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DEVELOPMENT AND CHARACTERIZATION OF POLY-HERBAL ANTACID FLOATING TABLETS

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ABSTRACT

One of the most prevalent gastrointestinal (GI) issues of our time, gastric ulcers (GUs) are open sores that form on the inside of the stomach's mucosal lining and affect about 10% of the global population. Due to the breakdown of the equilibrium between the gastric mucosa's natural defence mechanism, aggressive factors (such as the secretion of gastric acid and pepsin, oxidants, and free radicals,), and exogenous factors (such as *Helicobacter pylori* infection, alcohol use, and non-steroidal anti-inflammatory drugs), the disorder is multifactorial and complex. In the modern era, H2 antihistamines, proto-pump inhibitors, ulcer protectants, and antiulcer medications are used to treat and prevent GUs. Extended usage of these chemicals is frequently linked to problems such as diarrhoea, anaemia, and enterochromaffin-like (ECL) cell hyperplasia. Herbal remedies have been used since ancient times to treat a variety of disorders like gastro-protective and anti-ulcer activities. For the treatment of anti-ulcer activity Poly-herbs are used for treatment like Triphala powder(Amla, Harde, Baheda), pumpkin seed powder, black cumin seeds powder, fennel fruit powder, black raisin powder, fenugreek seeds powder all having the gastro-intestinal protective action and also soothes the mucosal lining of the stomach. Floating tablets is 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.pylori*, floating tablets, *Cucurbita maxima*, *Terminalia bellerica*, *Emblica officinalis*, *Terminalia chebula*, *Nigella sativa*, *Trigonella foenum graceum*, *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] The frequency rate of peptic ulcer and associated complications varies according to the time and region, with highest incidence of bleeding PUD was 80%, perforated PUD was 12% with a total of around 140 per 1,00,000 population. Usually, after 15-45 minutes of meal, epigastric pain occurs while the duodenal lesions develop after few hours of the meal due to excessive pepsin secretion.[2]

The global estimates of peptic ulcers cover up to 5-10% population. However, ulcer incidence, mortality risks have been decreasing worldwide in the past few years. 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]

Almost 90% of the ulcers are caused by H. pylori, which are distributed according to different ethnicities. So, H. pylori should be managed with various drugs as it causes the risk of gastric cancer development. These gastroenterological bacteria infect 10% population in the rural and western countries, while affects more than 50% in the developing countries, but only a few develop clinical symptoms.[4] NSAIDs like diclofenac and aspirin secondary risk factors of gastric ulcer. Peptic ulcer disease varies according to the age groups: 22% in 0-5yrs, 55% in 6-10yrs and 86% in 11-20yrs.[5]

Diagnosis of peptic ulcer can be assessed by urease test, which is rapid and easily available, but not reliable alone. Invasive tests such as 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.

Herbs and plant extracts have medicinal property which is considered safe, effective and have a promising role in peptic ulcer management. Phytomedicinal plants are proved to be auxiliary therapy for the treatment of peptic ulcers. 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, hydroxycinnamic and phenolic acid have therapeutic significance.[7] 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*.

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.[8]

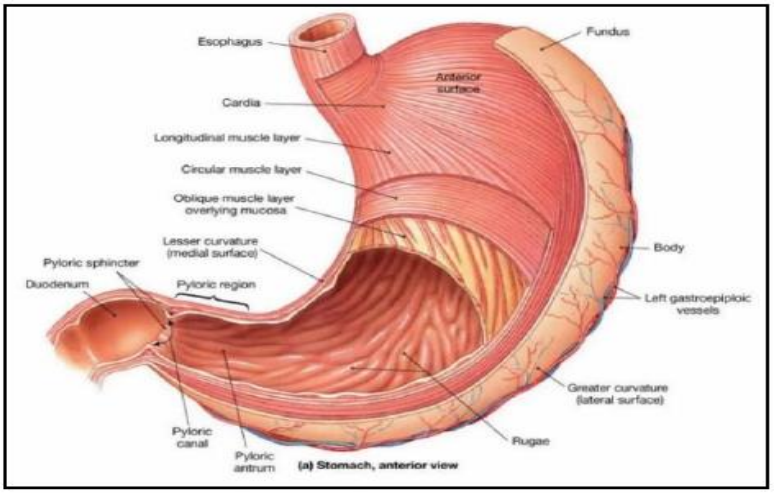


Fig. 1: Anatomy of stomach.

Stomach is divided into four parts[09]

1) Cardia- It connects the oesophagus with stomach. It also has a sphincter muscle that prevent the back flow of food from stomach to duodenum.
2) Fundus- It is grey dome- shaped part located on the upper left side next to cardia.
3) Body- It helps in storage and churning of the food properly, covering almost 80% of the total area of stomach.
4) Pylorus-It's funnel-like shape helps in passage of food from stomach to duodenum. It consists of a muscular valve known as pyloric sphincter that regulate the passage of Chyme, and prevent the back flow of Chyme from stomach to duodenum.

Diagnostic test for peptic ulcer

A. Invasive

Table 1: Invasive diagnostic test.

Test	Advantages	Disadvantages	Comments
Rapid urease test	Rapid, cheap	Low sensitivity (>85%)	Not a confirmation test for eradication
Histology	Sensitive	Time consuming	Can cause false errors
Microbiological culture	Antibiotic testing	Time-consuming	No sensitivity
Polymerase chain reaction	Susceptible testing	Not widely available	No standardization method available
Endoscopic biopsy	Later stage diagnosis	Expensive	Sensitivity (90%) Indicated in severe chronic condition

B. Noninvasive

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	Lacks 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
Antibody test	Low cost	Prevalence dependent	Not used as confirmatory test

Floating tablets

One type of gastro-retentive medication administration technique is the floating tablet. Drugs with a limited window of absorption, those less soluble in water in the alkaline pH of the

small intestine, and those less stable in the intestinal or colonic environment can all have their bioavailability increased by the use of gastro-retentive systems, which lengthen the residence time of dosage forms in the stomach. The key to developing oral controlled release dosage forms is not only to extend the drug's administration beyond 12 hours, but also to extend the dosage forms presence in the upper gastrointestinal system or stomach, where the medication is released for the desired amount of time. Fast gastrointestinal transit may cause partial drug release from the drug delivery device in the absorption zone, which would reduce the dose's effectiveness.[10]

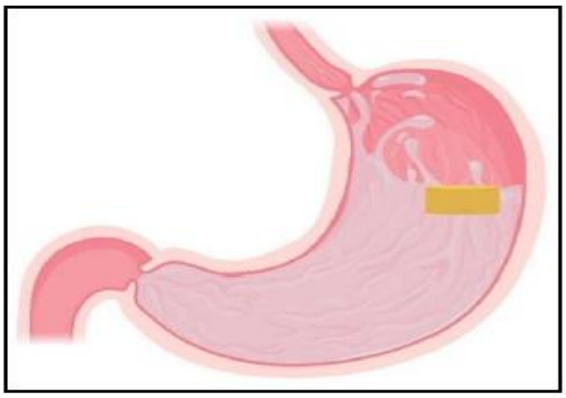


Fig. 2: Floating tablet.

Controlling the gastric residence time in the GIT is one of the most practical ways to achieve a prolonged and predictable drug delivery profile. This allow to maintain the drug reservoir above its absorption area, which is the stomach, and release the drug in a controlled manner to achieve zero order kinetics for an extended period of time. This will improve bioavailability and improve the pharmacokinetic and pharmacodynamic profile. Because of the upper gastrointestinal tract's limited absorption window, floating drug delivery is appropriate for medications with low bioavailability. Benefits include increased therapeutic efficacy, enhanced bioavailability, and potential dose size reduction. Since dosage forms stay in the stomach longer than conventional dosage forms, the ability to extend and control the emptying time is a major asset. Gastric emptying of dosage forms is a highly variable process.

Selected plants for the antiulcer activity

Name of plant	Botanical name	Family	Synonyms	Part which are used
Pumpkin seeds	*Cucurbita pepo, C. maxima*	Cucurbitaceae	Pepitas	Seed

Triphla powder	*Emblica officinalis (AMLA)*	Euphorbiaceae	Emblica, Indian goose berry, amla	Dry fresh fruit
	Terminalia bellerica (BAHEDA)	Combretaceae	Beleric myrobalan, baheda, bibhitak	Dry ripe fruit
	Terminalia chebula (HARDE)	Combretaceae	Myrobalan	Dry fruit
Black cumin	*Nigella sativa*	Ranunculaceae	Myrobalan	seeds
Black raisin	*Vitis vinifera*	Vitaceae	Zabeeb, Maneka, dried grapes	Dried fruit
Fennel	*Foeniculum vulgare Miller*	Apiaceae (Umbelliferae)	fennel fruit, Bhang, Cannabis,	Dried fruit
Fenugreek	*Nigella sativa*	Ranunculaceae		seeds

MATERIAL AND METHODS

Selection of plants: Total 10 plants were selected on the basis of review of literature. Out of 10 plants, 6 plants were selected on the basis of different criteria regarding acid neutralizing activity.

Collection of plants: Plants were collected from different regions and different areas (powder of Triphala, pumpkin seeds, black cumin seeds, black raisin fruits, fennel fruits, fenugreek seeds) of Gandhinagar, Gujarat, India. All are blended and powder is obtained which is used.

Authentication of plants: Plants were authenticated using its morphological, and physico-chemical parameters and maintained in the pharmacognosy department of sharda school of pharmacy, Gandhinagar, Gujarat for further reference.

Method of preparation of extract

Accurately weigh 10gm of triphala powder, 10gm pumpkin seed powder, 10gmfennel fruit powder, 10gm black raisin fruit powder, 10gm black cumin powder, 10gm fenugreek seed powder taken in the conical flask. In that 500ml of water is added. Place conical flask for 24hrs without disturbing (MACERATION). After 24hrs filter the solution with muslin cloth and mark the filtrate as no.1. To the residue, add 250ml of water and boil for 3hr on water bath. Filter the solution with muslin cloth and mark the filtrate as no.2. To the residue, add 100ml of water and boil for 1hr on water bath. Filter the solution with muslin cloth and mark

the filtrate as no.3. Filter no. 1,2,3 taken in the porcelain dish to evaporate the water. Calculate the percentage yield of prepared extract.

Formula for floating tablet

Table 3: List of contents of floating tablets.

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

Preparation of floating tablets

Direct compression

Weigh 100mg of Extract in mortar and pestle, Add Excipients in appropriate quantity (150mg of 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. Blend properly in mortar and pestle with continuous stirring in single direction. The mixed powder is then compressed into tablets using a tablet press.

Table 4: Formulation of herbal floating tablets.

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

Evaluation parameters

Pre-compression parameters[11,12]

1. **Bulk density:** It is a ratio of mass of powder to bulk volume. Accurately weighed quantity of powder was carefully poured in to graduated measuring cylinder through large funnel and volume was measured, which is called initial bulk volume. It is expressed in gm/ml and is given by the formula:

Bulk density=M/Vo

Where, M = mass of the powder

Vo = bulk volume of the powder.

2. **Tapped density:** 30 gm 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 (θ):** 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 = $\tan^{-1}$(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 flowability 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[13,14]

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 deviated from ± 5% of the standard value was determined.

2. **Hardness test:** Hardness of the tablets was determined by Monsanto Hardness Tester. The tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger is placed in contact with the tablet, and a zero reading is taken. The upper plunger is then forced against a spring bolt until the tablet fractures. As the spring is compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of fracture is recorded and the zero reading is deducted from it. Three tablets from each batch were selected and evaluated, and the average value with standard deviation was recorded.

3. **Weight Variation test (U.S.P.):** Take 20 tablet and weighed individually. Calculate average weight and compare the individual tablet weight to the average. The tablet pass the U.S.P. test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

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

4. **Friability test:** Friability of tablets was performed in Roche Friabilator. It consists of a plastic chamber that revolves at 25rpm. Ten tablets were weighed together and then placed in the chamber. The friabilator was rotated for 100 revolutions/min. The tablets are then dusted and re-weighed.

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

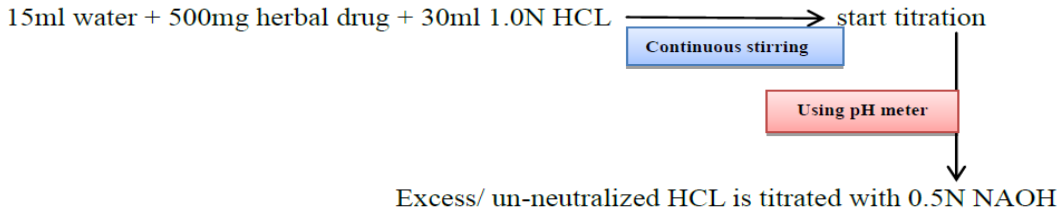
Where, W1 =Weight of Tablets (Initial / Before Tumbling)

W2 = Weight of Tablets (After Tumbling or friability)

5. ***In vitro* buoyancy or floating studies[15]:** *In vitro* buoyancy was determined by the measurement of floating lag time (FLT) and total floating time (TFT). Tablet was placed in a 100 ml beaker containing 0.1 N. HCL. Time required for tablet to rise on the surface of medium and float was determined as "FLT." It is expressed in seconds or minutes. The duration of time by which tablet constantly emerges on the surface of medium was determined as the "TFT." It is expressed in hrs. The experiments were conducted in triplicate. Polyherbal effervescence tablet generates CO2 gas thereby reducing the density and hence it remains buoyant for a prolonged time period releasing the drug slowly at the desired rate.

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 0.1 N HCl, 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)* [16]:** 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.



RESULTS AND DISCUSSION

Percentage yield of the prepared extract

$$\frac{\text{Weight of porcelain dish with extract} - \text{weight of empty porcelain dish}}{\text{Weight of empty porcelain dish}} \times 100$$

$$\frac{429.72-326.93}{429.72} \times 100$$

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
70 mg	5.7
80 mg	4.9
90 mg	4.2
100 mg	3.9
110 mg	4.0
120 mg	3.8

Pre-formulation studies

Table 6: Result of Pre-formulation studies.

Parameters	B1	B2	B3	B4
Bulk density (g/ml)	0.80	0.96	1.13	1.20
Tapped density (g/ml)	0.91	1.09	1.27	1.35
Angle of repose (°)	30.25	29.64	28.65	25.12
Compressibility index (%)	12.08	11.92	11.02	11.11
Hausner ratio	1.13	1.13	1.12	1.125

Post-compression studies

Table 7: Result of Post-compression studies.

Formulation code	Diameter (mm)	Thickness (mm)	Hardness (kg/cm2)	Friability (%)	Average weight (mg)
B1	12	5	4.7	0.92	498
B2	12	4.9	4.3	0.91	502
B3	12	4.7	4.1	0.87	482
B4	12	4.6	4.5	0.93	499.6

Buoyancy studies of floating tablet

Table 8: Result of 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

At time 0sec **At time 15sec** **At time 32sec**

Figure 3: Floating lag time.

***In vitro* dissolution studies**

Table 9: Result of *In vivo* dissolution studies.

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

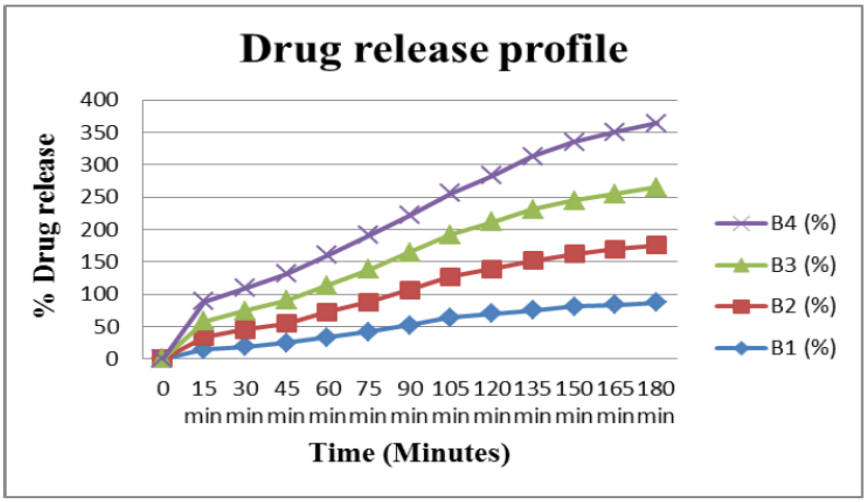


Figure 4: Drug release profile.

***In vitro* model for the acid neutralizing capacity**

Table 10: Result of *In vitro* model for the acid neutralizing capacity.

Formulation code	Reading of Polyherbal drug (500mg)	Reading of standard drug Rantac
B1	5.4	3.8
B2	4.8	
B3	4.2	
B4	3.9	

Figure 5: pH of Polyherbal drug (500mg).

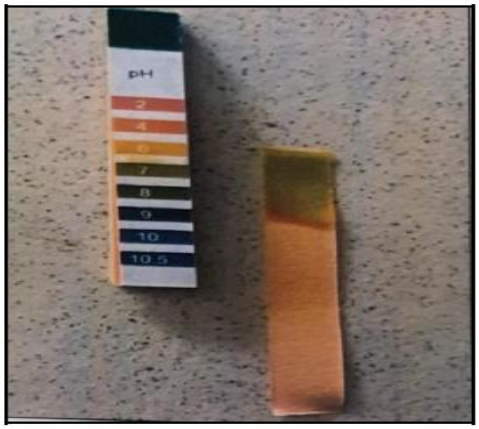


Figure 61: pH of Standard drug.

CONCLUSION

The current study was to develop and characterize the poly-herbal formulation. The herbal antacid tablet was made using a few traditionally used medicinal plants such as triphala, pumpkin seed, black raisin, fennel, fenugreek, black cumin were selected and authenticated for designing of orally administrable solid dosage forms. These plants are well reported for anti-ulcerogenic activity in literature. Using an allopathic medicines which leads to various side effects. To counter the negative effects of allopathic medicines aqueous extracts of the plants were used in the current study. The effectiveness of the developed tablet as well as other pertinent evaluations has been assessed. In order to explain study findings, various evaluation parameters were performed. As all the pre analysis showed good outcomes, one more step is to formulate novel polyherbal formulation. Conventional tablets were prepared and studied for its preformulation and post- formulation parameters. But as conventional tablets have several limitations like short half-life and fast elimination which can be overcome by developing floating drug delivery system. Polyherbal floating tablets were formulated and evaluated which would retain at the delivery site for much longer time and produce its therapeutic action. Also buoyancy studies like floating lag time and total floating

time was also assessed and in-vitro model for the acid neutralizing capacity was also experimented.

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