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ORIGINAL RESEARCH ARTICLE

Process Validation of *Chandrodaya Varti* – an *Ayurvedic* Ophthalmic Suppository

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ABSTARCT

Chandrodaya Varti is a herbomineral ophthalmic suppository. It is used in the various eye aliments like Cataract, Pterygium, Night blindness, Granular Eyelid disorder, Itching, conjunctivitis. Therefore, in present study an attempt has been made to prepare standard operative procedure of *Chandrodaya Varti*. *Chandrodaya Varti* constitutes 9 ingredients, in which 6 herbal, 1 mineral, 1 sea and 1 animal origin drugs are present. *Chandrodaya Varti* was prepared in five batches having an average batch size of 500 g and subjected to the levigation for 6 hrs. On an average 441.4 g of finished product was obtained. The standard deviation of in process was found 4.025 which are significant.

Key words: *Chandrodaya Varti*, Validation, herbomineral ophthalmic suppository.

INTRODUCTION

Safety and efficacy of a drug mainly depends on the method of preparation. To assess the quality of a finished product, there should be some basic standards as well as methods of preparation. There are several parameters for testing the quality of a chemical drug, which have, are true indicators. So, there is no problem in assessing a synthetic drug's quality. As far as the preparation used in *Ayurvedic* system of medicine, a drug formulation or design may not be a problem, because many formulations are well documented in classical texts. But, there is confusion with respect to standards to be followed while preparing a formulation as well as basic parameters to assess the quality of the finished product. By keeping this in mind an attempt has been made to validate the process of *Chandrodaya Varti*.

Chandrodaya Varti is a classical herbomineral ophthalmic Suppository. It is a main drug of choice for the various ophthalmic diseases in *Ayurvedic* system of medicines since ancient time. It is widely used in various type of eye ailments like Cataract, Pterygium, Night blindness, Granular Eyelid disorder, Itching, conjunctivitis. Various methods for the preparation of *Chandrodaya Varti* are available in the different classical texts. The ingredients and processes are almost same for the preparation of *Chandrodaya varti* as per the reference available in different classical texts. However, scientific data regarding various processes and steps involved in *Chandrodaya Varti* is not available. By considering these points, an effort has been made to standardize & validate the method of preparation of *Chandrodaya Varti* for increasing its Safety, efficacy and acceptance at global level.

MATERIAL AND METHODS

Chandrodaya Varti was prepared as per the reference available in *Sharangdhara Samhita*[1]. The ratio the ingredients of *Chandrodaya Varti* have been shown in the (**Table 1)**. Raw materials were procured from the pharmacy and subjected to the identification on the basis of their macroscopic and microscopical characters in the Department of Pharmacognosy.

Manahshila (Realgar) was lavigated with the juice of *Bijora Nimbu* (*Citrus limon* Burm.) and subjected to drying [2]. The process was repeated for 7 times before using it for the further process. Results obtained during processing of the *Manahshila* have been presented in the (**Table 2 & Table 3)**. *Swedana* of *Sankha Nabhi* was done by boiling under the juice of lemon (*Citrus acida* Linn.) for the duration of three hours[3]. Then, it was washed with hot water and kept for drying. The results obtained during processing of the

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Sankha Nabhi have been presented in the (**Table 4 & Table 5)**.

Before preparation of *Chandrodaya Varti*, all raw drugs were powdered[4] individually in disintegrator and passed through mesh no. 200 size [5]. Then, all materials mixed together in appropriate proportion and subjected to levigation with the milk of Goat for the duration of 6 hrs in the wet grinder. After completion of levigation conical shaped suppositories was prepared and subjected to the drying in oven at 40°C. The results obtained during the preparation of *Chandrodaya Varti* have been presented in (**Table 5).** Total 5 batches of *Chandrodaya Varti* were prepared.

RESULTS AND OBSERVATION

Total 440 ml *Nimbu Swarasa* was required for 7 *Bhavanas*, in which 80 ml *Nimbu Swarasa* was required for first Bhavna and 60 ml for rest of *Bhavanas*. pH of *Nimbu Swarasa* during *Shodhana* was 2.84 – 3.34. Duration of levigation was 60 min for first Bhavna[6] and 45 min. for rest of *Bhavanas*. *Manahshila* was hard, rough, dull orange and lustrous before *Shodhana*[7]. After *Shodhana*, *Manahshila* became soft, smooth, orange and lusterless. The weight of *Manahshila* increased after *Shodhana*.

During *Shodhana* procedure, average 1 *l* of *Nimbu Swarasa* was required. Thus total 4 liters of *Nimbu Swarasa* was used for *Shodhana* of 1 kg of *Sankha Nabhi*. pH of *Nimbu Swarasa* during *Shodhana* was between 2.80 – 3.27. The temperature of *Nimbu Swarasa* was observed in between 90^0 C - 100^0 C during Swedana procedure. *Sankha Nabhi* was hard, smooth, dull white with grey spots and lustrous before *Shodhana*. After *Shodhana*, *Sankha Nabhi* pieces became whitish and lusterless. The colour of *Nimbu Swarasa* became muddy yellow, pH was 2.76 – 3.13 and it was more viscous than before *Shodhana*. White powder like substance was deposited at the bottom of *Dola Yantra*[8].

The colour of powder after mixing of all ingredients became orange. Before levigation, the mass of ingredients completely dipped under *Aja Dugdha*. During levigation, it was difficult to reduce the particle size of herbal drugs further due to the presence of fibres of raw materials and same in case of *Sankha Nabhi* due to it hard nature. Trituration was done until Subhavita Lakshanas were observed. Pleasant smell was felt during levigation from Bhavita material. Initially the colour of paste was orange, which ultimately turned to brown colour. After completion of levigation process, *Varti* was prepared in shape of *Yava* (Barley).

DISCUSSION

Traditional health sciences (THS) of various countries have evolved within different epistemologies and perspectives on disease, cause and cure. The epistemic framework, principles, concepts and practice are quite different from those of Western biomedicine. While there is a contemporary value in applying modern science and technology tools for creating objective and verifiable standards for traditional knowledge products and concepts.

In the present work, process validation of *Chandrodaya Varti* was done by subjecting it to preparation in multiple batches and all the results and observations were noted at each step and outcome was monitored with statistical analysis.

Shodhana of *Manahshila* was carried out by levigation with *Bijora Nimbu Swarasa*. In this procedure, crude *Manahshila* was converted in to minute particles thus to increase its bio-availability and media also plays key role to make wide safety range as in one of study showed that topical citrate has a most favorable effect on the incidence of corneal ulceration and perforation after alkali burning[9]. *Bhavana* is a process of triturating the material with specified liquid media for a particular time limit. The purpose of *Bhavana* is to reduce the particle size, untoward effect and increased bioavailability of the drugs. *Bhavana* procedure is completed in two phases. In first phase, continuous levigation is done with specified liquid media for particular time limit and in second phase the levigated mass is allowed for complete dryness.

The purpose of *Sankha Nabhi Shodhana* is removal of the physical impurities. *Sankha Nabhi* is animal origin drug which is found in sea water. Due to long exposure of sea water a coating was developed on outer layer and excreta of animal were deposited inner of layer of the *Sankha Nabhi*. Classical texts suggest that generally acidic media is used for the *Shodhana* of sea origin drugs. It may be due to highly corrosive nature of acidic media is able to remove the deposition of external impurities after Swedana Process.

Shodhana of *Sankha Nabhi* was carried out in 5 batches by applying *Swedana* as a principle using *Nimbu Swarasa* as media for 3 hrs in *Dola Yantra*. For *Shodhana* procedure, each batch of *Sankha Nabhi*, 1 kg was taken and average four litres of *Nimbu Swarasa* was required for each batch to complete *Swedana* process. When the level of *Nimbu Swarasa* decreased, at an average one litre

of extra *Nimbu Swarasa* was added for each batch to maintain the level of media. The average weight loss of 2.86 % (Standard deviation of 0.00451) was observed in *Shankha Nabhi Shodhana*. It may be due to removal of impurities or some particles dissolved in acidic media and escaped through the pores of cotton cloth during *Shodhana* procedure. Some impurities may be lost during washing with hot water after *Shodhana*.

During *Shodhana* procedure, it was observed that the colour of media i.e. *Nimbu Swarasa* was changed yellow to turbid yellow and more viscous which may be due to the reaction between media and substance.

Chandrodaya Varti was prepared in five batches having an average batch size of 500 g. Average 441.4 g of finished product was obtained after preparation of *Chandrodaya Varti*. It had a standard deviation of 4.025 which is within permissible limits. Loss of 11.04 % was encountered. It may be due to manual handling and adherence of mixture in wet grinder. The colour of powder after mixing of all ingredients became orange. Before levigation, the mass of ingredients completely dipped under *Aja Dugdha*. During levigation, it was difficult to reduce the particle size of herbal drugs further due to the presence of fibres of raw materials and same in case of *Sankha Nabhi* due to it hard nature. Trituration was done until desired characters were observed. Pleasant smell was felt during levigation from paste. Initially the colour of paste was orange, which ultimately turned to brown colour. After completion of levigation process, *Varti* was prepared in shape of *Yava* (Barley).

Table 1: Ingredients and ratio of *Chandrodaya Varti*

S. No	Drug	Latin name	Part used	Proportion
1	*Sankha*	Conch shell	*Nabhi*	1
2	*Bibhitaki*	*Terminalia belerica* Roxb.	Endosperm	1
3	*Haritaki*	*Terminalia chebula* Retz.	Fruit	1
4	*Manahshila*	Realgar	Mineral	1
5	*Pippali*	*Piper longum* Linn.	Fruit	1
6	*Maricha*	*Piper nigrum* Linn.	Fruit	1
7	*Kustha*	*Saussurea lappa* C.B.Clarke	Root	1
8	*Vacha*	*Acorus calamus* Linn.	Rhizome	1
9	*Aja Dugdha*		Goat milk	Q.S.

Table 2: Ingredients and their quantity for *Manahshila Shodhana*

S. No	Ingredients	Quantity Per Batch
1	*Ashuddha Manahshila*	500 g
2	*Nimbu Swarasa*	450 ml (60 – 80 ml for each *Bhavana*)

Table 3: Results obtained during process of *Manahshila Shodhana*

Processing Stage	Weight of *Manahshila* (gm)					Average (g)
	A_1	A_2	A_3	A_4	A_5	
Before *Shodhana*	500	500	500	500	500	500
After *Shodhana*	558	550	560	556	554	555.6

Table 4: Ingredients and their quantity for *Sankha Nabhi Shodhana*

Ingredient	Quantity Per Batch	Total Quantity	Proportion
Ashuddha Sankha Nabhi	1.000 kg	15.000 kg	1
Nimbu Swarasa	4 *l*	20 *l*	4

Table 5: Results obtained during process of *Sankha Nabhi Shodhana*

Processing Stage	Weight of *Sankha Nabhi* (kg)					Avg.
	A_1	A_2	A_3	A_4	A_5	
Before *Shodhana*	1.000	1.000	1.000	1.000	1.000	1.000
After *Shodhana*	0.977	0.971	0.974	0.970	0.965	0.9714

Table 6: Results of *Chandrodaya Varti* preparation

S. No	Ingredients	Batch					Avg.
		I	II	III	IV	V	
1	Weight of ingredients (g)	500	500	500	500	500	500
2	Media for *Bhavana* (ml)	1000	1000	1000	1000	1000	1000
3	Duration for *Bhavana* (hr.)	4	4	4	4	4	4
4	Final weight of product (g)	425	445	451	443	445	441.8
5	Colour of final product	Brown	Brown	Brown	Brown	Brown	Brown

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