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Original Article

FORMULATION AND EVALUATION OF POLYHERBAL FLOATING EFFERVESCENCE TABLET CONTAINING PEDALIUM MUREX AND TRIBULUS TERRESTRIS FRUIT EXTRACTS

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ABSTRACT

Objective: The present investigation was based on the design and evaluation of floating tablets of *Pedalium murex* and *Tribulus terrestris* fruit extracts as the medicinal source and the excipients that can enhance the bioactivity and prolong the gastric retention time.

Methods: The fruit extracts were prepared from the powdered dry fruits of *Pedalium murex* and *Tribulus terrestris* using Soxhelt apparatus for 8 h. direct compression technique was used for the formulation of polyherbal floating effervescence tablets which consists of different compositions of Hydroxy Propyl Methyl Cellulose (HPMC K4M, HPMC K15M), Micro Crystalline Cellulose (MCC) and Sodium bicarbonate ($NaHCO_3$). The formulations were evaluated for thickness, hardness, friability, average weight variation, drug content, floating lag time, duration of floating and *in vitro* drug release. The data obtained from the *in vitro* dissolution studies were fitted in different models.

Results: All the tablets were satisfactory during the preformulation studies while F11 polyherbal formulation showed the maximum floating time of 15 h, minimum floatation lag time of 35 s and drug release of 100.12%. The dissolution kinetic studies for the optimum formulation was found to follow Korsemeyer and Peppas model with R^2 value, rate constant K_K and n as 0.9819, 1.0492 and 1.7385 respectively with a significance of $P<0.05$ and showed better results compared to that of film coated herbal tablets.

Conclusion: Thus this polyherbal floating effervescence tablets can be used not only as an effective drug release method for herbal drugs to enhance their bioactivity but also as a replacement for film coated herbal tablets.

Keywords: *Pedalium murex*, *Tribulus terrestris*, Gastric retention time, Polyherbal floating effervescence tablet, Hydroxypropyl methyl cellulose

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INTRODUCTION

From earliest times plants has been used by mankind in an attempt to cure diseases, disorders and relieve physical pain and suffering. The knowledge on the medicinal properties of the plants was found out using trial and error method. It was found that most of the storage organs of the plants such as roots, seeds, leaves, bark, wood, or other parts of the plant are used as medicine [1]. The plant tissues consist of flavonoids, alkaloids, glycosides, phenols, saponins, tannins and steroids that are responsible for its medicinal value [2].

Pedalium murex Linn (family: *Pedaliaceae*) commonly known as 'large caltrops' is a shrub found in tropical Africa and in arid and coastal regions of India, Pakistan and Srilanka [3]. It grows up to 2 to 3 feet having irregularly shaped leaves and bear small yellow coloured flowers as in fig. 1(A). The fruits are pale yellowish brown colour, 4 angled indehiscent and hard pyramidal with 4 sharp spines as in fig. 1(B). The powder is dark brown and is rich in flavonoids, sapogenin and several alkaloids like pedalithin, diosmetin, dinatin, pedalin dinatin-7-glucuronide [4-6]. *Pedalium murex* is considered to be demulcent and diuretic, antispasmodic, aphrodisiac improves appetite, and reduces strangury, urinary discharges, vesical calculi, cough, asthma, skin diseases and heart trouble. [7, 8].

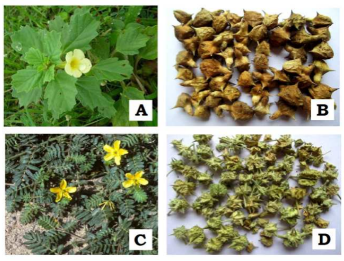

Fig. 1: *Pedalium murex* A) plant B) dried fruits, *Tribulus terrestris* C) plant D) dried fruits

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Tribulus terrestris is commonly known as puncture vine grows to a height of 1 to 2 feet with pinnate compound leaves and yellow flowers as in fig. 1(C). The fruits are stellate shaped five segmented carpels with short stiff spines as in fig. 1(D). The fruit powder is greyish brown and contains flavonoids, alkaloids, glycosides, steroids and saponin derivatives like tigogenin, hecogenin, diosgenin, ruscogenin, chlorogenin and sarsasapogenin and sulphatedfuro and spiro saponins [10, 11]. Tribulus terrestris is used in folk medicine in the form of tonic as an aphrodisiac, analgesic, astringent, stomachic, antihypertensive, diuretic, lithontriptic and urinary anti-infective [12, 13].

Ayurvedic formulations that can be taken as internal medicine are generally classified into pattika (tablet), churna (powder), ashava/arista (fermented preparations), vati/guggulu preparations (resin), ghrita preparations (ghee based) and bhasma/rasha (calcinated products). Each dosage form has its own method of ingestion and has a different response time and drug retention time [14].

The present investigation was intended to formulate and evaluate the polyherbal formulation containing *Pedalium murex* and *Tribulus terrestris* fruit extracts. The polyherbal effervescence tablet formulation comes under the classification of pattika and is a combination of Ayurvedic plant drug and acts as the replacement for the currently marketed film coated herbal tablets. Effervescent mixtures help in masking the objectionable taste of the herbal drugs and provide a pleasant taste due to carbonation [15].

MATERIALS AND METHODS

Materials

Pedalium murex and *Tribulus terrestris* dried fruits obtained from the local market and the plants obtained from Nadarmedu, Erode, Tamil

Nadu, India were compared and identified by Dr. N. Anjanadevi, Department of Botany, Vellalar College for Women, Erode, Tamil Nadu, India. They were also submitted and authenticated by Mr. Rakesh G. Vadhyar, Botanical Assistant, Botanical Survey of India Southern Regional Centre, Coimbatore, Tamil Nadu. The dried fruits of *Pedalium murex and Tribulus terrestris* were crushed using the hammer mill to remove the hard exoskeleton and then, it was pulverized using mixer grinder. The powder from the grinded mass was removed using sieve shaker and particles that passed through mesh no. 20 (0.841 mm) were collected and used for the study. Pharmaceutical grades of hydroxypropyl methylcellulose (HPMC K4M, HPMC K15M) from Otto Chemie Pvt Ltd., Mumbai, microcrystalline cellulose (MCC), sodium bicarbonate ($NaHCO_3$), magnesium stearate and talc were utilized in this study.

Preparation of extracts [16]

About 15 grams of powder was used for extraction in Soxhlet apparatus with different solvents namely ethanol, methanol, n-hexane and petroleum ether separately. All extracts were concentrated using hot air oven and the residue was dried in a desiccator. This residue acts as the medicinal ingredient to the tablet. The solvent with the higher yield is used for further studies. The absorption maximum of the extracts dissolved in 0.1 N HCl was studied between 400-700 nm regions using Elico double beam UV-visible spectrophotometer.

FT-IR studies and phytochemical screening [17]

Both the *Pedalium murex* and *Tribulus terrestris* fruit extracts were tested using Fourier transform infrared (FT-IR) Spectroscopy to confirm the presence of phytochemicals in the sample.

Preparation of polyherbal tablet [18-20]

The different ingredients for formulations are given as in table 1 below. 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.

Table 1: Formulation of polyherbal effervescence floating tablet

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Drug	80	80	80	80	80	80	80	80	80	80	80	80
HPMC K4M	---	---	120	120	---	---	140	140	---	---	160	160
HPMC K15M	120	120	---	---	140	140	---	---	160	160	---	---
MCC	165	130	165	130	145	110	145	110	125	90	125	90
$NaHCO_3$	125	160	125	160	125	160	125	160	125	160	125	160
Talc	5	5	5	5	5	5	5	5	5	5	5	5
Magnesium stearate	5	5	5	5	5	5	5	5	5	5	5	5
Total	500	500	500	500	500	500	500	500	500	500	500	500

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

The granules were punched into tablets using direct compression technique. The blank formulation (or) placebo (HPMC+ MCC+$NaHCO_3$) and polyherbal formulation were also tested using FTIR Spectrometer.

The standard parameters that have to be evaluated for prepared tablets were namely weight variation, hardness, friability, disintegration time and stability. In weight variation study, a random sample of twenty tablets was selected and the average weight was calculated. Then this weight was compared with individual tablets weight. The hardness was measured using Pfizer hardness, where the tablets were placed in contact between the plungers and the force of the fracture was recorded. The friability was determined using Roche friabilator at a constant rpm. Six tablets from each formulation were tested.

Evaluation methods for polyherbal floating tablets

1. *In vitro* buoyancy studies [21]

The Polyherbal tablet was placed in a 100 ml beaker containing 0.1 N HCl. The time taken for the tablet to rise and float on the surface as floating lag time. 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.

2. *In vitro* dissolution studies [22, 23]

The release rate of polyherbal floating tablets was determined. The dissolution test was performed using United States Pharmacopeia (USP) type II paddle apparatus with an agitation speed of 50 rpm in 0.1 N HCL maintained at 37±0.5 °C. At appropriate time intervals, the samples were withdrawn and assayed spectrophotometrically using Elico double beam UV-visible spectrophotometer at λmax 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.

3. Rate kinetic studies [24]

The release rate kinetics of the formulations was analyzed and the data obtained were fitted into Zero order, First order, Higuchi model and Kozmeyer Peppas model using equations in table 2.

Table 2: Mathematical Models for drug dissolution

Model	Mathematical equation	Release mechanism
Zero Order	$C = C_0 - K_0 t$	Diffusion Mechanism
First Order	$\log C = \log C_0 - K_1 . t/2.303$	Fick's first law, diffusion mechanism
Higuchi Model	$Q_0/Q_t = K_H . t^{1/2}$	Diffusion medium based mechanism in Fick's first law
Kozmeyer Peppas Model	$Ct/C_\infty = K_K . t^n$	Semi-empirical model, diffusion based

RESULTS AND DISCUSSION

It was found that the ethanol produces the maximum yield of 6.5% and 12.3% for *Pedalium murex* and *Tribulus terrestris* respectively. The wavelength of maximum absorbance (λmax) for *Pedalium murex* and *Tribulus terrestris* were found to be 666 nm in 0.1 N HCl.

FT-IR spectral studies

From the FT-IR Spectroscopy reports shown in fig. 2, it is clear that both *Pedalium murex* and *Tribulus terrestris* are rich in phytochemicals such as phyto-steroids, flavonoids, alkaloids, sapogenin and glycosides. The report also depicts that there are no interactions and also the drug and polymer are compatible to develop a stable product.

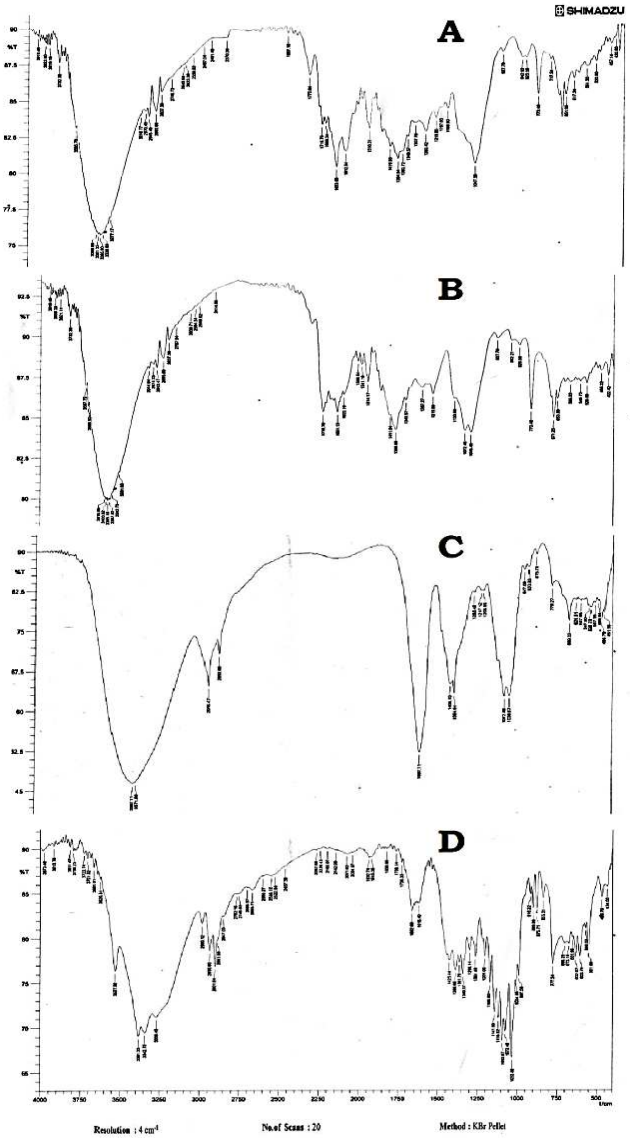

Fig. 2: FTIR Spectroscopy A) *Pedalium murex* B) *Tribulus terrestris* C) HPMC+MCC+$NaHCO_3$ D)Polyherbal formulation

Preformulation studies

The pre-formulation study results obtained on various parameters on granules were found satisfactory. The granules obtained for the batches (F1-F12) were satisfactory. No rat holing, capping or sticking was observed during the flow of granules from the hopper. The compressibility index and Hausner's ratio values obtained for granules of all the batches and were found to be in the range of 14.36-17.96 and 1.167–1.219 (<1.25) respectively as shown in table 3. The prepared tablets were greenish brown coloured with a smooth surface having acceptable elegance.

Table 3: Evaluation parameter of powder blend

	Angle of repose degree °	LBD gm/cm²	TBD gm/cm²	Compressibility index %	Hausner's ratio	Flow character
F1	34.7	0.485	0.575	15.65	1.185	Good
F2	35.1	0.484	0.585	17.26	1.208	Fair
F3	35.6	0.478	0.582	17.87	1.217	Fair
F4	35.6	0.488	0.592	17.57	1.213	Fair
F5	35.1	0.495	0.578	14.36	1.167	Good
F6	34.2	0.487	0.572	14.86	1.174	Good
F7	34.6	0.492	0.581	15.31	1.181	Good
F8	35.5	0.485	0.579	16.23	1.194	Fair
F9	35.3	0.491	0.575	14.61	1.171	Good
F10	34.3	0.475	0.579	17.96	1.219	Fair
F11	35.1	0.494	0.583	15.26	1.180	Good
F12	35.5	0.490	0.581	15.66	1.186	Good

(Number of experiments n=3, mean), LBD-Loose Bulk Density, TBD-Tapped Bulk Density

Post compressional parameters

The maximum weight variation of the tablets was±1.8%, which falls within the acceptable range of±5%, hence the tablets passed the weight variation test. Hardness for tablets of all batches was in the range of 4.92 to 5.35 kg/cm^2, which falls above the limit of not less than 3.0 kg/cm^2. Friability value for tablets of none of the batch was more than 0.37%. The thickness of the tablets of all the batches was found in the range of 4.77-4.82 mm indicating fairly acceptable tablets as shown in table 4.

Table 4: Evaluation parameter of tablet

	Evaluation parameters				
	Thickness (mm)	**Hardness (kg/cm2)**	**Friability (%)**	**Average weight variation**	**Drug content (%)**
F1	4.65±0.096	5.10±0.191	0.36±0.010	500.1±1.304	100.02±0.334
F2	4.68±0.090	5.01±0.254	0.34±0.013	500.7±1.795	100.12±0.319
F3	4.72±0.128	4.92±0.157	0.37±0.017	499.0±1.633	100.00±0.191
F4	4.69±0.130	5.27±0.275	0.33±0.027	499.7±1.247	100.07±0.304
F5	4.78±0.111	5.18±0.219	0.37±0.016	500.3±1.699	100.03±0.320
F6	4.73±0.118	5.35±0.096	0.35±0.019	500.6±1.367	100.18±0.121
F7	4.65±0.108	5.33±0.197	0.33±0.019	500.1±0.837	100.10±0.129
F8	4.73±0.099	5.25±0.171	0.36±0.021	500.3±0.804	100.18±0.381
F9	4.70±0.071	5.05±0.096	0.35±0.023	500.9±1.170	100.12±0.109
F10	4.68±0080	5.32±0.121	0.34±0.021	500.6±0.932	100.12±0.186
F11	4.77±0.085	5.13±0.149	0.33±0.017	500.5±1.080	100.23±0.122
F12	4.69±0.067	5.05±0.150	0.37±0.026	499.9±0.534	100.16±0.170

(Number of experiments n=3, mean±SD)

***In vitro* buoyancy studies**

The time taken for the tablets to rise to the surface and float is the floating lag time. The gas generated is trapped and protected within the gel, formed by hydration of the polymer, thus decreasing the density of the tablet. As the density of the tablet falls, the tablet became buoyant. The floating lag time ranged from 35 s to 50 s. From the table 5, it was found that the formulation F11 has the minimum floating lag time of 35 s and maximum total floating time of 15 h with 100.12% drug content. Thus it was taken as the optimum formulation. Hence stability studies were carried out on F11 and there was a marginal increase of moisture content and hardness, while no change in the friability was found, showing that these changes were within the specified limits.

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

Table 5: Result of floating property of herbal tablet

Formulation code	Floating lag time (s)	Total floating duration (h)
F1	44	5.5
F2	55	3.5
F3	50	6.5
F4	52	4.5
F5	45	6.5
F6	40	5
F7	39	8
F8	42	5.5
F9	37	12.5
F10	40	10.5
F11	35	15
F12	39	12.5

(Number of experiments n=3, mean)

***In vitro* dissolution studies of prepared tablets**

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 the fig. 3. Eight batches of formulations (F1-F8) which had HPMC composition up to 140 mg had an earlier release of drug for the same amount of sodium bicarbonate. In this, F7 had the longest floating time of 8 h. In the remaining four batches of formulations, F10 got completely dissolved at 10.5 h but the other three batches of F9, F11 and F12 showed floating time larger than 12 h.

The disadvantage of the Ayurvedic formulation is the drug stability and most of the plant-based drugs are delivered in the form of film coated tablet, which has the dissolution of 97.6% at 45 min and to overcome this issue a new technique is required [25]. Thus from the results obtained, it was found that the bioavailability of the drug has been enhanced compared to that of the film coated tablets.

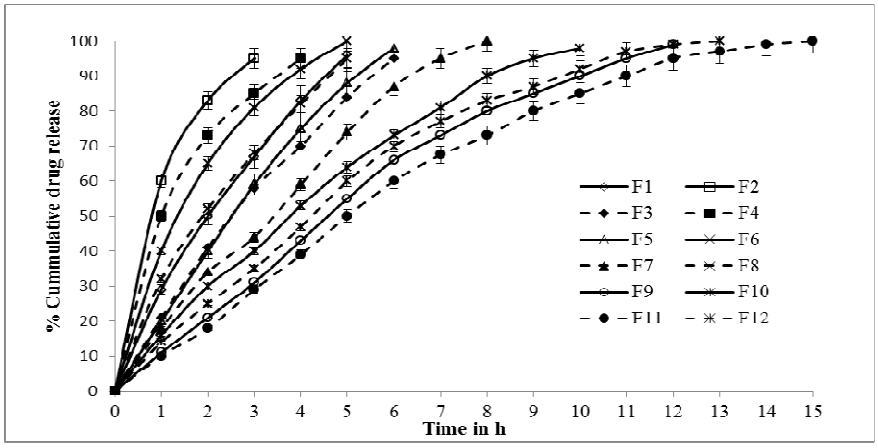

Fig. 3: *In vitro* dissolution profiles for different formulations, (Number of experiments n=3, mean±SD)

Release kinetics

The various kinetic models were analyzed for all the formulations. It was found from the table 6 that the optimum formulation was F11 i.e. having HPMC K4M had the minimum floating lag time and higher drug release. The optimized formulation F11 was found to follow typical Korsmeyer and Peppas model, which clearly indicated by their relatively higher R^2 value of 0.9819 compared to the zero order, first order regression coefficient values and Higuchi diffusion model. The entire exponent 'n' values were found to be greater than 1 indicating that all the formulations were following Case II transport. Also, the rate constant K_K and n were 1.0492 and 1.7385 with a significance of $P<0.05$.

Table 6: Dissolution kinetics analysis

	Zero Order		First Order		Highuchi		Korsmeyer-Peppas		
	K_0	R^2	K_1	R^2	K_H	R^2	K_K	n	R^2
F1	20.37	0.9503	0.2462	0.8066	39.88	0.9503	1.4732	1.4661	0.9975
F2	34.82	0.6971	0.4673	0.9266	56.53	0.9879	1.7914	0.7975	0.9843
F3	16.83	0.9705	0.1937	0.7805	35.53	0.9283	1.3451	1.6621	0.9941
F4	26.69	0.7575	0.3376	0.8930	48.49	0.9853	1.7119	0.9038	0.9912
F5	17.33	0.9712	0.2195	0.8098	36.52	0.9163	1.3272	1.7576	0.9901
F6	23.92	0.8312	0.3087	0.8945	45.40	0.9814	1.6311	1.1163	0.9831
F7	13.95	0.9782	0.1768	0.7719	32.45	0.9095	1.2616	1.6978	0.9954
F8	20.35	0.9331	0.2408	0.7998	39.96	0.9625	1.5051	1.3551	0.9987
F9	9.12	0.9549	0.1126	0.8156	26.68	0.9101	1.0591	1.8220	0.9854
F10	11.03	0.9421	0.1350	0.8499	29.52	0.9398	1.2377	1.5679	0.9937
F11	7.97	0.9276	0.1069	0.8377	25.42	0.9255	1.0492	1.7385	0.9819
F12	9.30	0.8997	0.1267	0.8443	27.76	0.9419	1.1744	1.5982	0.9798

(Number of experiments n=3, mean)

CONCLUSION

Pedalium murex and *Tribulus terrestris* were found to blend with the polymer matrix and other excipients. The herbal extracts were found to have a rich source of chemical constituents that act as a cure for various diseases. Floating was successfully achieved at the taken concentration of HPMC K4M or HPMC K15M, MCC and sodium bicarbonate. Among all the formulations, formulation F11 showed promising results releasing 100.12% with a floating lag time of 35 s and total floating time of 15 h. Thus this new attempt of developing polyherbal floating effervescence tablets proves not only to be used as an effective drug release method for herbal drugs to enhance their bioactivity but also as a better replacement for film coated tablets.

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CONFLICT OF INTERESTS

Declare none

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