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DESIGN, DEVELOPMENT AND EVALUATION OF POLYHERBAL TABLET OF TWO ANTI-ULCER LEAVES

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Gastro retentive drug delivery system, Hydroxypropyl methylcellulose-K4M, *Cordia wallichi*, *Abrus precatorius*, Polyherbal tablets

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ABSTRACT: Aim: The present study was to develop and evaluate antiulcer polyherbal tablet as designing of oral herbal formulation. The methanolic extracts of *Abrus precatorius* (MEAP) and *Cordia wallichi (*MECW) leaves were used in different concentrations in the formulations. **Materials and Method:** The current exploration was to design a gastro-retentive drug delivery system of MEAP and MECW using swelling polymer through the wet granulation method. All the formulations were evaluated for weight variation, hardness, friability, drug content, and *in-vitro* dissolution. In this gastro-retentive dosage form using hydroxypropyl methylcellulose-K_4M was prepared to develop sustain release tablets, which could remain in the stomach for longer periods of time, delivering the drug to the site of action. **Results:** Pre and Post-compression parameters of all the formulations were within the Pharmacopoeial limits, and *in-vitro* drug release of F8 formulation was found to be 98.29% in 12 h. **Conclusion:** Dissolution studies of the composition, it was concluded that the formulation F8, which is containing 200 mg of polyherbal extracts, 140 mg of HPMC-K_4M, 85 mg of MCC, 65 mg of sodium bicarbonate, 5 mg of magnesium stearate, and 5 mg of Talc is the best formulation. F8 possessed a quick buoyancy lag time of 34 s and a maximum total floating time of 12 h. As the consequence of this study, it may accomplish that the floating tablets using HPMC-K_4M are a hydrophilic polymer that increases the gross register tonnage of the dissolution fluid to deliver the drug in a sustained manner.

INTRODUCTION: Pharmaceutical manufacturers all over the world are also focusing on plant-based medicines. In the early development of modern medicine, biologically active compounds from higher plants have played a vital role in providing medicines to combat various diseases. Plant-derived medicines continue to occupy an important niche in the treatment of diseases in developing countries worldwide.

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Abrus precatorius and *Cordia wallichi* leaves are already reported for their antiulcer properties [1-3]. It is used by some local Ayurvedic practitioners for general Gastric ulcer ailments. Floating gastro-retentive tablets of methanolic extracts of the two selected plant leaves were prepared to increase the bioavailability and site-specific and local therapy for the ulcers.

The gastro-retentive drug delivery systems (GTDDS) can assist in improving the oral bio-availability of various pharmaceutical drugs that have an absorption window in a particular region of gastrointestinal (GI) tract [4]. The design of new oral controlled drug delivery system should be aimed toward achieving maximum pharmacological action of the drugs on targeted site.

The present scenario of the global market is in urgent need of standardized and reproducible herbal preparations, which can be achieved by the formulation of modern herbal dosage forms and their evaluation by modern techniques. Solid oral dosage forms represent the preferred class of product for orally administered drugs. Advantage beings unit dosage forms, easy to handle and transport, convenient and safe.

MATERIALS AND METHODS:

Material: The authentic plant materials were collected from Kamrup district, Assam, and identified and authenticated by Dr. T. G. Gohil, taxonomist and HOD of Botany, Botanist in BKM Science College, Valsad (Gujurat) bearing the Plant authentification no. Bkm/Bio/37/2018. A voucher specimen of the collected plants was prepared and maintained in the Botany department of BKM Science College received botanic identity, and the identity was confirmed by correlating their morphological and microscopical characters.

Pharmaceutical grades of hydroxypropyl methyl-cellulose (HPMC K4M) from Otto Chemie Pvt Ltd., Mumbai, microcrystalline cellulose (MCC), sodium bicarbonate ($NaHCO_3$), magnesium stearate, and talc were purchased from (Loba chemicals Ltd. Mumbai) and other chemicals of analytical grade were utilized in this study. Gallic acid (R_f 0.66), quercetin (R_f 0.79), and glycyrrhizin (R_f 0.22) were used as a marker compound for evaluation of the tablet formulation as these compounds are previously estimated and quantified by the HPTLC method in both the plant extracts. Standards Gallic acid 99.5% (HPLC grade), Quercetin 99.5% (HPLC grade) and Glycyrrhizin 99.5% (HPLC grade) were purchased from Sigma-Aldrich (Mumbai).

Preparation of Polyherbal (Floating) Tablet: The Polyherbal tablet contains a uniform mixture of drug, polymer, and other excipients, including the gas-generating agent. The tablets were prepared by direct compression method. Weighed quantities of ingredients given in **Table 1**. The measured quantities of drug, HPMC, MCC, and $NaHCO_3$ were mixed thoroughly using a mortar and pistil. In order to obtain the granules, the mixture was passed through the 20 mm sieves. The granules were dried in a hot air oven and at last talc and magnesium stearate were added to the blend. Powder blend was compressed into tablet using 16 station tablet punching machine with 10 mm punch.

TABLE 1: FORMULATION OF POLYHERBAL FLOATING TABLETS

		Formulations								
S. no.	**Ingredients**	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
1	Polyherbal Extract	200	200	200	200	200	200	200	200	200
2	HPMCK4M	60	60	60	100	100	100	140	140	140
4	MCC	185	165	145	145	125	105	105	85	65
5	$NaHCO_3$	45	65	85	45	65	85	45	65	85
6	Talc	5	5	5	5	5	5	5	5	5
7	Magnesium Stearate	5	5	5	5	5	5	5	5	5
Total Weight		500	500	500	500	500	500	500	500	500

HPMC-Hydroxy propyl methyl cellulose, MCC-Micro crystalline cellulose

Characterization:

Preformulation Studies: Flow properties of granules. The flow properties of granules (before compression) were characterized in terms of angle of repose, Carr's index, and Hausner's ratio. For determination of angle of repose (θ), the granules were poured through the walls of a funnel, which was fixed at a position such that its lower tip was at a height of exactly 2.0 cm above hard surface.

The granules were poured till the time when upper tip of the pile surface touched the lower tip of funnel. The $\tan^{-1}$ of (height of the pile/radius of its base) provided the angle of repose.

Bulk density tapped density; Carr's index and Hausner's ratio were calculated using tap density apparatus [5-7].

Evaluation of Tablets:

Diameter and Thickness: The diameter and thickness of the tablet were measured by using a vernier caliper. It is expressed in mm. Six tablets were selected at random from each batch, and the mean; standard deviation values were calculated The thickness of the tablet is important in producing tablet identical in appearance. Thickness can vary with no change in weight because of the difference in density of the powders [8, 9].

Hardness Test: Hardness or tablet crushing strength (the force required to break a tablet in a diametric compression) was measured using a Monsanto tester. Six tablets from each batch were selected and evaluated, and the average value with standard deviation was recorded. The mean ± standard deviation values of hardness were calculated [8, 9].

Friability Test: Friability test is performed to evaluate the ability of the tablets to withstand abrasion in packing, handling, and transporting. The Friability of tablets was determined using a friabilator (Roche friabilitor). Ten preweighed tablets were placed in the friabilator, operated for 4 minutes at 25 rpm. After 100 revolutions, the tablets were taken out, dedusted, and reweighed. The percentage friability of tablets was measured as per the following formula [10].

% Friability = (Initial weight - final weight) / (Initial weight) × 100

Weight Variation Test: Uniformity of weight test as described in the Indian Pharmacopeia was followed; a small variation in the weight of the individual tablet is liable to occur. Therefore, a little variation is allowed in the weight of tablets by the pharmacopeia. The following percentage deviation in weight variation is allowed. To study weight variation, 20 tablets of each batch were weighed using an analytical electronic balance, and the mean weight was calculated. Not more than 2 tablets should deviate from the average weight of the tablets [11] **Table 2.**

***In-vitro* Buoyancy or Floating Studies:** *In-vitro* buoyancy was determined by the measurement of floating lag time (FLT) and total floating time (TFT). Tablet was placed in a 100 ml beaker containing 0.1 N. HCl. The time required for the tablet to rise on the surface of medium and float was determined as "FLT." It is expressed in seconds or minutes. The duration of time by which tablet constantly emerges on the surface of medium was determined as the "TFT." It is expressed in h.

The experiments were conducted in triplicate. Polyherbal effervescence tablet generates CO_2 gas, thereby reducing the density, and hence it remains buoyant for a prolonged time period releasing the drug slowly at the desired rate [12].

***In-vitro* Dissolution Studies:** The release rate of polyherbal floating tablets was performed. *In-vitro* dissolution study in USP dissolution apparatus Type II, in 900 ml 0.1 N HCL (p^H 1.2), maintained at 37 ± 0.5 °C at a speed of 50 rpm. At suitable time intervals, aliquots (5 ml) were withdrawn and immediately replaced with an equal volume of fresh dissolution medium to maintain a constant volume for drug dissolution. The samples were filtered through a 0.45 µ membrane filter and diluted to a suitable concentration with 0.1 N HCL. At appropriate time intervals, the samples were withdrawn and assayed spectrophotometrically using Shimarzu double beam UV-visible spectrophotometer at 274 nm λ_{max} after filtration through Whatman filter paper and with suitable dilutions. The methodology for in vitro dissolution was kept the same for all the batches prepared. The experiment was done in triplicates. Cumulative percentage drug release was calculated using an equation obtained from a standard calibration curve [13].

Drug Release Kinetic Study of Optimized Formulation: Drug release kinetics was obtained by applying the release data to various models such as zero order, first order, Higuchi matrix, and Korsmeyer-Peppas model. Several kinetic models have been proposed to describe the release characteristics of a drug from a matrix. The three parameters were used to study the release mechanism, *i.e.*, release rate constant (k), correlation coefficient (R), and release exponent (n) and determine the best fit model for optimized formulation [14].

TABLE 2: RELATION BETWEEN AVERAGE TABLET WEIGHT AND % DEVIATION ALLOWED AS PER IP

Average Tablet Weight	Deviation Allowed %
80 mg or less	10
More than 80 mg but<250 mg	7.5
250 mg or more	5

RESULTS AND DISCUSSION:

Flow Properties of Granules: The pre-formulation study results obtained on various parameters on granules were found satisfactory.

The granules obtained for the batches (F1-F9) were satisfactory. No ratholing, capping, or sticking was observed during the flow of granules from the hopper. The compressibility index and Hausner's ratio values were obtained for granules of all the

batches and were found to be in the range of 14.36-17.96 and 1.10-1.219 (<1.25) respectively as shown in **Table 3**. All these values indicate that the prepared granules exhibited good flow properties.

TABLE 3: CHARACTERIZATION OF GRANULES

Parameters	Powder blend for								
	FI	F2	F3	F4	F5	F6	F7	F8	F9
Angle of repose	35.2±0.058º	35.4±0.115º	35.2±0.153º	34.2±0.115º	35.17±0.058º	34.40±0.100º	35.2±0.100º	35.1±0.173º	34.23±0.058º
Loose bulk density (g/cm3)	0.470±0.005	0.461±0.014	0.478±0.004	0.474±0.010	0.473±0.017	0.480±0.004	0.460±0.033	0.492±0.021	0.482±0.016
Tapped bulk density (g/cm3)	0.517±0.004	0.522±0.001	0.524±0.004	0.540±0.003	0.520±0.004	0.555±0.010	0.520±0.002	0.575±0.002	0.569±0.019
Hausner ratio	1.10±0.023	1.22±0.061	1.21±0.017	1.24±0.047	1.22±0.071	1.16±0.030	1.15±0.133	1.17±0.085	1.24±0.028
Compressibility Index (%)	15.63±0.617	17.9±2.85	17.8±0.868	17.6±2.29	14.3±3.78	14.5±0.38	16.6±6.64	17.2±4.24	16.9±1.25
Flow character	Good	Fair	Fair	Fair	Good	Good	Fair	Good	Good

Number of experiments n=6, mean), LBD-Loose Bulk Density, TBD-Tapped Bulk Density greenish brown coloured with a smooth surface having acceptable elegance.

Diameter and Thickness: Diameter of tablets of all batches were observed in between 10 mm The thickness of the tablets of all the batches were found in the range of 4.69-4.79 mm indicating fairly acceptable. Results were given in **Table 4.**

Hardness Test: The hardness of all the tablets was found to be in the range of 5.2 kg/cm²-5.5 kg/cm². Results were given in **Table 4.**

Friability Test: Friability value for tablets of none of the batch was more than 0.38%, <1% indicating good mechanical resistance.

Weight Variation Test: The maximum weight variation of the tablets was ±0.08%, which falls within the acceptable range of ± 5%; hence the tablets, passed the weight variation test. Results were given in **Table 4.**

TABLE 4: POST COMPRESSION PARAMETER OF FLOATING TABLET

		Evaluation Parameters			
	Diameter (mm)	Thickness (mm)	Hardness (kg/cm2)	Friability (%)	Average Weight Variation
F1	10	4.69±0.09	5.4±0.13	0.38±0.01	499.7±0.52
F2	10	4.70±0.09	5.3±0.12	0.20±0.02	499.7±0.46
F3	10	4.79±0.12	5.4±0.06	0.32±0.01	499.7±0.34
F4	10	4.69±0.13	5.4±0.07	0.36±0.02	499.9±0.25
F5	10	4.71±0.11	5.5±0.04	0.33±0.02	500.0±0.24
F6	10	4.72±0.08	5.6±0.04	0.35±0.01	500.0±0.68
F7	10	4.77±0.08	5.2±0.05	0.33±0.02	499.6±0.71
F8	10	4.79±0.01	5.2±0.06	0.34±0.02	499.6±0.19
F9	10	4.70±0.06	5.4±0.09	0.32±0.01	500.1±0.54

Number of experiments n=10, 10, 13, 20 (mean) ± SD

In-vitro **Buoyancy or Floating Studies:** The results of FLT and TFT are shown in **Table 5.** The gas generated is trapped and protected within the gel, formed by the hydration of the polymer, thus decreasing the density of the tablet. As the density of the tablet falls, the tablet became buoyant.

FIG. 1: PHOTOGRAPHS OF IN-*VITRO* BOUNCY STUDY OF OPTIMIZED FORMULATION F8 AT DIFFERENT TIMES, A (10 MIN), B (2 H), C (12 H)

The floating lag time ranged from 34 s to 55 s. From **Table 5**, it was found that the formulation F8 has a minimum floating lag time of 34 s and a maximum total floating time of 12 h. Thus, it was taken as the optimum formulation. Photographs of *in-vitro* buoyancy study of optimized formulation F8 as shown in **Fig. 1.**

TABLE 5: BUOYANCY OR FLOATING LAG TIME AND TOTAL FLOATING TIME

Formulation Code	Floating Lag time (Sec) (±SD, n=3) FLT	Total Floating Time (h) TFT	Tablet shape
F1	44±0.5	5.5	Swollen and Retained integrity
F2	55±0.6	3.5	Swollen and Retained integrity
F3	50±0.4	6.5	Swollen and Retained integrity
F4	52±0.5	4.5	Swollen and Retained integrity
F5	45±0.4	6.5	Swollen and Retained integrity
F6	50±0.5	8	Swollen and Retained integrity
F7	42±0.3	10.5	Swollen and Retained integrity
F8	34±0.2	12	Swollen and Retained integrity
F9	38±0.4	11.5	Swollen and Retained integrity

*All values are expressed in mean ± standard deviation, n=3. FLT: Floating lag time

***In-vitro* Dissolution Studies:** The *in-vitro* dissolution studies were conducted for all formulations in triplicate, and the dissolution graph was drawn with error bars pertaining to the standard deviation of the three tests. All tablets retained their integrity throughout the study and released the drug in a controlled manner, as shown in **Fig. 3**. Nine batches of formulations (F1-F9) which had HPMC composition up to 140 mg had an earlier release of drug for the same amount of sodium bicarbonate. Amongst all these formulations the F8 formulation composed of 140:65 ratio of HPMC K_4M and $NaHCO_3$ showed 23.56% of drug release at 1 h, and 98.29% of drug release was obtained at the end of 12 h, which will meet the required concentration of the drug targeted to upper part of the GIT, thus was selected for further studies as an optimized formulation.

TABLE 6*: IN-VITRO* DRUG RELEASE OF F1 F9 FORMULATION

Time (H)	Cumulative % Drug Release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	39.22	13.6	15.4	25.71	20.15	31.52	17.34	23.56	22.34
2	48.33	19.33	23.57	33.87	38.21	46.65	29.91	43.19	29.99
3	62.12	21.54	31.04	40.47	45.42	54.25	37.2	49.09	50.2
4	75.55	25.22	38.25	43.62	52.26	60.23	46.68	56.61	57.68
5	84.44	28.44	44.15	47.62	58.23	68.38	53.73	61.33	59.73
6	93.63	32.23	49.23	53.43	64.69	77.13	60.92	67.36	65.92
7	99.67	38.7	53.7	59.7	69.15	85.32	66.53	73.75	75.53
8		41.55	57.55	64.23	74.58	92.51	71.2	78.04	78.12
9		46.2	63.22	70.31	81.28	97.45	77.08	84.14	79.08
10		50.34	66.11	73.61	85.12	99.12	80.12	88.92	80.12
11		54.77	69.23	77.13	89.35	100.35	83.35	93.55	82.35
12		57.28	70.58	79.21	92.73	100.23	85.26	98.29	92.26

Drug Release Kinetic Study of Optimized Formulation: The various kinetic models were analyzed for all the formulations. It was found from **Table 7** that the optimum formulation was F8 *i.e*., having HPMC K_4M had the minimum floating lag time and higher drug release. Among all the formulations, F8 found to be best fitted in Higuchi kinetics with RH value of 0.9960, followed by zero-order (RO = 0.921) and first-order (RF = 0.488) kinetics. This explains that drug release from the Polyherbal floating tablet followed primarily diffusion-controlled release mechanism. Further, to confirm the drug release mechanism from the formulations, the *in-vitro* drug release data at various time points were fitted into the Korsemayer-Peppas equation. The obtained nP values of all the formulations were greater than 0.45 and less than 1. Hence, it is revealed that the mechanism of drug release was a non-Fickian or anomalous diffusion.

TABLE 7: DRUG RELEASE KINETICS AND MODEL FITTING DATA OF FLOATING CONTROLLED RELEASE POLYHERBAL TABLETS

Formulation Code	Zero-order Release Kinetics		First-order Release Kinetics		Korsmeyer–Peppas equation			Higuchi Kinetic Model	
	R_O^2	K_O	R_F^2	K_F	R_{KP}^2	n	K_{KP}	R_H^2	K_H
F1	0.926	12.99	0.537	0.198	0.522	0.938	1.441	0.995	37.93
F2	0.978	4.343	0.608	0.092	0.691	0.712	1.028	0.966	16.68
F3	0.949	5.535	0.552	0.099	0.677	0.789	1.119	0.991	21.85
F4	0.928	5.682	0.485	0.089	0.579	0.908	1.020	0.993	22.70
F5	0.931	6.885	0.512	0.096	0.632	0.890	1.120	0.995	27.51
F6	0.892	7.508	0.461	0.093	0.569	0.987	1.088	0.989	30.55
F7	0.943	6.724	0.552	0.099	0.676	0.831	1.149	0.990	26.63
F8	0.921	7.049	0.488	0.094	0.603	0.931	1.101	0.996	28.31
F9	0.882	6.579	0.496	0.095	0.622	0.899	1.111	0.977	26.76

CONCLUSION: The effect of ingredients in the polyherbal tablet was analyzed, where HPMCK_4M contributed as the floating matrix, MCC to decrease the bulk density of the tablet, and sodium bicarbonate to initiate the dissolution process.

Formulation F8 has a minimum floating lag time of 34 s and a maximum total floating time of 12 h. Amongst all these formulations, the F8 formulation composed of 140:65 ratio of HPMC K_4M and $NaHCO_3$ showed 23.56% of drug release at 1 h and 98.29% of drug release was obtained at the end of 12 h, which will meet the required concentration of the drug targeted to the upper part of the GIT, thus was selected for further, studies as an optimized formulation.

Release F8 also found to be best fitted in Higuchi kinetics with RH value of 0.9960, followed by zero-order (RO = 0.921) and first-order (R_F = 0.488) kinetics.

This explains that drug release from the Polyherbal floating tablet followed a primarily diffusion-controlled release mechanism. Hence, finally, it can be concluded that the prepared Polyherbal floating gastroretentive tablet of *Abrus precatorius* (MEAP) and *Cordia wallichi (*MECW) leaf extracts may prove to be potential candidate for safe and effective controlled drug delivery over an extended period of time for GDDS.

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