Research Article

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PHARMACEUTICAL STANDARDIZATION AND PRELIMINARY PHYSICO-CHEMICAL PROFILE OF SHANKHA VATI (TABLET)

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ABSTRACT

Shankha Vati was processed as per the process of Vati Kalpana described in classics. It contained Imli Kshar, Sendha Namak, Kala Namak, Bid Namak, Samudra Namak, Shankha Bhasma, Hing, Sounth, Kali Mirch, Pippali, Kajjali, Shuddha Vatsanabha, bhavana was given in nimbu ras and DCP, Starch, and MCC were used as excipients to obtain the finished product. In this manner three samples of Shankha Vati were prepared. To understand the changes that occurred during the preparation of Shankha Vati it was prepared in 3 batches and was analyzed by using modern parameters such as average weight, uniformity of weight of Tablets, Diameter, thickness, Hardness, Friability, Thin layer chromatography and disintegration. After the analysis it was observed that sample A, B, C were blackish brown in color, circular, compressed and flat. The uniformity of weight of tablets, diameter, hardness, friability, disintegration of samples of Shankha Vati A, B and C were approximately similar. Thin layer chromatography reports of 3 sample of Shankha Vati also comply. The present study revealed that there was no significant variation in the analytical values among all tree samples of Shankha Vati.

Keywords: Shankha Vati, Uniformity of weight of tablets, Friability, Thin layer chromatography, Disintegration.

INTRODUCTION

Shankha Vati is a herbomineral formulation of Ayurved representing the group of Vati Kalpana. In the present study the selected Shankha Vati contained imli Kshar, Sendha Namak, Kala Namak, Shankha Bhasma, Hing, Sounth, Kali Mirch, Pippali, Kajjali, and Shu. Vatsanabh for the treatment of all types of ajirna, jwara, gulma, panduroga, Kustha, Sula, Prameha, vatarakta and severe sotha, vata-pitta-kaphaja roga. It is an important formulation mentioned in Rasatantasara as well as in many other classical books of ayurveda with different compositions for the treatment of different disorders. Vati Kalpana (Tablet) is a unique dosage form used for systemic administration. Shankha Vati is indicated for the treatment of various disorders, which are discussed with rationality. The Standards of quality of any medicine is quite important for the reproducibility of the therapeutic effect. The central council of research in Ayurveda and siddha has published a standard protocol, where in analytical parameter must be followed for the quality production of Ayurvedic medicine.

Shankha Vati was prepared by giving bhavana of nimbu ras and by using excipients of DCP, Starch, and MCC in the prescribed quantity. The analytical testing is significant for all three batches.

MATERIALS AND METHODS

Shankha Vati contains total 15 ingredients. The details of parts and quantity used are given below in table 1. All the ingredients for this Kalpa were collected from local authentic market and identified and authenticated at the Quality control laboratory of Unijules life Science Ltd, Kalmeshwar, Nagpur, Maharashtra. All these herbal ingredients passed quality parameters described in API.

Ingredients

Each batch of 2kg was prepared which contains Shankha vati 250mg

For the preparation of Shankha Vati Vatsanabha shodhan was carried out by using gomutra. Herbal ingredients were powdered by pulverizes and sifted from sieve no. 80. All the above ingredients were mixed homogenously in mass mixer. Obtained material was dried in electric air drier for temperature not more than 60°. Fresh Nimbu swaras was added to end runner containing all ingredient for giving bhavana. Purified Vatsanabha and Shankha Bhasma were added to the ingredients which were mixed in a mass mixer. Excipients were added to the mixture for proper binding of the tablets. Tablets of Shankha Vati were prepared in double punch rotary tablet making machine GT-B-53 (Ganesh Pharma Tech, Ahmadabad, India). Weight after each pharmaceutical process was noted to observe the processing loss.

Table 1: Ingredients of Shankha Vati

Sl. No.	Composition / Raw Material	Each tablet of 250 mg mg = milligram	Each tablet of 2 kg kg = kilogram
1	Imli kshar (Tamarind Alkali)	32.26	258.080
2	Sendha Namak (Rock Salt)	12.9	103.200
3	Kala Namak (Black Salt)	6.45	51.600
4	Bid Namak (Bid Salt)	6.45	51.600
5	Samudra Namak	6.45	51.600
6	Shankha Bhasma (Conch Shell)	32.26	258.080
7	Hing (Asafoetida)	32.26	258.080
8	Sounth (Dry Ginger)	32.26	258.080
9	Kali Mirchi (Black Pipper)	32.26	258.080
10	Pipalli (Long Pepper)	32.26	258.080
11	Kajjali	16.12	128.960
12	Shu Vatsanabha-Bhavana-	8.06	64.480
	Bhavana-		
13	Nimbu ras- (Lemon Juice)	q.s.	
	Excipients		
14	DCP	10	80
15	Starch	12.5	100
16	MCC	7.5	50

*Reference: Rasatantrasara

PHYSICO-CHEMICAL ANALYSIS

Analytical Study

To ensure reproducibility of the Shankha Vati, the analytical methods were applied to three samples which were prepared with the same ingredients following the same manufacturing method and were coded as samples A, B and C. They were analyzed to obtain parameters, such as average weight, uniformity of weight of tablets, diameters, thickness, hardness, friability, Thin layer chromatography, disintegration according to the quality control manual of ayurveda siddha and unani medicine (the standard protocol mentioned in books)

The test was done as per the standard pharmaceutical laboratory process given in appendix 3 (physical test determination) of the Ayurvedic pharmacopeia of India.

Ayurvedic parameters

1. Color
2. Odor
3. Taste

Modern parameters

1. Average weight
2. Uniformity of weight of tablets
3. Diameter
4. Thickness
5. Friability
6. Thin layer chromatography
7. HPTLC
8. Disintegration

Uniformity of weight of Tablets

Though small variation in the weight of individual tablets are inevitable and admissible the variation should not cross the limits that are specified in the pharmacopoeia for standardization 20 tablets are used. 20 tablets are weighed individually, and their average weight was calculated. Only uncoated tablets should be used. Following table shows the deviation from the average weight[1].

Table 2: The deviation from the average weight

Average weight	Percentage Deviation
80 mg or less	10
More than 80 mg & Less than 250 mg	7.5
More than 250 mg	5.0

Not more than 2 tablets should fall outside this limit if 20 tablets are taken for standardization.

However, in this case the test is considered satisfactory if more than one tablet exceeds the average weight by more than twice the deviation specified in the above table.

Diameter

For the diameter of official tablets, the diameters are given officially in 32nd of an inch. The largest being 2/32 and the smallest 6/32[4].

Thickness

Determined by the amount of tablet material and the position of the punches in relation to each other during compression. The shorter the distance between the punches, thickness, the grater the pressure applied during compression and sometimes the harder the tablet.
Instrument Vernier Caliper[4].

Hardness

The tablet to be tested was placed between the spindle and anvil and pressure applied by turning the screw knob just to hold the tablet in position. The reading of the indicator on the scale was adjusted to zero. The pressure was applied until the tablet breaks. The reading was noted[1].

Friability

Though the tablets are compressed to satisfactory hardness during manufacturing may yet show considerable powdering after normal hardening giving it an undesired appearance. There tablets are described as friable tablets and may result due to addition of non-cohesive or even due to high proportion of dry additives. This can be measured by as instrument known as roche- friabilator. Tablets revolve 25 times in a minute while revolving the tablets

are automatically packed up from the casing and transferred to a plat form, which is at a height of 6 inches into the floor or the cylinder. At the end of 4 minutes the tablets are withdrawn and weighted. The percentage difference from their original weight is used to express friability. The tablets having not more than 1.6 % friability value are considered satisfactory[1].

Thin layer chromatography

Thin layer chromatography is a technique in which a solute under goes distribution between two phases, stationary phase acting through adsorption and a mobile phase in the form of a liquid. Identification can be affected by observation of spots of identical RF value and about equal magnitude obtained, respectively with as known and a reference sample chromatographed on the same plate a visual comparison of the size and intensity of the spots usually serves for semi-quantitative estimation[1].

Disintegration

Apparatus required: Disintegration test apparatus.
Method: Place five tablets in the tube. Insert the guided disc above the tablets, in the tube and raise and lower the tube in such a manner that the complete up and down moment is repeated thirty times a minute. The tablets are disintegrated when no particles remain above the gauze which will not readily pass through it. The time required for five tablets to disintegrate in the manner prescribe is unless otherwise stated in the monograph not more than fifteen minutes. Whenever the masticated tablets are concerned they should in addition to stated quality of drug respond favorably to the standard prescribed for tablets[2].

HPTLC

HPTLC plate was developed to a distance of 8 cm using Ethyl acetate: Methanol: Water in 6:1:4 ratio and petroleum Benzene and Ethyl acetate in 3:1 ratio as mobile phase. After development, the plate was allowed to dry in air and examined under ultraviolet rays (254nm). It shows major spot. The observed wavelength is under 280nm.

OBSERVATION AND RESULT

Description of sample A, B, C blackish brown color, circular, compressed, flat, uncoated tablets.

Table 3: Ayurvedic parameters

Test	Sample A	Sample B	Sample C
Color	Blackish Brown	Blackish Brown	Blackish Brown
Odour	Hinga Gandha	Hinga Gandha	Hinga Gandha
Taste	Lavan, Amla	Lavan, Amla	Lavan, Amla

Table 4: Modern parameters

Sl. No.	Test	Sample A	Sample B	Sample C
1.	Average weight	0.2530gm	0.2540gm	0.2590gm
2.	Uniformity of weight of Tablet	0.242-0.2624gm	0.2448-0.2626gm	0.2509-0.2591gm
3.	Diameter	8.19mm	8.18mm	8.26mm
4.	Thickness	3.16mm	3.59mm	3.51mm
5.	Hardness	2.00kg/sq.cm	1.50kg/sq.cm	2.3kg/sq.cm
6.	Friability	0.02%w/w	0.02%w/w	0.53%w/w
7.	Thin layer chromatography	Complies	Complies	Complies
8.	Disintegration	14min-15min	10min-12min	13min-14min

Following parameters were set as standards

Table 5: Parameters for Shankha vati.

Test Name	Parameters
Color	Blackish Brown
Average Weight	0.2530 - 0.2590gm
Uniformity of weight	more than +/- 5%
Diameter	8.18mm - 8.26mm
Thickness	3.51mm – 3.61mm
Hardness	1.5kg/sq.cm – 2.5kg/sq.mm
Friability	NMT 1% w/w
Disintegration time	NMT 20 min

As a part of standardization process and to check batch to batch consistency, fingerprint of HPTLC was obtained for three consecutive batches. CAMAG Linomat 5, Switzerland. The occurrence of same no. of spots and fingerprint structure on HPTLC plates confirms the consistency of finished product such a stipulation for obtaining HPTLC including number of spot and corresponding RF values gives the guidelines for preparation of Shankha Vati (Tablet). Hence all the three samples of Shankha Vati do not show significant difference.

Sample A Shows Peaks of Rf 0.02, 0.06, 0.13, 0.37, 0.44, 0.56, 0.67, 0.72, 0.80 simple B shown peak of Rf 0.00, 0.04, 0.10, 0.22, 0.25, 0.55, 0.65, 0.71, 0.77 & sample C Shown peak of Rf 0.01, 0.05, 0.11, 0.20, 0.24, 0.53, 0.66, 0.70, 0.79.

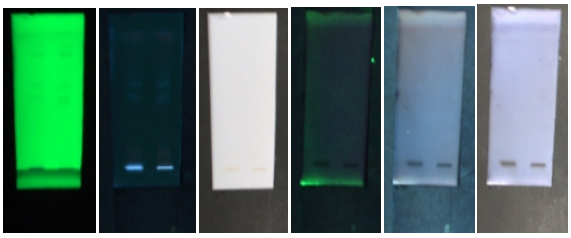

Figure 1: HPTLC of samples

DISCUSSION

Shankha Vati was prepared by method mentioned in rasatantrasara. An appropriate processing sequence was strictly followed and changes observed during each pharmaceutical step were noted. There was no significant processing loss. Physico–Chemical analysis is essential to check quality of the product and its biological activity. In this study we had analyzed the Shankha vati as per ayurvedic as well as modern parameters. In all three samples the quality control parameters for this drug does not show significant difference in their value. The analytical parameters for Shankha vati (tablets) which is prepared by the above said method may be as per above table.

CONCLUSION

From above study we can conclude that the Shankha vati (tablet) prepared by the method mentioned in Rasatantrasara in three batches do not show any significant difference in physicochemical analysis. Hence, we can say that Shankha vati (tablet) prepared by this method complies the standards parameters. Therefore, the pharmaceutical and analytical parameters for Shankha vati (tablet) are valid and the above said method is the standard one.

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