Research Article

Design, Development and Evaluation of a Polyherbal Floating Tablet for Gastric Ulcer

Priyanka Maisuria [a], Abhishek Joshi [b*], Sanjay Saravaiya [c] Sujal Gajjar [d], Hitiksha Patel [d], Aum Pandya [d], Sachin Narkhede [e]

[a] Assistant Professor, Department of Pharmacology, Smt BNB Swaminarayan Pharmacy College, Salvav, Vapi, Gujarat, India.
[b] Faculty of Pharmacy, Department of Pharmacology, Uka Tarsadia University, Maliba Campus, Bardoli, Gujarat, India.
[c] Assistant Professor, Department of Pharmaceutics, Smt BNB Swaminarayan Pharmacy College, Salvav, Vapi, Gujarat, India.
[d] Research Scholar, Smt BNB Swaminarayan Pharmacy College, Salvav, Vapi, Gujarat, India.
[e] Principal, Smt BNB Swaminarayan Pharmacy College, Salvav, Vapi, Gujarat, India.
***Corresponding author's E-mail:** abhishekjoshi0813@gmail.com

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ABSTRACT

An imbalance between aggressive components such as gastric juice, pepsin, bile, and Helicobacter pylori bacteria is the primary cause of gastric ulcers, which are characterized by open sores on the stomach lining and cause substantial discomfort. The primary causes of stomach ulcers include chronic NSAID usage (80% of cases), Helicobacter pylori infection (10%), and hyperacidity (8–10%) brought on by stress, alcohol, heredity, smoking, and spicy food. Antacids, proton pump inhibitors, and histamine H2 receptor blockers were the mainstays of traditional therapy regimens aimed at lowering stomach acid. Nevertheless, long-term antibiotic usage included concerns of toxicity and antibiotic resistance, and these therapies were unable to completely remove Helicobacter pylori, the primary cause of ulcers. Anti-ulcer drugs must thus be safe, efficacious, and reasonably priced. A potential treatment option are herbal medications, which have naturally occurring active compounds with anti-ulcer qualities. Phytochemicals that are known to provide gastroprotection include those found in mulberry (*Morus alba*), neem (*Azadirachta indica*), banana (Musa spp.), licorice (*Glycyrrhiza glabra*), and aloe vera (*Aloe barbadensis*). Drugs that must be absorbed in certain parts of the gastrointestinal tract can have their bioavailability increased using gastro-retentive drug delivery systems (GTDDS). The study investigated the creation of a gastro-retentive floating tablet comprising three herbal extracts for the treatment of stomach ulcers using ethyl cellulose (EC) and hydroxypropyl methylcellulose (HPMC). The physical characteristics and floating time of the tablets were examined using sodium bicarbonate and citric acid as effervescent agents, with the goal of extending gastric residency. In order to effectively treat ulcers, the goal was to create a polyherbal extract floating system in an HPMC-EC matrix with a short floating lag time and a long gastrointestinal residency that would enable persistent curcuminoid release.

Keywords: Polyherbal floating tablet, neem, mulberry, banana, gastric ulcer, gastro-retentive drug delivery system.

1 INTRODUCTION

Gastric ulcers are open sores on the stomach lining that cause scorching or dull discomfort during meals, along with nausea and vomiting [1–3]. Ulceration is produced by an imbalance between aggressive and defensive factors, including gastric juice, pepsin, bile, and Helicobacter pylori bacteria [4–6]. The two most common causes of gastric ulcers are chronic use of aspirin and non-steroidal anti-inflammatory drugs (NSAIDs), which accounts for about 80% of cases; Helicobacter pylori infection, which accounts for 10% of cases; and excess stomach acidity, or hyperacidity, which accounts for about 8–10% of cases and is caused by factors like heredity, smoking, stress, alcohol, and spicy food [7–9].

The prior treatment focused on reducing stomach acid output with the use of antacids, histamine, H2 receptor blockers, and proton pump inhibitors since it was believed that excessive gastric acid secretion was the primary cause of the gastric ulcer [10–12]. Nevertheless, Helicobacter pylori, the primary cause of stomach ulcers, could not be eradicated by those drugs. Antibiotics have the potential to eradicate Helicobacter pylori, but their long-term use is problematic since they can lead to toxicity and the development of antibiotic resistance in bacteria[13–15]. Thus, there is a critical need for anti-ulcer medications that are affordable, effective, and safe. Herbal medicines containing naturally occurring active chemicals that may have anti-ulcer properties are a promising new avenue for treating stomach ulcers. Pharmaceutical companies worldwide are shifting their attention to plant-based medications. The use of biologically active chemicals from higher plants has been crucial in the development of modern medicine for treating many ailments. Plant-derived medications have a crucial role in treating illnesses in impoverished nations globally.

GTDDS, or gastro-retentive drug delivery systems, can help increase the oral bioavailability of a variety of pharmaceuticals that have a window of absorption in a specific area of the gastrointestinal (GI) tract [16]. The goal of designing a novel oral controlled drug delivery system should be to maximize the medications' pharmacological effect at the intended location.

Several plants are renowned for their phytochemicals that combat gastric ulcers[17]. Mulberry (*Morus alba*) leaves contain flavonoids and alkaloids with protective effects on the gastric lining [18]. Neem (*Azadirachta indica*) is rich in compounds such as nimbin and azadirachtin, known for their anti-inflammatory and anti-ulcer properties [19–21]. Banana (Musa spp.) provides a polysaccharide-rich mucilage that enhances the stomach's mucosal barrier and

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prevents ulcer formation [22]. Additionally, licorice (*Glycyrrhiza glabra*) contains glycyrrhizin, which promotes mucus secretion and reduces stomach acid [23], while aloe vera (*Aloe barbadensis*) is utilized for its mucilaginous gel that soothes and heals the gastric mucosa [24]. In order to provide greater bioavailability, the medications must be retained in the stomach for a duration of three to four hours in order to cure gastric ulcers efficiently. Because it involves local drug delivery in the stomach and extends the residence length of an oral dose form there, gastric retention is thus the best method. The buoyant drug delivery system concept provides a prolonged residence period and continuous medication release [25].

In this study, the use of EC and HPMC together to manufacture a gastro-retentive floating tablet containing three extracts as the active ingredient for the treatment of stomach ulcers was examined. The effervescent agents that were utilized were citric acid and sodium bicarbonate. Investigations were conducted on the physical properties of tablets and the impact of effervescent agents on floating time for extended residence times. Thus, the goal of this study was to create a polyherbal extract floating system that is gastro-retentive in an HPMC-EC matrix. In order for the curcuminoids to release sustainably and cure stomach ulcers, the tablet is anticipated to have a short floating lag time and a long residency period in the gastrointestinal region.

2 MATERIALS AND METHODS

2.1 Materials

Raw bananas, mulberry leaves, and neem leaves were purchased at the Vapi, Gujarat, local market. The leaves of mulberry and neem were dried in a hot air oven for 48 hours at 50°C. The mashed fruit pulp was dried in a drier to make banana powder. Following drying, the product was ground up and put through a 20-mesh filter. Sigma Aldrich provided the ethyl cellulose, HPMC E15, and HPMC K4M. Chemcodyes produces the following products, which are acquired in India: magnesium stearate, citric acid, sodium bicarbonate, hexane, acetone, lactose, and talc.

2.2 Preparation of extract

2.2.1 Preparation of Neem extract

500 g of neem leaves were carefully cleaned in water, dried between 35 and 40 degrees Celsius, and then ground into a fine powder using an electric grinder. For eighteen hours, 3,000 milliliters of 96% ethanol and pulverized neem leaf were heated at 78°C in a soxhlet device. After this, a Rota Vapor (BUCHI Rota Vapor R114, Switzerland) was used to dry the ethanolic extract of neem leaf powder.

2.2.2 Preparation of Mulberry extract

Mulberry leaves (500 g) were carefully washed with water, dried at 35°C-40°C, then crushed using an electric grinder. Pulverized mulberry leaf was placed in a soxhlet device with 3,000 cc of 96% ethanol and heated to 78°C for 18 hours. The ethanolic extract of mulberry leaf powder was dried using a Rota Vapor (BUCHI Rota Vapor R-114, Switzerland).

2.2.3 Preparation of Banana extract

Banana powder (500 g) was produced using the preceding process, rinsed completely in water, and dried at 35°C-40°C. The powder was then placed in a soxhlet device containing 3,000 mL of 96% ethanol and heated for 18 hours at 78°C. The ethanolic extract of banana powder was dried with a Rota Vapor (BUCHI Rota Vapor R-114, Switzerland).

The extracts from sections 2.2.1, 2.2.2, and 2.2.3 were thoroughly combined.

2.3 Preformulation studies

Prior to compression, the powder's flow characteristics were described using Hausner's ratio, Carr's index, and angle of repose. The powder was poured through the walls of a funnel that was set such that its bottom tip was exactly 2.0 cm above a hard surface in order to calculate the angle of repose (θ). Powder was added until the lower tip of the funnel was contacted by the top point of the pile surface. The angle of repose was given by tan-1 of (height of the pile/radius of its base) [26].

2.4 Tablet Preparation

The direct compression method was used to create the floating tablets containing many herbs. According to the formulation design shown in Table No. 1, precise amounts of polyherbal extract, HPMC K4M, HPMC E15, ethyl cellulose, sodium bicarbonate, citric acid, and lactose were weighed. For fifteen minutes, the components were completely mixed. Subsequently, the precisely measured amounts of magnesium stearate and talc were added to the mixture and stirred for approximately ten minutes. After that, the mixture was compressed using a tablet compression device (ERWEKA EP-1, Germany) [27].

Table 1: Composition of Polyherbal floating tablet

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Polyherbal extract	100	100	100	100	100	100
HPMC K4M	100	150	100	-	-	-
HPMC E15	-	-	-	100	150	100
EC	100	100	150	100	100	150
Sodium Bicarbonate	100	100	100	100	100	100
Citric acid	25	25	25	25	25	25
Lactose	50	50	50	50	50	50
Magnesium stearate	15	15	15	15	15	15
Talc	10	10	10	10	10	10
Total weight	550	550	550	550	550	550

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2.5 Evaluation of tablets [28]

2.5.1 Diameter and thickness

A vernier caliper was used to measure the tablet's thickness and diameter. It's stated in millimeters. From each batch, six tablets were chosen at random, and the mean and standard deviation were computed. When creating tablets with an identical look, tablet thickness matters. Because of the variations in the powders' densities, thickness can fluctuate without affecting weight.

2.5.2 Hardness Test

A Monsanto tester was used to assess the hardness or tablet crushing strength (the force needed to break a tablet in a diametric compression). Each batch consisted of six tablets that were chosen, assessed, and the average value along with the standard deviation was noted. The hardness values' mean ± standard deviation were computed.

2.5.3 Friability Test

A friability test is used to determine how well the tablets can resist abrasion duringhandling, packaging, and transportation. A Roche friabilitor, sometimes known as a friabilator, was used to assess the friability of tablets. The friabilator was set up with ten preweighed tablets and ran for four minutes at 25 rpm. Following one hundred rotations, the tablets were removed, brushed off, and weighed again. The % friability of the tablets was calculated using the formula below.

% Friability = (Initial weight - final weight) / (Initial weight) × 100 ……. (1)

2.5.4 Weight Variation

The Indian Pharmacopeia's guidelines for the uniformity of weight testing were adhered to; nonetheless, there may be a slight variance in the weight of each tablet. As a result, the pharmacopeia permits a small amount of variance in pill weight. The weight variance is permitted to vary by the following percentage. An analytical electronic balance was used to weigh 20 tablets from each batch in order to determine the mean weight and examine weight variance. The average weight of the tablets should vary by no more than two. 11 (Table 2).

Table 2: Relationship between average tablet weight and % deviation as per IP

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

2.6 *In vitro* dissolution studies [29]

A polyherbal floating tablet release rate analysis was conducted. In vitro dissolution investigation using a USP dissolving apparatus Type II, with 900 ml of 0.1 N HCL (pH 1.2) and 50 rpm of speed maintained at 37 ± 0.5 °C. To maintain a consistent volume for drug dissolution, aliquots (5 ml) were removed at appropriate intervals and promptly replaced with an equal volume of fresh dissolution medium. After passing through a 0.45 µ membrane filter, the samples were diluted with 0.1 N HCL to the appropriate concentration.

The samples were taken out at the proper intervals and subjected to spectrophotometric analysis at 274 nm λmax using a Shimarzu double beam UV-visible spectrophotometer. This was done after filtering the samples using Whatman filter paper and using the required dilutions.

The in vitro dissolving technique was used consistently to each batch that was made. Three copies of the experiment were conducted. A standard calibration curve was used to generate an equation that was used to compute the cumulative percentage of medication release.

2.7 *Invitro* Buoyancy or floating studies[29]

Total floating time (TFT) and floating lag time (FLT) measurements were used to calculate in-vitro buoyancy. The tablet was put into a 100 ml beaker with 0.1 N HCl in it. "FLT" stands for the amount of time needed for the tablet to rise to the medium's surface and float. It is stated in minutes or seconds. The "TFT" was defined as the amount of time that the tablet continuously appears on the medium's surface. It has a h expression.

Figure 1: Floating polyherbal tablet

3 RESULTS AND DISCUSSION

3.1 Flow properties of Powder

The pre-formulation research findings were deemed good based on a variety of powder criteria. For the batches (F1–F9), the powders obtained were enough. There was no sticking, ratholing, or capping seen as the powder were flowing out of the hopper. As indicated in Table No. 3, the compressibility index and Hausner's ratio values for the powders from each batch were determined to be between 14.36 and 17.96 and 1.10 and 1.219 (<1.25), respectively. The produced granules showed good flow characteristics, as shown by all of these values.

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3.2 Diameter and thickness of tablets

Tablet diameters in all batches ranged between 10 mm. Tablet thickness in all batches ranged from 4.69 to 4.79 mm, suggesting satisfactory quality. Table 4 presents the results.

3.3 Hardness test

The hardness of all the tablets was determined to be between 5.2 kg/cm² and 5.5 kg/cm. The results were presented in Table 4.

3.4 Friability test

The friability value of none of the tablets in the collection exceeded 0.38%, which is less than 1% and suggests that the tablets have adequate mechanical resistance.

3.5 Weight variation test

The tablets have successfully passed the weight variation test, as their maximum weight variation was ±0.08%, which is within the permissible range of ± 5%. In Table 4, the results were presented.

Table 3: Flow properties of powder

Parameters	Powder blend for								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Angle of repose	34.2	35.1	35.2	34.2	35.4	34.3	35.2	35.1	34.3
Loose bulk density (g/cm^3)	0.48	0.46	0.46	0.47	0.47	0.49	0.47	0.48	0.48
Tapped density (g/cm^3)	0.51	0.53	0.52	0.52	0.52	0.55	0.51	0.58	0.59
Hausner ratio	1.12	1.22	1.23	1.22	1.21	1.19	1.16	1.18	1.2
Compressibility index (%)	15.62	17.7	17.5	17.6	14.2	14.7	14.5	17.2	16.8
Flow character	Good	Fair	Fair	Good	Good	Fair	Good	Good	Good

Table 4: Post compression parameters of tablets

	Evaluation Parameters				
	Diameter (mm)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Average Weight Variation
F1	10	4.69	5.4	0.38	499
F2	10	4.76	5.6	0.20	499
F3	10	4.72	5.3	0.32	500
F4	10	4.71	5.4	0.36	499
F5	10	4.77	5.4	0.33	499
F6	10	4.65	5.2	0.35	499
F7	10	4.58	5.2	0.35	499
F8	10	4.70	5.3	0.34	500
F9	10	4.78	5.2	0.32	499

Table 5: *In vitro* drug release of F1 to F9 Formulation

	Cumulative % Drug Release								
Time (H)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	22.37
1	39.21	13.7	15.4	25.71	20.14	31.58	17.34	23.4	29.58
2	48.32	19.32	23.54	33.84	38.27	46.57	29.91	43.2	50.7
3	62.11	21.53	31.05	40.46	45.32	54.27	37.5	49.08	57.69
4	75.57	25.21	38.35	43.62	52.34	60.58	46.69	56.62	59.75
5	84.45	28.42	44.14	47.66	58.36	68.47	53.87	61.37	66.87
6	93.62	32.21	49.56	53.42	64.70	77.15	60.99	67.40	76.34
7	99.68	38.74	52.8	59.8	74.68	85.35	66.48	73.76	78.14
8		41.53	57.56	64.32	81.34	92.45	71.54	78.08	79.06
9		46.32	63.21	70.32	85.23	97.35	77.09	84.17	80.15
10		50.38	66.12	73.63	89.56	99.15	80.14	88.93	82.33
11		54.78	69.24	77.15	92.87	100.32	83.45	93.57	85.34
12		57.24	70.59	79.32	85.64	100.23	85.27	98.27	92.24

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3.6 *In vitro* dissolution studies

For every formulation, three *in-vitro* dissolution investigations were carried out, and the dissolution graph had error bars representing the three tests' standard deviations painted on it. Over the course of the trial, every pill maintained its integrity and delivered the medication under controlled conditions. Drug release for the same quantity of sodium bicarbonate occurred sooner in nine batches of formulations (F1-F9) with an HPMC content of up to 140 mg. Out of all these formulations, the F8 formulation—which is made up of a 140:65 ratio of HPMC K4M and $NaHCO_3$—showed 23.56% drug release at one hour and 98.29% drug release at the end of twelve hours. This will meet the necessary concentration of the drug targeted to the upper part of the GIT and was therefore chosen for additional research as an optimized formulation.

3.7 *In vitro* Buoyancy of floating studies

Table 6 displays the FLT and TFT findings. The gel that is created when the polymer hydrates traps and protects the gas produced, lowering the tablet's density. As the tablet's density decreased, it became buoyant. There was a 34 to 55-second floating lag time. The formulation F8 has a minimum floating lag time of 34 s and a maximum total floating period of 12 h, according to Table 6. It was therefore considered to be the best formulation.

Table 6: Buoyancy or floating lag time and total floating time

Formulation Code	Floating Lag time (sec)	Total Floating Time (h)	Tablet shape
F1	44	5.5	Swollen and Retained integrity
F2	55	3.5	Swollen and Retained integrity
F3	50	6.5	Swollen and Retained integrity
F4	53	4.5	Swollen and Retained integrity
F5	45	6.5	Swollen and Retained integrity
F6	42	8	Swollen and Retained integrity
F7	34	10.5	Swollen and Retained integrity
F8	42	12	Swollen and Retained integrity
F9	38	11.5	Swollen and Retained integrity

4 CONCLUSION

The pre-formulation research findings demonstrated good powder characteristics for the batches (F1–F9). The powders exhibited no sticking, ratholing, or capping, and had compressibility index values between 14.36 and 17.96 and Hausner's ratio values between 1.10 and 1.219, indicating good flow properties. Tablet diameters and thicknesses were consistent, with satisfactory hardness (5.2 kg/cm² to 5.5 kg/cm²) and friability (≤0.38%). Weight variation was within the acceptable range (±0.08%).

In-vitro dissolution studies showed that all tablets-maintained integrity and provided controlled drug release. Notably, formulation F8, with a 140:65 ratio of HPMC K4M to NaHCO3, exhibited optimal performance, achieving 23.56% drug release at one hour and 98.29% at twelve hours. This formulation was chosen for further research due to its ability to maintain the necessary drug concentration in the upper gastrointestinal tract.

Additionally, F8 had the shortest floating lag time (34 seconds) and the longest total floating period (12 hours), making it the best formulation. These results suggest that F8 is a promising candidate for gastro-retentive drug delivery, providing prolonged residence time and controlled drug release for effective treatment of gastric ulcers.

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