

# Formulation Development, Characterization And Estimation Of Acid Neutralization Capacity Of Shadanga Paniya For Treatment Of Gastric Acidity

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**ABSTRACT:** Herbal treatment is the form of medicine which include herbs and this herbs are used in situation such as treatment of gastric acidity or ulcers<sup>[1]</sup>. A Shadanga Paniya is a popular Ayurvedic formulation which contain natural herbs and the formulation is used in hyper acidity, ulcerative dyspepsia and other acid peptic disorders<sup>[2]</sup>. By formulating ayurvedic powder into tablet the dosage uniformity and patient compliance can be increased and adulteration can be decreased<sup>[3]</sup>. The present work deals with develop and evaluate Shadanga Paniya tablets using starch and acaciaas a binder. By selected herbs with the tendency to neutralize acid in the stomach are selected and a tablet is formed<sup>[4]</sup>. The acid neutralizing capacities of the herbs were analyzed by Back titration method<sup>[4]</sup>. After the back titration the tablets were prepared and this prepared tablets were evaluated for different parameters such as weight variation, thickness uniformity, hardness, friability, disintegration time and acid neutralizing capacity (ANC)<sup>[4]</sup>. Herbal drug shows fewer side effects as compare to OTC drugs. So nowadays peoples are moving towards herbal products. So, present study is based on back titration for the herbal drugs used for acidity and formulate them into tablet dosage form and evaluate them.

**KEYWORDS;** Gastric Acidity, Shadanga Paniya, Liquorice, Back titration, Tablet.

## INTRODUCTION

Gastric acid, gastric juice or stomach acid is digestive fluid formed within the stomach lining<sup>[5]</sup>. Gastric acidity is caused by increased gastric juices which are found in the stomach. They contain numerous compounds, including hydrochloric acid (HCl), pepsin, lipase, mucin, intrinsic factor, peptides, nucleic acids and electrolytes<sup>[6]</sup>. Gastric acid plays key role in digestion of proteins by activating digestive enzymes, which together breakdown long chains of amino acid of proteins<sup>[5]</sup>. HCl is strong acid having pH is 2-3 and it is important component in gastric juice. HCl plays important role in protecting the stomach and intestines from pathogens. Due to certain disease condition such as ulcer HCl secretion is increased in stomach. By using herbal treatment this increased HCl secretion can be decreased.

In this present work ayurvedic formulation Shadanga Paniya and herb like liquorice is used. This herbal unit dosage form is used in ayurveda for gastric acidity. Shadanga Paniya granules were prepared by using different herbs like Khus- Vetiver, Shunti-Ginger, Garo- Indian fumitory, Musta-Nutgrass, Chandana- Sandalwood, Pitpapra – Fumaria Indica

- Khus- Vetiver : It is perennial bunchgrass of *Chrysopogon zizanioides*. It is commonly known as vetiver and khus. Family : Poaceae<sup>[7]</sup>.
- Shunti- Ginger : Ginger contain dried rhizomes of *Zingiber officinale* belonging to family Zingiberaceae . It is widely used as a spice and a folk medicine<sup>[8]</sup>.
- Musta- Nutgrass : It is also known as purple nutsedge or nutgrass or java grass belong to family Cyperaceae. It contain perennial herb & fibrous roots of *Cyperus rotundus*<sup>[9]</sup>.
- Garo – Indian fumitory : Synonyms : *Fumaria parviflora* var. *indica* . It contain pinkish to whitish flowers of *Fumaria indica* belonging to family Papaveraceae [Poppy family]. It is used in fever, influenza, liver complaints, pains, etc. It is used in treatment of constipation and dyspepsia<sup>[10]</sup>.

□ Chandana- Sandalwood : It consist of heartwood of stems and roots of *Santalum album* Linn . **Family:** Santalaceae; R.Br. It used as stimulant and disinfectant of genitourinary tract<sup>[11]</sup>.

It reduces excessive thirst, burning sensation, restlessness, and distaste. It further helps increasing appetite. It is helpful in all following symptoms.

1. Burning sensation
2. Restlessness
3. Irritability
4. Sweating
5. Headache
6. Body aches and muscle aches
7. Dehydration
8. Loss of appetite
9. Feeling weakness in the body

## 10. Lethargy

## 11. Liquorice:

**Scientific name:** Glycyrrhiza glabra**Kingdom:** *Plantae* **Family:** *Fabaceae***Subfamily:** *Faboideae* **Genus:***Glycyrrhiza* **Species:***G. glabra*

**Liquorice (UK)** or **liquorice (US)** is the common name of *Glycyrrhiza glabra*, a flowering plant of the bean family Fabaceae. From the root of Liquorice sweet, aromatic flavouring can be extracted, therefore it is used as flavouring agent. Liquorice are the dried roots of glycyrrhiza glabra.<sup>[16]</sup> It contain Saponin Glycyrrhizin as main chemical constituent which shows significant therapeutic effect on chronic gastric ulcer. Also used in treatment of digestive problem, menopausal symptoms, cough, and bacterial and viral infection.<sup>[17-18]</sup>

**Ulcer Treatment and Prevention:**

According to multiple research liquorice is effective in prevention and treatment of ulcers. It does this by increasing mucus production in the stomach, soothing the stomach lining<sup>[19]</sup>. Liquorice promotes healing by increasing blood supply to the stomach. Liquorice also prevents ulcers from forming in the first place by suppressing gastrin production in the body. Gastrin is a hormone that stimulates gastric acid production, which can lead to ulcer formation<sup>[21]</sup>.

**MATERIAL AND METHDOLOGY:****A. Selection of samples:**

In India numerous herbal remedies are used for treatment of a number of ailments. Among them symptoms of acidity such as heart burn are treated at the household level by use of substances such as ginger, cinnamon etc. The commonly used antacid remedies were identified from available literature and common practice. Commonly consumed commercial antacid drugs and natural antacid remedies were identified based on a literature survey and their availability.

**Preparation of samples:**

Commonly consumed commercial antacids drugs and natural antacid remedies were collected and it crushed to form fine powder.

**B. Analysis of the antacid content of the selected sample:**

Analysis of selected antacid was carried out by Back titration method. In this method, an antacid is dissolved in an excess of acid and is titrated against a known concentration of base until an endpoint is reached. The molarity of neutralized acid is equal to the difference between the moles of acid added and therefore the moles of base required for the back titration. A back titration may also be called an indirect titration.

Sr. No	Material	Quantity(gm)
1	Khus-Vetiver	12
	Shunti- Ginger	20
	Musta Nutgrass	25
	Garo- Indian Fumitory	25
	Sandalwood	25
2	<b>Other Ingredients</b>	
	Liquorice	10
	Amla	10
	Ginger	10
	Triphala	10
3	<b>Excepients</b>	
	Starch	15
	Acacia	20

	Lactose	q. s.
	Ethanol	q. s.

### 6.3 Procedure

#### A. Back Titration Method:

The antacid formulation is dissolved in a known amount of surplus HCl and is titrated with an alkali, NaOH(aq) until enough OH<sup>-</sup> (from the NaOH solution) has been added to completely react with the excess H<sup>+</sup> (from the excess HCl in the solution). A portion of the added acid is neutralized by the antacid; the remainder is neutralized by the NaOH added. An equilibrium is reached when the number of moles of NaOH added is equal to the number of moles of HCl remaining after the reaction with the antacid. HCl acts as the source of H<sup>+</sup>(aq) and NaOH as the source of OH<sup>-</sup>(aq). At the endpoint of the titration, the acid will be totally neutralized by the base.

1 g of each formulation was weighed and crushed using mortar and pestle. It was then transferred into a conical flask and 25ml of 0.1 molarity of HCL was added to each sample, 2-3 drops of phenolphthalein indicator were added. The samples were then titrated against

0.1 M NaOH. The titrations were repeated until concordant values were obtained.

The experiments were undertaken under standard laboratory conditions. Standardization of HCl and NaOH was carried out as per the USP method.

#### B. Preparation of granules by wet granulation:

Tablets were prepared by using by non-aqueous wet granulation method containing drug i.e. Ginger, nutgrass, Vetiver, Red sandalwood, Indian Fumitory etc. Acacia 20 mg, Starch 15 mg, were triturated into fine powder. Then the granules were prepared by adding sufficient quantity of granulating liquid containing Ethyl alcohol to make a damp mass. This wet mass was passed through sieve no 16 and dried to get uniform granules. The granules were made such as granules has sufficient fines to fill empty spaces between coarse granules for better compression characteristics. The prepared and evaluated granules were compressed into biconvex shaped tablets using a Rotary Tablet Compression machine with average weight of 500 mg. The tablets were evaluated for the average weight, hardness, thickness, friability and disintegration test.

#### Powder Characteristics

##### 1. Angle of Repose:

Angle of repose was determined using cylinder method. The blend was poured through a cylinder that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and the angle of repose (q) was calculated using the formula.

$$\Theta = \tan^{-1}(h/r)$$

##### 2. Bulk density:

Apparent bulk density ( $\rho_b$ ) was determined by pouring blend into a graduated cylinder. The bulk volume ( $V_b$ ) and weight of the powder (M) was determined. The bulk density was calculated using the formula.

$$\rho_b = m/V_b$$

##### 3. Tapped density:

It was determined by placing a graduated cylinder, containing a known mass of drug excipients blend, which was tapped for a fixed time until the powder bed volume has reached a minimum. The minimum volume ( $V_t$ ) occupied in the cylinder and the weight (m) of the blend was measured. The tapped density ( $\rho_t$ ) was calculated using the following formula.

$$\rho_t = m/V_t$$

##### 4. Hausner ratio:

Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula Hausner ratio =  $\rho_t/\rho_b$  Where  $\rho_t$  is tapped density and  $\rho_b$  is bulk density lower Hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25).

#### Preparation of Tablets:

The granules were made such as granules has sufficient fines to fill empty spaces between coarse granules for better compression characteristics. The prepared and evaluated granules were compressed into biconvex shaped tablets using a Rotary Tablet Compression machine with average weight of 500 mg. The tablets were evaluated for average weight, hardness, thickness, friability and disintegration test. Evaluation of Tablets:

Tablets were evaluated for various parameters like Weight Variation, Thickness Uniformity, Hardness, Friability and disintegration time.

##### 1. Weight Variation:

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation test if not more than two of the individual tablet weight deviate from the average Weight

##### 2. Thickness uniformity:

Three tablets were selected randomly from each batch and thickness was measured by using Vernier Caliper.

##### 3. Hardness:

Hardness or table crushing strength ( $F_0$ ) the force required to break a tablet in a diametric compression was measured using Pfizer MSW 704.

##### 4. Friability:

Friability of the tablets was determined using Roche Friabilator. This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Preweighed sample of tablets was placed in the Friabilator and were subjected to 100 revolutions. Tablets were dedusted using a soft muslin cloth and reweighed, the friability (f) is given by the formula:  $\{(W1-W2/W1)\} \times 100$  Where, W1 is weight of the tablets before the test and W2 is the weight of the tablet after the test.

### 5. Disintegration time:

The Disintegration test was carried out using tablet Disintegration Test machine, IP standard. Tablets were placed in Test apparatus and distilled water was used as the disintegration medium. The time required to obtain complete disintegration of tablets was noted.

### CALCULATION

#### Back Titration: Equation: 1

moles of acid neutralized

$$= \text{moles of acid added} - \text{moles of alkali required}$$

$$= (\text{Volume HCl} \times \text{Molarity HCl}) - (\text{Volume NaOH} \times \text{Molarity NaOH})$$

#### Equation: 2

acid neutralizing capacity per gram of antacid

$$= \text{Moles of HCL neutralized} / \text{grams of antacid}^{[2]}$$

Back titration is carried out using the herbs like Amla, Liquorice, Ginger, Triphala. Among these herbs the Liquorice has more acid neutralizing capacity, so Liquorice is added in Shadanga Paniyato increase its efficacy.

Granules of Shadanga Paniya & Liquorice were prepared by wet granulation method using acacia and starch as binder<sup>[22]</sup>. After granulation of Shadanga Paniya & Liquorice preformulation study was carried out by using following parameters:

- **Angle of Repose:**  $\Theta = \tan^{-1} (h/r)$
- **Bulk density:**  $f_b = m/V_b$
- **Tapped density:**  $f_t = m/V_t$
- **Hausner ratio** =  $f_t/f_b$

Tablets were prepared by wet granulation method which involves the massing of a mix of dry primary powder particles using a granulating fluid like alcohol. The fluid contains a solvent (Alcohol) which can be removed by drying. The prepared tablets were evaluated using following parameters:<sup>[23-27]</sup>

- **Weight Variation**
- **Thickness uniformity**
- **Hardness**
- **Friability**
- **Disintegration time.**

### RESULT AND DISCUSSION

#### 1. Back Titration:

**Table 1: Acid neutralizing capacity of selected herbs**

Sr. No.	Herbs	Acid neutralizing capacity (mol/gm)
1	Amla	0.7
2	Suntha	1.3
3	<b>Liquorice</b>	<b>1.85</b>
4	Triphala	0.7

The acid neutralizing capacity of liquorice was more than other herbs so liquorice was incorporated in further procedure of tablet preparation.

**Table 2: Formula for various Batches of Shadanga Paniya Tablets**

Batch Code	Granules (mg)	Liquorice (mg)	Acacia (mg)	Starch (mg)	Lactose (mg)
S-1	300	25	5	10	200

S-2	300	25	15	15	200
<b>S-3</b>	<b>300</b>	<b>25</b>	<b>20</b>	<b>15</b>	<b>200</b>
S-4	300	25	25	15	200

The S-3 batch found to be most optimize batch.

**Table 3: Micromeritics properties of prepared blend**

Batch Code	Angle of repose ( <sup>0</sup> C)	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Hausner Ratio
S-1	25.75	0.43	0.80	1.86
S-2	28.36	0.40	0.78	1.95
<b>S-3</b>	<b>30.92</b>	<b>0.60</b>	<b>0.75</b>	<b>1.25</b>
S-4	33.40	0.55	0.82	1.49

**Table 4: Physical Parameters of Evaluation**

Batch Code	Weight Variation	Thickness (mm)	Hardness (kg/cm <sup>2</sup> )	Friability (%)	Disintegration Time(sec)
S-1	>5%	5.18	3.0	0.89	36
S-2	>5%	5.20	4.0	0.86	48
<b>S-3</b>	<b>&gt;5%</b>	<b>5.20</b>	<b>4.5</b>	<b>0.74</b>	<b>60</b>
S-4	>5%	5.22	5.5	0.86	76

## CONCLUSION

Shadanga Paniya is useful in gastric acidity & it has also other health benefits. Liquorice reduces acidity by neutralizing acidity in the stomach, and reducing the amount of acid that is refluxed into the esophagus or emptied into the duodenum. The combination of Shadanga Paniya and Liquorice shows greater efficacy. The formulation of tablet shows greater efficacy and ease of administration than granules. Tablets are easy to carry and handling. So in combination they show relatively higher efficacy.

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