

FORMULATION DEVELOPMENT, CHARACTERIZATION & ESTIMATION OF ACID NEUTRALIZATION CAPACITY OF SHANKHA BHASMA TABLETS FOR THE TREATMENT OF DYSPEPSIA

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ABSTRACT

Shankha Bhasma is a popular *Ayurvedic* formulation which is used in hyperacidity, indigestion, ulcerative dyspepsia and other acid peptic disorders. The dosage uniformity and patient compliance can be increased and adulteration can be decreased in ayurvedic powders by formulating them into tablets. The aim of the present work is to develop and evaluate Shankha Bhasma tablets using starch and acacia as a binder. Shankha Bhasma was evaluated for calcium content by titrimetric analysis. The granules were prepared by wet granulation method and the flowability of granules was studied. The prepared tablets were evaluated for different parameters such as weight variation, thickness uniformity, hardness, friability, disintegration time and acid neutralizing capacity (ANC).

Keywords: Shankha Bhasma; Tablet; Dyspepsia.

INTRODUCTION

Shankha Bhasma derived from Conch shell is an Ayurvedic formulation popularly used for the treatment dyspepsia and indigestion [1]. Shankha (*Turbinella pyrum*) is the member of Mollusc's largest class Gastropoda. These molluscs are enclosed in a shell and the shell is very hard & dense calcareous structure. Shankha bhasma is commonly prepared from Conch shell which is mentioned in several Ayurvedic literatures [2, 3]. Classically, Shankha Bhasma is alkaline in nature, Balya (increasing strength), Grahni and is indicated in Amlapitta (Hyperacidity), Agnimandhya (Digestive insufficiency), Grahani (irritable bowel syndrome) and Parinama Shula (Ulcerative Dyspepsia, Duodenal Ulcer) [4]. Its acid neutralizing capacity, speed of antacid action and prolonged buffering action were excellent. In another research Shankha bhasma caused significant reduction in ulcer index in both the indomethacine and cold resistant models [5]. Shankha Bhasma basically contains inorganic substances such as Carbonates of Calcium, Iron, Magnesium & Calcium oxide. It is used for indigestion, flatulence, abdominal pain, vomiting belching, diarrhoea, belching & gastritis.

The term dyspepsia has been derived from the greek words *dys* which means bad and *peptin* which means digestion. Dyspepsia is often generally defined as persistent or recurrent pain or discomfort in the upper part of the abdomen. The various symptoms of dyspepsia include epigastric pain, postprandial fullness, early satiety, anorexia, belching, nausea and vomiting, upper abdominal bloating and even heartburn and regurgitation [6, 7]. ANC value of Shankha bhasma was calculated by Rosset-Rice test. ANC is a measure of the overall buffering capacity against acidification for a solution [8, 9]. Oral route of drug administration is perhaps the most appealing route for the delivery of drugs. Of the various dosage forms administered orally, the tablet is one of the most preferred dosage forms because of its ease of manufacturing, convenience in administration, accurate dosing, stability compared with oral liquids, and because it is more tamperproof than capsules. The bioavailability of the drug is dependent on in vivo disintegration, dissolution & various physiological factors.

The objective of this study is to develop characterise & evaluate Shankha Bhasma tablets using Starch and acacia as a binder for the treatment of "Dyspepsia (Amlapitta)". The prepared tablets were evaluated for different parameters such as weight variation, thickness uniformity, hardness, friability, disintegration time and ANC.

MATERIAL AND METHODS

Shankha Bhasma was obtained from Rasa Shastra Laboratory of Rajiv Gandhi South Campus, Banaras Hindu University. Acacia,

starch and Lactose were obtained from Pharmaceutical Technology Laboratory of Rajiv Gandhi South Campus, Banaras Hindu University.

Determination of % calcium content [10]

Shankha Bhasma was first analyzed for calcium content. For the determination of calcium content the sample (0.1gm) was first dissolved in 3 ml of dilute HCl. It was then further diluted with 10 ml of distilled water. The mixture was then boiled for 10- 15 minutes, cooled and diluted to 50ml with distilled water. The mixture was then back titrated with 0.05M disodium edetate using eriochrome black as indicator.

Preparation of granules of mixed blend of drug and excipients

Shankha Bhasma was sifted through 40# sieve on a vibratory sifter and collected in a suitable container. Granules of Shankha Bhasma were prepared by wet granulation method using acacia and starch as binder. Granules were prepared manually on laboratory scale using mortar pestle to form the wet mass with subsequent passing of the wet mass through 10 # sieve to get the uniform sized granules.

Evaluation of micromeretic properties of prepared blend [11, 12]

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

$$\theta = \tan^{-1} \left(\frac{h}{r} \right)$$

2. Bulk density

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

$$\rho_b = \frac{m}{V_b}$$

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 (ρ_t) was calculated using the following formula.

$$\rho_t = \frac{m}{V_t}$$

4. Hausner ratio

Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula

$$\text{Hausner ratio} = \frac{\rho_t}{\rho_b}$$

Where ρ_t is tapped density and ρ_b is bulk density lower Hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25)

Preparation of Shankh Bhasma Tablets:

Tablets were prepared with each tablet containing 300 mg of drug (Table 1) using MAC tablet compression machine.

Table 1: Formula for various Batches of Shankha Bhasma Tablets

Batch Code	Drug (mg)	Acacia (mg)	Starch (mg)	Lactose (mg)
S-1	300	5	10	200
S-2	300	7.5	15	200
S-3	300	10	15	200
S-4	300	15	15	200
S-5	300	20	15	200
S-6	300	25	15	200

Evaluation of Shankha Bhasma Tablets [13-15]

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.

Table 2: Micromeretic properties of prepared blend

Batch No.	Angle of repose	Bulk Density	Tapped Density	Hausner Ratio
S-1	320	0.36±0.03	0.49±0.02	1.36±0.02
S-2	300	0.40±0.01	0.52±0.04	1.30±0.02
S-3	290	0.41±0.05	0.50±0.03	1.21±0.04
S-4	330	0.38±0.03	0.54±0.05	1.42±0.04
S-5	320	0.33±0.04	0.46±0.04	1.39±0.04
S-6	330	0.36±0.04	0.51±0.02	1.41±0.03

Table 3: Physical Parameters of Evaluation

Batch No.	Weight Variation	Thickness (mm)	Hardness (kg/ cm ²)	Friability (%)	Disintegration time (sec)
S-1	>5%	5.18	3.0± 0.2	0.89± 0.2	36
S-2	>5%	5.16	3.5± 0.2	0.87± 0.2	38
S-3	>5%	5.16	3.5± 0.5	0.86± 0.4	39
S-4	>5%	5.20	4.0± 0.5	0.86± 0.3	48
S-5	>5%	5.20	4.5± 0.5	0.74± 0.2	60
S-6	>5%	5.22	5.5± 0.5	0.68± 0.2	76

RESULTS AND DISCUSSION

The calcium content of the Shankha Bhasma was determined by titrimetric analysis and was found to be 58% w/ w. As seen from the Table 2 the flowability of the prepared blend was average. All the batches were evaluated for various evaluation parameters of the

2. Thickness uniformity

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

3. Hardness

Hardness or tablet crushing strength (Fo) 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:

$$f = \left(1 - \frac{W_o}{W}\right) \times 100$$

Where W_o is weight of the tablets before the test and W 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.

Acid Neutralising Capacity [8, 9]

The method used was Rossett Rice Test. The pH profile during the neutralisation reaction was followed by adding 70 ml of 0.1 N HCl and 30 ml of distilled water, to a 500 ml beaker. When the temperature was maintained at 37°C, an equivalent weight of powdered tablet sample was added.

Simultaneously 0.1 N HCl was added at a rate of 4 ml per minute from a burette. A pH meter was attached to the reacting vessel, to record the pH during the neutralisation reaction.

The time taken to reach pH 3.0 and Rossett-Rice time i.e. the time during which the pH maintained between pH 3.0 and 5.0, was noted. The Rossett-Rice test attempted to stimulate the stomach, and to record the pH profile during acid neutralization.

tablets. As seen from Table 3 the hardness of the tablets was found to be in the range of 3 to 6.0 kg/ cm². The percentage weight loss in friability test was less than 0.87. Batch no. S-1, S-2 and S-3 shows relatively less disintegration time. Thickness was uniform in almost all the batches. Science the material was free flowing; tablets were obtained with uniform weight, due to uniform die fill. Tablets were

obtained in the range with acceptable weight variations i.e. less than 5%. The acid neutralising capacity, expressed in m. Eq. of HCl consumed, was found to be in the range of 4.20 to 4.44 for different batches (Table 4). Overall the prepared tablet batches were of good quality with respect to hardness, friability, weight variation, thickness, disintegration time and acid neutralising capacity.

Table 4: Acid neutralising capacity, expressed in m. Eq. of HCl consumed

Batch No.	Acid Neutralising Capacity (m. Eq. of HCl consumed)
S-1	4.38
S-2	4.41
S-3	4.31
S-4	4.36
S-5	4.44
S-6	4.20

CONCLUSION

Review of the literature on Shankha Bhasma and Ayurvedic formulations strongly indicates that, Ayurvedic formulations are finding an increasing range of application in pharmaceutical research and dosage form design. In conclusion, an effective tablet formulation was obtained using acacia and starch as a binder which had a good balance over disintegration time, hardness and friability. The formulation was also developed with the aim of using an economical and laboratory feasible method. Also such type of formulation is not available in the market. The aim also includes authenticating and subjecting Ayurvedic formulations to some degree of analytical standards and specifications.

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