ABSTRACT

Results: cough, asthma, skin diseases and heart trouble. [7, 8].

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.

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: Pedalaceae) commonly known as 'large caltrops' is a shrub found in tropical Africa and in arid and coastal regions of India, Pakistan and Sri Lanka [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 indents 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 pedalin, 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].

Source: Herb sheet 3230 and 4420, Digital Flora of Karnataka by Herbarium JCB is licensed under a Creative Commons Attribution-Non Commercial-ShareAlike 4.0 International License. URL: http://florakarnataka.ces.iisc.ernet.in.

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, chlorogenic 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 pattiaka (tablet), churna (powder), ashawa/arista (fomented preparations), vati/paggulu 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. Effervescence 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

Fig. 1: Pedalium murex A) plant B) dried fruits, Tribulus terrestris C) plant D) dried fruits
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. Vadhya, Botanical Assistant, Botanical Survey of India Southern Regional Centre, Coimbatore, Tamil Nadu. The dried fruits of Pedalium murex and Tribulus terestris 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, pharmaceutical grades of hydroxypropyl methylcellulose (MCC), sodium bicarbonate (NaHCO₃), 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 terestris 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 NaHCO₃ were mixed thoroughly using a mortar and pestil. 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.

| 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  |
| NaHCO₃          | 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+NaHCO₃) 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 CO₂ 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 = Ct/K₀ t             | Diffusion Mechanism |
| First Order         | log C = log C₀-K₀ t/0.5 | Fick's first law, diffusion mechanism |
| Higuchi Model       | Q/q₀ = Kₘ t^{1/2}        | Diffusion medium based mechanism in Fick's first law |
| Kozmeyer Peppas Model | Ct/C₀ = Kₘ 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 terestris respectively. The wavelength of maximum absorbance (λmax) for Pedalium murex and Tribulus terestris 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 terestris 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.
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                     | 0.494        | 0.585        | 17.26                    | 1.208          | Fair          |
| F3     | 35.6                     | 0.478        | 0.592        | 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/cm², which falls below the limit of not less than 3.0 kg/cm². Friability value for tablets of none of the batches 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.

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 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.

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 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.

Table 4: Evaluation parameter of tablet

| Formulation | Thickness (mm) | Hardness (kg/cm²) | Friability (%) | Average weight variation | Drug content (%) |
|-------------|----------------|------------------|---------------|--------------------------|------------------|
| F1          | 4.65±0.096     | 5.10±0.191       | 0.36±0.010    | 500.11±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     | 5.35±0.197       | 0.35±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±0.080     | 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)

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               | 52                    | 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)
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 R² 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 and n were 1.0492 and 1.7385 with a significance of P<0.05.

Table 6: Dissolution kinetics analysis

|       | Zero Order | First Order | Higuchi | Korsmeyer-Peppas |
|-------|------------|-------------|---------|------------------|
|       | k₀         | R²          | k₁      | R²               | K₁      | R²               | Kᵦ      | R²               | n      | R²               |
| 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          | 48.49   | 0.9853           | 1.7119  | 0.9038           | 0.9912 |
| F4    | 26.69      | 0.7575      | 0.3376  | 0.8930          | 35.53   | 0.9283           | 1.3451  | 1.6621           | 0.9941 |
| 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      | 0.8671      | 0.3761  | 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           | 0.9878 |
| F9    | 9.12       | 0.5954      | 0.1126  | 0.8156          | 26.68   | 0.9101           | 1.0591  | 1.8220           | 0.9854 |
| F10   | 11.03      | 0.9421      | 0.3505  | 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 |

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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