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Development and Characterisation of Poly-Herbal Antacid Floating Tablets

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ABSTRACT:

One of the most prevalent Gastrointestinal issue of our time, gastric ulcers are open sores that form on the Inside of the stomach's mucosal lining and effect about 10% of the global population. Due to the breakdown of the equilibrium between the gastric mucosa's natural defence mechanism , aggressive factor (such as oxidants and free radicals)and exogenous factor (such as H.pylori infection, alcohol use ,NSAID)the disorder is multifactorial and complex. In the modern era, H2 histamine, proto- pump inhibitors ,ulcer protectants, antiulcer medication used to treat and prevent GUs.for the treatment of antiulcer activity poly herbs are used for treatment like triphala powder , pumpkin seed powder,black cumin seed powder,black resin powder all having the gastrointestinal protective action and also soothes the mucosal lining of stomach. Floating tablets prepared by the direct compression method to increase the residence time of drug in the stomach.Aqueous extract is prepared by Maceration technique and excipients sodium bicarbonate, HPMC K4H, sodium CMC, citric acid is added and mixed properly with mortar and pestle. Evaluation is performed like pre-compression evaluation,post-compression evaluation, floating lag time and total floating time is evaluated.

KEYWORDS: Antacid, H.pyloi, floating tablets, Cucurbita maxima, Terminalia bellerica, Emblica officinalis, Terminalia chebula, Nigella sativa, Trigonella foenum graceun, Vitis Vinifera, Foeniculum vulgare Miller

Introduction:

In this modern era, the risk of developing serious diseases is rising due to unhealthy and contemporary lifestyle. Studies revealed that Gastric and Peptic Ulcer Disease (PUD)are the commonly developed acid-induced abrasions, generally in the stomach and proximal duodenum.

(1). Peptic ulcer frequency and complications vary by time and region. The highest incidence includes 80% for bleeding ulcers and 12% for perforated ulcers, affecting about 140 per 100,000 people. Epigastric pain typically begins 15–45 minutes after eating, while duodenal ulcers cause pain a few hours post-meal due to increased pepsin secretion.

(2). Duodenal ulcers are four times more frequent in men than epigastric ulcers. The pathophysiological factors associated with peptic ulcers are NSAIDS, Helicobacter pylori (H.pylori), tobacco consumption

.**(3).**About 90% of ulcers are caused by H. Pylori, with prevalence varying by ethnicity and region. It infects around 10% of people in rural and Western countries, and over 50% in developing nations, though few show symptoms. Due to its link to gastric cancer, H. Pylori should be treated with appropriate medications**.**

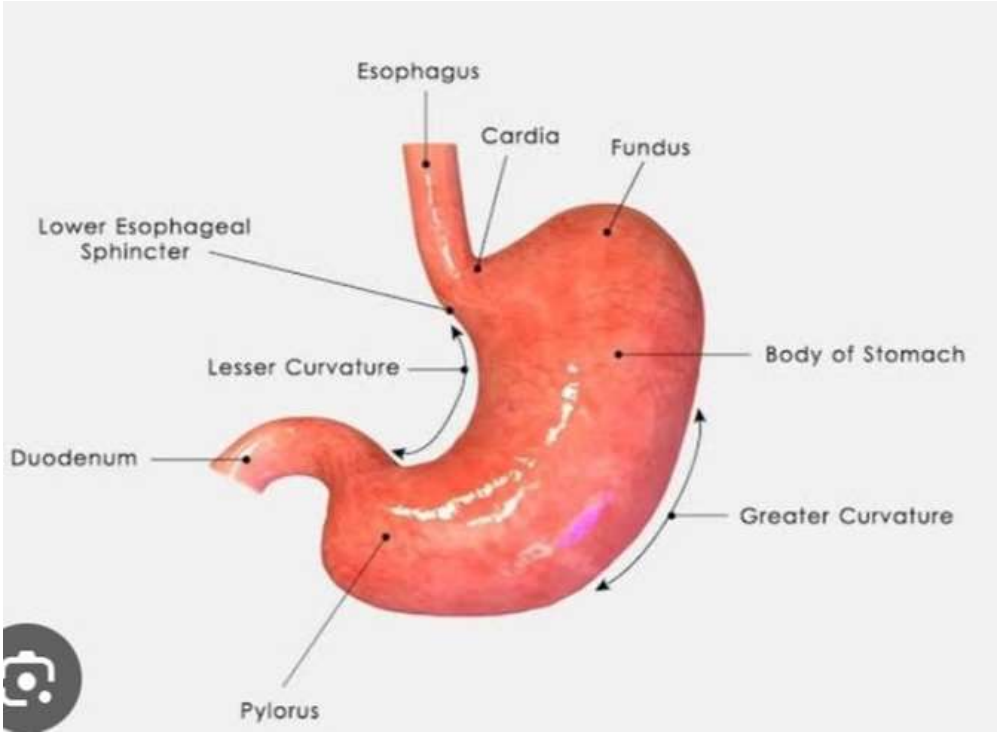
(4).NSAIDs like diclofenac and aspirin secondary risk factors of gastric ulcer. Peptic ulcer disease varies according to the age groups: 22% in 0 Syrs,55% in 6-10yrs and 86% in 11- 20yrs.b]

(5). Diagnosis of peptic ulcer can be assessed by urease test which is rapid and easily available, but not reliable alone . invasive teat like endoscopy, histopathology and non-invasive tests like stool antigen test, urea breath test, urinary,and saliva antibody test are considered Diagnostic gold standards for peptic ulcer. Clinically, gastric ulcers can be diagnosed by X-Ray or endoscopy to identify the exact location and size. Suppression of acid secretion is essential for the prevention of gastric cancer development

(6). Another pharmaceutical approach is gastro- retentive systems (hydrogels, floating, bioadhesive, and swellable)which control the delivery of drugs to the site of action.Various plants have antioxidant activity,which helps in retaining the peptic acid level showing its gastro- protective action.Phytoconstituents present in medicinal plants such as flavanols (quercetin, rutin, and Gingerol), flavones (apigenin, luteolin), anthocyanidins, isoflavones (daidzein, genistein),tannins (gallic acid,catechin), saponins (glycyrrhizin),lignin, hydrodynamics and phenolic acid have therapeutic significance." Flavonoids work on ulcers in different mechanistic ways, including reduction in oxidative stress by scavenging property, elevating mucus production in the stomach, inhibiting the growth of H. Pylori. **(7).**

Review of disease:

General anatomy of stomach:



Stomach is a J-shaped cylindrical organ whose upper part is oesophagus and lower part is connected to duodenum. Stomach consists of convex curvature which extends to the liver and concave border which runs to the abdominal wall.

Table 1: Invasive diagnostic test

Rapid urease test	Rapid,cheap	Low sensitivity(>85%)	Not a confirmation test for eradication
Histology	Sensitive	Time consuming	Can cause false error
Microbiological culture	Antibiotic testing	Time consuming	No sensitivity
Polymerase chain reaction	Susceptible testing	Not widely available	No standardization method available
Endoscopy biopsy	Large scale diagnosis	Expensive	Sensitivity(90%),indicated in severe chronic condition

Table 2: Non-invasive diagnostic test

Test	**Advantages**	**Disadvantages**	**Comments**
Urea breath test	Initial diagnostic test	Patient non- compliance, costly	Sensitivity (95- 100%),used to confirm PPI therapy
Serology	Initial diagnostic test	Lack-sensitivity	Not used as confirmatory test, used for population study
Stool antigen test	Cheap	Inconvenient	Used to confirm therapy, sensitivity (90-98%)
Rapid urine test and ELISA	Sensitive	More expensive	Not used as confirmatory test

Preparation of floating tablets:

Direct compression

Weigh 100mng of Extract in mortar and pestle, Add Excipients in appropriate quantity (15(F Sodium bicarbonate, 150mg of HPMC K4H, 75mg of sodium CMC and 75mg of citric acid). Pass all the ingredients through a sieve #60 for uniform size distribution. By properly in mortar and pestle with continuous stirring in single direction. The mixed pov then compressed into tablets using a tablet press.

Sr.no.	**Content**	**Quantity**	**Role of ingredients**
1	Herbal extract	100mg	Antacid,Anti- ulcer, Antioxidant
2	Sodium bicarbonate	150mg	Induced carbon dioxide generation
3	HPMC K4H	150mg	Polymer
4	Sodium CMC	75mg	Polymer
5	Citric acid	75mg	Effervescent agent, ensure buoyancy of tablet
6	Talc	1%	Lubricant
7	Magnesium stearate	0.5%	Lubricant

Formulation of herbal floating tablets:

Sr.no.	Material required	Quantity to be wieghted	Batch 1	Batch 2	Batch 3	Batch 4 (final batch)
1	Poly herbal extract	100mg	70mg	85mg	90mg	100mg
2	Sodium bicarbonate	150mg	100mg	125mg	140mg	150mg
3	HPMC K4H	150mg	75mg	135mg	120mg	150mg
4	Sodium CMC	75mg	80mg	60mg	70mg	75mg
5	Citric acid	75mg	65mg	75mg	60mg	75mg
6	Talc	1%	1%	1%	1%	1%
7	Magnesium stearate	0.5%	0.5%	0.5%	0.5%	0.5%

Pre-compression parameters

1. **Bulk density**

Bulk density=M/Vo

Where, M =mass of the powder Vo =bulk volume of the powder.

2. **Tapped density:** 30gm of powder was introduced into a clean, dry 100 ml measuring cylinder. The cylinder was then tapped several times (100)from a constant height and the tapped volume was read. It is expressed in gm/ml and is given by:

Tapped density=M/Vt

Where, M =mass of the powder

Vt= final tapping volume of the powder.

3. **Angle of repose (0):** It is defined as the maximum angle possible between the surface of the pile of the powder and the horizontal plane. Fixed funnel method was used. A funnel was fixed with its tip at a given height h,above a flat

horizontal surface to which a graph paper was placed. Powder was carefully poured through a funnel till the apex of the conical pile just touches the tip of the funnel.

Angle of repose Ø= tan (h/r) Where, h=height of the pile R=radius of pile

4. **Compressibility Index (Carr's Index):** Compressibility Index is used as an important parameter to determine the flow behaviour of the powder. It is indirectly related to the relative flow property rate, cohesiveness and particle size. Carr's index can be represented

By equation:

Compressibility index (%)=(Tapped density-Bulk Density) X 100 / Tapped density

5. **Hausner's ratio:** Hausner's ratio is used to predict the followability of the powders. This method is similar to compressibility Index. Hausner's ratio can be represented

By Equation

Hausner's ratio=Tapped density / bulk density

Post-compression parameters

1. **Shape**, **Thickness and Dimensions**: Six tablets of each batch were selected and measured for thickness and diameter using vernier callipers. The extent to which the thickness of each tablet deviatedfrom+5% Of the standard value was determined.

6. **In-vitro drug release study:** The release rate was determined using USP Dissolution Testing Apparatus II (Paddle type). The dissolution test was performed using 900 ml of 0.1N HCI, at 37+0.5°C and 50 rpm. Aliquot volume was withdrawn from the dissolution apparatus hourly for 8hr, and the samples were replaced with fresh dissolution medium.after filtration and suitable dilution the amount of drug release was determined from the calibration curve.

7. **Evaluation of acid neutralizing capacity (In-vitro)**:The in-vitro model the acid neutralizing capacity of an antacid is the amount of hydrochloric acid that it can Neutralize. 30.0 ml of 1.0 (N) hydrochloric acid volumetric standard (VS) is added into the aqueous extract of polyherbal mixture drug (500mg),the standard antacid Rantac with continuous stirring with the magnetic stirrer for 15 min accurately. After this, titration is started Immediately and the excess hydrochloric acid is titrated with 0.5N sodium Hydroxide. Compare the reading of herbal drug tested and the standard drug Rantac.

8. 15ml water+ 50Omg herbal drug + 30ml 1.0N HCL -Continuous Stirring-Start titration Using pH meter-Excess/ un-neutralized HCL Is titrated with 0.5N NAOH

Results and discussion:

Percentage yield of the prepared extract

Weight of porcelain dish with extract-weight of empty porcelain dish X100

Weight of empty porcelain dish

429.72-326,93 X 100

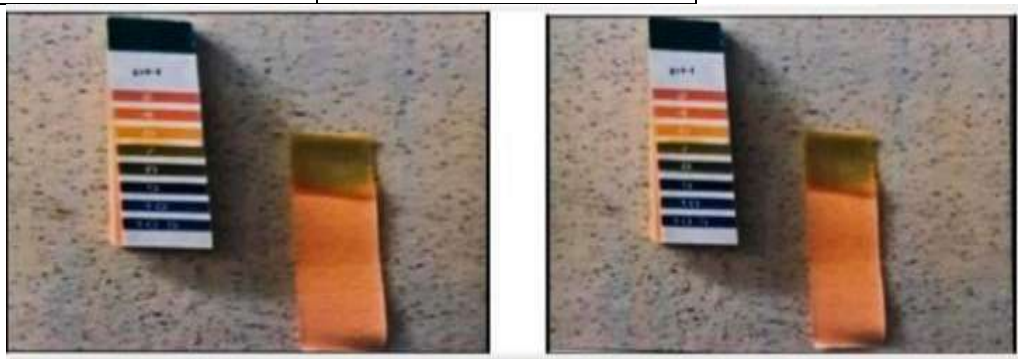
429.72

=23.920gm

Acid neutralizing capacity of different strengths of extract

Table 5: Acid neutralizing capacity of different strengths of extract

Quantity of extract	**Acid neutralizing capacity**
70mg	5.7
80mg	4.9
90mg	4.2
100mg	3.9
110mg	4.0
129mg	3.8



Average weight of a tablet	**Percentage deviation**
130mg or less	10
>130mg and <324mg	7.5
324mg or more	5

Table 7:

Time	B1(%)	B2(%)	B3(%)	B4 B4(%)(%)
0	0	0	0	0
15min	15.04	19.21	23.81	31.01
30min	19.33	25.71	29.65	34.80
45min	24.90	30.16	35.76	40.51
60min	33.24	39.26	41.01	46.69
75min	41.96	46.39	49.91	52.73
90min	52.20	54.41	57.72	57.34
105min	63.71	63.02	65.38	63.16
120min	69.89	69.11	72.24	71.84
135min	75.55	76.61	78.49	82.28
150min	81.45	80.32	83.22	90.24
165min	84.06	85.46	85.63	95.41
180min	87.19	88.51	89.75	98.10

Buoyancy studies of floating tablet : Table: Buoyancy studies of floating tablet

Formulation code	Floating lag time(sec)	Total floating time (hrs)
B1	44 sec	1.5
B2	47 sec	2
B3	38 sec	3
B4	32 sec	3.5

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