Original Article

Pharmaceutical Standardization of *Shatavari* Granules

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Abstract:

Standardization is necessary to maintain batch to batch consistency as well as for repeated preparation of drug on large scale. Modification of ancient dosage forms and development of new dosage forms is a continuous process which has significant contribution in flourishing the science with changing life style and favor of people. Preparation of granules is one of modified form of *Ghana* (solid preparations of herbal extract) and *Khanda Kalpana* (solid preparations similar to granules). *Shatavari* granule is a well known formulation for its beneficial properties such as *Stanyajanana* (*galactagogue*), *Balya* (immuno-modulators), *Rasayana* (rejuvenator), *Amlapittahara* (act as antacid in hyperacidity) etc. Present study has elaborated standardization of *Shatavari* granules. Three batches of *Shatavari* granules were prepared by adopting reference of Vriddha Vaidya and analyzed as per mentioned in Ayurvedic Pharmacopia of India (API). The average time required for preparation of *Shatavari* granules was 6.40 hours. A constant heat of 90^0C-100^0C was maintained throughout the procedure. The analytical study revealed average observed values of Loss on drying (at 105 ^{0}C), Total ash, Acid Insoluble ash, Alcohol Soluble extractives, Water Soluble extractive, pH, Bulk density and Tap density were 3%, 5.7 %, 0.5%, 25%, 54%, 4.0 (10% aqueous solution), 0.642 gm/ml, 0.810 gm/ml respectively. Particle size of prepared batches was 2 to 4 mm size. Antimicrobial study showed complete absence of any bacterial contamination. Vigilant hygienic care while following every step, temperature for heating and accessing completion stage of procedure are the key points during preparation of *Shatavari* granules.

Key words: Standardization, *Shatavari,* Granules

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Introduction:

Bhaishajya Kalpana, a pharmaceutical branch of Ayurveda has contributed several innovative dosage forms. *Avaleha* and *Kahanda Kalpanas* are dealt under the preview of *Ghana Kriya* where the semisolid to solid form of dosage have been described. Conversion of dosage form in to more suitable for modern era with additional benefits of palatability and presentation is always essential. *Shatavari* is potential drug possessing properties such as *Stanyajanana* (*galactagogue*), *Balya* (immuno-modulator), *Brihan* (health promoter), *Rasayana* (rejuvenator), *Vajikarana* (aphrodisiac), *Amlapittahara* (act as antacid in hyperacidity) [1] and also possesses immuno-modulatory, anti-abortifacient activity, Antidepressant, Anti-diarrhoeal, Antiulcerogenic action, antibacterial, analgesic,

Antioxidant properties [2]. Present study was planned to change conventional form of *Shatavari Guda* to granules with addition of colour and flavor. Standardization of formulation is need of the hour to generate evidence for existing literature and for reproducibility. Standardization of the *Shatavari* granules was carried out in large batches and parameters for quality assurance were also studied.

Materials and Methods:

Raw materials like *Shatavari* root (*Asparagus racemosa*) (Pic 1) and *Ela* (*Elettaria cardamom*) were collected from authentic sources and were validated by pharmacognosy lab and preparation of *Shatavari* Granules was carried out at Ayurved Rasashala, Mahatma Gandhi Ayurved college hospital and research center, Salod (H), Wardha, Maharashtra. Organoleptic characters, microscopic characters, physicochemical analysis, microbial contamination were studied in analytical lab as per API standards.

Preparation of *Shatavari* granules:

General method of preparation [3] emphasized for *Khanda paka* is followed in the preparation of *Shatavari* granules. The formulation composition is similar to that of *Shatavari Guda* but instead of jagary, sugar was preferred (Table-1). Course powder of *Shatavari* root (1 kg) were taken vessel and soaked in eight parts of water overnight. Decoction of *Shatavari* root was prepared by reducing it to 1/4th (Pic 2)and filtered through a cotton cloth. 2.5 parts of sugar to that of *Shatavari* was added in prepared decoction and was heated on mild fire (*Mandagni*) i.e. 90^{0}C-100^{0}C till it attained more than two thread consistency of sugar syrup. At this stage, the contents were removed from the heat source. Thus obtained mass was dried in hot air oven for 4 hrs at 60^{0}C and subjected to multi mill in sieve no 2 to obtain Granules.(Pic 3) *Shatvari* Granules were then taken in coating pan and saffron colour and fine powdered *Ela* was added, this was once again dried in hot air oven for 2 hrs. Thus formed granules were sealed and packed in container. Similarly three more batches were prepared to generate standard manufacturing process.

Analytical study:

Analytical study was done to establish the basic standards for *Shatavari* granules as there is no Pharmacopeia Standard guideline. The formulation was first tested for organoleptic parameters such as color, odor and test (Table 2). Physiochemical analysis includes Loss on drying at 105^{0}C, Total ash, Acid Insoluble ash, Alcohol Soluble extractives, Water Soluble extractive, pH, Bulk density, Tap density and Particle Size (Table 3)**.** Microbiological specifications were tested to validate its safety for internal use. ***E**nterobacteriaceae*, Total fungus count, *E-coli*, *Salmonella*, *Staphylococcus Aureus* and *Pseudomonas Aueruginosa* were performed as per CCRAS parameters (Table 4). Analysis of samples were conducted in analytical lab of Mahatma Gandhi Ayurved college hospital and research center, Salod (H), Wardha, Maharashtra, as per API standards.

Observations and results:

After adding *Sharkara* to the decoction effervescence was observed which subsided on constant stirring. Gradual thickening of syrup, consistency of *Tantumatwam* (thread like) and *Darvi*

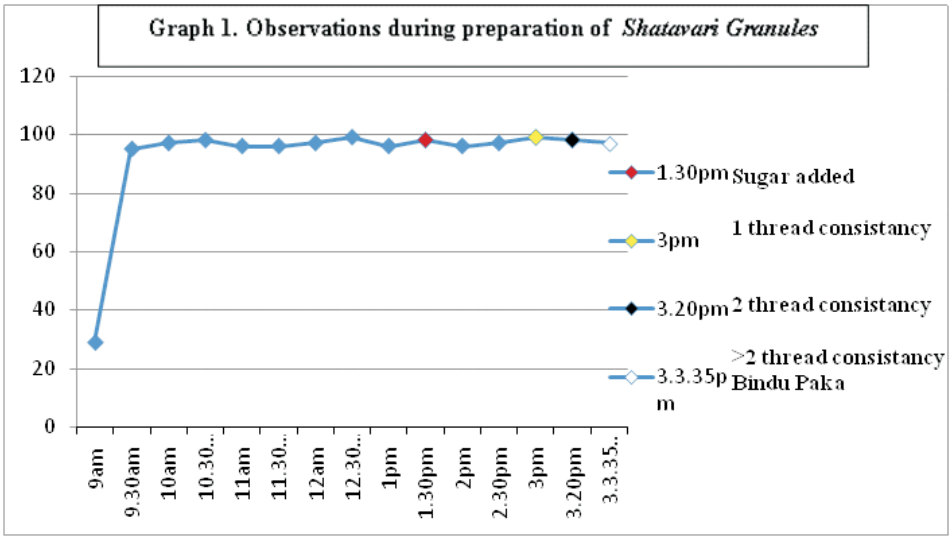

Table no.1: Quantity of ingredients and yield obtained in preparation of *Shatavari* granules				
Batch	***Shatavari Kwatha* (in *l.*)**	***Sharkara* (in Kg)**	**Time required for preparation**	**Final Yield (in Kg)**
SG1	4	10	6hr 35min	11.10
SG2	4	10	6hr 42min	10.90
SG3	4	10	6hr 45min	11.20
		Avg.	**6hr 40min**	**11.06**

Table no.2: Average result of organoleptic parameters of *Shatavari* granules				
Parameters	**Pharmacopeia Standard**	**Committee standard**	**Observations**	**Inference**
Color	Not available	Cream	Cream	Acceptable
Odor	Not available	None	None	Acceptable
Taste	Not available	Sweetish	Sweetish	Acceptable

Table no.3: Average result of physico-chemical parameters of *Shatavari* granules				
Parameters Evaluated	**Pharmacopeia Standard**	**Committee standard**	**Avg. of three Batches**	**Inference**
Loss on drying at 105^0C	Not available	Not more than 6%	3%	Acceptable
Total ash	Not available	Not more than 6%	5.7 %	Acceptable
Acid Insoluble ash	Not available	Not more than 0.5%	0.5%	Acceptable
Alcohol Soluble extractives	Not available	Not less than 20%	25%	Acceptable
Water –Soluble extractive	Not available	Not less than 50%	54%	Acceptable
pH	Not available	-	4.0 (10% aqueous solution)	Acceptable
Bulk density	Not available	0.642gm/ml	0.642 gm/ml	Acceptable
Tap density	Not available	0.810 gm/ml	0.810 gm/ml	Acceptable
Particle Size	Not available	2 to 4 mm size	2 to 4 mm size	Acceptable

Table no.4: Average result of Microbiological specifications of *Shatavari* granules for Internal Use			
Parameters as per CCRAS	**Pharmacopeia Standard**	**Observations**	**Inference**
Enterobacteriaceae	10^3 / g	Absent	Acceptable
Total fungus count	Maximum 10^3 / gm	Absent	Acceptable
E-coli	Maximum 10/ gm	Absent	Acceptable
Salmonella	None	Absent	Acceptable
Staphylococcus aureus	Absent	Absent	Acceptable
Pseudomonas aueruginosa	Absent	Absent	Acceptable

Pralepa (adhesion of syrup to spoon) was observed in 1hr 30 min of heating. After 1hr 50 min of heating, the syrup was found to be in two thread consistency with *Apsumajjan* (Dipping in water). *Bindu paka* (Settled drop of syrup in water) with *Patitastu Na Shiryate* (not instant dissolution in water) was observed at 2 hr and 5 min (Graph 1). Average 11.06 kg of *Shatavari* Granules were obtained in three batches (Table 1).

Discussion:

Shatavari Guda generally composes of fresh *Swaras* (juice) extracted from *Shatavari* roots but in present study *Shatavari Kwatha* was preferred as procuring fresh *Shatavari Moola* each time for large scale production is not feasible. According to Dalhana, *Kwatha* (decoction) can also be called as *Swarasa*; hence it advisable to use *Kwatha* [4].

Excessive frothing was observed after adding sugar to decoction which need continuous observation and stirring. As the moisture content reduces in syrup cohesive force increases and further application of heat imparts kinetic movement to the sugar molecules, where as when it is cooled loss of kinetic movement makes the sugar molecules to coalesce. This explains the reasoning behind thickening and solidifying on cooling. Sugar percentage upto 60-70 are required for granules preparations which can be accessed when mixture of Sugar and *Shatavari kwath* reaches more than two thread consistency. This stage indicates less moisture content in the granules. Average time required for preparation of *Shatavari* granules was 6 hr 40 min, after adding *Sharkara* to the decoction it took average 1hr 30min to attain one thread consistency and next 20-30 min for formation of desired consistency required for preparation of granules. Temperature during whole process is maintained under 100^{0}C for optimum preservation of active constituents in the product.

Before undertaking preparation of *Shatavari* granules in large batches, standardization was carried out in laboratory and analytical standards were set by quality control department. Decoction prepared from *Shatavari* was cream color hence obtained batches were also having cream color. Flavor was added to make it more palatable. Loss on drying at 105^{0} C indicates presence of moisture content. If moisture content is more than permissible limit then there the formulation is more likely to get infected by fungal growth. Moreover unwanted changes can also occur due to presence more moisture. In prepared batches moisture content is much less (3%) i.e. this formulation has more stability. Acid insoluble ash represents presence of inorganic content which is not expected in pure herbal formulation. The obtained value of acid insoluble ash in all batches is negligible. Insignificant difference is observed in alcohol soluble extractives which may be due to addition of flavor. The extractive values namely water-soluble and alcohol soluble indicates the amount of active constituent in given amount of plant material when extracted with respective solvents, a lower value compared to standard value indicates presence of exhausted material [6]. However for *Shatavari* granules no such standards are found mentioned hence the obtained values in present study can be considered for future studies. Water soluble extractive value is also nearly

Pic1 Raw *Shatavari*

Pic2 Preparation of *Shatavari Kwatha*

Pic 3 *Shatavari* Granules

same in all three batches. This value is related with dissolution in gastrointestinal tract and assimilation along with other liquid media. More water solubility is helpful for internal administration of *Shatavari* granules with milk as vehicle. The physical parameter such as pH was determined to avoid gastric irritation. All samples showed acidic pH.

One important characteristic is tapped bulk density, or simply tapped (tap) density: that is, the maximum packing density of a powder (or blend of powders) achieved under the influence of well defined, externally applied forces. The minimum packed volume thus achieved depends on a number of factors including particle size distribution, true density, particle shape and cohesiveness due to surface forces including moisture. Therefore, the tap density of a material can be used to predict both its flow properties and its compressibility [7]. Observed densities of samples are within committee standard. Finer the particle size more will be solubility and thus more will be the gastrointestinal absorption. The granules of all batches were fine enough to pass through 80-100 mesh size. As all batches were prepared by taking required hygienic care and by utilizing sterilized instruments, thus result of microbial content study showed absence of *Enterobacteriaceae*, fungus count, *E-coli, Salmonella, Staphylococcus aureus* and *Pseudomonas aueruginosa.* The pharmacopeial standards for Shatavari granules are not available hence the analytical results of present study may prove torchbearer towards establishing analytical standards for *Shatavari* granules.

Conclusions:

10.06 kg *Shatavari* granules can be prepared from 1 kg *Shatavari* root in average 6.40 hrs at 90-100 ^{0}C continuously maintained temperature. Constant hygiene is required to rule out any possibility of microbial contaminations during preparation of granules. As standards for *Shatavari* granules are not mentioned in API, hence analytical findings of present study can be considered for future research.

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