University for their tenacity and enthusiasm in bringing this journal.

Happy Reading!!

Editorial Team.
NUJPS

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INVITED ARTICLE

DEVELOPMENT AND VALIDATION OF HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHIC METHOD FOR SIMULTANEOUS ESTIMATION OF CILNIDIPINE AND VALSARTAN ITS STANDARD MIXTURE USING BOX-BEHNKEN DESIGN

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Abstract

High performance thin layer chromatography (HPTLC) method has been developed for the separation of cilnidipine and valsartan using pre-coated silica gel aluminium plate 60F254, with UV detection at 300 nm. Box- Behnken design was applied for multivariate optimization of the experimental conditions of HPTLC method. Three independent factors: Ethyl acetate content in mobile phase composition, saturation time and migration distance whereas Rf was taken as response which was used to design mathematical models. The predicted optimum assay conditions consisted of toluene: methanol: ethyl acetate: GAA (6:2:2:0.1, v/v/v/v), respectively as the mobile phase. The method was validated according to ICH guidelines.

Keywords: *Cilnidipine, valsartan, HPTLC, Box- Behnken design, validation*

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Introduction

Cilnidipine (CIL) chemically is 3-(*E*)-3-Phenyl-2-propenyl 5-2-methoxyethyl 2,6-dimethyl-4-(*m*-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate (fig. 1a) and Valsartan (VAL) 3-methyl-2-[N-({4-[2-(2H-1, 2, 3, 4 tetrazol- 5yl phenyl] phenyl} methyl) pentanamido] butanoic acid (fig. 1b) both are commonly used to for the treatment of hypertension [1-3].

CIL is official in Japanese Pharmacopoeia (JP) and VAL is official in United States Pharmacopoeia (USP) and Indian Pharmacopoeia (IP) [4-6].

The extensive literature survey revealed that several methods are available such as UV-spectrometry [7-11], RP-HPLC [12-16], UPLC [17], LC-MS [18], HPTLC [19-22] etc. for estimation of CIL and VAL individually or in combination with other drugs. Based on literature survey few analytical methods such as UV spectroscopy (second order derivative and simultaneous estimation) [23, 24] and HPTLC (forced degradation study) [25] method have been reported so far for simultaneous estimation of these drugs in their combined dosage form. However, all reported method lacks systematic study of various factors affecting separation of these drugs and appropriate statistical treatment of obtained data using suitable design of experiment. Hence, it was thought of interest to develop and validate a chromatographic method (HPTLC) using Box- Behnken design.

Now-a-days regulatory authorities are promoting and requesting the application of experimental design approach to understand chromatographic selectivity and support better method control, including method transfer [26]. The main objective of the work to develop and validate (as per ICH guideline) analytical method for simultaneous estimation of afore mentioned drugs with experimental design approach in their standard mixture and provide information on the effect of various factors and their interaction effects on the separation characteristics. The optimization of chromatographic factors like ethyl acetate concentration in mobile phase, saturation time and migration distance have significant effect on chromatographic separation. All these independent factors can easily be optimized using the design of experiments (DOE) that is used to obtain the optimum conditions with good assurance of quality. Design space is generated through experimental design that shows the flexible region in which post approval changes are not required during any of changes in the parameters (ICH Q8 (R2). When one needs to optimize more than one response at a time the use of Derringer's desirability function was first used in chromatography by the scientist Deming; to get better resolution and shorter analysis time as objective functions to get better separation quality [27,28].

The present research was aimed at development and optimization of a new HPTLC method for the simultaneous estimation of CIL and VAL from standard mixture.

Materials and Methods

Materials

Standards of CIL and VAL were obtained from Torrent Research Centre, Gujarat as gift samples. AR grade toluene, methanol, ethyl Acetate, and Glacial acetic acid (GAA) were supplied by Finar chemicals Ltd, Ahmadabad. The formulation available in Japanese market had a label claim of 10 mg Cilnidipine and 80 mg Valsartan. Hence, as per the label claim the standard mixture was prepared using both drugs for their simultaneous analysis.

Instrumentation

Analytical HPTLC Camag Hamilton syringe (100 µL) on pre-coated silica gel aluminium plate 60F254, (10 ×10 cm; E. Merck, Darmstadt, Germany) using a Linomat V Camag (Muttenz, Switzerland) sample applicator. The plates were prewashed by methanol and activated at 60 °C for 2.5 min prior to chromatography. Before the application of sample it was filtered to 0.22 µm Nylon filter. Constant application rate, 0.1 µL/s was applied and the space between the two bands was 10 mm. The slit dimension was kept at 5 x 0.45 mm and 10 mm/s scanning speed was employed. The mobile phase composition of toluene: methanol: ethyl acetate: GAA (6:2:2:0.1, v/v/v/v). Linear ascending development was carried out in 10 x 10 cm twin – trough glass chamber saturated with the mobile phase to a distance of 80 mm. The optimized saturation time for the mobile phase was 30 min at room temperature (25 ± 2 °C) and at relative humidity of 55 ± 5 %. Subsequent to the development, TLC plates were dried in a current of air with the help of an air dryer. Densitometer scanning performed on Camag TLC scanner III in the absorbance mode was tired ait 300 nm to see if there was any difference in the absorptivity. The source of radiation utilizing was a deuterium lamp emitting a continuous UV spectrum in the range of 200- 300 nm. Evaluation was done using linear regression analysis via peak areas. Experimental design (Box- Behnken design), desirability function and data analysis calculations were performed by using Design-Expert ® version 7.0.0.

Preparation of standard stock solutions

Accurately weighed portions of CIL (50 mg) and VAL (50 mg) were transferred individually to amber colored volumetric flasks (50 mL), dissolved and diluted to the mark with methanol to obtain standard stock solutions having concentrations of CIL (1000 µg/mL) and VAL (1000 µg/mL) respectively.

Selection of wavelength for detection

Overlain spectra of CIL (20 µg/mL) and VAL (20 µg/mL) were recorded by scanning standard drug solutions in the range of 200-400 nm against methanol as a blank in UV-Visible spectrophotometer. The optimum wavelength for detection was set at 219 nm from overlain spectrum.

Preparation of standard mixture solution

Accurately weighed portions of CIL (10 mg) and VAL (80 mg) were transferred to

50 mL amber colored volumetric flask, and diluted to the mark with methanol to obtain standard mixture solution having concentration of CIL (200 µg/mL) and VAL (1600 µg/mL) respectively.

Preparation of test solution

Accurately weighed the portions of CIL (20 mg) and VAL (160 mg) and were transferred to 50 mL amber colored volumetric flasks and was sonicated for 10 min to get clear solution and diluted to the mark with methanol and then filtered by Whatman filter paper No. 41 to get the test solution having concentration of CIL (400 µg/mL) and VAL (3200 µg/mL) respectively.

Method optimization using design of experiment (DOE)

Response Surface Methodology (RSM) is a collection of mathematical and statistical techniques useful for the modelling and analysis of problems in which a response of interest is influenced by several variables and the goal is to optimize this response and to understand how the response changes in a given direction by adjusting the design variables. When there is more than one response then it is important to find the compromise optimum that does not optimize only one response. When there are constraints on the design data, then the experimental design has to meet requirements of the constraints.

The Box-Behnken design was specifically selected since it requires fewer runs than a central composite design while working with three or four variables. Box-Behnken statistical screening design was used to optimize the compositional parameters and to evaluate interaction effects and quadratic effects of the mobile phase composition, saturation time and migration distance on the retardation factor (R_f) of the drugs [29]. A 17-run, was set up to standardize the chromatographic conditions which are likely to be employed using Design Expert. Proportion of ethyl acetate in mobile phase (X_1), saturation time (X_2), and migration distance (X_3) were selected as factors. The higher and lower values of factors were selected as mentioned in (Table 1). Retardation factor (R_f) and area of the drug were taken as responses (Y).

The non-linear computer generated quadratic model is given as

$$Y=b_0 \text{''} b_1 X_1 + b_2 X_2 \text{''} b_3 X_3 \text{''} b_4 X_1 X_2 \text{''} b_5 X_1 X_3 + b_6 X_2 X_3 \text{''} b_7 X_1^2 + b_8 X_2^2 + b_9 X_3^2 \text{———-———————————————————(1)}$$

Where, b_0, b_1……. b_9 etc are coefficients.

Method validation [30]

Linearity and range

The aliquots of 1.0, 1.5, 2.0 2.5, 3.0 µL from the standard mixture solutions 200 µg/mL of CIL and 1600 µg/mL of VAL were spotted on TLC plate using spotter that gave 200-600 ng/band for CIL and 1600-4800 ng/band for VAL. The peak areas obtained were plotted against concentration and regression analysis was used to interpret the data. Range is the

interval between upper and lower concentration (amount) of analyte in sample for which it has been demonstrated that the analytical method has suitable level of precision accuracy and linearity.

Precision

Method precision

Method precision was performed by preparing the test solution for six times and 1 µL of each test solution was applied on same TLC plate (400 ng/band of CIL and 3200 ng/band of VAL). Plate was developed and analyzed. The areas of six replicate bands were measured and % RSD was calculated.

Intermediate precision (Reproducibility)

The intraday and interday precision of the proposed method was determined by analyzing mixed standard solution having 400 ng/band of CIL and 3200 ng/band of VAL on the same day and on different days. The results were reported in terms of relative standard deviation (%RSD).

Accuracy (% recovery study)

The accuracy of the methods was determined by calculating recoveries of CIL and VAL by the standard addition method. Known amounts of standard solution of CIL (400 ng/band) and VAL (3200 ng/band) with three different concentrations of standards (320, 400 and 480 ng/band for CIL and 2560, 3200 and 3840 ng/band of VAL) at 80%, 100% and 120% respectively were added to pre-quantified sample solutions.

Limit of detection (LOD) and limit of quantitation (LOQ)

The limits of detection and quantification of the developed method were calculated from the standard deviation of the intercepts and mean slope of the calibration curves of CIL and VAL using the formulae as given below.

$$LOD = 3.3 \times \sigma/S \quad (2)$$

$$LOQ = 10 \times \sigma/S \quad (3)$$

Where, σ = the standard deviation of the response

S = slope of the calibration curve

Robustness

The robustness of an analytical method is a measure of its capacity to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage. Minor changes in mobile phase ratio, chamber saturation time and migration distance were evaluated during method robustness.

Analysis of standard mixture

Standard mixture was prepared because the formulation was not available in the Indian market as it is newly launched combination of drugs. So, the standards of CIL (20 mg) and VAL (160 mg) were taken in mortar and pestle; mixed thoroughly and transferred to 50 mL volumetric flask. It

was then sonicated for 10 min and volume was made up to mark with methanol and filtered with Whatman filter paper No. 41 to obtain the sample stock solution for the determination of 400 ng/spot CIL and 3200 ng/spot of VAL was evaluated using the proposed method and peak area was calculated. The amount of CIL and VAL were determined by fitting the peak area into the respective regression line equations.

Results and Discussion

Optimization of mobile phase using Box-Behnken design

Box–Behnken experimental design is an orthogonal design. Based on the previous trials with chosen solvents the factor levels were decided, which were evenly spaced and coded for low, medium and high settings, as "1, 0 and +1. The experimental parameters and its responses for all the 17 optimized runs are shown in the Table 2. The values of response Y_1 (R_f of Valsartan) and Y_2 (R_f of CIL) ranged from 0.43-0.60 and 0.73-0.81 respectively.

The selection of model for analysing the response was done after comparing several statistical parameters including Standard deviation (SD), R-square values and predicted residual sum of square (PRESS). The model having low SD, higher R-square value and lower

PRESS values were selected. The details of these significant parameters are mentioned in Table 3 which suggested quadratic model was best fit for analysing both the responses. The predicted R-Square of 0.7586 and 0.8627 are in reasonable agreement with the adjusted R-Square of 0.7488 and 0.9633 for Y_1 and Y_2 respectively. The higher value of correlation coefficients signifies an excellent correlation between the independent variables. All the above considerations indicate an excellent adequacy of the regression model.

For estimation of significance of the model, the analysis of variance (ANOVA) was applied. Using 5% significance level, a model is considered significant if the *p*-value (significance probability value) is less than 0.05. The Model F-values of 6.30 and 47.63 retardation factor (R_f) of VALand CIL, respectively, implies the model is significant. Values of "Prob > F" less than 0.05 indicate model terms are significant. Therefore, X_1, X_2, X_3 and X_3^2 are significant model terms for VAL and X_1 and X_2 are significant model terms for CIL.

The mathematical relationship in the form of a polynomial equation generated by Design-Expert® 7.0 software for the measured responses, Y_1 and Y_2, are shown below as equation 1 and 2, respectively.

$$Y_1 = +3.68750 + 0.143\ X_1 - 0.060\ X_2 - 0.066\ X_3 - 6.000\ X_1 X_2 - 5.000\ X_1 X_3 + 4.500\ X_2 X_3 + 0.030\ (X_1)^2 + 7.000\ (X_2)^2 + 3.500\ (X_3)^2 \quad (4)$$

$$Y_2 = +0.352 + 0.092\ X_1 + 2.850\ X_2 + 4.900\ X_3 + 0.000\ X_1 X_2 - 5.000\ X_1 X_3 - 5.000\ X_2 X_3 + 4.000\ (X_1)^2 + 4.000\ (X_2)\ 1.500\ (X_3)^2 \quad (5)$$

The above equations represent the quantitative effect of independent variables (X_1, X_2, and X_3) and their interactions on the responses (Y_1 and Y_2). A positive sign represents a synergistic effect, while a negative sign indicates an antagonistic effect. The theoretical values of Y_1 and Y_2 were obtained by substituting the values of X_1-X_3 into the above equation.

The relationship between the dependent and independent variables was further elucidated using perturbation and response surface plots. A perturbation graph was plotted to find those factors that affect the response most significantly. A steep slope or curvature in a factor shows that the response is sensitive to that factor. A relatively flat line shows insensitivity to change in that particular factor. In case of response Y_1, factors X_3 show a steep slope whereas X_1 and X_2 exhibit slight slope. Whereas in case of response Y_2, factor X_1 shows a steep slope and factor X_2 and X_3 exhibit slight slope. Figure 2 represents perturbation plot for responses Y_1 and Y_2.

Three-dimensional (3D) and contour response surface plots for the measured responses were formed, based on the model polynomial functions to assess the change of the response surface. Also the relationship between the dependent and independent variables can be further understood by these plots. Figure 3 (a) and (b) represents the effect of factors X_1, X_2, and X_3 on the response Y_1 and Y_2.

It could be seen in Figure 3 (a) that the factors X_1, X_2 and X_3 increases, there is no effect on the response Y_1 and in Figure 3 (b), the factors X_1, X_2 and X_3 increases; there is an increase on the response Y_2.

In order to get the best chromatographic performance, the multi-criteria methodology was employed by means of Derringer's desirability function [Figure 4(a)]. Individual desirability functions range from 0 (undesired response) to 1 (fully desired response). If any of the responses or factors falls outside their desirability range, the overall function becomes zero.

Validation of chosen model

After studying the effect of the independent variables on the responses, the levels of these variables that give the optimum response were determined. To perform the optimization of mobile phase that would yield a minimum value of VAL with maximum value of CIL, the three responses were over laid and software generates the overlay plot [Figure 4(b)] using the goals as shown in Table 4. Any point in the overlaid region will satisfy our desired criteria. To validate the model, three such points were chosen as check point 1, 2 and 3 for which the predicted values were: X_1 (1.84, 2.12 and .58), X_2 (29.92, 30.23 and 30.77), X_3 (80, 80 and 70.47) for CIL and VAL respectively. For confirmation, a fresh mixture in triplicate was prepared at the optimum levels of the independent variables, and the resultant mixture were evaluated for the responses. The experimental values obtained for estimation of CIL and VAL are given in the **Table 5**, which were in close agreement

with the predicted values. The % error was less than 10% indicating the good predictability of the chosen model.

Method validation

Linearity

Linear responses were observed in the concentration range of 200-600 ng/band for CIL and 1600- 4800 ng/band for Valsartan. Correlation co-efficient for calibration curve of CIL and VALwere found to be 0.9985 and 0.998 respectively. 3D chromatogram of standard CIL and VALin linearity range is depicted in Figure 5. The results for linearity study of CIL and VALis depicted in Table 6.

The regression line equations for CIL and VALare as following:

y = 4.9614x + 1160.3 for CIL

y = 0.5363x + 945.02 for Valsartan

Where, y= Peak area

x= Concentration in ng/band

Precision

Method precision

The % RSD of method precision of CIL and VAL were found to be 0.4390 and 1.105 respectively.

Intra-day and Inter-day precision

Mean % RSD for intra-day precision of CIL and VAL were found to be 0.423 and 1.213 respectively. The Mean RSD for inter day precision of CIL and VAL was found to be 0.404 and 1.282 respectively.

The % RSD values were found to be <2% indicating that the method is precise.

Accuracy

Accuracy of the method was confirmed by recovery of drugs from their standard mixture by spiking it at three levels. The % RSD of CIL and VAL were found to be 0.3512 and 0.2426, respectively. The data for accuracy of CIL and VAL are depicted in Table 7 and Table 8 respectively.

Limit of detection (LOD) and limit of quantitation (LOQ)

The LOD for CIL and VAL were found to be 2.406 ng/band and 21.04 ng/band respectively. The LOQ for CIL and VAL were found to be 7.292 ng/band and 63.76 ng/band respectively.

The data for LOD and LOQ of CIL and VAL are depicted in Table 9.

Robustness

For change in chamber saturation time by ± 5 min, % RSD for peak area was found to be 0.175 % and 0.478 % for CIL and VAL respectively. For change in mobile phase ratio by ± 0.5 mL, % RSD for peak area was found to be 0.224 % and 0.453% for CIL and VAL respectively. For change in migration distance by ± 5 mm, % RSD for peak area was found to be 0.314% and 0.506 % for CIL and VAL respectively.

Robustness data clearly shows that the proposed method is robust at small but deliberate changes that are shown in Table 10.

Analysis of standard mixture by proposed method

CIL (10 mg) and VAL (80 mg) were taken in mortar and pestle and mixed properly and transferred the powered mixture in to 50 mL volumetric flask. Sonicated for 10 min and made up the volume with methanol up to the mark and filtered. The assay results in **Table 11** which was obtained by using the proposed method for the analysis of a standard mixture were in good agreement with the labeled amounts of CIL and VAL.

Conclusion

The HPTLC method was developed and validated as per ICH guidelines wherein the mobile phase optimization was done using the Box- Behnken design. The optimization of mobile phase using experimental design helped us for better understanding of the effect of one or more factors at the same time on the desired parameters. So, this approach could be time saving and beneficial to study the interacting and most contributing factors affecting separation of CIL and VAL in standard mixture. Based on the results, obtained from the analysis using described method, it can be concluded that the method has linear response in the range of 200-600 ng/band for Cilnidipine and 1600-4800 ng/band for Valsartan. The method shows that the % RSD values of both the drugs from their standard mixtures for precision lies within its corresponding limit of 2. LOD and LOQ values were also low so, detection of drugs in very low concentration was possible using this method. So, it can be concluded that the proposed analytical methods have great promise for simultaneous determination of CIL and VAL in standard mixture.

Acknowledgement

The authors express sincere gratitude towards Torrent Research Centre, Bhat for providing standards of Cilnidipine and Valsartan as a gift samples.

Declaration of conflict of interest

The authors report no conflict of interest.

Table 1: Variables selected in Box – Behnken design

Factors	Variables	Levels		
		Low (-)	Nominal (0)	High (+)
A	Change in amount of Ethyl acetate in mobile phase composition(mL)	1.5	2	2.5
B	Change in saturation time (min)	25	30	35
C	Change in migration time (mm)	70	80	90

Table 2: Box-Behnken design: Independent (X) and dependent variables (Y)

Sr. No.	X1	X2	X3	Y1	Y2
1	1.5	25	80	0.43	0.73
2	1.5	30	70	0.47	0.73
3	1.5	30	90	0.51	0.74
4	1.5	35	80	0.48	0.74
5	2	25	70	0.47	0.76
6	2	25	90	0.47	0.76
7	2	30	80	0.46	0.77
8	2	30	80	0.46	0.76
9	2	30	80	0.46	0.77
10	2	30	80	0.46	0.77
11	2	30	80	0.46	0.77
12	2	35	70	0.51	0.78
13	2	35	90	0.6	0.77
14	2.5	25	80	0.52	0.8
15	2.5	30	70	0.5	0.8
16	2.5	30	90	0.53	0.8
17	2.5	35	80	0.51	0.81

a) X1: Amount of ethyl acetate (mL), b) X2: Saturation time (min) and c) X3: Migration distance (mm) d) Y1: Retardation factor (Rf) of Valsartan, e) Y2: Retardation factor (Rf) of CIL

Table 3: Statistical analysis for measured responses

Model	Co-efficient	Y_1	Y_2
	b_1	+0.143	+0.092
	b_2	- 0.060	+2.850
	b_3	-0.066	+4.900
	$b_{12}(X_1X_2)$	-6.000	+0.000
	$b_{13}(X_1X_3)$	-5.000	- 5.000
	$b_{23}(X_2X_3)$	+4.500	-5.000
	$(X_1)^2$	+0.030	+4.000
	$(X_2)^2$	+7.000	+4.000
	$(X_3)^2$	+3.500	+1.500
Linear	R^2	0.4882	0.9770
	Adjusted R^2	0.3701	0.9717
	Predicted R^2	0.0809	0.9598
	PRESS	0.023	3.874
Quadratic	R^2	0.8901	0.9839
	Adjusted R^2	0.7488	0.9633
	Predicted R^2	0.7586	0.8627
	PRESS	0.044	1.325
Sp. Cubic	R^2	1.0000	0.9917
	Adjusted R^2	1.0000	0.9668
	Predicted R^2	-	-
	PRESS	-	-
2FI	R^2	0.4882	0.9822
	Adjusted R^2	0.3680	0.9715
	Predicted R^2	-0.396	0.9417
	PRESS	0.035	5.622

Table 4: Goals of multi-criteria optimization for each response

Factor and Response	Goal	Lower limit	Upper Limit
Amount of Ethyl acetate	In range	1.5	2.5
Saturation time	In range	25	35
Migration time	In range	70	90
R_f of CIL	In range	0.4	0.5
R_f of VAL	In range	0.7	0.8

Table 5: Validation of chosen model

Variables	Values	Response	Observed Values	Predicted Values	% Error
Check Point 1					
X1	1.84	Y1	0.72	0.75	4.16
X2	29.92	Y2	0.47	0.45	-4.25
X3	80				
Check Point 2					
X1	2.12	Y1	0.77	0.76	1.29
X2	30.23	Y2	0.45	0.46	2.22
X3	80				
Check Point 3					
X1	1.58	Y1	0.71	0.73	2.81
X2	30.77	Y2	0.47	0.46	-2.12
X3	70.47				

Table 6: Results of linearity for CIL and Valsartan

Parameters	CIL	Valsartan
Linearity range (ng/spot)	200 - 600	1600 - 4800
Regression line equation	y = 4.9614x + 1160.3	y = 0.5363x + 945.02
Slope ± S.D. (n= 3)	4.9614 ± 0.0023	0.5363 ± 0.00026
Y- intercept ± S.D. (n= 3)	1160.3 ± 3.619	945.02 ± 3.419
Correlation coefficient (R^2)	R^2 = 0.999	R^2 = 0.998

Table 7: Recovery data of CIL

Sr. No.	Amount taken (ng/band)	Amount added (ng/band)	Area	Amount Recovery (ng/band)	% Recovery	Mean % Recovery
1	400	320	4722.56	717.99	99.72	99.71
		320	4720.44	717.56	99.66	
		320	4724.35	718.35	99.77	
2	400	400	5143.29	802.79	100.34	100.35
		400	5149.4	804.27	100.50	
		400	5138.10	801.74	100.21	
3	400	480	5529.16	880.57	100.06	99.78
		480	5519.02	878.52	99.83	
		480	5502.91	875.27	99.46	

Mean= 99.94
Standard Deviation = 0.3510%
Relative Standard Deviation = 0.3512

Table 8: Recovery data of VAL

Sr. No.	Amount taken (ng/band)	Amount added (ng/band)	Area	Amount Recovery (ng/band)	% Recovery	Mean % Recovery
1	3200	2560	4025.98	5744.84	99.73	99.78
		2560	4037.05	5765.48	100.09	
		2560	4019.56	5732.87	99.52	
2	3200	3200	4375.05	6395.70	99.93	99.88
		3200	4362.49	6372.1	99.56	
		3200	4383.19	6410.90	100.17	
3	3200	3840	4694.55	6991.47	99.31	99.42
		3840	4713.69	7027.16	99.81	
		3840	4689.03	6981.18	99.16	

Mean = 99.69
Standard Deviation = 0.2419
% Relative Standard Deviation = 0.2426

Table 9: LOD and LOQ data

Parameters	CIL	VAL
Standard deviation of the Y- intercepts of the three calibration curves (6)	3.6198	3.4190
Mean slope of the three calibration curves (S)	4.9638	0.6362
LOD = 3.3 × (SD/Slope) (ng/band)	2.406	21.04
LOQ = 10 × (SD/Slope) (ng/band)	7.292	63.76

Table 10: Robustness parameters for CIL and VAL

Sr No.	CIL (400 ng/band)			VAL(3200 ng/band)		
1.	Change in chamber saturation time					
	Normal Condition (30 min)	Changed Condition (25 min)	Changed Condition (35 min)	Normal Condition (30 min)	Changed Condition (25 min)	Changed Condition (35 min)
Area	3129.53	3132.72	3140.26	2590.26	2599.32	2614.86
Mean	3134.17			2601.48		
SD	5.51			12.4414		
% RSD	0.1758			0.4782		
R_f	0.52	0.51	0.53	0.73	0.74	0.77
2.	Change in amount of Ethyl acetate					
	Normal Condition (2 mL)	Changed Condition (1.5 mL)	Changed Condition (2.5 mL)	Normal Condition (2 mL)	Changed Condition (1.5 mL)	Changed Condition (2.5 mL)
Area	3129.82	3132.01	3118.90	2650.38	2662.09	2674.54
Mean	3126.91			2662.337		
SD	7.022			12.081		
% RSD	0.2245			0.4538		
R_f	0.51	0.51	0.52	0.74	0.73	0.74
3.	Change in migration distance					
	Normal Condition (90 mm)	Changed Condition (70 mm)	Changed Condition (80 mm)	Normal Condition (90 mm)	Changed Condition (70 mm)	Changed Condition (80 mm)
Area	3128.44	3130.45	3146.42	2655.48	2653.99	2678.04
Mean	3135.10			2662.503		
SD	9.8519			13.4757		
% RSD	0.314			0.5061		
R_f	0.52	0.50	0.51	0.72	0.74	0.73

Table 11: Estimation of CIL and VAL in standard mixture

Drug	Label claim (mg)	Amount found (mg)	% Label claim
CIL	10	9.90	99.02
VAL	80	79.01	98.77

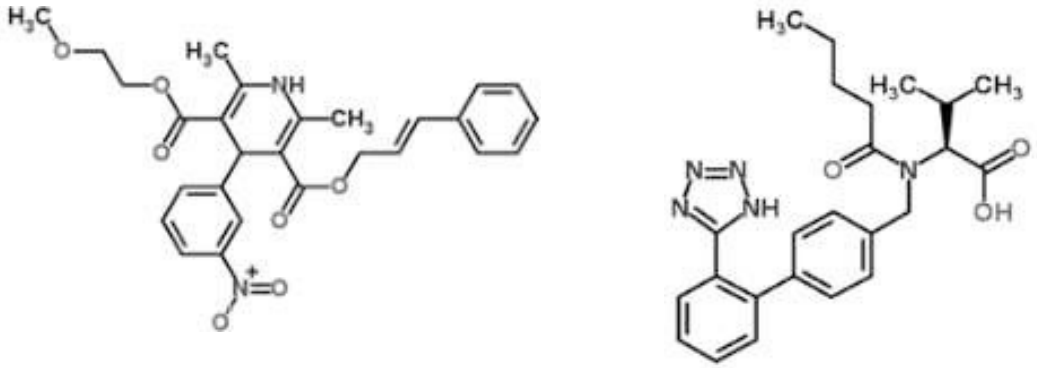


Figure 1: Chemical structure of (a) CIL and (b) VAL

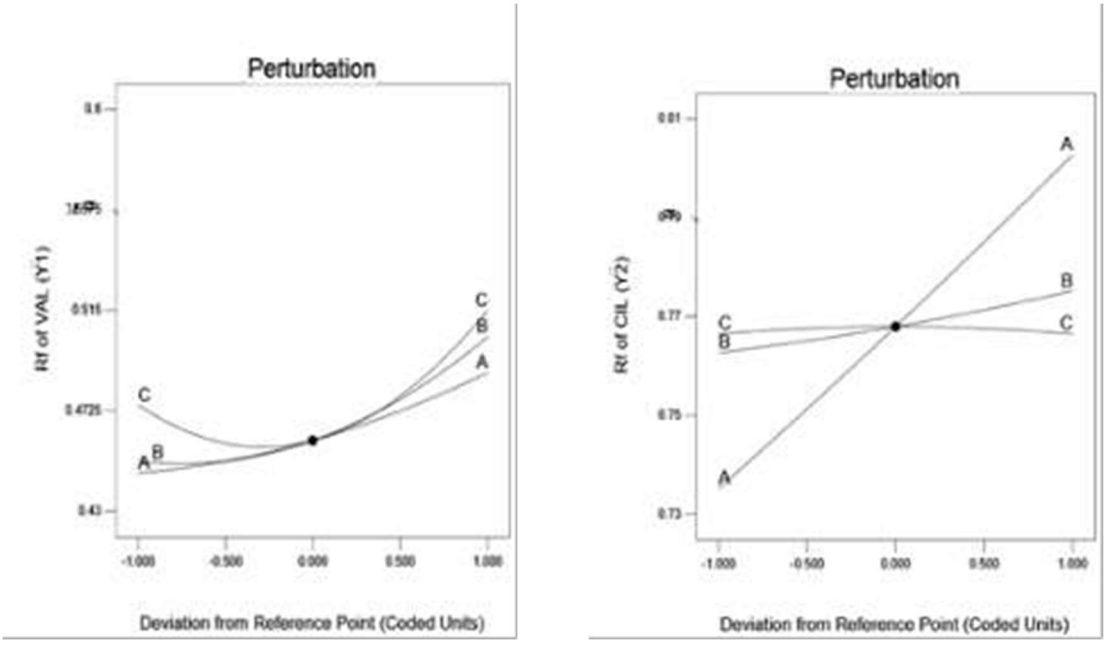
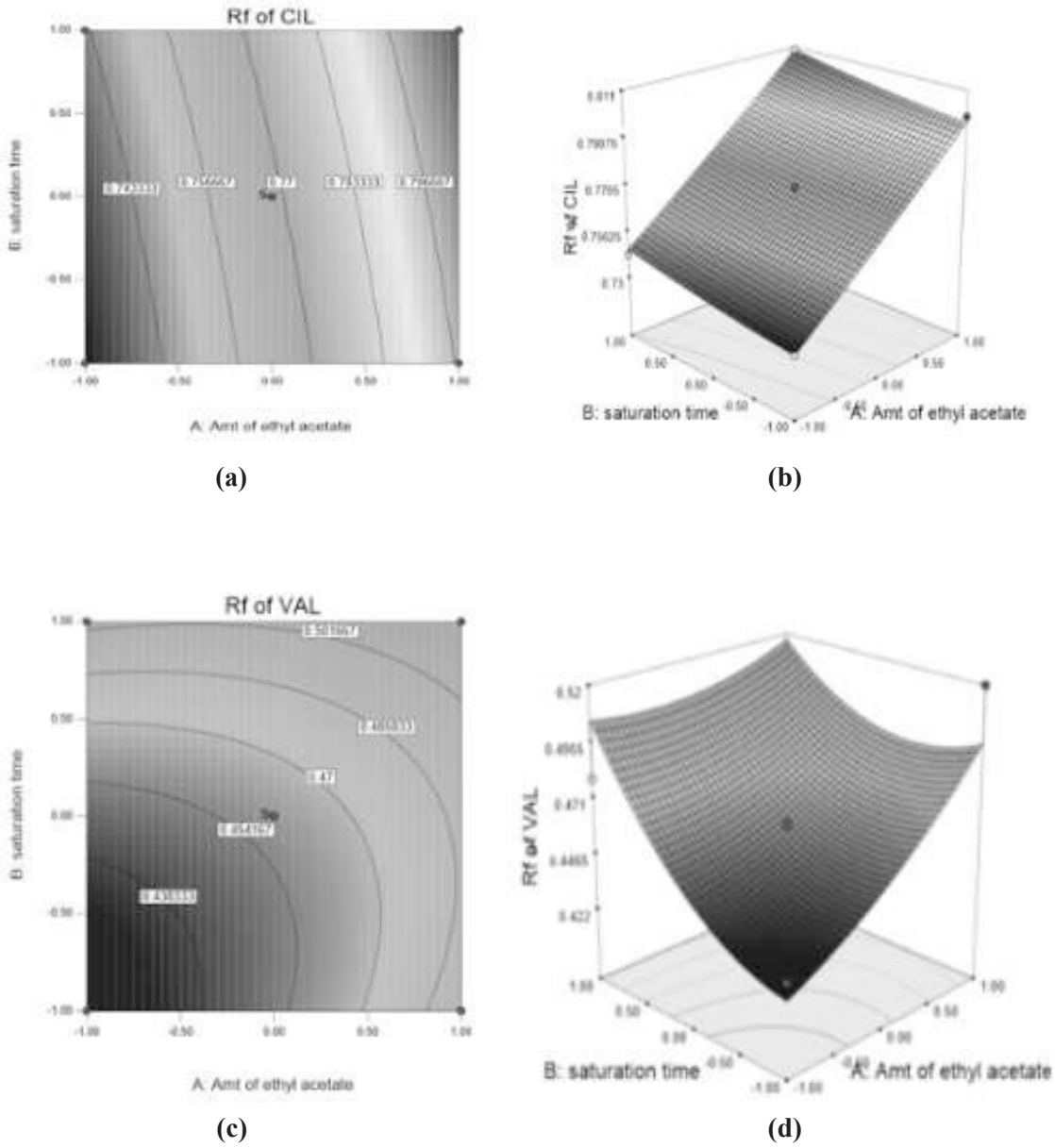


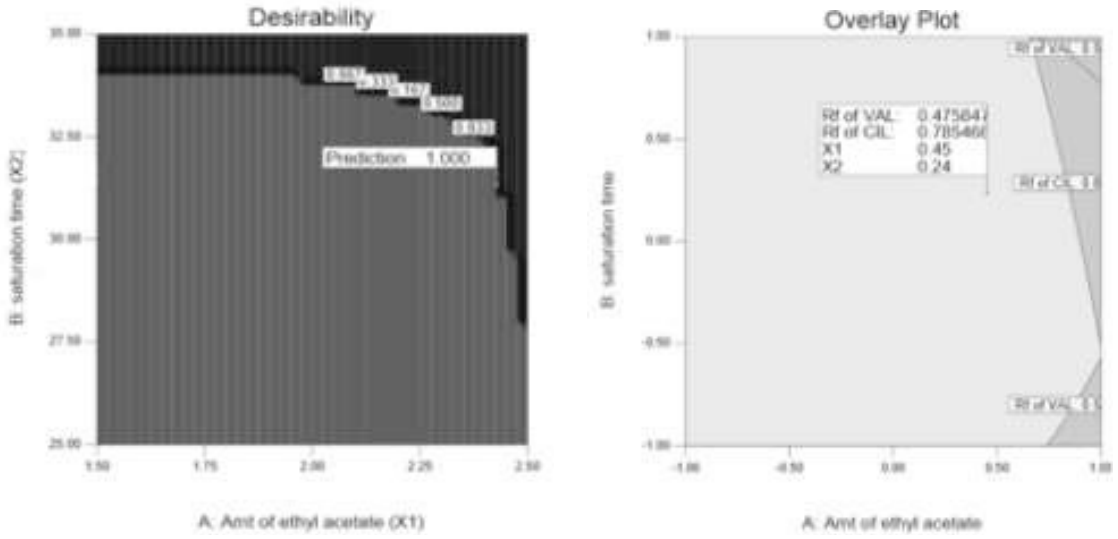
Figure 2: Perturbation graph for effect of individual factor on response (a) Y1 retardation factor of VAL and (b) Y2 retardation factor of CIL



(a) **(b)**

(c) **(d)**

Figure 3: The effect of mobile phase, saturation time, and migration distance on retardation factor in (a) Contour plot and (b) 3D Response surface plot for CIL (c) Contour plot and (d) 3D Response surface plot for Valsartan



(a) **(b)**

Figure 4: (a) Desirability Plot and (b) Overlay Plot of Experimental Design

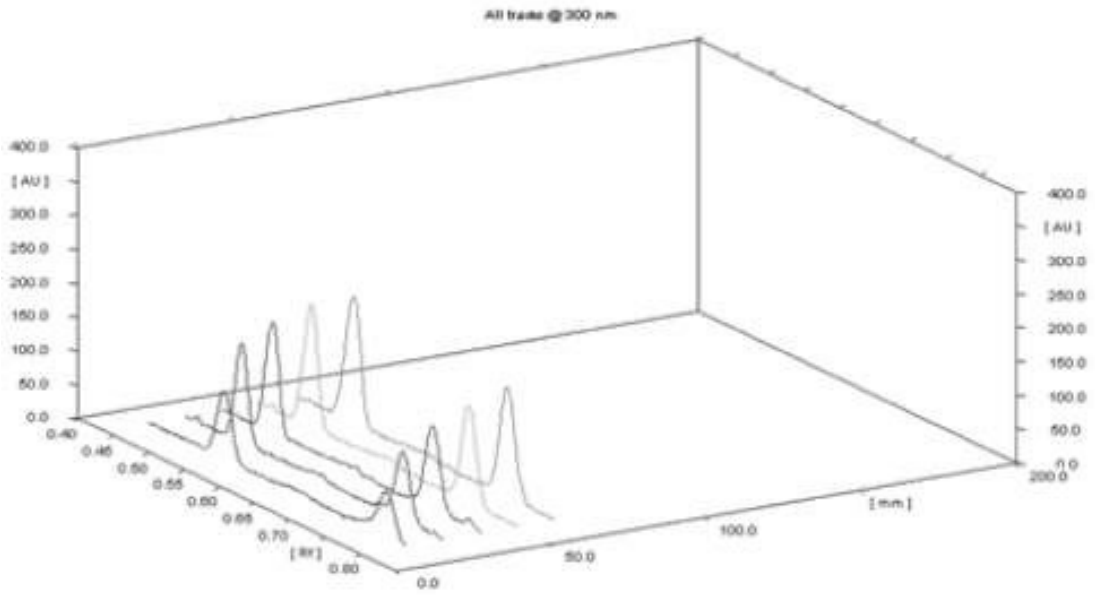


Figure 5: 3D chromatogram of CIL (200-600 ng/band) and VAL (1600- 4800 ng/band)

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INVITED ARTICLE

EVALUATION OF THE ANTIOXIDANT PROPERTY OF THE ETHANOLIC EXTRACTS OF CHONEMORPHA MACROPHYLLA ROOTS

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Abstract

Ethanol extracts of *C. macrophylla* roots were prepared using 50% and 95% ethanol and were named as CMRH and CMRE respectively. Preliminary phytochemical studies were performed and identified the presence of polyphenols and flavonoids. Antioxidant studies of both the extracts were performed using ABTS scavenging assay, DPPH scavenging assay, nitric oxide scavenging assay and lipid peroxidation assay methods. The IC_{50} values of CMRH, CMRE and rutin in ABTS assay were 5.63±0.74, 2.30±0.20 and 3.03±0.06 µg/ml respectively. In the DPPH assay, the IC_{50} values were 71±0.58, 72.33±2.89 and 32.08±0.88 µg/ml respectively. IC_{50} values obtained in nitric oxide scavenging assay were around 1 mg/ml for both the samples. The IC_{50} values obtained in LPO assay were 210±10.0 µg/ml and 230±2.0 µg/ml for CMRE and BHA respectively. The IC_{50} value obtained in LPO assay for CMRH was above 1 mg/ml. All of the above results indicate the antioxidant potential of both the extracts and it can possibly due to the polyphenols and flavonoid antioxidants present in the plant.

Keywords: *C. macrophylla roots, evaluation of antioxidant property, ABTS scavenging assay, DPPH scavenging assay, nitric oxide scavenging assay, Lipid peroxidation assay.*

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Introduction

Plants are being examined closely for new antioxidants, owing to the beneficial health effects of phytochemical antioxidants. Antioxidants through its free radical scavenging activity are expected to protect cells from the attack of free radicals. The consumption of antioxidants containing polyphenols and flavonoids found to decrease the incidents of diseases related to oxidative stress[1]. Excessive oxidative stress has been implicated in the pathology and complications of *Diabetes mellitus*[2]. Free radical action leading to oxidative damage of lipids and DNA is also reported[3]. According to WHO, 65 to 80% of the people of the developing countries depend on medicinal plants for treatment[4]. Use of *C. macrophylla* roots is mentioned in many Ayurvedic preparations[5]. Synonyms of C. macrophylla are *C. fragrans* and *C. grandiflora*. Thus it was decided to evaluate the traditional claims to find a sustainable, ecofriendly, nontoxic and low cost agent for humanity. The flavonoid content in the methanol fraction of the CMRH was determined by aluminium chloride colorimetric assay. The value determined of flavonoid by extrapolation from graph is 24.45 µg/ml equivalent to rutin[6].

Materials and Methods:

Two different extracts of *C. macrophylla* roots were prepared using 50% and 95% ethanol and were used for the studies[6]. The extract prepared using ethanol 50% was named as CMRH and the ethanol 95% extract was named as CMRE. The plants were identified by Dr. K V George, Professor of Botany, CMS College, Kottayam and the voucher specimen number is KRK/UCP/CMS/505.

Preparation of the test solutions:

The standard rutin and the extracts for testing were weighed accurately and separately dissolved in distilled DMSO to get stock solutions of 10 µg/ml. These solutions were serially diluted with DMSO to obtain the required lower dilutions and were used for antioxidant studies.

ABTS assay:

ABTS solution 2mM concentration was prepared in distilled water(100 ml) and added 17 mM potassium persulphate to it(0.3 ml). Potassium persulphate solution (17 mM) was prepared in distilled water. Serial dilutions of stock solution ranging from 100 µg/ml to 1.56 µg/ml of the extract were made using DMSO. The above prepared dilutions (20 µl), DMSO (100 µl) and ABTS 2 mM solution (16 µl) were taken in the wells of 96 well micro-titer plate, mixed and allowed to react. Same volume of DMSO alone was served as blank. The experiment was performed in triplicate. Absorbance was measured after 20 minutes using a micro plate reader at 750 nm against to respective blanks. Control was also performed in a similar manner omitting the test samples[7].

DPPH radical scavenging assay:

DPPH solution100 µM was prepared in methanol. Serial dilutions of stock solution ranging from 1000 µg/ml to 15.6 µg/ml of

the extract were made using DMSO. DPPH solution 200 µl was taken in the wells of the micro-titer plate, 50 µl of each of the test sample or the standard solution was added separately to the wells of the micro-titer plate. Control and blank were performed in a similar way as in the previous assay. The plates were incubated at 37°C for 30 minutes and the absorbance was measured at 490 nm, using a micro plate reader against the respective blanks[8].

Nitric oxide scavenging assay:

Sodium nitroprusside solution 10 mM was prepared in distilled water. Acetic acid 50% and 20% were used to prepare naphthyl ethylene diaminedihydrochloride solution (NEDD, 0.1%w/v) and sulphanilic acid solution (0.33% w/v) respectively. Serial dilutions of stock solutions ranging from 1000 to 15.6 µg/ml of the extract were made in DMSO. The reaction mixture containing sodium nitroprusside (10 mM, 4ml), phosphate buffer saline (PBS, pH-7.4, 1 ml) and the extract in DMSO (1ml) at various concentrations and standard were separately incubated at 25°C for 150 minutes. After incubation 50 µl of each of the reaction mixture containing nitrite ion was added to wells in a micro-titer plate, sulphanilic acid (100 µl) was added, mixed well and allowed to stand for 5 minutes for completion of diazotisation. Then 100µl of NEDD reagent was added, mixed and allowed to stand for 30 minutes in diffused light. The pink colour developed was measured at 540 nm against blanks in a microplate reader. Control experiment was also performed in the same way without the test extract[9].

Lipid peroxidation assay:

Ferric chloride solution 2mM, Trichloroacetic acid solution (50%v/v) (TCA), Thiobarbituric acid solution (0.37%w/v) (TBA) and phosphate buffer (pH-7.4) were prepared in distilled water. Egg lecithin: The egg yolk was separated and washed with acetone until the yellow colour disappeared. The solvent was evaporated to yield a creamy white powder. The powder was dissolved in phosphate buffer, pH-7.4 at a concentration of 3 mg/ml and used for further analysis. Serial dilutions of stock solutions ranging from 1000 to 15.6 µg/ml of the extract were made in DMSO. The reaction mixture containing egg lecithin (1 ml), ferric chloride solution (0.02 ml) and extract or standard (0.1 ml) in DMSO at various concentrations were incubated for 1 hour at 37°C. After incubation 15% TCA (2ml) and 0.37% TBA (2 ml) were added. Then the reaction mixture was boiled for 15 minutes, cooled, centrifuged and separated the supernatant. Transferred 100 µl each of the supernatant liquid to wells in a micro titer plate and the absorbance was measured at 540 nm using a microplate reader against respective blanks[10]. Control experiment was performed in a similar way without the test extract. All the experiments were performed in triplicate.

Statistical analysis:

All the antioxidant assays were performed in triplicate and the results were presented as mean ± standard deviation (SD).

Results:

The results of antioxidant evaluations performed by ABTS, DPPH and nitric oxide scavenging assay are depicted in table1. The IC_{50} values determined for CMRH, CMRE and the known antioxidant rutin were 5.63±0.74, 2.30±0.20 and 3.03±0.06 µg/ml respectively in the ABTS radical scavenging assay studies. In the DPPH assay, the IC_{50} values of CMRH, CMRE and the known antioxidant rutin were 71.0±10.58, 72.33±2.89 and 32.08±0.88 µg/ml respectively. IC_{50} values obtained in nitric oxide scavenging assay method for CMRH, CMRE and rutin were Ã 1000, 923.33±7.5 and 86±2.0 µg/ml respectively.

Table 1: Antioxidant activity of test samples

Samples	IC_{50} ± SD values in µg/ml by methods			
	Nitric oxide	ABTS	DPPH	LPO assay
CMRE	923.33±7.5	2.30±.0.20	72.33±2.89	210 ± 10.00
CMRH	>1000.00	5.63±0.74	71±10.58	> 1000
Rutin	86± 2.00	3.03±0.06	32.08 ± 0.88	-
BHA	-	-	-	230.00 ±2.00

n=3

In the LPO assay the IC50 values of CMRE and the known antioxidant BHA were 210±10.00 and 230±2.0 µg/ml respectively.

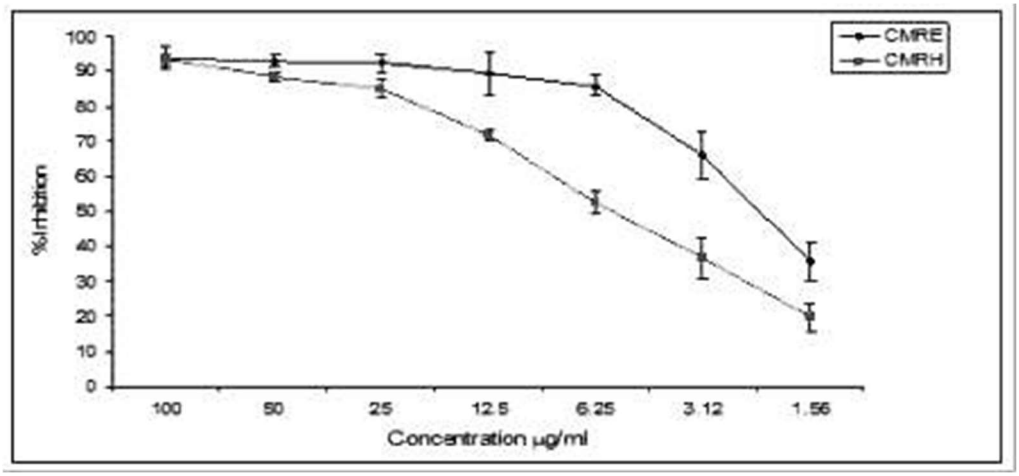

Fig.1 ABTS radical scavenging assay of CMRE and CMRH

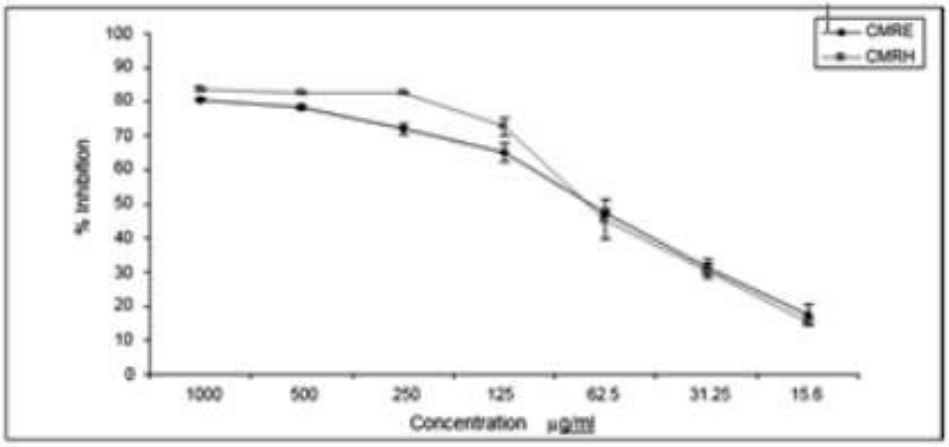

Fig.2 DPPH radical scavenging assay of CMRE and CMRH

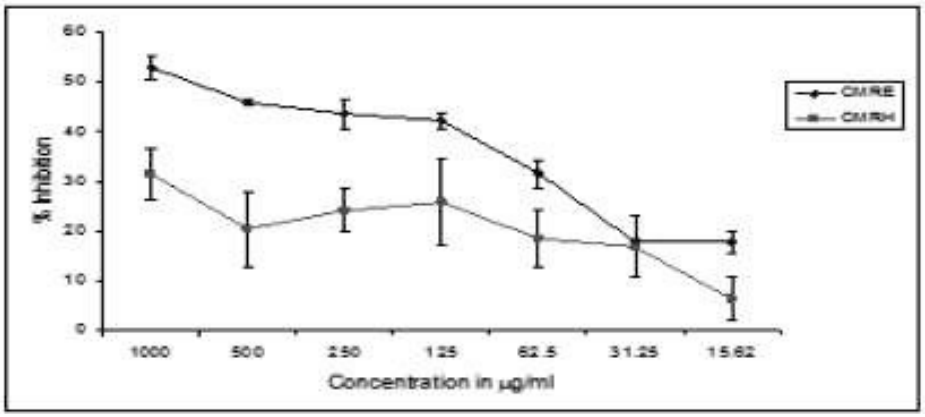

Fig. 3 Nitric oxide radical scavenging assay of CMRE and CMRH

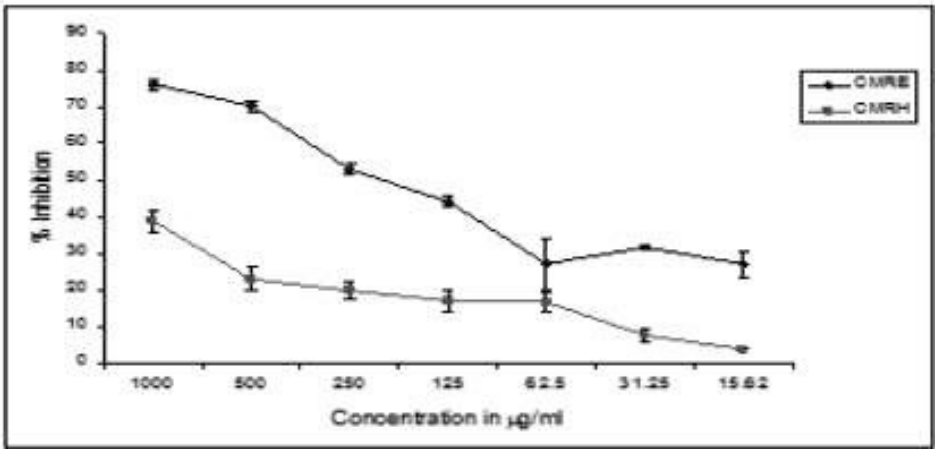

Fig.4 Lipid peroxidation inhibition assay of CMRE and CMRH

Discussion:

Polyphenols are widely distributed in plants are beneficial for human health due to its antioxidant activity through free radical scavenging[11]. Antioxidant activity determination has become one of the important evaluation methods for the neutraceutical and therapeutic effects of traditional medicines[12]. Results of several studies indicate the relationship between antioxidant activity of plant polyphenols and flavonoids[13, 14, 15]. ABTS assay and DPPH assay will work both in the aqueous and organic systems. Thus it can be used to evaluate both hydrophilic and lipophilic antioxidants. In addition to that, the ABTS assay can be performed in a wide range of pH. The hydrogen/electron transfer from the antioxidants to DPPH radical occur in the DPPH radical scavenging assay[16]. In the ethanol 50% extract of *C. macrophylla* root, phenolic and flavonoid content were detected, estimated and reported already[6]. The IC_{50} values of both the extracts and of the known antioxidant rutin were found to be less than 10 µg/ml in ABTS method. The IC_{50} value of rutin was found to be almost half the IC_{50} values of CMRE and CMRH in ABTS method. In the DPPH method, the IC_{50} values of both the extracts and of rutin were found to be less than 100 µg/ml. In the DPPH method, the IC_{50} value of CMRH was found to be less than that of rutin and was found to be more than that of CMRE. The IC_{50} value obtained in the nitric oxide scavenging assay for rutin was around 0.1 mg/ml and that of both the extracts were above 1 mg/ml. In the lipid peroxidation assay method, IC_{50} obtained for CMRE and BHA were around 200 µg/ml and that of CMRH was above 1000 µg/ml.

The results obtained from all the evaluation methods indicate the antioxidant property of both the extracts. The antioxidant effects of both the extracts were comparable with that of rutin in both, ABTS and DPPH methods. In the lipid peroxidation assay, the antioxidant activity of CMRE was almost equal to that of BHA. These results are matching well with the polyphenol and flavonoid content reported earlier[6].

Conclusion:

The results obtained in all the four different methods of antioxidant studies indicate the antioxidant property of both the extracts CMRE and CMRH. The antioxidant property demonstrated can probably be due to the polyphenols and flavonoids present in the extracts. As there are already reported ability of plant polyphenols and flavonoids to prevent DNA as well as cell damage, future studies can be performed to evaluate the anticancer and antidiabetic studies on this plant.

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PT001

Preparation, characterization and evaluation of PEGylated polymeric nanoparticles of anastrazole

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Anastrozole loaded Pegylated polymeric nanoparticles were formulated by Ethanol precipitation method. A Hydrophilic polymer, Poly (ethylene glycol)-5000-monomethylether, was used as a Pegylating agent. Glutaraldehyde and Gelatin was selected as a Cross linking agent and polymer respectively Process variables and formulation variable were optimized to achieve quality product of Pegylated nanoparticles. Mean particle size of anastrozole loaded pegylated gelatin nanoparticles were determined by Malvern particle size analyzer and were 192 nm. Entrapment efficiency was found by RP HPLC (Reverse phase high performance liquid chromatography) method was 63.3± 2.3%. Dialysis bag method was used to determine % drug release. Lyophilization study revealed low concentration of sucrose result the best cryoprotectant for this formulation. MCF-7 cell line in MTT assay was used to perform Cell viability study. Stability study showed that lyophilized gelatin nanoparticles were stable at 2-8°C/ambient humidity for the period of one year ($p < 0.05$). Hence, anastrazole loaded gelatin nanoparticles with small particles size, high drug entrapment and PEG coated nanoparticles were prepared. Hence, anastrazole loaded gelatin nanoparticles with small particles size, high drug entrapment and PEG coated nanoparticles were prepared.

PT002

Nanoformulations: Advent of Novel Strategies for Mammary Carcinoma Drug Targeting and Theranostics

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Mammary cell carcinoma (Breast cancer) is the second most prevalent cancer in females worldwide. Breast cancers count about 25-32% of all female cancers in Indian cities. The advent of novel nanoformulations including organic, inorganic and polymeric nanoparticles, polymeric micelles, dendrimers and lipid based nanocarrier systems (liposomes ,nanoemulsions , microemulsions, Nanostructured lipid carriers), polymer-lipid hybrid nanoparticles, quantum dots have transformed the dosage form designing in oncology. Reduced systemic cytotoxicity and true molecular targeting of chemotherapeutics and diagnostic agents to tumor and tumor vasculature can be achieved by tethering higly specific targeting moieties such as ligands for folate receptor, transferrin receptor Ab , Mab (Trastuzumab), Fab' or scFv HER 2 antibody fragments on nanoformulations using linkers and spacers. Using tumor specific nanoparticles conjugated to antibodies, various biomarkers have been accurately quantified in a single breast tumor section. They can even be utilized for proteome analysis of individual tumor. The tumor specificity, biodistribution, stability of nanoformulation in bloodstream, drug release kinetics, nanoformulation accumulation, cellular internalization and drug release are important paramaters that decide the ultimate efficacy and applicability of these formulations to target tumors or the neovasculature. This review describes the application and the unmet challenges of novel formulation strategies that have been designed for breast cancer targeting and theranostics.

PT003

Preparation and Characterization of S-SMEDDS Containing Flurbiprofen

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Aim of the present work is to prepare solid self-microemulsifying drug delivery system(S-SMEDDS) of poorly water soluble drug i.e. Flurbiprofen with a view to enhancement of dissolution. The solubility of Flurbiprofen was determined in different oils, surfactants and co surfactants to select component of formulation. Pseudo ternary phase diagrams were constructed to identify the efficient self-emulsification region. Nine batches of self-microemulsifying drug delivery system (SMEDDS) were prepared by using Smix(4:1). Optimization was carried out using 3^2 full factorial design. Multiple regression analysis was carried out and response surfaces were obtained. Optimized formulation was selected based on % drug release (PDR) in 30 minutes and droplet size. Optimized formulation was subjected to solidify by adsorbing it on Aerosil 200. Prepared formulations were characterized by different parameters such as droplet size, poly-dispersity index (PDI), drug content and PDR. The dissolution profile of the optimized formulation was compared with the marketed product. The SMEDDS were successfully prepared using Capryol 90 as an oil, tween 80 and PEG 400 were selected as the surfactant and co-surfactant respectively. SMEDDS have shown satisfactory results when evaluated for droplet size, PDI and PDR. S-SMEDDS was also successfully formulated using Aerosil 200 as a carrier. The S-SMEDDS also showed fine droplet size and better dissolution In the aspect of novel drug delivery, day by day new pharmaceutical technologies are developed. Attempt was made to modify the liposomal and similar drug delivery and formulation of novasome was done. Novasomes can be defined as the modified form of liposomes which is 0.1-1.0 micron in diameter containing 2-7 bilayer membranes consisting unstructured space which occupies large amorphous core of hydrophilic i.e. water soluble and hydrophobic i.e. water insoluble drug substances. The two-seven bilayer structure of novasome helps to incorporate both water soluble and insoluble drugs. In the structure of novasome molecule, there is hydrophilic head group attached to hydrophobic tail including long chain of fatty acids, alcohol derivatives, amino acids and glycerol-lipids. The formulating components of novasome are targetting molecule, charge producing agents & non-phospolipid sufactants. Most popular devices for the preparation of novasome are Microfluidizer^R; Microfluidics Corp. (Newton, Mass), “French” type press or other high shear producing devices. The common technologies which are used for the preparation are; ether injection, microfluidization, hand shaking method, reverse phase evaporation, multiple membrane extrusion & sonication. It contain of optimized batch after reconstitution. The S-SMEDDS was filled in capsule to make a deliverable dosage form. The outcome of this study reveals the immense potential of S-SMEDDS for delivery of Flurbiprofen by improving its dissolution profile.

PT004

Novasome- Advances in Liposome and Niosomes

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In the aspect of novel drug delivery, day by day new pharmaceutical technologies are developed. Attempt was made to modify the liposomal and similar drug delivery and formulation of novasome was done. Novasomes can be defined as the modified form of liposomes which is 0.1-1.0 micron in diameter containing 2-7 bilayer membranes consisting unstructured space which occupies large amorphous core of hydrophilic i.e. water soluble and hydrophobic i.e. water insoluble drug substances. The two-seven bilayer structure of novasome helps to incorporate both water soluble and insoluble drugs. In the structure of novasome molecule, there is hydrophilic head group attached to hydrophobic tail including long chain of fatty acids, alcohol derivatives, amino acids and glycerol-lipids. The formulating components of novasome are targetting molecule, charge producing agents & non-phospolipid sufactants. Most popular devices for the preparation of novasome are MicrofluidizerR; Microfluidics Corp. (Newton, Mass), “French” type press or other high shear producing devices. The common technologies which are used for the preparation are; ether injection, microfluidization, hand shaking method, reverse phase evaporation, multiple membrane extrusion & sonication. It contain channels of lipoprotein which acts as a pathway for discharge of targeting molecule. It helps to overcome stability related problem of liposomes in biological fluid and their targeting efficiency. Its modified entrapment efficiency and encapsulation process gives better dosing frequency and applied in various fields like cosmetics, dermatology, chemical, food, personal care, etc. It is the most advanced derma cosmetic technology which expands limits of dermatology. Many researches are going on this technology as an innovation in liposome.

PT005

Niosomal gel as novel drug delivery for ocular fungal infection

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Keratitis is an inflammation of the layers of the cornea associated with bacterial or viral microorganisms that invade into the corneal stromal, resulting in inflammation and ultimately, destruction of these structures. Eye drops are frequently used dosage form in eye infections however such formulation have major drawback such as short duration of action, tear production, non-productive absorption, transient residence time, impermiability of corneal epithelium and multiple dosing. These problems can be minimized by use of Niosomal formulation. Niosomes are bilayer vesicle made up of non-ionic surfactant, having potential applications in the delivery of hydrophobic and hydrophilic drug. Vesicles were prepared by various method such as solvent injection method, bubble method, coaccervation phase separation method, thin film hydration method and trans-membrane pH gradient method. Niosomes can be administered by various route such as intramuscular, intravenous, subcutaneous, ocular, and oral and transdermal. Niosomes are characterized by different parameters such as, particle size, entrapment efficiency, drug content, SEM, TEM and Zeta potential analysis etc. Literature showed that niosomes have highest entrapment efficiency, more stable than liposome, and also sustained or controlled delivery of drug can be obtained by modifying the vesicular structure. Niosomal gel can be formulated using gelling agent to maintain drug localization for extended period of time. Hence niosomal gel may have its potential applications for the treatment of eye disorders then the conventional ocular therapy and also can improve the ocular bioavailability with minimal loss of drug.

PT006

Development and characterization of herbal emulgel in efficacious treatment of alopecia

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Androgenic alopecia (AGA) is a grim problem in most of the individuals irrespective of gender and age. Minoxidil is used in topical formulations for the treatment of hair loss. Minoxidil possesses log P value 1.24 which makes it suitable for encapsulating it in microemulsion globules. Additionally tea tree and neem oil have showed synergistic effect in alopecia. The aim of the present investigation was to evaluate microemulsion comprised of neem:tea tree oil (1.5:1) as a vehicle to develop microemulsion based lotion (MBL) of Minoxidil for the treatment of alopecia. Scheffe mixture experimental design was adopted to optimize the amount of oil (X_1), Smix (Surfactant and cosurfactant) (X_2) and water (X_3) in the microemulsion. The formulations were assessed for globule size (nm) (Y_1) and flux (µg/cm^2/hr) (Y_2). The microemulsion containing 25% oil, 30% Smix and 45% water was selected as the optimized batch. The globule size and flux of the optimized batch were 22.35±2.29 nm and 81.36±10.52 µg/cm^2/hr respectively. Drug containing microemulsion was converted into lotion employing 0.5% w/w Carbopol 934P as a thickening agent. Cuteneous uptake of minoxidil was confirmed by laser scanning microscopy. The optimized lotion showed better penetration, retention and minimal irritation potential in excised rat skin as compared to the commercial solution (MFML). The cumulative amount of minoxidil permeated after 8 h was 26.83±1.08 µgcm^{-2} which implies lesser permeation and greater retention of in to skin to as compared to MFML. It can be concluded that the MBL with herbal oils could be a promising vehicle for hair loss treatment.

PT007

Potential of Novel Vesicular Drug Delivery Systems

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Modification in designing of the drugs in the vesicular system has made beneficial changes to the pre-existing drugs. It improves therapeutic efficacies of drugs by controlling and sustaining the physiological actions. To brought a new life to the drugs, various modified drug delivery systems like niosomes, transfersomes, pharmacosomes, ethosomes, sphingosomes, colloidosomes, herbosomes, novasomes and cubosomes etc. have been developed and check for their efficacies. Each new system achieves advantages over the older vesicular systems, improves therapeutic value and reduces toxicity of given drug. The new decade of vesicular delivery has extend and open new doors of drug delivery by achieving successful modification of various future vesicular systems like cryptosomes, discomes, emulsomes, enzymosome, genosome, photosomes, virosomes, vesosomes, proteosomes etc. It increases the bioavailability and therapeutic value of the drug and finally reduces the adverse effects. The novel pro-vesicular drug delivery, coating of vesicles, layerosomes, ufasomes systems etc. have also been successfully developed having more stabilities in comparison to older vesicular drug delivery systems. They are used for gene delivery, tumor targeting to brain, to increase permeability of drugs. In recent years, the intravesicle route has been exploited either as an adjunct to an oral regimen or as a second-line treatment for Neurogenic bladder. It also used for the delivery of herbal drugs and improves therapeutic response and reduces toxicity. It concludes that, vesicular and or intravesicular drug delivery system might be new promising way of drug targeting in a specific disease.

PT008

Formulation Development and Optimization of Medicated Chewing Gum for Treatment of Oral Candidiasis

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Oral candidiasis is the fungal infection by candida species in mucus membrane of mouth which affects several patients suffering from immuno-suppressed conditions including AIDS, denture stomatitis as well as the side-effects of chemotherapy for cancer. Current treatment of oral candidiasis is available in variety of formulations like buccal tablet, buccal gel, buccal film, buccal spray, ointment, mouthwash, etc.; however, the drug retention time in oral cavity is limited as well as semi-solid formulations like gel and ointment are not patient compliant. Medicated chewing gum (MCG) is comparatively newer concept whereby the drug is delivered in chewing gum, which supposed to be chewed for about half hour to release the drug in oral cavity. Availability of newer directly compressible chewing gum bases has drastically improved the research in field of MCG due to easy adoptability by pharmaceutical industry. Aloze moiety - the most preferred category of antibiotic for such fungal infection, was selected as model drug. Drug particles were coated to achieve taste masking in oral cavity. Excipients of various categories were explored and varied in preliminary trials to study their effects on processing parameters (i.e. micromeritics property) and the formulation parameters (i.e. chewiness and drug release profile). A 3^2 full factorial design was applied to evaluate the effect of concentrations of gum base and softening agent on MCG formulation. Optimized formulation was developed based experimental design and was found to be superior in comparison with conventional formulation. Exhaustive research on MCG may evolve the patient-friendly formulations in market.

PT009

Miconazole Dissolution Enhancement by Preparation of Nanosuspension using Media Milling Technique

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Miconazole is an imidazole derivative and broad-spectrum antifiungal agent has higher efficacy in the treatment of the protozoal and anaerobic bacterial infection of dermal, buccal, and vagina. Miconazole belonging to BCS class II drug exhibits limited dissolution properties because of its poor water solubility which also limits its antifungal effect. In the present investigation, miconazole nanosuspensions is produced to increase its dissolution rate by media milling technique using poloxamer 407 as stabilizer and polystyrene beads as milling media at laboratory scale. Characterization of prepared nanosuspension was done with respect to particle size, poly-dispersity index, zeta potential, differential scanning calorimeter, saturation solubility, dissolution study. Antimicrobial activity of miconazole nanosuspension was compared with coarse suspension by using an agar well diffusion method. Media milling time, concentration of milling media and milling speed show considerable effect on particle size of miconazole nanosuspensions. The *in vitro* dissolution rate of the optimized miconazole nanosuspensions was enhanced (97.63% in 60 min.) as compare to coarse miconazole suspension (42.54% in 60 min.) mainly because of smaller particle size (159.7nm). The results showed that the miconazole nanosuspension also showed superior antifungal activity as well. The nanosuspension of miconazole could be used as prospective drug delivery system to enhance dissolution rate of poorly soluble drug.

PT010

Dry Powder Inhaler for Chronic Obstructive Pulmonary Disorder

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Chronic Obstructive Pulmonary Disorder is a disorder which makes lungs hard to breath. Mainly three categories of drugs are used in COPD which are adrenergic agonists, corticosteroids, cromones and anti cholinergics*. Dry powder inhaler contributes to number of DPI pharmaceutical products due to its unique advantage of being propellant free device.* A dry powder inhaler is the formulation through which drug is delivered to the lungs in the form of dry powder. Most of the formulation consists of micronized drug blended with large carrier particle. Carrier particle used can enhance their flow to reduce aggregation. Most commonly used excipient is lactose monohydrate. When DPI is actuated then formulation gets fluidized and enters into patient air flow where drug particles are separated from carrier particle and are carried deep into lungs. Micronized drug particle size ranges from 1-5 µm to reach peripheral airway. Particles having size larger than 5 µm usually gets deposited in oral cavity and particles smaller than 0.5 µm may not get deposited since they move by Brownian motion and settle very slowly. .Fine particle can determine by different technique like inertial method, light-scattering methods, and imaging methods.

PT011

Study of critical formulation and process parameters influencing mini-tablet formulation using concept of QbD

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Mini-tablets are the tablets having a diameter less than 4mm. Mini-tablets are more advantageous because they are easy to manufacture and has less stability issues when compared with pellets. Mini-tablets are either delivered by filling it in capsule/ sachets or compressed into tablets. The objective of this project is to identify the critical process and formulation parameter influencing manufacturing of mini-tablet containing a model drug by applying concept of Quality by design and also to determine a suitable way to dose the mini-tablets. Initially QTPP was prepared followed by CQA identification and risk assessment to find out Critical material attribute and critical process parameter. Different manufacturing processes were evaluated and wet granulation process was selected based on the obtained data over direct compression and dry granulation process. Mini-tablets were prepared using micro-tip tooling. In WG process a DoE study (Box behnken design) was performed with 3 factors such as Pharmatose 200M:Avicel PH 101 ratio, amount of water for granulation (%) and kneading time (seconds) and responses such as flow properties, particle size distribution, %RSD of weight variation during compression, disintegration time and dissolution @T30 were evaluated. From study it was observed that with the increasing the amount of lactose and binder the granules formed were harder, thus, retarding dissolution. After the Design of experiment study a suitable way of dosing the mini-tablets to patient was evaluated. Mini-tablet in capsule was considered to be the potential approach which has advantages of accurate dosing, added stability due to capsule shell, ease of administration (in case part dosing is to be carried out) and economical approach.

PTB012

Drug Selection Criterion for Oral Sustained Release Formulations

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Controlled dosage formulations are designed so as to deliver the drug in a predetermined and predefined constant rate preferably via zero order kinetics. The time period is mimicked in a manner that it equals the amount of the drug getting eliminated from the body with respect to time. This maintains steady levels of drug in plasma, minimizes fluctuations, improves repeated dosing, associated discomfort and hence, enhances patient compliance and therapy. Various factors that may affect the dosage form design of a controlled release dosage form include; the physicochemical properties of the drug, excipients, the patho-physiological condition to be treated, type of dosage form and the routes of administration. Apart from these several other factors may also be considered such as cost associated, age of patient, type of packaging material, therapeutics, dose etc. Similarly, factors as the methodology to be used, equipments, temperature of formulation, stirring speed; and other environmental and process variables that may somehow react or interact and cause significant or non-significant alterations to the drug affecting the bioavailability and therapeutics. The present article focuses on such parameters that should be considered prior to formulation of oral sustained release dosage forms.

PT013

Formulation and Evaluation of Fast Dissolving Tablet Containing Tadalafil

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Oral Routes Of drug administration have wide acceptance up to 50-60% of total dosage forms. Tadalafil is a BCS class II drug having low solubility and high permeability which is beneficial in case of erectile dysfunction, so it is very important to find appropriate formulation approaches to improve aqueous solubility and bioavailability of poorly aqueous soluble drug. Present study was aimed to enhance the solubility of the tadalafil by encapsulating the drug in to HPβCD by formulating inclusion complexation by kneading method and inclusion complex of drug and HPβCD was prepared and in the ratio 1:1,1:2,1:3 and 1:4 For compatibility study FTIR, DSC and XRD were carried for drug excipients and inclusion complex. This characterization study showed no interaction in drug and excipients. The Fast dissolving tablets of Tadalafil were prepared by direct compression technique using different superdisintegrants like crosspovidone, crosscarmelose sodium, sodium starch glycolate, mannitol use as compression aids, and strawberry as flavouring agent, magnesium sterate as lubricant and talc as glidant. A Total nine number of formulation were prepared and evaluated. The solubility study of drug was evaluated over a period of 48 hr and increasing effect was found with increasing concentration of cyclodextrin. Friability was found less than 1%. The Disintegartion Time for all formulations varied from 38-83 sec. The drug release was found to be more than 90% after 10 min with highest concentration of HPβ-cyclodextrin. It concludes that, the cyclodextrin with hydroxyl group shown better results in solubility enhancement.

PT014

Brain Delivery of Reservatrol Nanostructured Lipid Carriers In situ Gel: Design and Characterization

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The objective of present research work was to investigate the brain specific targeting of nanostructured lipid carriers (NLCs) based in-situ nasal gel of resveratrol for treatment of Alzheimer's disease. Oral administration of resveratrol shows poor bioavailability (only 40%) due to extensive first pass metabolism, which can be avoided by nasal administration of drug. The NLCs of resveratrol were prepared by melt emulsification probe sonication method. The NLC system composed of cetyl palmitate, capmul MCM, acrysol K150, poloxamer 188 and tween 80. The main parameters affecting formulation were identified through Plackett Burman design. Then 2^3 fractional factorial design was employed using drug concentration (X_1:5-10 mg), surfactant concentration (X_2: 50- 350 mg) and solubilizer concentration (X_3: 100-200 mg) as independent variables. Design batches were evaluated for particle size, zeta potential, PDI, entrapment efficiency and drug loading. The optimized batch FD 6 showed particle size 90 nm, zeta potential-21.1, PDI 0.283, drug loading 17.77 and entrapment efficiency 88.86%. Finally NLC was converted into in-situ gel using gellan gum as gelling agent and evaluated. Thus resveratrol NLCs based in-situ gel may be a promising drug-targeting system for the treatment of Alzheimer 's disease.

PT015

In-Vitro Cytotoxicity of Liposomal Artesunate against Breast Cancer Cell Line: First Experience

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Artesunate is well known and prescribed anti malarial agent at present time, but its *in-vitro* and *in-vivo* cytotoxicity profile against various cancer cell lines are also proved by recent researchers. We have investigated and determine its *in-vitro* cytotoxicity in breast cancer cell line (MCF-7) and determine its *in-vivo* release pattern. Cytotoxicity was analyzed by MTT assay. First we prepare and optimize the liposomal formulation and then divided it in three group *ie.* Blank control group (RPMI-1640), negative control group (untreated cells) and liposomal treated group. Cultured metastatic 100 µl ($10x10^6$) MCF-7 cell lines were seeded on 96- well plate and then liposomal formulation in the range of 10- 100µg/ml was added to each well plate, now plate was incubated at 37^0C for 4 hrs to the complete reaction. After reaction purple color formazan were solubilized at 150 µl DMSO at 37^0C for 10 min. The absorbances were measured at 570 nm using microtitre plate reader. The inhibitory concentration (IC_{50}) values were determined from the curve which is plotted between regents concentration verses cell viability at 24 hrs of incubation. In this experiment we interrelated the cytotoxic behavior of drug at breast tumor vasculature and optimized the dose of drug for cancer purpose.

PT016

Formulation and Evaluation of Semisolid Gel Preparation Containing Polyherbal Extracts

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Natural source is one of the most important sources for the herbal drug. Because of its non-toxicity, easily availability and biocompatible nature, the herbal drugs have their own choice in preparation of various dosage forms. In The present investigation the semisolid gel preparation using different herbal extract was prepared in different concentration .The require properties of gel preparation were studied are viscosity, spreadability, pH, diffusion study and antimicrobial activity. Around nine formulations were prepared and among these the optimized formulation was exposed to antimicrobial activity. The gelling agent carbopol 940P was used and form a clear transparent gel. The effect of permission enhancer was analyzed during diffusion study. All results were found satisfactorily and the zone of inhibition for antimicrobial activity shown positive result. The herbal extract of Nirgundi (Vitex Negundo), Gulvel(Tinospora cordifolia), Lodhra (Symlocus Racemosa), Haldi (Curcuma Longa), Neem (Azadirachta Indica) were used. At Last, it concluded that, herbal medicine is promising alternative and best solution in treatment of various diseases.

PT017

Prospects of Continuous Manufacturing in Pharmaceutical Industry

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Pharmaceutical industry is excelling in the discovery of many new chemical actives as well as development of innovative and generic products. All these products are manufactured by means of batch processing and it is well behind many other industries which are using continuous processing at a greater efficiency and yields. In majority of modern industries continuous manufacturing has gradually replaced traditional batch manufacturing. There are inherent desires in industry for continuous process from start-to-finish production lines to provide improved efficiencies and cost optimisations without compromising on quality of products. Continuous manufacturing processes offers high efficiency, better quality and reduced resources which has been evolved as an efficient alternative for achieving higher productivity, decreased variations in quality, higher yields and profitable processes with lower costs. Continuous processing technologies provide one possible path forward for the industry to reduce the cost of manufacturing with the objective to convert selected unit operations and processes from batch to continuous mode along with appropriate real time characterization using state of the art process analytical technologies. Need for Continuous processing has helped to set up new in-process monitoring and controls. The FDA has also supporting continuous manufacturing and laid down Quality by design (QbD) approach as per ICH guidelines. Process Analytical Technology (PAT) is an integral part of QbD. This will help manufacturer to develop new efficient tools for use during development, manufacturing and quality assurance. There has been introduction of innovative equipment and processing polymers to support continuous processing technology.

PT018

Microballoons: A Novel Approach in Gastro-Retention Floating Drug Delivery System (FDDS)

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Oral controlled release dosage forms face several physiological restrictions like inability to retain and position the controlled drug delivery system within the targeted region of the gastrointestinal tract (GIT) due to fluctuation in gastric emptying. This results in non uniform absorption pattern, inadequate medication release and shorter residence time of the dosage form in the stomach. As the fallout of this episode there is inadequate absorption of the drug having absorption window predominantly, in the upper area of GIT. These contemplations have provoked to the development of oral controlled release dosage forms with gastroretentive properties. Microballoons (Hollow microspheres) hold certification as one of the potential approaches for gastric retention. Microballoons are spherical empty particles without core and can remain in the gastric region for delayed periods. They significantly increase the gastric residence time of medication, thereby enhance bioavailability, improves patient compliance by reducing dosing frequency, lessen the medication waste, enhance retention of medication which solubilize only in stomach, enhance solubility for medications that are less soluble at a higher pH environment. In the present review preparation methods, characterization, advantages, disadvantages, mechanism of drug release from microballoons, applications and list of the drugs formulated as microballoons are discussed.

PT019

Microencapsulation: A Review

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The present review covers the detail methods used for microencapsulation techniques. The microencapsulation technique firstly developed in paper industry in 1931 and then it developed in pharmaceutical use for gelatinized coating. The microencapsulation technique developed for mainly stability of the pharmaceutical ingradient from various contaminating agents, and protecting from environment. The microcapsulae is a micron sized particle having active pharmaceutical ingradient as a core which is covered with inert polymeric coating material employing various physicochemical, mechanical technique for encapsulation. Mechanism and Kinetics of Drug Release from microcapsule which give specific pharmacological action are Diffusion, Dissolution, Osmosis, Erosion. The microcapsules can be classified according to mechanisms drug release from microspheres are Degradation controlled monolithic system, Diffusion controlled monolithic system, Diffusion controlled reservoir system, and Erosion while morphologically Mononuclear (core-shell), Polynuclear, Matrix encapsulation. The various techniques for The preparation of microcapsule are two Physical methods which includes Air-suspension coating, Coacervation and microencapsulation, Simple coacervation, Complex coacervation, Aqueous phase separation,Organic phase separation Rapid expansion of supercritical fluids, Gas anti-solvent (GAS), Particles from gas-saturated solution, Centrifugal extrusion, Pan coating, Spray Drying, Spray congealing. And Chemical methods include Solvent evaporation, Polymerization, Interfacial polymerization, Emulsion polymerisation. The review also covers the advantages of microcapsule and concludes the microencpasulatrion technology is far more in developing stage and can be challenging in pharmaceutical field as may be emerging in supportive role as nanotechnology develops in pharmacy.

PT020

In-Situ Nanoprecipitation: A Revolutionary Approach for Design of Solid Lipid Nanoparticles of Etravirine

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Nanocarriers present major advantages of enhanced safety and efficacy of drug molecules by altering its pharmacokinetic and pharmacodynamics properties. The industrial manufacturing feasibility of nano drug delivery technology (nanocarriers) is limited due to several shortcomings such as high input of energy, substantial use of organic solvents, multiple steps, instability, difficulty to process heat labile drugs, difficulty in scalability and higher cost. In the present investigation we present *in-situ* SLN of Etravirine (an antiretroviral drug) wherein these shortcomings were overcome. *In-situ* SLN of Etravirine is intelligent extrapolation of nanoprecipitation technique. The formulation development comprised of mixing of solvent component A containing drug, lipid, surfactant with an aqueous Component B. The components are ready sterilized by filtration through 0.22 micron membrane filters. Among several lipids evaluated, lipid which gave average particle size range 300-350nm with a wide size distribution was selected. The optimized formulation of Etravirine *in-situ* SLN exhibited high entrapment efficiency >90% and colloidal stability 2 hr. In-vitro characterization like FTIR, DSC, XRD and SEM were performed. Stability was confirmed as per ICH guidelines. Wide particle size distribution ranging from 30-1000nm with an average particle size 350 nm reproducibly suggested the possibility of particle size based targeting to multianatomical HIV reservoirs with larger particle >200nm accumulating in RES organs like liver, spleen, lung, kidney and the smaller particle <200 accumulating in remote sites like brain, bone marrow and genital organs. *In-situ* SLN presents simple technology for the development of SLN of etravirine with the prospects of targetting multiple HIV reservoirs.

PTB021

Formulation Development of a Novel Polymeric Chewing Gum Base for Drug Delivery

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Medicated chewing gum consists of a masticatory gum base which gives the chewing gum its "chew." Conventional chewing gums use elastomers as a major portion of gum base which are resistant in environment and thus become a persistent pollutant. The present work focuses on developing a novel gum base made of hydrophilic polymers such as Polyvinyl acetate, Pectin and Polyvinylpyrrolidone along with lauric acid, calcium carbonate, glycerol triacetate and formulating the chewing gum by adding glycerine, sorbitol, fillers and flavouring agents to the varying proportions of gum base to develop an optimized formulation. A model drug was incorporated to the final formulation to study the drug release profile. The gum base was characterized Differential Scanning Calorimetry (DSC), Fourier Transform Infrared Spectroscopy (FTIR), and Scanning Electron Microscopy (SEM). The results indicate that the gum base can further be optimized by substituting the polymers used or using a combination of various polymers to obtain a formulation which may be given commercial as well as environmental acceptance.

PT022

Posaconazole loaded nail drug delivery developed by plastibase technology in treatment of Onychomycosis

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Onychomycosis is a widespread nail disease affecting nail plate and nail bed covering 14 % of population globally. The aim of the present work was to develop and characterize nail drug delivery system for Posaconazole, an antifungal drug. The success of Posaconazole is limited due to its poor aqueous solubility. A microemulsion based system was developed and subsequently incorporated into gel prepared by novel plastibase technology. The microemulsion containing 4.0% oil, 40.0 % Smix, and 56.0% water was selected as an optimized batch. The drug loading capacity and mean globule size of optimized batch were 18.23 mg/ml and 63.34 nm, respectively. *Ex vivo* permeation studies were undertaken using bovine hoof (for nail plate) and human cadaver skin (nail bed). Drug–excipient incompatibility was studied by diffused reflectance FTIR. Microemulsion-based Posaconazole gel (MBPG) revealed better penetration and retention in human skin as well as bovine hoof relative to plain gel of Posaconazol (PGP). The spherical shape of globule was confirmed by Transmission electron microscopy. MBPG revealed better activity against *Trichophyton rubrum* and *Candida albicans* than PGP. Short term stability studies showed that MBPG was stable at refrigeration and room temperature for 3 months. Confocal Laser Scanning Microscopy (CLSM) of the developed formulation exhibited remarkable penetration in the target site. In a nutshell, microemulsion based gel prepared by plastibase technology could be a hopeful approach in Onychomycosis as far as therapeutic and organoleptic properties are concerned.

PT023

Orifice Ionic Gelation Technique: Formulation and Evaluation of Mucoadhesive Microcapsules of Antianginal Drug

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Scientist increasing interest to develop mucoadhesive microcapsules by orifice ionic gelation technique for novel drug delivery system to mask the bitter taste of drug, prolong the intimate contact time at the application and absorption site, prolonging the drug release, achieve the controlled the drug release and drug targeting. So the aim of the present research works to formulation and evaluation of mucoadhesive microcapsules of ranolazine (RNZ) as an antianginal agent by orifice ionic gelation technique using different concentration of mucoadhesive polymer like sodium alginate (SA), hydroxyl propyl methyl cellulose (HPMC), methyl cellulose (MC), sodium carboxy methyl cellulose (Na-CMC) and carbopol. The prepared mucoadhesive microcapsules formulations were characterised for study of surface morphology and size by SEM analysis, percent yield, percent encapsulation efficiency, percent mucoadhesive strength and *in-vitro* drug release. Fourier transformer infrared spectroscopy indicates no significant drug polymer interaction. F2 mucoadhesive microcapsules formulation was 500 µm in size, large spherical, good flow and showed 85% highest percent encapsulation efficiency. Mucoadhesive microcapsules showed *in-vitro* drug release for prolong period of time with highest percent mucoadhesive strength at 8 hrs. So F2 mucoadhesive microcapsules formulation of SA and MC was found to be suitable for enhancement of bioavailability of drug and to develop controlled release product.

PT024

Oral Delivery of Anticancer Agents: Recent Nano-Targeting Strategies

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Generally, intravenous route was considered to be the most preferred route for administration of anticancer agents. Intravenous administration leads to rapid onset of action and complete bioavailability of drugs. On the contrary, this route of administration offers several drawbacks like, toxicity to normal tissues, hospitalization of the patients, discomfort of injection, poor patient acceptability, etc. In order to overcome the aforementioned problems, attempts were going on towards the development of oral administration of anticancer agents. Oral administration of anticancer agent will lead to improvement in quality of life of patients, reduced cost of treatment, improved patient acceptability, etc. However, oral administration of anticancer agents offers several challenges because of poor solubility of anticancer agents, reduced bioavailability, inter-subject variability, etc. To overcome these challenges several approaches have been investigated by scientific community. This includes modulation of P-gp, use of biconjugates, microparticulate, solid dispersion, and nanoparticulate carrier systems. Amongst these, nanoparticulate drug delivery systems have been proved to effective due to their good targeting abilities and improved oral absorption of drugs. This paper will highlight some of the breakthrough nano-based technologies that emerged as a milestone in the field of oral administration of anticancer agents for the treatment of cancer.

PT025

Use of Natural Gums in the Preparation of Colon Specific Drug Delivery System of Metronidazole

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Natural gums or polysaccharides are amongst most commonly used excipients due to their economy, safety, easy availability and mandability. This study explored the use of three natural gums namely xyloglucan (XG) (extracted out from tamarind gum), tamarind gum (TG) and locust bean gum (LB); as a colon specific polymer. Different drug : excipient ratio were studied in the preparation of colonic drug delivery employing Metronidazole as a model drug. Colon specificity of these polymers was found in the formulation of colon targeted tablet of the Metronidazole (100 mg), in the magnitude of Tamarind gum< Locust bean gum < Xyloglucan. In vitro characterization of the proposed delivery proven the efficiency of xyloglucan as colon targeted polymer since it protected drug from being released under conditions mimicking mouth to colon transit. X-ray studies in human volunteer with barium sulphate as a tracer in matrix tablet prepared with xyloglucan as matrixing agent and xyloglucan mucilage as a granulating agent was representative of the final formulation and protected the tracer from being released in the stomach and small intestine. On entering the ascending colon, the tablets commenced to release the tracer indicating the digestion of the gum by the enzymatic action of colonic bacteria. The tablet eroded in the ascending colon resulted in distribution of released tracer in the ascending colon. It was concluded that xyloglucan is a potential carrier for drug targeting to colon.

PT026

Formulation and Evaluation of Microencapsules of Ranolazine by Inotropic Gelation Technique

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Microencapsulation is emerging technology to dissolve the desired drug in the polymeric matrix that have potential for the development of controlled release of drug delivery systems. Ranolazine is an antianginal agent used in treatment of ischemia or heart pain. This research article emphasis on microencapsules contain ranolazine were prepared by ionotropic gelation method with the help of different concentration of coat materials. Then characterized the microencapsules for particle size and surface morphology by scanning electron microscopy, percent yield, percent entrapment efficiency and percent cumulative drug release profile. Fourier transformer infra red microscopy indicated no significant interaction between core and coat. The formulation (F1) microencapsules formulation found to be of good flow with particle size 500µm and depicted prolonged percent cumulative release of drug up to 96.28% at 8 hours. Therefore, Ionotropic gelation method has potential application in delivery of drug and enhancement of bioavailability.

PT027

Formulation, Optimization, Characterization and *In Vivo* Anti-Ulcer Evaluation of Esomeprazole magnesium trihydrate Gastroresistant Microspheres

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The objective of the present study was to prepare gastroresistant microspheres of Esomeprazole magnesium trihydrate (EMT) so as to prevent its degradation in acidic environment of stomach. EMT loaded gastroresistant microspheres were prepared using HPMC Acetate Succinate (HPMCAS) as the gastroresistant polymer by 'non-aqueous solvent evaporation' or 'O/O emulsion solvent evaporation' technique. Based on the principle of Design of Experiments (DoEs), a 3-factor 3-level factorial design was used to optimize EMT: HPMCAS ratio, concentration of Span 80 and stirring speed with respect to percent entrapment efficiency and particle size. FTIR study indicated compatibility between drug and polymer. DSC study revealed that the drug was molecularly dispersed in the polymer. The optimized batch showed 49.63±1.23% drug entrapment and 170.12±3.36 µm particle size. SEM study showed that microspheres were spherical in shape**.** *In vitro* drug release study showed only 4.28% drug release in simulated gastric media in 2 hr and 93.46±1.20% release in simulated intestinal media after 1 hr from optimized batch of microspheres. *In vivo* anti-ulcer activity demonstrated that EMT loaded microspheres were able to significantly reduce ethanol induced ulcer formation in rats' stomach as compared to aqueous solution of EMT. The results of this investigation conclusively show that the developed gastroresistant microspheres of EMT prevented drug release in acidic environment of stomach which would lead to a significant improvement in its intestinal absorption.

PT028

A Panorama on Dry Powder Inhaler as a Tool for Pulmonary Drug Delivery

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Dry powder inhalers (DPI) are the devices used to augment delivery of drug with little scope of variability. DPI pose numerous merits over other pulmonary drug delivery systems (metered dose inhalers, nebulizers etc.). DPI does not require any propellants nor is it difficult to carry. It also provides direct drug delivery deep into the lungs. Though the name appears to be easy, but this formulation faces numerous challenges, especially patient variability in terms of age, clinical conditions and inspiratory flow. Dry powder inhalers are loose assemblage of micronized drug with large carrier particles. Micronized drug must have a size of 1-5 µm required for deeper lung deposition. Two types of devices, active and passive are used in the inhalation formulation. Passive are breathe actuated while active devices function automatically. In India, several passive devices are available such as Rotahaler, Revolizer, Handihaler, Turbohaler, Aerolizer etc. Its significance can be recognized from the fact that it can be used for the successful delivery of several small molecules such as anti-tubercular, anti-asthmatic as well as for biopharmaceuticals.

PT029

Formulation and optimization of modified release delivery system of Quetiapine fumarate

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A BCS class II drug Quetiapine fumarate (QF) showing pH dependent solubility, and majorly absorbed from upper GI tract was selected as model drug. Gastro-retention combined with microenvironment pH (pH_M) modulation technique was studied. Formulation was developed in the form of multi-unit capsule comprising of two components (i) bilayer erodible plug (EP) and (ii) mucoadhesive alginate beads (MAB). Sustained release (SR) layer of the EP was and MAB were optimized by applying 3 x 2 full factorial design. SR layer was added gas generating agents to float capsule for initial 8h. Independent variables selected for SR layer were HPMC K100LV and Polyox® 303 WSR while that of MAB were Acrypol® 934P and fumaric acid. Responses selected for SR layer were percentage drug release at 2h (Q_{2h}), 8h (Q_{8h}) and erosion time. For MAB, responses were percentage drug release at 2h (Q_{2h}), 8h (Q_{8h}) and mucoadhesion potential. Optimized components were filled into Eudragit® L 100-55 coated hard gelatin capsule body. Optimized capsule formulation showed erosion time of 7.5 h, 57% mucoadhesion potential, and > 90% drug release at 18 h. Surface pH of multilayer alginate beads was measured at regular time interval to ascertain acidic microenvironment. To mimic precise *in vivo* conditions, *in vitro* drug release study was performed using modified bio- relevant dissolution apparatus. *In vitro* drug release kinetic of final optimized formulation was best described by Weibull kinetic model. Short term stability study was performed as per ICH guidelines for optimized batch.

PT030

Design and Optimization of Controlled Release Felbamate Tablets containing HPMC by D–optimal Mixture Design and *In Vitro - In Vivo* Investigations

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Felbamate, an antiepileptic drug, has to be administered multiple times a day in order to obtain proper restorative action against seizures. This leads to poor control over treatment because of fluctuating plasma levels and poor patient compliance. Hence, controlled release HPMC matrix tablets of felbamate were formulated to overcome these drawbacks. The formulation variables were optimized by D-optimal approach which can elucidate the effect of all variables simultaneously in formulation optimization. Results of pre-formulation studies such as DSC and FTIR showed compatibility of drug with the selected excipients. *In vitro* drug release at the end of 2, 8 and 20 h were taken as the response parameters for the optimization study by D-optimal design. The results enabled selection of the formulation with the desired drug release pattern approaching to zero order. The optimized batch was subjected to *in vivo* pharmacokinetic studies in rabbits. The *in vivo* pharmacokinetic studies in rabbits showed extended release of drug up to 24 h. The relative bioavailability of controlled release felbamate tablet was found to be 368.54% when calculated by Kinetica® software. Thus, the felbamate controlled release tablets optimized by D-optimal approach can reduce the dosing frequency, improve therapy and patient compliance.

PT031

Formulation Development and Optimization of Anti Hypertensive Orally Disintegrating Tablet

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Tablet formulations have been the most widely accepted formulation by pharmaceutical industries duet to ease of manufacturing, regulatory compliance and patient acceptability; hence, the research and development in innovative solid oral formulations has always been the priority by majority of pharma companies. Orally disintegrating tablets (ODT) are unique innovative formulation which may be formulated as conventional tablet, but improves biopharmaceutics of drug leading to better therapeutic benefits to patients. ODT disintegrates instantly on patient tongue and enhance the systemic drug absorption through buccal mucosa (avoiding first pass metabolism), as well as the unabsorbed residues moves to upper part of gastro-intestinal track for further absorption. The aim of the present investigation was to formulate and optimize the ODT formulation of model drug (anti-hypertensive drug having reduced bioavailability due to high first pass metabolism). Several formulation excipients like mannitol, micro-crystalline cellulose, cross-povidone, cross-carmellose sodium, sodium starch glycolate, aspartame, magnesium stearate, etc. were explored by varying the proportions. Dry powder mixture which is ready for compression were evaluated for micromeritics properties and the developed ODT formulations were evaluated for tablet properties especially for disintegrating time. Further optimization of ODT were performed to improve the flow properties and reduction of disintegration time. Various process parameters in direct compression like lubrication time compression force, blending time, etc. also explored to optimize the formulation to obtain the desired properties. In conclusion the performance of ODT is significantly affected by type and amount of super-disintegrants as well as by process parameters.

PT032

Formulation and Evaluation of Novel Enteric Coated Mini tablets of a Proton Pump Inhibitor

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In recent era various technologies have been designed in research and development of site specific drug release oral drug delivery system to overcome various physiological difficulties such as variation in gastric retention and emptying time. Enteric drug delivery system is selected for those drugs which are unstable in gastric acid or are effectively absorbed from intestinal neutral and basic environment. Enteric coated minitablets (diameter 3 mm) of a Proton Pump Inhibitor, such as, omeprazole were prepared by direct compression technique. Omeprazole is highly unstable in presence of moisture, heat and organic solvents, hence unnecessary exposure to these can be avoided. Directly compressed minitablets required less coating material compared to granules, due to their constant specific surface area, smooth outer surface and robust mechanical properties. Six batches of core tablets of Omeprazole were prepared using mannitol, sodium carbonate, crospovidone, and magnesium stearate. Prepared core tablets were optimized with respect to hardness, friability and disintegration. Optimized formulation were coated with Methocel E5LV and Eudragit L100 upto 6%, 8%, 10% and 12%, respectively increase in weight. Prepared enteric coated minitablets were evaluated for hardness, friability, weight variation, disintegration time, dissolution and drug content. Batches coated with Eudragit L100 up to 10 % increase in weight gave acceptable evaluation results.

PT033

Development and Characterization of Bioadhesive Ocular Inserts

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Aim of this study was the preparation and characterization of *in situ* gelling ophthalmic inserts of Lomefloxacin Hydrochloride based on bio-adhesive polymers. Inserts were prepared from using various composition of different hydrophilic polymers (κ-carrageenan, HPMC K15M, Locust bean gum, Chitosan and PVP K30) using solvent casting method. The prepared formulations were evaluated for physicochemical parameters, water uptake capacity, mass loss during hydration and *in-vitro* release study. A 3^2 full factorial design was used to investigate the combined effect of two independent variables in the preparation of ophthalmic inserts. The amount of κ-carrageenan (X1) and Locust bean gum (X2) were taken as independent variables and evaluated for various parameters. The prepared formulations showed a positive effect on thickness and bio-adhesive strength. Water uptake capacity was significantly affected by amount of both polymers. X1 showed positive effect while X2 showed negative effect on water uptake. The mass loss during hydration was significantly affected by both polymers negatively. Percentage drug release t90 was found to increase with increase in X1 compared to X2 may be due to formation of more compact matrix. HET-CAM test showed no irritation potential to the eye. Inserts prepared from blend of κ-carrageenan and Locust bean gums were provided good *in situ* gelling behaviour, sustainment drug release of 90% during 10h as well as bio-adhesive properties.

PT034

Formulation Development of Sublingual Film containing Metoprolol Tartrate

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Sublingual region offers an effective and alternative site for systemic administration of drugs due to rich blood supply that ensures rapid introduction of the drug directly into systemic circulation, avoidance of first pass metabolism and pre-systemic elimination in the gastrointestinal region. In the present study, sublingual film of Metoprolol Tartrate is formulated using pullulan as film forming agent. Metoprolol Tartrate is an anti-hypertensive drug. Sublingual films were evaluated for various parameters including in-vitro disintegration time, drug content, mechanical properties namely thickness, percentage elongation and tensile strength, in-vitro dissolution study and taste masking. Film containing 50 mg Metoprolol Tartrate in 5% w/v pullulan solution along with 0.2:1 of PG: polymer ratio produced acceptable in-vitro disintegration time (29 s). As the drug is bitter in taste, taste masking study was carried out using Hydroxypropyl ß-cyclodextrin (HP ß CD). Metoprolol tartrate: HP ß CD at the ratio of 1:1 resulted in complete taste masking. However, it was observed that addition of HP ß CD increased in-vitro disintegration time to 2 min 48s which is due to increased film thickness. Optimization of Metoprolol tartrate: HP ß CD (1:0.5) resulted in acceptable in-vitro disintegration time (45 s) upon addition of 8% crosscarmellose sodium as disintegrant. Complete taste masking was obtained using sucralose along with HP ß CD. The drug content was estimated to be 50mg (100%). Thus, it can be concluded that quick disintegrating sublingual film of Metoprolol Tartrate provides immediate release of drug in the treatment of hypertension.

PT035

Development and Characterization of Microemulsion for Intranasal Delivery of Antipsychotic Drug

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In the present study, microemulsion and mucoadhesive microemulsion containing the antipsychotic drug were developed to increase solubility of the poorly soluble drug in the components of microemulsion and sustained release of the drug was achieved by converting it into the gel form. Formulation was characterized by performing mucosal diffusion, stability and nasal ciliotoxicity study for both microemulsion and mucoadhesive microemulsion. For nasal delivery, a challenge existing in formulation development is the solubilization of poorly water-soluble drug having solubility of 2.8µg/ml and to enhance the brain uptake of the drug in an o/w microemulsion, for making it suitable for intranasal delivery. The optimal microemulsion formulation consisted of Oleic acid, Tween 80:Isopropyl alcohol (IPA) (3:1) and water, with a maximum solubility of the drug up to 92 mg/ml and final formulation didn't exhibit ciliotoxicity in nasal ciliotoxicity study. The optimized formulation in both the form microemulsion and mucoadhesive microemulsion formulation were characterized for drug content, pH, percentage transmittance, globule size, zeta potential with *in vitro* release studies using dialysis bag diffusion technique and *Ex vivo* diffusion study using Standard Franz Diffusion cell. Mucoadhesive microemulsion increases the residence time of drug in nasal cavity ultimately promoting diffusion of drug in the naso-mucosal membrane in sustained manner. So, controlled release of drug with longer duration of action was obtained.

PT036

Formulation and Investigation of Solid Dispersions of Sulfamethoxazole in Sodium Starch Glycolate

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Scientist focused their interest to develop solid dispersion (SD) for enhancement of oral bioavailability of poorly water-soluble drugs. The different solid dispersion formulation of sulphamethoxazole (SMZ) was prepared by kneading method using a water soluble carrier sodium starch co-glycolate (SSG). SMZSD subjected for percent yield, percent drug content, Fourier transformer infra red spectroscopy (FTIR), Differential scanning calorimetry (DSC) and percent cumulative drug release. FTIR and DSC showed alteration in to amorphous form from crystalline phase. $SMZSD_1$ formulation showed 5.0 times increase in dissolution as compare to pure SMZ. Final concluded that SSG potentially enhanced dissolution of poorly soluble drugs by kneading method.

PT037

Formulation and Development of Lyotropic Liquid Crystalline Gel for Topical Delivery of Diclofenac Sodium

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Chronic pain due to inflammatory disorders, adversely affect the quality life of patients. NSAIDs are widely used for symptomatic relief of acute and chronic pain due to inflammation. Topical application of NSAIDs is limited due to poor permeation through stratum corneum. Lyotropic liquid crystals (LCC) prepared from polar lipids can overcome this problem as they resemble the intercellular matrix of the stratum corneum. Furthermore they can improve the solubility of the drug and provide controlled release. Hence the present study deals with the formulation of LCC gel of an NSAID, Diclofenac sodium,using Imwitor 948, glyceryl monostearate and water. The prepared formulations were characterized for organoleptic characteristics, cross polarized microscopy, assay, homogeneity, pH, spreadability, skin irritation test, tissue histopathology, *in vitro* drug diffusion, *ex vivo* drug permeation and *in vivo* pharmacodynamic study. The cross polarized microscopy revealed that the LCC was lamellar in nature. No signs of irritation in skin irritation test and no morphological changes observed in tissue histopathology confirmed the safety of LCC on topical application. *In vitro* drug diffusion study revealed the sustained release of drug from LCC and *ex vivo* drug permeation study showed that higher amount of drug was deposited in skin from LCC as compared to marketed formulation. The drug release from LCC was found to follow Higuchi model. *In vivo* pharmacodynamic study exhibited improved anti inflammatory activity of optimized formulation as compared to marketed formulation which persisted for 24 hrs. The formulation was also found to be stable for 3 months at 25ºC.

PT038

Lipid based Nanocarrier Drug Delivery System

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Nanotechnology is developing exponentially, considering it pharmaceutically; the main objective of developing nanocarriers is targeted drug delivery for achieving the desired therapeutic effect to overcome the diseased condition. The concept of nanotechnology was developed and promoted by Eric Drexler. The lipid based nanocarriers has became one of the advancing approaches for targeted drug delivery system. Lipid based nanocarriers have aroused a new and more efficient as well as compatible targeted drug delivery system. This review consists detailed explanation about lipid based nanocarrier including its characteristics, preparation methodologies and its available formulations. It also contain about Solid lipid nanocarriers SLNs (e.g. polymer-lipid hybrid nanoparticles) , classification of solid lipid nanocarriers for delivery of bioactives. Further review consist of nanostructured lipid carrier (NLC), the lipid nanocarrier that acts as a bioactive carrier system which has been developed to overcome limitations of the solid lipid nanocarriers (SLN). Nanostructured lipid carriers (NLCs) consist advanced nanostructure as matrix of lipid. This nanostructure enhances drug packaging and efficiently incorporates the drug into lipid carrier matrix. In addition, the review also consists of Lipid drug conjugates (LDC) nanoparticle, developed as a solution for low capacity of SLNs to pack hydrophilic drugs at the time of its preparation. High potency hydrophilic drugs which are required in low dose can be incorporated in the matrix of SLNs, low drug packaging was obsereved for other most of the hydrophilic drugs. Overcoming the limitation of SLNs, the LDC nanocarriers were having with higher drug packing capacity. Thus the review consists of detailed explanation and preparation techniques of lipid based nanocarrier drug delivery system.

PT039

Formulation of Aripiprazole Loaded Poly (Caprolactone) Nanoparticles: Optimization and *In vivo* Pharmacokinetics

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In the present investigation, a Quality by Design strategy was applied for formulation and optimization of aripiprazole (APZ) loaded PCL nanoparticles (APNPs) using nanoprecipitation method. The optimization of developed APNPs was done using Box Behnken design keeping entrapment efficiency (%EE) and particle size (PS) as critical quality attributes. Characterization of optimized APNPs was done using DSC, FT-IR, PXRD and TEM studies and they were evaluated for drug release, hemocompatibility and nasal toxicity. PS, zeta potential and %EE of optimized APNPs were found to be 199.2 ±5.65 nm, -21.4 ±4.6 mV and 69.2±2.34% respectively. *In vitro* release study showed 90 ± 2.69% drug release after 8 h and *ex vivo* drug release study across goat nasal mucosa demonstrated sustained drug release. Nasal toxicity study indicated safety of developed formulation for intranasal administration. APNPs administered via intranasal route facilitated the brain distribution of APZ incorporated with the $AUC_{0'!8}$ in rat brain approximately 2 times higher than that of APNPs administered via intravenous route. Moreover, increase in Cmax and decrease in Tmax was also observed which might help in reduction in dose as well as dose related side effects associated with APZ. The results of the study indicate that intranasally administered APZ loaded PCL NPs can potentially transport APZ via nose to brain and can serve as a non invasive alternative for the delivery of APZ to brain.

PT040

Surgical Site Infection: Need of Novel Formulation Strategies

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A surgical site infection (SSI) is a pathological condition that occurs after surgery. The nosocomial infection may be superficial or associated with the implants. Micro-organisms and biofilm is the major cause of SSI. The cultured micro-organisms ranges from omnipresent S*taphylococcus aureus* to methicillin-resistant *Staphylococcus aureus*. SSI accounts for 77% of deaths occurring in infected patients. It accounts roughly more than 15 million cases per year in USA. Although advances have been made in infection control practice through improved ventilation, sterilization procedures, obstacles, surgical procedures and prophylactic antibiotics; SSIs remain a substantial cause with morbidity rate of 3%. Centre for Disease Control and Prevention has commented upon the importance of preparation of patient before surgical procedure and care to be taken during and after the surgeries. Antibiotics administered before the surgical procedures decrease incidence of SSI. Oral antibiotics like Imipenem and Cilastatin, Meropenem, Cefotetan, Vancomycin, Gentamycin, Netilimicin can be used for the treatment of SSI's. Current therapies include topical ointment containing Mupirocin, Bacitracin, Polymixin B, Neomycin and Erythromycin, Povidone-iodine spray, Gentamicin-collagen implants on the site which have been proved to be beneficial. A modification to the current therapy is highly desired and local drug delivery system can prove to be efficient in the field. Novel formulation such as mucoadhesive films impregnated with controlled release microspheres containing antibiotics can avoid the systemic absorption and will allow dose reduction of antibiotic. Thus, novel formulation providing controlled release of antibiotic can be used for treatment or prophylaxis of SSI with improved patient compliance.

PT041

Design, Development and Characterization of Modified Release Technology for the High Dose and Poorly Compressible Drug

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Drugs like Metformin have poor flow and compression characteristics and additionally have a high dose and therefore difficult to formulate as tablets. Co-processing of drug substance and excipient via spray drying can be used for the improving the compressibility of drug substance and simultaneously by selection of proper excipient modified release of the drug can be achieved. Spray drying of drug substance and excipient was performed and resulting spray dried powder was compressed in to tablet and characterization of spray dried powder and tablet was performed. In the formulation different polymers (Methocel®, Klucel®, Natrosol® and Manucol®) were screened as excipient for co-processing with drug substance. These polymers were used in the different drug to polymer ratio(1:0:5, 1:0:3, and 1:0:1) to optimize the concentration of polymer. Spray dried powder was evaluated for percentage yield, moisture content, loss on drying and flow properties. Then this powder was compressed to tablet and was characterized for the hardness, friability, tensile strength and in-vitro dissolution study. Formulation F7 which contains drug and Methocel in 1:0:5 ratio had good flow properties and showed sustained release for 12 hours.

PT042

Bioavailability Enhancement of Febuxostat Using Nanocrystal Approach

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Febuxostat (FEB) is having low aqueous solubility, vulnerability to enzymatic degradation and also presence of food significantly decreases the C_{max} and AUC of FEB as compared to unfed state. Thus, the objective of present study was to develop FEB nanocrystal, using ball milling technology, for improving its bioavailability and eliminate food effect on its bioavailability. Stabilizers, HPMC VLV, PVA, PVP K30, Poloxamer 188 and Soluplus®, were screened on the basis of their ability to stabilize FEB nanocrystals. Preliminary trials were performed to study the effect of various process parameters of milling process. On the basis of results of preliminary trials, effect of stirring time and amount of bead were selected for further systematical optimization using central composite design. Particle size (D50 and D90) and size distribution (SPAN) were taken as responses for the evaluation of design batches. Optimized batch was evaluated for its solid phase characterization using SEM, XRD and DSC which depicted conversion of crystalline FEB into amorphous form. Optimized batch was showing significant improvement in saturation solubility as well as in vitro drug release behavior as compared to pure FEB and physical mixture of pure FEB and stabilizer. In vivo pharmacokinetic study in rat model showed increase in oral bioavailability as well as elimination of effect of food on bioavailability of optimized FEB nanocrystal formulation as compared to pure FEB. The study proved the potential of nanocrystal as potential and versatile approach for bioavailability enhancement of poorly soluble drugs.

PT043

Formulation and investigation of *in-vivo* anti-ischemic activity of anti-anginal drug loaded microspheres in wistar albino rats

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Ranolazine is an antiischemic/antianginal agent employed in therapy of cardiovascular diseases such as myocardial infarction, variant and exercise-induced angina and arrhythmias constipation, headache, nausea and dizziness are the most common side effects. So the aim of the present research work was to formulation characterization and *in-vivo* antiischemic activity of RZ loaded ethyl cellulose microspheres in albino wistar rats. RZ microspheres were developed by oil-in-water (o/w) emulsion solvent diffusion evaporation technique with different ratio of drug and ethyl cellulose as a polymer in order to achieve high entrapment efficiency and prolonged release characteristics. The prepared microspheres were subjected for characterization by scanning electron microscopy (SEM), percent yield, Fourier transformer infra red spectroscopy (FTIR), X-ray diffraction (XRD), percent entrapment efficiency and percent drug release. The size of microspheres formulations (F1 to F6) were in range of 20±1.2 to 54±1.7µm, percent yield 78.21±2.31 to 94.24±1.21%, percent drug entrapment efficiency 53.25±0.65 to 85.76±0.78% and percent drug release 56.87 ± 0.34 to 92.74 ± 0.83 % up to 12 hrs. XRD and IR studies showed no interaction between drug and polymer; no degradation during microspheres preparation and stable at storage conditions. Then compare in-vivo activity of optimized F2 microspheres formulation to standard drug in 120-200g of Albino wistar rats of either sex. The results of present study reflect that successfully prepared free flowing RZ loaded EC microspheres and showed a significant reduction in level of cardiac biomarker LDH and CK-MB enzyme for prolong period of time with respect to standard in isoproterenol induced myocardiac infraction (MI) rats.

PT044

Bioavailability Enhancement of hydrochlorothiazide by solid dispersion technique using novel carrier

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Poor solubility of drug molecules is the major issue in the development of pharmaceutical formulations. The present work is addressed to overcome this issue by developing solid dispersion (SD) of model drug hydrochlorothiazide (HCT). Novel excipient, Crodurate RH 40 is employed in this study with an aim to establish its application in such formulation. Different concentration of the same (sole and in combination with PEG 4000) were used as carrier. Fusion method was used to prepare solid dispersion. Physical, performance and structural characterizations were performed for developed solid dispersion formulation. Crodurate RH 40 (1:1) remarkably increased solubility of HCT equivalent to PEG 4000. FTIR and DSC study of solid dispersion batches containing HCT and Crodurate RH 40 confirmed existence of solid dispersion. The results of short term stability study revealed stable characteristics of formulations. Substantially the problem of aging was not observed from Crodurate RH 40 which is a common problem in PEG 4000. Pharmacokinetics study of HCT SD was performed using New Zealand rabbits. The quantification of HCT from human plasma was made RP-HPLC using double liquid-liquid extraction at 271 nm. Remarkable difference in AUC between HCT SD (3368.24) and HCT suspension (2117.88) was observed. The relative bioavailability of HCT SD and HCT suspension was found to be 159.09%. In a nutshell, Crodurate RH 40 can be successfully used as a hydrophilic solid dispersion carrier in place of problematic conventional carriers.

PT045

Solubility Enhancement of novel analgesic and anti-inflammatory agent for Arthritis

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Solubility is defined as dissolution of solid particles in a saturated solution to give homogeneous system at a certain temprature and pressure. Oral route is the most desirable and peferable for administration of drugs for their systemic effect. Scientists face major challenges related to poor solubility in the development of formulations which are given by oral route. Solubility is important parameter to achieve desired pharmacological response. About 40% of orally administered drugs have poor water solubility. Poorly soluble drug has poor dissolution in GIT, which leads to incomplete and erractic absorption and finally it limits clinical utility. Because of solubility problem, bioavailability of many drugs get affected and hence solubility enhancement becomes necessary. The insufficient dissolution rate of drug is the limitating factor in the oral bioavailability of poorly water soluble compound. Any drug to be absorbed, must be present in the form of solution at the site of absorption.Various techniques are used for solubility enhacement of poorly soluble drug such as physical and chemical modification, micronization, pH adjustment, solid dispersion, nanosuspension, use of superdisintegrant, liquid solid technique, complexation, co-solvency, crystal engineering, salt formation, micellar solubilization, hydrotrophy etc. Selection of solubility enhancement technique depends on drug property, site of absorption and characteristics of required dosage form. Novel anti inflammatory drugs have poor solubility and dissolution which can be enhanced by using suitable technique.

PT046

Sustained Release Thiolated Chitosan Nanoparticulate Ophthalmic Drug Delivery of Prulifloxacin

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The ocular bioavailability of floxacin can be increased by increasing either corneal drug permeation or by increasing the precorneal drug residence time of the drug. Thus, the present investigation was development and characterization of prulifloxacin containing nanoparticulate ocular drug delivery system using thiolated chitosan. Low to medium grade Chitosans were used for thiolation using thioglycolic acid, EDAC HCl and NHS by dialysis at laboratory and analyzed by FTIR, DSC and XRD. The drug loaded nanoparticles were prepared by a modified ionic gelation method using TPP and different processing variables were optimized by particle size and zeta potential. The optimized nanoparticles were characterized by Scanning Electron Microscopy (SEM). Then the optimized drug nanoparticles were loaded in an *in situ* gelling system containing thermosensitive and pH sensitive polymer previously optimized by clarity, gel strength, *invitro* gelling efficiency study. All the batches showed nano range size particles (15 - 225 nm) and displayed spherical smooth morphology. The drug incorporation efficiency was 54.50-96.00%. The gel formulation also exhibited greater mucoadhesive strength which was less affected by temperature, ionic strength and pH of the environment. The *in vitro* drug release profile showed a sustained release over a period of 12 hrs. Optimized formulation with marketed formulation were evaluated for the ocular irritation study, stability study and antimicrobial efficacy study, found nonirritant and stable after three months study and effective. Thus, the combined nanoparticulate *in situ* gel forming system containing thiolated chitosan was found more suitable for sustained ocular drug delivery.

PT047

Consequence of release modifiers on oxcarbazepine release from pellets

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The release of drug from modified release dosage form is critical. The release from the pellets can be modified using pore formers, super disintegrants and swellable hydrophilic polymers. The aim of this study is to get an insight into the release modifying effects of different release modifiers and for that oxcarbazepine pellets were prepared by extrusion spheronization process. To investigate effect of release modifier on oxcarbazepine release from pellets two groups of release modifiers were defined: disintegrants and pore formers. Cross carmellose sodium (CCS) and sodium starch glycolate (SSG) were used as super disintegrant ; sodium chloride as water soluble pore former ; tween 80, polyethyleneglycol 400 (PEG400) and polyethyleneglycol 4000 (PEG4000) as surfactant base pore former and camphor as subliming agent. All of the release modifier-containing pellets showed a faster release compared to the reference pellets. Pellets containing super disintegrant exhibited a much higher drug release compared with pellets containing pore formers due to their surface increasing effects. Among all the pore formers sodium chloride showed slower drug release.

PT048

Preparation and Evaluation of Ibuprofen by solid dispersion Technique

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Ibuprofen (NSAIDS) is poorly water soluble, an 2-(4-Isobutylphenyl)propanoic acid, employed in the treatment of arthritis and rheumatism. Due to the low and erratic levels of absorption, it has poorly water-solubility. Solid dispersions (SD) overcome the limitations that are associated with such type of drug by using aqueous soluble carriers and enhanced dissolution. To enhance the dissolution of poor water soluble drug, solid dispersion was prepared by using solvent method with the help of hydroxyl propyl methyl cellulose (HPMC) polymer as a water soluble carrier. The prepared solid dispersions were evaluated by percent yield and drug content. Fourier transformer infra red spectroscopy was studied for determination of interaction between core and carrier. The rate of drug release was decreased as well as increase in concentration of polymer due to less swelling of higher concentration of HPMC. The *in-vitro* drug release result show that the rate of dissolution of ibuprofen was sustained when formulated in solid dispersion than pure ibuprofen. The final conclusion of this research is that HPMC act as a good release resistor.

PT049

Solubility Enhancement of Valsartan By Using Modified Porous Starch As A Carrier

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The objective of this work was to improve aqueous solubility of poorly water soluble drugs by using modified porous starch as solid dispersion carrier. Solvent exchange method was used to prepare the modified porous starch, where alcohol was used as exchange solvent to avoid contraction and collapse of aquagel due to direct air drying. The yield was found to be 80% .The flow property of the prepared modified porous starch was good. The solubility of Valsartan was increased when solid dispersions were prepared with solvent evaporation method. Other methods used to prepare modified porous starch solid dispersion were kneading method, cogriding method and physical mixture. This was done to compare solubility enhancement achieved by individual technique. The solid dispersions were prepared using solvent evaporation technique, in which drug is mixed with a suitable solvent and the carrier is triturated in a mortar and pestle. Then the drug dispersion is slowly mixed with the carrier and dried. The dried solid dispersion were further evaluated for drug content and drug entrapment and compared with marketed preparation. Thus, this study confirms that modified porous starch can be developed and utilized as carrier to improve the solubility of poorly water soluble BCS class II drugs thereby improving its dissolution rate and bioavailability.

PT050

Design and Development of self-microemulsifying formulation of Nimodipine, a BCS class II drug

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Nowadays self-emulsifying drug delivery systems are in focus by the researchers to enhance solubility and bioavailability of drug due to its potential to keep drug in dissolved state after oral administration. In present research work Nimodipine self-micro emulsifying drug delivery system (SMEDDS) was developed using various oils, surfactants and co-surfactants. Formulation optimization was done using simplex lattice design. Seven batches were prepared and evaluated for emulsification time, globule size, drug release and percent transmittance. Solidification of liquid SMEDDS can be done using Syloid, Neusilin US2, Fujicalin and Avicel PH 102. Solid SMEDDS further evaluated for globular size, emulsification time, DSC, XRD and transmittance. Stability of selected batches was done for 1, 2, 3 and 6 months at room and accelerated temperature. Capryol 90, Crempphore EL and PEG 400 were used as oil, surfactant, co-surfactant respectively. Among the adsorbants, syloid was chosen for solidification. Solid SMEDDS had excellent flow properties and can be filled easily into capsule. Liquid and solid SMEDDS have shown comparable dissolution and showed about 85% drug released within 5 mins and complete drug released within 10 mins. Both the liquid and solid SMEDDS were stable. Thus SMEDDS can be considered as potential approach for delivery of BCS class II and IV drugs.

PT051

Comparative evaluation of Antimicrobial Activity of Topical Products

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Various pharmaceutical and OTC products are available which are either antiseptic, antibacterial and antifungal. These products are supposed to show antimicrobial effect in upper layers of the skin when applied topically. In present work, selected products are evaluated for Organoleptic, Physicochemical properties like pH, spreadability, extrability and Antimicrobial activity by standard I.P procedures. The microbial organisms employed for the study are *Bacillus subtilis, Staphylococcus aureus, Escherichia coli* and *Pseudomonas aeruginosa*. Amongst all topical products, highest antimicrobial activity was observed with Nadoxin cream as compare with standard Gentamycin samples. Minimum activity was observed with Vicco, other products showed the activity against all organisms in increasing order, measured by zone of inhibition produced in suitable media. Cup plate method was followed with positive and negative controls and products with proper dilution in diffusible vehicle were inoculated and incubated plates were observed for zone of inhibition. Nadifloxacin was concluded as most active product. Nadoxin containing Nadifloxacin is a topical fluoroquinolone antibiotic for the treatment of acne vulgaris. Result of antimicrobial activity shows that it is good candidate for topical marketed products as antimicrobial agent having effect on both gram positive and gram negative infection. The study revealed that the label claims of these products can be well justified.

PT052

Nose to Brain Targeting: A Boost to Novel Drug Delivery System

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Brain-an organ of soft nervous tissue being protected by the thick bones of the skull, suspended in cerebrospinal fluid, and isolated from the blood stream by the blood brain barrier, so delivery of drug to the brain is the most outrageous challenge in the existing continuum. Blood brain barrier provide barrier for exchange of small and large molecules, charged molecules, growth factors, and many therapeutic agents used to treat diseases related to brain viz: infectious disease, depression, neurodegenerative disease, brain tumor etc. By novel drug delivery system various efforts were made to furnish the drug across blood brain barrier by exosomes, receptor-mediated permabilitizers, microbubble etc. Olfactory nerve, located within the mucosa of the nasal cavity is the only site where the nervous system is directly contacted with brain so this boot can be utilized for administration of various biomolecules. Among all, nasal route is a secure and credible to procure faster effect, requires low dose of concentration and avoids intestinal metabolism and first pass effect. This route minimizes the lag time, having rapid absorption and onset of action. Moreover, it put up self-medication along patient comfort and patient compliance. This poster discusses the various advantages and mechanism of direct delivery of therapeutic agent, applications and marketed preparation.

PT053

Wound Healing: History, Present & Future Prospective

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A wound is damage in the epithelial integrity of the skin, with disruption of the structure and function of underlying normal tissue. The process of healing is triggered by injury at the tissue; it is divided into four phases, Coagulation & haemostasis phase, inflammatory phase, Proliferative phase, and Remodelling phase. Various factors like medical and therapeutic interventions hinder the process of wound healing. Wound dressings and devices form an important segment of the wound care market worldwide. The variety of wound types resulted in a wide range of wound dressings available in market targeting different aspects of the healing process. Newer dosage form have developed beginning with crude applications of plant herbs like turmeric, aloevera, and honey latest tissue-engineered scaffolds like artificial skin tissue. Reasonable cost and Minimal inconvenience to the patient should be ideal characteristic of the dressing for rapid healing of wound. Improvement in the traditional wound healing formulations resulted in development of newer modern dressing such as gels, hydrogels, thin ûlms and foam sheets, which are classiûed based on materials from which they are produced. Novel techniques can be used for reducing healing time by modifying inflammatory phase and accelerating the proliferative phase. Wound healing formulations like gels are evaluated for gel strength, permeability, drug release, viscosity and spreadability whereas, films are evaluated for mechanical properties such as tensile strength, elongation, bio-adhesion, swelling and in-vitro drug release.

PT054

Design and Development of Alcohol Resistant Controlled Drug Delivery System of Lansoprazole

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Abuse deterrent technology is need for the hour, where number of drugs show premature extraction in stomach in presence of alcohol, leading to erroneous release pattern. From regulatory point of view, it is necessary to develop alcohol resistant drug delivery system to meet therapeutic need of essential API. Lansoprazole is BCS class-II drug, having more hydrophobic part, when comes in contact with alcohol, its solubility increases and gives uncontrolled drug release. Moreover, Lansoprazole is acid labile drug and uncontrolled drug release in stomach gives degradation of drug and loss of therapeutic activity. In present work, alcohol resistant controlled release enteric coated matrix tablet of Lansoprazole was prepared to avoid alcohol induced dose dumping. Prepared formulations were optimised for release retarding polymers' concentrations and enteric coated polymers, in presence of different strength alcohol media, using full factorial design. Optimised formulation gives alcohol resistance with controlled release of Lansoprazole up to 12 hours. Different characterization parameters like hardness, in vitro drug release without and with 5% alcohol, 20% alcohol and 40% alcohol was done. Optimized formulation was compared with reference product, Lansoprazole SR tablet, LANZOL, to prove protection from alcohol dose dumping.

PT055

Vaccines, Herbal and other Therapies of swine flu

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Swine-origin influenza A (H1N1) virus is the causative agent of Swine flu. H1N1 strain was first recognized in month of April 2009 at Mexico and within 2 months it became the first pandemic of 21st century. Swine flu shows symptoms like fever, cough, sore throat, diarrhoea, vomiting, myalgia and joint pains. Antiviral medications like oseltamivir and zanamivir, neuraminidase inhibitor which mainly target the early phase of the infection are available. Now a days two different brands of vaccines – Pandemrix and Celvapan have been developed for all people over six months of age to protect against H1N1 virus. Herbal therapies like *Sambucus nigra*, *Echinacea purpurea*, *Wasabia japonica* and immune enhancers like *Allium sativum*, *Ocimum sanctum* etc. are also available for the same. In short this poster collects the brief information about Swine flu and about their treatments which will help the human population.

PT056

Nano-particulate Approach: A Qualified Treatment for Inflammatory Bowel Disease

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Inflammatory bowel disease (IBD), a grouped term for Ulcerative colitis and Crohn's disease, is a cascade of inflammatory responses of undefined etiology. Either pathogenic or residing luminal bacteria stimulate these inflammatory events. It is characterized by substantial decrease in colonic pH accompanied by disrupted and disturbed intestinal barrier. For a majority of affected people, IBD serves as a lifelong illness. Its therapy aims at bringing flares into a state of remission and maintaining it for long. The conventional treatment is limited in terms of local delivery and employs a threat of systemic absorption of the formulation thereby posing high risks of side effects or adverse drug reactions. The major concern in IBD treatment is local targeting, reducing side effects and achieving deep remissions. Size of the drug delivery plays a crucial role in targeting inflamed colon. A preferential uptake of nano- sized formulation by intestinal mucosa has been proved to be beneficial, thus nano-particulate approach stands as a ground breaking approach for colon targeted drug delivery. Various developments have been made using nano particles as a tool to target the colon for the treatment of IBD. This review put forth various breakthrough advancements employed to achieve successful treatment of IBD with maximum therapy and close to zero unwanted effects.

PT057

QbD assisted development of self-microemulsifying drug delivery system for efavirenz

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Human immunodeficiency virus is a lentivirus that causes acquired immunodeficiency syndrome, a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections. The present investigation is aimed to develop self-microemulsifying drug delivery system (SMEDDs) using cremophore RH 40 to improve solubility and *in-vivo* oral bioavailability of a BCS class II Anti HIV agent efavirenz. The current studies involve systematic development, optimization and evaluation of the SMEDDs of efavirenz employing rational QbD-based approach. The patient prospective quality target product profile (QTPP) and critical quality attributes (CQAs) were remarked. Preformulation studies along with initial risk assessment facilitated selection of lipids: oil phase X_1, surfactant X_2 and the co-surfactant X_3. Simplex Lattice mixture design was applied to optimize liquid SMEDDs using formulation variables. The liquid SMEDDs were evaluated for droplet size, emulsification time, Percentage transmittance, *in vitro* drug release study and pharmacokinetic study. Moreover, Stability study performed at 25°/65% RH and 40 °C/75% RH. The optimized SMEDDs showed best results in terms of smaller droplet size (50.25±0.23 nm), emulsification time (29±2 second) and percentage drug release (86±0.81 % in 60 min). Stability study revealed that optimized batch was stable for 2 months. The rate and extent of drug *in-vitro* dissolution from liquid SMEDDs was significantly higher than Marketed formulation. *In vivo* pharmacokinetic parameters revealed remarkable difference in AUC, C_{max}, t_{max} and K_a of developed formulation and marketed formulation. The results demonstrate the potential of SMEDDs as a means of improving solubility and hence the *in-vivo* oral bioavailability.

PT058

Toxicity: Challenges within Nanoparticles

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The challenges lie within the nanoparticles; the curse of toxicity is hidden in the purse of gifted applications of nanoparticles. Toxicity of nanoparticles is induced via various routes; inhalational being the most significant amongst them. Toxicity arises due to oxidative stress, alteration of homeostasis, gene expression, pro-inflammatory responses, cellular signaling events and their physicochemical properties like increased surface area leading to increased reactivity. The nanoparticle uptake in the cell is by phagocytosis and its recognition is done by toll-like receptors. Mainly the mechanism of toxicity is cytotoxicity which results into cell lysis and apoptosis. The imbalance caused by the nanoparticles in the immune system leads to incidence of autoimmune, allergic, genotoxicity and even neoplastic issues. Regulations regarding the nanoparticle toxicities are needed along with reliable toxicity test systems to cope with this issue. In-vitro and in-vivo tests should be developed so as to keep a check over the toxicities. Thus this poster says from the study collected that the toxicity of nanoparticle toxicity challenges the boon of its applications.

PT059

Recent Advances in Transdermal Drug Delivery System

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Transdermal route of drug delivery offers a potential non-invasive way of drug administration with several advantages including avoidance of first-pass metabolism, sustained release of drug, self-administration, ease of elimination of therapy at any point of time and better patient compliance. Till date, various formulations viz. patches, liposomes, niosomes, transferosomes, tattoos as well as needle less injections and devices have been developed for efficient drug delivery. Researchers have explored various physical and chemical methods for enhancing drug permeability through transdermal route, including the application of heat, electricity, magnetic field, ultrasound, microneedle and chemical enhancers. However many challenges such as skin as a barrier, molecular weight and polarity of drug, faster onset of action, eliminating the chances of local irritation as well as damage to drug delivery system are yet to address for developing effective and robust drug delivery system for drugs which can only be delivered via invasive routes today. The present review aims at showcasing the recent advances in transdermal drug delivery systems with special emphasis on efficient delivery drugs which cannot be administered via oral route.

PT060

Development and Optimization of Oral Disintegrating Tablets of Esmomeprazole Enteric Coated Pellets

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Aim of the present study is to develop and optimize Oral disintegrating tablets containing enteric coated Esomeprazole Magnesium pellets. QbD Approach was applied to investigate Critical Quality Attributes and Critical Process Parameters that ensure Quality of the product. Formulation of enteric coated pellets was done by coating on non pareil seeds in Fluid Bed Coater. Coating was done in three consecutive layers. First layer contains drug Esomeprazole Magnesium and HPMC E5/Kollicoat IR as film forming polymer. Second coat was done to prevent interaction of drug to enteric coat; also it acts like a base for enteric coat to be more appropriate. Third coat was done with enteric coating polymer Eudragit L 30 D-55. During the formulation development process parameters like air flow rate, spray rate of the coating solution, atomization pressure and input temperature were also varied and premeditated to have an optimized set of conditions that result in efficient pellets. Pellets having highest drug load and good flow properties and release profile close to desired (no release up to 2 hours and more than 85% release in subsequent 1 hour) were selected for preparation of ODTs and characterized for their sphericity, flow properties, SEM analysis, cumulative percentage drug release, drug content, % yield and % drug load. ODTs containing pellets were prepared using micro crystalline cellulose as a cushioning agent and crosscarmellose sodium. The individual amounts of two was optimized using 2^3 factorial design to obtain the shortest disintegration time. Mathematical models were generated to explain disintegration time with respect to micro crystalline cellulose and crosscarmellose sodium. Validation of mathematical models was done by preparing a check point batch. The formulation showing quickest disintegration time was thoroughly characterized for intactness of pellets. SEM analysis and dissolution profile confirmed the intactness of pellets in ODTs. The desired goal of preparing ODTs with minimum Disintegration time, less than 10 % drug release up to 2 hrs and at least 85 % drug release in the next hour was achieved.

PT061

Extended drug delivery using implantation technology in hydrogel contact lenses: *In vitro* and *in vivo* evaluation

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Glaucoma is commonly treated using eye drops, which is highly inefficient due to rapid clearance (low residence time) from ocular surface. Contact lenses are ideally suited for controlled drug delivery to cornea, but incorporation of any drug loaded particulate system (formulation) affect the optical and physical property of contact lenses. The objective of present work was to implant timolol maleate (TM) loaded ethyl cellulose nanoparticle-laden ring in hydrogel contact lenses that could provide controlled drug delivery at therapeutic rates without compromising critical lens properties. TM-implant lenses were developed, by dispersing TM encapsulated ethyl cellulose nanoparticles in acrylate hydrogel (fabricated as ring implant) and implanted same in hydrogel contact lenses (sandwich system). The TM-ethyl cellulose nanoparticles were prepared by double emulsion method at different ratios of TM to ethyl cellulose. The X-ray diffraction studies revealed the transformation of TM to amorphous state. *In vitro* release kinetic data showed sustained drug release within the therapeutic window for 168 hours (NP 1:3 batch) with 150 µg loading. Cytotoxicity and ocular irritation study demonstrated the safety of TM-implant contact lenses. *In vivo* pharmacokinetic studies in rabbit tear fluid showed significant increase in mean residence time (MRT) and area under curve (AUC), with TM-implant contact lenses in comparison to eye drop therapy. *In vivo* pharmacodynamic data in rabbit model showed sustained reduction in intra ocular pressure for 192 hours. The study demonstrated the promising potential of implantation technology to treat glaucoma using contact lenses, and could serve as a platform for other ocular diseases.

PT062

Solid Lipid Nanoparticles: An excellent tool for delivering drugs in various diseases

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Nanocarriers have prominently evolved in the field of pharmaceutical technology due to their unique physicochemical and size-dependent properties. One such nanocarrier system which has been widely accepted and extensively employed for oral, topical and parenteral drug delivery comprises of lipid based nanocarriers. It consists of nano-emulsions, liposomes, niosomes, polymeric micelles and lipid nanoparticles (LNs). Out of all, LNs have been promising nanocarrier offering lymphatic targeting of bio-actives and drugs to targeted sites, enhancing its biological activity. LNs can be engineered in the form of solid lipid nanoparticles (SLNs), nanostructured lipid carriers (NLCs), lipid drug conjugates (LDCs) and lipid nano-capsules (LNCs). SLNs have enticed amassed consideration during the last decade. It has proven excellent physical stability as they are biocompatible and biodegradable in nature. Apart from being physiologically tolerable, it improves the drug absorption in gastrointestinal tract (GIT) due to their nano-size and protecting the encapsulated drug from chemical and enzymatic degradation. It helps in modifying the therapeutic profiles and pharmacokinetic factors as compared to free drugs when administered thereby minimising the adverse side effects. Considering various advantages over the other drug delivery systems, LNs especially SLNs have been considered as an excellent tool for delivering lipophilic as well as hydrophilic drugs. This review will demonstrate the various routes of administration for SLN used in numerous diseases along with its advantages and challenges/drawbacks associated with it.

PT063

QbD Approach for Formulation Development of Orally Disintegrating Sustained Release Tablets (ODT-SR) of Losartan Potassium

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The aim of this study was to formulate and develop ODT-SR of a highly soluble drug Losartan Potassium using QbD principles. Initially the mucoadhesive microspheres were prepared and they were compressed in to the form of an Orally Disintegrating Tablet. For Microspheres, Initially risk assessment was performed to obtain critical material and process parameters. A Plackett- Burman design was than employed to find out most significant parameters. A 3^2 full factorial design was then used to find out main, interaction and quadratic effects of independent variables on response. Optimized batch was than compressed as an Orally Disintegrating Tablet. By Risk assessment, eight parameters were selected for further study.
%Entrapment (Y1) and %Drug release (Y2) were selected as Critical Quality Attributes. Pareto ranking analysis suggested Drug: Polymer ratio(X1) and Stirring Speed(X2) were the most significant affecting parameters out of eight high risk variables. Optimization using Response Surface Methodology further clarified the relationship between the variables and CQAs and a design Space was established. The robustness of the process was also confirmed based on predicted and observed values. The optimized batch was than compressed and it releases the drug as per zero order kinetics. It can be concluded that ODT-SR can be successfully formulated using QbD principles.

PT064

Liquisolid Compacts: A novel approach for solubility enhancement

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About 40-50% of the drugs available in the market are water insoluble. It is a challenge for the pharmaceutical industry to formulate dosage forms containing these drugs. These are several approaches to address the issue of solubility. One of the novel and promising approaches is the "Liquisolid Compact Technique". In this technique, water insoluble drug is dissolved in nonvolatile solvents like PG, PEG 400, PEG 600, Tween 80, Span 80 etc. This is followed by addition of carrier materials such as MCC, starch, lactose etc. and Coating material like colloidal silicon dioxide. This will provide free flowing, compressible solids which has improved solubility and/or dissolution. The liquisolid compact technology is in its early stages of development with extensive research currently focused on. It is envisaged that liquisolid compacts could play a major role in the formulation development of lipophilic drugs.

PT065

Scientific Approaches to Stabilize Olmesartan Medoxomil Tablets

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Olmesartan Medoxomil is an angiotensin II receptor antagonist which blocks the vasoconstrictive effect of rennin-angiotensin system and aldosterone release, thereby reducing blood-pressure and possibly preventing vascular remodeling related to arteriosclerosis. ACE inhibitor is used to treat hypertension. The objective of the present study was formulation and stabilization of an immediate release tablets of an antihypertensive drug, Olmesartan Medoxomil. Tablets of Olmesartan Medoxomil were initially prepared by direct compression approach which resulted in poor flowability of the blend. Then the tablets were prepared by wet granulation techniques and the result was found to be matched with reference product with desired dissolution patterns. Formulation optimization trials had been taken with different excipients and final optimized formulation was charged for stability studies. During stability, the result showed increased impurity level of impurity A. Upon investigation the impurity level increased by oxidation reaction, moisture and change in pH. Again repeated trial batch and used moisture barrier coating with multi pack used for product stability like multi layer bottle with molecular sieve (high capacity for moisture absorption), heavy weight bottle with molecular sieve, heavy weight bottle with desiccant (1gm) + Pharmakeep (oxygen scavenger i.e used for oxygen absorption/protection). Finally stability result shown drug product stable packing configuration with heavy weight bottle with desiccant (1gm) + Pharmakeep i.e impurity level with in limit/ specification. In conclusion, chosen approach is useful to stabilize Olmesartan Medoxomil IR tablets.

PT066

Formulation development of nasal spray for highly metabolized drugs

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Highly metabolised drugs need modified approach to deliver in systemic circulation. Nasal route is one of the alternatives which avoid GIT, in case of Domperidon, an antiemetic drug. The aim of this investigation is to prepare muchoadhesive microemulsion based nasal spray containing Domperidone (DM) to accomplish rapid delivery of drug directly into blood stream for anti-emetic action. Domperidone mucoadhesive microemulsion (DMM) was prepared using titraion method and characterized for drug content, globule size, size distribution and zeta potential. The microemulsion containing 6.3% Oleic acid, 80.50% S_{mix} (Labrasol:PG:1:1) and 13.19% (w/w) aqueous phase that displayed 99.99% Transmittance, 19 nm globule size and polydispersity index of 0.121±0.016 was selected for further incorporation of PEO P7 as a mucoadhesive component. Final formulation was filled into suitable container for nasal spray and evaluated for spray pattern, spray angle, content uniformity and pressure-drop effect. Prepared nasal spray was was evaluated for it's mucoadhesion and *in-vitro* permeation. Prepared formulation shows significantly higher rate and extent of permeation as compare to marketed formulation DOMSTAL®.

PT067

Asenapine Nanoemulsion for Transnasal Delivery: Formulation Consideration and Pharmacodynamic Evaluation

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The purpose of this investigation is to prepare and evaluate Asenapine nanoemulsion (ANE) and mucoadhesive nanoemulsion (MANE) for rapid drug delivery to the brain for treatment of schizophrenia. The ANE formulations were prepared by the high pressure homogenization using design of experiments (doe) approach and evaluated for physicochemical properties. They were also subjected to *ex vivo* studies namely diffusion study and nasal ciliotoxicity. Pharmacodynamic assessments (apomorphine–induced compulsive behaviour and spontaneous motor activity) were performed using mice. ANE formulations were transparent and stable with mean globule size below 100 nm. In pharmacodynamic studies, groups administered with Asenapine formulations through intranasal route gave better therapeutic efficiency indicating the potential of intranasal route. This investigation demonstrates a more rapid and larger extent of transport of Asenapine into the mice brain with intranasal MANE, which may prove useful for treatment of schizophrenic patients.

PT068

Combinational approach to enhance permeation of drugs via transscleral route for posterior disorders

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Eye is primarily divided into the anterior and posterior segments. Diseases for posterior region include age related macular degeneration, uveitis, diabetic retinopathy, endophthalmitis etc. Delivery of drugs to the posterior segment of eye is very difficult due to the barriers present in the eye. Different routes of administration to posterior region include topical, systemic, intravitreal, intracameral, etc. Generally, the intraviteal injections are given to treat the posterior region of the eye but treating with single injection is not possible. So, multiple injections are used which can damage the eye. To avoid this transscleral iontophorosis is used which is a non-invasive and deliver drugs directly to the posterior region. Transscleral route passes the lens-iris diaphragm and delivers drugs to vitreous and retina through choroid. Transscleral route is used to deliver genes, steroids, antibiotics etc. Iontophorosis employs low electric current to deliver drugs across the tissue. Systems such as liposome, solid lipid nanoparticles, nanostructured lipid carriers, polymeric nanoparticles are successfully used for iontophorotic route. Colloidal systems ranging from 100 to 1000 nm can be used along with transscleral iontophorosis to give control release of drugs, reduce dosing frequency, enhance permeation, and specific site targeting. The transscleral iontophorotic route with nanoparticulate system can be very promising for the delivery of drugs to eye for enhanced permeation and controlled release of drug.

PT069

Asymmetric Doxorubicin LIPOMER: Shape enabled bypass of the Reticulo Endothelial System

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Bypass of the reticulo endothelial system (RES) is an important strategy to enable high drug accumulation in tumours. Stealth nanoparticles using hydrophilic polymers like PEG facilitate bypass of the RES thereby enabling passive drug accumulation in tumours by EPR effect. Altered particle shape is a less explored promising strategy for stealth based delivery to tumours. Nevertheless the design of non-spherical or asymmetric particles poses significant challenges. The present study discloses design of doxorubicin (Dox) LIPOMER, which are lipid-polymer hybrid nanoparticles of asymmetric shape by a simple modified nanoprecipitation technique. The role of solute-solute and solute-solvent interaction on particle asymmetry was established and related to Marangoni effect. The drug: lipid: polymer ratio was optimized to obtain asymmetric Dox LIPOMER of average size <200nm and >80% entrapment efficiency. SEM confirmed the asymmetric shape. FTIR established complexation of Dox with the polymer. Zeta potential of -26mV suggested good colloidal stability. XRD and DSC indicated decreased crystallinity. Dox LIPOMER exhibited good stability as per ICH guidelines. Good serum stability upto 6 hours and <20 % haemolysis in vitro confirmed safety for intravenous administration. Comparative evaluation of spherical and asymmetric Dox LIPOMER in vitro confirmed evasion of phagocytic uptake by asymmetric Dox LIPOMER confirming RES bypass. Asymmetric Dox LIPOMER is a promising nanocarrier for shape directed passive targetting to tumours.

PT070

Mucoadhesive Microspheres for Intranasal Delivery of an Anti-allergic Drug

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Peroral route has been considered the most convenient route of drug delivery. However this route has several potential disadvantages like extensive hepatic first-pass metabolism. Among different alternative mucosal route the nasal route has gained importance in recent years. Chlorpheniramine Maleate (CPM) is a first generation alkylamine antihistamine drug used in the treatment of allergic conditions such as rhinitis and urticaria. CPM has lower bioavailability due to hepatic first-pass metabolism. Hence delivering CPM through nasal route by means of mucoadhesive microspheres will not only improve its bioavailability but also improve patient compliance by decreasing dosing frequency. For nasal drug delivery, size of microspheres and its mucoadhesive strength play an important role, as this two key parameter decide the deposition site and adhesion time of the microspheres in the nasal cavity. Hence, the objective of present study was to check the influence of polymer combination on the three key parameters viz particle size, percentage entrapment efficiency (PEE) and mucoadhesion of CPM loaded mucoadhesive microspheres. The mucoadhesive microspheres were prepared using sodium alginate (SAL) as matrix polymer and either HPMC E5, NaCMC or Carbopol-934P as mucoadhesive polymer in different ratios. Prepared microspheres were evaluated for particle size, PEE and mucoadhesion. Particle size of all the batches is in the range of 42.34 µm to 55.39 µm. Results shows that mucoadhesion was maximum with microspheres where Carbopol-934P was used as mucoadhesive polymer. However PEE was maximum with HPMC-E5 as mucoadhesive polymer. Further drug-polymer compatibility study confirms compatibility of CPM with SAL and HPMC-E5.

PT071

Medicated Chewing Gum: A Recent Trend of Drug Delivery System

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In past few decades pharmaceutical research and development had opened several avenues in formulations of novel &/or targeted formulations in form of solid dosage forms, nano-formulations, parentral system, etc. However, the industrial scale adaptability has been observed in solid formulations due to ease of manufacturing, regulatory approvals, patient compliance, etc. A medicated chewing gum (MCG) is one of the examples of such innovative drug delivery which has attracted the attention of researchers as single-dose formulation for wide range of patients. MCG needs to be chewed for about half hour, leading to drug release due to mastication in oral cavity, which may either absorbed for systemic circulation or may be therapeutically active for local action. MCG are not supposed to be swallowed and to be expelled out after due time course, which makes it patient friendly formulation. MCG contains insoluble gum base consisting of several excipients of different categories like elastomers, emulsifiers, fillers, waxes, antioxidants, softeners, sweeteners, food grade colourings, & flavouring agents. This present review highlights the salient features of MCG and its excipients, employed method of formulations, and its evaluations for chewiness & drug release. The review would also focus on recent innovations in excipients, methodologies for formulations, newer testing assemblies, regulatory aspects of MCG and its marketed formulations. This review would comprehensively summarized the past, present and future of MCG; which in-turn would be beneficial for newer research scientists for exploring research in formulation of MCG.

PT072

Development of Technology for Oral Controlled Delivery of Poorly Soluble Drugs

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Drugs like Hydrochlorthiazide (HTZ) belong to BCS class II and therefore exhibit slow dissolution rate. Additionally these are predominantly absorbed from stomach. Hence the present study was divided in to two steps. In the first step solid dispersion was prepared to increase the dissolution rate of the drug and in the next step gastroretentive tablets were prepared for the site specific absorption (gastric) of the drug. Solubility of the drug enhanced around 12 times (from 0.7mg/ml to 3.95mg/mL) by preparing solid dispersion (SD) with PVP K 30 using solvent evaporation method. Differential scanning calorimetry (DSC) and fourier transform infrared spectroscopy (FTIR) were carried out to study the amorphous form of drug and drug-excipient interactions, respectively. A simplex centroid design was employed for optimization of amount of HPMC K15M, Carbopol 974P and Lactose in the preparation of gastroretentive tablets of the solid dispersion of HTZ. Developed formulation was evaluated for % drug release at 2, 8 and 24 hours, mucoadhesive strength and floating lag time. Formulation F2 containing polymer HPMC K 15M (3.03%) and Carbopol 934P (12.12%) exhibited the required floatation, bioadhesion and drug release characteristic and therefore was studied for stability. The F2 tablets remained stable over a period of one month at ambient conditions for the critical characteristics. Thus, the prepared gastroretentive formulation proved to be a successful technique for controlled delivery of poorly soluble drugs.

PT073

Development and Evaluation of Nebivolol Hydrochloride Transdermal Matrix Patches Containing Eudragit E 100 Polymer

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The aim of the present investigation was to develop and evaluate the matrix type of transdermal drug delivery system (TDDS) of Nebivolol Hydrochloride (NBH). The matrix types of TDDS of NBH were prepared by solvent evaporation technique. Eight formulations A1, A2, A3, A4, A5, A6, A7, and A8 were composed of Eudragit E 100 polymer with copolymer Polyvinyl Pyrollidone (PVP) in the ratio of 10:1 and 10:2 with 3% chemical enhancers of n-octanol, isopropyl myristate (IPM), oleic acid and l methanol respectively. All the formulations were prepared with 25 % Dibutyl phthalate in the methanol solvent system. The *in-vitro* release studies and *ex-vivo* permeation studies of prepared TDDS were carried out by using modified Franz diffusion cell and in the medium containing phosphate buffer (pH 7.4). The percentage of drug releases from the patches were 27.87%, 28.82%, 33.31%, 35.05%, 20.28%, 27.39%,22.26% and 24.15% in 8 hours respectively. Four patches (A1 – A4) were selected for *ex-vivo* permeation studies and the A4 patch was showed the best release up to 31.92% in 8 hours. Based on the release profile of A4 patch containing Eudragit E 100/ PVP (10:2) with 25% dibutyl phthalate and 3% of IPM chemical enhancer was found the best choice of prepared TDDS of NBH.

PT074

Formulation and Evaluation of Mouth Dissolving Film for Effective Treatment of Chemotherapy Induced Nausea and Vomiting

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Aim of present work is to formulate a fast dissolving film of potent 5-HT3 specific receptor inhibitor Palonosetron HCL used in treatment of Chemotherapy induced nausea and vomiting. Fast dissolving films provide ease of administration for patient who is mentally ill, disabled and uncooperative; requires no water; have quick disintegration and dissolution of the dosage form. Formulation was prepared by the solvent casting method using Film Forming Polymer hydroxyl propyl methyl cellulose and propylene glycol, glycerin as plasticizer. Final formulation was optimized by 3^2 factorial design by taking concentration of polymer and plasticizer and independent variable. Film was evaluated for its stability studies, complete dissolving time, mechanical properties, tensile strength, % elongation at break, thickness of film, drug content uniformity, in vitro dissolution study, stability study, scanning electron microscopy. The studies indicate that the stable quick disintegrating and quick dissolving oral thin strip can efficiently be formulated for Palonosetron HCL.

PT075

Formulation, Evaluation and Optimization of Solid Lipid Nanoparticles of Voriconazole

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This study was concerned with preparing Solid Lipid Nanoparticles (SLNs) of Voriconazole, a poorly water soluble drug with a view to enhance its efficacy, reducing dose as well as side effects and to evaluate its potential for tissue targeting. Microemulsion method was used to prepare nanoparticles. Pre-formulation studies were undertaken for selection of excipients like lipids, surfactant and co-surfactants. Ternary phase diagrams were plotted to optimize surfactant: co-surfactant (Smix) ratio and Lipid: Smix ratio. A 3^2 full factorial design was applied to obtain an optimized formulation. Optimized SLNs were lyophilized. They were characterized for particle size, entrapment efficiency, zeta potential, TEM, DSC studies, drug content, *in vivo* drug release study and stability studies. Preformulation study suggested that, there was no interaction between drug and excipients. From solubility data, Geloel:Compritol = 4:1 ratio was selected as lipid phase, Cremophor ELP as surfactant and propylene glycol as co surfactant. Smix ratio was selected as 3:1 from phase diagram. Optimization of formula by 3^2 full factorial design gave lipid: Smix = 1:4 and Smix= 4:1 ratio with ZAvg 70 mm and EE of 62%. DSC studies revealed higher entrapment of drug within SLNs which is confirmed by HPLC assay. In vitro drug release study showed 96% drug release at the end of 48 hours. *In vivo* study provided proof for tissue targeting. Freeze dried SLNs found to be stable for period of one month. These results provide proof for targeted as well as sustained delivery of Voriconazole. Further, dose reduction reduces side effects.

PT076

Formulation development of multiparticulate system for Naproxen

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Multiparticulate system as dosage form has gained attention and has proved worthwhile. Pellets, Microspheres, Minitablets are few examples of such system. Drugs with high daily dose and requiring immediate release have been a challenge to be formulated in form of pellets. As an alternative to it, minitablets (tablets with diameter less than or equal to 3 mm) has proved to be promising. NSAIDs have been prescribed since many decades for inflammation and pain. Chronic therapy of NSAIDs is required in case of arthritis where it is prescribed with high daily dose. Hence, Naproxen, one such agent used for arthritis, was selected as model drug to be formulated as minitablets. Preliminary trials were conducted and on basis of it, optimization was performed using experimental design. The blends were compressed using 3mm SC punch for manufacturing minitablets. The tablets were evaluated for friability, thickness, disintegration and assay. Further, the tablets were filled in empty capsule depending on required weight, based on assay, and were evaluated for % drug release in Dissolution medium recommended by Office of Generic Drugs (OGD). These minitablets were compared with marketed immediate release formulation in terms of drug release. On basis of the dissolution data, it was concluded that, minitablets are comparable to marketed immediate release dosage form of naproxen.

PT077

Formulation of Cyclodextrin-complexed Raloxifene HCl Hydrogel and its Permeability Evaluation through Microporated Pig Ear Skin

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Currently marketed oral formulations of Raloxifene hydrochloride (RH) demonstrate poor bioavailability (only 2%) due to its poor aqueous solubility and extensive first pass metabolism. In the present investigation, a combination of two approaches viz. inclusion complexation and microneedle induced skin microporation were used for enhancement of transdermal permeation of Raloxifene hydrochloride. The complexes of drug with cyclodextrins were prepared using different methods. The formulations were optimized based on phase solubility, DSC, FT-IR spectroscopy and XRD analysis. Optimized batches were incorporated in carbopol hydrogel and characterized for *in vitro* drug release. *Ex vivo* drug permeation and deposition study was also carried out through intact as well as microporated pig ear skin to establish the transdermal permeation potential of optimized batches. The safety and stability were finally ascertained using histopathology and stability studies as per ICH guidelines, respectively. A_p-type phase solubility diagram indicated the formation of higher order complexes with improved solubility (> 3-fold) which was further confirmed by *in vitro* characterization. *Ex vivo* study revealed maximum drug permeation from RH-HPβCD (molar ratio, 1:2.5) complex in 24h through intact skin (42.9±1.34 %) which further improved when evaluated through microporated skin (58.4±1.87 %). No signs of irritation were evident in histopathological sections. The formulations were found stable over a period of 3 months under room temperature conditions. Conclusively, a non-irritant and safe transdermal formulation with a potential to overcome the limitations of currently marketed formulations of Raloxifene HCl has been developed which further require preclinical and clinical investigations for its successful commercialization.

PT078

Preparation & Characterization of Nanocrystals of an Antiobesity Drug

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Nanocrystals is an emerging and promising approach for increasing solubility and dissolution rate. The present study aims at preparing Nanocrystals of a poorly water soluble antiobesity drug using solvent-antisolvent method with a view to enhance its dissolution and saturated solubility. Drug solution of antiobesity drug in acetone was added to solution of Poloxamer 188 (antisolvent system) under continuous homogenization. The effect of Various process and formulation parameters were screened like homogenization speed, homogenization time, type of stabilizer, solvent to antisolvent ratio, drug concentration and stabilizer concentration. With a view to enhance physical stability of this colloidal system, Nanocrystals were freeze dried using D-mannitol. They were characterized for particle size, XRD and DSC studies, SEM, drug content, saturation solubility, dissolution studies and FTIR studies. Stability studies were performed at 25°C ± 2°C/ 60% RH ± 5% RH for one month. Nanocrystals were successfully prepared using solvent antisolvent precipitation using high speed homogenizer. Poloxamer 188 yielded Nanocrystals in nanometer range. In XRD and DSC studies, it was revealed that physical state of drug was not changed but decreased in crystallinity was observed. In SEM, it was observed that particles were covered with stabilizers. Freeze dried Nanocrystals showed drastic increase in saturation solubility & dissolution rate as compared to pure drug. Moreover, freeze dried Nanocrystals were found to be stable over a period of one month.

PT079

Formulation and evaluation of brain targeted nanoconstructs of nevirapine

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The objective of the present study is the brain targeting of tween 80-coated PLA and PLGA nanoparticles of nevirapine for effective treatment of HIV-associated CNS complications. Nevirapine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) with activity against Human Immunodeficiency Virus Type 1 (HIV-1). It has very low CSF-plasma ratio (0.2-0.3) and can cause life threatening hepatotoxicity which is the major adverse effect of the drug. The formulated nanoparticulate system can deliver the drug to CNS in optimum concentration improving CSF to plasma ratio showing controlled and sustained release and reduction of toxicity. The PLGA and PLA nanoparticles were prepared using nanoprecipitation technique and were characterized. The optimised formulation of PLGA nanoparticles showed particle size of 105.1 nm and zeta potential of -13 mV with 76.65% entrapment while PLA nanoparticles showed particle size of 119.8 nm and zeta potential of -15.8 mV with entrapment of 74.59%. The *in vitro* release study performed using dialysis bag showed that drug release from NVP loaded PLGA nanoparticles followed Korsmeyer- peppas and showed fickian drug release. The *in vivo* studies show nanoparticles of nevirapine increased the time spent by the drug in plasma by ten times magnitude and decreased the elimination of drug from the body.

PT080

Development and Evaluation of Transdermal Patch Containing Aceclofenac and Thiocolchicoside for Treatment of Gout

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The present study was to develop a suitable transdermal matrix patch of Aceclofenac and Thiocolchicoside with different proportions of HPMC K15 and Eudragit RL100 as polymers and Methanol: Dichloromethane (1:1) were used as solvent system.The prepared transdermal patches were subjected to different physicochemical evaluation. The drug-polymer interaction studies were performed using Fourier transform infrared spectroscopic (FTIR) technique and Differential Scanning Calorimetry (DSC) and results showed there was no interaction of drug with polymers. The pharmacokinetic (PK) study of Aceclofenac and Thiocolchicoside transdermal administration was compared with oral administration. This study was carried out in albino wistar rat. C_{max} in case of Aceclofenac and Thiocolchicoside oral and transdermal preparation was calculated. T_{max} was found to be also higher than oral in transdermal preparation. Final batch was optimized on the basis of similarity factor value (f_2), J flux at 24 hours and highest drug release profile. The optimized batch was subjected to the stability study and *In-vivo* characterization which include pharmacokinetic and skin irritation study. The Transdermal Drug Delivery System was found to be stable at 40°Cand 75% RH. Optimized formula had HPMC K15M (75%) and Eudragit RL100 (25%) to show controlled release and acceptable physicochemical properties. The Transdermal Drug Delivery System was found to show higher AUC0-t, Mean residence time, and longer $t_{1/2}$ as compared to oral formulation.

PT081

Development and Characterization of Poly Herbal Shampoo Employing QbD Principles

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The present study was conducted for preparation and evaluation of herbal anti dandruff shampoo. For preparation of anti dandruff shampoo Methi, Neem, and Lemon were used. Literature review reported Neem and Methi as antifungal activity while Lemon as cleansing agent. As development of polyherbal formulation is very complex, QbD principles and Box Behken design was employed to select the optimum concentration of selected herbs. The minimum (-1) and maximum (+1) level of Neem, Methi and Lemon were 0, 0, 0 and 5, 5, 3 respectively. Zone of inhibition and cleaning action were considered as dependent responses for applied DoE. Multiple linear regression equations derived by DoE were assisted to understand the main and interactive effects effect of various independent variables on selected responses. The results of this study indicated optimum level of SLES was 20%V/V which is under maximum usage limit (23%V/V). To impart remarkable structure in formulation, Xanthan Gum was optimized from 1 to 7 % W/V, out of which 1%W/V was considered as optimum. The final blend of extract (derived by contour plot and overlay plot) was Methi:9.04%v/v, Neem:6.43%v/v, Lemon:4.53%v/v. The product was evaluated for orgnoleptic properties, pourability, foaming capacity (FC), water washability, pH, specific gravity (SG), rheology, zone of inhibition (ZOI) and cleaning action (CA). An optimized formulation revealed 15mm (ZOI), 29% (CA), 23ml (FC), 6.8 (pH), 1.023 g/cm^3 (SG). The results of short term stability study revealed stable characteristics of developed formulation.

PT082

Glucose Sensing and Self-Regulated insulin Release by Novel Approach of Nanogel

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According to the World Health Organization (WHO), diabetes is currently one of the biggest health concerns that the world is faced with. According to statistics from the International Diabetes Federation (IDF), India has more diabetics than any other nation of the world. Current estimates peg the number of diabetics in the country at about 62 million – an increase of over 10 million from 2011 when estimates suggested that about 50.8 million people in the country were suffering from the disease. Currently available marketed formulations having drawbacks such as patient incompliance, stability and dose dumping. In the recent formulation of nanogel for treatment of diabetic patients. Nowadays various glucose stimuli responsive polymers like glucose oxidase (GOx), carbohydrate- concanavalin A (Con A) and phenylboronic acid (PBA) derivatives available for preparation of nano-networking formulations with the help of this kind of polymers in the formulations of nanogel. Glucose molecules can easily penetrate and diffuse through the gel, that penetrated glucose molecules trigger release of the enzyme that convert in to gluconic acid which results in acidity, which triggers the release of the insulin therefore regulation of insulin release influenced by diffusion of glucose molecules. it can achieve constant and self-regulative release of insulin to maintain the blood glucose level.

PT083

Formulation, Optimization and Evaluation of Mucoadhesive Bilayered Tablet of Mirtazapine

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The present investigation was carried out with the aim to formulate, optimize and evaluate Mucoadhesive Bilayered Tablet of Mirtazapine that can adhere to cheek pouch of buccal cavity. Tablet was prepared by direct compression method. Mirtazapine is an atypical antidepressant of the piperazinoazepine class, a tetracyclic compound with an anxiolytic effect and used primarily in the treatment of major depressive disorder. Depression is the most common affective disorder which affects as many as 1 in 4 people in their teen ages. One of the major problems that Mirtazapine have is that the drug undergoes extensive first pass metabolism, and also shows GIT related side effects which results in only 50% bioavailability after oral administration of the formulation. In the present work Mucoadhesive buccal tablet containing Mirtazapine was formulated using Carbopol 934P as a primary polymer along with HPMC K4M and HPMC E15LV as secondary polymers and ethyl cellulose as a backing layer. Mirtazapine tablet batches were studied for weight uniformity, hardness, thickness, friability, surface pH, swelling studies, mucoadhesive strength, *ex-vivo* residence time, *in vitro* drug release study and drug content as per pharmacopoeial specification. Finally batch F6, out of all the batches that were studied in detail, was observed as optimized batch. The formulated mucoadhesive bilayered tablet of Mirtazapine was found out to be with enhanced bioavailability and prolonged therapeutic effect for the better management of depression.

PT084

Microneedles: A Novel Trend for Transdermal Delivery Technology

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The transdermal route has very good advantages in drug delivery system like ease of use, avoidance of first pass metabolism, controlled drug delivery, lack of pain during application etc. Thus this drug delivery system overcomes many limitations associated with the more common oral and parenteral routes. However this route is limited by the presence of stratum corneum, which inhibit penetration of foreign material. Several techniques are used to overcome these limitations like ultrasound, electroporation, chemical medication, iontophoresis, sonophoresis, etc. However these methods suffer limitation in delivering hydrophilic and large molecular weight active compound. So, by using micro needles these limitations can be overcome. Use of micro needles creates micron-sized transport pathways in the skin that enhances the range of drug list that can be delivered by this route. Micro needles are also used to deliver drug in a painless manner by penetrating the upper layer of the skin without reaching the nerve while overcoming the limitation caused by stratum corneum. Micro needles are micronized needles made from biodegradable polymer, ranging from 25 to 2000 μm in height, made up of variety of the material and shape. The present poster discuss the various fabrication techniques of micro needles like microelectromechanical system, the design, components of micro needles and the applications of micro needles in pharmaceutical as a drug delivery system.

PT085

Formulation, Development and Characterisation of Tolterodine Tartrate Extended Release Multiple Unit Pellet System

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Tolterodine Tartrate is Muscarinic receptor antagonist which is used in the treatment of Urinary frequency in patients with over active Bladder syndrome. The aim of the present work is to develop an extended release dosage form of Tolterodine tartrate using Multiparticulate drug delivery system. The purpose of selecting multiparticulate system is to develop a formulation having all the advantages of Conventional/monolithic system and yet do not have disadvantage of alteration in drug release due to unit to unit variation. To design this dosage form, first of all inert cores of suitable size were selected and drug was coated onto the pellets along with binder followed by coating with extended release polymer. The controlled release coated pellets were further coated with drug layering solution followed by extended release coating of ethyl cellulose in from of aqueous dispersion along with binder. The prepared pellets were subjected to seal coat by using opadry clear. The curing time required at each stage of coating was optimized to achieve the complete coating. These pellet were filled in the capsules of suitable size. The coated pellets were evaluated for assay, percentage yield, particle size distribution and in-vitro drug release study. The formula was optimized to generate the formulation which gives same release profile as that of marketed formulation.

PT086

Topical Delivery of Isotretinoin & Clindamycin HCl Liposomal Gel to treat Acne Disorder

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The objective of this study was to prepared isotretinoin and clindamycin HCl liposomal gel to treat acne with less systemic toxicity and avoid the problems related with conventional therapy. Conventional therapy of isotretinoin and clindamycin HCl have number of problems include lower skin penetration, mucocutaneous side effect, skin irritation and short duration of action. Liposomal gel not only removes the problem related with conventional therapy but also allows sebaceous gland targeting, improved photostability, reduction of systemic side effect in the case of isotretinoin and also reduction of drug leakage from liposomes due to gel formulation providing long duration of action. For this liposomes were first prepared by the thin film hydration and then gel base was mixed with liposomal dispersion to prepare liposomal gel. Then finally liposomal gel formulation was characterized and evaluated for physical appearance, pH, viscosity, spreadability, drug content and uniformity, skin irritation study and in vitro skin penetration and deposition study.

PT087

Development of Technology for Oral Controlled Delivery of Drug Belonging To BCS Class I

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The aim of present study is to prepare multiparticulate matrix system of Venlafaxine HCl (VH) that provides sustained release up to 24 hrs which is comparable to marketed formulation. VH pellets were prepared by extrusion- spheronization technique using various matrixing polymers and their combinations. Out of these formulations, pellets having EC in minimum amount in formulation was selected. To control release of VH, it was further coated with Ethocel standard premium 45 cp (4% w/v) in pan coater. Coated pellets equivalent to 50 mg drug were compressed into tablet using polyox WSR 303 and dicalcium phosphate. Central composite design (CCD) was applied using polyox WSR 303 & dicalcium phosphate as independent variables and percent drug release at 1, 8 and 12 hr as dependent variables. Results revealed that both the variables had significant effect on percent drug release. Design was further validated by evaluating check point batch. FTIR study showed no interaction of drug-excipients. SEM study revealed that pellets remained intact even after compression and drug release was not affected by compression pressure. 25 mg VH was added in outer matrix of polyox WSR 303 & DCP & 50mg equivalent coated pellets were taken for compression into tablet (V batch). Drug release profile comparable to that of market formulations could be obtained. So it is concluded that multiparticulate matrix system can be successfully used to control release of highly water soluble drugs.

PT088

The Treatment of Colorectal Cancer

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Colorectal cancer (CRC), also known as bowel cancer, is the fourth leading cause of cancer-related deaths for both men and women worldwide. The current trend of treating this ailment involves use of chemotherapeutic agents, mostly administered parentally which becomes painful for the patient as well as the session per treatment is also very long with the side-effects associated to the body and the damage caused to the normal cells and tissues by the potent chemotherapeutic agents. Oral chemotherapy is an important step towards the patients dream: “Convenient Painless Chemotherapy”. Researchers worldwide are striving enough for developing a convenient dosage form for oral chemotherapy which is stable and efficient, causing minimal side-effects offered by conventional chemotherapy. Drug targeting directly towards the site of affected region increases the availability of the drug in its most effective concentration. The traditional techniques of colon targeted drug delivery systems (time controlled release systems, pH dependent release systems, pulsin cap system, osmotically controlled system) has been widely evaluated and expertized by researchers. Nano-particulate drug delivery systems have been proven to be most efficient in terms of controlled release, several alternative routes of uptake and also site-specific and selective targeting of the formulation towards affected regions. Thereby employing the traditional techniques of colon targeting in the current state-of-art of nano-particulate drug delivery systems can prove to be a boon for the colorectal cancer affected patients. This review highlights the application of traditional colon targeted drug delivery systems and nano-particles based drug delivery system for the treatment of colorectal cancer.

PT089

Development of Nano Delivery System using the Chitosan and Mesoporus Silica: A review

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Development of drug delivery system using the chitosan and mesoporus silica in that chitosan works for targeted delivery and the mesoporus silica for the carrier of nano delivery of poorly bioavailable drugs. Development of chemically modified chitosan or its derivatives having wide applications in drug delivery systems. Chitosan is widely applicable because of its polysaccharide nature and its cationic character and availability of primary amino groups, which are responsible for its many properties such as mucoadhesion, controlled drug release, transfection, *in situ* gelation, and permeation enhancement. And the mesoporus silica having the benefits of mesoporous materials in drug delivery applications stem from their large surface area and pore volume. These properties enable the materials to accommodate large amounts of payload molecules, protect them from premature degradation, and promote controlled and fast release.by using the combination of chitosan and silica a new approach of drug delivery system is developed that will discuss here. It shows the great applicability of both in advancement of drug delivery system.

PT090

Development of Inhalable Lipid-Polymer Hybrid Nanoparticles Loaded With D-Cycloserine for Multi Drug Resistant Tuberculosis: Optimization, *In Vitro* and *In Vivo* Evaluation

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Current therapeutic management of Multi drug resistant tuberculosis (MDR-TB) is inadequate due to non-compliance, lengthy course of treatment and drug related side effects. This can be overcome by applying drug delivery technology. Thus, in the present study, Cycloserine loaded Lipid-Polymer Hybrid nanoparticles were prepared by a modified double emulsion solvent evaporation method (DESE) and the particle characteristics including morphology and particle size measurements were performed by SEM, TEM and Particle size analyzer. Polymer interaction and drug incorporation was confirmed by XRD, DSC and FTIR. Drug content, Encapsulation efficiency and particle properties were also determined. Particle aerodynamic study was performed by Twin stage glass impinger. Biodegradable Polymeric nanoparticles (PNs) of D-CS were designed and optimized using 2^3 factorial design to study the influence of formulation variables on particle size, polydispersity index and entrapment efficiency of PNs. The average particle size and Drug entrapment ranged between 81 nm to 152 nm and 90.27% to 96.04% respectively. XRD, DSC and FTIR studies confirmed the drug entrapment within the nanoparticle matrix. Shape and surface morphology of nanoparticles was confirmed by SEM and TEM and particles were found to be spherical in shape. The *in-vitro* release studies showed controlled and uniform release for longer duration and the *in-vivo* toxicity study was also promising. Respirable fraction up to 87.06 % demonstrates the formulation suitability for deep lung delivery. Taken together, these results indicate that the Lipid-Polymer Hybrid could be a potential alternative to the existing conventional therapy in MDR-TB.

PT091

Dry Powder Inhaler of Rifampicin: A Preferable Choice to Improve Deeper Lung Deposition for Treatment of Tuberculosis

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The objective of the research work was to investigate rifampicin dry powder inhaler (DPI) prepared by a new method to achieve an enhanced lung deposition. Using several grades of coarse and fine lactose, several preliminary batches of the rifampicin were prepared. Devices such as Rotahaler® and Revolizer® were used in the trials, of which Rotahaler® exhibited better results. On the basis of evaluation parameters of the trial batches, the coarse and fine lactose grades, Inhalac® 230 and Inhalac® 400 were finalised. *In vitro* lung deposition studies were further evaluated using Andersen cascade impactor and rotahaler device. Performance of DPI was assessed on the basis of fine particle fraction (FPF), mass median aerodynamic diameter (MMAD) and the geometric standard deviation (GSD). The MMAD was found to be in the range of 4.3-5.8µm. The maximum FPF obtained was 28.37%. The results confirmed that the amount of fine lactose in DPI plays a vital role in the fluidization as well as the lung deposition.

PT092

Microwave Treatment: Innovative Approach for Development of Orally Disintegrating Tablets by Direct Compression

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Orally disintegrating tablets (ODTs) are gaining importance as extremely patient friendly oral formulations. Ideally suited for geriatric patients and patients of dysphagia, administration without water presents a singular advantage. A significant challenge in ODT development is optimizing low disintegration time (DT) with high hardness. Reported approaches for ODT development which include lyophilisation, vacuum drying and or use of high functional excipients, achieve low DT nonetheless with a severe compromise on hardness, coupled with high cost. The simpler and low cost direct compression approaches enabled higher hardness but less rapid disintegration. We present an innovative Direct Compression approach for ODT development adapting one additional step of microwave treatment. Lamotrigine (LMG) an anti-epileptic and BCS II drug was selected as model. Based on molecular modelling we predicted enhancement of solubility of LMG when complexed with βCD and confirmed the same through experimentation. Complexation also provided the added advantage of taste masking. The ODTs were prepared by direct compression and subsequently subjected to microwave treatment. An innovative strategy of controlled humidification was arrived at to develop optimized LMG-ODT. Sodium starch glycolate, Ac-Di-Sol and crosspovidone were evaluated as superdisintegrants, while DC lactose, pregelatinized starch and mannitol (Perlitol-200) were screened as diluents. Optimization was achieved using the 2^3 factorial design to obtain DT of <25 sec and hardness $\geq$5Kg/cm^2 and good stability as per ICH guidelines. Microwave treatment presents an innovative yet practical approach for development of ODTs.

PT093

Formulation Development of Floating Granules of NSAIDs with Enhanced Bioavailability and Reduced Side-Effects

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The present study was undertaken with an aim to formulate, develop and evaluate gastro retentive floating pellets of Diclofenac Potassium, which could release the drug in a sustained manner over a period of 22 h. Hydrophobic matrix forming agents such as Compritol® 888 ATO and a hydrophilic polymer Methocel® K15M (hydroxy propyl methyl cellulose) were used in different ratios for the preparation of pellets by keeping concentration of gas generating agent sodium bicarbonate constant. The formulation was optimized by Central Composite Rotatable Design- Response Surface Methodology (CCRD- RSM) using design expert 8.0.7.1. The pellets were prepared by hot melt pelletization technique by using high shear mixer granulator with heating jacket. Prepared pellets were evaluated with respect to floating time, $T_{50\%}$ (time require for 50% drug release), DSC, Floating lag time, in vitro drug release. The optimized formulation showed satisfactory sustained drug release (98.2%) and remained buoyant on the surface of the medium for more than 22h. At the same time, the microenvironment pH of the pellets increased thus reducing GI side effects associated with NSAIDs (Non Steroidal Anti Inflammatory Drug) such as mild dyspepsia to life threatening complications perforation, ulcer, bleeds. It can be concluded that floating drug delivery system of Diclofenac Potassium can be successfully formulated as an approach to increase gastric residence time thereby improving its bioavailability and reduces GI side effects associated with NSAIDs.

PT094

Vaginal film-current status and future aspects

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Vaginal drug delivery specifically refers to delivery of drugs within or through the vaginal mucosa for local or systemic therapeutic action. Various vaginal dosage forms are available including suppository, gel, tablet, capsule, cream but each of these dosage forms have limitations associated with them such as low residence time, leakage, messiness, multiple daily dosing and discomfort. Vaginal film is a thin solid dosage form composed of aqueous polymers mixed with plasticizer which overcomes these disadvantages. In addition, it provide patient comfort and convenience. Depending upon the disease and duration of action required, film can be formulated to provide fast dissolving property or controlled release property. The type and amount of polymer plays important role in providing desired duration of action. Commonly used polymers for vaginal film include Chitosan, Sodium alginate, HPMC, Pectin, Poloxamer and Carbopol. Vaginal films are formulated for various conditions which include vaginal candidiasis, bacterial vaginosis, Herpes infection, AIDS and as a contraceptive. Vaginal films are characterized by different parameters such as tensile strength, folding endurance, elongation at break, swelling index, moisture content, bioadhesive strength, in-vitro and in-vivo study. Currently, VCF® is the only marketed vaginal film containing 28% Nonoxynol-9 in polyvinyl alcohol base used as a spermeticide. Vaginal film containing Dapivirine and Tenoflovir is under clinical trial. Besides these, naturally occurring agents such as curcumin is also explored for the treatment of cervical cancer. Packaging is an important requirement for film stability. These films can be dispensed as single pouch, a blister card with multiple unit or a continuous roll dispenser.

PT095

Formulation and Evaluation of Thiocolchicoside Niosomes for the Pain Management of Rheumatoid Arthritis

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Rheumatoid arthritis (RA) is an autoimmune disease that causes chronic inflammation of the joints & can also cause inflammation of the tissue around the joints, as well as in other organs in the body. About 1.5 million people in the world have rheumatoid arthritis (RA). Nearly three times as many women have the disease as men. The aim of the present research work was to formulate and evaluate controlled drug delivery of Thiocolchicoside Niosomes for the pain management of rheumatoid arthritis. Niosomes were prepared by thin film hydration method using span 60 and cholesterol. The formulation and the process parameters were optimized by screening method. The effect of independent variables i.e., molar ratio of Span 60: Cholesterol (X1), hydration volume (X2) and sonication time (X3) on dependent variables i.e., vesicle size (Y1) and % EE (Y2) was studied. The 2^3 full factorial statistical design was applied. T3 batch was optimized which exhibited 80.5 % entrapment efficiency, 244.3 nm vesicle size and -34.4 mV zeta potential that indicated suitability for topical application and long term stability. % In vitro study (using dialysis tube) showed 93.12% drug release after 24 hrs and niosomes was stable in refrigerated condition for 30 days. Thus, from obtained results it is concluded that prepared Niosomes can be a good candidate for controlled delivery of Thiocolchicoside by reducing dose frequency, to improve patient compliance and also to improve therapeutic effeciveness.

PT096

Studies on pH-independent controlled release oral formulation of a weakly basic drug

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The purpose of this research work was the development of pH-independent controlled release oral tablets of weak base. A combination of polymers such as hydroxypropyl methyl cellulose, ethyl cellulose and HPMC phthalate were used in different proportions. Different grades of hydroxypropyl methyl cellulose and ethyl cellulose was evaluated. The effect of polymer concentration on drug release profile was investigated. Characterization was done by Differential Scanning Calorimeter (DSC) and FTIR. The drug formulations prepared by direct compression were evaluated for drug content uniformity, dissolution rate or release kinetics. The data obtained from the assay of drug was statistically evaluated using analysis of variance at 99% confidence limit. The in vitro release data was analyzed using difference factor and similarity factor. A comparison of the release profiles between the formulated optimized product and marketed product would be evaluated statistically.

PT097

Development and Optimization of an In-house Designed Apparatus for in-vitro release of Medicated Chewing Gum

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Medicated chewing gums offers various advantages over conventional drug delivery systems as it is not swallowed unlike tablets and considered as a friendly oral mucosal drug delivery system. It consists of a water in-soluble gum base and other ingredients. For the evaluation and determination of drug release from the chewing gum, European Pharmacopoeia has adopted an in-vitro compendial apparatus but USP has not adopted any such apparatus yet. Erweka DRT-3 is dissolution tester is being considered to gain acceptance by FDA for chewing gums. The current work focuses on testing the release of active ingredient from medicated chewing gum using an in-house designed apparatus which consists of especially designed reciprocating pistons to give the masticating effect to the chewing gum. Several marketed chewing gums were tested for drug release for the optimization of in-house apparatus. The assembly could further be optimized to give the desired results which can gain commercial acceptance.

PT098

Modulation in Bioavailability of Poorly Soluble Drugs by Lipid Based Drug Delivery System

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Lipid based drug delivery system is an increasing approach to overcome the solubility problems. The main objective of the present study was to prepare a lipid based formulation of BCS class II drugs which increases drug's bioavailability by increasing solubility and reducing hepatic first pass metabolism. Ibuprofen was used as a model drug. Lipid based formulation was converted into a solid powder by adsorbing carrier into a liquid formulation. Solid state properties of powder, surface morphology and *in-vitro* drug release of the lipid based formulation were investigated and compared with Emprofen® soft gelatin capsule. The evaluation of lipid based formulation was done using DSC, XRD and SEM. Blend of Tween 80 (25%) and Oleic acid (75%) was optimized as lipid carrier and Aerosil as an adsorbent. XRD of developed formulation confirmed the molecularly dispersed state of Ibuprofen in the final formulation. The solid intermediate was filled in hard gelatin capsule which showed faster drug release rate as compared to Emprofen®. In house and pharmacopoeial specifications of final formulation were within acceptable limits. Pharmacokinetics study of developed formulation was performed using New Zealand rabbits. The results indicated significant increment in bioavailability compared to plain Ibuprofen. *In vivo* properties of developed formulation and Emprofen® were quite similar. Moreover, there was no any significant difference in AUC, Cmax, tmax and Ka of developed formulation and Emprofen® (t test, $p<0.05$). It can be concluded that potential use of lipid based formulation helps in improving bioavailability of BCS class II drugs.

PT099

Transdermal iontophoretic delivery of lornoxicam proniosomal formulation

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The challenge in permeation of drug through skin is always its inherent barriers. Specifically, the stratum corneum layer plays an important role as rate-controlling membrane. Number of approaches has been explored by scientists to improve the permeation of drugs through stratum corneum of the skin. The aim of work is to study the effect of current density, on/off ratio, and pulse frequency on transdermal iontophoretic transport of prepared lornoxicam proniosomes. The combined approaches of drug carriers and iontophoretic technique could offer advantages over individual approach when used alone. For example, it enhances the drug transport as much as possible compared to individual method and also neutral drugs could be charged by using charged drug carriers for iontophoresis. Studies concluded that the transdermal permeation of lornoxicam from vesicular systems was significantly enhanced by iontophoretic technique. The increase in cumulative penetration and steady-state flux of lornoxicam were found due to the properties of the pulse electric current applied, such as density, frequency, and on/off interval ratio. The synergistic effect of iontophoresis with proniosomal gel developed a new area for delivery of vesicular systems through skin using iontophoretic technique.

PT100

Preliminary Investigations of Oral Effervescent Pellets of Diphenhydramine

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Diphenhydramine (DPH) is a first generation antihistamine drug, used for the treatments of antiemetic, antitussive and as ingredient in common cold preparations. Development of conventional preparations like syrups, suspension exhibits content uniformity, stability and contamination issues. Thus, in the present study effervescent pellets was developed for DPH. Orodispersible formulation contains effervescent agents to accelerate the disintegration and the solution form of drug is beneficial to pediatric patients. Pellets are small, free-ûowing, spherical particulates prepared by the agglomeration of ûne powders of drugs and excipients. Effervescent formulations show higher absorption; prevent the degradation or inactivation of the active ingredient, less irritation and greater tolerability. Citric acid, tartaric acid, sodium bicarbonate and sodium starch glycolate (SSG) were used in pellet formulation. Poly ethyl glycol 1500 (PEG1500) was used as meltable binder. The melt extrusion process was used to develop pellets. Optimized formulation containing, preheated citric acid 12%, sodium bicarbonate 36%, PEG 1500 0.5% and SSG 0.2% shown disintegration in 5.87±0.25 sec, carbon dioxide amount 0.260± 0.0082gm and 75% drug release in 10 min. The study was further extended to optimize effervescent formulation. Present study proved the potential of developed formulation for effervescent pellets of DPH.

PT101

Solubility Assessment of Olanzapine using various lipids for Self Emulsifying Drug Delivery System

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Lipid based Self Emulsifying Drug Delivery System (SEDDS) is widely used to improve the oral bioavailability of poorly soluble drugs. Olanzapine is a potent atypical Antipsychotic drug used in the treatment of schizophrenia and other psychotic disorders. It belongs to BCS II category having poor solubility and thus reduced bioavailability. The attempt was made to improve solubility of olanzapine using various lipids viz. caproyl 90, labrafac WL1349, cartor oil, PEG 400, maisine, caproyl 90, labrafil, labrasol etc and surfactants viz. transcutol HP, lauroglycol FCC as per the Higuchi and Connors method. The solubility of olanzapine in various lipids was evaluated by UV Visible Spectrophotometry at 226 › using methanol as standard. Amongst all transcutol HP as surfactant and caproyl 90 as lipid demonstrated highest solubility. The solubility of olanzapine was further improved by preparing self emulsifying drug delivery system.

PT102

Antibacterial Activity of Henna Leaves

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Antibiotics are used in the treatment and prevention of bacterial infections. They may act as bactericidal or bacteriostatic. Products obtained from natural sources are closely linked to medicine as they are used for treatment and prevention of different diseases. In response to external stimuli, plants and microorganisms produces natural products which are considered as secondary metabolite. These natural products show wide pharmacological activities due to which they have remarkable importance in pharmaceutical industries. *Lawsoniainermis* (*Lanthraceae*) which is commonly known as 'Henna' is widely used in the cosmetic industry as a stain for hands and hair. It is also active against some skin diseases. The use of henna in jaundice, enlargement of spleen is reported. Antifungal activity of ethanolic extract of whole plant of henna is also reported. So the present work is performed with the objective to study antibacterial activity of extract of henna leaves. It is considered that quinones and napthoquinones are present as secondary metabolites in henna leaves. The antibacterial activity of quinones is also reported. The cold aqueous extraction of henna leaves was carried out here. The antibacterial activity of the extract of henna leaves has been performed on *Staphylococcus aureus* and *E. Coli*. The extract shows better activity against *S. aureus.*

PT103

Complexation: A Technique to Enhance Solubilityty of Poorly Water Soluble Drugs

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Many drugs are discovered but 80-85 % of the drug are categorized into BCS class II/IV, have poor solubility. Various approaches are used to increase the aqueous solubility of BCS class II/IV drugs like solid dispersion, Self-Micro Emulsifying Drug Delivery System, Complexation, Nano suspension etc. Complexation is one of the most popular technique used to enhance solubility and cyclodextrin is commonly used excipient for complexation. Cyclodextrin is non-reducing, crystalline, water soluble, cyclic oligosaccharides. Cyclodextrin complexation is a reversible association between two or more molecules to form a non-bonded entity molecules with a well-defined stoichiometry. Cyclodextrin ring has a hydrophilic exterior and lipophilic core in which appropriately sized organic molecules can form non-covalent inclusion complexes resulting in to increase in aqueous solubility and chemical stability of poorly water soluble drug. Cyclodextrin of pharmaceutical relevance contains 6,7 or 8 dextrose molecule bound in a 1,4 configuration to form ring of various diameter. Different methods such as physical mixing, kneading, freeze drying, spray drying techniques are used to formulate complex. The complex is characterized using various solid state characterization techniques like Fourier Transform Infrared Spectroscopy, X-Ray Diffraction, Differential Scanning Colorimetery, Differential Scanning Electron microscope. The complexation approaches easy to scale up and has wide acceptability by industry.

PT104

Characterization of Oral Spray Formulation of Ondansetron Hydrochloride : An Ex Vivo Study

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Ondansetron hydrochloride is a selective $5HT_3$ receptor antagonist, which is used for the treatment of Chemotherapy-induced as well as post-operative nausea and vomiting. Oral bioavailability of the anti-emetic drug is approximately 60-70% having extremely bitter taste and its plasma half life is 3-5 hours. The aim of the present work is to prepare an oral spray formulation of ondansetron hydrochloride and to characterize the formulation by taste masking and ex vivo permeation study. Oral (buccal or sublingual) route has been selected because buccal mucosa is highly rich with blood supply and permeation through buccal mucosa is relatively higher than the per oral route. From the preliminary screening of excipients, Xylitol (0.27 % w/v) was selected as a sweetener, PEG 400 (60 % v/v) as a viscosity enhancer and Menthol (0.01 % w/v) as a permeation enhancer. Taste masking of prepared oralspray solution was done to determine the bitterness level as different coded values. A 2^3 full factorial design was applied for the preparation of oral spray and pH, viscosity and % CDR were selected as response variables. *In vitro* drug release was found to be 85% at t_{15}. Based on the drug release data, an *ex vivo* permeation study was performed using a Franz diffusion cell for the optimized batch, which showed approximately 70% drug release in 15 minutes.

PT105

Multiparticulate Sustain Drug Delivery System of Flurbiprofen

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The objective of present investigation was to develop a pH independent enteric coated extended release pellets containing flurbiprofen. The extrusion spheronization method was used to prepare pellets using microcrystalline cellulose and dicalcium phosphate dihydrate as pellet forming agents. Core pellets were coated with polymers Eudragit RS-100 and Eudragit RL-100 in a fluid bed coater to achieve a sustainable release for 24 hours. The pellet formulation was optimized and studied for various physicochemical parameters such as SEM study, *in-vitro* drug release and stability studies. Drug-excipients sinteraction was studied by DSC and FTIR. The studies shown that there was no interaction between drug and excipients. The average particle size of pellets was 325.90±23.38 µm and showed excellent flow properties. The optimized formulation FT4 showed 96.43% drug released for a period of 24 hrs i.e. first 2 hrs no drug release was observed and gradually drug release was increased up to 24 hrs. The stability studies of formulation FT4 showed no significant changes in drug content, physicochemical parameters and release pattern. Sustain release particulate drug delivery system of flurbiprofen achieved site specific release to lower part of gastrointestinal tract.

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PH037	Antinociceptive activity of methanolic extract of leaves of Grewia asiatica	Vasoya Vishal	Smt. N.M. Padalia Pharmacy College, Ahmedabad, Gujarat.
PH038	Medicinal Plants as Potential Wound Healing Agents: A Review	Jaiswal Ritika	Institute of Pharmacy, Nirma University, Ahmedabad. Gujarat.
PH039	Comparison study of Radioprotective Potential of Two Bamboo Species Phyllostachys parvifolia and Bambusa arundinacea Leaf Extract on Ionizing Radiation Induced Genome Damage: an in Vitro Cytogenetic Study.	Patel Mansi	Institute of Pharmacy, Nirma University, Ahmedabad. Gujarat.
PH040	Pharmacognostic Study, Characterization of Marker Compounds and Pharmacological Review of Aerial Parts of Hygrophila auriculata (Schumach) Heine	Nigam Vijay	Patanjali Herbal Research Centre, Patanjali Yogpeeth, Haridwar.

PH001

Cytotoxic Effect of Different Fractions of Root of *Aerva javanica* on *Vero* Cell Line

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Various herbs are prescribed for the cure of kidney disease in the ancient literature. The term "Pasanabheda" has been cited in the literature to identify the group of plants which have been extensively used in the indigenous system of medicine to dissolve urinary calculi and stones. Approximately 28 species of *Aerva* genus are reported. Roots of *Aerva javanica* was reported as controversial and pasanbheda to treat kidney troubles. The plant, *Aerva javanica* possesses nephroprotective activity. In present work, we have fractionated the alcoholic extract to hexane, chloroform, ethyl acetate, n-butanol and aqueous fractions. All fractions of root of *Aerva javanica w*ere studied for *in-vitro* cytotoxicity study using MTT assay on the Vero cells at various concentration using Cisplatin as a standard. The *n*-hexane fraction shows maximum cell viability as compared to other fractions on Vero cell line. Aqueous extract of *Aerva javanica* root shows significant cytotoxicity as compared to other fractions on the Vero cells while *n*-Hexane fraction shows maximum cell viability as compared to other fractions and Cisplatin. Based on the above finding we can conclude that the aqueous fraction can be further studied for their anticancer and *n*-hexane fraction can be studied for proliferation enhancing property on Vero cell line as supportive work to nephroprotective report for this plant.

PH002

Neuroprotective Effects of *Ficus racemosa* Against Intracerebroventricular Colchicine-induced Cognitive Impairment

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Alzheimer's disease (AD) is a progressive neurodegenerative disorder characterized by deposition of amyloid β fibrils in senile plaques. The present study was designed to investigate the possible neuroprotective effect of pet ether extract of *Ficus racemosa* against colchicine-induced cognitive impairment and associated oxidative damage in rats. Neurotoxin i.e. Colchicine was administered intracerebroventricularly in the lateral ventricle for the induction of Alzheimer's disease. For the assessment of behavioural parameters, locomotor, rotarod, Y maze, elevated plus maze, two compartment and open field performance tests were used. Various biochemical parameters such as lipid peroxidation, reduced glutathione, superoxide dismutase, catalase and acetylcholinesterase were also assessed. Neurotoxin caused marked memory impairment and oxidative damage. Chronic treatment for 21 days with pet ether *F. racemosa* extract (200 and 400 mg/kg, p.o.) showed significant reverse action against colchicine-induced memory impairment and oxidative damage. Besides, *Ficus racemosa* significantly reversed colchicine administered increase in acetylcholinesterase activity. Pet ether extract of *F. racemosa* showed a reduction in the MDA level and an increase in the GSH, SOD and CAT levels compared to colchicine treated control rats. From the above result, present study indicates protective effect of *Ficus racemosa* against colchicine-induced cognitive impairment and associated oxidative damage.

PH003

Development and Characterization of Ibuprofen Dispersible Tablets using Isapghula Husk Powder as Disintegrant

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Ibuprofen an uncoated tablet produces a uniform dispersion or suspension in water without any stirring at room temperature. Because of difficulty in swallowing ability with age, elderly patients complain that it is difficult to take in the form of tablets. The dispersible tablet is dissolved or dispersed in water before administration. It is easy to take dispersible tablet than capsules. It is also easy for mentally ill patients, for small children, dysphagic patients, unconscious and patients having nausea, motion sickness, allergic attack or cough.

Ibuprofen is a low soluble drug. In this study, dispersible tablets of Ibuprofen were formulated by direct compression method using natural disintegrant such as ispaghula husk powder. Various concentration of ispaghula husk such as 5%, 10%, 15% and 20% were used with other ingredient like starch, lactose, magnesium stearate, purified talc and aspartame. Preparations were characterized for the official standards and were compared with marketed products. It was found that all the preparations were passed with acceptable limits of standard given for dispersible tablets. This study shows that formulations prepared by using 15% Isaphgula husk powder have good dissolution and uniform dispersion characteristics which is required for dispersion tablets as compared to marketed disintegrating tablets of ibuprofen. It is also concluded that natural gums present in Isaphgula husk can be used as disintegrant and it was effective in low concentration.

PH004

Study of Pharmacognostic Profile & Evaluation of Herbicidal and Pesticidal Activity of *Parthenium hysterophorus*

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Parthenium hysterophorus is declared invasive weed & it is threatening the biodiversity and human health in several areas of India. The sesquiterpene lactone parthenin that is biosynthesized by this species is thought to play a role in the allelopathic interference with surrounded plants. Therefore parthenium management would remain a great concern of the century. Detailed pharmacognostic study of leaf, stem and root were performed, that indicated the plant was dicot. In proximate analysis of plant, the value of loss on drying was found to be 4.05±0.5 % w/v. The total ash, acid insoluble ash & water soluble ash were found to be 14.28±0.72% w/w, 4.76±0.24% w/w & 9.52±0.48 % w/w respectively. The alcohol soluble extractive, water soluble extractive values were found to be 32±1.0% w/v, 16±0.95 % w/v respectively. Phytochemical screening of aqueous extract of *P. hysterophorus* showed the presence of triterpenoids, alkaloids, flavonoids, steroids and glycosides. The developed emulsion using aqueous extract of *P. hysterophorus* has shown herbicidal activity on selective monocot species at the dose of 12 ml/liter at a concentration of 16.00 % w/v after six days of treatment. It has also produced potential pesticidal/ insecticidal effect on selective dicot species at the dose of 10 ml/liter at a concentration of 13.32 % w/v after the seven days of treatment. Comparing prepared emulsion with marketed product it has not shown any toxic effect because of its bio degradable nature. By this way, appreciable quantity of nutrients in parthenium can be utilized to nourish the crops and majority of green parthenium can be destroyed also.

PH005

Evaluation of Antioxidant and Anti-inflammatory Activities of *Bergenia ciliata* Extracts: an *in Vitro* Analysis

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The study was carried out to perform evaluation of aqueous and methanol extracts of *B. ciliata* rhizomes for *in vitro* antioxidant and anti-inflammatory activity. The evaluation was also carried out in order to check the contents of various primary and secondary metabolites of plants such as carbohydrates, proteins, phenolics, flavonoids and saponins. The presence of carbohydrates, proteins, phenolics and flavonoids was found to be higher in methanol extract whereas the saponin content was found to be higher in aqueous extract. The IR spectra of both the extracts were also compared wherein both showed presence of large number of –OH groups indicating higher content of polyphenolic compounds. The *in vitro* antioxidant activities of both the extracts were evaluated by three different assays viz. DPPH (2,2-Diphenyl-1-picrylhydrazyl) free-radical scavenging assay, modified 2,2'-azinobis(3-ethylbenzothiazoline)-6-sulfonic acid (ABTS) radical cation decolorization assay and Trolox Equivalent Antioxidant Capacity (TEAC) assay. It was observed that methanol extract was more potent in scavenging free radicals as compared to the aqueous extract. The *in vitro* anti-inflammatory activities of both the extracts were evaluated by protein denaturation assay and proteinase inhibitory action. Methanol extract exhibited higher potency as compared to aqueous extract in both the assays. The results of the study reveal that the methanol extract has more potent antioxidant and anti-inflammatory activity than the aqueous extract and this may be attributed to the higher content of phenolics and flavonoids present in the methanol extract. The methanol extract must be further subjected to bioactivity guided fractionation in order to find out the potent bioactive.

PH006

Preparation and Evaluation of Polyherbal Formulation for the Management of Liver Disease: Jaundice

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In the present time there is a worldwide need of liver protective formulation which will provide health safety and cost effective treatments in jaundice. Drug induced immunoallergic hepatitis is characterized by acute liver injury accompanied by signs and symptoms of hypersensitivity. These serious consequences of drug induced liver injury are fortunately rare, but they can develop even though the causative agent is stopped promptly. Importantly, these outcomes can result in death or need for liver transplantation. Therefore, in the present study *Bhangro, Kadu, Kariyatu* and *Vikalo* are selected for the development of formulation for hepatic disorders based literature review. Standardization and evaluation of the prepared formulation has been done using standard parameters such as organoleptic characters, physico-chemical parameter, estimation of active constituents, heavy metal analysis, microbial analysis. Formulation was evaluated for its *Ex- Vivo* hepatoprotective activity and *in Vitro* cytotoxicity. In house prepared formulation was in permissible limit as mentioned in Ayurvedic Pharmacopoeia of India. The *ex vivo* hepatoprotective and *in vitro* cytotoxicity study data showed the prepared syrup was safe. No cytotoxicity was observed. On the basis of obtained data we can concluded that prepared syrup and its ingredients were consistent with various quality and purity parameters.

PH007

Antidepressant Activity of Ethanolic Extract of *Calendula officinalis* in Laboratory Animals

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Calendula officinalis has an activity against many viruses and has a weak antibacterial as well as antihepatotoxic, immunostimulating, and healing activities. The objective of the present work was to study the antidepressant activity of ethanolic extract of *Calendula officinalis* (EtCO) in laboratory animals. The extract was carried out by using soxhlet extraction method. Antidepressant activity was carried out by using forced swim test in mice, tail suspension test in mice and locomotor activity test in mice. The antidepressant activity of ethanolic extract of *Calendula officinalis* were studied at doses of 100, 200 and 400 mg/kg. Imipramine (30 mg/kg, i.p) was selected as reference standard and it showed significant antidepressant activity in mice. A dose dependent reduction in immobility time was observed in forced swim and tail suspension test. Whereas the extract significantly increases the exploratory behaviour in mice. The EtCO has significant increase in locomotor activity. The finding from the present investigation indicates that extract has significant antidepressant activity as shown by its effects on different experimentally induced different models.

PH008

NIR Spectroscopy: A Potential New Mean of Assessing Multicomponent Polyherbal Formulation on Way Before and After Extraction

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Traditional polyherbal medicine and their preparations have been widely used for the thousands of years in developing and developed countries owing to its natural origin and lesser side effects or dissatisfaction with the results of synthetic drugs. To establish a real time identification system in favor of near infrared-spectroscopy & powder microscopy. The multivariate chemo metric technique PCA, HCA use and allow an overall evaluation of the significant difference between groups and discriminate of polyherbal powder & extract. The authenticated individual herbal, polyherbal pulverized powders & the soxlet-methanolic dry extract both shifted through eighty meshes. The samples were subjected to NIR spectral detection from 750 to 2500 nm at the interval of 1 nm. The powder microscopy of polyherbal powder is standard operating procedure. Original spectra for lot of heart-leaved moonseed, Indian Kino, Indian Liac, Ram's horn, Fenugreek, black berry , polyherbal powder and extract form can see by naked eye. It is easier to discriminate in context relative intensities of different samples on the differences some wavelength region in context registered generic functional (NIR sensitive CH, OH, NH) group by eye when viewing spectra that have undergone a first derivative transformation. The principal component analysis is able to distinguish of objects as a function on PC scores. Chemo metric method PCA & HCA is established as a reference library which significantly influence real time quality monitoring of uncontrolled natural variation plant kingdom. NIR analysis is useful because a sample may be rapidly tested without destroying its integrity.

PH009

Phytochemical Analysis and Antioxidant Activity of *G. flavescens*

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Grewia flavescens (Tiliaceae) popularly known as "donkeys berry", is a shrub distributed in southern India and in Aravali regions of North Gujarat. The plant is known for its nutritional value and roots and stems are traditionally reported to be used in inflammation, fever, and kidney stone and for bone fracture healing**.** Despite of many ethno medicinal reports, sufficient scientific work on pharmacognosy of this plant has not been reported so far, so in this present study we have studied preliminary phytochemical analysis and *in vitro* antioxidant effects of different plant parts of *G. flavescens*. Phytochemical studies indicated presence of sterols, carbohydrate, phenolics, saponins, protein and flavonoids while alkaloids are found to be absent. Total saponins, protein, carbohydrate content of the aqueous and methanolic extracts of stem, root and leaf of *G. flavescens* were done. Saponins were found to be higher in aqueous extract of root and leaf. The hydrolyzed extract of stem and root contained higher amount of carbohydrate while total protein content of aqueous extract was found to be higher than methanolic extract. The total phenol and flavonoid content of different extract of stem, root and leaf of *G. flavescens* showed that methanolic extracts of stem and root contained higher amount of phenolics and flavonoids as compared to the aqueous extract. The antioxidant assay using 2-diphenyl-1-picryl-hydrazyl-hydrate(DPPH) anion assay, 2'-azinobis(3-ethylbenzo thiazoline **(**ABTS), radical cation decolorization assay, and trolox equivalent antioxidant activity were done for stem, root and leaf of *G. flavescens*, and amongst all methanolic extracts of stem and root showed the higher antioxidant potential.

PH010

In -Vitro Cytotoxicity Studies of the Anti-cancer Potential of Fractions of Root Bark of *Oroxylum indicum* in Human Breast Carcinoma Cells

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The use of medicinal plants for the treatment of various diseases is as old as human civilization and has obtained a worldwide significance in the primary healthcare system. In spite of their structural complexity and many unknown chemical constituents, they have been frequently prescribed because of their use and efficacy, contributing to the disclosure of their therapeutic properties. *Oroxylum indicum*, commonly known as Syonakh (tetu), belongs to the family *Bignoniaceae*. It is used as an astringent, carminative, diuretic, stomachic, aphrodisiac and has high potential for stimulating digestion, curing fevers, coughs and preventing other respiratory disorders. The present study has been conducted to evaluate the anticancer potential of different fractions of root bark of *Oroxylum indicum*. The different fractions were tested for their cytotoxicity using the brine shrimp lethality assay, and MTT assay using MCF 7 breast cancer cell line. The chloroform, ethylacetate and n-butanol fraction showed lethality in the brine shrimps. The n-butanol fraction of *Oroxylum indicum* showed the highest toxicity on MCF 7 cell line, with 70.41% inhibition in the MTT assay. In conclusion, amongst all the tested fractions, the *n*-butanol fraction of the root bark of *Oroxylum indicum*, might be considered as potential source of anticancer compounds. Further studies are necessary for chemical characterization of the active principles and more extensive biological evaluations.

PH011

A Study on *Nyctanthes arbortristis* an Antidiabetic Plant on Carbohydrate Metabolizing Enzymes

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India leads the world with largest number of diabetic subjects being termed the "Diabetes capital of the world". Because of the limitations of recently available drugs there has been a conspicuous resurgence of interest in the use of another approach for treatment of diabetes has been emerging out. Antidiabetic agent may exert blood glucose lowering effect by altering the activity of enzymes involved in glucose metabolism. Earlier reports mention that in untreated diabetes, there is increase in the activity of α-amylase, Glucose 6 Phosphatase (G6Pase), while decrease in the activity of Glucose 6 Phosphate dehydrogenase (G6PD) in humans as well as in animal models. The *Nyctanthes arbortristis* leaf (Oleaceae) extract has also been proved scientifically to have significant antidiabetic activity. However, mechanisms of action whereby *Nyctanthes arbortristis* exert blood glucose lowering effects remain speculative. So, research was aimed to validate the medicinal uses of *Nyctanthes arbortristis* for activities mentioned above. Methanolic extract and fractions of *Nyctanthes arbortristis* were prepared by soxhlet extraction method and assayed for α-amylase, G6Pase and G6PD activity and compared with respective enzyme inhibitor or activator. Ethyl acetate and Chloroform fraction shows a good α-amylase and G6Pase activity and is comparable with standard enzyme inhibitor acarbose and sodium vanadate respectively. Fractions of methanolic extract of *Nyctanthes arbortristis* were inactive against G6PD. The phytochemical analysis of ethyl acetate and chloroform fraction shows presence of alkaloid, steroid and flavonoid which may responsible for antidiabetic and enzyme inhibitory activity of *Nyctanthes arbortristis*. Future prospective of this study would be applicability of this method *in vivo*.

PH012

Anti-arthritic Activity of *Tecoma stans* (Linn.) Leaves

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Rheumatoid arthritis is a chronic inflammatory disease mostly infective type involving small joints, characterized by stiffness and pains in joints resulting from progressive destruction of articular and periarticular structures. Many researchers have proved that alkaloids, terpenes, flavonoids, catechins, quinones, anthoxanthins and anthocyanins phytoconstituents are responsible for anti-inflammatory activity. *Tecoma stans* (Linn.) have Bignoniaceae family. The *Tecoma stans* leaves are used in diabetes and roots are used as diuretic, vermifuge and tonic. The different Pharmacological review of *Tecoma stans* leaves shows that it is having anti-inflammatory, antimicrobial, antidiabetic, anticancer, antioxidant and antifungal activities. *T. stans* leaves were extracted with alcohol and water. Successively also extracted with petroleum ether, chloroform, methanol and water. All the extracts were tested for Antiarthritic activity using standard drug Diclofenac sodium. The significant Antiarthritic activity was exhibited in alcohol, water and successive methanol extracts of *T. stans* leaves. The investigations results justify that the *T. stans* leaves having good antiarthritic activity due to presence of alkaloid, flavonoid, tannins, steroids and the plant is worth for isolation of phytoconstituents and different pharmacological investigations.

PH013

Ethanolic Extract of Clove and Its Analgesic Effect

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The analgesic effect of clove is due to essential oil present in it. The present study was done to identify the analgesic effect of clove using hot plate test. Eugenol an aromatic compound derived from essential oil of clove exerts the analgesic activity. The analgesic effect of clove which is due to the eugenol using the chemical acetic acid test, as well as thermal methods. Eugenol has been capability to inhibiting the prostaglandins and other inflammatory mediators such as leukotrienes. Eugenol also reduces the rat paw edema and pleural exudates in carrageenan-induced inflammation model. Eugenol also blocks the pain receptors and exerts the analgesic effects. The ethanolic extracts of clove have been shows activity against the dental carries and periodontal diseases. Dried buds were extracted using soxhlet apparatus with 300 ml ethanol to prepare ethanolic extract. Extract reduced to dryness with vaccum evaporator yielded 15% ethanolic extracts. Eugenol is the main component of clove as well as it has analgesic and anti-inflammatory activity. It was assumed that ethanolic extracts of clove was initially acting on the opioid receptors which block them and shows the analgesic effects. Analgesic effect of extract calculated as maximal possible effect [MPE (%)=[test response time –basal response time) / (cut 0ff time –basal response time)* 100%]. All the results presented as mean ± SEM of %MPE repeated measures of ANOVA followed by post hoc Tukey‘s test was used for comparison of %MPE after injection of drugs. The differences were considered statistically significant when $p<0.05$ observed.

PH014

Curcumin: Surface Modification to Improve Water Solubility and Bioavailability

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Curcumin is known since ancient times in ailing different pharmacological disorders like anti-inflammatory, wound healing, anti-tumor and many more. Very complex research has been worked on by taking curcumin as chief moiety. Curcumin comes under Biological Classification System (BCS) class IV drug having characteristic with low solubility and low permeability making it the key disadvantage in considering it as drug of choice for various drugs. In the current research we have taken this common problem into focus and conjugated the drug with different vectors like glutathione, carnosine, soy lecithin and many more. All the vectors were individually studied at different concentration with varying curcumin concentration in ratio of 9:1, 8:3 and 7:3 curcumin and vector respectively. The conjugation was approved by FTIR, NMR and U.V. visible spectroscopy. Different parameters to validate the change in solubility and bioavailability were quantitative solubility, particle size, entrapment efficiency, drug loading, anti-oxidant parameters, organ analysis. There was an increase in 30%, 20% and 40% solubility in water of curcumin-glutathione, curcumin-soy lecithin and curcumin-carnosine respectively. There are different similar methods like decreasing the particle size to a nano level may increase the solubility and permeability but we are not dealing with such complicated phenomenon. A simple modification in the macro form that increase the solubility by 15% in water and thereby increasing tissue bioavailability.

PH015

Effect of Roots of *Aerva javanica* on *Vero* Cell Line

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Ever since the beginning of human civilization, medicinal plants have been used by mankind owing to their therapeutic value. Nature has been a source of medicine for thousands of years and an impressive number of modern drugs have evolved from natural sources. Various herbs are prescribed for the cure of kidney disease in the ancient literature. The term "Pasanabheda" has been cited in the literature to identify the group of plants which have been extensively used in the indigenous system of medicine to dissolve urinary calculi and stones. Approximately 28 species of *Aerva* genus are reported. Roots and flowers are reported to possess hypoglycaemic, antioxidant, anthelmintic, analgesic, antimalarial activities and medicinal properties against rheumatism and kidney troubles. The Pasanabheda category plant, *Aerva javanica* possesses nephroprotective activity. In present work, we have studied aqueous and alcoholic extracts of root of *Aerva javanica* at various concentration using Cisplatin as a standard. The *in-vitro* cytotoxicity study was carried out using MTT assay on the Vero cell. The aqueous extract of *Aerva javanica* root shows 73.94% cytotoxicity or inhibition at the dose of 1000 µg/ml on vero cell. Alcoholic extract of *Aerva javanica* root does not show significant cytotoxicity or inhibition. It shows 37.5% cytotoxicity/inhibition at the dose of 1000µg/ml on vero cells. Thus the aqueous extract shows toxicity at higher concentration, while alcoholic extract is not showing significant cytotoxic effect on the vero cells.

PH016

Therapeutic Potential of Mushrooms

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Mushrooms, are neither plant nor animals, and have been placed in a kingdom called Myceteae. In Charaka Samhita, an ancient medical treartise, use of mushrooms is found as food and medicine. However, with increasing awareness of mushrooms as health food, recent researches showed the presence of biologically active substance with medicinal value in it. While most of the work was focused on anti-cancer and immunological properties of mushrooms, other potentially important therapeutic properties including liver protection, anti-inflammatory, anti-oxidants, anti-hypertensive, cholesterol-lowering, anti-fibrotic, anti-diabetic, anti-viral and anti-microbial are also present. The nine essential amino acids required by humans are found in mushroom proteins. Nutrients like phosphorus, iron and vitamins, including thiamine, riboflavin, niacin, ergosterol and ascorbic acid are also present.Some of the therapeutically important mushrooms include *Ganoderma leucidum,* containing a number of water soluble polysaccharides demonstrating anti-tumour and immune-stimulating activity. Hot water extract of *Phellinus linteus* showed the strongest evidence of tumor proliferation supperession. *Grifola frondosa* showed presence of polysaccharide-protein complex and exhibit immunological enhancement alongwith anti-HIV, antihypertension, antidiabetic, and antiobesity activity. A polysacchride isolated from *Trametes versicolor* showed chemo preventitive activity while polysacchropeptide inhibit HIV I in an in vitro model . Various species of mushroom have been an important source for deriving important pharmaceutical product with proven medical application. The present review explores the therapeutic potential of various species of mushroom.

PH017

M. Pruriens Seed Extracts as Angiotensin Converting Enzyme Inhibitor

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The *in vitro* angiotensin-converting enzyme (ACE) inhibitory activity of *M. Pruriens* seed extract was examined to evaluate its use as a remedy against hypertension. Seeds were collected from Whitestone Healthcare Pvt. Ltd. Bhopal in central India. Powdered seed was extracted by hydroalcoholic solvent. Solvent was removed using buthci type rotary evaporator and the extract was subjected to freeze drying in a lyophilizer till dry powder was obtained. ACE inhibitory activity was assayed by measuring the release of HA from the substrate HHL. The IC_{50} value is defined as the concentration required to decrease the ACE activity by 50%. The percent inhibition curves were plotted using a minimum of five determinations for each sample concentration. Seed extract of this herb significantly inhibited ($p < 0.05$) ACE activity (IC50 = 1.10 ±0.01mg/ml). TLC & HPTLC of the extract was performed using l-Dopa as the marker compound. The results confirmed potential empirical use of the plant for the management of hypertension. The active compounds for ACE inhibition probably resulted from synergic many molecules present in the extract, isolation of various compounds from the fractions is going in our lab.

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PH018

Anti Acetylcholinesterase Activity of *Nardostachys jatamansi* : a Drug of Choice for Cognitive Disorders

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Loss of cholinergic neurons is the hallmark of learning and memory deficit. Acetylcholine (Ach) is a major neurotransmitter of cholinergic transmission and which act upon muscarinic and nicotinic receptors. Acetylcholinesterase (AchE) is the enzyme which hydrolyses Ach and terminates the action of Ach. AchE inhibitors are the best available pharmacotherapy for the treatment of various neurological and cognitive disorders. Hexane fraction of *Nardostachys jatamansi* has been proved scientifically for significant AchE inhibitory activity. AchE inhibitory activity was evaluated *in-vitro* by Ellman's method. In the present study hexane fraction of *Nardostachys jatamansi* was further fractionated by column chromatography method and subfractions were confirmed by TLC finger printing. Hexane fraction and its column sub fractions (C 1-12) was assayed for AchE inhibitory activity at final concentration of 100 µg/ml. Donepezil hydrochloride was used as a standard AchE inhibitor. The % inhibition of column subfractions C-9, C-11 and C-12 shows less significant activity compare to hexane fraction and standard. The % inhibition of other column subfraction was not significant. From the present study it is concluded that AchE inhibitory activity is not due to a single compound but it is the synergistic activity of all the compounds present in the hexane fraction. Phytochemical and spectroscopic study of hexane fraction was done. Phytochemical screening of hexane fraction shows presence of alkaloids and steroids which may be responsible for AchE inhibitory activity of *Nardostachys jatamansi.*

PH019

Development and Pharmacological Evidence of Antitussive, Anti-inflammatory,and Anti-oxidant Activity of Herbal Cough Syrup

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The study was aimed at evaluating the antitussive, anti-inflammatory and antioxidants effects of herbal syrup containing *Adhatoda vasica* L, *Curcuma longa* Linn, *Ephedra vulgaris* L, *Glycyrrhiza glabra* Linn, *Operculina turpethum* Linn, *Piper longum* Linn, *Ocimum sanctum* Linn, *Solanum xanthocarpum* Schrad and *Zingiber officinalis* Rosc, providing experimental evidence for its quality, safety, efficacy and uniformity of herbal cough syrup. Antitussive evaluations were carried out with sulphur dioxide induced cough in mice; anti-inflammatory effects were assessed by carrageenan induced rat paw edema in rats and antioxidants activity were carried out with DPPH and hydrogen peroxide scavenging method. For antitussive activity, Higher dose of herbal cough syrup exhibited significant ($p<0.001$) cough suppression induced by sulphur dioxide compared to vehicle treated control group. Herbal syrup showed significant reduced paw edema induced by carrageenan in dose dependent manner at various time intervals. For antioxidant activity, the scavenging effect was increased with increasing concentration of the formulations in DPPH as well as hydrogen peroxide scavenging method. From the experimental evidence, we conclude that herbal cough syrup exhibited significant dose dependent antitussive, anti-inflammatory and *in-vitro* anti-oxidant activity.

PH020

Natural Skin Whitening Agents

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Skin whitening agents are ingredients that interfere with any step of melanogenesis or melanin transfer. Skin pigmentation is influenced by various factors like haemoglobin in blood vessels, carotenoids in the dermis and the amount of dark pigment, melanin, in the epidermis. The production of melanin by special cells called melanocytes found in the basal layer of the epidermis occurs through the action of the enzyme tyrosinase.Pigmentation in skin is also due to various physiological processes like density of melanocytes, synthesis of melanin and distribution of melanin in the supra basal layers of the skin. The mechanism of action of skin whitening agents can be tyrosinase inhibition, interference with melanosome maturation and transfer and melanocyte loss. Skin-lightening agents can be classified as tyrosinase inhibitors, anti-oxidants, vitamins, peptides and alpha hydroxyl acids and derivatives.Arbutin from the leaves of the bearberry (*Arctophylos urva ursi),* glabridin from liquorice roots (*Glycyrrhiza glabra*), Aloesin from *Aloe* species and Kojic acid (bacterial metabolite) act as tyrosinase inhibitors. 2-Oxy resveratrol from *Morus alba* extract, Kaempferol from *Crocus sativus* extract and Procynadins from grapefruit extract also show skin lightening effects. The gallocatechins present in green tea are responsible for tyrosinase inhibitory activity and thus produce skin whitening. Curcuminoids from Turmeric act as effective anti-oxidant and skin lightening agent. Soybean extract reduce melanin transfer and block melanogenesis pathway. These natural compounds can prove to be very promising for developing safer and effective skin whitening formulations.

PH021

Anti Proliferative Activity of *Gendarussa vulgaris* on Breast Cancer Cell Line

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Breast cancer remains the second most common cause of cancer death in women. Eighty per cent of women diagnosed are alive at five years. It is the leading cause of death in women aged 40-55 years. Potential herb *Gendarussa vulgaris* is a bioactive plant that has been used as an ethnomedicine to treat various diseases. *Gendarussa vulgaris* plant exhibits antioxidant, hepatoprotective, anthelmintic, anti inflammatory, antiarthritic, antiangiogenic, antimicrobial, analgesic and antianxiety activities. This experiment is aimed to evaluate the cytotoxic effect of the leaf and root of *Gendarussa vulgaris on* MCF7 cell line. The effect of defatted methanolic extract of leaf and root of *Gendarussa vulgaris* at 100, 500, 1000 µg/ml concentration has been studied, using Vinblastine as a standard on MCF 7 breast carcinoma cell line using MTT cell viability assay. MTT cell viability assay of methanolic extract of leaf shows 58.2% cytotoxity at 1000µg/ml concentration,where as methanolic root extract does not show any significant activity on the MCF 7 cells. The cytotoxicity of methanolic leaf extract of *Gendarussa vulgaris* shows significant activity and can thus be further evaluated for its anti cancer activity via various mechanisms, which may result in identification of potential lead molecule for the treatment of breast cancer.

PH022

Antidiabetic Activity of *Firmiana Colorata (Roxb.)* in Alloxan Induced Diabetes in Laboratory Animals

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The objective was to evaluate the effect of petroleum ether extract of *Firmiana colorata* (PEFC) in alloxan induced diabetes in mice. The leaves were collected, authenticated, shade dried, pulverized into coarse powder and successive extracted with pet ether by using soxhlet extractor. For evaluation of antidiabetic activity, swiss albino mice weighing between 20-25 g were selected. Alloxan (70 mg\kg, i.v.) was injected in all animals. After 48 hrs blood glucose was determined by GOD\POD method. The mice having blood glucose above 300 mg\dl (diabetic) were randomly divided into five groups i.e. groups I – vehicle, Group II – glyburide (10 mg/kg, p.o.), Group III – PEFC (100mg/kg, p.o.) Group IV- PEFC (200 mg/kg, p.o.), Group V PEFC (400 mg/kg, p.o.). Blood samples were withdrawn at 2, 4, 6, 24 h for acute study, 7 and 14 days for subacute study, and 21 and 28 days for chronic study. Body weight, serum glucose and oral glucose tolerance test were evaluated. Treatment with PEFC showed significant reduction of serum glucose, increased body weight and OGTT, at the doses of (100, 200 and 400 mg/kg, p.o.) increased the tolerance for glucose significantly ($p<0.01$), suggesting increased peripheral utilization of glucose as compared to control group.

PH023

Cytotoxic Activity of Aqueous Extract of Leaf of *Maytenus emarginata* on HepG2 Cell Line

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Chemotherapy is a treatment where the drugs are used to attack the cancer cells. The drug enters through the blood stream, travels throughout the body killing the cancer cells at their sites and hence it is called a ”systemic treatment”. Chemotherapeutic drugs are chemically designed in such a way that they target the cells that divide and grow rapidly and ultimately resulting in the destruction of the cells. Drugs derived from natural products have been used to treat many diseases since the ancient times and they have also been mentioned for their use in the ancient literature. *Maytenus emarginata* is a wildly growing plant in the dry areas of India, belonging to the *Celastraceae* family. The plants of the *Celastraceae* family are used in jaundice, snake bite, cancer, as stimulant, anti-leukemic, anti-bacterial, insect repellent, etc. The present investigation was aimed to study the effect of aqueous fraction of hydroalcoholic extract of leaf of *Maytenus emarginata* on HepG2 cell line using MTT cell viability assay method, using vinblastine as a standard drug. The aqueous fraction of leaf of *Maytenus emarginata* shows 90 % cell viability as compared to standard drug. Hence, it shows negligible cytotoxic effect on the Hep G2 cell line. Further studies can be performed to investigate the cytostatic based anti-cancer potential of *Maytenus emarginata* using different assay methods, targeting various mechanisms involved in cancer.

PH024

Antiarthritic Activity of *Butea monosperma* Extract in Experimental Animals

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For the present investigations, leaves of *Butea monosperma* were used to evaluate the antiarthritic activity. The leaves of *Butea monosperma* were collected and dried in shade and subjected for successive extraction with Petroleum ether, Ethyl acetate and Methanol using soxhlet apparatus. After getting extract, preliminary phytochemical studies were carried out. For the induction of arthritis, 0.1 mL of freund’s complete adjuvant containing 1.0 mg dry heat-killed *Mycobacterium tuberculosis* per milliliter sterile paraffin oil injected into sub planter region of the left hind paw of rat. Chronic administration of higher dose showed significant decrease in paw volume, arthritic score and normal gain in body weight compared to vehicle treated animal. The hematological parameters (Hb, RBC, WBC, ESR and CRP) in the arthritic rats were significantly recover to normal by administration of 400 mg/kg of all extract. From the above results, the present investigations suggest that the higher dose of pet ether, ethyl acetate and ethanolic extract of *Butea monosperma* exhibits significant anti arthritic activity.

PH025

Permanent Hair Removal as an Alternative Treatment to LASER using Thanaka Powder and Kusuma oil.

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Unwanted hair growth is a problem faced by many women and men as well. They spend quite a lot of money and energy to remove them by chemical/physical ways like tweezing, threading, waxing or by using shaving creams. Laser is also one of the ways but the main drawback is side-effects to the portion of skin where the radiation is exposed. Hence as alternative the herbal treatment is introduced which is having no side-effects and quite cheaper. The admixture of kusuma oil and thanaka powder is being used since last 400 years in Myanmar. Thanaka in Burmese means 'elephant'; it is named so because of its tree-size being huge. Mainly grows in regions of Myanmar, Thailand, Afghanistan and also belts of Pakistan, its powder has coumarin and marmesin as main active constituents. Available in three grades A,B,C; grade A is used for hair removing purpose. On the other hand kusuma oil gives moisturizing effect. Belonging to Sapindaceae family, the kusuma oil is extracted from white seeds of *Schieichera oleosa*. Commonly known as Ceylon oak or lac tree, this oil has oleic acid, stearic acid, gadoleic acid and arachidic acid. It is yellowish brown in colour with faint odour of bitter almond. The mechanism behind the treatment is complete destruction of hair-roots on repeated application of this paste after weakening the growth. The pharmacological evaluation of this experiment needs to be carried out on animal models.

PH026

In-Vitro Cytotoxity Activity of *Gendarussa vulgaris* on *Vero* Cell Line

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One of the ethnomedicinal herb *Gendarussa vulgaris* is used to treat various alignments like chronic rheumatism and also to treat fever, cough, jaundice, thrush, arthritis, cephalgia, hemiplegia, facial paralysis, otalgia, hemicrania, bronchitis and liver disorders. Experimentally root and leaf of *Gendarussa vulgaris* exhibits antioxidant, hepatoprotective, anti inflammatory, antiarthritic, antimicrobial and antianxiety activities. This experiment is aimed to evaluate the cytotoxic effect of the leaf and root of *Gendarussa vulgaris* on *Vero* cell line. The effect of defatted methanolic extract of leaf and root of *Gendarussa vulgaris* at 100, 500, 1000 µg/ml concentration has been studied, using Cisplatin as a standard on MCF 7 breast carcinoma cell line using MTT cell viability assay. MTT cell viability assay of methanolic extract of leaf shows 75.89 % cytotoxity at 1000µg/ml concentration, whereas methanolic root extract does not show any significant activity on the Vero cells. The cytotoxicity of methanolic leaf extract of *Gendarussa vulgaris* shows significant activity and can thus be further evaluated for its anti cancer activity via various mechanisms, which may result in identification of potential lead molecule for cancer.

PH027

Evaluation of Anticonvulsant Activity of Leaf Extracts of *Ocimum Sanctum* in Experimental Animals

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Ocimum sanctum leaves has been used from long time in traditional medicine. The main objective of the work was to evaluate the anticonvulsant activity of *Ocimum sanctum*. Extraction was carried out by successive extraction in a soxhlet apparatus. Anticonvulsant activity of petroleum ether and methanolic extract of *Ocimum sanctum* leaves was evaluated using Pentylenetetrazole (PTZ) induced convulsions in mice and maximal electro shock (MES) induced Convulsions. Petroleum ether extract of *Ocimum sanctum* leaves shows the presence of steroids, terpenoids, alkaloids, glycosides, flavonoids, proteins, tannins, and carbohydrate while methanolic extract of *Ocimum sanctum* showed the presence of steroids, alkaloids, flavonoids, proteins and carbohydrates. The higher dose of petroleum ether extract (200 and 400 mg/kg) showed significant increased onset of convulsions. 100 mg/kg dose did not show any significant activity. Methanolic extract of Ocimum sanctum (400 mg/kg) showed significant activity. From the above result, we can conclude that petroleum ether and methanol extracts contained chemial constituents which could be active against Pentylenetetrazole induced convulsions which indicate the ethnomedicinal application of the plant.

PH028

In Vitro Cytotoxic Activity of Hydro-alcoholic Extract and Its Fractions of Leaf of *Gymnosporia montana* on Hepg2 Cell Line

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Gymnosporia montana (known as Vikro), occurring throughout the arid, dry areas of India, is traditionally claimed to be useful in various ailments. It has great potential as hepatoprotective drug. The present investigation was aimed to study the effect of hydro-alcoholic extract and its fractions of leaf of *Gymnosporia montana* on HepG2 cell line. The percentage cell viability of HepG2 cell line was carried out using trypan blue and the effects of different extracts of *Gymnosporia montana* on HepG2 cell line was carried out using MTT assay. The hydro-alcoholic extract shows 16.12% cytotoxicity at 1000 µg/ml and the fractions of hydro-alcoholic extract; petroleum ether and toluene shows 44.94% and 22.23% cytotoxicity at 1000 µg/ml respectively. Petroleum ether fraction is comparatively more cytotoxic as compared to the hydro-alcoholic extract and toluene fraction of the leaf of *Gymnosporia montana*.

PH029

In Vitro Antituberculosis Activity of Selected Ethanomedicinal Plants

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Tuberculosis holds one of the top places on the list of the main cause of death in India. At times , the patients fail to respond to treatment with anti tubercular drugs, drug resistance being one of the reasons. The increasing incidence of MDR-TB and XDR-TB worldwide highlight the urgent need to search for newer anti-tubercular drug. So, the present study was aimed to carried out the evaluatation of the antitubercular activity of selected ethanomedicinal plants. The aqueous, hydro-alcoholic (70%) and alcoholic extracts were prepared and evaluated for their antitubercular activity on *Mycobacterium smegmatis* using cup and bore method. All the extracts were evaluated in triplicate. Isoniazide and Rifampicin were used as standard antitubercular drug. The zone of inhibition was taken to assess antitubercular activity. Amongst all the plants tested ; tulsi, vasaka, and nagarmoth shows potent antitubercular activity as compared to other ethanomedicinal plants. Thus, its result supports the uses of these ethanomedicinal plants in traditional medicine and can be further evaluated for its antitubercular activity on pathogenic strain of *Mycobacterium tuberculosis*.

PH030

Millets – An Important Medicinal Crop and its Role as Pharmaceutical and Nutritional Agent

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A good and proper nutrition includes an adequate, well balanced diet with regular physical activity which makes an individual's good health and the Keystone for life. Everyone requires nutrition in their daily life as their own way as per body's need to maintain good and proper health. From that one of the major source of nutrition is crops mainly grain crops which is consumed worldwide as a source of energy. Crops like wheat, rice, millets, oats barley etc. are used as food source by many individuals in their daily life. As cereals have its benefits of nutritional source, also have other properties like high adaptability, easy harvesting process, and high yield which makes these grains more important in present condition. So the cultivation of crop in food industry, pharmaceutical industry, and nutraceutical industry has been increased. In the present review, the major focus has been kept on one of the category of crop that is commonly known as Millet. Millets are grains that come under grass family having higher nutritional value. Millet are also good source of phosphorus, manganese, magnesium and calcium like minerals. Presence of which reduce risk of heart disease, important for energy metabolism, for condition like osteoporosis, low density bone disease etc. In a way it serve the purpose of its use as pharmaceutical and nutritional agent.

PH031

Preparation of Hepatoprotective Syrup of *Gymnosporia montana*

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Piperine, has been well established bioenhancer if used in combination with other drugs. It reduces the drug dose, danger of drug resistance and toxicity of drugs. Piperine has been reported to bring about its bioenhancement effect by different mechanism including, DNA receptor binding, modulation of cell signal transduction, or by inhibition of drug efflux pump. The major objective of this paper is to explore the bioenhancement effect of piperine on the hepatoprotective activity. *Gymnosporia montana* (known as Vikro), belonging to family *Celeastraceae* occurring throughout the arid, dry areas of India, is traditionally claimed to be useful in various ailments specially in liver damages. Ethanomedicinally fresh leaves of Vikalo are chewed in tribal regions of Gujarat to cure jaundice. The hepatoprotective activity of the ethanol extracts of leaves of *Gymnosporia montana*. On basis of these reviews our aim is to prepare hepatoprotective syrup of methanolic extract of *Gymnosporia montana* with an additive aqueous extract of *Piper longum* as hepatoprotective and bioavailability enhancer to increase the hepatoprotective effect of prepared syrup. Evaluation parameters like viscosity, density, pH, microbial limit tests, and specific gravity of prepared syrup were measured as per the standard procedures and were compared with the standard values. It can be concluded that methanolic extract of *G. motana* could be formulated in combination of piperine as a bioenhancer for better protection of liver from the liver toxicants as well as for the treatment of the liver disorders.

PH032

Investigation of Antitussive Activity of Polyherbomineral Formulations on Cough Reflex Induced by Different Cough Induced Models in Mice

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The respiratory disease cough is an important defensive pulmonary reflex. It removes fluids, irritants, or foreign substances. When cough becomes non-productive and require suppression , we use opioid receptor agonists which not only have respiratory suppressant activity but also produce side effects such as sedation, addiction potential and constipation . The current study was performed to evaluate the antitussive activity of polyherbomineral formulation by ammonium liquor and sulphur dioxide gas induced cough reflex models in mice. Healthy albino mice (25-30 g) of either sex were grouped into seven groups and each group contain six animals. Group I considered as control, Group II and III received lab prepared herbomineral formulation (LPHF) (250 & 500 mg/kg, per oral), Group VI and VII treated with marketed formulation (MF) (250 & 500 mg/kg, per oral), Group IV and V were positive control and treated with standard (10 & 20 mg/kg, per oral) at a dose of 0.3 ml/mice, orally. Antitussive activity of LPHF and MF were studied by Ammonium liquor and sulphur dioxide gas induced cough in mice. All the formulations used showed significant antitussive activity in different cough induced model. Because poly herbomineral formulation contained hyoscyamine and hyoscine active constituent which induced a cough suppressant pharmacological effect and represents an attractive approach in phytotherapeutic managements. Thus, these formulations can prove to be useful for alleviating cough.

PH033

In-Vitro Nephro-Protective Activity of the Commonly Used Indigenous Medicinal Plants

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The most common complication in the cancer patients is renal failure, owing to the potential nephro-toxicity of several anti-neoplastic agents. Effectively overcoming this principal toxicity will impart significant benefit to patients with many types of cancer. The ethno botany and ubiquitous plants as a source of medicine has been an ancient practice and is an important component of the health care system providing a rich resource for natural drug research and development. Natural products from medicinal plants, either as pure compounds or as standardized extracts, provide unlimited opportunities for new drug leads, because of unmatched availability of chemical diversity. In the present study, six commonly used plants, Amla, Baheda, Harde, Ashwagandha, Turmeric and Kali Musli are selected. The *in-vitro* nephro-protective activity has been studied using MTT assay on the Vero cell line using cisplatin as a standard drug for toxicity. The alcoholic and aqueous extracts of the above drugs has been tested for their cell viability at different concentrations, ranging from 100 µg/ml to1000 µg/ml. From the performed assay, almost all the plants revealed an enhanced activity on the Vero cells, promoting their use as potential nephro-protective agents. The possible mechanism of action can further be validated by identifying the molecules from the plant extracts and subjecting them to various studies like docking studies, and their binding affinity with the targets.

PH034

Antioxidant Activity, Protective and Curative Effects of *Sphaeranthus indicus linn*. Flower Head Extract against Oxidative Stress Induced Liver Damage

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Sphaeranthus indicus (SI) Linn. (Asteraceae) is widely used medicine in Ayurvedic system in the treatment of variety of diseases like epilepsy, mental illness, jaundice, hepatic disorders, diabetes, leprosy, fever, cough, hernia, hemorrhoids, helminthiasis and skin diseases. Flower head of SI were extracted successively with petroleum ether, chloroform, ethylacetate, ethanol and water using Soxhlet's apparatus. The total flavonoids (TF), total phenolics (TP) and tannin (TT) content of were determined using quercetin and tannic acid equivalents, as standard. Free radical scavenging activities of all extracts were evaluated using standard *in vitro* methods- reducing power assay, DPPH, OH, nitric oxide, superoxide and inhibition of lipid per oxidation. Among all extracts, TP and TT contents were found more in ethanolic extract (64.23±1.64 and 11.96±0.49 mg/gm of dried extract, respectively) while flavonoids content in ethylacetate fractions (28.25± 0.84 mg/gm of dried extract). All extracts have concentration dependent free radical scavenging potential as well as inhibitory effect against lipid peroxidation in decreasing manner ascorbic acid> ethanolic> ethyl acetate> aqueous> chloroform> petroleum ether extract. Liver damage was induced by administering of carbon tetrachloride on alternate days, for 5 days and the extracts were given orally daily, for 7 days at doses of 100, 200 and 400 mg/kg p.o., b.w., i.e. total 12 days treatment. In the both i.e. curative and prophylactic study, ethanolic extract showed signiûcant effect against CCl_4-induced liver damage, comparable to silymarin. Hepatoprotective potential of ethanolic extract was further supported by decrease in pentobarbitone sleeping time and improved hepatic tissue histopathology. Study results suggest that either polyphenolic content, alkaloids and triterpenoids might be responsible for free radical scavenging property as well as protective and curative effect against CCl_4 induced damage.

PH035

Comparative Evaluation of Antioxidant Activity and Phytochemical Screening of Medicinally Important Bamboo Species Growing in India

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Herbals can be used as one type of complementary and alternative medicine. People use herbal to try to maintain or improve their health. Many people believe that products labeled “natural” are always safe and good for them. In recent era, there has been great demand for herbal products in developed countries. The aim of the present study was evaluation of antioxidant activity and phytochemical screening of three bamboo species Leaves of several bamboo species have been used to treat a variety of diseases for thousands of years. The medicinal effects of bamboo leaves are mostly attributed to their bioactive polyphenol constituents. Bamboo species was selected showing maximum flavonoids content similarity with that of tulsi. So,further studies were carried out using Bamboo species. In India, About 136 bamboo species are available. It is reported that bamboo species are rich sources of flavone c-glycosides which are known to have strong antioxidant activity. Antioxidants have the ability to protect organisms from damage caused by free radical-induced oxidative stress. A lot of research is being carried out worldwide directed toward finding natural antioxidants of plant origin. Three Bamboo species namely *Bambusa aurndinaceae, Bambusa vulagris* and *Dendrocalamus stictus* were selected for present study. Phytochemical screening of both the plants species indicates presence of saponins, tannins, phenolics, carbohydrates, phytosterols and high amount of flavonoids which act as antioxidanst.

PH036

Evaluation of Antidepressant Activity of *Butea monosperma* Using Animal Models

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The leaves of *Butea monosperma* were used for the study. The objective of the present work was to study the antidepressant activity of aqueous extract of *Butea monosperma* (AqBM) in laboratory animals. Aqueous extract of *Butea monosperma* was carried out with successive extraction method by soxhlet apparatus. Aqueous extract was then subjected to preliminary phytochemical studies to identify chemical constituents. Antidepressant activity was carried out by using forced swim test in mice, tail suspension test in mice and locomotor activity. The animals were divided into five groups. Gp I- vehicle, Gp II- standard, Gp III- AqBM (100 mg/kg), Gp IV-AqBM (200 mg/kg), Gp V-AqBM (400 mg/kg). In forced swim test and tail suspension test, each animals were observed for the duration of immobility for a period of 6 min. For locomotor activity, mice would be individually placed in actophotometer and would be counted for 10 min duration. All the test drug would be administered by orally one hour prior to behavioural studies. Oral administration of aqueous extract of *Butea monosperma* at a dose 200 and 400 mg/kg produced significant reduction in immobility in forced swim and tail suspension test and also increase in locomotor activity. AqBM (100 mg/kg) did not show antidepressant activity.

PH037

Antinociceptive Activity of Methanolic Extract of Leaves of *Grewia asiatica*

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Grewia asiatica (Tiliaceae) is traditionally used as antioxidant, antihyperglycaemic, radioprotective, hepatoprotective, antifungal and antiviral. Number of Indian medicinal plants has been claimed for their antinociceptive activity in the traditional system of medicine, but all of them have not been reported scientifically. In view of the above, the present study was to evaluate antinociceptive activity of methanolic extract of leaves of *Grewia asiatica* (MeGA). Antinociceptive activity of *Grewia asiatica* was evaluated in writhing, hot plate, tail flick and formalin models in mice. Oral administration of MeGA at a dose100 mg/kg (42.08 %), 200 mg/kg (62.11 %), 400 mg/kg (65.21 %) inhibition in acetic acid induced writhing model as compared to vehicle treated animals. Higher dose of MeGA (200 and 400 mg/kg) showed significant central analgesic activity on hot plate test tail flick and formalin induced pain as compared to vehicle treated animals. The MeGA exhibits antinociceptive activity at the peripheral and central levels, which supported the traditional use of the *Grewia asiatica* in the treatment of some painful diseases.

PH038

Medicinal Plants as Potential Wound Healing Agents: A Review

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Wounds are major cases of physical disabilities caused by physical, chemical, microbial (or) immunological insults. It involves opening or breaking of skin causing disturbance in the normal skin anatomy and function involving interaction of complex cascade of cellular and bio chemical actions ultimately healing to the restoration of structural and functional integrity with regain of strength of injured tissues. Extrinsic factors like pressure, friction, temperature, infection and intrinsic factors like age, nutritional status, underlying disease processes affect wound healing process. Mechanism of wound healing involves phases like inflammatory phase, proliferation and repair phase and lastly remodeling phase. It also involves activation of neutrophils, keratinocytes, fibroblasts, endothelial cells, macrophages, platelets, growth factors and cytokines. Release essential growth factors, proteases and cytokines that are important for the initiation and progression of wound healing (e.g., platelet-derived growth factor, transforming growth factor-β). Key elements of maturation include collagen cross-linking, collagen remodeling, synthesis of extracellular matrix and wound contraction stimulated angiogenesis. Plants have immense potential for management and treatment of wounds which are not only cheap and affordable but are also safe. Extracts of about 78 Indian plants e.g. *Azadirachta indica, Butea monosperma, Datura alba, Lawsonia alba* etc. have been reported for their wound healing activity through excision, incision and dead space models. About 24 plants have been enlisted with their mechanism of wound healing either by enhancing keratinocyte multiplication and migration, expression of proliferation related factors and epidermis formation, increasing vascular permeability and angiogenesis, or by enhanced VEGF expression or TGF-β1.

PH039

Comparison study of Radioprotective Potential of Two Bamboo Species *Phyllostachys parvifolia* and *Bambusa arundinacea* Leaf Extract on Ionizing Radiation Induced Genome Damage: an in Vitro Cytogenetic Study

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India is the second largest reserve of bamboo in world after China. Bamboo species are used in India as well as in China for treatment of various diseases. Bamboo species are rich sources of antioxidants. Many papers have reported that Antioxidants of Bamboo (AOB) are used to treat many free radial mediated diseases. Chemical constituents present in bamboo have characteristics to act as ideal radioprotector. So the present study was undertaken to examine and to compare the radio protective effect of the leaf extract of two bamboo species *Phyllostachys parvifolia* and *Bambusa arundinacea a*gainst radiation induced genomic damage in cultured human peripheral lymphocytes by cytokinesis blocked micronucleus assay. Fresh whole blood was exposed to 5Gy of Cobalt-60 gamma radiation with or without a 30min pre-treatment with 3µl and 5µl of hydro alcoholic leaf extract for comparison. The results obtained were analyzed statistically by Student's t-test, results were considered statistically significant when $P<0.05$.The decrease in the frequency of radiation induced micronuclei formation was compared for both the species at the selected concentration of hydro alcoholic leaf extract.

PH040

Pharmacognostic Study, Characterization of Marker Compounds and Pharmacological Review of Aerial Parts of *Hygrophila auriculata* (Schumach) Heine

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Hygrophila auriculata belonging to family Acanthaceae; is also known as *Asteracantha longifolia* and commonly known as "Neermulli, Talmakhana, Kokilaksha & Iksura" is a common plant growing in marshy and water logged areas. The plant is an important medicinal herb, widely distributed in India and is used for different medicinal purposes. Asteracantha longifolia (L.) Nees, Acanthaceae, is a source of the Ayurvedic drug, 'Kokilaaksha' and the Unani drug, Talimakhana. The aerial parts of are acrid, bitter, aphrodisiac, tonic, sedative, used for blood disorders. The plant is known to possess antitumor, hypoglycemic, aphrodisiac, antibacterial, free radical scavenging and lipid peroxidation, hepatoprotective and haematopoietic activity. It contains lupeol, stigmasterol, butelin, fatty acids, and alkaloids. It is also used commercially as an ingredient of some over the counter (OTC) formulations in liver disorder and those prescribed by general tonic. Many constituents have been reported from the plant *Asteracantha longifolia*. In the present study extracted aerial parts of Asteracantha longifolia were subjected to isolation and purification of phytoconstutients as marker. Isolation of phytoconstutients was done by Column chromatography using gradient elution with different mobile phases and silica gel as stationary phase. Petroleum Ether fractions were subjected to Gas chromatography to isolate fatty acids and lipids. Four fatty acids were isolated by gas chromatography. The compounds are Palmitic acid, Stearic acid, Oleic acid and Linoleic acid respectively.

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PC001

Effect of Stem Bark of *Terminalia arjuna* in Post-menopausal Osteoporosis

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Many herbal drugs have been traditionally used in Ayurveda to accelerate the healing of bone fractures and to strengthen the bones. However, no scientific study has been done to validate their usefulness in the alleviation of osteoporosis. The stem bark of *Terminalia arjuna* is traditionally acclaimed to heal bone fractures rapidly. The aqueous extract (TAA) and methanolic extract (TAM) of stem bark of *T. arjuna* were evaluated *in vitro* for their effect on calcium deposition in bones. Both extracts were also studied for their efficacy against post-menopausal osteoporosis using ovariactomized rat model, at doses of 250 and 500 mg/kg/bw. Estrogen treated ovariactomized rats served as positive control. TAM showed maximum activity in *in vivo* study, hence, it was further fractionated by extracting it successively with solvents of increasing polarity. N-butanol fraction of TAM (TAM-Nbut) caused significant increase in calcium deposition in bone as compared to other fractions. Saponin (TAM- Nbut-S) fraction and aglycone fraction (TAM-Nbut-A) were isolated from TAM-Nbut. Both the fractions showed significant activity in *in vitro* efficacy study, however, aglycone fraction was found to be more potent than saponin fraction. The results indicate that a sapogenin is responsible for the anti-osteoporotic activity of *T. arjuna.*

PC002

A Case Report of a Fatal Anaphalytic Reaction Followed by Inj.Benzathine Penicillin

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This case report is a rare occurrence of a patient who was on penicillin prophylaxis for the last 18 years, developed fatal anaphylactic shock after 18 years of administration of benzathine penicillin, which was taken as a monthly prophylaxis for rheumatic heart diseases. Benzathine penicillin, a repository penicillin preparation is used as the drug of choice for prophylaxis in Rheumatic Heart Disease (RHD). The most common adverse effect noted with penicillin are the hypersensitivity reactions ranging from maculopapular rash to anaphylaxis. . Fatal episodes of anaphylaxis have followed even with skin testing with minute quantities of the drug. There is no reliable means to confirm a history of penicillin allergy. It is said that less than 1% of persons who previously received penicillin without incident will have allergic reaction when given penicillin. In this case such a happening was observed. This itself is a rare instance and hence needs to be reported. The patient did not show any signs of hypersensitivity with test dose given prior to the full dose injection. Appropriate CRP, inotropic agents and all life saving measures were applied to revive the patient. Despite timely, appropriate and aggressive management of this case of anaphylactic shock it had a fatal outcome. This questions the age old practice of giving a test dose of benzathine penicillin to ensure patient safety with respect to hypersensitivity reaction. This adverse drug reaction was reported to ADR monitoring Centre, NHL Municipal Medical College, Ahmedabad and report Id. is 2015-46258.

PC003

Antidiabetic Activity of Ethanolic Extract of *Zingiber officinalis* on Experimental Animal

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Diabetes mellitus is metabolic disorder characterized by high blood sugar level associated with other manifestation in most of the cases diabetes mellitus develop due to deficiency of insulin. Present study is deal with the administration of selected herbal drug for better use of synthetic oral hypoglycemic drug, the induction of diabetes was successful by injecting alloxan monohydrate 200mg/kg /I.P and was confirm by blood glucose level. In present investigation *Zingiber officinalis* (ZO) was use for evaluation of antidiabetic activity. Concomitant administration of ZO+ metformin and ethanolic extract of *Zingiber officinalis* + metformin with normal and optimized dose respectively causes significantly synergistic decrease in blood glucose level.

PC004

Anti-Arthritic Activity of *Anthocephalus cadamba* Against Type II Collagen Induced Arthritis in Experimental Rats

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Anthocephalus cadamba is a medicinal plant belonging to the family Rubiaceae. The main objective of the present study was to investigate the Antiarthritic activity of the ethanolic extract of *Anthocephalus cadamba* (EtAC) at the dose of 100mg/kg, 200 mg/kg and 400 mg/kg on Type II Collagen induced Arthritis in experimental rats. Ethanolic extract was prepared by successive extraction method using soxhlet apparatus. Rheumatoid arthritis was induced by 0.1 ml of Collagen type II with incomplete frieund's adjuvant into the subplantar injection of rat paw. Results indicated that, significant increase in rat paw volume and reduce in body weight was observed in collagen type II induced arthritic rats, whereas oral administration of ethanolic extract of *Anthocephalus cadamba* and Diclofenac sodium treated groups showed significant decrease in paw volume, arthritic score and normal gain in body weight. The hematological parameters (Hb, RBC, WBC, ESR and CRP) in the arthritic rats were significantly recovered to normal by administration of EtAC. Further, the histopathological studies indicated less abnormality in EtAC treated groups when compared to the arthritic control group. Findings from the present investigations suggests that the ethanolic extract of *Anthocephalus cadamba* exhibits significant anti arthritic activity.

PC005

Investigation of Farsenoid X Receptor Ligand Ivermectin in Experimentally Induced Diabetic Dyslipidemia in Rats

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Diabetic dyslipidemia occurs due to effects of insulin resistance on abnormal lipid levels. Farnesoid X receptor is the member of nuclear receptor and plays an important role in liver, intestine, adipose tissue & vascular wall, and is activated by bile acid. Farnesoid X receptor regulates bile acid synthesis, conjugation and transport, as well as various aspects of lipid and glucose metabolism. All of the above are involved in diabetic dyslipidemia. In view of the above, we evaluated Farnesoid X receptor ligand-Ivermectin in experimentally induced diabetic dyslipidemia in rats. Healthy male Wistar Albino rats (~260 gm) were randomly allocated into seven groups (n=6); Group I Normal Control received R.O water, Group II Vehicle Control received 0.5% w/v Carboxymethyl cellulose suspension, Groups III-VII were given fructose diet (FD) for 28 days. In addition to this, Group IV received Metformin + Atorvastatin (45mg/kg+10mg/kg; p.o.), Group V-VII received Ivermectin 0.2mg/kg, 0.6mg/kg, and 1.8mg/kg, once daily, p.o. for 28 days, respectively. Body weight and food intake were calculated weekly and daily respectively. After 28 days, animals were sacrificed and serum samples were harvested for various biochemical analysis. Serum glucose level, oral glucose tolerance test, total cholesterol (TC), triglyceride (TG), low density lipoprotein (LDL), very low density lipoprotein (VLDL), high density lipoprotein (HDL), urea, creatinine, albumin and antioxidant: malondialdehyde (MDA), superoxide dismutase (SOD), and catalase (CAT) were evaluated after 28 days. One way analysis of variance (ANOVA) followed by post-hoc dunnett's test was performed for statistical analysis with $p<0.05$ set as statistical significance. Ivermectin (0.2mg/kg, 0.6mg/kg and 1.8mg/kg) treatment debased glucose, TC, LDL, VLDL, TG, urea, creatinine, MDA levels; augmented serum HDL, SOD and CAT levels. It also improved glucose tolerance pattern. So, it was concluded that Ivermectin, a Farnesoid X receptor ligand is a promising drug candidate against diabetic dyslipidemia.

PC006

A Novel Model for NSAID Induced Gastroenteropathy and the Proposed Role of TNF-α: Way Forward for the Discovery of Futuristic Therapeutic Interventions

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Management of NSAID-induced gastrointestinal toxicity is a challenge and requires the availability of appropriate experimental animal models that are as close to humans as possible and a proper understanding of its etiopathogenesis. Our first objective was to develop a rat model for NSAID-induced gastroenteropathy and also to explore if co-administration of NSAID and proton pump inhibitor (PPI) contributes to exacerbation of NSAID-enteropathy. Rats were treated twice daily with pantoprazole sodium (PTZ; 10 mg/kg peroral) or vehicle for a total of 10 days. In some experiments, Diclofenac sodium (DCF; 9 mg/kg) or vehicle was administered orally twice daily for the final 5 days of PTZ/vehicle administration. After the last dose on 9th day, rats in all the groups were fasted but water was provided *ad libitum.* 12 hours after the last dose on 10th day, rats in all the groups were euthanized and their gastrointestinal tracts were assessed for haemorrhagic lesions, lipid peroxidation, intestinal permeability and gastrointestinal luminal pH alterations. Changes in haemoglobin, haematocrit and serum levels of albumin, total protein, ALT and bilirubin were calculated. The macroscopic, histological and biochemical evidences suggested that administration of DCF resulted in significant gastroenteropathic damage and co-administration of PTZ resulted in significant exacerbation of NSAID enteropathy. Based on literature search we have also developed the probable cascade and interplay between various confounding factors of gastroenteropathy with special focus on TNF-α as a promising futuristic therapeutic target. Translation of this knowledge may aid in development of clinically relevant therapeutic interventions/strategies for the management of NSAID induced gastroenteropathy.

PC007

Anti-Hyperlipidemic Potential of Gallic Acid Isolated from Fruit Juice of *Emblica officinalis* in Various Rodent Models: Role of LPL Enzymes

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From the age of mythology, *Emblica officinalis* has been used traditionally in Indian traditional system for the management of numerous ailments. Hyperlipidemia is one of the major risk factor in progression of atherosclerotic lesions. The present study was planned to investigate the anti-hyperlipidemic potential of *E. officinalis* and its active constituent i.e. gallic acid in various experimental animal models of hyperlipidemia. Hyperlipidemia was induced with intoxication of tyloxapol and poloxamer-407 and showed significant rise in the plasma triglyceride and lipid levels. Oral corn oil load also supported the rise in the plasma TG levels with trivial elevation of total cholesterol level without affecting HDL level. Prior-treatment with gallic acid and fruit juice showed significant protection against rise in TG levels in all three experimental animal models. Systemic administration of tyloxapol and poloxamer-407 inhibits lipoprotein lipase enzymes which were reactivated by the treatment of gallic acid a well as fruit juice of *E. officinalis.* Simultaneously, gallic acid and fruit juice of *E. officinalis* also showed decrease in lipid absorbance from intestine resulted into anti-hyperlipidemic action upon oral corn oil load. Treatment with fruit juice of *E. officinalis* and its active constituent, i.e. gallic acid, exhibited thriving protective potential against factors which are answerable for causing hyperlipidemia and ultimately inhibits progression of atherosclerotic lesions.

PC008

A Case Report of Clofazimine Induced Ichthyosis, Enterophaty in a Patient of Leprosy

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Clofazimine is a fat-soluble iminophenazine red dye used in combination with Rifampicin and Dapsone as multidrug therapy (MDT) for the treatment of leprosy and to treat Mycobacterium avium infections in AIDS patients. Adverse effects to clofazimine are dose related gastrointestinal effects are the most common in the form of nausea, vomiting and abdominal pain in about 40-50% of the users. These gastrointestinal problems seen to be benign but can lead to fatal outcome. Our case, reports this adverse occurrence in a patient who was prescribed tablet clofazimine in the dose of 100 mg three times a day for three months and experienced this fatal gastrointestinal adverse effects. The dose consumed by this patient was a higher dose range reflecting the association of clofazimine with this dose related side effects. The reason for this could be deposition of crystals of clofazimine in the wall of the small bowel and in the mesenteric lymph nodes, liver and spleen on chronic ingestion of the drug. Although clofazimine was immediately withdrawn still the reaction did not resolve and turned out to be fatal despite appropriate treatment measures. Clofazimine induced Enteropathy is a rare but well-recognized condition reported in some literatures. Rarely, patients have died from bowel obstructions and intestinal bleeding, or required abdominal surgery to correct the same problem. Autopsies performed on those who have died while on clofazimine show Crystal-like aggregates in the intestinal mucosa, liver, spleen and lymph nodes. Though occurrence of cases is rare but serious and sometimes deaths have also been noted. Hence careful and appropriate prescribing is mandated by the prescriber to decrease the incidence of adverse drug reactions. This adverse drug reaction was reported to ADR monitoring center, NHL Municipal Medical College, Ahmedabad and report Id. is 2015-31086.

PC009

Pre-diabetic Screening Campaign: An Effort to Decrease the National Diabetic Burden

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Pre-diabetes is a medical stage in which blood glucose level is higher than the normal but not yet high enough to be diabetic. People with Pre-diabetes are more likely to develop diabetes. Early detection of Pre-diabetes and proper treatment will decrease the risk of development of type 2 diabetes by 58% or prolong the prevalence of diabetes. The objective of study was to identify undiagnosed pre-diabetic patients & refer them to appropriate health care professionals and to spread awareness in the people of all classes about the danger of neglecting diabetes and to train budding pharmacists. A Pre-diabetes screening camp was organized at high footfall areas of Navi Mumbai such as Panvel, Govandi and Kalsekar Technical Campus after informing the public by distributing handbills, displaying banners, and family physicians. A diabetic risk score devised by Mohan et al. and Finish Diabetes Association was used. The details of BMI, family history, blood glucose levels etc were recorded. Based on the risk score participants at high risk were identified, counseled and referred to appropriate health care professionals. Informative handbills about Pre-diabetes were distributed to public in different languages.

Results showed that out of 406 participants, screened and counseled, 88.42 percent were at low risk. 3.44 percent and 8.12 percent were found to be diabetic and pre-diabetic respectively. It was concluded from the study that this 3 days campaign created awareness among the people of targeted areas. By and large such attempts would eventually help to decrease the diabetic burden in the general population through appropriate intervention of competent pharmacists.

PC010

A Drug Interaction Leading to Adverse Drug Reaction-Hypokalemia in a Patient of Guillain Barre Syndrome (GBS)

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Aminoglycosides like Amikacin are continuously being used in clinical practice because of its efficacy and synergism with penicillins. The incidence of nephrotoxicity from aminoglycoside has increased upto 20% in past few decades. This case report represents severe hypokalemia following Amikacin. Amikacin along with cefoperazone, inhaled Salbutamol and Levetiracetam was prescribed in a patient of GBS for lower respiratory tract infection on first day of admission. After two days of starting the drug therapy, level of potassium reached upto 2.1 mmol/L. After 10 days of Amikacin was withdrawn among all other drugs and within two days, potassium level improved upto 4.1 mmol/L. The possible mechanism could be aminoglycoside induced renal toxicity which may manifest renal tubular dysfunction. Aminoglycoside induced renal tubular dysfunction could result in diffuse damage or distal renal tubular acidosis. Severe hypokalemia may be an outcome of drug interactions between Amikacin, Cefoperazone Salbutamol and Levetiracetam. Salbutamol induced hypokalemia is due to increased uptake of potassium by skeletal muscles. Levetiracetam and Cefoperazone also rarely cause hypokalemia by unknown mechanisms so , hence possibility of drug interaction has to be kept in mind when patient receives multiple drugs. This adverse drug reaction was reported to ADR monitoring centre according to pharmacovigilence programme of India, report Id is 2015-31086.

PC011

Methylglyoxal, Advanced Glycation End Products and Neurodegeneration

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Parkinson disease, Alzheimer's disease, prion disease, etc. are the neurodegenerative disorders affecting major population of the world by various kind of disabilities. Amongst all the neurodegenerative disorders, Alzheimer's disease is the most common form of neurodegeneration. It is characterized by the aggregation of A-beta peptides and formation of neurofibrillary tangles from the phosphorylated tau protein. Methylgloxal (MG) is the byproduct of the glycolytic pathway. It is the most common source of advanced glycation end products (AGE). AGE and MG both were reported to be increase in patients with Alzheimer's disease (AD). They are also related with increased oxidative stress in AD. MG can increase the level of phosphorylated tau protein and can act as the neurotoxic mediator of oxidative stress. AGEs can also enhance reactive oxygen species formation and can exaggerate the process of apoptosis and cellular dysfunction. Hence, MG and AGEs may be the potential targets for the treatment of neurodegenerative disorders like AD by reducing carbonyl stress and pathophysiological modifications. This review has been formulated to represent the mechanical aspects of involvement of MG and AGE in development of AD.

PC012

Newer Antidepressants Triggering Suicidal Ideation: An Area of Concern

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In March 2004 the US FDA warned physician and patient regarding increase risk of suicide with 10 new antidepressant (Bupropion, Citalopram, Fluoxetine, Fluvoxamine, Mirtazapine, Nefazodone, Paroxetine, Sertraline, Escitalopram and Venlafaxine). Depression is a common disorder with an average national deficit of 77% for psychiatrists in India; depression comes in the 20 leading cause of disability according to WHO. Antidepressant drugs especially SSRIs have been reported to increase suicidal ideation especially in adolescent and young adults. This case series comprises of four such cases which presented to emergency medicine department. We studied four cases admitted to emergency department of a tertiary care hospital in month of august 2015 with attempted suicide. On examining their records all of them were prescribed antidepressants, like Tab. Escitalopram, Tab. Amitriptyline Tab. Clomipramine, Tab. Duloxetine. The association of increase suicidal attempts /ideation with antidepressant drugs themselves has been reported in the West but data in the Indian population is lacking. Antidepressant are widely used not only for treatment of depression but also many other psychiatric illnesses. It is still unclear whether suicidal ideation is because of these drugs or the progression of the disease. We identified all patients who had received at least one prescription for one or more antidepressants. We recorded all such patients who attempted suicide. All four patients were discharged after recovery. The association between suicidal tendency and antidepressant medication is still unclear. So these case studies is an attempt to provide supporting evidence of the relationship between Antidepressant use and the risk of suicidal ideation necessitating more care full prescribing by the physicians.

PC013

Mechanisms of Neuronal Degeneration and Strategies for Regeneration

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Neurodegenerative diseases comprises of several diseases of neurological origin. Although basic mechanism involves neuronal cell death, all the diseases have difference in pathophysiology. Moreover, each disease has characteristic clinical presentation which differs from each other anatomically and/or functionally. Neurodegenerative diseases are characterized by progressive, irreversible neuronal cell loss or apoptosis. As a consequence of neuronal death, the neuronal networking is altered. A characteristic of many neurodegenerative diseases which include Huntington's disease, Parkinson's disease, Alzheimer's disease, spinal cord injury, amyotrophic lateral sclerosis (ALS), and brain trauma, is neuronal cell death. The estimated lifetime risk of developing neurodegenerative disease is nearly 1 in 5 for women (17.2%) and 1 in 10 for men (9.1%). It is estimated that there are currently about 18 million people worldwide with neurodegenerative disease. With the advancements in latest biotechnological tools and molecular studies in last two decades, the research in the field of neuronal regeneration has accelerated. Several strategies have now been developed for neuronal regeneration. However, discoveries are still limited in scope. Regeneration strategies include stem cells transplantation, altering of patient's own stem cells, and the use of technologically driven biomaterials that emit biochemical signals to stimulate stem cells into action etc. The latest development includes generation of glial cells from stem cells. The present review aims at discussing the mechanisms and strategies of neuronal degeneration and regeneration.

PC014

Antipsychotic-Induced Hyponatremia: Case Series

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Hyponatraemia is known to occur as a rare but clinically important adverse reaction to treatment with different psychotropic drugs, including SSRI and antiepileptic drugs. The prevalence of hyponatremia has been estimated as 15% and 11% in general and psychiatric hospital settings, respectively. It can cause significant morbidity by way of an osmotic demyelinating encephalopathy which may lead to serious consequences, such as lethargy, confusion, coma, and occasionally death. In our case series of 4 cases, patients were on Escitalopram, oxcarbazepine, and olanzapine respectively. The commonest serotonin-reuptake inhibitors (SSRIs), causing hyponatremia is reported to be due to escitalopram. In our case series 2 patients were on escitalopram which is known to cause hyponatremia. Hyponatremia due to oxcarbazepine may occur because of the following reasons. The first reason being that there is no proper physiological stimuli but increased secretion of hypothalamic production and hypophyseal release of AVP(arginine-vasopressin) secondary to SIADH (like antipsychotic, antidepressants). The second explaination is via potentiating the endogenous AVP release in the kidney at the level of renal tubule. Hyponatremia due to antidepressants like TCAs, SNRIs, and SSRIs have one another mechanism that serotonin (5-HT) can cause release of AVP from neurohypophysis. Both the newer atypical antipsychotics and the older drugs have been associated with the development of hyponatraemia. Physicians, psychiatrists and other healthcare workers should be aware of the possibility of hyponatraemia associated with the use of psychotropic drugs. In all of the cases the culprit drug was withdrawn and patients were discharged with uneventful outcome. These adverse drug reactions were reported to ADR monitoring Centre and forwarded to the National Coordinating Centre under Pharmacovigilance Programme of India.

PC015

Withania somnifera Answers Neurodevelopmental Disorder-Attention Deficit Hyperactivity Disorder (ADHD)

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One of the common neurodevelopmental disorders is Attention Deficit Hyperactivity Disorder (ADHD) whose global epidemiological studies showed that 5% of children and 2.5% of adults suffer from it. The studies showed that males are more prone to ADHD than females with ratio 2:1 in children and 1.6:1 in adults. The DSM-IV scale for diagnosis divides symptoms into aggressiveness, impulsiveness and hyperactivity. The social-isolation of Rats model easily mimics the symptoms of ADHD in Rats. Thus, in this study, Social Isolation (SI) model was used to study the effectiveness of *Withania somnifera* in ADHD against standard drug caffeine. Caffeine serves as a CNS stimulant which is a type of drug used in ADHD treatment. SI rearing impairs retention of spatial attention in the Elevated plus Maze test and Passive Avoidance which is independent of age and gender of the animals. The deficits were found to be persistent and *Withania somnifera* improved them in a similar way as caffeine. Behavioral aggressiveness like rearing, violent wrestling, biting act and tail rattle was reduced by *Withania somnifera* (Ashwagandha) at both the tested doses. All the behavioral parameters in Elevated Plus Maze model, Operant Conditioning Chamber and Passive Avoidance showed significant alteration with *Withania somnifera* treatment indicating that the drug has neuroprotective effect in ADHD.

PC016

A Meta-Analysis on Medication Error

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Medication errors have been long and growing common universal problem in health care which can be easily controlled. This meta-analysis study covers original researches related to all four types of medication errors: prescribing error, transcription error, administration error and dispensing error. Seventeen English language original literatures were selected for study from Proquest and Pubmed database. The result shows that total medication error rate to medication order was 0.169 (CI 95%: 0.149-0.189), Prescription error rate to total medication error was 0.196 (CI 95%: 0.142-0.249), Transcription error rate to total medication error was 0.153 (CI 95%: 0.093-0.213), Administration error rate to total medication error was 0.530 (CI 95%: 0.449-0.611), Dispensing error rate to total medication error was 0.214 (CI 95%: 0.149-0.280). Investigation was done by I^2 for Heterogeneity and Funnel plot for publication bias. Analysis was performed with the help of Comprehensive Meta-Analysis software. Medication errors are a reality in healthcare services. The medication process is significantly prone to get errors, during prescription, drug administration and dispensing. This study indicates the need of vigilance to prevent the medication errors. Clinical pharmacists can play a major role and their interventions and can effectively reduce medication errors. This study forms the base for implementation of Clinical Pharmacy Services (Pharmaceutical Care) for patient care in Indian healthcare system.

PC017

Do Electronic-Cigarettes Require Regulations?

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Electronic cigarettes (E-cigarettes) are hand-held, battery-operated devices that deliver vaporized liquid "E-juice" containing flavorings and/or nicotine. E-cigarettes create a mist for inhalation which usually contains nicotine. The vapor from E-cigarettes does not contain carbon monoxide or the other toxic products of combustion as in conventional tobacco smoke. Smoke is exhaled as a visible mist, simulating cigarette smoke called "Vaping" which mimics the behavioural and sensory aspects of smoking. Nicotine in E-cigarettes is delivered more quickly than most forms of Nicotine Replacement Therapy (NRT) like nicotine gums and patches but comparatively at slower rate than conventional tobacco smoking and thus reduces the span of systemic nicotine delivery. Main objectives of E-Cigarettes are smoking cessation, relapse prevention and temporary abstinence as substitute. Studies show that E-cigarettes reduce the withdrawal symptoms. As E-cigarettes deliver nicotine more slowly than conventional cigarettes, they have lower potential for abuse theoretically. However, till date, no long-term studies are carried out for abuse potential and safety issues. Despite significant detrimental effects on society, major concerns about their quality, composition in terms of nicotine content and flavours used, inadequate and inaccurate labelling, majority of the countries do not have regulations for E-cigarettes. For people, who have failed to quit with current approved therapies, E-cigarettes may offer an alternative. However, their overall effectiveness, safety and impact on public health remain controversial. In conclusion, E-cigarettes require regulations from drug control authorities with clear cut indications about their benefits and risks for their judicious use.

PC018

Influence of Diabetes on Tuberculosis Management: Need for a Collaborative Care

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According to the WHO, TB now ranks besides HIV as a leading cause of death. It was estimated that, worldwide 9.6 million people were badly affected with TB in 2014. India is one of the few countries with largest number of TB cases (23% of global total, 2014) and population with diabetes (65.1 million, 2013). Research shows that, infection such as TB may activate the onset of diabetes and worsen glycemic control in known diabetics. Studies concluded that the presence of diabetes negatively affects TB treatment outcomes by delaying time to microbiological response, increased failure rates in non-drug resistance cases and by increasing risk of relapse or death. Based on this situation, it is necessary to screen TB patients for diabetes to rule out undiagnosed diabetes and to improve anti-TB treatment outcomes by better diabetes care. We searched PubMed and Google Scholar database with reference to some of the relevant articles and reports of observational studies for TB patients. Our review is aimed to summarize prevalence of diabetes and impaired fasting glucose (IFG) among TB patients, factors associated with prevalence of diabetes and possible pharmacological issues that may arise in co-management of TB and diabetes.

PC019

Pharmacological Evaluation of Ayurvedic Proprietary Medicine Herbolean Capsule for Antihyperlipidemic Activity

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The term hyperlipidaemia means high lipid levels. Hyperlipidaemia includes several conditions, but it usually means high cholesterol and high triglyceride levels. Ayurvedic herbolean capsule is used for the evaluation for antihyperlipidemic activity. Main objective was to investigate anti-hyperlipidemic effect of formulation using Poloxamer 407 induced hyperlipidemia in rat.Wistar rats were divided into four groups: NC-normal control- receives vehicle, DC-disease control (poloxamer 100mg/kg i.p.), DF-Diseased treated with Formulation in 0.5% Na-CMC (17.26 mg/kg p.o.), DS- Diseased treated with fenofibrate (100mg/kg p.o.). Hyperlipidaemia was induced by poloxamer 407 (100mg/kg i.p). Treatment was given to rat orally once a day for day 1 to day 7. On the next day finofibrate (100mg/kg p.o) was given to the DS group and after one hour hyperlipidaemia was induced by poloxamer (100 mg/kg i.p). The blood sample was collected immediately from the retro orbital plexus after the induction after the 8 hour. The serum was separated and the total cholesterol and triglyceride levels were measured using diagnostic colorimetric kit. The results showed that the levels of total cholesterol and triglyceride were significantly decreased in the group of disease treated with formulation than disease control group. Therefore from this study we can conclude that the Herbolean capsule is having the antihyperlipidemic activity.

PC020

Healthcare in Digital Age; Opportunities and Challenges in *e* Health

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e Health is a global issue but successful e Health implementation is very dependent on the local context. The future of healthcare is connected, patient-centered, mobile and social. The key concerns for healthcare in digital age are to identify the core areas of growth and disruption in digital health, to distinguish between hype and real opportunity in digital health, to define basic e Health concepts and to describe the development of the field as well as what the success factors and barriers are for eHealth implementation. Opportunities and challenges for e Health are to identify major challenges facing doctors and patients as medicine transitions from analog to digital, how digital health is re-defining the physician, to recognize the emerging role of the e-patient in health care, how to critically analyze the risks and opportunities facing individuals and health organizations as they transition to the digital health space and how to use twitter like an expert to leverage public dialogue, both personally and professionally. Advanced information, electronic health record, advanced-tools/devices, computer-based systems and telecommunications technologies have a central role to play in transforming our health care system. The overall health IT endgame is the right one, creating a continuous and integrated care cycle that helps drive the best patient care outcomes. Healthcare in digital age is all about analyzing e Health strategies and adapting them in relation to your specific context.

PC021

PI3K Potential Target for the Cancer

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The phosphoinositide 3-kinase (PI3K) pathway is a key path for signal transduction system which play an important role in various cellular functions like cell growth, survival, proliferation, differentiation, motility, survival and intracellular trafficking, which further lead to cancer. Overexpression of this pathway may lead to the cancer and other diseases like CNS disease, diabetes, HPV infection, herpes virus infection, CVS disease, etc. This in turn offers both an opportunity and a challenge for cancer therapy and other disease therapy. PI3Ks are divided into three classes according to their structural characteristics and substrate specificity. The most commonly studied are class I enzymes that are activated directly by cell surface receptors. Class I PI3Ks are further divided into class IA enzymes, which are activated by RTKs, GPCRs and certain oncogenes such as the small G protein RAS, and class IB enzymes, which are regulated exclusively by GPCRs. Momentous efforts are going on to investigate the potential and challenges for the development of new chemical entity for cancer through this pathway. As compounds that target PI3K (or AKT and mTOR) progress through clinical trials, potential issues associated with toxicity and resistance can be expected. Oncogenic changes in other components in the PI3K pathway, or other parallel and/or interconnected pathways, may also render cancer cells resistant to PI3K inhibition. It is therefore important to identify new therapeutic targets for the development of drugs that may be used either in place of PI3K inhibitors or to enhance the efficacy of PI3K inhibitors at subtoxic doses.

PC022

Antimalarial Activity of Indian Propolis

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Propolis is a natural resinous mixture produced by bees from substances collected from parts of plants, buds and exudates. It protects their hives against microbial attack and climate changes. It is reported for antimicrobial and antifungal activity. In this study, the antimalarial activity of hydroalcoholic extract of Indian propolis was evaluated in *Plasmodium berghei* induced malaria in Swiss albino mice. Malaria was induced in all mice except normal control by intraperitoneal injection of *P. berghei* infected blood obtained from donor mice on day 0. Group 1 served as normal control and received saline. Group 2 (disease control) received infected blood. Group 3 received chloroquine (25 mg/kg, i. p) and served as a standard. Test group *viz.* group 4, 5 and 6 received 25, 75 and 250 mg/kg of hydroalcoholic extract of propolis respectively *per oral* route. Animals received either chloroquine or propolis for consecutive 3 days. Body weight, food intake, water intake and rectal temperature were recorded. Hemoglobin, Packed Cell Volume (PCV), % parasitemia, % protection and survival rate were measured. Propolis at 75 mg dose showed significant improvement in % paracitemia, rectal temperature and body weight but not in food intake, water intake, hemoglobin level, PCV, % protection and % survival. Propolis at 250 mg significantly improved all parameters. Indian propolis was effective in reducing parasite load, disease associated complications and mortality therefore showed significant antimalarial effect.

PC023

Herbal Boons for Diabetic Retinopathy

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Diabetic Retinopathy (DR) is defined as a diabetic microvasculature complication which leads to pericytic cell death, alongside the formation of macular edema as a result of chronic hyperglycaemic condition. It is estimated that the number of people with DR will grow from 126.6 million in 2010 to 191.0 million by 2030 globally. The prevalence of DR in India is about 18% of the whole urban population of India who have diabetic mellitus. Thus, it is a matter of concern and a need has arisen for the development of effective medications treating DR. There are various ways to curb DR which includes strict glucose control, blood pressure control, regular examination of eyes and so on. Currently, drugs like Lucentis or Bevacizumab have gained large popularity in its treatment but alongside, there has been successful research on herbs which can find a place for successful treatment against the symptoms of diabetic retinopathy. This review summarizes the development of various herbs like Methi, Flax Seeds, Guggul, Onion, Garlic, and Berry Fruits for diabetic retinopathy. They have shown positive results for treating various anti-inflammatory symptoms or complications of diabetic retinopathy and can be developed into formulations for treating the same.

PC024

Metabolomics in Pharmacology

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Metabolomics is a science dealing with chemical process involving metabolites. The metabolites may be end products / intermediates or by products of processes of metabolism. Their quality and quantity reflect metabolic phenotype of an organism. The metabolic phenotype is a result of interaction between organism's genotype and environment. Metabolomics helps to understand the detailed aspect of this interaction. Many combined instrumental techniques like LC-MS and NMR have become popular. It is an advanced toll of biological science which provides an over view of an organism's genotype. The Metabolomics is an important tool for pharmacological research and discovery. It provides a great insight to understand interaction between drug and organism's body at pharmacokinetics, pharmacodynamic and pharmaco therapeutic level. It also provides an effective and inexpensive tool to evaluate drug safety and drug efficacy. This approach would make concept of 'personalized medicine' a realistic tool for benefits of patients. It also provides an accurate and precise means for identification of newer drug targets, validations of targets, optimization of lead and ADMET screening. It also helps to understands molecular mechanism of toxicity and helps to predict toxicity at early stage in pre-clinical and clinical studies during drug development and research. The science of metabolomics involves the use of many modern analytical techniques including HPLC (High Performance Liquid Chromatography), GC-MS (Gas Chromatography-Mass Spectrometry), LC-MS (Liquid Chromatography Mass Spectrometry), NMR (Nuclear Magnetic Resonance), Crystallography, FT-MS (Fourier Transform ion cyclotron resonance Mass Spectrometry) and LIF detection. Nowadays, one or more different techniques are combined for better resolution, accuracy and precision. The budding science of metabolomics has a unique prospectus in pharmacological research.

PC025

A Study on Evaluation of Appropriateness of Antimalarial Therapy

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Malaria is a parasitic disease which can be easily prevented and treated. It is a big challenge to control malaria due to the emergence of drug resistance. The novel treatment should be based on how to prevent transmission of infection and the emergence of resistance. In Plasmodium falciparum malaria, Artemisinin-based combination therapy is the mainstay of treatment, and their efficacy must be preserved. Therefore care should be taken not to use these drugs indiscriminately to prevent the emergence of Artemisinin resistance. Chloroquine is the first line drug for Plasmodium vivax infections and should be maintained as the most efficacious therapy. It has been found recently that there are reports of failures of primaquine as antirelapse therapy for P.vivax malaria, from different regions including some parts of India. Incomplete or incorrect dosing or poor compliance are also one of the main reasons for the treatment failure. On the basis of WHO guidelines, the present data (n=24) indicates that total number of cases with inappropriate duration was 12, missed drug cases were 3 and inappropriate drug selection cases were 2. Out of 8 cases of Artesunate containing prescriptions, one case was prescribed with Artesunate as monotherapy. Overall inappropriateness was 41.66% (n=10) and appropriateness was 58.33% (n=14). Therefore care should be taken to ensure rational use of the few remaining effective drugs. The role of clinical pharmacist comes into picture to prevent such a bad scenario.

PC026

Pharmacological Effect of Acetoacetate in Diclofenac Induced Peptic Ulcer

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The objective of this work was to study the effect of ketone bodies in peptic ulcer by using Diclofenac as inducing agent. Peptic ulcer disease is the most common disease worldwide. Diclofenac sodium is the highest prescribed drug amongst the analgesics, antipyretics and anti-inflammatory agents. Diclofenac sodium induces peptic ulcer in rats because of its prostaglandin inhibitory properties. Acetoacetate, a ketone body is the chemical produced by our body and it breaks down the fat for energy consumption. Wistar rats were taken for the study. They were divided in 4 groups: Normal control, Disease control, Positive control and Test (each of 6 animals). Peptic ulcer was induced with Diclofenac sodium. Diclofenac sodium (20mg/kg), acetoacetate (5.26mg/kg) and ranitidine (13.5mg/kg) were given for 4 days consecutively. Animals were euthanized on the fifth day. The stomach was isolated for ulcer index tissue measurement, estimation of oxidative stress parameter and histopathological studies. Results showed that there was a significant decrease in the ulcer index and catalase level in all the groups compared to disease control group. Significant increases in the levels of markers of oxidative stress i.e. SOD and lipid peroxidation was observed in test group. Histopathological analysis shows decrease in inflammatory cells in test and positive control group in comparison to disease group. Acetoacetate showed protective action against Diclofenac sodium induced peptic ulcer.

PC027

Animal Models for Cancer Cachexia

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Cancer cachexia is a complex metabolic syndrome characterized by negative energy balance resulting from loss of adipose tissue and skeletal muscle mass leading to progressive weight loss irrespective of nutritional intake. It also triggers a chronic, systemic inflammatory response thereby generating cytokine imbalance. This irreversible condition is prevalent in many late stage cancers accompanied by anorexia, early satiety, weakness, anemia and edema, which further affects quality of life. Various animal models are available to induce cancer, however only few are known to mimic cachectic condition. Thus, specific animal models for cancer cachexia are established which can be classified into syngeneic, xenograft, carcinogen-induced and genetically modified animals. In case of syngeneic models, animal cell cultures are implanted subcutaneously or orthotopically whereas, in xenograft models, tissue is of human origin – major disadvantages of both being high risk of false therapeutic results because of lack of metastasis in the former and lack of reproducibility of tumor-host interactions in the later. In carcinogen-induced tumour models, degree and duration of oncogenesis remains highly variable and much resemblance to clinical conditions is not observed whereas, genetically engineered animals resemble human cancers to a greater extent since they occur spontaneously and apparently do not have major drawbacks. Considering these aspects, an attempt is made hereby to discuss various animal models of cancer-cachexia and elaborate on their pros and cons and possible applications to help researchers to come up with efficacious treatments for the disorder in days to come.

PC028

Novel Signal Transduction Pathways in Breast Cancer: A Review

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Breast cancer, the leading cause of death worldwide, is treated by monotherapy or combination therapy. In spite of extensive ongoing research, there is a need for identifying new pathways on which different drugs can act. This review includes several pathways which have been implicated in growth of cancer cells and angiogenesis along with novel drug targets. Majority of treatments are combination of drugs inhibiting several pathways. Some targets leading to breast cancer includes micrornas, receptor tyrosine kinase, hormone receptors, Human Epidermal Growth Receptors (HER2), Ubiquiton Proteasome System (UPS), Heat Shock Protein 90 (HSP90), PI3K/AKT/mtor pathways and RAS/RAF/MEK/MAPK pathways. Currently available therapies have several limitations like higher side effects and health care costs. In the light of this, newer targeted therapies are needed to treat breast cancer.

PC029

Tyrosine Kinase Modulation: New Emerging Target for Breast Cancer Management

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Breast cancer is a malignant proliferation of cellular constituent of breast. Mortality burden due to disease in India is around 50,000 per year and over 90,000 new cases are registered every year. One of the most conventional classifications is according to type of tumor and histological grade, which includes the expression of estrogen receptor (ER), progesterone receptor (PR), and tyrosine kinase (TK) receptor. The targets of breast cancer are interconnected to great extent making pathophysiology more complex. With advancement in the knowledge of cellular processes and signaling pathways involved in the pathogenesis, the recent attention of researcher is to develop novice targeted treatment protocol that can be incorporated in the armamentarium against breast cancer. The role of TK in cancer molecular pathogenesis is colossal and recently kinases have come in vogue as promising anticancer drug targets. The TK family comprises growth factor receptors like Epidermal Growth Factor Receptor (EGFR), Vascular Endothelial Growth Factor (VEGF), Fibroblast growth factor (FGFR), Platelet Derived Growth Factor (PDGF) and Insulin Growth Factor (IGF). EGFR over amplification leads to suppression of apoptosis, proliferation and invasion. VEGF controls angiogenesis. PDGF and FGF control blood vessel development and cell growth. IGF-1 receptor plays a critical role in cell survival and anti-apoptosis. Considering the notion of cooperativity between proteins that induce breast cancer, it is likely that therapeutic combinations aimed at multiple molecular targets may prove to be more efficacious than mono specific therapy in the treatment of breast cancer.

PC030

Remission of Diabetes and Bariatric Surgery

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Diabetes is a chronic metabolic disorder in which insulin resistance occurs and 8.3% of the population suffer from it worldwide. It is not completely curable however, various drugs viz. biguanides, sulfonylurea, GLP-1(Glucagon like Peptide-1) analogues, DPP-4(dipeptidyl peptidase-4) inhibitors are available which can improve glucose intolerance by various mechanisms but can't eliminate the diabetes completely. On the other hand, bariatric surgery has been reported to remit type II diabetic condition. This surgery is done on stomach and/or intestine to those who are extremely obese and have BMI (Body mass index) more than 30. There are mainly two types of bariatric surgeries viz. restrictive and malabsorptive – former is done by physically restricting the size of the stomach while in latter one some part of the stomach is removed in addition to restriction of the stomach. There are some hypotheses related to ghrelin and GLP-1 which suggest how diabetes remission occurs post bariatric surgery. Ghrelin is a hormone which induces appetite and inhibits insulin secretion while, GLP-1 is protein which helps in insulin secretion. Reports suggest that GLP-1 increases three folds after bariatric surgery in majority of the patients; however, its level was found to be variable in few post-surgery. The review will be discussing the co-relation of GLP-1 and Ghrelin with bariatric surgery and its subsequent possible effect on insulin secretion and/or concentration.

PC031

Review upon Physiology of Aging Process

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Aging is progressive, intrinsic, inventible and irreversible functional decline or a gradual deterioration of physiological function with age. It refers to the biological process of growing old in a deleterious sense called senescence. Human aging is associated with a wide range of physical changes that makes a person more susceptible to death but limit his/her normal function and render him more susceptible to a number of diseases. Different people age at different rate and different ways. There is no way to quantify ageing. Scientist theorize that aging likely results from a combination of many factors like radiation, free radicals, lack of nutrition and exercise, repeated cellular reproductive demand, insufficient sleep, poison and excessive sexual activity. Scientists have proposed various theories to explain the processes / changes involved in physiology of aging like Orgel's theory, Free radical theory, Developmental theory, DNA damage theory and Telomeric theory. It is important to know the causes of aging, because while treating any disease, one must first understand the problem, so that afterwards the precise remedy can be applied. Approaching on or a combination of the following theories with a specialized treatment protocol will assist the aging problem on different levels and helps to slow down and eradicate some of the so-called pillars of aging.

PC032

Pharmacological Evaluation of Herbomineral Formulation for Aphrodisiac Activity in Mice

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Aphrodisiac agents are used to modify the impaired sexual functions of human beings. There are certain most commonly used ayurvedic medicines which are empirically used as promising aphrodisiacs in traditional medicine practice in cases of sexual debility or depressed desire. This study was carried out to evaluate Ayurvedic proprietary medicine for the aphrodisiac potential. Adult Swiss mice (25–30gm) were used for the study. All the animals were allowed to acclimatize in the test cage 7 days prior to experimentation. The mice were randomly divided into 3 groups comprising 6 male and 6 female animals in each group. The animals were treated for 28 days continuously and subjected to mounting behaviour test on day 28 of treatment. Same animals were used for the assessment of mating performance. Results showed that in the mounting behaviour test formulation and standard group has shown significant improvement in mounting behaviour which was comparable to standard. In matting assessment test both test as well as standard group female mice has showed presence of sperm while taking vaginal smear of the all the female animals. The test treated group shows significantly increased sexual function than the normal control and having activity comparable to standard treated group. Therefore it can be concluded that this formulation has potential activity for improving sexual dysfunction in male.

PC033

Review on Cyborg Technologies in Medicine

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Cyborg are originated from the concept of cybernetics, which is referred as mixture of both organism and technology. Cyborg is a cybernetic organism which will be implanted in the human body which amplifies the capabilities through machine technology. Cybernetics began as a study connecting the field of control systems electrical networks, mechanical engineering, logic models, and biology etc. Cyborg technologies have their own advantages and disadvantages. There are many parts of human body that can be transplanted using cyborg technologies like limbs, hand, eye, ear, brain, heart, cardiac pacemakers etc. It is essential to know about recent development in cyborg technologies in medicine about its cost, advantages and disadvantages etc.

PC034

Aldose Reductase in Various Disorders

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Aldose reductase is an aldehyde metabolic enzyme which is involved in polyol pathway, a pathway for glucose metabolism, which functions majorly as an intensive control glycemic condition. In diabetic condition, intracellular glucose is increased in various tissues like nerve, retina, kidney, blood vessels and brain. Non-phosphorylated glucose is converted into sorbitol with the help of aldose reductase enzyme and NADPH as a cofactor. Sorbitol is further converted into fructose in the presence of sorbitol dehydrogenase enzyme. So, accumulation of sorbitol and fructose in cells leads to increased intracellular osmolarity which is again responsible for osmotic cell injury. NADPH leads to low cofactor availability for glutathione reductase and this reduces the glutathione levels in the cell. This leads to oxidative cell injury in the cells. Aldose reductase is the major rate limiting enzyme in whole pathway. The major disorders caused due to disturbance in polyol pathway are diabetes and its complications like cardiovascular problems, neuropathy, nephropathy, retinopathy and cataract. Diabetic nephropathy leads to glomerular hyperfiltration that results in decrease of glomerular function over proteinuria, decreased glomerular filtration rate and renal failure. Oxidative stress plays a major role in the pathogenesis of diabetic retinopathy and cardiovascular complication by injuring retinal and myocardial cells. Retinal cell injury leads to complications like cataract, glaucoma, and myocardial ischemic injury causing atherosclerosis and vascular damage. Hence, with the use of aldose reductase inhibitor, these diabetic complications can be minimized.

PC035

Prospect of Therapeutic Target of PI3 Kinase in Various Disease and Disorders

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The PI3K is belonging to the lipid kinase family. Its major role is in phosphorylation of various cell functions. PI3Ks has three different classes with different activity. Major classes are class I, class II and class III. PI3K has multiple functions like cell functions like growth, proliferation, differentiation, motility, survival and intercellular trafficking. In breast cancer and most of the other cancer mutation in isoform p110α is observed. This mutation causes the kinase to be active. Akt has significant role in variety of proteins regulation. Both upstream and downstream PI3 kinase pathway has been a potential target for the drug development in breast cancer. Phosphatidylinositide 3-kinases (PI3-K) phosphorylate the 3rd hydroxyl position of the inositide head of phosphoinositide lipids, phosphatidylinositide (PtdIns), phosphatidylinositol (3)-phosphate (Ptdlns(4) P) and phosphatidylinositol (4,5)- bisphosphate (Ptdlns(4,5) P2). Similarly, P13-K appears to inhibit serine threonine kinase. PI3-K activation in response of GSK3 results in increased IL-10 production and plays important role in inflammation. The PI3K pathway has the key role in viral infection as well as in neurodegenerative disease. Different examples of PI3 kinase inhibitors are Wortmannin, Quercetin, LY-294002, BKM 120, GDC-0941 and so many others are in the phase 1 clinical trials. Thus, inhibition of PI3K can be useful treatment of breast cancer, HIV/ AIDS, Thyroid cancer, Intestinal inflammation, Alzheimer disease, and Parkinson disease.

PC036

Development Approaches for Malaria Vaccine

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Malaria is a very complex parasitic infection and causing parasites have very complex life cycle. Currently there are very large numbers of vaccines available none of the vaccine is targeting parasitic infection. Malarial parasite possesses numerous antigens for development of the vaccine. Each developmental stage had a vaccine developed specifically to target the parasite. The aim of our research paper is to identify the future scope of malarial vaccine and identify different antigens. Presently several antigens are identify to elicit the immunity of individual. The primary target for malaria vaccines is on the plasmodium falciparum strain. The circumsporozoites (CS) it's a parasitic protein earlier used for the vaccine development. Due to it negative impact like it has low efficacy, reactogenicity and low immunogenicity so it is not used nowadays.Presently in the market variety of vaccines available but for parasitic infection only two types of vaccines are available. For P. falciparum type of malarial infection Type 1 vaccine is mostly use in sub-Saharan Africa. Another type of vaccine is Type 2 vaccine generally famous as "Traveller's Vaccines". It was developed with aim the individuals with no previous exposure and to prevent all cases of clinical symptoms. The effectivity of the any vaccine is based on its availability, noticeable adverse effects and contraindications, inconvenience and compliance. There is no vaccine available for any particular type of symptoms and not a single vaccine yet available to avoid malaria. There are several vaccine are under development mainly targeting different event of parasites life cycle such as its blood stage and etc. Some of the vaccines targeting pre-erythrocytic stage are nowadays very promising and showing good result so far. Our aim to get introduce with such type of research and to study different approaches for vaccine development.

PC037

Molecular Mechanism Leading To Cancer Cachexia

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Cancer cachexia is a multi-factorial syndrome which leads to reduce body mass thereby impairing quality of life and reducing survival rate. It occurs in the advanced stages of cancer and leads to mortality in approximately 22% of the cases. Reduced body mass in cachexia is due to progressive loss of adipose tissue and skeletal muscle which results in the "wasting" condition and increases the energy expenditure is due to elevated thermogenesis in skeletal muscle and adipose tissue – all of which are hallmark features of cachexia. Loss of adipose tissue is due to the elevated lipolysis while loss of skeletal muscle is due to reduced protein synthesis and increased degradation of proteins. Protein degradation occurs as a result of activation of the ubiquitin- proteosome and lysosomal pathways whereas, decreased protein synthesis is due to reduced elongation of the initiation factor and reduced binding with the 40s ribosomal subunit. Altered cell bioenergetics on the other hand, result due to increased expression of the uncoupled proteins and activation of the cori cycle. In addition to this, various tumor-host interaction derived factors such as lipid mobilizing factor (LMF), tumor-necrosis factor-α (TNF-α), interferon-γ (INF-γ), interleukin-6 (IL-6) induce various inflammatory reactions, thereby aggravating the cachectic condition. Considering all these aspects, this review puts forward various reported as well as other possible molecular mechanisms responsible for cancer cachexia which can be exploited in future to develop novel treatments for the disorder.

PC038

Prevalence of Vitamin B12 Deficiency and its Implication in India

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Vitamin B12 is a water soluble vitamin and it is naturally present in some foods, also available as dietary supplement and as prescription medication. It is also known as cobalamin and is important for the body to work properly. It acts as a cofactor that is integral to methylation processes which are important in reactions related to DNA and cell metabolism, therefore, deficiency of vitamin B12 may lead to disruption of DNA and cell metabolism which may cause serious clinical consequences. Vitamin B12 deficiency can be characterized by fatigue, constipation, megaloblastic anaemia, weakness, weight loss, loss of appetite. It can also cause some neurological changes like numbness and tingling in the hands and feet. In India, very little appreciation is been given to vitamin B12 deficiency among the Indian medical professionals and policy makers. This may be due to various reason like no routine measurement of vitamin B12 level clinically and signs of specific neurological or haematological syndrome consistent with vitamin B12 deficiency are rare.

PC039

Quality Assurance in Community Pharmacy

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Quality assurance is wide spread and well accepted concept in the field of pharmacy and health care to certify quality. In India, it is more focused and well practiced in industry, pharmacy academic institutions and hospital/healthcare institution. Elements of quality assurance are defined set agreed terms and standards of the process and care in respective organization. Community pharmacy is the place where medicines are stocked and dispensed under the supervision of registered pharmacist that governs & control by drug and cosmetic act 1940 and its rule therein time to time. It is evident that role and responsibility of community pharmacy is in shift from its traditional role to extended/advanced role in health care. Clinical pharmacy service through community pharmacy in Gujarat/ India is in infancy. Professional services rendered at most of community/retail pharmacy is less focused, though being regularly inspected and checked by appointed competent authority. Quality assurance of community pharmacy and its services is a well-accepted practice at overseas. The same is lacking in Indian health care system. Therefore, an attempt has been made to propose quality assurance standards in practice management, patient care services and quality improvement at community pharmacy.

PC040

Experimental Models for Senile Cataract

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Cataract, a leading cause of blindness globally, is opacity of the eye lens due to aggregation of high molecular proteins which impairs the vision. Cataract is responsible for 51% of world blindness according to the World Health Organization. Till date, there is no pharmacological therapy available for this blinding disease. Surgery is the only treatment available at present to sustain the vision.Various experimental models has been used long enough to understand the pathogenetic basis of human cataract. The physiology of the lens development and ageing is similar in mammals and the life span of these laboratory animals is also very short compared to that of humans and hence number of progenies can be studied within a short time span. However, none of the models exactly mimics the progression of human cataract because of short life but are helpful in instigating the mechanisms involved in protein aggregation and development of opacity. Hence the evaluation of drugs which can delay or prevent these processes may be possible by these models. There are number of animal models available for senile and hereditary cataract. This review summarizes various in-vivo and in-vitro models of senile cataract. The in-vivo animal models are helpful in developing nuclear, cortical or posterior subcapsular cataract involving either oxidative or osmotic stress. The in-vitro models involves isolation of the lens and developing of the cataract by agents causing oxidative stress. Hence agents which can delay or prevent these mechanisms can be studied by these models.

PC041

Assessment of Knowledge, Attitude and Practice of Reporting of Adverse Drug Reaction among Family Physicians in Surat City

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Majority of the patients first contact the family physicians (FPs) for treatment. If adverse drug reaction (ADR) occurs necessary measure are taken and ADR managed but usually not reported. The present study was conducted to assess knowledge, attitude and practice of reporting of ADR among family physicians.The study was a prospective, cross-sectional and questionnaire based study. The correctly filled forms from 90 family physicians were analyzed based on 20 questions (Knowledge 10, attitude 5, practice 5).Majority of family physicians were aware regarding the occurrence of ADR and 59% of them were aware that all the ADRs should be reported. Majority of (71%) the physicians do not know that there is ADR reporting form. About 93% FPs are aware that reporting of ADR is necessary and it will increase patient safety (92%). ADR can be reported by any health care professionals as informed by 78% of physicians. However, about 71% do not know how to report and where to report ADR? Only few of them (19%) have reported ADR. The family physicians of Surat have adequate knowledge about pharmacovigilance and aware that ADR should be reported for safety of patients. However, most of them have not yet reported any ADR due to various reasons.

PC042

Analgesic and Anti-inflammatory Effect of *Curculigo orchioides* in Laboratory Animals

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Curculigo orchioides is used traditionally for treating bronchitis, diabetes, skin disease and cancer. The objective of the present work was to evaluate the effect of the analgesic and anti-inflammatory properties of aqueous extract of *Curculigo orchioides* in laboratory animals. From acute oral toxicity studies (OECD-423 guidelines), no mortality was observed even at the highest dose of aqueous extract of *Curculigo orchioides* (2000 mg/kg, p.o.). At a dose of 100, 200 and 400 mg/kg, p.o.; the aqueous extract of *Curculigo orchioides* significantly attenuated the writhing responses induced by an intraperitoneal injection of acetic acid and at dose of 200 and 400 mg/kg, p.o. , the aqueous extract of *Curculigo orchioides* (200 and 400 mg/kg, p.o.) significantly increased pain latencies in tail immersion and hot plate test. In addition, the higher doses of aqueous extract of *Curculigo orchioides* (200 and 400 mg/kg, p.o.) were shown to inhibit carrageenan, serotonin and histamine induced paw edema. These results therefore indicate that *Curculigo orchioides* leaves contains biologically active principles, which have potentials for the treatment of inflammatory processes.

PC043

"Role of Serine Protease Inhibitors in Prognosis of Neurodegenerative Disorders"

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Serine protease inhibitors belong to a supergene family that include α-1 Anti chymotrypsin (ACT), Antitrypsin, antithrombin & angiotensin. Serine protease inhibitors are acute phase proteins synthesized in response to pro-inflammatory cytokines. It has been found that α-1 Anti chymotrypsin (ACT) plays an important role in Alzheimer's disease. ACT is over expressed in reactive astrocytes of patients with neurodegenerative disorders. Moreover ACT is tightly associated with virtually all amyloid plaques in AD brain. Under the influence of increased ACT levels astrocytosis occurs where change in astrocyte shape & function results from a new expression of gene & likely secondary reaction to ongoing neurodegeneration. This inflammatory response virtually leads to an increased proliferation of the neurodegenerative diseases. Recent studies show that astrocytic expression of ACT in APP transgenic mice leads to increased plaque deposition in the brain so these studies suggest that increased load of ACT promotes αβ amyloid deposition. In this review we will summarize the probable mechanisms of neurodegenerative disease proliferation and moreover study the role of serine protease inhibitors for the same. This may shed light on how novel treatments for disorders like Alzheimer's disease can be developed in the future.

PC044

Correlation between Clinical Presentation and Treatment Protocol on Outcome of Acute Lymphoblastic Leukaemia (ALL) at a Tertiary Care Centre

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The aim of the present study was to determine correlation between improvement in event free survival (EFS) and overall survival (OS) in different treatment protocol (BFM-90, MCP841) and clinical presentation among children and adolescents with acute lymphoblastic leukaemia (ALL). In a nonrandomised retrospective observational single-centric study, total 127 patients were enrolled who were being diagnosed and treated at Hemato-Oncology Clinic, Vedanta Institute of Medical Sciences, Ahmedabad from the year 2006 to 2012 and were followed up till 2015. Patients were grouped according to their treatment protocol (BFM-90 MCP841). Data of serum biochemistry, complete blood count and immunophenotype were also recorded. Total 127 patients were included in the study from which 92 were male and 35 were female. 88 patients were enrolled in BFM-90 and 39 patients were enrolled in MCP841. A total of 84 (6.14%) patients had complete remission (CR). Overall survival (OS) and event free survival (EFS) for BFM-90 and MCP-841 at the end of 2015 were78.26%, 62 (70.45%) and 60.52%, 22 (56.41%) respectively. 62% patients had haemoglobin level below 10 g/dL, 70% were having less than 20,000 /cmm WBC, 67% were having less than 200×10^{-3} /cmm platelet count, 55% were having normal SGPT level (5-40). 28.34% patients had Pre-B cell, 10.23% had early pre B cell, 1.57 had mature B cell and 6.29% had T cell immunophenotype. Survival curve was generated using Kaplan Meier survival analysis which showed higher survival in BFM-90 protocol. Results of our study suggest that OS and EFS in BFM-90 protocol were higher as compared to MCP-841 protocol. Patients with T-ALL immunophenotyping had poor prognosis.

PC045

Protein Tyrosine Kinase: Role in Various Diseases

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Protein tyrosine kinase is an enzyme that carry out functions of various protein mediators by phosphorylation. They play major role in cell division, apoptosis, immune response, growth, tissue repair and inflammation. Around 90 genes of tyrosine kinase have been found till today with 5 pseudogenes. The BRK suppression in breast carcinoma cells has been found to be effective in decreasing chemotherapeutic resistance level of Bcl-x and somatic mutation in EGFR delete genetic material in case of non- small cell cancer. Overexpression of RON receptor tyrosine kinase in colorectal lead to aberrant activation of various signalling pathways that facilitate colorectal cancer cell growth. Novel antibody Zt /g4-Maytansinoid Conjugates is target for colorectal cancer therapy. IRS-1, a major substrate for insulin receptor which downstream the signal of insulin but impact of three mutations in IRS-1 in NIDDM Patient has been identified. It has also been found that mutation in TYROBP gene disrupt normal growth of bone and abnormality in brain with people suffering from polycystic lipomemberaneous osteodysplasia with sclerosing leukoencephalopathy. Activation of p38 Mitogen Activated protein tyrosine kinase pathway is critical in HIV -1 replication in primary T lymphocyte and blocking this pathway was therapeutic approach for treatment of HIV infection. Thus, the review focus light on diseases etiology, pathophysiology, mutation in genes and therapeutic treatments available as well as ongoing research.

PC046

Antiurolithiatic Activity of Flavonoids rich Fraction of *Bryophyllum pinnatum* Lam. against Ethylene Glycol induced Urolithiasis in Rats.

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Urolithiasis denoted as stone originating anywhere in urinary tract and damages the renal calculi. Many allopathy and surgical treatment available for the treatment of urolithiasis, but it may causes serious complications and they also impose a great load of costs to the healthcare system. Hence the search for antilithiatic drugs from natural sources has assumed greater importance. *Bryophyllum pinnatum* leaves useful in the treatment of lithiasis. The flavonoids rich fraction of *Brophyllum pinnatum* (FBP) was evaluated for urolithiaisis. Urolithiasis was induced in rats by administration of Ethylene glycol (EG) (0.75 % in drinking water) and rats were treated with flavonoids rich fraction of *Brophyllum pinnatum* and Cystone as a standard drug for 28 days. After 28 days measured the various biochemical parameters in urine, serum and kidney homogenate. Co-administration of FBP with EG has apparently significant increase the Urine volume, and increase the level of calculus inhibitors like Magnesium, Citrate and lowering the level of the calculus promoters like Calcium, Oxalate Uric acid. These results indicate the Flavonoids rich fraction of *Bryophyllum pinnatum* Linn. showed significant activity against urolithiasis which may be because of its diuretic and antioxidant activity and its ability to increase inhibitors and decrease promoters' levels.

PC047

Anti-diabetic Activity of DLX4 in STZ Induced Diabetic Rats

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In view suggested Anti-diabetic potential. The sample of Glibenclamide derivative DLX4 was obtained from Deshpande Laboratories, Bhopal at a dose of 10mg/kg. It has been found that the mechanism of the glibenclamide derivative was similar to Glibenclamide (Standard drug) i.e. acts in peripheral tissues. In this experiment Streptozotocin was used at a single dose of 60mg/kg and it was administrated to all the three groups of rats i.e. STZ Control, Test and Standard respectively. During experimental procedure following parameters were observed: mortality (daily), body weight (alternate days), food and water consumption (daily), clinical signs (daily). In this study it was observed that glibenclamide derivative DLX4 (10mg/kg) significantly reduced blood glucose level and urine glucose level in Group 3 (test group) as compared with Group 2 STZ Control and Group 4 Glibenclamide (standard group) which had been induced by Streptozotocin. It also showed significant reduction serum biochemical parameters (Cholesterol, Triglycerides, SGOT, SGPT, ALP, Total Protein), haematological parameters RBC, WBC, Neutophils, Monocytes as compared to Group 1 Vehicle Control and Group 2 STZ Control and Group 4 Glibenclamide (standard) groups whereas it shows significant increase in Eosinophils, Basophils, Lymphocytes, Haemoglobin, PCV as compared to Group 1 Vehicle Control, Group 2 STZ Control and Group 4 Glibenclamide (standard) groups. It also showed slower increase in body weight and significantly increase in food consumption and water uptake as compared with Group 2 STZ Control and Group 4 Glibenclamide (standard) groups. Hence it can be concluded that Glibenclamide derivative DLX4 possess anti-diabetic activity.

PC048

Effect of Pongamol on Colitis Induced by TNBS in Balb/c Mice

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Pongamol a furanoflavanoid obtained from *Pongamia pinnata* (L.) seeds that has anti-oxidant, anti-diabetic, sunscreen properties; rendering it a natural drug having prophylactic and therapeutic property. But, the effect of pongamol on colitis has not been studied till now. So, in present study we evaluated the effect of pongamol on TNBS induced colitis. Colitis was induced in the Balb/c mice by rectal administration of 2% solution of TNBS in ethanol. Pongamol was administered in two doses 100 and 200 mg/kg and sulfasalazine (100 mg/kg) as reference for seven consecutive days to colitic mice. On 8th day mice were sacrificed and degree of inflammation was assessed by macroscopic, microscopic, and biochemical estimation of colon. In colon tissues myeloperoxidase, nitric oxide, malondialdehyde, catalase, superoxide dismutase, and reduced glutathione level were measured. Treatment with pongamol significantly and dose dependently inhibited macroscopic damage such as colon edema, length and weight, histological changes such as cellular infiltration, tissue necrosis, mucosal and submucosal damage, reduce the activity of myeloperoxidase. Depressed malondialdehyde and nitric oxide level and help in restoring the level of superoxide dismutase and reduced glutathione to normal when compare to the experimental colitic group, but, the level of catalase is not significantly restored. We concluded that pongamol has therapeutic effect on experimental colitis through its anti-oxidation and immunomodulation property which ultimately reduce the production of inflammatory mediator by the immune cells.

PC049

Assessment of Health Related Quality of Life (HRQoL) in Women With Polycystic Ovary Syndrome

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Polycystic ovary syndrome (PCOS) is the most frequent female endocrine disorder affecting 5-10% of women at reproductive age worldwide. The symptoms of PCOS like acne, hirsutism, irregular menses, amenorrhoea, obesity and subfertility are major source of psychological morbidity and can negatively affect quality of life (QoL). There are many questionnaires for health status assessment including disease specific questionnaire – PCOSQ. This questionnaire is not compatible in women with Indian community as well as factors like economy and social stress are not included. A self-generated disease specific questionnaire was developed which measures health related quality of life and focuses on multiple aspects of women of Indian community. This questionnaire encompasses five PCOS symptoms like body weight, body hair, menstrual problems, infertility problems and acne. Each symptom includes health domain such as physiological, psychological, social and economic. Women diagnosed with PCOS in outpatient department for menstrual irregularity was recruited in study. The case report form and quality of life questionnaire was filled up by patients. The responses of patients from questionnaire were ranked as per decided definite scale. One way ANOVA followed by Tukey's test was performed to discriminate HRQoL of study participants. Result shows that infertility related physiological as well as psychological problems have higher distress causing impact on quality of life of PCOS patients. From the study, it has been concluded that this questionnaire is a promising tool and integrative approach for HRQoL assessment in women with PCOS.

PC050

New Insight into Statin Induced Myopathy

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Cardiovascular disease (CVD) constitutes one of the major causes of deaths and disabilities, globally claiming 17.3 million lives a year. Statins, the inhibitors of 3-hydroxy-3-methylglutaryl coenzyme A (HMGCoA) reductase, are drug of choice to control hyperlipidemia a major contributing risk factor of CVD. However these wonder drugs are associated with muscle weakness. About 0.5%-20% of statin recipients develop adverse effects on skeletal muscles, from slight myalgia to rhabdomyolysis, including reports of muscle contractility. Various mechanisms have been proposed explaining statin induced myopathy. These include genetic determinants; alteration in myocyte membrane cholesterol; impaired calcium signalling; lowering of farnesyl pyrophosphate and geranyl geranyl pyrophosphate; influence on AKT/mTOR signalling pathway; depletion of ubiquinone/ coenzyme Q10 and induction of apoptosis and reactive oxygen species production. Thus various agents mediating through different molecular mechanisms are researched to overcome statin induced myopathy. L-carnitine supplementation has been found to reduce myoglobin concentrations, and post exercise serum creatinine kinase in exercise-induced muscle damage; Creatine monohydrate supplementation may improve muscle mass and strength, decrease apoptosis and intracellular calcium build-up, preclude oxidative stress, and diminish cell death in a nonspecific fashion. Leucine appears to be the most potent of all amino acids in stimulating muscle protein synthesis through mTOR pathway. New generation β_2 agonist drugs like Formeterol and salmeterol have beneficial and significant anabolic effect on skeletal muscle at micro molar doses. Important role of dietary 5Ø—ß3 poly unsaturated fatty acids (PUFA) and Coenzyme Q 10 supplementation on inflammation, synthesis of protein, and its effectiveness in thin body mass sparing is a topic of research. Nonetheless, to date, experimental proof of short-term and long-term effects of supplementation in myopathies with heterogeneous physiopathology is missing.

PC051

Ebola Virus: Current Trends

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In recent days nature has presented a new viral challenge i.e. Ebola virus. Ebola virus was first observed in Marburg, Germany in the year 1967 and the outbreak of disease was observed in the year 2014. There are no effective treatments available and the discovered treatments are still under trial; therefore it is necessary to understand various features of this virus including its classification, history, composition, and replication. Many efforts have been put forward by various researchers for development of vaccines for Ebola virus disease. Non-replicating vaccines and replicating vaccines are the types of vaccines that have been tried for the development of proper treatment of Ebola virus disease. Due to lack of medicines and the ability of virus to develop resistance, there is a need to develop new prevention measures and treatment. Newer targets are required to be understood and determined for effective pharmacotherapy. Current treatments and available novel targets for development of vaccines or drugs against these diseases need to be understood to develop effective pharmacotherapy to treat Ebola virus disease. Ebola virus is a great threat to human life due to lack of awareness for Ebola virus disease. It has proved to be a challenge to pharmaceutical companies all over the world. This review can provide insight to many scientists for future development of new therapies in prevention and cure of Ebola virus disease.

PC052

Mechanisms of Cardiotoxicity

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Advances in drug discovery have led to introduction of new drugs. Pharma market has faced call backs of some valued therapeutically effective drugs due to various side effects and one of these is cardio toxicity. This leads to great loss for the industry and also poses deleterious effects on an individual's wellbeing. Also detrimental environmental changes have effects on cardiomyocyte. Having knowledge of mechanisms of cardio toxicity, newer protective drugs can be developed. An attempt has been made in this review to know the mechanisms involved in progression of cardio toxicity. Traditionally hypoxia was considered as the root cause for cardiotoxicity. An early response to oxygen imbalance biochemical changes occur but further exploration has shown that there are tissue signaling factors and remodelling signals activated in response to chronic hypoxia. Remodelling signals through a series of factors cause change in Calcium homeostasis that in turn caused apoptosis. Inhibition of tyrosine kinase receptor, which is mechanism of some anticancer drugs, leads to cardiac cell death. Ion exchange pump variation, inflammatory responses, oxidative stress and other miscellaneous mechanisms have been found in relation to cardio toxicity. Knowing the mechanisms involved in cardiotoxicity, triggering factors can be targeted and research can be concentrated towards inventing a new molecule which will work on these targets and provide cardio protection. Further scientific exploration in this field is necessary to gain specific knowledge about cellular and molecular changes occurring in cardiomyocyte injury, which can provide new ways to tackle cardiotoxicity issue.

PC053

Risk Factors Contributing to Preeclampsia: Risk Analysis

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Preeclampsia is pregnancy induced hypertension with high blood pressure and proteinuria which causes maternal organ dysfunction. It usually occurs in third trimester of pregnancy and may worsen over time. In low income and developing countries, preeclampsia is the common cause of maternal and child mortality affecting about 3-5% of pregnancies. It is associated with 50,000 maternal death worldwide every year. There are many risk factors associated with it which includes age of under 20 or over 40, family history of hypertension, cardiovascular diseases, diabetes, stress, obesity, underweight women, diet, vitamin D and folic acid deficiency, caffeine intake, smoking, alcohol, socio-economic status, air pollution, environmental chemicals, and multiple pregnancy. Poor antenatal care plays a major role for the development of this condition. Several studies have shown the association of these risk factors and preeclampsia. However, very few studies have been done in India co-relating the lifestyle with the development of preeclampsia. Pregnant women who conceived at early age and with multiple pregnancies at higher gestational age are also found to be at more risk of preeclampsia. Low-dose aspirin, calcium, diet and lifestyle intervention has shown benefit in prevention of preeclampsia. Although more research is required to reduce risk of preeclampsia and causes related to it. Better obstetric care at the time of pregnancy and delivery would be able to reduce the risk of preeclampsia.

PC054

Merits and Demerits of Diagnostic Modalities in Colon Cancer

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Colon cancer is the third most diagnosed cancer in men followed by prostate and lung cancer and second in women after breast cancer. Due to limited resources in the health care system, there was considerable debate about the imaging modality that offers the best non-invasive examination of colon cancer such as detection and characterization. The uses of multiple diagnostic modalities are both costly and time-consuming. In the last decade, the median of colon cancer patient's survival have increased significantly (~20%) due to the introduction of new routine diagnostic modalities. These are Fecal Occult Blood Testing (FOBT), Fecal Immunochemical Test (FIT), Flexible Sigmoidoscopy, Colonoscopy, CT-colonography or Virtual colonoscopy, MR colonography, Fluoro-Deoxy-Glucose Positron Emission Tomography (FDG-PET), etc. Therefore, in the present review article; the authors have summarized the various merits and demerits of routine diagnostic modalities available in the colon cancer.

PC055

Lipopolysaccharide (LPS) and Muramyl Dipeptide (MDP) Induced Chronic Liver Injury in High Fat Diet Fed Rats – A Possible Model for "Non Alcoholic Fatty Liver Disease (NAFLD)"

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Nonalcoholic fatty liver disease (NAFLD) refers to the spectrum of diseases characterized by fatty infiltration of the liver ranging from steatosis, steatohepatitis, or cirrhosis, which links the innate immunity through the metabolic disorders. Pathogenic mechanisms for such liver injury include alteration of intestinal microbiota, infections with viruses and alteration in signaling of Pattern Recognition Receptors (PRRs) such as Toll like receptors (TLRs) and Nod like receptors (NLRs). Alteration of PRR signaling may contribute to inappropriate innate and adaptive immune response leads to NAFLD. Further, liver is a lymphoid organ with overwhelming innate immune response through modulation of TLR4 and NLRP3 receptor, expressed on various liver cells. In our study, Lipopolysaccharide and Muramyl dipeptide, agonists at TLR4 and NLRP3 respectively, were injected subcutaneously in HFD-fed rats to induce chronic liver injury such as nonalcoholic fatty liver disease. Various parameters such as body weight, SGOT, SGPT, ALP, Total protein, Triglyceride, Albumin, Bilirubin were measured at regular interval to evaluate established model.

PC056

Novel Targets for Parkinsons Disease

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Parkinsons disease (PD) is a chronic, progressive, neurodegenerative disorder with an estimated prevalence of 0.031 to 0.3 per cent in people worldwide. It is estimated that more than 1 percent of population over age 55 years are afflicted with Parkinson's disease. Conventional treatments that are available have high failure rates or numerous side effects and the current treatment of Parkinsons disease is based on Dopamine replacement therapy but this leads to long tersm complications and side effects. Keeping in view this requirement, it is necessary to explore newer targets and how it will help in developing new therapies with less complications as compared to conventional therapies. It is the need of time to explore novel targets like alpha-synuclein, parkin, tau protein, lrrk2, metabotropic receptors and many more to develop novel treatments for Parkinsons. The important recent advances in novel targets will underlie the development of novel dopaminergic and non-dopaminergic drugs for Parkinson's disease, and also for the motor complications that arise from the use of existing therapies. By performing extensive literature survey it was attempted to identify some of important and novel targets involved in pathogenesis of Parkinsonism. Understanding of pathophysiology underlying these targets may help in future for the development of drugs in treatment of Parkinsonism. This will provide an insight in future scientific research.

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DD001

Design, Synthesis and Antitubercular Activity of Some Cinnamoyl Thiocarbamides

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Tuberculosis is a contagious disease with high mortality worldwide. The statistics indicate that 3 million people worldwide die annually from complication of TB. There are estimated 8 million of new cases each year, 95 % of which occur in developing country. There is emergence to develop new molecules for tuberculosis therapy. In present work thiacarbamide (thiourea) derivatives were designed taking thiacetazone as lead molecules. Cinnamoyl thiacarbamide derivatives were designed with proper rational. Docking analysis was carried out using GOLD 5.1 with mycolic acid cyclopropane synthase receptor with PDB code 1 KPG to know proper interaction of proposed compound with target. All the compounds show good binding score. Cinnamoyl Thiocarbamides were synthesized and characterized with the physical and spectral characteristics. All the compounds were screened for in-vitro anitubercular activity using Lewenstein Jenson (LJ) method on H37RV strain of Mycobacterium tuberculosis at 10 µg/ml and 50 µg/ml. They exhibit promising antitubercular activity at 10 µg/ml concentration level with % inhibition in the range of 24-91 %. The cytotoxicity studies of synthesized compounds were carried out on normal VERO cell line. Out of five compounds screened, one compound 1-cinnamoyl-3-(4-fluorophenyl)-thiocarbamide was found to be toxic at 100 µg/ml concentration level.

DD002

Targeted Therapy for Helicobacter pylori Infection: Design, Synthesis and Evaluation of Small Molecule Inhibitors

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Helicobacter pylori (H. pylori) colonizes in the gastric mucosa of more than 50% of the world's population with infection rates much higher (~80%) in developing countries including India. Major manifestations of H. pylori infection include peptic ulcer, stomach and upper small intestine ulcers, and is an important cause of gastric cancer and gastric mucosa-associated lymphoid tissue lymphoma (MALT-lymphoma). Due to increased resistance to the current antibiotic based triple and quadruple therapies, there is an urgent need to identify new drug target to overcome the drug resistance in H. pylori to the current therapy. Inosine-52 - monophosphate dehydrogenase (IMPDH) is an enzyme involved in the first important step in the de novo biosynthesis of purine (guanine) nucleotide which catalyzes the oxidation of IMP to XMP, which is further converted into GMP by GMP synthase. Inhibition of IMPDH would lead to decrease in the guanine nucleotide pool that is needed for the microbial proliferation. To study and validate IMPDH as a potential target for the H. pylori therapy we have taken efforts in design and synthesis of small molecules belonging to different scaffolds. Synthesized small molecules were further analyzed using biochemical assays using in-house cloned, expressed and purified recombinant HpIMPDH. The detailed study for the development of targeted drug discovery will be discussed in our poster presentation.

DD003

Crystal Engineering in Pharmaceutical Drug Development:

Co-Crystallization

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More than 40 percent of the newly discovered moieties are poorly water soluble and falls under category II or Category IV of Biopharmaceutical Classification System. Co-crystallization is recognized as one of the established method for the improvement of physiochemical properties of Active Pharmaceutical Ingredient (API) in pharmaceutical research and development. By the application of crystal engineering, conversion of drug moiety into co-crystal form is proven to be an effective approach to achieve desired physiochemical properties. Motive of co-crystallization is to convert poor water soluble drugs into co-crystal forms with the help of various co-crystallization techniques. Solvates, hydrates, amorphous solids, polymorphs, pure forms and co-crystals are common forms which influence bioavailability, physiochemical properties, stability and other characteristics of API. To overcome the problem of unsuitable physiochemical properties, one of the most frequently used approach to alter the API physiochemical properties is salt formation, which is opted over more than 50 percent of drugs present in market. Major limitation with salt formation is compulsion of presence of ionizable site on API. On contrary, co-crystallization methodology is free from such limitations; API in spite of any acidic, basic, or ionizable groups can be co-crystallized. Hydrogen bonding plays an important role in co-crystal engineering, as it is responsible for the majority of directed intermolecular interactions in molecular solids, which lead to directed self-assembly of different components. By the use of crystal engineering, conversion of drug moiety into co-crystal form is practically feasible as compare to other strategies used for improving solubility of API.

DD004

Insilico Studies on Series of Pyrazolopyridine Derivatives as Dual PDE3 and PDE4 Inhibitors: An Approach to Design Novel Anti-Asthmatic and Bronchodilatory Agents

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Recent advances support synergistic effects of PDE3A and PDE4B inhibitors for anti-asthmatic and bronchodilatory activity. In order to exploit PDE3 and PDE4 inhibitors dual action for new drug applications, 2D QSAR studies were performed on five series of pyrazolopyridine derivatives by MLR, PLS and ANN using TSAR software. Highly predictive and statistically significant models generated for all three [PDE3, PDE4, Sum of activity (PDE3+PDE4)] using leaving out each of 3 groups in turn cross validation and the most robust models obtained. The Physicochemical descriptors, electronic, topological contribute significantly towards PDE3 activity whereas steric & electronic for PDE4 activity and electronic and topological for sum of activity (PDE3+PDE4). The model demonstrated good fit for PDE3 has MLR ($r^2_{training}$ 0.822, r^2cv 0.809, r^2_{test} 0.796), PLS ($r^2_{training}$ 0.822, r^2_{test} 0.799), ANN ($r^2_{training}$ 0.849, r^2_{test} 0.802), model best for PDE4 activity has MLR ($r^2_{training}$ 0.907, r^2cv of 0.890, predictive r^2_{test} 0.0748), PLS ($r^2_{training}$ 0.907, r^2_{test} 0.748), ANN ($r^2_{training}$ 0.894,r^2_{test} 0.757) and good model for sum of activity (PDE3+PDE4) are MLR (r^2 training 0.82, r^2cv of 0.77, r^2 test 0.74), PLS ($r^2_{training}$ 0.825, r^2_{test} of 0.781), ANN ($r^2_{training}$ 0.849, r^2_{test} 0.683).This study may aid in development and optimization of novel more potent and decreased side effects dual PDE3 and PDE4 inhibitory activity lead compounds for contend disease.

DD005

Synthesis of Indolyl Chalcone Hybrids as Potential Anti-mitotic and Anti-angiogenic Agents

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The rapid spread of breast cancer and ovarian cancer which are the most common type of cancer in women in the developing world. This has encouraged an intense worldwide search for new compounds which may has less side effect and also overcome the problem of resistance by becoming a new addition to the existing class of vascular disrupting agents and anti-mitotic agents. Literature reveals that 2-acetylbenzimidazole molecule and indole-3-carboxaldehyde associated with a wide range of biological activities such as anticancer, anti-inflammatory, analgesic anthelmintic etc. In this research study, a series of 30 indolylchalcone hybrids were synthesized by claisen-schmidt condensation of N-1 substituted indole-3-carboxaldehyde and N1 substituted 2-acetyl-benzimidazole. The N-alkylation/arylation, mono-methylation on indole 3-carboxaldehyde were achieved by using alkylating and arylating agents in presence of green catalyst such as anhydrous potassium carbonate (K2CO3) and PEG-400 act as Phase transfer catalyst. The structures of all the synthesized compounds were characterized from their IR spectra and confirmed from their 1H-NMR spectra. After that the indolylchalcone hybrids were preliminary screened for antimitotic activity and evaluated by using Allium cepa root meristematic cells and then subjected to in-vitro anticancer activity against human breast adenocarcinoma cell line MCF-7 and also human ovarian adenocarcinoma cell line A-2780. These indolyl chalcone hybrids shows potent antiangiogenic activity by chorioallantoic membrane (CAM) assay method.

DD006

Microwave Synthesis and Characterization of Spiroketal Derivatives from 4-Nitrobenzaldehyde

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The present invention related to synthesis of spiroketal compounds, these are structural subunits found in many biologically active natural products originated from a variety of sources including marine macrolides, ionophores, polyether antibiotics, vegetable, insect, microbes, and fungal sources. Spiroketals are cyclic ketals in which two rings are joined by a single spiro atom, and the two ketal oxygen flanking the spiro atom, each belonging to one of the rings. Because of their stereo chemical features and biological activity, organic compounds with bicyclic structure are of great interest. Various spiroketals derivatives (A1-A4) were synthesized by Iodine-catalyzed Biginelli-type condensation under microwave irradiations by using 4-nitro benzaldehyde, urea and barbituric acid. All compounds were obtained in good yield. The structures of spiroketals derivatives (A1-A4) were confirmed from the analysis of their FT-IR, 1H-NMR and Mass spectra.

DD007

Exploring Benzimidazole, Benzoxazole and Benzthiazole Derivatives' Potency against ROCK-2 by Performing 3D-QSAR

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Rho kinase (ROCK) with a weight of 160 kDa is functionally serine/threonine kinase protein. Rho/Rho kinase cascade which denotes binding of RhoA (GTP-binding monomeric protein) with an affecter molecule Rho-kinase has physiological function of contraction, proliferation and migration in cells. Rho kinase in its activated state, which is

when bound to RhoA, plays a major role in Ca+2 sensitization by phosphorylating threonine 696 and 853 of MYPT1 (myosin phosphatase targeting subunit 1) which is a myosin binding subunit and henceforth inhibiting myosin phosphatase activity. Rho Kinase-2 (ROCK-2) has become a promising molecular target for treatment of multiple sclerosis, inflammatory disorders, myocardial ischemia, cancer migration and spinal cord injury. To study the relationship between the Benzimidazole, Benzoxazole and Benzthiazole derivatives and ROCK-2 inhibition, we have performed a three-dimensional quantitative structure-activity relationship (3D-QSAR) study based on the rigid alignment of compounds. Highly predictive 3D-QSAR models, with q2 values of 0.76 and 0.72, were obtained. These models were in good agreement with the structural characteristics of the binding pocket of ROCK-2 and provided some structural insights for the improvement of ROCK-2 inhibitors.

DD008

Synthesis and Screening of Some Novel Adamantly Derivatives as Anti-Tubercular Agents

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With the emergence to drug resistance with existing anti-tuberculosis drugs there is an urgent need of more potent and safe drugs for the treatment of tuberculosis. Structure activity relationship (SAR) study of ethambutol analogue suggested that ethylene diamine chain is essential for anti-tuberculosis activity. SQ-109 is one of the ethambutol analogues in Phase-II Clinical study which contains adamantly ring. So it was thought of interest to combine ethylene diamine chain with adamantyl ring using phenyl ring as a spacer to enhance lipophilicity of the molecule which may help in penetration through the cell wall. Six novel adamantyl derivatives were synthesized, characterized and screened for the anti-tubercular potential using Alamar Blue Assay against H37Rv strain. Compounds LMHD-12 and LMHD-19were found to be the most potent with MIC value of 0.8µg/ml and 1.6µg/ml respectively.

DD009

Molecular Modeling Studies of 2,6-Disubstituted Pyridazinone Derivatives as c-Met Kinase Inhibitors

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Aberrant activation of receptor tyrosine kinase c-Met has been demonstrated to be implicated in several human cancers and anti-cancer drug resistance. Therefore, c-met kinase is considered to be one of the most promising therapeutic target for the development of anticancer agents. In this study, a set of 29 analogues of 2, 6-disubstituted pyridazinone derivatives were used to develop three-dimensional quantitative structure–activity relationship (3DQSAR) models. All molecules were aligned by distill (rigid body) alignment for the development of Comparative molecular field analysis (CoMFA) and comparative molecular similarity indices analysis (CoMSIA) models. CoMFA and CoMSIA models were found statistically significant with cross-validated coefficients (q2) of 0.667 and 0.690, respectively and reliable in terms of prediction results. The derived contour maps from 3D QSAR models revealed the significant structural features required for improving c-Met kinase inhibitory activity. The information obtained from this study may provide guidance for the design and structural modifications of these derivatives for better c-met kinase inhibitory activity.

DD010

Studies and Evaluation of Antimicrobial and Anticancer Activity of 4 and 5-Substituted Methylsulfonyl Benzothiazole

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A series of novel 4 and 5-substituted methylsulfonyl benzothiazole (MSBT) compounds having amide, alkoxy, sulfonamide, nitro and amine functionality were synthesized from sequential reactions on 5-ethoxy-2-(methylsulfonyl)benzo[d]thiazole such as nitration, reduction, sulphonation, dealkylation etc. All synthesized compounds were screened against antimicrobial and selected screened for anticancer activity. Antimicrobial activities studies reveled that among all compounds screened, out of MSBT-07, MSBT-11, MSBT-12, MSBT-14, MSBT-19, and MSBT-27 were found to have promising antimicrobial activity at MIC range of 4 to 50 µg/ml against selected bacterial as well as fungal species. Compounds having good antimicrobial activity were screened for cervical cancer (HeLA cell lines). Of these MSBT-07 and MSBT-12 significantly reduced the cell growth. Consequently their calculated GI50 values were found to be 0.1 or <0.1 µM.

DD011

In-vitro Cytotoxicity Assay of Quinoxalines

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Major objective of work is in-vitro cytotoxicity assay of newly synthesized quinoxaline derivatives and estimated deaths due to the cancer in human beings in US. Current data provides the highly active and safe anti-cancer synthesized quinoxaline derivatives and their in-vitro assay (60-cell line panel) under the Developmental Therapeutic Programme (DTP) at National Cancer Institute(NCI-USA). A series of new quinoxaline derivatives has been prepared and confirmed to the structure by spectral study. Among synthesized compounds 3h has been show highest activity against Leukemia RPMI-8226 cell lines (GI50: 1.11 µM) as compared to other tested compounds. It is to be noted that compound 3e has been show significant activity against cancer cell lines (GI50: 1.11 µM). We conclude that the ongoing studies of targeted agents in conjunction with chemotherapy may show whether there are alternative option for new and safer medicine for cancer in future as well as opens the new doors in era of cancer research.

DD012

Recent Approaches of Green Chemistry

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Manufacturing of active pharmaceutical ingredients using hazardous and toxic reaction are nowadays major concern as it affects health and safety of the workers as well as the environment. The replacement of toxic solvents used for the synthesis as well as using greener techniques is becoming attractive alternatives. The majority of solvents used for synthesis, purification, separation, analysis and extraction is toxic. One of the green chemistry approaches is to replace the toxic solvents used for different purposes with greener solvents. Atom economy is also important aspects to increase the yield of the final product with reduction in by products. Synthesis of chemical compounds using "green catalysts" also affects the efficiency of the product. Green catalysts used in the synthesis not only decrease reaction time, but it also increases yield of the final product as well as reduce use of solvents. Alternative synthetic strategies are employed to decrease the use of toxic solvents as well as to decrease the energy consumption during the synthesis. Microwave assisted organic synthesis is nowadays employed in place of conventional synthesis as it doesn't require the use of solvents and considered as greener process. Other techniques like biocatalysis, self-thermo-regulated systems, soluble polymers, etc. are considered as eco-friendly methodologies as these techniques do not require solvents or use of less solvent as compared to conventional methods.

DD013

Synthesis and Biological Evaluation of some Novel Substituted Nitroimidazole Derivatives as Antitubercular Agents

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Tuberculosis (TB) is a leading cause of mortality resulting from a bacterial infection. With the emergence of resistance to first line drug therapy (MDR-TB and XDR-TB), the need for anti-TB drug was not overstated. Nitro-imidazole is part of an exciting new class of compounds currently undergoing clinical evaluation as novel TB therapeutics, its mechanism of action involves reduction of nitro group and subsequent formation of nitric oxide. Distance between "N" and "O" of active compounds had been taken into consideration for anti-tubercular activity of nitro-imidazoles and based on that new compounds were designed. Different nitro-imidazole derivatives were synthesized, and characterized by IR, MASS and1H-NMR spectroscopy. All the synthesized compounds were screened for anti-tuberculosis activity by Alamar Blue assay against H37Rv and found to exhibit significant anti-tuberculosis activity with MIC's ranging from 3.25 µg/ml to 12.5 µg/ml.

DD014

Antimicrobial Activity Study of Novel Spiroketal Derivatives Synthesized From 4-Nitrobenzaldehyde

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Spiroketal are cyclic ketal in which two rings are joined by a single Spiro atom, and the two ketal oxygen flanking the spiro atom, each belonging to one of the rings. Because of their stereo chemical features and biological activity, organic compounds with bicyclic structure are of great interest. All the synthesized derivatives (A1-A4) were evaluated for their in-vitro antimicrobial activity against various strains of bacteria such as Bacillus subtilis, Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa and of fungi such as Aspergillus niger and Candida albicans and also compared with reference drugs (Amoxicillin and Miconazole). The present studies demonstrated that, synthesized Spiroketal derivatives A1 and A4 were found to be have good antimicrobial activity against the various strains.

DD015

Identification of Novel Pf DHODH Inhibitors as Antimalarial Agents via Pharmacophore-Based Virtual Screening Followed By Molecular Docking Study

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In this study, we described pharmacophore-based virtual screening combined with docking study as a rational strategy for identification of novel hits as PfDHODH inhibitors. Pharmacophore models were established by using the GALAHAD module with IC50 values ranging from 0.013 μM to 142 μM. The best pharmacophore model consists of three hydrogen bond acceptor (HBA), one hydrogen bond donor (HBD) and one hydrophobic (HY) features. The pharmacophore models were validated through receiver operating characteristic (ROC) and Günere-Henry (GH) scoring methods. Pharmacophore model as a 3D search query was searched against IBS database. Several compounds with different structures (scaffolds) were retrieved as hits. Among these molecules, those who have a QFIT value more than 81 were docked on PfDHODH to further explore the binding mode of these compounds. Finally, in silico pharmacokinetic and toxicities were predicted for best docked molecules. The hits reported here showed good potential to be PfDHODH inhibitors.

DD016

Discovery, Synthesis and Evaluation of Substituted Tetrahydrocarbazoles as Dual Pathway Inhibitors

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Cancer drug resistance is a growing concern. It can be addressed by mechanism based targeting of cancer by inhibiting multiple pathways. The extracellular signal regulated kinase (ERK) is one of the important molecular target in cancer that controls diverse cellular processes. Similarly, the pRb (retinoblastoma protein) is a tumor suppressor protein and its function is to prevent excessive cell growth by inhibiting cell cycle progression. When the cell is ready to divide, pRb is phosphorylated, becomes inactive and allows cell cycle progression. Herein, we discovered a new series of tetrahydrocarbazoles as dual inhibitors of pERK and pRb phosphorylation. The in-house small molecule

library was screened for inhibition of pERK and pRb phosphorylation, which led to the discovery of tetrahydrocarbazole series of compounds as potential leads. Compound (1) is the dual inhibitor lead identified through screening, displaying inhibition of pERK and pRb phosphorylation with IC50 values of 5.5 and 4.8 μM, respectively. A short SAR studies will be discussed.

DD017

Pharmacophore Modelling, Molecular Dynamics Simulations and Molecular Docking Approach for the Designing of Novel Motor Inhibitors.

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Cancer is a second major disease after metabolic disorders where number of cases of death are increasing gradually. Mammalian Target of Rapamycine (mTOR) is one of the most important target for treatment of cancer, specifically for breast and lung cancer. Computational tools are important for rational drug design which correlates structural properties with activity of the molecules. In the present research work eight chemical structures were selected which possesses remarkable activity on mTOR receptor. Pharmacophore models were generated using GASP module of Sybyl X. The best model was selected which have four features viz. 1 Donor Atom, 1 Acceptor Site and 2 Hydrophobic site. This model was taken as query and virtual screening was performed using three different databases viz. National Cancer Institute (NCI) database, Intel Bio Screen (IBS) database and Zinc database. Further top five virtual hits having highest QFIT values from each database were taken and checked for the toxicity through the OSIRIES property explorer. The virtual hits which found non-toxic were selected for further evaluation. Molecular docking study of all non-toxic virtual hits of different databases were performed on the simulated protein of mTOR (4JT6) by using GOLD 5.2. Virtual hits M401059 (NCI), STOCK2S-35330 (IBS) and ZINC96132086 (ZINC) showed good docking score with similar binding interactions as that of the standard. Hence further these molecules were modified as per the Molecular Dynamics and Molecular Simulations (MD/MS) assisted docking study for the mTOR inhibition.

DD018

In-silico Pharmacophore Screening and Molecular Docking Studies of Some Pyridazinone Derivatives

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The term ‘In silico’ or computational methods are virtual screening techniques used for the discovery of novel molecules of potential pharmaceutical interests and for advancement in therapeutics. The in silico studies considered as complementary to in vivo and in vitro biological studies are performed by using a computer and are playing increasingly larger and more important role in drug discovery and development. Pyridazinones are the derivatives of pyridazine possessing a magic azomethine (-NH-N=CH-) moiety. The pyridazinones are six membered heterocyclic compounds that also contains a cyclic amide moiety in their ring structure that plays an important role in exhibiting various pharmacological activity ranging from cardiovascular properties, anti-inflammatory, antidiabetic, analgesic, anti-AIDS, anti-cancer, anti-microbial and anticonvulsant activities. In-silico inverse Pharmacophore screening using PharmMapper web server was done to find out the putative therapeutic targets for pyridazinones. The targets identified using in-silico method like Tyrosine phosphatases (PDB ID- 1NWL), Sorbitol dehydrogenase (PDB ID- 1PL6), Cell division protein kinase 2 (PDB ID - 2B54), Mitogen activated protein kinase 14 (PDB ID-2ZB1), Glucocorticoid receptor (PDB ID- 3CLD) were further screened by molecular docking approach to find best target among these. Docking scores and interactions of pyridazinones revealed Mitogen activated protein kinase 14 as its putative target. MAP 14 kinase is already a well-established anti-inflammatory mediator receptor protein hence this study emphasized that pyridazinones could be developed as anti-inflammatory lead compounds.

DD019

Design and Synthesis of PTP1B Inhibitors as Anti-Diabetic Agents

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Developing selective protein tyrosine phosphatase 1B (PTP1B) inhibitor is a challenging task since two decades. PTP1B is a negative regulator of insulin signalling and thereby inhibition of it causes increased glucose uptake in insulin sensitive cells. Till date, many diverse small molecules have been explored for PTB1B inhibition but only three reached upto clinical stage namely, ertiprotafib, trodusquemine, and JTT-551. The major failure reason is the selectivity issue with other enzymes of protein tyrosine phosphatase family. So, in this continuous search of novel small molecules as PTP1B inhibitors, we performed 3D-QSAR study of published chalcone derivatives. The constructed CoMFA and CoMSIA models revealed statistical significance and good predictive abilities. On the basis of the contour maps, significant regions for steric, electrostatic, hydrophobic, H-bond interactions were identified to enhance the bioactivity. Based on the results of in-silico study, 12 heterocyclic molecules were designed, synthesized and characterized by mass spectroscopy. Their pharmacological screening for in-vitro PTP1B inhibition and in-vivo anti-diabetic activity will be carried out in near future

DD020

A One Pot, Solvent Free and Catalyst Free Synthesis of Substituted 2-Amino-5-Aryl-1,3,4-Oxadiazoles under Microwave Irradiation and their In-vitro Anti-malarial Study

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The present work is aimed to explore quinazolinone based cyclic guanidine derivatives for potential use in the treatment of Alzheimer's disease (AD). We report the synthesis and biological evaluation of 2-iminoquinazolinone derivatives series as acetylcholine esterase (AChE) and buterylcholine esterase (BuChE) enzyme inhibitors. Acetylcholine level plays a major role for the accumulation of amyloid-beta plaque in the brain of patients having Alzheimer's disease so the approach adapted was to synthesize heterocyclic templates having dual activity as cholinesterase inhibitors and beta-amyloid aggregation inhibitors. Cholinergic hypothesis suggest that small heterocyclic molecules are responsible for maintaining the level of acetylcholine in human brain. Research intimates variety of fused and non-fused ring systems as cholinesterase inhibitors (ChEIs) as per the developments in the cholinergic hypothesis. For example, tacrine (I), an acridine derivative, is one of the well-known ChEI developed to treat AD since long time. Also a recent study on screening of Turkish marine sponges, oroidin (II) was identified from Agelas oroides having cyclic guanidine ring which shows a moderate level of AChE inhibition. After analyzing the basic core of tacrine (tricyclic ring system) and the guanidine ring containing oroidin (II) it was planned to synthesize a ring system which is of type III and to evaluate the derivatives against cholinesterase enzymes. Among the synthesized compounds some derivatives show good AChE and BuChE activity.

DD021

Synthesis of Triazine Based Pyrazolines Derivatives and Their Anti-Inflammatory, Antiurolithic Activity

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The triazine and Pyrazoline are prominent nitrogen containing heterocyclic compounds and exhibits wide range biological activities. The synthesis of triazine based pyrazoline has been a developing field within the realm of heterocyclic chemistry. A broad range of therapeutic activities and industrial application, the triazine pyrazoline core became a center of attraction for organic chemists. The triazine based chalcones are the finest preliminary resources for the synthesis of substituted pyrazolines. Synthesis of pyrazolines has been reported by the stroke of nucleophiles like hydrazine hydrate or phenyl hydrazine, substituted phenyl hydrazine etc. on chalcones in solvents like acetic acid, methanol, pyridine, alcohol. The pyrazoline derivatives with a triazine group at the any position have been shown to possess good biological properties and exhibit excellent pharmacological properties. We have designed novel compounds (hybrid compounds) by combining these two cores and synthesized a series of novel triazine pyrazoline derivatives of biological interest. Designed analogues were synthesized by sequential reactions of 1-(4-(4,6-dimethoxy-1,3,5-triazin-2-ylamino)phenyl) ethanone. All the synthesized compounds (5a-l) were screened for their anti-inflammatory (trypsin inhibition method) and anti-urolithic (Calcium oxalate crystallization method) potential. The test compounds were exhibited moderate to significant anti-inflammatory activities and show modrate anti-urolithlic activities. A short SAR will be discussed.

DD022

ATR Specific Novel Therapeutics for Cancer

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Chemotherapy and radiotherapy have been traditionally used as a part of combinatorial therapy for the treatment of cancer cells. However, DNA damage through such treatment simultaneously leads to the activation of certain checkpoint pathways which aid in the survival of treated cancer cells. ATR is one such key mediator acting as apical regulator in response to DNA damage. It primarily signals DNA damage to S/G2 phase initiating cell cycle checkpoint for maintaining genomic integrity via cell cycle arrest, DNA repair or apoptosis. Due to its inherent role in DDR, disruption of ATR pathway can serve as a potential strategy in enhancing the effect of radio and chemotherapy. Reported inhibitor Torin 2 exhibits strong inhibitory action against ATR, ATM and DNA- PKs in the kinativ scan. Here, we present a systematic design of inhibitors for ATR as well as preliminary molecular biology of the kinase importance while considering ATR inhibition.

DD023

Ligand Based Pharmacophore Modelling, Virtual Screening, Designing of Molecules, Docking & Simulation Studies of Anaplastic Lymphoma Kinase Inhibitors as Anticancer Agents.

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Anaplastic lymphoma kinase is transmembrane type of receptor tyrosine kinase. ALK in cancer includes, from very rare cancers to the more prevalent non-small-cell lung cancer. Genetic alteration, abnormal expression & activation of ALK occur in the cytoplasm of cancer cells due to chromosomic rearrangement in ALK proto oncogene. More than a dozen of ALK fusion proteins and ALK mutations are responsible for resistance to the current treatment, like in case of crizotinib in NSCLC. The

oncogenic activation of ALK has generated considerable interest in target based drug discovery, to overcome the limitation of resistance due to current treatment. In the present study, we have generated ligand base pharmacophore model using 7 most active molecules from literature by GALAHAD methodology. From the 20 models, the best model was selected having Specificity-5.2650 & Energy-0.13.The model consists of 6 features including 3 hydrophobic, 1 H-bond donor, 1 H-bond acceptor and 1-positively charged N. The pharmacophore model was validated by GH scoring and ROC methods having its Enrichment ration-5.48, sensitivity-0.78 and specicity-0.91 respectively. Virtual screening was performed using NCI database. After applying Lipinski rule, 1278 hits were obtained having its highest Qfit value of 93.41. Top 5 molecules were taken into consideration for Scaffold selection and designing of molecules. Docking and simulation studies were also carried out on the designed molecules.

DD024

Pharmacophore Modeling study, synthesis and screening of some novel DPP-IV inhibitors

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Diabetes Mellitus is a chronic metabolic disorder characterized by hyperglycemia, often combined with insulin resistance. DPP-IV inhibition shows increased level of GLP-1(Glucagon like Peptide-1) and GIP (Gastric Inhibitory Polypeptide), which directly increases the insulin secretion and production with decreased level of glucagon. So, DPP-IV inhibitors ultimately lower free blood glucose level and shows anti-diabetic activity. As a part of lead identification, pharmacophore modeling study was carried out. Generated pharmacophore model consists of one HBA, one HBD and two hydrophobic features. Generated pharmacophore model was validated by various parameters, and best validated pharmacophore was used to identify lead molecule. Virtual screening was carried out using in-house database followed layout designed and synthesized some novel Aminal derivatives which were further evaluated by in vitro DPP-IV inhibition. Compound 1A and 1B shows a good inhibition with IC50 0.03 µg/ ml and 0.05 µg/ ml respectively.

DD025

Synthesis, Spectral Characterization and Anticancer Evaluation of Some Novel Cyanopyridone Derivatives

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Novel cyanopyridone derivatives were synthesized by condensation of benzaldehyde and malononitrile to give benzyledenemalononitrile followed by condensation with CH acid in presence of piperidine catalyst. Cyanopyridone derivatives also synthesized by direct condensation of aldehyde, amines and CH acid in presence of piperidine. Both the method shown same physical data of final compounds. The synthesized compounds were characterized by FT-IR, Mass by Electron Spray Ionisation technique and NMR (H1 and C13) spectral analysis. Synthesized compounds were evaluated for in vitro anticancer activity against colon cancer (HT-29), HeLa, liver (Hep-G2), breast cancer (MDA-MB-435), non-small cell lung cancer (NCI-H226) and other NCI-60 cell lines. Synthesized Compounds F2 and F17 were shown potent activity on MDA-MB-435 and HeLa cell lines. Synthesized Compounds F8, F11, F12, F30 were shown moderate activity against all tested cell lines. From SAR study of different synthesized compounds it is concluded that the presence of different amine group on pyridine nitrogen affect the anticancer potency of synthesized compounds. Substitution of electron withdrawing and donating groups were done on the 3rd, 4th and 5th position of aromatic ring and aromatic amine. Compound F2 was reported potent activity against (breast cancer cell line) MCF-7 and (renal cell line) A498 of NCI-60 panel. Further studies on five compounds of same series were done against above mentioned cell lines. The result indicates moderate activity in both the cell lines.

DD026

Benzoxazepine Moiety as mTOR Inhibitor for the Treatment of Lung Cancer: 3D-QSAR, Molecular Dynamics Simulations and Molecular Docking Studies.

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According to WHO statistics, lung cancer is one of the leading causes of death among all other types of cancer. Many genes get mutated in lung cancer but involvement of EGFR and KRAS are more common. Unavailability of drugs or resistance to the available drugs is the major problem in the treatment of lung cancer. In the present research, mTOR was selected as an alternative target for the treatment of lung cancer which involves PI3K/AKT/mTOR pathway. 28 synthetic mTOR inhibitors were selected from the literature. Ligand based approach (CoMFA and CoMSIA) and structure based approach (molecular dynamics simulations assisted molecular docking study) were applied for the identification of important features of benzoxazepine moiety, responsible for mTOR inhibition. Three different alignments were tried to obtain best QSAR model, of which, distill was found to be the best method, as it gave good statistical results. In CoMFA, Leave One Out (LOO) cross validated coefficients (q2), conventional coefficient (r2) and predicted correlation coefficient (r2pred) values were found to be 0.615, 0.990 and 0.930, respectively. Similarly in CoMSIA, q2, r2ncv and r2pred values were found to be 0.748, 0.986 and 0.933, respectively. Molecular dynamics and simulations study revealed that B-chain of mTOR protein was stable at and above 500 FS with respect to temperature (at and above 298K), Potential energy (at and above 7669.72 kJ/mol) and kinetic energy (at and above 4009.77 kJ/mol). Molecular docking study was performed on simulated protein of mTOR which helped to correlate interactions of amino acids surrounded to the ligand with contour maps generated by QSAR method. Important features of benzoxazepine were identified by contour maps and molecular docking study which would be useful to design novel molecules as mTOR inhibitors for the treatment of lung cancer.

DD027

Synthesis, Characterization and Anthelmintic Screening of Bioactive Fluoro Benzothiazole Comprising Potent Heterocyclic Moieties

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Fluorobenzothiazoles exhibit the wide range of biological activities. In present study, we made an attempt to link fluorobenzothiazole with thiazolidinone in hope of getting potent biodynamic moieties. Hence 4-fluoro-3-chloro aniline was treated with potassium thiocynate (KSCN) in presence of glacial acetic acid and bromine, which was neutralized with ammonia to get 2-amino-6 fluoro-7-chloro (1,3) benzothiazole which was further treated with 4- nitrobenzaldehyde in presence of ethanol , concentrated hydrochloric acid which was refluxed to obtain Schiff's base. A mixture of Schiff's base and 2-thioglycolic acid was refluxed, upon cooling triturated with 10% sodium bicarbonate solution to get 3-[6'-fluoro-7'-chloro(1',3')benzothiazol-2'-yl]4-nitrophenyl(1,3) thiazolidine-4-one and which was further treated with equimolar quantities of various aromatic amines in presence of DMF to get new bioactive fluoro benzothiazole comprising potent heterocyclic compounds. Structures of these compounds have been established by melting point, TLC, elemental analysis, UV, IR, 1HNMR and MASS data. The compounds showed significant anthelmintic activity against Perituma posthuma (earthworms) of equal size obtained from horticulture department, when compared with standard drugs piperazine citrate and albendazole.

DD028

3D-Structure Activity Relationship Studies, Molecular Docking Studies and in-silico ADME studies of Propanoic acid Derivatives for Antidiabetic Activity Targeting GPR40

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GPR40 agonists stimulate insulin secretion in a glucose-dependent manner and correct impaired glucose tolerance in a single dose in rodents, suggestive of such molecules being insulinotropic. Present work describes the studies applied to a series of 3-aryl-3-ethoxypropanoic acid derivatives focusing on 3D QSAR: COMFA, COMSIA & HQSAR using SYBYL-X 1.2. Distill alignment yielded very good statistical results among other three methods. 3D-QSAR models with good correlation and predictive power were obtained based on a training set of 41 molecules. Predictive r^2 of 0.910 was obtained for CoMFA: steric and electrostatic fields ($r^2 = 0.992$, $q^2 = 0.693$). CoMSIA with combined steric, electrostatic, hydrophobic and hydrogen bond acceptor fields ($r^2 = 0.976$, $q^2 = 0.668$) gave a predictive r^2 of 0.904. Validation was carried out to test the predictivity and strength of the generated model. The best hologram model was generated using histogram length of 59 having 4 optimum components and the optimal atom count 3-6 gave the best model with q^2 and r^2 of 0.682 and 0.900 respectively. Contour maps provided information on positively & negatively contributing fragments. This was further utilized to design molecules among which KAG-11, 14, 15, 16 & 19 showed good docking scores than reference compound TAK-875. In addition, *in-silico* ADME properties to predict pharmacokinetics at the organ level have been studied. The comprehensive information obtained from this study can be further explored for structural modification and detailed investigations of this class of molecules to arrive at possibly newer and more potent analogues of antidiabetic agents.

DD029

Antimicrobial Evolution of Novel Coumarin Hybrid Thiosemicarbazone Derivatives and Their One Pot Synthesis

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A convenient, one-pot, multi-component protocol for the preparation of 2-(1-(2-oxo-2H-chromen-3-yl)ethylidene) hydrazinecarbothioamide derivatives has been achieved. Here, firstly we have reported synthesis of 3-acetyl-2H-chromen-2-one using starch sulfuric acid and cellulose sulfuric acid as a biodegradable catalyst. Subsequently, we also carried out the reaction of isothiocynates, hydrazine hydrate and 3-acetyl-2H-chromen-2-one in the presence of catalytic amount of glacial acetic acid in refluxing ethanol to afford corresponding 2-(1-(2-oxo-2H-chromen-3-yl) ethylidene) hydrazine carbothioamide derivatives in high to excellent yields. All synthesized compounds were characterized by FT-IR, 1H-NMR, mass spectroscopy and elemental analysis. In addition, all synthesized compounds were screened for antimicrobial activity. All compounds were found to be good to excellent active against all four bacterial strain and one fungal strain.

DD030

All Drugs are Chemicals but All Chemicals are Not Drugs.

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Pharmaceutical science deals with the drug and is marketed in global range in the form of medicines for healthcare. Only the drug can bind with specific receptor to show desired biological action in-vivo whereas other chemicals fail to show the same. All drugs are xenobiotics originated from outer source (xeno) which is active in biological (biotics) system having less toxicity done by phase-I to phase-IV trials to pass the clinical aspects. Designing of lead molecule to most potent molecule and finally after crossing so many clinical trials this drug comes to the market in the form of some formulations incorporated with excipients. Paracetamol is para hydroxy acetanilide used as antipyretic because it binds at the receptor of heat regulating centre of cerebellum of brain but removing para hydroxy group it will become acetanilide which fails to bind at the same receptor to possess the biological activity. A specific drug can bind at specific receptor among huge receptors present in the body because its chemical structure fits at that specific receptor only and not for all receptors. No doubt that drug is definitely a chemical entity but all chemical entity never comes to the category of drug. Disease is such an unwanted manifestation to all but when it attacks to any body then medication is the first priority to get well soon and that is managed by drug. Organic substances which only bind on receptor bed in the form of medicine has capability to fight with disease which is biochemical malfunction of normal health.

DD031

Synthesis & Antihyperlipidemic Activity of Some Novel Acetal Derivatives and Their Effect on Autophagy

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Degradation processes are important for optimal functioning of eukaryotic cells. Autophagy plays crucial role in obesity and atherosclerosis as a lipid lowering agents. Earlier in our laboratory S, N acetal derivatives were synthesised and screened for their effect on autophagy. Some of the compounds have exhibited potent lipid lowering activity. All compounds were also screened for effect on autophagy by western blot analysis. Compounds were found to induce autophagy. Thus those compounds may help in lipolysis within the cell also. So it was planned to synthesize few more derivatives of the series and screen it for in-vivo lipid lowering activity. Five newer molecules were synthesized and evaluated for their antihyperlipidemic activity using poloxamer 407 induced hyperlipidemic in rat model.

DD032

Design, Synthesis and Evaluation of Purine Derivatives

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Cancer is disease in which a group of cells display uncontrolled growth, invasion and sometimes metastasis. Cyclin dependant kinase is an important enzyme in cell regulation. Inhibitor of ATP binding site of CDK is reported as anticancer agents. Purine is promising scaffold for CDK inhibitors. So it was planned to design and synthesize some purine derivatives on 6 position of purine as aryl and heterocyclic substituents. Designed compounds were synthesized by suitable method and purified. Various reactions were monitored by TLC. Seven compounds were synthesised and confirmed by IR, NMR and Mass Spectroscopy. All synthesized compounds were evaluated for their activity as cytotoxic agents by MTT assay on various cell lines. MCF-7(Breast cancer cell line), HCT-15(Colon cancer cell line), NCI-H522 (Lung cancer cell line), HEP-3B(Liver cancer cell line) and Vero(epidermal kidney normal cell line) were used for evaluation. IC50 value was determined for synthesize compounds and methotrexate. All compounds showed cytotoxic activity. Compound having benzthiazole has good activity on NCI-H522 (IC50= 4.561 µM), MCF-7 (IC50= 4.972 µM), HEP-3B (IC50= 5.253 µM), HCT-15 (IC50= 5.784 µM) cell lines but less potent than methotrexate. Compound having 4-nitro substituent has good activity on NCI-H522 (IC50= 5.345 µM), MCF-7 (IC50= 4.145 µM), HEP-3B (IC50= 6.287 µM), HCT-15 (IC50= 6.424 µM) cell line but less potent than methotrexate. Among all synthesized compounds, benzthiazole substituted compound has IC50 = 39.67 µM compared to methotrexate IC50= 47.54 µM on normal Vero Cell line. Compounds having hydrophobic group showing more potent compare to others.

DD033

Chemistry of Dark Red Coloured Liquid Tissue Having Deep Metallic Odour Through Oxygenated A, B-Unsaturated Aldehyde

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Blood is a liquid tissue having red in colour with characteristic metallic smell or odour. Smells are notoriously hard to pin down, describe and identify but most people agree that the smell of fresh blood has a distinct, metallic tang. It might be assumed this comes from the iron in the blood, but an organic compound - a type of aldehyde - is to blame. (2E)-3-(3-pentyl-2-oxiranyl)acryaldehyde or trans-4,5-Epoxy-(E)-2-decenal or (2E)-3-[(2S,3S)-3-pentyloxiran-2-yl]prop-2-enal all are same substances having aldehyde moiety (-CHO).Unsaturated fatty acid has tendency to undergo rancidification due to the presence of double bond (σ: sigma bond and π: pi bond) in oxidative catabolism in-vivo by oxidase enzyme and in-vitro due to air oxidation. Unsaturated part undergoes reaction steps by Initiation, Propagation and Termination steps followed by free radical formation in Initiation step, peroxide formation in Propagation step and hydro-peroxide step in Termination step which produce obnoxious smell due to the formation of epoxide. Since blood is a biological fluid tissue so it produces metallic smell of characteristic odour. Metallic odour of flesh or blood comes from the rancidification of linoleic acid is due to oxidation of unsaturated bonds by oxygen through initiation, propagation and termination steps of α,β-unsaturation of acid into oxygenated aldehyde. The unpleasant foul smell is generated by biochemical oxidative reactions both in-vivo & in-vitro. LogP of this substance is 1.73 so it is semipolar in nature due to three membered oxirane ring and double bond and aldehyde linkage, so it is easily atomized into the atmospheric environment to disperse the odour.

DD034

Design of Novel Apoptosis Inducer as Anticancer Agents Using Computational Approaches

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According to WHO report 2014, 14.1 million adult

in the world were diagnosed with cancer and 8.2 million deaths occurred in 2012. In India, nearly 3 million patients are suffering from the disease annually, nearly 5000,000 people die by cancer. According to WHO, this number is expected to rise to 7000,000 by 2015. So, to overcome this problem there is a need to design and synthesize novel anticancer agents. Apoptosis is the process of preprogramed cell death. The regulation of apoptosis is relevant and differentiates between a normal body of cells and cancer cells by loss of control. Procasepase3 is responsible for activation caspase enzyme and activation of caspase enzyme leads apoptosis. Various computational approaches like 3D QSAR study and Pharmacophore study were used to design novel apoptosis inducers. 3D QSAR and pharmacophore study were performed on previously reported compounds which are responsible for activation procasepase3 enzyme. 3D QSAR study was done using CoMFA and CoMSIA for the data set of 27 different benzothiazole derivatives in order to design Procasepase3 inducer. The study produced model with satisfactory q2 of 0.736 and 0.751 for CoMFA and CoMSIA respectively. 7 features (1 hydrophobic, 3 donor and 3 acceptor) pharmacophore was generated using different scaffold of procasepase3 enzyme inducer using GASP.

DD035

Gamma Secretase Activating Protein: Ingenious Target for Alzheimer's Disease

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Alzheimer's disease is a form of progressive dementia followed by decline in cognitive abilities, neurological reflexes and learning ability characterized by the presence of amyloid beta plaques and neurofibrillary tangles, their progression being complemented by several cross talks between interconnected cell signaling pathways predominant in brain cells. Gamma secretase activating protein (GSAP) involved in beta amyloid pathway is 854 amino acid long protein (around 98 kD) which is processed into an active 16kD protein with the help of regulators like Caspase 3 and 5 Lipoxygenase at caspase 3 processing domain present towards the C terminal at 737DLD739 position. In a sequential proteolytic cleavage of APP and C-99 fragment by BACE-1 and γ-secretase respectively, active GSAP is assumed to bring C-99 fragment and γ-secretase in close proximity by forming a ternary complex, which leads to the production of Aβ40 and Aβ42 that deposit as amyloid plaques. We aim to clone and express GSAP in prokaryotic as well as in eukaryotic cells, in highly efficient expression vectors (such as pET19b, pET 32a, pMalc5X His, pcDNA 4) having different tags. And, further to study the binding efficiency of GSAP with potent inhibitors using X-ray crystallography. GSAP's role as an activator of β-amyloid production makes it a promising therapeutic target for treatment of Alzheimer's disease.

DD036

Comparative Logarithmic Partition Coefficient Study of Synthesized Five Membered Lactam Derivatives for Lipophilicity

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Five membered heterocyclic moiety has been synthesized by reacting between $C_6H_5NHNH_2$ and NH_2NH_2 with β-keto ester by condensation reaction to get the desired moiety which on alkaline $KMnO_4$ oxidation gives the corresponding -COOH derivatives in two series. The four compounds (I & II) of 1st series and (II & IV) of 2nd series were characterized. Log P profile of all four compounds: Reagents: [Highest] Phenyl hydrazine>Ethyl acetoacetate>Hydrazine hydrate [Lowest]; Compounds: [Highest] I (5-methyl-2-phenyl-1,2-dihydro-3H-pyrazol-3-one)>II(5-oxo-1-phenyl-2,5-

dihydro-1H-pyrazole-3-carboxylic acid) > III (5-methyl-1,2-dihydro-3H-pyrazol-3-one)>IV(5-oxo-2,5-dihydro-1H-pyrazole-3-carboxylic acid)> [Lowest] Log P of all the said items is totally dependent on the polarity and solubility of the matters. The hydrophobicity and hydrophilicity of all synthesized four compounds depend on log P values due to the substituted functional groups of pyrazolone ring. C_6H_5/CH_3/COOH the three main chromophore groups change their log P parameters as well as surface tension. Log P profile: I>II; III>IV and Surface tension profile: I<II; III<IV. Solubility of all compounds depends on the substitutions. C_6H_5 group is more lipophilic than CH_3 and COOH group is more hydrophilic so IV becomes liquid but II becomes solid due to the presence of C_6H_5 ring but I is more lipophilic than III due to the presence of C_6H_5 ring in I and III is more hydrophilic due to the presence of CH_3 group. Main ring pyrazolone is common in all I-IV: I (C_6H_5+CH_3), II (C_6H_5+COOH), III (CH_3), IV (COOH). I & III produce white compounds and II & IV are orange compounds in which IV is found liquid and rest all are solids which have been characterized by UV spectra and obeys wavelength of UV & Visible spectra.

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PA001

Simultaneous Evaluation of Cocktail Substrate Assay System for Inhibition Screening of CYP2B6, CYP2C9, CYP2E1 & CYP3A4 by MCR-706 and MCR-742 Using Human Liver Microsomes

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The study aimed to investigate 1. HPLC-UV method development for simultaneous evaluation of the activities of four cytochrome P450's and 2. Simultaneous evaluation of cocktail substrate assay system for inhibition screening of CYP2B6, CYP2C9, CYP2E1 & CYP3A4 by MCR-706 and MCR-742 using human liver microsomes. More particularly, the present invention relates to a method for simultaneous evaluation of the activity of probe substrates & their inhibition by selective inhibitors & new molecular entities using isocratic liquid chromatography-ultraviolet method in a single run accessed via two approaches, the individual probe substrate method and the cocktail probe substrate method. The substrate disappearance rate for CYP2C9 (diclofenac 4'-hydroxylation) and CYP2E1 (chlorzoxazone 6-hydroxylation), was quantified at 230 nm while for CYP2B6 (efavirenz 8-hydroxylation) and CYP3A4 (atorvastatin o-hydroxylation) was quantified at 247 nm. The method developed was validated to test the inhibition potential of four CYP isoforms by using their known selective inhibitors (clopidogrel, CYP2B6; fluoxetine, CYP2C9; and ketoconazole, CYP3A4). The IC50 (μm) values were determined using the individual substrates and substrate cocktail and were consistent with those reported in the literature. This validated assay was further used to evaluate the inhibition potential of MCR-706 and MCR-742 towards four major human hepatic CYP450 enzymes (CYP2B6, CYP2C9, CYP2E1, and CYP3A4). Thus the potential inhibitory activity of MCR-706 on DIC, ATV, CHZ and EFV hydroxylation can be judged as CYP2C9>CYP3A4>CYP2E1>CYP2B6. The observations for MCR-742 showed that it was till undergoing metabolism suggesting it does not have significant inhibitory effect on any of these isoforms.

PA002

Validated RP-HPLC Method for Simultaneous Estimation of Levsulpiride and Pantoprazole in Capsule Formulation

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A new simple, precise, accurate and specific RP-HPLC method has been developed and validated for estimation of levosulpiride and pantoprazole in capsule formulation. The stationary phase consisted of Zorbax SB C_{18} column (250 mm × 4.6 mm i.d., 5μm) and mobile phase 20mM potassium dihydrogen phosphate buffer (pH 4.8) with 10mM octane sulphonic acid and acetonitrile (60:40 v/v). The detection was carried out at 290 nm at a flow rate of 1 ml/min. Both the drugs were well resolved free from interference. The method was statistically validated for linearity, precision, accuracy, robustness and specificity as per ICH guidelines. Linearity was observed in the concentration range of 2.5– 30 mg/ml for levosulpiride and 1.33-15.96 mg/ml for pantoprazole. The precision data indicates high reproducibility of method with % CV less than 2. The % recovery was found to be 100.66% and 99.38% for levosulpiride and pantoprazole respectively. The proposed method can be used for simultaneous estimation of levosulpiride and pantoprazole in combination pharmaceutical formulations.

PA003

Development and Validation of HPTLC Method for Simultaneous Estimation of Diclofenac Sodium and Serratiopeptidase in Pharmaceutical Dosage Form

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High-Performance Thin-Layer Chromatography (HPTLC) Method has been developed and validated for simultaneous estimation of Diclofenac Sodium and Serratiopeptidase. The separation was achieved on precoated silica gel 60 F_{254} aluminium plate as stationary phase and Toluene: Ethyl acetate: Methanol: Glacial acetic acid (6.0: 2.0: 2.0: 0.1 v/v/v/v) as mobile phase. The densitometry scanning was performed on Camag TLC scanner III in the reflectance-absorption mode at 236.20 nm and operated by winCATS software. The R_f values were found to be 0.665 ± 0.005 and 0.434 ± 0.004 for Diclofenac Sodium and Serratiopeptidase respectively. Beer's law obeyed in concentration range of 40-640 ng/spot and 100-1600 ng/spot in Distilled water for Diclofenac Sodium and Serratiopeptidase respectively. The method was validated for specificity, linearity, accuracy, precision, LOD and LOQ. The percent assay of marketed formulation was 101.1 ± 0.6772 and 101.9 ± 0.7367 % of Diclofenac Sodium and Serratiopeptidase respectively. The proposed method is simple, accurate, and precise since they are recommended for routine analysis.

PA004

Quality by Design Based Development and Validation of Chlorpheniramine Maleate & Dextromethorphan Hydrobromide in Syrup Formulation

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The aim of the study was to improve a robust RP-HPLC method for the determination of Chlorpheniramine maleate & Dextromethorphan hydrobromide. A Design Expert software (version-9.0.6.2) was used. A factorial design was used to check the effect of Tri fluoro Acetic Acid, column oven temperature on the resolution & tailing of the peaks. The range of Tri fluoro Acetic Acid was 1 (lower level) to 2ml (Higher level) & for column oven temperature 15ºC (lower level) to 20ºC (Higher level). The chromatographic condition of the optimized method contained column Phenomenox (4.6×150, 5µm), Mobile phase A- 1.5ml Tri Fluoro Acetic Acid in 1000ml water & B-100% Acetonitrile, flow rate-0.9 ml/min, column temp-20ºc, wavelength 275nm. The best resolution & tailing was found to be 4.9& 1.3 respectively. The validation of the optimized method was carried out according to ICH Q2R1 guidelines. The method was validated for specificity, linearity, accuracy and precision. The method was found to be linear in the range of 50% to 150%. The correlation coefficient was found to be 0.999. The % recovery was found between 98% to102% & the precision was found to be less than 2% (RSD). The results prove that quality by design concept could be successfully useful to optimize the HPLC chromatographic method for chlorpheniramine maleate & dextromethorphan hydrobromide with minimum number of trials.

PA005

Validation of Autoclave Using Chemical and Biological Indicators

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Process validation is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics. The sterile product manufacturing requires use of validated sterilization technique as it affects directly the quality of the sterile product. The present work was aimed to validate the sterilization cycle of an autoclave using chemical and biological indicators using different indicators by performing various cycles with varying load patterns. Biological Indicators are preparation of bacteria, in the form of either spores or vegetative cells that are prepared and maintained under such controlled conditions that they can be used to validate or monitor sterilization processes. Chemical Indicator is a chemical preparation which shows some changes after exposure in sterilizer, because they have sensitivity at particular temperature or pressure. Various indicators used were Biological Indicators (Spore Strip, Prospore Ampoule, Prospore Capsule, Protest) and Chemical Indicators (ProChem SSW, ProChem OK Cycle, Emu-Graph 7). All the indicators used for testing have given positive results. No spores or any other kind of bacterial growth was found in the media and other products sterilized using that particular autoclave. From all the data and records we can conclude that the functioning of the autoclave was satisfactory and it sterilized the load completely.

PA006

Bioanalytical Method Development and Validation of Aprepitant: Quality by Design (QbD) Approach

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Aprepitant, an antiemetic drug prescribed for use in chemotherapy/postoperative nausea and vomiting is going off patent in year 2027.A simple, precise and economic reverse phase high performance liquid chromatography (HPLC) method has been developed using QbD Approach and validated for Aprepitant in human plasma. Plackett–Burman experimental design was utilized to screen the effect of mobile phase pH, ûow rate, column temperature, injection volume and methanol concentration on peak resolution and USP tailing as per ICHQ2R1. Diazepam was used as an internal standard for the analysis. The detection of Diazepam and Aprepitant was done by using XDB-C18 HPLC column using methanol: water as a mobile phase at a wavelength 220nm. The chromatographic optimization was done in human plasma using mobile phase at 0.8mL/min flow rate. Retention time for Diazepam and Aprepitant was 5.9 min and 9.1min respectively. The developed method was tested for linearity range and validated in the terms of selectivity, precision, accuracy, stability and robustness. The results showed that QbD approach can be effectively utilized for the HPLC method development in least possible runs.

PA007

Development of Quality Control Parameter of HEPASAVE Syrup

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Herbal medicines can be used one type of complementary and alternative medicine. People use herbal medicines to try to maintain or improve their health. Many people believe that products labelled "natural" are always safe and good for them. In recent era, there has been great demand for herbal products in developed countries. So it is necessary to perform evaluation of polyherbal formulation. The present research work aims for development of quality control parameters of hepasave syrup, a polyherbal formulation. Hepasave syrup has been procured from Cadila Pharmaceuticals Ltd. It is basically used as hepatoprotective agent, bitter tonic and antioxidant. It is the lozenges solution which is made of combination of few medicinal plants, *Phyllanthus emblica, Terminalia chebula, Terminalia bellerica, Adhatoda vasica, Andrographis paniculata, Picrorrhiza kurroa* . In the present work various parameters of the given formulation checked for physicochemical properties, and preliminary Thin Layer Chromatography using different biomarkers, Gallic acid, Vasicine, Andrographolide, and Kutkin.

PA008

Stability Indicating Assay Method for Creatine in Bulk and Nutritional Supplements and its Validation

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The HPTLC method was developed and validated. Thin layer chromatographic aluminum plates precoated with silica gel 60 F254 was used as the stationary phase. All the peaks were resolved using a system consisting of acetone: methanol: water: ammonia (7:2:1:1 v/v/v/v) which gave compact spots. Rf value of creatine was found to be 0.22 ± 0.03. Creatine was subjected to stress conditions like acid and alkaline hydrolysis, hydrolytic and oxidation conditions, thermal and photolytic degradation. Absorbance mode at 254nm and 510nm were chosen as wavelength maxima for the degradant. The degradation of drug was obtained under acidic, alkaline, hydrolysis and oxidation conditions. Linearity, precision, limit of detection (LOD), limit of quantification (LOQ), specificity and accuracy were found at 254nm and 510nm. At 254nm linearity was obtained in the range of 2000-6000ng/spot and the correlation coefficient (r) was found to be 0.9979 and At 510 nm linearity was obtained in the range of 1000-3000ng/spot and the correlation coefficient (r) was found to be 0.9974. The LOD values were found to be 449.59ng/spot and 88.05 ng/spot at 254nm and 510nm respectively. The LOQ values were found to be 1362.42 ng/spot and 282.79 ng/spot at 254nm and 510nm respectively.

PA009

Spectrofluorimetric Method for Estimation of Ofloxacin

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A simple spectrofluorimetric method had been developed and validated for estimation of ofloxacin in tablet dosage form. Ofloxacin is a second generation fluoroquinolone antibiotic. It if effective against various gram positive and gram negative bacterial infections. Literature review revealed that many analytical method are reported for the estimation of ofloxacin from different matrices, but very few spectrofluorimetric methods are available. Hence, it was thought to develop a simple spectrofluorimetric method for estimation of ofloxacin. The method was developed using 5% acetic acid as a solvent for ofloxacin as it enhances the fluorescence of ofloxacin. Analysis was carried out in synchronous mode. Excitation and emission wavelengths were found to be 295 and 480 nm respectively. The method was validated as per ICH guideline for analytical method validation. The method was found to be linear in concentration range 0.05-1 µg/mL with correlation coefficient 0.995. The % RSD values for intraday and interday precision were 0.42 and 0.37 respectively. The values for limit of detection and limit of quantification were found to be 0.01 and 0.03 µg/mL respectively. The % accuracy was found to be 99.3-100.7%. The method proved its potential to be specific for ofloxacin as there is no any interference was found by usual tablet excipients. The method was successfully applied for estimation of ofloxacin from marketed tablet formulation.

PA010

Development and Validation of Analytical Method for Simultaneous Estimation of Tobramycin Sulphate and Dexamethasone Sodium Phosphate in Its Bulk and Pharmaceutical Dosage Form

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A simple, sensitive and precise method based on Reverse Phase High Performance Liquid Chromatography (RP-HPLC) has been developed for the simultaneous estimation of Tobramycin sulphate and Dexamethasone sodium phosphate in bulk and combined dosage forms. Chromatographic separation was performed on kromasil C_{18} column with particle size 5 µm (250 × 4.6 mm) with mobile phase acetonitrile and 10 mM KH_2PO_4 buffer (pH 5) (25:75, v/v) using flow rate 0.6 ml/min and detection wavelength was carried out at 205 nm. Calibration curves were linear within the ranges of 50-150 µg/ml for Tobramycin sulphate and Dexamethasone sodium phosphate. The retention time of Tobramycin sulphate and Dexamethasone sodium phosphate were 4.180 ±0.02 and 5.141 ±0.00 min respectively. The recovery was 99.44 - 101.68% and 99.5 – 101.29% for Tobramycin sulphate and Dexamethasone sodium phosphate respectively. The proposed method proved to be specific, robust and accurate and has good signal to noise ratio with well resolved peaks for determination of Tobramycin sulphate and Dexamethasone sodium in bulk and combined dosage forms.

PA011

Bioanalytical Method Validation: A Comparison of Various Guidelines

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Bioanalytical method validation plays an essential role in assessment and analysis of pharmacokinetic, pharmacodynamic, bioavailability, toxicology, bioequivalence and comparability studies that gives assurance for the quantification of analyte/s in biological fluids. The US FDA in 2001, ANVISA in 2003 and EMA in 2009 released guidelines on bioanalytical method validation. The review compares and summarizes these regulatory guidelines issued by US FDA, EMA and ANVISA that evaluates the parameters for validation viz. specificity, selectivity, linearity, range, carry over effect, accuracy, recovery, precision: three levels as repeatability (intra-run precision), intermediate precision (inter-run precision) and reproducibility (inter-laboratory precision), calibration/ standard curve including lower limit of quantification (LLOQ) and concentration response, limit of detection (LOD), limit of quantification (LOQ), stability studies consist of freeze and thaw stability, short-term temperature stability, long-term stability, stock solution stability and post preparative stability, robustness, dilution integrity, parallelism, incurred sample reproducibility, matrix effect, stability in whole blood along with effect of anti-coagulants, haemolysed and lipemic samples. Acceptance criteria for all the bioanalytical method validation parameters vary according to the different guidelines. Matrix effect, carry-over effect, incurred sample reanalysis, dilution integrity, recovery, stability in whole blood parameters are not mentioned in some of these guidelines.

PA012

Analytical Method Development and Validation of Vitamin E Acetate from Multivitamin dosage form using Quality by Design Approach

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A simple, efficient and reproducible RP-HPLC method for determination of Vitamin E Acetate from multivitamin tablet dosage form has been developed and validated using Quality by Design approach. As vitamin E acetate is a fat soluble vitamin. It requires extraction from multivitamin dosage form. The extraction was carried out by using n-Hexane and Dimethyl sulfoxide. The chromatographic separation was carried out using Partisil ODS-3 (100 mm × 5 mm, 4µ) column using the mobile phase consist of Methanol: Acetonitrile:1% OPA in water (75:20:5). The flow rate was 1.0 ml/min and effluent was detected at 254 nm. The retention time of vitamin E Acetate was 6.96. Quality by Design approach was applied to the development trials for optimization of analytical method. The multilevel categorical design (3^2) was applied. It is a type of Full Factorial design. Temperature and Acetonitrile composition in mobile phase were two critical parameters observed. The response was on number of Plate counts and Retention time of vitamin E Acetate. Chromatographic peak purity results indicated the absence of co eluting peaks with the main peak of vitamin E Acetate. The method was validated using ICH Guideline and the acceptance criteria for system suitability, specificity, accuracy, linearity, precision were met in all classes. The values of all the parameters were within the prescribed limits. Hence, the method could be successfully applied for routine analysis of Vitamin E acetate from multivitamin dosage forms.

PA013

Isolation, Characterization and Estimation of Active Constituent from *Achyranthes aspera* Linn. Plant

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Phytochemical screening of *Achyranthes aspera* Linn. revealed the presence of steroids, alkaloids and glycosides. The present study describes the development of a sensitive and selective validated HPTLC method for the quantification of the 20-Hydroxyecdysone from the plant *Achyranthes aspera*. 20-Hydroxyecdysone was isolated from the roots of *Achyranthes aspera* and was characterized by spectrophotometric methods. Validated HPTLC method was developed for the estimation of 20-Hydroxyecdysone in plant. Camag TLC scanner 3 with CATS4 software was used for densitometry scanning. The detection was performed at 254 nm. The proposed method was validated in terms of linearity, precision, accuracy and sensitivity as per ICH guidelines. The mobile phase optimized was Chloroform: Methanol: Ammonia (80:20:2 v/v/v) which gave good resolution for 20-Hydroxyecdysone at Rf 0.41± 0.03. The linearity (r^2=0.998) was found to be within range 600-2100 ng/spot with average % recovery of 100.64%. The LOD was found to be 50ng/spot and LOQ was found to be 152.3ng/spot. The proposed method was successfully applied for estimation of 20-Hydroxyecdysone in roots and seeds of *Achyranthes aspera* and the amount of 20-Hydroxyecdysone in roots and seeds was found to be 0.176% and 0.069%w/w respectively.

PA014

Drug and Excipient Compatibility Study of Selected β Blockers Drugs

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The drug and excipient compatibility study is an important part in the development of all dosage forms i.e. during preformulation stage. The interaction between drugs and excipients can impact on the physical and chemical nature, the stability, therapeutic efficacy and consequently safety of the drugs. The list of drugs selected for drug and excipient compatibility studies were β blockers drugs (β adrenergic blocking agent, β antagonists, β adrenergic), which can be used in the treatment and management of arrhythmias, heart failure, hypertension and myocardial infarction. A study was carried out to investigate compatibility of β blockers drugs (like, atenolol, labetalol hydrochloride, bisoprolol fumarate, metoprolol succinate, carvidilol and propranalol hydrochloride) with the pharmaceutical excipients of povidone. The binary mixture (1:1) of β blockers with the excipient were stored for the duration of 6 month at 40°C/ 75% RH. This binary mixture of products exhibited to oxidative stress condition and the stressed samples were analyzed at the interval of 1 month of assay and related substance with the technique of high performance liquid chromatography (HPLC).

PA015

TLC-Bioautography Assisted Screening of Various Plant Extracts for Potential Antimicrobial Constituent and its Isolation, Characterization and Estimation Using Developed Validated HPTLC Method

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TLC-Bioautography is used as a screening tool to identify target directed antimicrobial constituent of plant extracts. It was planned to identify, isolate, purify and characterize the potent Antimicrobial constituent from extracts. The isolated constituent was estimated in plant extract using developed validated HPTLC method. Optimized conditions for TLC-Bioautography were established. Various extracts of 10 plants were screened for its antimicrobial activity against gram positive (*S. aureus*) bacterial strain. Among them methanolic extract of *Pongamia pinnata* seed oil was identified as potent antimicrobial and the targeted antimicrobial constituent was isolated and characterized as Pongamol by using various spectrophotometric methods. Simple and validated HPTLC method was developed for quantification of Pongamol. The separation was performed on pre-coated silica G60 F254TLC plates by using n-Hexane: Diethyl ether: 1,4 Dioxane (8:1.7:0.3, v/v/v) as mobile phase with Rf 0.38 ± 0.02 for pongamol. Method was developed at 352 nm. The proposed method was validated as per the ICH guidelines. HPTLC method was validated. Linearity was found to be within range 300- 700 ng/spot with average % recovery of 99.62% for Pongamol. The correlation coefficient for Pongamol was 0.992. LOD and LOQ were found to be 38.29ng/spot and 116.06ng/spot respectively. Pongamol was quantified to be 0.316%w/v in *Pongamia pinnata* plant extract. TLC-Bioautography was used as a screening tool for antibacterial activity of plant extracts and target directed isolation of potent antimicrobial constituent; Pongamol. A Simple, sensitive and selective HPTLC method for estimation of Pongamol in seed oil of *Pongamia pinnata* was developed.

PA016

Development and Validation of High Performance Thin Layer Chromatographic Method for Simultaneous Estimation of Cilnidipine and Valsartan its Standard Mixture Using Box- Behnken Design

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High performance thin layer chromatography (HPTLC) method has been developed for the separation of Cilnidipine and Valsartan using pre-coated silica gel aluminium plate 60F254, with UV detection at 300 nm. Box- Behnken design was applied for multivariate optimization of the experimental conditions of HPTLC method. Three independent factors: Ethyl acetate content in mobile phase composition, saturation time and migration distance whereas R_f of both drugs were taken as response which was used to design mathematical models. The quadratic model was found to be best fit for both responses. The predicted optimum assay conditions consisted of toluene: methanol: ethyl acetate: GAA (6:2:2:0.1, v/v/v/v), respectively as the mobile phase. The method was validated according to ICH guidelines. Linear responses were observed in the concentration range of 200-600 ng/band for Cilnidipine and 1600- 4800 ng/band for Valsartan. Mean % RSD for intra-day precision of Cilnidipine and Valsartan were found to be 0.423 and 1.213 respectively. The mean % RSD for inter day precision of Cilnidipine and Valsartan was found to be 0.404 and 1.282 respectively. The % RSD of Cilnidipine and Valsartan were found to be 0.3512 and 0.2426, respectively. The LOD for Cilnidipine and Valsartan were found to be 2.406 ng/band and 21.04 ng/band respectively. The LOQ for Cilnidipine and Valsartan were found to be 7.292 ng/band and 63.76 ng/band respectively. The amount of Cilnidipine and Valsartan were found to be 99.07% and 98.77% from their physical mixture.

PA017

Stability Indicating Super Critical Fluid Chromatography Method for Determination of Aripiprazole in Tablet Dosage Form

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A simple, sensitive, highly accurate and ecofriendly super critical fluid chromatography method has been developed and validated for the determination of Aripiprazole in a tablet dosage form. The method for separation of Aripiprazole was achieved using a C_{18} reverse-phase fused-core column (Inertsil ODS-5 µm C18, 150 mm×4.6mm) as stationary phase; and mobile phase contains supercritical carbon dioxide ($SC\text{-}CO_2$) at a flow rate of 2.5 ml/min and modifier as Isopropyl alcohol at flow rate of 0.2 ml/min with detection at 257 nm. Linearity was established in the range of 80-180 µg/ml. The R_t value was found to be 0.75 for Aripiprazole. The percent recovery was found to be 98.6% –98.75% for Aripiprazole. The method was validated as per ICH guidelines for selectivity, linearity, precision, LOD, LOQ and recovery. The LOD and LOQ were found to be 9.714 and 29.438 ng/ml respectively. Stress degradation studies were carried out using ICH recommended condition like acid, base, oxidation, neutral, photolytic and thermal degradation. It was found that the drug was labile to hydrolytic, oxidative and thermal degradation. It was also found that drug was stable in photolytic condition. The result of tablet analysis and recovery studies revealed accuracy and precision of the method. The proposed method was found to be successfully rapid, accurate, precise, selective, sensitive, suitable and can be applied for the determination of Aripiprazole in tablet dosage form.

PA018

Various Innovative Techniques in Mass Spectrometer: From Shotgun to Q-Exactive Mass Spectrometer

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When the concept of mass spectrometer is applied to proteomic field, it is difficult to achieve both selectivity and sensitivity and it limits analysis of biological samples. A combination of liquid chromatography and tandem mass spectrometry, shotgun proteomics, is used for analysis of digested peptides with limited parameters. Some innovative techniques such as Q-Exactive mass spectrometer is available with much better sensitivity and selectivity when comes to sample analysis. It involves the use of orbitrap mass analyzer with quadrupole filter for initial assortment according to analyte mass. Thus it is capable of providing mass filtering with better resolution and accurate mass measurement. Another advantage is targeted analysis in two approach: parallel reaction monitoring and single ion monitoring. SIM isolates analytes in marked range along with precursor ions using quadrupole system. PRM works in same way except it passes analytes to high energy collision dissociation element for fragmentation before analysis in orbitrap. Thus in the field of consumer driven science and proteomics it play important role. It allows researchers to discover new biomarkers and application in the medical consumer.

PA019

Chromatographic Densitometric Method Development and Validation for the Estimation of Apigenin in *Ocimum basilicum* L. Seeds (Takhmaria)

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A simple, selective, precise, and accurate high-performance thin-layer chromatographic (HPTLC) method has been developed for the quantification of *ocimum basilicum* seeds for their apigenin content. Densitometric evaluation was carried out on precoated silica gel G60 F_{254} plates as stationary phase and with toluene–acetone– formic acid (5:4:1, *v/v/v*) as the mobile phase. Scanning and densitometric evaluation were done at 340nm. Developed method showed good linear relationship with r^2=0.995 with respect to area in concentration range between the concentration of 100–600 ng/band. The developed method was validated according to ICH guideline for accuracy, precision, range linearity, limit of detection (LOD), and limit of quantification (LOQ) and was demonstrated for estimation of apigenin in *Ocimum basilicum* seeds. Developed method was able to be applied for identification and quantification of apigenin in complex mixtures of phytochemicals and could be extended to marker-based standardization of plant samples as well as extracts.

PA020

Recent Advancements in Nano-scaled Biosensors

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In current scenario, biosensors are tremendously grown in the market of disease diagnosis and treatment. Various fields including pharmaceutical, medical science, forensic science, food industries and many more are widely using biosensors as per their need. Combination of nano materials with these biosensors leads to a tremendously increased application of its sensing capabilities as the disease markers, pathogenic bacteria monitoring, virus recognition and disease biomarker detection. These nano-scaled biosensors are greater in all the aspects than the traditional ones. Nano-scaled biosensors are known for its greater speed, better sensitivity and specificity as well as selectivity. These extremely flexible sensors broaden the arena of detection and recognition. A tremendously increased use of nano scaled biosensors in detection of cancer is explained in this review using carbon nanotubes with TiO_2 and gold particles. Besides this, surface modified quantum dot techniques, surface plasmon resonance, fibre optics, acoustic waves and quartz crystals are field of interest. So, the review will give the outline about the recent trends in development of biosensors using nano particles and nanomechanical systems.

PA021

Isolation, Characterization and Estimation of Active Constituent of *Limonia acidissima*

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General Phytochemical screening of the bark and fruit pulp powder of *Limonia acidissima* revealed the presence of steroids, alkaloids, phenolic compounds, saponins, and flavonoids Limodissimin A was isolated from the bark of plant and characterized by physicochemical and spectrophotometric methods. Simple and validated HPTLC method was developed for the estimation of Limodissimin A in bark of *Limonia acidissima*. The separation was performed on TLC aluminium plates pre-coated with silica G60 F254 followed by detection of Limodissimin A by derivatizing the plate with vanillinphosphoric acid reagent. The method was developed at 575nm. The proposed method was validated in terms of linearity, precision, accuracy and sensitivity as per the ICH guidelines. The mobile phase optimized was neat Hexane (99%) without any saturation, optimum polarity for proper separation and resolution of Limodissimin A from other constituents of bark with Rf 0.57 ± 0.03. The linearity was found to be within range 24-56 µg/spot with mean average % recovery of 95.16% for Limodissimin A. The correlation coefficient for Limodissimin A was 0.997. The LOD and LOQ for Limodissimin A were found to be 1.94 µg/spot and 5.92 µg/spot respectively. A Simple, sensitive and selective HPTLC method for the estimation of Limodissimin A in bark of *Limonia acidissima* was developed and the amount of Limodissimin A in bark was found to be 0.275%w/w ± 0.024%.

PA022

Simultaneous RP-HPLC Assessment of Febuxostat and Ketorolac Tromethamine in Tablet Dosage Form for Degradation Behavior Under Stressed Conditions

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Simultaneous assessment of Febuxostat (FB) and Ketorolac tromethamine (KT) was carried out under various stressed conditions by a novel, precise, rapid and selective RP-HPLC stability indicating method. Method was validated as per ICH Q2 (R1) guideline in tablet dosage form. Agilent eclipus C18 (250×4.6mm, 5 µm particle size) column with a mobile phase consisting of phosphate buffer (KH_2PO_4) and acetonitrile (pH=4 adjusted with o-phosphoric acid) in a ratio of 60:40 v/v at a flow rate of 0.9 ml/min was used for isocratic separation. The eluent then monitored at 321 nm. FB and KT were retained at 7.533 min and 3.797 min, respectively. The calibration plots of FB and KT were linear over the concentration range of 50-150 µg/ml and 18.75 to 56.25 µg/ml with correlation coefficients (r^2) of 0.9980 and 0.9984, respectively. The method shows consistent recoveries for FB and KT (99-101%). The proposed stability method was used to check the degradation behavior of FB and KT under the different degradative conditions. There was no interference between detection of FB and DP with their degradation products under various stressed conditions. The suggested validated RP-HPLC method was found to be specific, sensitive, stability indicating and was effectively applicable for analysis of tablet dosage form.

PA023

Development of Dissolution Controlled Salts of Pramipexole to be used as Long Acting Depot Formulation

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Dissolution controlled salt preparation is one of the technique for the formulation of long acting depot formulation. Pramipexole is dopamine agonist and effective as monotherapy in early Parkinson's disease and as an adjunct to levodopa in patients with motor fluctuations. The formation of insoluble salt can be simple approach to modify a drug compound to obtain a sustained release profile. In present work different salts of Pramipexole were developed like Pamoate, Palmitate and Laureate by using precipitation method and reaction conditions were optimized. The melting point of obtained salts were 190-200 p C, 80-90 p C corresponding Pamoate and Laureate, Palmitate. The results of melting point further supported by DSC analysis. The prepared salts were evaluated for saturation solubility after 24 hrs in different media like water, phosphate buffer pH- 5.5, 6.8 and 7.4. Optimized salts showed substantial reduction in solubility of Pramipexole. The reduction in solubility of pamoate is 78.6, 62.1, 20.8 and 13.5 times in water, buffer pH- 5.5, 6.8, 7.4 as that of pramipexole. Similarly in case of Palmitate solubility retarded by 11.9, 7.6, 8.1, 12. 6 and in Laureate 19.4, 8.2, 9.2, 11.5 times in water, buffer pH- 5.5, 6.8, 7.4 respectively than drug. The obtained results were positive, hence can be develop into depot formulation. The synthesized dissolution controlled salts further can be formulated as long acting injectables and further evaluate by *in-vivo* drug release and toxicity study.

PA024

Estimation of Lopinavir and Ritonavir in Human Plasma by SPE Method Using HPLC-ESI-MS/MS

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A simple, sensitive, rapid, selective and reproducible HPLC-ESI-MS/MS method was developed and validated for the estimation of Lopinavir and Ritonavir in human plasma using Propranolol as internal standard. MS/MS analysis was performed in positive electrospray ionization (ESI) mode with multiple reaction monitoring (MRM) using mass transition *m/z* 629.3>183.1 for Lopinavir, *m/z* 721.3>296.1 for Ritonavir & *m/z* 260.2>116.2 for Propranolol (internal standard - ISTD). MRM transitions for both analytes and internal standard (ISTD) were performed on a triple quadrupole mass spectrometer. Simultaneous extraction method involves the most sample cleanup method – solid phase extraction. Chromatographic separation was achieved with Kinetex C18 (100 X 4.6mm) 2.6µ column. Isocratic mobile phase consist of 5mM ammonium formate in water (pH 4.50±0.05) and methanol (15:85v/v), with the flow of 0.550mL/min. All the analytes and internal standards were eluted within 3.2 min chromatographic run. Linearity in plasma was observed over the concentration range 15 - 10000 ng/mL for Lopinavir and 3 - 2000 ng/mL for Ritonavir. The lower limit of quantification (LLOQ) for both analytes was achieved with 10µL injection volume. Different stabilities like bench top stability, auto sampler stability, freeze and thaw stability, long term stability in matrix and stock and working solution stability was performed for Lopinavir & Ritonavir.

PA025

UPLC-MS/MS Bio Analytical Method Development and Validation for Nebivolol, a Beta-Blocker in Human Plasma

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In present study, ultra-performance liquid-chromatography tandem mass spectrometry (UPLC-MS/MS) method for the determination of Nebivolol in human plasma was developed. Nebivolol–d4 was used as the internal standard (IS). The plasma samples were subjected to solid phase extraction on Phenomenex Strata-X™ cartridges. Analytical column HSS C18 (50 mm × 2.1 mm, 1.8µm particle size) was used under isocratic conditions with the mobile phase consisting of 0.1% (v/v) formic acid in water-acetonitrile (22:78, v/v), and detected by positive ion in multiple reaction monitoring (MRM) mode. The precursor '! product ion transition for Nebivolol and IS were 406.2 '! 151.1(m/z) and 410.2 '! 151.1(m/z), respectively. The validated assay consisted by wide dynamic concentration range of 0.050-150 ng/mL. Matrix effect was described by post-column analyte infusion experiment. The mean absolute extraction recovery of analyte and IS was 80.2 % across four levels of quality control samples. Stability of Nebivolol in plasma was established under different conditions like freeze and thaw, processed sample, bench top and long term.

PA026

Microwave-Assisted Hydrolytic Forced Degradation Study of Antipsychotic Drugs

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Forced degradation or stress studies of drug substances play an integral role in the development of pharmaceutical products. Antipsychotic drugs like Lurasidone hydrochloride, Paliperidone and Risperidone are unstable and degrade when exposed to alkaline conditions. Microwave dielectric heating is a non quantum mechanical effect and it leads to volumetric heating of the sample. So microwave has significant advantages compared to conventional thermal heating. The aim of this study was to expose the three drugs to alkaline hydrolysis using microwave-assisted and conventional way of heating method to perform a forced degradation. An Anton-Paar Synthos Microwave Synthesizer was used for Lurasidone hydrochloride, Paliperidone and Risperidone alkaline hydrolysis in 0.5N, 0.1N and 5N Sodium Hydroxide, respectively. To achieve desired and comparable degradation the microwave irradiation program used was 300W power and temperature of 40°C for 4min (56%) for Lurasidone; 50°C for 15min (33%) for Paliperidone and 90°C for 10 min (23%) for Risperidone. Whereas conventional way of heating at the same temperature as applied for microwave heating for 1hr (53%), 2hr (37%) and 15hr (24%) for Lurasidone, Paliperidone and Risperidone, respectively. The degradation products formed were separated on C-18 column in reverse phase mode using liquid chromatographic technique. The degradation products generated under conventional and microwave heating methods were compared with respect to retention time to make conclusion that microwave energy can be used to take over conventional method of heating for hydrolytic forced degradation study.

PA027

Development and Validation of RP-HPLC Method for Quantification of Betulinic acid in *Vitex negundo L.* and its Polyherbal Formulations

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The *Vitex negundo*, which is traditional Indian medicine, has been used for treatment of various diseases. A simple, sensitive, precise and accurate RP-HPLC method has been developed for the analysis of *Vitex negundo* L. samples and its polyherbal formulations for their betulinic acid content. The extraction was checked using different solvents like methanol, chloroform, 95% ethanol, acetone and dichloromethane. It was found chloroform was good extraction solvent that allowed extraction of betulinic acid with highest content. The method involves RP C18 column with methanol-acetonitrile-water (90:5:5 % v/v/v) pH 2.5 adjusted with ortho phosphoric acid as mobile phase and UV detection at 270 nm. The flow rate was 1.3 ml/min. The retention time was 2.29 min. The linearity range was 5-30 µg/ml. The method was validated for linearity range, precision, LOD, LOQ, robustness and accuracy. Mean recovery was 99.16-100.76 %. The method was successfully applied for the quantification of betulinic acid in leaves, seeds of *Vitex negundo* L. and its polyherbal formulations. The results demonstrated that the content of betulinic acid was depending on different extraction solvents and ensure its clinical benefits.

PA028

Simultaneous Estimation of Drugs Used for Treatment of Erectile Dysfunctioning in Bulk and in Their Combined Dosage Form

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A simple, precise and accurate UV Spectrophotometric method (Absorbance Ratio method) and Stability indicating RP-HPLC method have been developed for simultaneous estimation of drugs used for treatment of erectile dysfunctioning (Sildenafil Citrate and Dapoxetine Hydrochloride). The developed methods were validated as per ICH guidelines Q2-R1. In Absorbance Ratio method, the spectra of Sildenafil Citrate and Dapoxetine Hydrochloride were taken and wavelengths 239.0 (i.e. Iso-Absorptive point) and 292.0 nm (λmax of SC) were selected for the formation of the Q-Ratio equations. The linearity for Sildenafil Citrate was found to be 4-20 µg/ml and 5-25 µg/ml for Dapoxetine Hydrochloride. The developed method was validated as per ICH guideline and was found to be precise with % RSD < 2 and accuracy was found to be in range. In RP-HPLC method, separation was achieved on a Hypersil BDS C_{18} (150 mm x 4.6 mm, i.d. 5µm) column, kept at ambient temperature, using a mobile phase consisting of 0.2 % OPA in water and acetonitrile (40:60 v/v) at a flow rate of 1 ml/min and UV detection at 239 nm. The linearity was observed in the concentration range of 20-60 µg/ml for Sildenafil Citrate and 12-36 µg/ml for Dapoxetine Hydrochloride. Also the stability-indicating nature of the RP-HPLC method was established by applying various forced degradation conditions like acid hydrolysis, base hydrolysis, oxidation and thermal stress conditions. The results clearly indicated that the developed RP-HPLC method would be suitable for simultaneous estimation of both the drugs in presence of degradant products. Both the developed methods have shown potential utility for simultaneous estimation of both the drugs in bulk and in their combination.

PA029

Simultaneous Estimation of Doxycycline & Ornidazole in Bulk Drug & Its Marketed Formulation by RP-HPLC Method Using QbD Approach

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Doxycycline (DOX) & Ornidazole (ORD) are antibiotic drugs. The combination of these drugs has beneficial effect in malaria. A simple sensitive & validated RP-HPLC method has been developed for simultaneous estimation of this drug in bulk drug & in tablet dosage form. After optimization of chromatographic conditions, C_8 column was used as a stationary phase & separation was carried out using phosphate buffer (pH 2.5): ACN: methanol (80:15:5 v/v/v) as a mobile phase at a flow rate of 1 mL/min with detection wavelength 293 nm. Liniarity was obtained in the range of 13-30 µg/mL (r2 = 0.996) for DOX & 50-150 µg/mL (r^2= 0.998) for ORD. Both the drugs are well separated using isocratic elution with RT of 2.385 min (ORD) & 5.431 min (DOX). The method was validated as per ICH guidelines. The marketed preparation was successfully analyzed using developed method with % recovery in the range of 98.96%-99.28% (DOX) & 98.5-99.04 (ORD). No interference from common excipients & impurities was observed.

PA030

Development and Validation of RP-HPLC And HPTLC Method for the Simultaneous Quantification of Rosmarinic Acid, Quercetin, Glycyrrhizin and Betulinic Acid in Polyherbal Immunostimulant Formulation

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Quantification of bioactive markers through modern analytical methods is very essential for establishing the authenticity and creditability of prescription and usage of herbal drugs formulations. In the present study, simultaneous quantification of rosmarinic acid (RA), quercetin (Q), glycyrrhizin (G) and betulinic acid (BA), in polyherbal formulation by reverse phase HPLC and HPTLC methods were developed. In the RP-HPLC method, separation of these four markers was achieved using a Phenomenex- C_{18} column (250mm × 4.6mm i.d., 5µ particle size). A mobile phase system constituted of solvent A (acetonitrile) and solvent B (water), PH 3.1 (adjusted with orthophosphoric acid 85%), was used, at gradient conditions, at a flow rate of 1.0 ml/min. Analysis was performed using PDA-detection at 239 nm. In the HPTLC method, mobile phase of ethyl acetate: toluene: methanol: formic acid (7: 1: 0.5: 0.5 v/v/v/v) was used on precoated plate of silica gel F_{254} and quantified by densitometric method. Validation of the methods was done to demonstrate its selectivity, linearity, precision and accuracy as per the ICH guidelines. Intra-day assay and inter-day assay precision of the analytes were less than 2%, and the average recovery rates obtained were in the range of 98–101% for all with % RSD below 2%. Correlation coefficient between 0.977 - 0.9999 for both the methods shows that the developed methods were accurate and precise. These methods can be used in routine analysis of polyherbal formulations. Statistical analysis proves that there were no statistical significance differences between two developed methods.

PA031

Development and Validation of Stability Indicating Chromatographic Method for Simultaneous Estimation of Metolazone and Spironolactonein: Its Combined Pharmaceutical Dosage Form

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Metolazone is a thiazide like diuretic and Spironolactone is a potassium sparing diuretic. Together these drugs have beneficial effects in congestive heart failure induced edema. A validated stability indicating thin layer chromatogaphy method has been developed for the concurrent estimation of Metolazone and Sprinolactone in their combined dosage form. It was performed using pre coated silica gel aluminium plate 60F254 as stationary phase and ethylactetate: chloroform: glacial acetic acid (5: 5: 0.1 v/v/v) as mobile phase. The R_f values for Metolazone and Spironolactone were found to be 0.51 and 0.77 respectively. The optimized conditions showed a liner response from 50-300ng/band (r^2 = 0.998) for metolazone and 200-1200ng/band (r^2 = 0.999) for spironolactone at 238 nm. The degradation products formed under different stress conditions were successfully separated from drug substances using the developed method. Metolazone was prone to acidic hydrolysis and photolysis while Spironolactone was prone to alkaline degradation.

PA032

Bioanalytical Method Development and Validation to Study Alteration in Bioavailability of Statins on Co - administration with Flavanoids

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A simple, validated and rapid High-Performance Thin Layer chromatographic method (HPTLC) was developed for the simultaneous estimation of Atorvastatin calcium and Rutin from the blood. Drugs were extracted from blood by liquid-liquid extraction using methanol. Separation was achieved on aluminum plates precoated with silica gel $60F_{254}$ as stationary phase and mixture of toluene: ethyl acetate: methanol: glacial acetic acid (4:4:1.5:0.5 v/v/v) as a mobile phase. For simultaneous estimation of both drugs, photometric evaluation was performed at 279 nm. *in-vivo* study was also carried out to check the lipid profile after administration of Atorvastatin Calcium (50mg/kg) and Rutin (100mg/kg) alone and in their combination (50+100 mg/kg). Blood samples were collected before and after 24 h of the treatment from the retro-orbital plexuses of rat eye. Blood samples were analyzed for serum cholesterol, triglycerides, LDL and HDL levels by using their respective enzyme immune assay kits. Hence a Simple, sensitive and selective HPTLC method for Atorvastatin calcium and Rutin estimation in blood was developed and which could be successfully applied in the pharmacokinetic evaluation of Atorvastatin calcium and Rutin in blood.

PA033

Reverse Phase Liquid Chromatographic Method for Simultaneous Estimation of Chlorzoxazone, Diclofenac Potassium and Pantoprazole Sodium Sesquihydrate in Bulk Drug & Marketed Preformulation

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A simple, reproducible & validated RP-HPLC method has been developed for simultaneous estimation of chlorzoxazone (CZ), diclofenac potassium (DCP) & pantoprazole (PPS) sodium sesquihydrate in bulk & marketed formulation. All three drugs are well separated in selected chromatographic conditions using isocratic mode of elution. Agilent XDB C_8 (150 *14.6 mm i.d, 5 µ) was used as stationary phase & methanol: ACN: Na_2HPO_4 buffer (10mm, pH 4.5) in the ratio of (40:30:30 v/v/v) was used as a mobile phase. Detection wavelength selected after optimization was 286 nm with 1mL/min of flow rate. With selected optimized chromatographic conditions all three drugs are well separated with RT of 2.45 min (CZ), 4.9 min (DCP) and 7.8 min (PPS). Linearity range was 20 to 100 µg/mL for CZ, 8 to 40 µg/mL for DCP & 4 to 20 µg/mL for PPS. The method was validated as per ICH guidelines. The method was successfully applied for estimation of these drugs in marketed formulations without any modification with % recovery of 97.6%, 97.6% & 97.9% for CZ, DCP, and PPS respectively. The results of analysis were validated as per ICH guidelines.

PA034

Review on Implementation of Quality by Design Approach for Impurity Profiling

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The understanding of shelf life, expiry periods, degradation kinetic study, stability indicating and impurity profiling is major concern. Present manuscript focussed on QbD approach for optimized forced degradation conditions. Analytical issue occurring at the last stage of long term stability study involves unpredicted impurities disturbing the monitoring of characterized impurities and raised so many regulatory issues related to that. QbD multivariate approach was evaluated within the framework of LC method. Initial allows the investigation of critical process parameters (CPPs), which have an impact on critical quality attributes (CQAs). Selection of primary and secondary parameters to get design space (DS) with help of polynomial equation and derringer's desirability value. Sorting out impurities with multivariate DoE approach can be supportive in time & cost reduction, which suggest robust process. In current time, application of ICH guidelines Q8 and Q9 are versatile for improve quality, safety, efficacy study of product and risk reduction.

PA035

Impact of Radio-sterilization on Stability of Pharmaceutical Products

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Radiosterilization has become more popular in pharmaceutical industry during past few years; the advantages of sterilization by ionizing radiation include high penetrating power, low measurable residues, small temperature rise, fewer variables to control and it can be carried out on finished pharmaceutical products. The technique utilises ionizing radiations like gamma rays, e-beam etc. for the sterilization of pharmaceuticals. The radiations kill the microbes by producing free radicals that are generated by breaking the chemicals bonds, which attack and alter nucleic acid and prevent cell division. But the ionizing radiation depending upon its type, dose and dose rate may interact with the active ingredient, excipient or packaging material. It may alter physicochemical property of the pharmaceuticals, causing degradation of the product. As irradiation may produce new radiolytic products, it may change the quality of the product and the degradants might be toxic for the patient. So there is a need of an hour to prove the safety of radio sterilisation, hence it is important to study the effect of radiation on pharmaceuticals after radiosterilization. This review summarizes the radiostability of active ingredients, excipients and final dosage forms including new drug delivery system from the published literature.

PA036

Functionalization of Silver Nanoparticles by Pyrophosphate for Colorimetric Sensing of Deferiprone Through Competitive Iron (III) Complexation

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Present work reports a novel colorimetric sensor to probe 'Deferiprone', an iron chelating drug, based on water dispersible silver nanoparticles (AgNPs). The AgNPs were prepared following a simple borohydride reduction method, which were then functionalized with pyrophosphate anions. These functionalized AgNPs were characterized by UV and Dynamic Light Scattering techniques. The modified AgNPs possessed cooperative binding ability for Fe^{3+} ions resulting in a distinct color change of the nanoparticles dispersion. However, this binding was competitively overruled in the presence of deferiprone, which prevented the aggregation of AgNPs. The consequent color response (as measured by UV spectrophotometer) was directly correlated to the amount of the drug present in the solution, which made it possible to fabricate a sensor for rapid estimation of deferiprone down to 6 μM. Several affecting parameters viz. the relative amounts of silver nanosuspension and pyrophosphate solution, the pH of the medium, and time were studied and suitably optimized. Furthermore, the colorimetric sensing was free from interference of other commonly used medications like naproxen, paracetamol, diclofenac, domperidone, omeprazole and rabeprazole.

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RA001

Regulatory and Statutory Hurdles in Development, Approval and Marketing of Generic Drug Products

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A generic drug product is thought to be 'essentially similar' and 'Bioequivalent' to an innovator product. Presently, the generic pharmaceutical industry is confronting trying times due to fierce competition and is entering into a consolidation phase. There is a budding concern that the drugs pipeline is drying up, several drug discovery technologies stood still, severe market competition have eroded the prices and more importantly investment circle is increasingly becoming cognisant of the risk occupied during drug development. In addition to the technical hurdles that a potential generic drug sponsor must overcome, there are a number of obstructions that many would portray as being of a legal and legislative nature. Various hurdles in generic development are: Legal hurdle (30-Months stay), Patent related issues, Exclusivities issues, Authorized Generics, Product hopping/swapping, Legislative issues, Marketing Hurdles etc. A prospective generic applicant facing a situation that could pose hurdles of this type would be given an opinion to apt regulatory and legal advice. Medicare Modernization Act, Citizen Petitions, Implementation of GDUFA are some of the ways to tackle these hurdles. The industry knows that it needs to amend for better future. However, not everyone is clear what those changes will be and how those changes are likely to occur. The predictive capabilities should be more accurate and the speed to develop and market should be increased. Expansions for the generic pharmaceutical industry are encouraging in near future as more brand-name drugs approaching off patent and payers push for cost reduction in wellbeing.

RA002

Comparative Study of Registration Process for Nutraceutical Products in US, Australia, Canada and India

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The term "Nutraceutical" was coined from "Nutrition" & "Pharmaceutical". Rules and regulations are different for nutraceuticals than a drug. "Nutraceutical" as "a food or part of food that provides medical or health benefits including the prevention and treatment of disease." It includes vitamins, amino acids, minerals, herbs, and other dietary supplements. The nutraceuticals are classified based on chemical constituents, traditional-nontraditional nutraceuticals and based on disease. This study is aimed to compare registration process of Nutraceuticals in India, US, Australia, Canada to conclude the comparative difference in regulatory authority, labeling, licensing, and ADR reporting requirement. In India the nutraceuticals is regulated by food safety and standard authority. The total Indian nutraceuticals market is expected to be approximately $5 billion in 2015. In Canada nutraceuticals are known as natural health product under the natural health product regulation. In US Nutraceutical is regulated by food and drug administration. In Australia the regulation is done by Therapeutic Goods Act amended in 1990.The registered medicines are at high risk label by AUST R and listed medicines are at low risk labeled by AUST L.

RA003

A Regulatory Technicalities for Drug Product Registration in Brazil

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In Brazil medicinal product registration is an extensive process. Pharmaceutical industries having domestic manufacturing have standing for market authorization of medicines. Validity of drug license depends on type of product ranging from 2-5 years and can renewed for similar time constantly. The API and excipients should be informed and administration, specifications, leaflets/labels, precautions, and relevant information regarding the drug products must be submitted in Portuguese language. Registration process for medicine may take more than a year. ANVISA provide a protocol number in case it takes more than 3 months for process, by which an applicant can start distribution in Brazil. In Latin America Brazil, Argentina, and Chile are countries which provide encouragement for generic product registration by deducting the registration fees for generics. In addition evaluation time for generic products can be shorten in Brazil than Chile or Argentina. The cost of registering a generic product is $2,000 as on 2005. Moreover method validation and BE study must be conducted in centers certified ANVISA, and price of generic must not be more than 65% of equivalent reference drug. Brazilian legislation states that activities related to manufacturing importing or marketing of any medicinal, cosmetic or pharmaceutical products can only be handled by authorized companies which registered with the Brazilian Ministry of Health.

RA004

Regulation of Over-The -Counter Drug Products: Comparison of Regulatory Requirements of US, Australia and India

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Over-the-counter (OTC) drug products are those which can be purchased by consumers without a doctor's prescription and can be used without the supervision of a healthcare professional. These products are segmented into different categories such as cough, cold and flu products, analgesics, dermatological products, gastrointestinal products, vitamins and minerals, ophthalmic products and others. The benefits of these products outweigh the risks and hence they have an acceptable safety margin to warrant unsupervised use in patients. The global market for OTC drug products was around 150.93 billion dollars in 2014 and it is steadily increasing. The regulations related to their registration, marketing and advertising differ from country to country. In the United States (US), the manufacturing, sale and advertisement of OTC products is regulated by Food and Drug Administration (FDA) and two regulatory pathways exists for marketing OTC products- by getting approval under applications like new prescription drugs or by following the OTC monograph regulation. Labeling for the OTC drug products is governed by the Drug Facts Rule. In case of Australia, it is necessary that all OTC medicines be imported into, supplied in, or exported from Australia should be either registered or listed (based on the risks associated with them) in the Australian Register of Therapeutic Goods (ARTG) and for this purpose a sponsoring company is required to submit an application to the Therapeutic Goods Administration (TGA). In India, all the drugs that are not included in the list of prescription drugs (prescription drugs are those that are included in two schedules of the Drug and Cosmetics Rules, 1945: Schedule H and Schedule X) are considered as non-prescription drugs (or OTC drugs) and they are regulated by the Drugs & Cosmetics Act (DCA) and it's subordinate legislation, the Drugs & Cosmetics Rule (DCR). This poster will provide a detailed analysis of the current similarities and differences with regards to OTC drug product regulations in US, Australia and India.

RA005

Regulatory requirements of Medical Devices in MENA countries

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The main purpose of regulatory environment for Medical Devices in the Middle East and the North African countries (MENA), to show their limits and their prospects. Although the Medical Devices market in the MENA region is diverse, most of the individual economies have shown sustainable growth. Medical Devices are one of the most important health intervention tools available for the prevention, diagnosis and treatment of diseases and for patient rehabilitation which is available in the market. The growth of demand for sophisticated pharmaceutical and medical products in the MENA region seen in recent years is only likely to continue. Despite of the overall positive economic development in most of the MENA countries the regulatory environment can be challenging and also important to mention in this context are the barriers for the continuing evolution of the regulatory environment in some of these emerging countries due to their political instability, non-transparency and corruption. Against this background the efforts of the Global Harmonization Task Force (GHTF) to harmonize the Medical Devices regulation, offer a valuable contribution to ease the regulatory interconnection and intercommunication between the individual countries and the international economic operators of the Medical Devices industry. The follower of GHTF - the International Medical Devices Regulators Forum (IMDRF) - builds on the strong foundational work of the GHTF and accelerates the international Medical Devices regulatory harmonization and convergence. The impact of the EU on the harmonization in these countries is rising.

RA006

Biosimilars: An Emerging Market Opportunities for Indian Pharmaceutical Industry

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In recent few years, there are many epic Biological products are going off patent which has generated an abridged route for the Biosimilar products which relies on the extensive comparability testing against Reference Biological Products (RBP) assuring product's quality, safety and efficacy. Biosimilars are product similar to biologics but not indicate to them. Thus they require distinct marketing approval with abounding documentation as they are not generic version of biologics. These made regulatory and administrators of different countries to establish strict balance between the cost benefit and risk management of the product. The first draft guideline for Biosimilars was established by Europe, subsequently Japan and USA has developed the draft guidelines. While recently India has established the biosimilars guideline in June 2012. India has vigorous Pharmaceutical Industry for the generic drug while it can become an emerging market for the Biopharmaceutical drug. The regulatory structure for the biosimilar in India is depicted in this article with comparison of the biosimilar guidelines established by India and WHO. The approval process will be based authenticating a comparability quality between the biosimilar products and original product due to small alteration may lead to intolerable modifications in safety and efficacy. In many cases non-clinical studies are more difficult and potentially expensive to perform where biosimilars are highly species specific. Thus there is need for stringent regulatory guidelines. The biosimilar market will soon be thriving above $80 billion price of drugs in next seven years.

RA007

Egyptian Market Status after Development of Biosimilar Registration Guideline

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Now a day, Pharmaceutical Market has the great opportunities due to the off patent of some Blockbuster Biologics during 2013-2020. In some semi regulated countries biosimilars were marketed before the development of the biosimilar registration guideline, Egypt is one of the semi-regulated country where the biosimilar registration guideline was finalized on 29th November 2014. Rather than this fact, biosimilars were registered in Egypt on the basis of generic drug registration pathway with bioavailability and bioequivalence studies. Biosimilars are different than the small molecule generics having different parameters for the approval of drug with quality, safety and efficacy. Thus approval of biosimilars based on the generic drugs may lead to the serious adverse event after the marketing authorization. In this article the marketing authorization procedures for biosimilars in Egypt will be discussed with the loopholes. While a case study depicting the result of biosimilar approval without specific guideline for biosimilar registration. There should be proper pathway to create a bridge between the approved biosimilars and established guideline with appropriate documentation to ensure safety and efficacy of the drug. There should be relevant and stringent regulation for the approval of the specific drug to avoid life threatening adverse events.

RA008

Implementation of Unique Device Identification (UDI) System for Regulating Medical Device Products in Healthcare Sector

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Medical Devices unlike other pharmaceutical products differ in their role in healthcare systems. They can be defined as an apparatus, instrument or an implant used to diagnose, treat or prevent diseases without any chemical reaction within the body. As the medical devices markets are emerging all around the globe it is becoming difficult to differentiate substandard medical devices along with the superior ones especially those which are included in Class III category providing more risks for patients if devices are counterfeit. As a reason for maintaining proper identification of quality assured medical device, U.S, EU and IMDRF committee groups has collaborated to develop a harmonized system of Unique Device Identification(UDI) for medical devices being manufactured in well developed countries."UDI FINAL RULE" has been initially established by FDA which indicates all the devices should have a specific identification number which makes them easier for distribution and use. UDI system for medical devices which will be fully completed over a period of seven years from now, could be a milestone towards the direction of ensuring the patient safety, post-marketing surveillance, quality and product origin. This study covers requirements for proper implementation of UDI and GUDID (Global Unique Device Identification Database) system and beneficial factors UDI may bring for regulating medical devices from manufacturing site to that of providing them to the healthcare professionals.

RA009

Travelling vaccine: A business model

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The global Indian is the travelling Indian. Though the internet has made the world available on the fingertip, it has not been able to substitute for personal visits and personal meetings in a true sense. As India prepares to play a never before important role in global political and economic affairs of the world, more and more Indians travel to different countries. Approximately 25% of Indian travellers put themselves at the risk of travel related diseases; as they travel to endemic zones. Vaccines are the best way to avoid infectious diseases and international travellers generally get them vaccinated in time before travel. However, there is no comprehensive service catering to this class of people. We propose here a business model for vaccination centers exclusively for international travellers. These centers will function initially in eight major Indian cities and offer four important vaccines in addition to the health advice to the certified international traveller. These centers will have the potential to evolve into comprehensive health care centers catering to the global Indian. In the second phase to be initiated after the break-even, the centers will be spread to other cities of the country. We propose a business model based on profit by volume to discourage, and to cope with, competition; and being a market leader by fulfilling a niche.

RA010

Overview of FDA Regulations on Health Claim for Food Labels

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The U.S. FDA in 1990 release the Nutritional Labeling and Educational Act (NLEA) for the establishment of the food label claim. Rules leading that the information provided by manufacture that is not misleading or false claim. NLEA set scientific standard is significant scientific agreement (SSA) standard for health claim. FDA has 21 CFR 101 for food labeling that identifying, claim, warning of label claim. After alternative legislation the Food and Drug Administration Modernization Act (FDAMC) provide health claim review. FDA provides Qualified Health Claim (QHC) which not only confirms the SSA standard but qualifying health claim for consumer use. FDA work on QHC which follows evidence based ranking system. This system has six steps which correlate the substance/disease to the evidence and gives one to four ranks. Rank which is finalized that gives “comfort level” and claim is scientifically valid. The system objective for health claim which meet the SSA standard. This system is apparent and reproducible for evaluation level for health claim for food. The system gives better nutritional and health information.

RA011

FDA's 505(b) (2) Drug Registration Pathway

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505(b)(2) is a type of New Drug Application (NDA) having investigations for safety and effectiveness on which applicant can rely for approval and which were not conducted by or for the applicant, and for which right of reference is not obtained by the applicant. The NDA application for drug sponsors it is a vehicle through which they formally propose the drug to the FDA to get approval of a new pharmaceutical for sale and marketing in the U.S. Under Food, Drug & cosmetic Act there are sections 505(b) and 505(j) – ANDA. Section 505(b) is further divided into sections 505(b) (1) – NDA and 505(b) (2). So 505(b) (2) is a type of application which is midway between NDA and ANDA. Drug products that may be submitted under section 505(b) (2) are not completely new products, yet they are not generics. These medications have both similarities and some differences from an innovator or brand drug. It is a potential pathway for approval where drug sponsors save both time and money. However, there are sponsors who are unsure for evaluation of the possible benefits of using 505(b)(2) application. So, a 505(b) (2) application is a type of application which is midway between NDA and ANDA, 505(b) (2) contains less data compared to NDA and more data than an ANDA. So we can say, that the 505(b) (2) is a rapid approval route.

RA012

Regulatory Requirements for Registration of Active Pharmaceutical Ingredients in Europe with Comparison to US and Canada

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Pharmaceutical products mainly depend on two basic constituent- Excipients and Active pharmaceutical ingredient (API). API is a substance or combination of substances which are used in the fabrication of the drug products and which has the main pharmaceutical action. In order to regulate the API's quality and development process a systematic documentation of API is required and this is where Active Substance Master File (ASMF), Drug Master File (DMF) plays the major role. DMF is compilation of confidential documents which are essential for the registration of API. Pharmaceutical manufacturer furnished the DMF and submitted only to the appropriate regulatory authority. DMF filling is compulsory when there is need for two or more firms to come together and develop or manufacture a new drug. Although DMF provide same purposes across different regulatory authorities they have different synonyms and specifications. In Europe it is known as a European Drug Master File (EDMF) or Active Substance Master File (ASMF) and it is also known as a US DMF and Canadian DMF in United States and Canada respectively. DMF is made up of Applicant Part and Restricted Part. Applicant part gives non-confidential information which is only disclosed to the license holder and restricted part gives confidential information which is only disclosed to the authorities. This study covers comparative overview of current API registration requirements across Europe, US and Canada.

RA013

A Commercial Viability of Pharmaceutical Technology: Case Study

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Several versatile technologies are available in current scenario to facilitate fabrication of effective drug delivery system. Nanotechnology is need of the hour which addresses the drawbacks of drug molecules like solubility and permeability. In present work, commercial stability of Nano crystallization technique is explored. In present project report, viability of a facility of commercial production of nanoparticles is derived. Technical aspect include infrastructure and equipment cost is considered which comes to Rs. 17,042,474. Against the expenses the revenue generation is proposed to be Rs. 1000-2000/ sample regularly with no. of beneficiary organizations. In nutshell a summary is prepared to propose for funding agency like MSME department. It is concluded that it is possible to create a facility to nurture the manufacturing industry with nano sized drug substances, which in turn can increase acceptability of hydrophobic molecules. The project has substantial future.

RA014

PDUFA: A Revolution in Drug Review Process

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Prescription Drug User Fee Act abbreviate as PDUFA was introduced in 1993 by United States Congress under which Pharmaceutical industries was bound to pay fees for drug review process for the drug they were willing to market which in turn facilitated the drug review process which was not that effective in past. The collected fees were bound to be for the use only in Centre for Drugs Evaluation and Research (CDER) or centre of Biologics Evaluation and Research (CBER) drug approval purposes. The fees were to be collected in 3 ways: Application Fee, Establishment Fee, and Product Fee. Waivers are also offered under the act in which fees reduction or refunds are availed for small businesses and in order to encourage the new research to develop a new drug. Five amendments were done to improvise the act and to smoothen the drug review process. On the whole, PDUFA revolutionised the development of new drugs for threatened disease by having a fast drug approval process.

RA015

Post Approval Regulatory Requirements Comparison Study between Europe, US and Australia

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A pharmaceutical product after being approved is deemed to have a change in its chemistry, manufacturing, controls, and may include many other changes in relation to the improvement or new findings. Change is inevitable and has to be confronted by the pharmaceutical industries for their business to run and to improve human health. Pharmaceutical regulations require that any change should be carefully studied and examined before implementation. The pharmaceutical regulatory policies are to be taken very seriously because, "if not" may result into discontinuation of supply to the market and also can cause serious health problems. Current study focuses on the regulations governing these changes. The study compares and contrasts the policies of US, Europe and Australia for the post approval changes of the drug products. Article provides guidance to the sponsors wishing for post approval changes in US, Europe and Australia. This is a comparative analysis of the guidelines for post approval changes proposed by the regulatory agencies of US, Europe and Australia and include several comparison of changes, the timelines and process flowcharts for proposed changes and respective fees defined in the guidelines. Along with this the initiative by ICH with ICH Q12 guidelines for lifecycle management, QbD approach, Quality risk management and better understanding of product and process knowledge will assist the sponsor to best implement the post approval changes.

RA016

Current Challenges in Biosimilars Development: An Important Approach for the Progressive Field

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Before 2020 an estimated $67 billion worth of patents of biological products are going to expire and Governments forced to reduce rapidly increasing health care costs, Biosimilars represents a major opportunity for the Pharmaceutical industry. Biosimilar is defined as a biological medicine similar in terms of quality, safety & efficacy to a biological medicine which is already approved for human use. While the expectations of cost savings & efficiency make the biosimilar market attractive, industries & their outsourcing partners planning to enter this market must be aware of current regulations & issues in the global marketplace & be prepared to respond quickly to changes. From last 10 years, Regulatory bodies worldwide have been focusing on developing regulations for Biosimilars. Although a Global development strategy is adopted, there are still some challenges. These challenges includes regulatory challenges due to uncertainty of regulatory pathways in many countries. This regulatory challenges covers interchangeability & substitution. Along with this the other challenges are molecular complexity, the financial reality, long term commitment, manufacturing process complexity, Quality, naming, Labeling, Pharmacovigilance & Risk management etc. Here all the challenges are discussed in detail. These challenges are the hurdles in the development of Biosimilars. Therefore early awareness of changes & challenges will allow biosimilar developers to face these challenges properly to move more rapidly into key markets & get the desired outcomes.

RA017

Green Tea – People's Perspective

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Green tea is made from *Camellia sinensis* leaves that have undergone minimal oxidation during processing. Green tea originated in China and has been used as medicine for thousands of years. In this project we intended to create awareness about green tea amongst people and to understand the perspective of people towards green tea. The survey was conducted on randomly selected 100 people. They were from different fields including students, businessman, gym instructors, housewives etc. Before conducting the survey, the subjects were given some basic information about green tea to the people. According to the survey data it was found that majority of the people are traditional tea drinkers though number of green tea drinkers are increasing. About 66% of people asked, were aware about the health benefits of green tea. About 72% agreed to switch to green tea if they are given proper knowledge of its health benefits and 79% of people said yes to recommend others to drink green tea if they get any health benefits from it and about 60% of people agreed upon paying more for green tea compared to traditional tea considering its advantages. Once/twice a cup of tea in a day can significantly improve our health and protect us from numerous diseases. So to summarize GREEN TEA is a healthy way to the future.

RA018

Section 3(D) of Indian Patents Act

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The Patents Act, which was enforced in 1970 facilitated the growth of a domestic pharma industry in India. Now we can see the result as India has become a major exporter of generics. In 2005, IPA was modified in section 3(d) to prevent ever greening of patents. The Patent Act 2005 (amended) defines invention and makes clear that any knowledge or thing already existing cannot be patented. According to the amendment, to acquire patent protection in India, the substance has to pass the criterion to go beyond establishing the novelty, non-obviousness, inventive steps and industrial application test which are mentioned in TRIPS agreement and also fulfil the additional improved efficacy incorporated under section 3(d). However the innovators feel that this amendment is not providing adequate patent protection for multinational drug companies. But still cases like Novartis v/s Union of India & others (for Gleevec patent.) and a German MNC, Boehringer Ingelheim, (for its respiratory drug, Spiriva) prove that Section 3(d) does not mean to violate the TRIPS directives rather prevents flippant patenting and at the same time does not hurdle valuable incremental innovations. It is compatible with TRIPS agreement. Removal of section 3 (d) will result in ever greening of patents. This will have an adverse effect on public health due to the delay in entry of generics in the market.

RA019

History and Current Perspective: Pharmacovigilance Programme of India

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India is coming up rapidly as a hub of global clinical trials, drug discovery & development, result of which Indian pharma industry is valued approx. Rs. 90,000 crores with an annual growth rate of 12 – 14 %. Many new drug molecules and medical devices are introduced in the Indian market every year which needs to be monitored for any Adverse Drug Reactions (ADRs) not only during the drug development process but also after it is marketed. Hence, MHFW, Government of India launched a nationwide PvPI in the year 2010 to control the safety of drugs. Information collected from healthcare providers and patients on the adverse effects of medications, biological products, herbal etc should be furnished in the ADR monitoring form. In June 2010, CDSCO, DGHS under the aegis of MHFW in collaboration with IPC began a national pharmacovigilance programme to safeguard the health of the patients by assuring drug safety with well-defined goal with predetermined road map to ensure its future growth and progress. Main objective of this programme is to guarantee that the benefits of utilization of medicines exceed the risks and hence protect the health of the Indian populace. Hence, the main activity of the PvPI is to gather, examine and analyze information on unfavorable medication responses (ADRs) to come at the conclusion to allow regulatory interference, other than conveying related risks to health personnel. Concluding, awareness about the ADR reporting amongst the healthcare suppliers can enhance the rate of reporting the nation over.

RA020

Quality by Design – A Tool to Assure the Quality of Pharmaceutical Products

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The Quality by Design (QbD) approach is well known in many fields, however it is implemented recently in the pharmaceutical field. This can be employed at each and every step of formulation development, process optimization, scale up and also during life cycle management of developed product. Based on the literature knowledge, the quality target product profiles (QTPPs) is to be prepared followed by identification of critical quality attributes (CQAs). The formulation development will focus on identified critical material (CMAs) and process attributes (CPAs) of drug substance as well as drug product. The design of experiments can also be applied to optimization of selected CMAs and CPAs which aid in preparation of updated risk assessment. Finally controlled strategies are prepared, which are a planned set of controls, identified for the high risk as well as medium risk attributes. During life cycle of product, if manufacturer abides to the derived controlled strategies, it assures the quality in the product. However as an added advantage, manufacturer can always suggest the further changes within the design space which will easily be approved by the regulatory authorities. Thus we can conclude that QbD is a tool which benefits the consumers by providing quality assured products as well as manufacturers by reducing and simplifying the post approval changes.

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