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Formulation and evaluation of herbal floating tablets

L Ramanamma *, K Pragnya, N Likhitha, M Bhargav, K Pravallika, Narendra and Jagadeesh Panda

Raghu College of Pharmacy, Visakhapatnam, India.

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Abstract

Herbal tablets are oral dosage form that float in stomach and remain there for long period of time. They are designed to improve the bioavailability of drugs and deliver them locally to the stomach. Floating tablets can offer several advantages, including sustained drug delivery and site- specific drug. This review explains about the advantages, disadvantages, applications, general formulation factors. General excipients used, methods of manufacturing, Evaluation parameters were described briefly. Brief note on pre- compressional studies of powder blend, preparation of floating tablets and post compression studies of tablets were mentioned.

Keywords: Herbal floating tablets; Amla; Ginger; Fenugreek; Isabgola husk; Cellulose

1. Introduction

Oral delivery of the drugs is the most preferable route of the drug delivery due to the ease of administration, patient compliance and flexibility in formulation etc from immediate release to site of specific delivery, oral dosage forms have really progressed. Gastro retentive dosage forms significantly extend the period of time, over which drug may be released and thus prolong dosing interval and increase patient compliance such retention systems are important for those drug that are degraded in the intestine like antacids and certain antibiotics, enzymes that act locally in the stomach. This system can be retained in the stomach and assist in improving the oral sustain delivery of drugs that have an absorption window in particular region of the gastrointestinal tract, thus ensuring optimal bioavailability. Prolonged gastric retention improves bioavailability, reduces drug waste and improves solubility of the drug that is less soluble in high pH environment.

Advantages

- Improved drug absorption
- Delivery of drugs for local action in the stomach
- Minimizing the mucosal irritation
- Treatment of gastro intestinal disorder
- Site specific drug delivery
- Ease of administration and better patient compliance
- Improved selectivity in receptor activation
- Reduced counter activity of the body

Disadvantages

- They are not suitable candidates for drugs with stability or solubility problems in the stomach
- Drugs which are absorbed along the entire GIT and which undergo first pass metabolism may not be desirable e.g. Nifedipine

* Corresponding author: L.Ramanamma

- The major disadvantage of a floating system is due to the necessity of a sufficient level of gastric fluids to float without sink. However this limitation can be overcome by coating the dosage form with bio adhesive polymers that easily adhere to gastric mucosa.
- patients should not have dosage prior going to bed.

2. Methods of manufacturing

The herbal floating tablets were prepared by using the following method:

- Wet granulation
- Direct compression
    - **Granulation:** It is the process in which primary powder particles are made to adhere to form a larger, multi-particles entities called granules. Pharmaceutically granules have size between 0.2 to 4.0 mm. Granulation is used to improve flow and compressibility of powders and to prevent segregation of the blend components. Granulation is mainly done by using two techniques.
- Dry granulation: It is the novel method for semi-automatic production of granules. The method is applicable to any solid dosage pharmaceutical products. Dry granulation method replaces existing solid dosage form development and manufacturing technologies offering more rapid development and better quality. In this process, the powder mixture is compressed without the use of heat and solvent. Two methods are used for dry granulation. The more widely used is slugging where the powder is recompressed and the resulting tablet are milled to yield the granules.
- Wet granulation: Wet granulation is the most commonly used granulation method. This process involves wet massing of powder blend with a granulating liquid, wet sizing and drying. The granulating liquid contains a solvent which must be volatile so that it can be removed by drying and must be non- toxic in nature. Typical liquid includes water, ethanol and Isopropyl alcohol. In the traditional wet granulation method, the wet mass is forced through a sieve to produce wet granules which are subsequently dried.
- Direct Compression: Direct compression is the most popular choice because it provides the shortest, most effective and least complex way to produce tablets. This is more suitable for moisture and heat sensitive API's since it eliminates wetting and drying steps and increase the stability of active ingredient by reducing detrimental (harmful) effects. In this process, API mixed with the excipients and lubricant, followed by compression which makes the product easy to process.

Table 1 List of drugs and chemicals

Si.no	Materials	Suppliers
1	Amla	Market
2	Ginger	Market
3	Fenugreek	Market
4	Isabgola husk	Market
5	Cellulose	Amster
6	Calcium Carbonate	Vinzai
7	Talc	Otto
8	Magnesium stearate	Otto

Table 2 Instruments used for preparation of herbal floating tablets

SI. NO	Name of instrument	Manufacturing company
1	Tablet hardness tester	Monsanto hardnesstester
2	Friability tester	Hicoh
3	Dissolution apparatus	Electro lab
4	UV visible double beam spectrophotometer	Analytical technologies limited
5	Tablet punching machine	Shakti an ISO 9001-2000 company

3. Methods

3.1. Preformulation study by FT-IR

FT-IR: It stands for Fourier Transform Infrared spectrophotometer, the preferred method of infrared spectroscopy. In Infrared spectroscopy, IR radiation is passed through a sample and some of it is passed through(transmitted). The resulting spectrum represents the molecular absorption and transmission, creating a molecular fingerprint of the sample.

So, information FT-IR can provide, are: → It can identify unknown materials.

→ It can determine the quality or consistency of a sample

→ It can determine the amount of components in a mixture. FT-IR is an effective analytical instrument for detecting functional groups and characterizing covalent bonding information.

3.2. Pre-compressional studies of powder blend

In the development of new dosage form, the pre-formulation study is the prior step in the potential drug development. It is the principal investigation in the drug development to obtained information on the known properties of the compound and the proposed development schedule. Following pre-compressional parameters were studied like-

- **Angle of repose:** It is the maximum angle that can be obtained between the freestanding surface of powder heap and the horizontal plane. It was determined by using fixed funnel method. Specified amount of powder drug was transferred to the funnel keeping the orifice of the funnel blocked by the thumb. When the powder was cleared from funnel then measured its angle of repose and measured in θ. Angle of repose (θ) = tan-1 h/r
- **Bulk density:** It is the ratio of the bulk mass of powder to the bulk volume. It is denoted by ρb. Bulk density is used to find out homogenecity.
- Bulk density (ρb) = M/Vb Where M is the mass of the sample, Vb bulk volume
- **Tapped density**: It is the ratio of the weight of powder to the minimum volume occupied in measuring cylinder. Tapped density is determined by placing a graduated cylinder containing a known mass of drug or formulation on a mechanical tapper apparatus which is operated at fixed no. of taps (1000) until the powder bed reached a minimum volume Tapped density (ρt) = weight of powder blend/Minimum volume occupied by cylinder.

3.2.1 Compressibility indices

- Carr's index: Based on the apparent bulk density and the tapped density, the percentage compressibility of the powder mixture was determined by the following formula.

Carr's index = Tapped density Bulk density × 100/Tapped Density

- Hausner's ratio: It is an indirect index of ease of measuring of powder flow. Lower Hausner's ratio

(1.25) Hausner's ratio = Tapped density/Bulk density.

3.3. Preparation of herbal floating tablets

Collection of plant materials - The fruits of Amla, Ginger rhizomes, Fenugreek seeds and Psyllium husk were collected from local market of Visakhapatnam, India.

3.3.1 Preparation of extracts

- **Preparation of Amla extract:** After removing seeds, fruits were washed with deionized water and dried in oven at 35-40 °C for 4-5 days till weight became constant. Dried amla pulp weighing 15 gm. was pounded and soaked in 50 ml of absolute ethanol and kept in 250 ml sterile conical flask at 37 °C with shaking at 120 rpm for 24 hrs. The content was filtered through Whatman filter paper No.1 and sterilized through 0.22µ member. The filtrates obtained were stored separately.

Figure 1 Amla extract

- **Preparation of ginger extract:** Ginger rhizomes were cleaned, washed, air dried and powdered for coarse particle size. 10 gm of powder was defatted using maceration. Then the clear solution was separated and referred as ginger aqueous extract.

Figure 2 Ginger extract

- **Preparation of fenugreek extract:** Few fenugreek seeds were grinded into coarse powder and then boiled with water, and mucilage was separated out.

Figure 3 Fenugreek powder

3.3.2 Formulation of tablet

All the ingredients were passed through sieve no. # 80 and weighed accurately on electronic balance according to formula. All the ingredients were mixed properly in mortar and pestle to get a uniform tablet blend and finally talc and magnesium stearate were mixed with the blend. Then tablet blend was weighed individually according to formula and compressed into tablet using single punch tablet machine according to different formula.

Figure 4 Tablets

Table 3 Measurements of materials

Ingredients	**Formulation(Quantity per20 tablets) 1**	**2**	**3**
Ginger extract	30mg	30mg	30mg
Amla extract	200mg	200mg	200mg
Fenugreek powder	20mg	20mg	20mg
Isabgola extract	75mg	75mg	75mg
Calcium Carbonate	2gm	2.03gm	2.04gm
Talc	0.4gm	0.43gm	0.4gm
Cellulose	1gm	1gm	1gm
Magnesium stearate	0.1gm	0.11gm	0.1gm

3.4. Post compression studies of tablets

The tablets were evaluated for various parameters after consideration of pre-formulation to overcome errors during formulation preparation.

- **Weight variation:** Weight variation test is run by weighing 10 tablets individually, calculating the average weight and comparing individual tablet weight to the average. The weight variation test would be a satisfactory method of determining the drug content uniformity of tablets.
- **Hardness:** Hardness also termed as tablet crushing strength. The tablet hardness was determined by Monsanto hardness tester. The tablet was placed lengthwise between upper and lower plunger and force applied by turning a threaded bolt until the tablet fractures and measured hardness of tablet in Kg/cm2.
- **Friability:** It is determined by Roche friabilator, subjects a number of tablets to combined effects of abrasion and shock by utilising a plastic chamber that revolves at 25 rpm, dropping tablet from inches distance operated for 100 revolutions. Pre-weighed tablets were dusted and re-weighed and according to standard limit, friability should be less than 1%. It is calculated by the formula.

% Friability = Initial weight–Final weight/Initial weight.

- **Disintegration test:** In the disintegration time study, six tablets were tested. Each tablet was put into 900 ml HCL solution (0.1N) at 37±20C. Time required for complete dispersion of a tablet was measured with the help of disintegration test device.
- **INVITRO Dissolution Study**: All the tablet dissolution studies were carried out for three tablets (triplicate) per formulation. USP Type II dissolution apparatus was used for drug release studies.

Table 4 Dissolution parameters

SI. NO	Dissolution parameters	
1	Speed of paddle	50rpm
2	Temperature	37+/-
3	Sampling	10minutes
4	Volume drawn	10ml
5	Dilution factor	10ml
6	Volume of Dissolution medium	900ml
7	Dissolution medium	0.1N hcl PH-1.5
8	Spectrophotometeric analysis	UV- visible at 240nm

4. Results

4.1. Pre-formulation studies

4.1.1 Estimation of hft by uv spectroscopy

Determination of λmax OF HFT

HERBAL FLOATING TABLET is estimated by UV / VIS spectrophotometer in 0.1N Hcl buffer

HFT is shown λmax at 240 nm in 0.1N Hcl buffer.

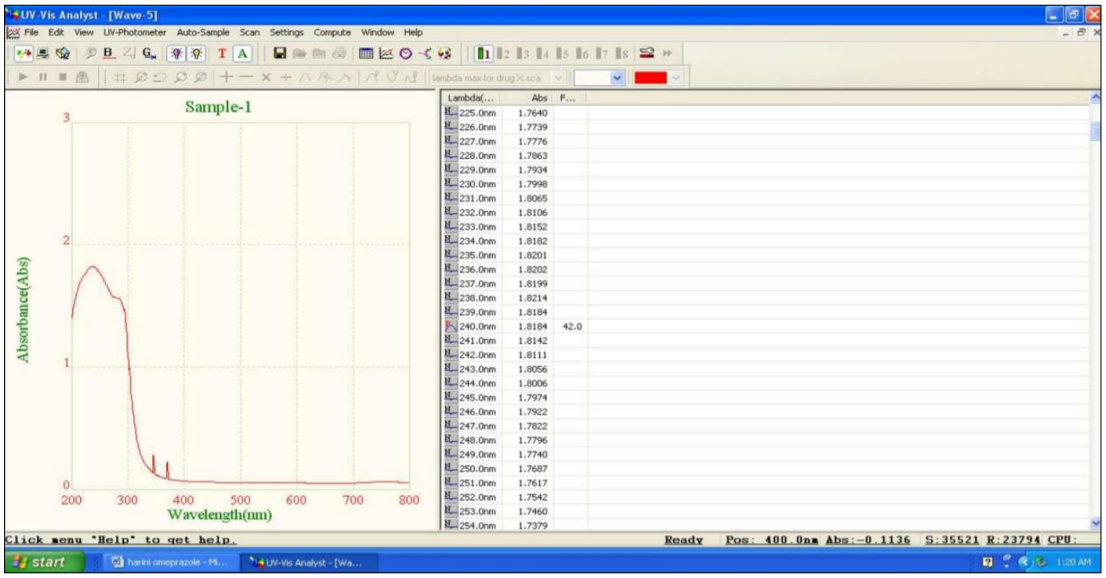

Figure 5 Lambda max of HFT

Table 5 Concentration and absorbance

Concentration (ug/ml)	Absorbance
1	0.1974
2	0.4092
4	0.4526
6	0.6787
8	0.7089
10	0.8293

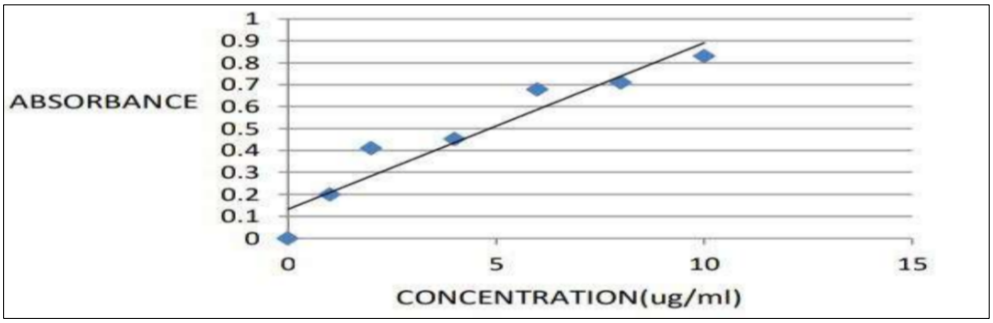

Figure 6 Standard calibration curve of HFT 0.1N Hcl

4.2. FTIR of ginger extract

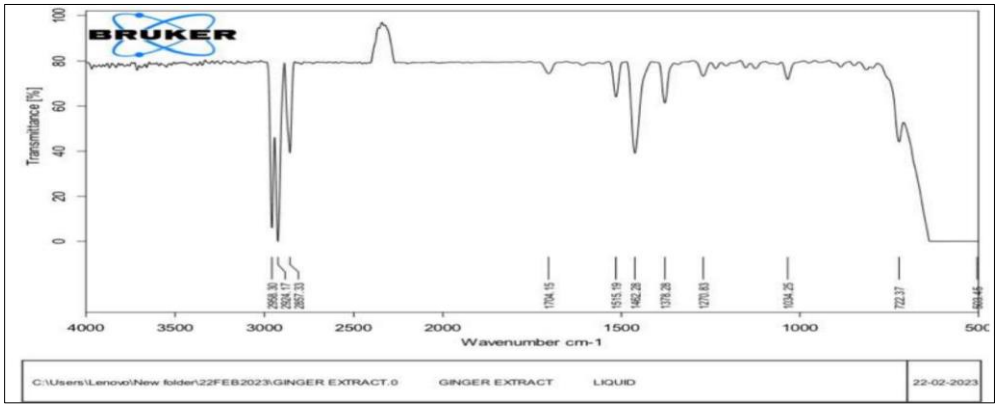

Figure 7 FTIR of ginger extract

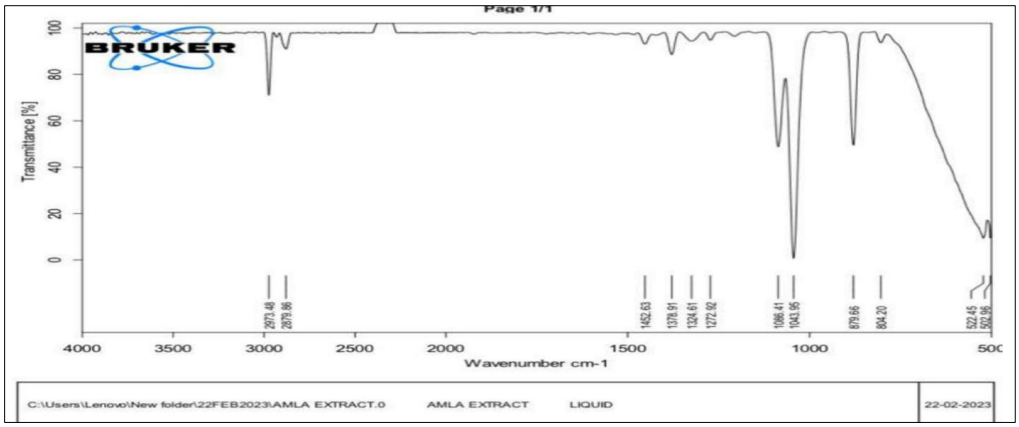

Figure 8 FTIR of Amla extract

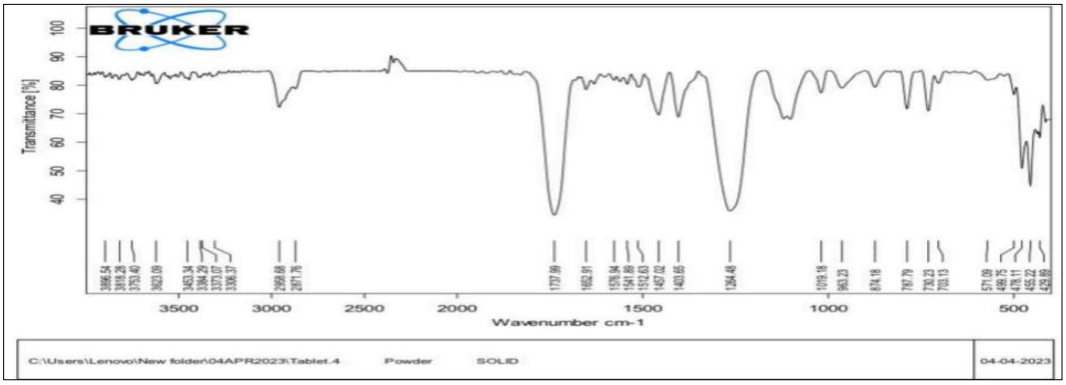

Figure 9 FTIR of ginger extract

Table 6 Vibration values

Sample	C-H stretching vibration	O-h stretching vibration
Ginger extract	29244.17	2857.33
Amla extract	2973.48	2879.86
Drug product	2958.68	2871.76

4.3. Precompressional evaluation

The pre compressional evaluation study was evaluated on HFT and the all ranges are within limit.

Table 7 Precompressional evaluation parameters

Parameters	Results
Bulk density	0.57
Tapped density	0.74
Angle of repose	11.08 degree
Compressibility index	22.90
Hausners ratio	1.2

4.4. *In vitro* dissolution data

Table 8 *In vitro* Dissolution data

TIME	% Drug dissolved F1	F2	F3
0	0%	0%	0%
10	63%	76.5	45%
20	81%	85.5%	85.5%
30	85.5%	90%	85.5%
40	86.4%	90%	90%
50	90%	94.5%	94.5%
60	94.5%	94.5%	99%

5. Discussion

In this study herbal floating tablets of ginger and amla extract were prepared by using direct compression method. Various post compression parameters viz hardness, friability, weight variation, dissolution, disintegration, and in vitro drug release were studied. The gastric floating tablets were formulated by direct compression method. This technique was used for a tablet which minimize processing steps and eliminated wetting and drying process. The physiochemical property shows satisfactory results by a tablet which are within the range of prescribed standards required investigation of the present study. Tablets were examined on the basis of weight uniformity (Denver instrument), friability (Roche friabilator), hardness (MONSANTO TYPE TABLET HARDNES TESTER), and estimation of drug content (UV-visible spectro-photometer) using calibration curve. The dissolution test was made in accordance with USP (paddle apparatus Varian DS 8000).50rpm speed, at a temperature of 37±0.5 °C in 0.1M HCL. Amount of drug release was measured in the intervals of 10, 20, 30, 40, 50, and 60 min and determined by UV-Visible Spectrophotometer (Model no: 1800) using calibration curve. All tests were made in accordance with the Indian Pharmacopeia and the United States Pharmacopeia.

5.1. Calibration curve of herbal floating tablets

The calibration curve of the herbal extract was obtained in the range of at the wave length of 240nm.

5.1.1 Formulation of herbal floating tablets

Three formulations of the herbal floating tablets were prepared according to the procedure described in the methodology different formulations used in the study.

5.1.2 FTIR studies

The spectral analysis data has shown that there were greater values for the optimized formulation mixture compared to the pure extract, so, it was concluded that there was no interaction

5.1.3 Pre-compression factors

The pre-compression data values for angle of repose were found in the range of 10.54 indicates good flow property of the mixed powder. Bulk densities and tapped densities of various formulations were found to be in the range of 0.45and 0.67respectively. Compressibility index of the prepared blends/granules fall in the range of 20.64 indicating that the blends/granules have the excellent compressibility. Hausner's ratio of the prepared blends/granules fall in the range of 1.2 indicated that the blends/granules have the required flow property and strength for compression

5.2. Post compression factors

Visual examination of tablets from each formulation batch showed circular shape

- **Hardness test:** Hardness of the three tablets of each batch was checked by Monsanto hardness tester and the data's the results showed that the hardness of the tablets was in the range of 2.5Kp/cm^2.

- **Friability test:** Friability of the ten tablets of each batch was checked by Roche Friabilator tester and the data' the results showed that the friability of the tablets was in the range of less than 1.
- **Disintegration test:** The disintegration of three tablets was observed with the help of disintegration apparatus and the data's result showed that the disintegration time of the tablets was 15minutes. Invitro dissolution studies
- **Determination of Dissolution Pattern: -** Freshly prepared test media of 900ml was placed in dissolution vessels of dissolution test apparatus USP model. Four samples of the matrix tablet of HFT (after weighing) was placed in different jar containing dissolution media and temperature was maintained at 37-0.5°C and paddle was rotated at the speed of 50rpm. At the specified time interval withdraw 5ml sample solution from each Vessel and filter. Further dilute the sample up to 10ml with dissolution medium.

Drug release = Conc. of HFTx Dilution Factor x Dissolution medium 1000 % of drug release = drug release x 100 Dose of drug

Dissolution studies were performed for all formulations. The mean values and standard deviations were calculated.

- In the first formulation we have taken ginger extract- amla extract- fenugreek mucilage- isabgolcalcium carbonate- 2gm, talc- 0.4gm, cellulose-1gm, magnesium stearate-0.1gm
- In the second formulation we have taken ginger extract- amla extract- fenugreek mucilage- isabgol- calcium carbonate-2.03gm, talc- 0.43gm, cellulose- 1gm, magnesium stearate-0.11gm.
- In the third formulation we have taken ginger extract- amala extract- fenugreek mucilage- isabgol- calcium carbonate-2.04gm, talc 0.4gm, cellulose- 1gm, magnesium stearate- 0.1gm

Conclusion

In this research work we have prepared herbal floating tablets with ginger and amla extract with different binder concentrations and disintegrating agent concentration and compared with pure drug and ginger and amla extract floating tablet. From the above discussion, among these formulations, got the better results in pre-compressional evaluations and in post compressional evolutions. The disintegration time for herbal floating tablets were to be within14mins and the percentage drug release was found to be 99% for 1 hour. Hence it was concluded that the herbal floating tablets formulations was the best formulation in our project work.

Compliance with ethical standards

Disclosure of conflict of interest

"Conflict of interest statement: None declared"

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