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Research Article

Evaluation of a Natural Polymer for the Development of Colon Specific Drug Delivery System

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Abstract

Objective: Polysaccharide gums represent one of the most abundant industrial raw materials and have been the subject of intensive research due to their sustainability, biodegradability and safety. The purpose of present study was to evaluate a novel polymer, *Anogeissus latifolia*, as a carrier in the development of colon targeted drug delivery system.

Method: The matrix tablets of Diclofenac sodium were prepared using a 3^2 randomized full factorial design. The amount of natural polymer (X1) and amount of HPMC K100M (X2) were selected as independent variables. While the percentage cumulative drug release in lag time (Y1) and percentage cumulative drug release at 12 hours (Y2) were selected as dependent variables. The developed formulations were evaluated for Hardness, Friability, Weight variation, Drug content and *in vitro* drug release behaviour.

Results: The outcomes of physicochemical evaluation of developed formulations showed that all formulations showed optimum hardness, friability within limit and uniform weight and drug content. The formulation containing 40 %w/v natural polymer and 10 %w/v HPMC K100M was found to be optimized in terms of minimum drug release in lag time (≤ 25%) and % cumulative drug release in 12 h (>95%).

Conclusion: The developed system exhibited a promising targeting behaviour proving *Anogeissus latifolia* gum to be an excellent carrier for colon targeting and thus it can be exploited commercially.

Keywords: *Anogeissus latifolia* gum; Colon targeted drug delivery system; Diclofenac sodium; HPMC K100M; *In vitro* dissolution.

Introduction

Targeted drug delivery into the colon is highly desirable for local treatment of bowel diseases such as ulcerative colitis, Chrohn's disease, amoebiasis, colon cancer and also for systemic delivery of protein and peptide drugs because of less digestive enzymatic activity compared to stomach and small intestine. To deliver the compounds in non degraded form to lower part of the Gastrointestinal Tract (GIT), they must first of all pass through the stomach, the upper part of intestine and must use the characteristics of the colon to specifically release the drugs in this part of digestive tract [1] .Various approaches have been developed for colon targeting including pH dependent systems, Time dependent system and Microbially triggered delivery system. The pH dependent delivery system protects the formulation in the stomach and proximal part of small intestine but it may start to dissolve in the lower part of small intestine and thus it shows poor site specificity [2]. Similarly time dependent delivery systems are not able to sense any variation in upper GIT transit time [3,4]. Colonic bacteria possess ability to degrade a variety of polysaccharides present in the diet that are not degraded either in stomach or small intestine. Hence, the use of biodegradable polymers holds great promise for drug delivery to colon [1].

Gums and mucilages are used as inert pharmaceutical excipients and also as medicinal agent. They are widely used in food and pharmaceutical industry as thickening, stabilizing emulsifying and disintegrating agents [5]. The polysaccharide gums represent one of the most abundant industrial raw materials and have been the subject of intensive research over comparable synthetic materials due to their sustainability, biodegradability and safety [6]. The most of the natural polymers are obtained from trees in the forms of gums as tree exudates. Tree exudates gum are polysaccharides with high molecular weight mainly composed of monosaccharide unit, uronic acid and to some extent proteins and fibers. The purpose of this study was to evaluate novel polymer derived from the tree exudates of *Anogeissus latifolia* (Combretaceae, Myrtales) as a colon specific drug delivery carrier. It is a large deciduous tree found in dry areas of India. It is also known as Gum ghatti or Indian gum. This plant exudates has been in use for a long time and its name is derived from the word "Ghat" which means a mountain pass because of its ancient mountain transportation routes. It is approved as a food additive in Japan and has Generally Recognized as Safe (GRAS) in United States.

Gum ghatti is an extremely complex polysaccharide that occurs in nature as mixed calcium and magnesium salts of uronic acid and/or ghattic acids and has also been reported to contain approximately 3% protein. It consists of L-arabinose, D-galactose, D-mannose, D-xylose and D-glucuronic acid in a 48:29:10:5:10 molar ratio and < 1% of rhamnose, which is present as nonproducing end groups. Gum contains alternating 4-*O*-substituted and 2-*O*-substituted μ-D-mannopyranose units and chains of 1 → 6 linked β-D galactopyranose units with side chains of L-arabinose units. This gum has been reported to be an excellent emulsifier, thickener and binder. The gum is comprised of around 80% soluble dietary fiber, acts as a prebiotic by supplying the matrix required to sustain the bacterial flora of the human colon. This hydrocolloid is resistant to gastrointestinal enzymes and known to be degraded enzymatically only by the specific microflora of the colon such as Bifidobacterium longum [6,7,9-11]. In this investigation, gum ghatti in the form of matrix tablets have been evaluated for its ability to deliver formulation to the colon using Diclofenac Sodium (DS) as a model drug.

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Experimental

Materials

Diclofenac Sodium (DS) was received as gift samples from Aarti drugs ltd., Mumbai. Natural polymer was received as gift sample from PJ Enterprises, Mumbai, India. Dicalcium phosphate, HPMC and magnesium Stearate were purchased from Loba Chemicals Pvt ltd., Mumbai, India.

Methods

Characterization of drug: Characterisation of drug was done by determining the solubility, melting point using capillary method and comparing the IR spectra of obtained drug with standard spectrum using FTIR spectroscopy [11].

Characterization of natural polymer: Natural polymer was characterized for swelling index, viscosity, pH of solution, acid insoluble ash, water soluble ash, alcohol soluble extractive [6,7,12-15]. The flow property of polymer was determined by calculating Carr's index, Hausner's ratio, Angle of repose.

Drug-excipient compatibility study: The drug-Excipient interaction study was carried out by physical observation and FTIR spectroscopy [8].

Physical observation: The physical interaction between DS and natural polymer, HPMC K 100 M, Dicalcium phosphate, Magnesium Stearate was studied in a stability chamber at temperature $55^0C\pm 2^0C$ for period of two weeks [8]. Samples like DS: natural polymer (1:1), DS: HPMC K 100 M (1:1), DS: DCP (1:1), Diclofenac Na: Magnesium Stearate (1:1) and between DS: natural polymer: HPMC K 100 M: Dicalcium phosphate: Magnesium Stearate (1:1:1:1) were kept for evaluation of interaction and observed for caking, liquefaction, color change or any other incompatibility.

Fourier transform infrared spectroscopy: IR spectroscopy was also used to determine the molecular interaction between polymer and drug (DS). For FTIR spectroscopy natural polymer (*Anogeissus latifolia* gum*)* and DS (in 1:1 ratio) were mixed with dried KBR in ratio 1:100. A small fraction of this mixture was compressed on Automatic IR Press at a pressure 10 ton to form transparent pellet. IR spectrum was obtained using FTIR spectrophotometer. The interaction between *Anogeissus latifolia* gum and DS was studied by comparing the spectrum of pure drug and the mixture.

Preparation of DS matrix tablet: Tablets weighing 300 mg containing 50 mg DS were prepared by direct compression method. Natural polymer and HPMC K 100 M were used in different proportion as per experimental design. Dicalcium phosphate was used as diluent and magnesium stearate as lubricant. The tablets were prepared by using tablet compression machine (Minipress 2D 8 stations) using 8 mm biconcave punch.

Experimental design: In the present investigation, after carrying out preliminary trials a 3^2 randomized full factorial design was used in development of the matrix tablet. In this design, 2 factors were evaluated each at 3 levels and experimental batches were prepared using all possible 9 combinations. The amount of natural polymer and amount of HPMC K 100 M were selected as independent variables. All the other formulation aspects and processing variables were kept invariant throughout the study period. The Percentage cumulative drug release in lag time and percentage cumulative drug release at 12 hours (Q_{12}) were selected as dependent variables. Formulations F1 to F9 were prepared by varying the levels of the independent variables as required by the experimental design and factors levels were suitably coded in table 1.

Coded levels	Actual value in percent	
	X_1	X_2
-1	20	10
0	30	20
1	40	30

Table 1: Translation of the coded levels in actual units.

Physicochemical evaluation of prepared batches: The prepared batches were evaluated for precompression parameters *viz.* bulk density tapped density, Carr's index, Hausner's ratio and angle of repose. While tablets were evaluated for weight variation, hardness, friability and drug content uniformity. Tablet hardness was evaluated using a Monsanto hardness tester, friability using Roche friabilator and weight variation using analytical balance [12,15].

Determination of uniformity of drug content: 20 tablets were weighed and powdered by using pestle mortar. An amount equivalent to 50 mg DS was shaken with 100 ml methanol and sonicated for 10 minute. The solution was filtered through Whatman filter paper and the content of DS was determined by measuring absorbance at 275 nm on double beam UV spectrophotometer (Jasco V-630) after suitable dilution [12].

***In vitro* drug release study:** All batches F1–F9 were further evaluated for *in vitro* drug release study. *In vitro* drug release study was carried out using USP apparatus II (Paddle) and the medium was 0.1N HCl (pH 1.2) and phosphate buffer pH 6.8. The quantity of dissolution medium was 900 ml. The speed of paddle was 50 rpm and temperature of dissolution medium was 37±0.5˚C. Dissolution study was carried out in 0.1 N HCl for 2 hrs and then placed in phosphate buffer (pH 6.8) until complete release of the drug. Five ml aliquots were withdrawn at fix intervals and replacement was made each time with five ml of fresh dissolution medium to maintain sink condition. Every time withdrawn sample was filtered through Whatman filter paper and analyzed drug content at 275 nm using UV-visible spectrophotometer, (Jasco V-630, Japan). *In vitro* drug release study for each sample was done in triplicate

Optimization data analysis: Response Surface Methodology (RSM) is a widely practiced approach in the development and optimization of drug delivery devices. Based on the principle of design of experiments, the methodology encompasses the use of various types of experimental designs, generation of polynomial equations and mapping of the response over the experimental domain to determine the optimum formulation. The technique requires minimum experimentation and time thus proving to be far more effective and cost-effective than the conventional methods of formulating dosage forms. Various computations for the current optimization study were performed using Design Expert® software (trial version 8.0.4; State-Ease Inc., Minneapolis, MN, USA). The values of % CDR in lag time and % CDR in 12 hours of all 9 batches (F1-F9) were put in Design Expert software and analysed [16].

Kinetic analysis of dissolution data: To study the mechanism of drug release from the matrix tablets, the drug release data of optimized batch were fitted to zero-order, first-order, Higuchi equations and Korsemeyer equation [17].

Stability study: The stability studies were carried out for the optimized formulation. The samples were stored at 40±2˚C and

75±5 %RH for three month to access their stability. The protocol of stability studies was in compliance with ICH guidelines for stability testing intended for the global market. After every 30 days the samples were withdrawn and characterized for hardness, friability, drug content and *in-vitro* drug release study [18].

Results and Discussion

Characterization of drug

Melting point: The melting point of the drug was found to be in the range of 282-284˚C which matches with the reported value.

Solubility: DS is a slightly soluble drug in distilled water and 0.1 N HCl. The solubility of drug was found to be 0.0010 mg/ml and 0.64 mg/ml in 0.1N HCl and phosphate buffer pH- 6.8 respectively.

FTIR spectrum of diclofenac sodium: The IR spectra of DS (Figure 1a) exhibited principal peaks at wavenumbers 1573, 756, 1509, 775, 1283, 1305 cm^{-1}.

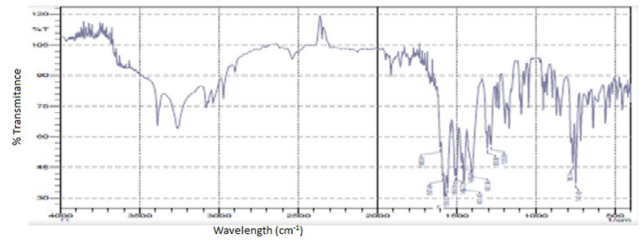

Figure 1a: IR spectrum of DS.

Characterisation of natural polymer: The results of physicochemical properties of *Anogeissus latifolia* gum are shown in table 2.

Parameter	Results
Solubility	Soluble in hot water, forming a viscous solution; practically insoluble in chloroform, acetone, methanol Also polymer swells in 0.1 N HCl and phosphate buffer and shows good gelling properties.
Moisture content (%)	3%
Ash Value	4%
Acid Insoluble ash	1.60%
Water soluble ash	1.40%
Viscosity 10% solution (Cps)	400
Swelling Index (%)	150
Heavy metals	Not more than 10 ppm
Ethanol soluble Extractive(%w/v)	0.8% w/v
Density (g/ml)	Bulk- 0.9 ± 0.010
	Tapped- 0.984 ± 0.011
Carr's index (%)	8.54 ± 0.78
Hausner's ratio	1.09 ± 0.055
Angle of repose (θ)	29.34˚ ± 0.53

Table 2: Characterisation of natural polymer.

The gum powder exhibited insolubility in common solvents except distilled water. The moisture content, ash value and all other parameters were within the limits as specified in official compendium. The values of angle of repose, Carr's index, Hausner's ratio indicated that the polymer has good flow property and compressibility.

FTIR spectrum of natural polymer: IR spectrum of natural polymer (Figure 1b) showed broad peaks at 3408.4 cm^{-1} (O-H stretching of carbohydrates), 2928, 1406, 1234 cm^{-1} (-CH_2 asymmetric stretching, scissoring and twisting and rocking vibration of methylene groups, 1445.35 cm^{-1} (-CH and -CH_2 in plane bending in carbohydrates), 1089.51cm^{-1} (-C-O stretching region as complex bands resulting from C-O and C-O-C stretching vibrations) and 643.71 cm^{-1} (pyranose ring).

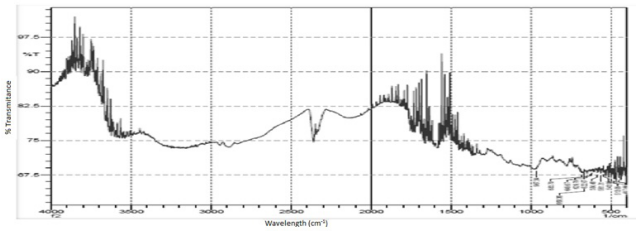

Figure 1b: IR spectrum of natural polymer.

Drug-excipients compatibility study: IR spectra of physical mixture of drug and polymer (Figure 1c) reveals that the principal peaks of DS for NH_2 at 3387cm^{-1}, aromatic at 1573 cm^{-1} and at 746 cm^{-1} (ortho-disubstituted phenol) are present in both, the spectra of pure drug and physical mixture with the natural polymer.

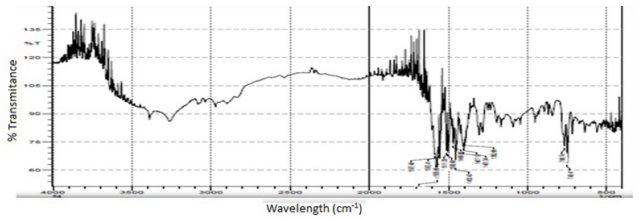

Figure 1c: IR spectra of drug +polymer.

FTIR studies suggested absence of any significant interaction between the polymer and the drug in the formulation.

Physicochemical evaluation: The physicochemical evaluation of developmental batches F1-F9 showed good flow property, uniformity of weight & drug content in powder blend as well as optimum hardness and friability limit specified for tablet formulations. The results are depicted in table 3 and table 4.

The precompression parameters of all batches were found to be in acceptable range indicating good flow behaviour.

Test / Batch	Bulk Density	Tapped density	Carr's index	Hausner's Ratio	Angle of repose
F1	0.73±0.034	0.79±0.003	7.59±1.1	1.08±0.0023	31.36±0.21
F2	0.69±0.065	0.75±0.003	8.01±0.51	1.07±0.005	31.99±0.25
F3	0.7±0.025	0.75±0.03	6.66±1.07	1.07±0.001	31.07±0.18
F4	0.74±0.005	0.81±0.001	8.02±0.66	1.08±0.005	32.61±0.04
F5	0.74±0.005	0.84±0.01	11.9±0.72	1.08±0.007	32.64±0.37
F6	0.68±0.04	0.73±0.02	6.84±0.61	1.07±0.007	30.81±0.22
F7	0.75±0.03	0.82±0.04	8.53±0.4	1.08±0.004	32.81±0.08
F8	0.82±0.042	0.88±0.056	6.81±0.56	1.09±0.005	33.16±0.22
F9	0.81±0.005	0.87±0.041	6.89±1.07	1.076±0.011	33.62±0.05

Table 3: Evaluation of developmental batches F1-F9 (powder blend).

The weight variation and friability was not more than 5% and 1% respectively. Good drug content uniformity was found among different batches of the tablets.

Test	Tablet weight (mg)	Hardness (Kg/cm²)	Friability (%)	Drug Content (%)
Batch				
F1	300.75±3.38	4.33±0.28	0.32±0.16	102.9±1.98
F2	298.25±4.6	5.13±0.32	0.44±0.19	100.5±0.57
F3	300.7±3.04	6.01±0.5	0.58±0.13	99.26±2.50
F4	302.9±4.16	6.50±0.5	0.24±0.15	96.60±2.75
F5	300.5±4.17	6.50±0.5	0.26±0.15	96.30±1.13
F6	299.9±4.16	6.00±0.45	0.66±0.10	98.96±1.15
F7	299.6±4.07	6.33±0.5	0.20±0.10	102.0±1.26
F8	301.0±3.62	5.83±0.28	0.21±0.16	96.63±2.56
F9	301.1±4.63	6.00±0.5	0.56±0.20	97.03±1.91

Table 4: Evaluation of developmental batches F1-F9 (tablets).

***In vitro* drug release study:** The result of *in vitro* drug release is depicted in figure 2. All formulations (F1 - F9) were able to retain tablet in intact form up to 12 hrs and also sustained drug release up to 12 hrs. All the developed batches were capable of preventing drug from being released completely in the physiological environment of stomach but showed certain drug release in the small intestine. The formulations F3 and F6 were able to minimize the drug release up to 25% in the lag time of 5 hrs. All the developed batches showed cumulative drug release more than 90% after 12 hrs.

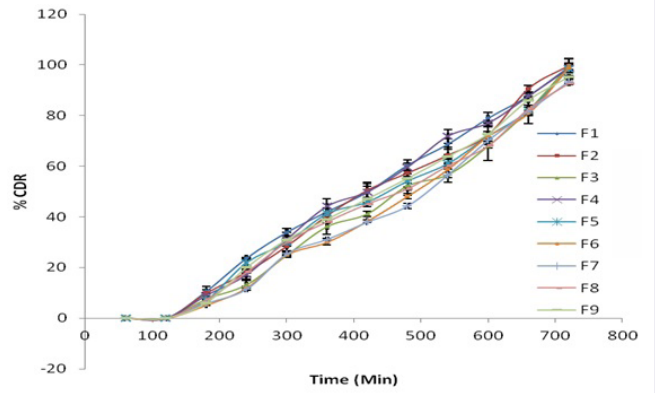

Figure 2: *In vitro* drug release profile of developmental batches (F1-F9).

The *in vitro* drug release studies revealed that formulations F1 to F9 containing respectively 20, 30 and 40 % of natural polymer (*Anogeissus latifolia* gum) were able to sustain the drug release for 12 hrs. Hwever, the purpose of colon targeted drug delivery system was not only to sustain the drug release up to 12 hrs but also to minimize drug release in the physiological environment of the stomach and intestine. Hence, the ability of the polymers used in the formulations to retain the integrity of tablet in upper GIT was the challenge.

The developed batches were able to prevent the drug release in acidic environment of stomach due the acid resistant property of natural polymer as well as low solubility of drug in acidic medium i.e., in first 2 hrs but unable to prevent the drug release in intestinal pH. Thus minimum drug release in lag time (5 hrs) i.e., drug release in between 20-25% was the basis of selection of optimized batch. The batches with higher concentration of natural polymer with low and intermediate concentration of HPMC K100M respectively showed minimum drug release i.e., ≤ 25% in lag time of 5 hrs. This can be explained on the basis that on increase in natural polymer concentration, hardness of tablets was increased and porosity was decreased which reduced the drug release in lag time. But the batch with higher concentration of both natural polymer and HPMC K100M showed more swelling in initial hours so unable to maintain drug release below 25% in lag time.

Optimization data analysis: The data obtained after putting all values for % CDR in lag time and % CDR in 12 hrs of all 9 batches analysed to get the optimum formulation based on the desired objective. Polynomial models including interaction and quadratic terms were generated for the entire response variables using Multiple Linear Regression Analysis (MLRA) approach. The general form of the MLRA model is represented in the Equation

$$Y = B_0 + B_1X_1 + B_2X_2 + B_3X_1X_2^2 + B_4X_1^2X_2^2 + B_5X_1^2X_2^2$$

Whereas, the B_0 is the arithmetic average of all the quantitative outcomes of nine runs and B_1 and B_2 are the coefficients computed from the observed experimental values of Y. X_1 and X_2 are the coded levels of independent variables. The interaction terms (X_1 and X_2) shows how the response values changes when the two factors are simultaneously changed. The polynomial equations can be used to draw conclusion after considering the magnitude coefficient and the mathematical sign that the coefficient carries. A high positive or negative value in the equation represent that by making a minor change in the setting of that factor one may obtain a significant change in the dependent variable. Statistical validity of the polynomials was established on the basis of Analysis of Variance (ANOVA) provision in the Design Expert software. Level of significance was considered at $p < 0.05$. The best-fitting mathematical model was selected based on the comparison of several statistical parameters, including the Coefficient of Variation (CV), the multiple correlation coefficient(R^2), the adjusted multiple correlation coefficient (adjusted R^2) and the Predicted Residual Sum of Squares (PRESS), provided by the software. PRESS indicates how well the model fits the data, and for the chosen model, it should be small relative to the other models under consideration. The 3-D response surface graphs and the 2-D contour plots also generated by the Design Expert software. These plots are very useful to see interaction effects of the factors on responses.

Model assessment for the dependent variable: %CDR in lag time

Final equation in terms of actual factors:

%Drug release in lag time = +57.38222-0.93533(X1)-1.11092(X-2)+0.036625(X1)(X2)

X1=Proportion of natural polymer (Gum Ghatti); X2=Proportion of. Of HPMC K 100

Source	Sum of squares	Df	Mean Square	F-value	P-value Probe>F	Significance
Model	50.07	2	25.03	18.23	0.0028	Significant
Conc. Of Natural polymer	0.13	1	0.13	0.094	0.7695	-
Conc. Of HPMC K100 M	49.94	1	49.94	36.36	0.0009	Significant
Residual	8.24	6	1.37			
Core total	58.31	8				

Table 5: Analysis of variance for Y1.

The Model F-value of 6.34 (Table 5) implies the model is significant. There is only a 3.72% chance that a "Model F-Value" this large could occur due to noise. Values of "Prob > F" less than 0.0500 indicate model terms are significant. In this case AB is significant model terms. Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model. The 3D response and contour plot is depicted in figures 3a and 3b.

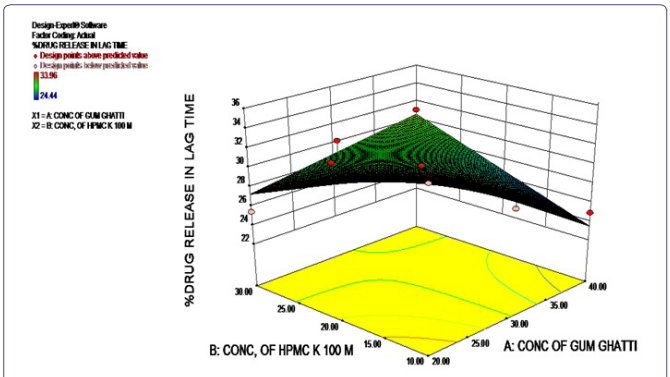

Figure 3a: 3D Response plot of %CDR in lag time.

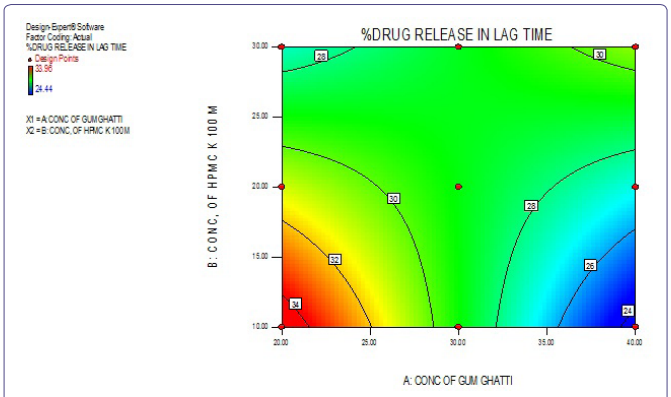

Figure 3b: Contour plot of % CDR in lag time.

Model assessment for the dependent variable: % CDR in 12h

Final equation in terms of actual factors:% CDR in 12 HRS= +102.49667+0.014667(X1)-0.28850(X2)

X1=Conc. of natural polymer (Gum Ghatti); X2=Conc. of HPMC k 100 M

source	Sum of squares	Df	Mean Square	F-value	P-value Probe>F	Significance
Model	78.43	3	26.14	6.34	0.0372	Significant
Conc. Of Natural Polymer	24.68	1	24.68	5.98	0.0582	-
Conc. HPMC K100 M	0.089	1	0.089	0.022	0.8891	-
AB	53.66	1	53.66	13.01	0.0154	Significant
Residual	20.62	5	4.12			
Core total	99.05	8				

Table 6: Analysis of variance for Y2.

The Model F-value of 18.23 (Table 6) implies the model is significant. There is only a 0.28% chance that a "Model F-Value" this large could occur due to noise. Values of "Prob > F" less than 0.0500 indicate model terms are significant. In this case B is significant model terms. Values greater than 0.1000 indicate the model terms are not significant. If there are many insignificant model terms (not counting those required to support hierarchy), model reduction may improve your model. The 3D response and contour plot is depicted in figures 4a and 4b.

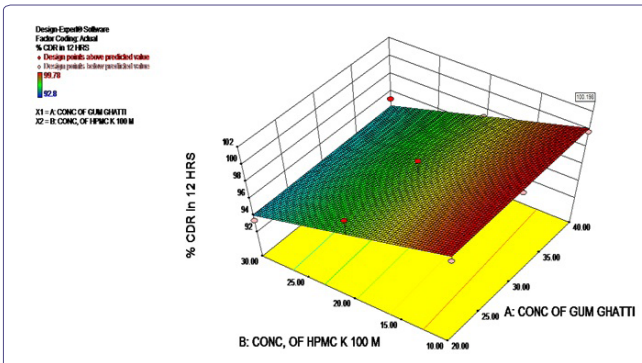

Figure 4a: 3D Response plot of %CDR in 12h.

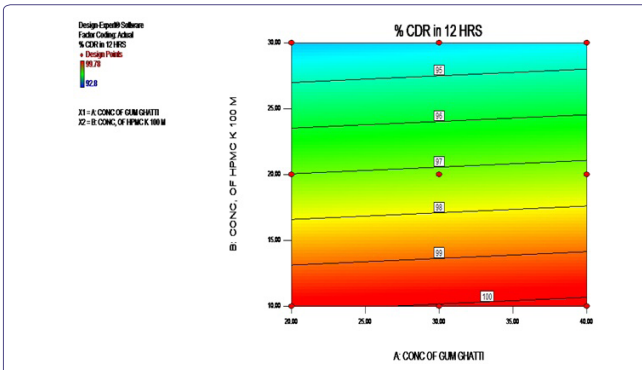

Figure 4b: Contour plot for % CDR in 12hrs

Solutions for optimized batch: After analysis of both independent variables (i.e., factor) and dependant variables (i.e., response) Design Expert® software gives solutions. One batch from the solutions provided by software was selected as an optimized batch based on desirability value depicted in table 7.

Sr. No.	Amount of natural polymer (%w/w)	Amount of HPMC K 100M	% CDR in 12 hrs	% CDR in lag time	Desirability
1	40%	10%	100.1	23.5	1

Table 7: Solution for optimized formulations.

The optimized batch was then developed and evaluated for various physicochemical properties and the results of physicochemical evaluation and *in vitro* drug release study for optimized formulation have been depicted in table 8 and figure 5 respectively.

Sr. No.	Evaluation Parameters	Result
1.	Weight Variation	300.6±2.78
2.	Hardness	5.83±0.28
3.	Friability (%)	0.46±0.13
4.	Drug content	100.26±0.5
5.	% CDR in lag time (5 h)	23.92±1.77
6.	%CDR (12h)	100.08±0.31

Table 8: Evaluation results for optimized formulation.

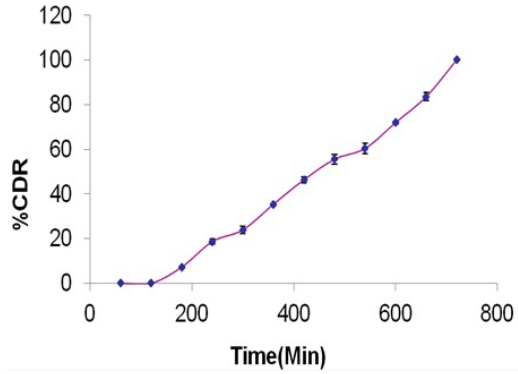

Figure 5: *In vitro* drug release profile of optimized batch.

Kinetic analysis of dissolution data: Drug release data of optimized formulation showed good fit into the zero order equation (r^2=0.9848), partially fitted in Higuchi equation (r^2=0.92) and also showed high linearity with Korsmeyer equation (r^2=0.94). The Korsmeyer-Peppas equation for drug release is given below:

$$Mt / M_{\infty} = Kt^{n}$$

Where, Mt=is the amount of drug released in time t; M_{∞}=amount of drug release at infinite time K is constant, and n represents the release exponent indicative of mechanism of drug release.

When n=0.5 means Fickian diffusion, 0.5>n<1.0 non-Fickian diffusion, and n=1.0 Case II diffusion. The release exponents (n) of the formulations suggest that depending on the formulation variables the drug release followed either Fickian or non-Fickian mechanism. The drug diffusion through most types of polymeric systems is often best described by Fickian diffusion.

Stability study: The stability studies were carried out for the optimized formulation. The optimized formulation did not show any significant change in hardness, friability and drug content when kept at accelerated conditions of temperature and humidity. Also no significant difference in values of *in vitro* drug release profile observed during the stability studies (Figure 6).

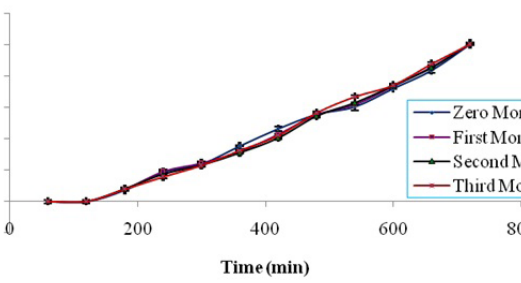

Figure 6: *In vitro* dissolution profile for stability batches.

The formulation was found to be stable under accelerated conditions of temperature and humidity showing proper hardness, optimum friability, uniform drug content and uniform *in vitro* drug release behaviour during 3 months accelerated stability studies.

Conclusion

This study exhibited that it is possible to control the release rate of Diclofenac sodium over a wide time scale using *Anogeissus latifolia* as a sustained release polymer. The combination of both natural and synthetic polymers can be a better choice in comparison to costly synthetic sustained release polymers to achieve desired sustained release effect of formulation. The present study provides a new alternative which is cheaper, having lesser side effects & biocompatible formulation of Diclofenac sodium in the treatment of IBD. Thus this polymer proved to be an excellent carrier for colon targeting and can be exploited commercially.

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Author(s)' Statement(s)

The author(s) declare(s) no conflict of interest.

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