



## FORMULATION AND EVALUATION OF HERBAL FLOATING TABLET BRAHMI FOR PEPTIC ULCER

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### ABSTRACT

*The Development and Assessment of a Herbal Floating Tablet for Peptic Ulcer Disease. The goal of creating a herbal floating tablet is to extend the drug's duration in the gastrointestinal tract.*

*This will increase the drug's bioavailability and result in greater absorption than with a conventional dose form. Due to its gastro-retentive feature, the medicine remains at the site of inflammation for a longer amount of time, resulting in a more targeted action and fewer adverse effects than with conventional dose forms. Both industrialised and developing nations have seen a sharp rise in the usage of herbal products in recent years.*

*One of the most significant medicinal plants, Bacopa Monnieri (Brahmi), has several beneficial properties including anti-ulcer, anti-inflammatory, anti-microbial, hepatoprotective, analgesic, antipyretic, anti-bacterial, and anti-fungal properties. Due to a number of factors, peptic ulcer disease is very common in the community.*

**KEYWORDS:** Brahmi, Formulation, Quality control parameters, Evaluation

### INTRODUCTION

A gastric ulcer is a break in the mucosa of the stomach lining that extends past the muscle and is larger than 5 mm in diameter. Between 45 and 50 percent of the stomach mucosa worldwide is colonised by Helicobacter pylori. Particularly in underdeveloped countries where the socioeconomic standing is poorer and the housing is more crowded, people are immunised against this bacterium at a young age. The second most frequent cause of stomach ulcers is NSAID use. When compared to those who don't, patients who take these drugs have a relative chance of getting stomach ulcers. NSAID drugs can cause ulceration through a variety of methods. Fresh juice from the entire Bacopa Monniera plant was tested by Rao et al. for Brahmi juice showed significant anti-ulcer effect, with the exception of ethanol-induced ulcers[1].

While cell shedding (microorganism DNA/mg of protein) and mucin secretion in terms of total carbohydrates: proteins ration (TC:P), two crucial parameters of defensive factors, were significantly decreased and increased respectively, indicating enhancement of protective mucosal factors, brahmi juice was found to have little to no effect on the offensive acid-pepsin secretion. In terms of TC:P, brahmi juice increased or either showed a potential to enhance individual carbs, but it also tended to increase mucosal glycoproteins. Drug delivery systems for floating tablets float in the stomach without slowing down the gastric emptying rate because their bulk density is lower than that of gastric fluids. Herbal floating tablet has a number of benefits. Its ability to prevent ulcers[2].



**RATIONALE**

Reason behind developing such kind of formulation is to promote herbal pharmaceuticals that have fewer side effects as considering human health. This formulation allows the medicine to spend the most time in gastric juice for prolong action.

Bacopa moniera commonly known as Brahmi is an important medicinal plant that has been attributed with medicinal properties in traditional literature. Bacopa mannieri have active ingredient i.e. Bacosides which have anti-ulcerogenic activity

Floating drug delivery system has a bulk remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period. While the system is floating on gastric content the drug is released slowly at the desired rate from system. After release of drug the residual system is emptied from the stomach.

The result in an increased gastro-retention time, reduce fluctuation and reduce the dose frequency and improve patient compliance.

**MATERIALS AND METHOD**

**Table 1: List of ingredients and quantity**

Ingredients	Quantity (1tablet in mg)
Brahmi powder	250mg
Liquorice	30mg
Sodium Carbonate	70mg
HPMC 4K	60mg
Talc	10mg
Magnesium Stearate	5mg

**Procedure**

Magnesium Stearate, Sodium Bicarbonate, and Talc were also used in the formulation of all the tablets utilizing the direct compression method and a polymer called HPMC 4K. All ingredients were carefully weighed using an electronic balance after being passed through sieve no. 80. To create a consistent tablet blend, the extract, HPMC, and Sodium Bicarbonate were thoroughly blended in a mortar and pestle. Finally, the mixture was combined with talc and magnesium stearate. Using a single punch tableting machine, the tablet blend was then crushed into individual tablets after being individually weighed in accordance with the formula[3].

**Evaluation**

**Preformulation**

1) ANGLE OF REPOSE

A glass funnel with a bottom diameter of 10 mm was positioned at a height of 2 cm over a smooth, level surface. A sample of about 10gm was pushed down the funnel until the tip of the pile produced touched the bottom. The radius of the powder cone was measured after a crude circle was drawn around the pile's base. was determined using the typical radius.

$$\tan \theta = H/R \dots\dots\dots(1)$$

Where,

$\theta$  = angle of repose

H= height of pile

R= average radius of powder cone

2) BULK DENSITY

By carefully pouring 25 gm of the sample mixture through a glass funnel and into a 100 ml graduated cylinder, the bulk densities (BD) of the prepared herbal powder mixture were ascertained. It was noted how much space the sample initially occupied. Using the following equation, given as eq. 2, the bulk density was determined[3].

$$BD = \frac{\text{Weight of Granules}}{\text{Volume of Packing}} \dots\dots\dots(2)$$

3) TAPPED DENSITY

By gently pouring 25gm of the sample combination through a glass funnel and into a 100ml graduated cylinder, the tapped density (TD) of the prepared herbal powder mixture was ascertained. When a steady volume was achieved, the cylinder was tapped from a height of 2 inches, and the average of all formulations was then reported..After tapping, the sample's final volume was measured, and the tapped density was determined using the equation 3 formula [4].

$$\text{Tap Density} = \frac{\text{Weight of Granule}}{\text{Tapped Volume}} \dots\dots\dots(3)$$



#### 4) COMPRESSIBILITY

An effective empirical guide is provided by Carr's compressibility. By comparing the bulk density and tapped density, it was possible to determine the compressibility of the herbal powder mixture.

Carr's Index:  $(TD-BD/TD*100)$ .....(4)

#### 5) HAUSNER RATIO

It also illustrates the densification of the herbal powder mixture brought on by feed hopper vibration, which was computed using the equation in Equation 5.

Hauser ratio =  $\frac{\text{Tapped volume}}{\text{Bulk volume}}$ .....(5)

#### 6) DRUG EXCIPIENTS COMPATIBILITY STUDY

Every excipient utilised in the formulations was mixed with medication concentrations that were reasonable given the final dose form. Each excipient was extensively mixed with the drug extract to increase molecular interactions between the two and, if possible, speed up the reaction. Each drug's extract and excipient mixture was placed separately into vials and stored for a month under study conditions of 40°C and 75% relative humidity for two weeks to track changes. Samples were examined for physical changes after 30 days of drug extract storage with excipients in varied ratios at room temperature, however the combination of Bacopa monniera extract and polymer showed no physical changes[5].

#### 7) STANDARD CURVE

Standard curve of Brahmi was prepared in methanol at their lambda max using UV spectrophotometer.

#### EVALUATION

1. Morphological Evaluation- Taste, form, color, and odor were all noticed.
2. Tablet Dimensions- Using a calibrated vernier caliper, thickness and diameter were determined. 10 formulation tablets are examined[6].
3. Hardness- The hardness of the tablet was assessed using a Monsanto hardness tester. A compressible spring is held between two plungers in a barrel that serves as the tester's main component. A zero reading was obtained by inserting the tablet into the bottom plunger. The tablet was fractured by rotating the threaded bolt until it pushed the upper plunger up against a spring. A pointer and a gauge were placed in the barrel to measure the force as the spring compressed. The zero-force data was subtracted from the fracture force before being reported. 10 formulation tablets are examined[7].
4. Friability- Roche The Friabilator is used to gauge the tablet's physical strength. The Friabilator held 20 tablets and was operated for 100 rotations. Then the tablets were reweighed and dusted.
5. Weight Variation- 20 tablets were chosen at random. Tablets were weighed, and the average weight and % deviation were also computed. Weight average: 445 mg[8]
6. Dissolution Study- The USP type-1 (Basket apparatus) was used to carry out the dissolution research. 900ml of 0.1N HCL served as the dissolving medium. The water bath used to hold the dissolving medium was thermostatically controlled and kept at a temperature of 37.0°C. The basket contained the tablet. The spin was maintained at 100 rpm. The dissolving medium was maintained constant by replacing the 5 ml of sample at regular intervals with an equivalent volume of dissolution medium. UV Spectrophotometer analysis was used to determine the drug content[9].
7. Buoyancy Time- The floating lag time was used to determine the in vitro buoyancy. 0.1 N HCl was added to a 100 ml beaker that contained the pills. The amount of time needed for the tablet to float and ascend to the surface was calculated as floating lag time[10].



**RESULT AND DISCUSSION**

**Table 2:- CHARACTERIZATION OF POWDER**

Srno.	Parameter	Observation
1.	Organoleptic characteristics- i. Color ii. Odor iii. Taste	Brown Pungent Bitter
2.	Angle of repose	Passable
3.	Bulk density	0.5 gm/ml
4.	Tapped density	0.66 gm/ml

**Table 3:-EVALUATION OF HERBAL FLOATING TABLET**

Sr. No.	Parameter	Observation
1.	Morphological evaluation	Deep brown color Slightly bitter
2.	Dimension	10mm
3.	Hardness	4 kg/cm <sup>2</sup>
4.	Friability	Passes
5.	Weight variation	Passes
6.	Dissolution Time	8hours

**Table 4:-Weight Variation**

Weight(in mg) of 20 tablets						
444	443	442	444	442	444	442
445	442	444	444	445	445	442
442	443	443	443	443	444	442

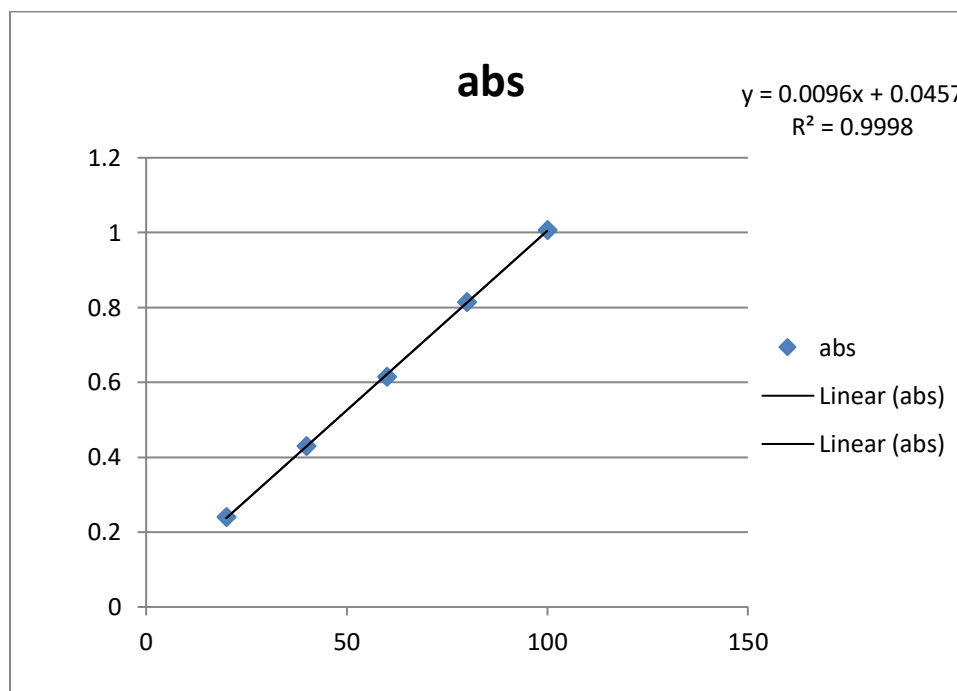
**Table 5:- Data of Dissolution Study**

Time (t) min	Abs. (y)	Conc. (µg/ml) (x)	Conc. (mg/ml)	Conc.Dilution factor(10)	Amt. Of drug Released (mg/900ml)	Amt. Of drug released (mg/5ml)	Cumulative amt. in 900 ml	%CDR
15	0.0679	2.88	0.00288	0.0288	25.9302	0.1448	26.075	10.43%
30	0.0721	3.02	0.00302	0.0302	27.2273	0.1529	27.525	11.01%
60	0.1045	6.62	0.00667	0.0667	59.6673	0.335	60.3	24.12%
120	0.1169	7.99	0.00799	0.0799	71.9123	0.4052	72.95	29.18%
180	0.1397	10.53	0.01053	0.1053	94.8763	0.5358	96.45	38.53%
240	0.1673	13.59	0.01359	0.1359	122.3838	0.6925	124.65	49.86%
300	0.1899	16.11	0.01611	0.1611	145.060	0.8230	148.15	59.26%
360	0.2057	17.86	0.01786	0.1786	160.7953	0.9155	164.8	65.92%
420	0.2276	20.29	0.02029	0.2029	182.6533	1.042	187.7	75.08%
480	0.2410	21.78	0.02178	0.2178	196.1053	1.123	202.75	80.91%



**Table 6:-Calibration Data of Brahmi**

Sr.No	Concentrations( $\mu\text{g/ml}$ )	Absorbance
1	20	0.2401
2	40	0.4298
3	60	0.6147
4	80	0.8144
5	100	1.007



**Figure 1:-Calibration chart**

## LIST OF REFERENCES

1. Singh HK, Dhawan BN. Neuropsychopharmacological effects of the Ayurvedic nootropic *Bacopa monniera* Linn.(Brahmi). *Indian Journal of Pharmacology*. 1997 Sep 1;29(5):359.
2. Tripathi KD. *Essentials of medical pharmacology*. JP Medical Ltd; 2013 Sep 30.
3. Rao CV, Sairam K, Goel RK. Experimental evaluation of *Bocopa monniera* on rat gastric ulceration and secretion. *Indian Journal of Physiology and Pharmacology*. 2000 Oct 24;44(4):435-41.
4. Goel RK, Sairam K, Babu MD, Tavares IA, Raman A. In vitro evaluation of *Bacopa monniera* on anti-*Helicobacter pylori* activity and accumulation of prostaglandins. *Phytomedicine*. 2003 Jan 1;10(6-7):523-7.
5. *Pharmacopoeia I*. Government of India ministry of health and family welfare Ghaziabad. Published by Indian Pharmacopoeia commission. 2010;1:49-83.
6. Chaudhuri PK, Srivastava R, Kumar S, Kumar S. Phytotoxic and antimicrobial constituents of *Bacopa monnieri* and *Holmskioldia sanguinea*. *Phytotherapy Research: An International Journal Devoted to Pharmacological and Toxicological Evaluation of Natural Product Derivatives*. 2004 Feb;18(2):114-7.
7. Mizokami Y, Oda K, Funao N, Nishimura A, Soen S, Kawai T, Ashida K, Sugano K. Vonoprazan prevents ulcer recurrence during long-term NSAID therapy: randomised, lansoprazole-controlled non-inferiority and single-blind extension study. *Gut*. 2018 Jun 1;67(6):1042-51.
8. Shah SH, Patel JK, Patel NV. Stomach specific floating drug delivery system: A review. *Int J Pharm Tech Res*. 2009 Jul;1(3):623-33.
9. Gaikwad VL, Bhatia MS. Polymers influencing transportability profile of drug. *Saudi Pharmaceutical Journal*. 2013 Oct 1;21(4):327-35.
10. Vohora SB, Khanna T, Athar M, Ahmad B. Analgesic activity of bacosine, a new triterpene isolated from *Bacopa monnieri*. *Fitoterapia (Milano)*. 1997;68(4):361-5.s