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Formulation and Evaluation of Herbal Floating Tablet for The Management of Gastric Ulcer

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ABSTRACT

Peptic ulcer is a common gastrointestinal disorder characterized by mucosal damage in the stomach or duodenum due to an imbalance between aggressive factors such as gastric acid and protective mucosal defence. Conventional anti-ulcer drugs, although effective, are often associated with high cost and adverse effects. Therefore, the present study aimed to develop and evaluate polyherbal floating tablets as a safer and more effective alternative for gastric ulcer management. The formulation incorporated extracts of Annona squamosa with sodium bicarbonate as a gas-generating agent to enhance buoyancy and prolong gastric retention. Tablets were prepared using the direct compression method by blending plant extracts with suitable polymers and excipients. The prepared formulations were evaluated for physicochemical properties and showed satisfactory results. The floating drug delivery system demonstrated potential for prolonged gastric residence time, which may improve therapeutic efficacy and patient compliance.

Keywords: Gastric Ulcer, *Annona squamosa*, Herbal Floating Tablet, Anti-ulcer activity, Gastroretentive drug delivery system

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INTRODUCTION

Gastric ulcer is a common disorder of the gastrointestinal system characterized by the formation of lesions in the stomach lining. This condition arises due to an imbalance between damaging factors, including gastric acid, pepsin, and oxidative stress, and the protective mechanisms of the gastric mucosa. It continues to be a significant health concern because of its widespread occurrence, associated complications, and its negative effect on patient quality of life. The prevalence of gastric ulcer tends to increase with advancing age, particularly among individuals between 55 and 65 years. In severe or untreated cases, it may lead to complications such as bleeding, perforation, and gastric outlet obstruction. [1]

The development of gastric ulcer is influenced by multiple factors, including increased gastric acid secretion, weakened mucosal defense, oxidative damage, and prolonged use of nonsteroidal anti-inflammatory drugs (NSAIDs). Although conventional treatments are available and effective, their long-term use is often associated with limitations such as adverse effects, recurrence, and higher treatment costs. [2-3] these drawbacks have encouraged the exploration of alternative therapeutic strategies, especially those based on herbal medicine.

Medicinal plants are widely recognized for their therapeutic potential and comparatively better safety profile. Among these, *Annona squamosa* has been reported to possess notable gastroprotective activity. The plant contains bioactive constituents, particularly alkaloids such as O-methylarmepavine, N-methylcorydaldine, and isocorydine, which exhibit antioxidant and antisecretory properties. These compounds help reduce gastric acid secretion and inhibit the H^+/K^+-ATPase enzyme system, thereby contributing to the protection of the gastric mucosa against ulcer formation. [28]

Based on these properties, the present study focuses on the development of a polyherbal formulation incorporating hydroalcoholic extract of *Annona squamosa* for the management of gastric ulcer. In addition, a floating drug delivery system was designed to prolong gastric residence time and provide sustained release of the active constituents. This approach is expected to enhance therapeutic effectiveness, reduce dosing frequency, improve bioavailability, and promote better patient compliance. The development of such a formulation may offer a promising herbal alternative for effective gastric ulcer treatment. [30]

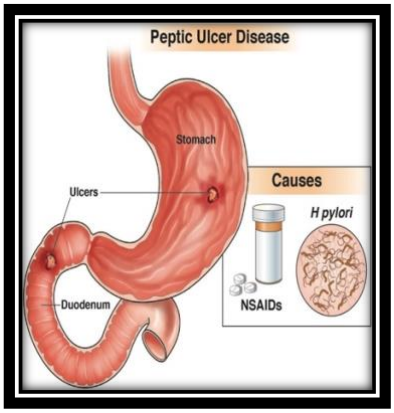


Figure 1: Peptic Ulcer

What Is Peptic Ulcer Disease?

Peptic ulcer disease is when painful sores form in the lining of the stomach, duodenum (start of the small intestine) or bowels. An ulcer can cause belly pain and, in some cases, bleeding or even a hole in the stomach or bowel. Ulcers often get better with antibiotics, acid-blocking medicines and not using non-steroidal anti-inflammatory drugs (NSAIDs) not treating an ulcer can lead to other health issues. About 4 million Americans have peptic ulcer disease.

Symptoms of peptic ulcers

Most common: pain

- The most common symptom of an ulcer is a burning pain in your stomach between your breastbone and your belly button.
- You may often feel this pain when your stomach is empty (often between meals), but it can happen at any time — even during the night.
- The pain could last from a few minutes to many hours and may sometimes wake you in the middle of the night.
- Stomach pain is often reduced by food, fluids or taking antacids.

Other possible symptoms:

While not as common as stomach pain, other symptoms could be:

- Upset stomach.
- Throwing up.
- Throwing up blood.
- Blood in the stool (black stool).
- Loss of appetite.
- Anaemia (low iron in your blood, which can make you feel weak and tired), when an ulcer bleeds without being treated.

Drug profile

Figure 2: *Annona squamosa* leaves

Table 1: Taxonomy [30]

Kingdom	Plantae
Division	Magnoliophyta
Class	Magnoliopsida
Subclass	Magnoliidae
Order	Magnoliales
Family	Annonaceae

Morphology

Character	Description
Type of leaf	Simple leaf
Arrangement	Alternate
Shape	Oblong, lanceolate, or elliptic-oblong
Size	Approximately 6–15 cm long and 2–5 cm wide
Apex	Acute or pointed
Margin	Entire (smooth margin)
Base	Rounded or slightly narrowed
Surface	Smooth and globous
Colour	Light green to dark green
Texture	Thin and membranous
Venation	Pinnate reticulate venation
Petiole	Short petiole present
Door	Aromatic when crushed
Taste	Slightly bitter

Additional Characteristics

- Young leaves are soft and pale green.
- Mature leaves become darker green and slightly leathery.
- Leaves shed during dry seasons in some climatic conditions.
- Crushing the leaves releases a characteristic herbal door due to volatile constituents.

Microscopic Features of Leaf

- Presence of epidermal cells with cuticle
- Normocytic stomata
- Calcium oxalate crystals
- Xylem vessels
- Fibbers and parenchymatous cells

Phytochemical investigations of *Annona squamosa*

Phytochemical investigations of *Annona squamosa* (commonly known as custard apple or sugar apple) leaves have revealed a wide spectrum of bioactive constituents with notable medicinal potential. The plant, belonging to the family Annonaceae, has been traditionally used to treat various ailments, including diabetes, inflammation, and infections. Leaf essential oil has been found to contain 59 chemical compounds, with a high concentration of terpenes and sesquiterpenes—particularly β-caryophyllene (31.1%), δ-adenine, α-murolene (5.5%), and α-cardinal (4.3%) (Kaur et al., 2015). Additionally, isoquinoline alkaloids such as dopamine, salsolinol, and coclaurine have been identified in both leaves and stems, along with other alkaloids like atropine, roemerine, and norisocoryline. [11] acetogenins—annoreticulin and isoannoreticulin—isolated from the leaves have demonstrated selective cytotoxicity against certain human tumor cells. Volatile and aromatic compounds, including borneol, camphor, carvone, eugenol, farnesol, geraniol, limonene, linalool, and methane, have also been reported (Patel et al., 2008). Moreover, the presence of flavonoid glycosides such as rhamnoside and quercetin-3-glycoside contributes to the plant's antioxidant and therapeutic properties. Phytochemical screening of extracts prepared using solvents like methanol, ethanol, chloroform, and water has consistently confirmed the presence of major compound classes such as alkaloids, flavonoids, tannins, saponins, glycosides, phenols, terpenoids, and steroids. These constituents are associated with diverse biological activities, including antimicrobial, antioxidant, anti-inflammatory, and anticancer effects. Advanced analytical techniques such as UV-Vi's spectroscopy, HPLC, GC-MS, and FTIR are commonly employed to further characterize and quantify these compounds. Overall, the phytochemical richness of *Annona squamosa* leaves supports their traditional use in herbal medicine and indicates strong potential for pharmaceutical and therapeutic applications. [18]

Applications

Antimicrobial activity

Annona squamosa L., commonly known as custard apple, has demonstrated significant antimicrobial potential, with various plant parts—particularly the stem bark, leaves, and seeds—exhibiting activity against a wide spectrum of microorganisms. [23] Methanolic extracts of the stem

bark showed notable *in vitro* antibacterial activity against both Gram-positive (*Bacillus coagulans*, *Bacillus subtilis*, *Staphylococcus aureus*, *Staphylococcus epidermidis*) and Gram-negative (*Escherichia coli*, *Vibrio alginolyticus*) bacterial strains. Flavonoids isolated from aqueous extracts not only exhibited antimicrobial effects against common microbial contaminants of pulses but also demonstrated 80% insecticidal activity against *Callosobruchus chinensis* at a concentration of 0.07 mg/mL. [3]

Antioxidant property

Annona squamosa, commonly known as custard apple or sugar apple, has demonstrated significant antioxidant activity due to its rich phytochemical composition. Various parts of the plant—including the leaves, fruit pulp, seeds, and bark—contain bioactive compounds such as flavonoids, phenolic acids, tannins, alkaloids, saponins, and acetogenins. Among these, flavonoids and phenolic compounds are primarily responsible for its antioxidant effects. Extracts prepared using solvents such as methanol, ethanol, and water have shown strong antioxidant potential, particularly those derived from the leaves and fruit pulp. [13] The antioxidant activity of *Annona squamosa* has been evaluated using several in vitro assays, including DPPH (2,2-diphenyl-1-picrylhydrazyl), ABTS (2,2′-azinobis (3-ethylbenzothiazoline-6-sulfonic acid)), FRAP (Ferric Reducing Antioxidant Power), and hydroxyl radical scavenging tests. Methanolic leaf extracts have demonstrated high free radical scavenging activity, often comparable to standard antioxidants like ascorbic acid. [13] The fruit pulp, which is rich in vitamin C and phenolic compounds, also contributes significantly to antioxidant activity. Methanol and aqueous extracts of the pulp have shown scavenging effects on DPPH, lipid peroxidation, nitric oxide, superoxide, and hydroxyl radicals. [23]

Anti-inflammatory effect

Annona squamosa (custard apple) demonstrates strong anti-inflammatory potential, attributed to its diverse phytochemical constituents such as flavonoids, alkaloids, saponins, and tannins. These compounds suppress inflammation by inhibiting the production of pro-inflammatory mediators, including prostaglandins, cytokines, and nitric oxide. Experimental investigations using animal models have shown that extracts of Annona squamosa leaves and seeds effectively reduce edema and inflammatory responses induced by carrageenan, a standard phlogiston agent used to evaluate anti-inflammatory activity. Carrageenan triggers the release of mediators like histamine and serotonin during the initial phase, kinas during the intermediate phase, and prostaglandins in the late phase, collectively contributing to the inflammatory process. Inflammation, characterized by cellular activation and cytokine release, underlies the pathogenesis of various diseases. [26]

Antiulcer activity

The anti-ulcer activity of Annona squamosa has been extensively studied using various experimental models, including cold restraint, pyloric ligation, aspirin-, alcohol-, and histamine-induced gastric and duodenal ulcers. Twelve compounds isolated from the twigs of Annona squamosa were evaluated, showing significant protection against ulcer formation. The chloroform and hexane fractions of the plant demonstrated notable anti-secretory activity by reducing free and total acidity, pepsin content, and plasma gastrin levels. These effects were further confirmed through in vitro inhibition of H^+/K^+-K-ATPase activity. [13] Active constituents such as (+)-O-methylarmepavine, N-methylcorydaldine, and isocorydine possess potent antisecretory properties that help protect against peptic ulceration. Similarly, the leaf extract of Annona squamosa exhibited protective effects against aspirin-induced gastric ulcers, supporting its therapeutic potential as a natural anti-ulcer agent. [23]

MATERIALS AND METHOD

Collection plant material: The biological source of custard apple leaves is *Annona squamosa L.* Family - Annonaceae.

Authentication of plant material:

The Authentication of leaves was done from Department of Botany, Ministry of Environment Forest & Climate Change Botanical Survey of India Western Regional Centre / 7- Koregoan Road Pune

Preparation of Extract by Soxhlet Method

The leaves of *Annona squamosa* were washed thoroughly with water to remove dust and foreign particles and then shade-dried at room temperature. The dried material was ground into a coarse powder using a mechanical grinder and passed through a suitable sieve to ensure uniform particle size. [19]

Figure 3: Dried Powder

The powdered plant material was extracted using a Soxhlet apparatus with a hydroalcoholic solvent system consisting of ethanol and water (70:30). Extraction was carried out at a controlled temperature range of **60–80°C** for multiple cycles until complete exhaustion of the plant material was achieved. [19]

Figure 4: Soxhlet Apparatus

After extraction, the obtained liquid extract was filtered and concentrated by gentle heating at 50 ± 5°C until a thick, semi-solid mass was formed.

Figure 5: Concentrate Extract

The concentrated extract was then dried to remove residual moisture and stored in an airtight container for further formulation studies. [1-2]

Figure 6: Dried sample

Preformulation studies

Organoleptic properties [10]

Characters	***A.squamosa* leaf**
Size	10-15 cm long and 3-35 cm wide
Shape	Alternate, bilateral, ovate- lanceolate
Venation	Reticulate
Apex	Acute
Base	Asymmetric
Margin	Simple, empirical
Colour	Light green both the surface
Odour	Unpleasant
Taste	Bitter, mucilaginous

Bulk Density:

Bulk density (BD) of the powder blend was determined using a standard method. A 25 g sample of the powder blend was carefully introduced into a 100 mL measuring cylinder without disturbing the powder bed. The initial volume occupied by the powder was noted, which represents the untapped volume. Bulk density was then calculated using the following formula. [1-2]

BD = Weight of powder blend/ Untapped volume of the packing

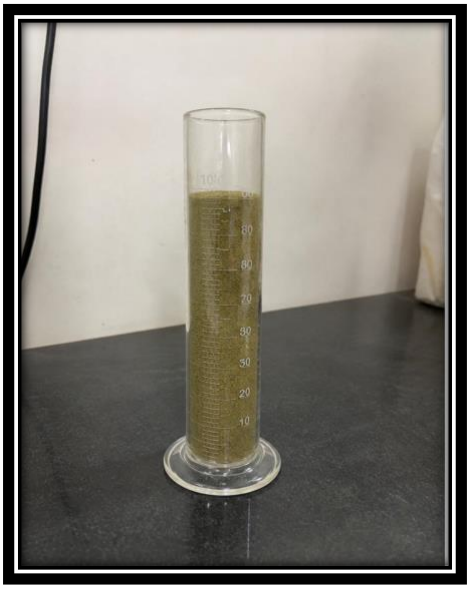


Figure 7: Bulk Density

Tapped Density:

Tapped density (TD) was measured by subjecting the same measuring cylinder containing the powder blend to mechanical tapping. The cylinder was allowed to fall freely from a height of approximately 2.5 cm onto a hard surface at one-second intervals. Tapping was continued until no further change in volume was observed. The final volume obtained after tapping was recorded as the tapped volume. Tapped density was calculated using the formula:

TD = Weight of powder blend/Tapped volume of the packing

Figure 8: Tapped density

Carr's Compressibility Index:

Carr's Compressibility Index was determined to evaluate the flow properties and compressibility of the powder blend. It was calculated based on the bulk and tapped density values using the

following equation:

Carr's Index (%) = [(TD-BD) x 100]/ BD

Hausner's Ratio:

Hausner's ratio is another parameter used to assess powder flow characteristics. It was calculated as the ratio of tapped density to bulk density using the formula:

Hausner's Ratio = Tapped density (TD)/ Bulk density (BD)

Angle of Repose:

The angle of repose was determined by the funnel method to assess the flow behaviour of the powder blend. A known quantity of powder was placed in a funnel, and the height of the funnel was adjusted so that its tip just touched the apex of the powder heap. The powder was allowed to flow freely onto a flat surface, forming a conical pile. The height (h) and radius (r) of the cone were measured, and the angle of repose (θ) was calculated using the equation:

$$\mathbf{Tan\ (\theta) = \ h/\ R}$$

Where, h and r are the height and radius of the powder cone

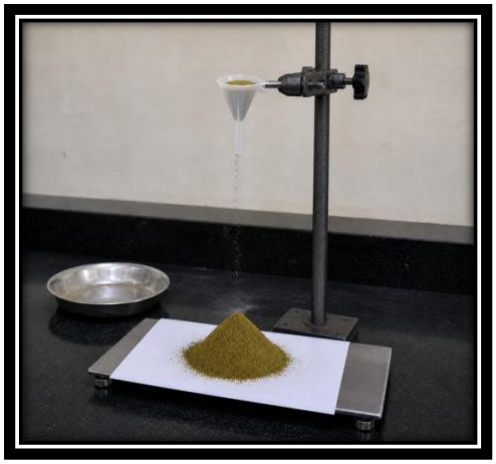


Figure 9: Angle of repose

Phytochemical Test

Test for Alkaloids:

Qualitative analysis for alkaloids was carried out using standard chemical tests. Approximately 0.5 g of the powdered sample was extracted with 5 mL of 1% hydrochloric acid and then filtered to obtain a clear solution. The resulting filtrate was subjected to the following tests [17]

Dragendorff's Test:

To 1 mL of the prepared filtrate, a few drops of Dragendorff's reagent were added. The development of an orange to reddish-brown precipitate was considered indicative of alkaloids.

Mayer's Test:

A portion (1 mL) of the filtrate was treated with 2–3 drops of Mayer's reagent. The formation of a cream or pale-yellow precipitate suggested the presence of alkaloids.

Wagner's Test:

To 1 mL of the filtrate, 2–3 drops of Wagner's reagent were added. The appearance of a reddish-brown precipitate indicated a positive result for alkaloids.

Hager's Test:

A small amount of Hager's reagent was added to 1 ml of the filtrate. the formation of a yellow crystalline precipitate was taken as evidence for the presence of alkaloids.

Tannic Acid Test:

To 1 mL of the acidic filtrate, a few drops of 10% tannic acid solution were added. The formation of a buff-coloured or pale precipitate indicated the presence of alkaloids.

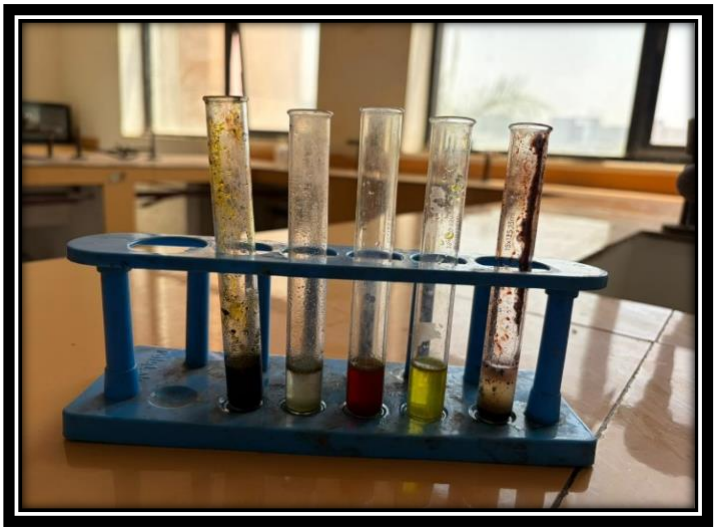


Figure 10: Chemical Test

Preparation of Floating Tablets:

Floating tablets were formulated by the direct compression technique. All raw materials were passed through an 80-mesh sieve to obtain uniform particle size and ensure proper mixing. Annona squamosa leaf extract (100 mg per tablet) was used as the active pharmaceutical ingredient. Hydroxypropyl methylcellulose (HPMC K100M) and Carbopol were employed as hydrophilic matrix-forming polymers. Sodium bicarbonate was incorporated as a gas-generating agent to impart buoyancy, while lactose was used as a diluent.

The plant extract was initially dissolved in isopropyl alcohol to facilitate uniform distribution within the formulation. This solution was gradually blended with the required quantities of polymers, Lactose, and sodium bicarbonate using gentle trituration in a mortar and pestle until a

homogeneous mixture was obtained. Subsequently, talc and magnesium stearate were added as glidant and lubricant, respectively, and mixed thoroughly Mortal Pestle. [19]

The prepared blend was directly compressed into tablets using a multi-punch tablet compression machine equipped with 12 mm flat-faced punches.

Figure 11: Tablet Punching Machine

Table 4: Formulation of floating tablets with different amount of polymer [19]

Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Herbal Extract	100	100	100	100	100	100	100	100	100
HPMC K100	40	60	80	40	60	80	40	60	80
Carbopol	20	20	20	20	20	20	30	30	30
Sodium bicarbonate	15	15	15	20	20	20	25	25	25
Talc	5	5	5	5	5	5	5	5	5
Magnesium stearate	4	4	4	4	4	4	4	4	4
Lactose	66	46	26	61	41	21	46	26	5
Total(mg)	250	250	250	250	250	250	250	250	250

Figure 12: Mixing of Ingredients

Figure 13: Batches

Figure 14: Herbal Floating Tablet

Evaluations Test

Weight Variation Test:

Twenty tablets from each formulation were individually weighed using a Sartorius electronic balance. The average weight was calculated, and the results were evaluated according to official pharmacopeia guidelines. [19]

Table 5: Weight variation table

Sr.No	Individual tablet Weight(mg)	Average tablet weight(mg)	Deviation(mg) = (W- avg)	% Deviation
1	240	250	-4.5	-1.84%
2	238	250	-6.5	-2.66%
3	235	250	-9.5	-3.88%
4	250	250	+5.5	+2.25%
5	247	250	+2.5	+1.02%
6	248	250	+3.5	+1.43%
7	247	250	+2.5	+1.02%
8	246	250	+1.5	+0.61%
9	245	250	+0.5	+0.20%
10	249	250	+4.5	+1.84%

Hardness Test:

The mechanical strength of the tablets was assessed by measuring the hardness of five tablets using a Pfizer hardness tester. The mean hardness value was then calculated. [2]

Figure 10: Hardness tester

Table 6: Hardness

Sr no	Hardness
1	2.6
2	2.9
3	2.8
4	3.0
5	3.5

Calculation:

Average hardness = (2.6 + 2.9 + 2.8 + 3.0 + 3.5)/ (5)

= (14.8)/ (5)

= 2.96

Thickness Measurement:

Tablet thickness was determined using a Vernier calliper. Five tablets were measured, and the average thickness was reported.

Friability Test:

Friability was evaluated using a Roche friabilator. A pre-weighed sample of tablets (W_0), typically 10 tablets, was placed in the apparatus and rotated for 100 revolutions. After dedusting, the tablets were reweighed (W). The percentage friability was calculated

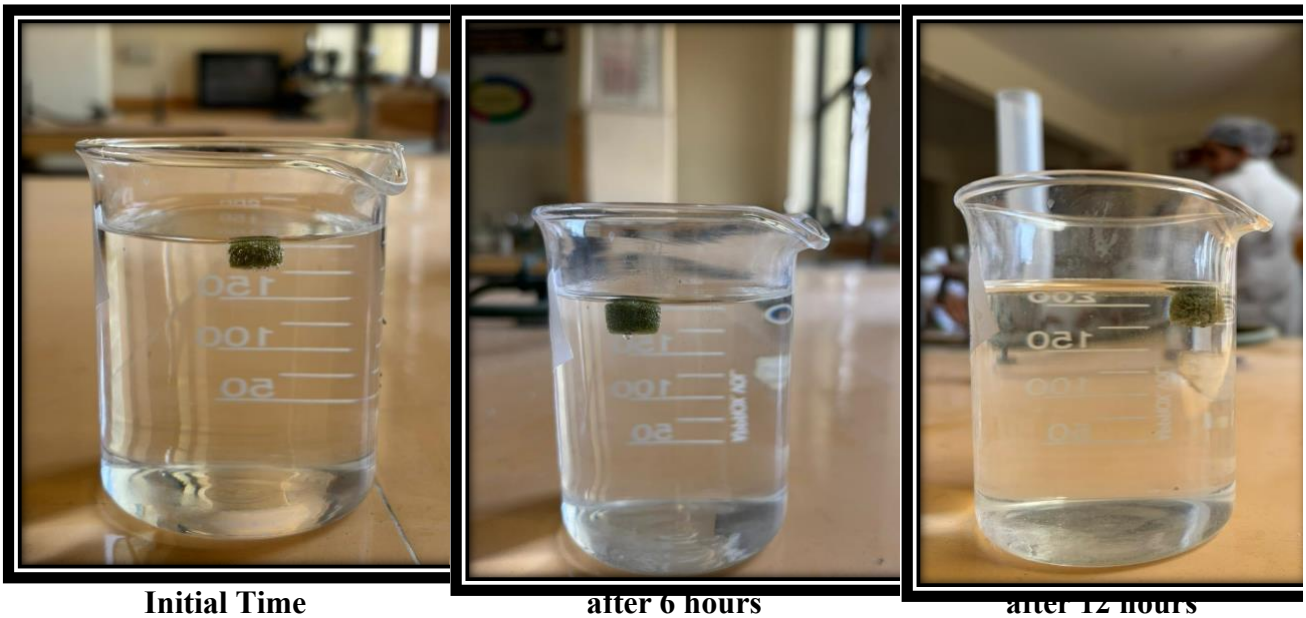
Figure 11: Friabilator

Calculations:

Friability (%) = W1-W2 / W1 * 100

= 2.357-2.341/ 2.357*100

= 0.67%



Initial Time after 6 hours after 12 hours

Figure 12. Floating Time of Tablet

Floating time of tablet

Floating behaviour of the tablets (In Vitro buoyancy studies) Floating 7 lag time and duration of floating of tablets are as shown in Table 5 Sodium bicarbonate was used as a gas-generating agent in order to float the tablet. The sodium bicarbonate induces CO2generation in the presence of dissolution medium (0.1 N HCl). The gas generated is trapped and protected within the gel formed by hydration of the polymer, thus decreasing the density of the tablet below 1 gm/mL, and the tablet becomes buoyant. Duration of floating for all batches was up to 12 hr

Swelling index

In vitro buoyancy study Swelling index of all floating matrix tablets are as shown in Concentration of HPMCK100M polymer increased, swelling index was increased. [19]

Table 7: Swelling Index

Batch code	Floating lag time (min)	Duration of floating(hr)	Swelling index
F1	2.5	12	2.13
F2	1.8	12	2.32
F3	1.9	12	1.89

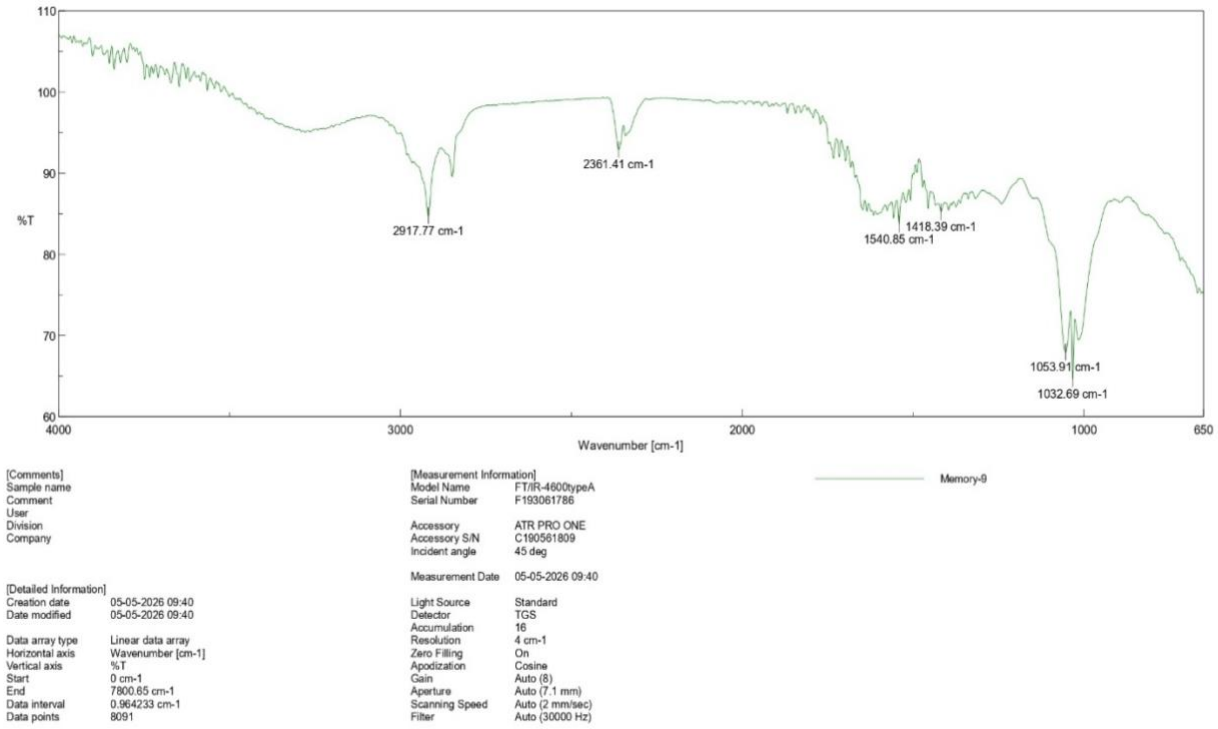
FTIR (Fourier Transform Infrared Spectroscopy)

FTIR in herbal floating tablets stands for Fourier Transform Infrared Spectroscopy. It is mainly used for drug–excipient compatibility studies and identification of functional groups in herbal formulations.

In herbal floating tablet research, FTIR helps confirm that the herbal extract does not chemically interact with polymers or excipients like HPMC, Carbopol, sodium bicarbonate, xanthan gum, etc.

Purpose of FTIR in Herbal Floating Tablets

1. Identify phytoconstituents
   - Detects functional groups such as:
     - O–H (alcohol/phenol)
     - C=O (carbonyl)
     - N–H (amine)
     - C–H stretching
2. Drug–polymer compatibility
   - Confirms no interaction between herbal drug and excipients.
   - Retention of characteristic peaks indicates formulation stability.
3. Stability evaluation
   - Used before and after formulation to ensure the herbal drug remains stable during compression and storage.



The FTIR spectrum shows characteristic absorption peaks at approximately 2917.77, 2361.41, 1540.85, 1418.39, 1053.91, and 1032.69 cm^{-1}**.** These peaks indicate the presence of functional groups commonly found in herbal constituents and excipients used in floating tablet formulations.

Table 8: FTIR

Peak (cm^{-1})	Functional Group	Possible Interpretation

2917.77 cm^{-1}	C–H stretching	Presence of aliphatic hydrocarbons (alkanes), indicating organic compounds/polymeric chains
2361.41 cm^{-1}	O=C=O stretching / atmospheric CO_2	Usually attributed to absorbed carbon dioxide
1540.85 cm^{-1}	N–H bending / C=C	Indicates amide group or aromatic constituents present in herbal extract
1418.39 cm^{-1}	C–H bending / O–H bending	Suggests phenolic compounds or carboxylate groups
1053.91 cm^{-1}	C–O stretching	Presence of alcohols, ethers, or polysaccharides
1032.69 cm^{-1}	C–O–C stretching	Indicates glycosides/carbohydrate-related constituents and polymeric materials

RESULTS AND DISCUSSION

Present investigation was evaluation of polyherbal formulation (floating tablet) of annona squamosal leaves extract, this all are traditional Ayurveda herbal drugs. The popularity of this drug is related to several beneficial properties, including, proven efficacy in controlling gastric and abdominal disorders. Standardization of this drugs was done using pharmacognostic, physicochemical parameters, preliminary photochemical quantification IJIRT 150403 of active investigation, constituents, and pharmacological investigation. Hydro alcoholic extract showed good in vivo anti-ulcer activity leaves may be due to cytoprotective, antisecretory and antioxidant potential of phytoconstituents present in the extract. Annona squamosa reduces gastric acidity, pepsin and gastrin level and inhibits H+-k+ ATPase pump. By decreases acid and pepsin secretion and increases mucin. Developed floating tablet were prepared by using hydroalcoholic extract of specific part of plant and Floating tablets was prepared by direct compression method using HPMC K100M and Carbopol as polymer, Sodium bicarbonate as a gas generating agent. The floating tablet remains up to12 hr. By selecting a suitable composition of polymer, the desire drug dissolution profile can be achieved. Development of sustained release formulation of can be advantageous, that can provide prolong gastric retention and increase efficacy of the dosage form

CONCLUSION:

The study successfully formulated and evaluated herbal floating tablets of Annona squamosa for the treatment of gastric ulcers. The tablets exhibited satisfactory physicochemical characteristics, including uniform weight, adequate hardness, low friability, and consistent thickness, confirming their stability and quality. The formulations showed an appropriate floating lag time and prolonged

buoyancy, ensuring extended gastric retention, which is essential for enhancing the local therapeutic effect in the stomach.

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