

Formulation and Evaluation of Shatavari Granules

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Abstract: Ayurveda has the oldest and the most developed herbal system in the world. The herbs are viewed as the spiritual essence. Shatavari (*Asparagus racemosus* Wild.) is one amongst the millions of plants having multitude of benefits. *Asparagus racemosus* (Shatavari) is recommended in the Ayurveda for the prevention and treatment of reproductive disorders of women such as sexual debility, ammenorrhea, dysmenorrhea, dysfunctional uterine bleeding, endometriosis, gonorrhea, prolapse of uterus etc. It is also recommended as a galactagogue in case of lactational inadequacy. *Asparagus racemosus* has been successfully used by some medical practitioners as an anti-inflammatory, anti-microbial and immunomodulator for many infectious diseases. *Asparagus racemosus* can also improve the milk production and reproduction capacity of dairy animals. The use of *Asparagus racemosus* can also boost the immune system and consequently prevent the infection of the udder and reproductive organs of cows. It can also be effectively used to reduce the stress of dairy animals and improve their productivity thus producing clean and healthy milk from them. The ancient history of India is very rich in herbal medicine and one of the oldest surviving system of health care in the world and known as Ayurveda derived from its ancient Sanskrit roots 'ayur' (life) and 'ved' (knowledge). It offers a rich, comprehensive outlook to a healthy life. Originated from India around 5000 years ago it has now spreaded its essence across the globe and has occupied a prime position in health care systems.

Keywords: Standardization, Shatavari root, Ayurveda, Granules

1. Introduction

Asparagus racemosus, traditionally known as Shatavari is one of the important medicinal herbs for human health care system. It belongs to Asparagaceae family. It is being traditionally used as female reproductive tonic. Shatavari is known by various names like Indeevari, Sukshamapatra, Bahusuta, Shatmooli, Narayani etc. Shatavari is having Madhur-tikta Ras (Sweet-bitter taste), Madhur Vipaka (Post digestive effect) and Sheet Virya (Cold Potency).[1] Besides many actions, diuretic, antispasmodic, rejuvenating, galactagogue, nervine tonic are important one. Gonorrhoea, leucorrhoea, tuberculosis, agalactia, inflammations, tumours, burning micturition are few of many conditions that can be treated with Shatavari. The basic principle of Ayurveda is "swasthasya swastha rakshanam athurasya vikar prasamanam".[2] Shatavari has important role to maintain Swasthya (Health) of female as having actions of Rasayan and Balya. Swasthya of fetus is dependent on Garbhini (Pregnant lady).

Wellbeing of Garbha (Fetus) can be achieved only through well being of Garbhini. Having Madhur Rasa, Shatavari is known to be Garbhasthapak (Maintains pregnancy), useful in the prevention of abortions. As it is Garbhaposhak (nutritive to fetus) and having anabolic action, useful for growing healthy baby and pregnant lady also. Galactagogue function of Shatavari is well known, useful in Stanyakhsya (inadequate lactation). Besides these, Shatavari has capacity to treat many female diseases (*Athurasya vikar prasamanam*) like polycystic ovarian diseases, Dysmenorrhoea, Premenstrual syndrome, Infertility and Menopause.[3] It means Shatavari is very potential plant, should be cultivated on large scale and utilized in various health issues of human beings especially in females.

2. Methodology

2.1 Search Criteria

Original articles, research papers published in journals and in Pub med central, Google scholar on Shatavari (*Asparagus racemosus*), and female disorders were studied out and related articles, papers were taken into consideration. Ayurveda literature including Samhita and Nighantu related to Shatavari (*Asparagus racemosus*) were also studied out.

Information regarding gynecological disorders was collected from Modern and Ayurveda literature. All the literature was especially studied for medicinal uses of Shatavari in female health issues and taken into consideration. Importance was given to clinical trials carried out on *Asparagus racemosus*. Finally results were obtained from all collected data and literatures studied.

Plant profile [4]

Kingdom: Plantae	Sub family: Asparagoideae	Synonyms: Indeevari, Sukshamapatra, Bahusuta, Shatmooli, Narayani, Bhiru, Virya, Madabhanjani, Shatpadi, Shatvirya
Clade: Angiosperms	Genus: <i>Asparagus</i>	
Order : Asparagales	Species: <i>Asparagus racemosus</i> L	
Family: Asparagaceae	Latin name: <i>Asparagus racemosus</i>	

Distribution

Plant occurs throughout India, tropical and subtropical parts including Andamans and almost commonly ascending up to an altitude of 4000 feet in the Himalayas and in Ceylon.

Plant Description

Shatavari is scandent climber, tall climbing excessively branched, prickly under shrub. Roots are tuberous; prickles 0.6 to 1.5 cm. straight or recurved; eladodes 2.5cm curved, terete, spreading in tufts of 2-6, channeled beneath. Flowers in racemes are 2.5-5cm. Pedicles 0.4cm, jointed in the middle; perianth 0.8-0.12 diameter, Anthers minute; oblong

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purplish; ovules 6-8 in each cell. Fruit a berry 0.4-0.6 cm diameter, Pea like, red, when ripe; fruit containing seeds.



Figure 1: Roots and leaves of Shatavari

Part used: Tuberous root

According to Ayurveda Classics, Shatavari should be used in wet state. But Research has proved that Shatavari in dry form also shows significant concentration of the active constituents. So, dried form of Shatavari can be used in absence of wet drug. [7]

Doses: Juice 10-20ml, decoction 50-100ml, powder 3-6gms.

Pharmacological actions:

Shukrajanan (Increases sperm count), Balya (Strengthening), Rasayan (Rejuvenating), Garbhaphoshak (Nutritive to fetus), Stanyajanana (Galactagogue), Shulhar (Relieves pain), Grahi (Constipating), Hrudya (Cordial), Mutral (Diuretics), Raktabharsmak (Hypotensive), Antiabortifacient.[8]

Chemical Constituents:

Important Chemical Constituents of Shatavari includes

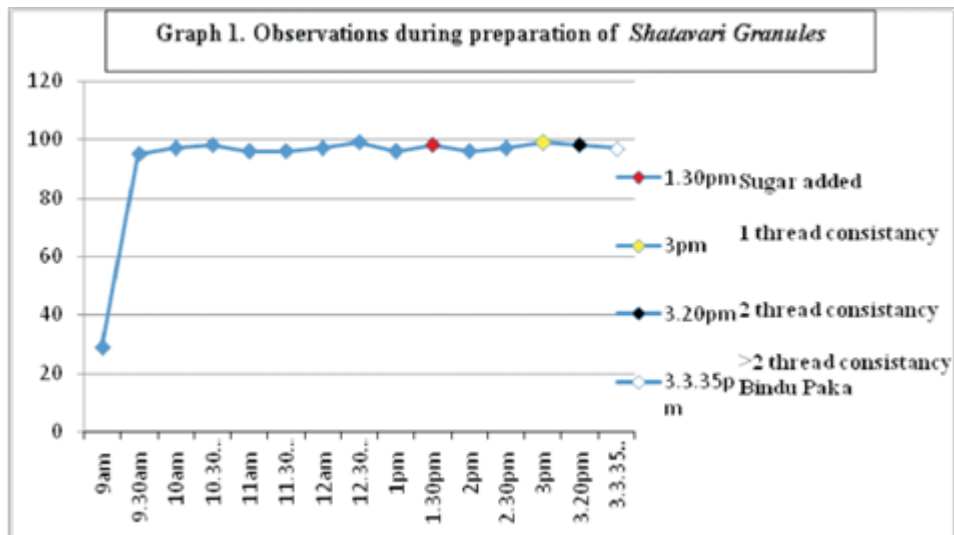
Saponins includes shatavarin 1, shatavarin 2, shatavarin 3, shatavarin 4 are present in roots.[9-11] Polycyclic alkaloid like asparagine A, and disaccharide in roots are also reported in some research.[12] Shatavari contains flavanoids, glycosides of quercetin, rutin and hyperoside are also present in flowers and fruits. Quercetin 3-glucuronide is present in leaves.[13] Few trace minerals like zinc (53.15), manganese (19.98), copper (5.29), cobalt (22.00 microgram per gram) along with calcium, magnesium, potassium, zinc and selenium.[14-15] The callus culture of Shatavari has shown synthesis of sarsasapogenin.[16] A new isoflavone, 8-methoxy-5, 6, 4'-trihydroxyisoflavone-7-O- β -d-glucopyranoside was also isolated from Shatavari previously.[17] The isolation and characterization of polycyclic alkaloid called asparagine,[18] isolation of a new 9, 10-dihydrophenanthrene derivative named racemosol and kaempferol were also done from the ethanolic root extract of *A. racemosus*.

3. Materials and Methods

Raw materials like *Shatavari* root (*Asparagus racemosus*) (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 analytically 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 C-100 C till it attained more than ⁰⁰ 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 4hrs at 60 C and subjected to multi mill in sieve no 2 to ⁰ obtain Granules.(Pic 3) *Shatavari* 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 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. *Enterobacteriaceae*, 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.

4. Observation and Results

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

Table 1: Quantity of ingredients and yield obtained in preparation of *Shatavari* granules

Batch	<i>Shatavari Kwatha</i> (in L.)	<i>Sharkara</i> (in Kg)	Time required for preparation	Final Yield (in Kg)
F1	4	10	6 hr 35 min	11.10
F2	4	10	6 hr 42 min	10.90
F3	4	10	6 hr 45 min	11.20
		Avg	6 hr 40	11.06

Table 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 3: Average result of physico-chemical 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
Parameters Evaluated	Pharmacopeia Standard	Committee standard	Avg. of three Batches	Inference
Loss on drying at 105 °C	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	0.642 gm/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 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
<i>E-coli</i>	Maximum 10 ³ /gm	Absent	Acceptable
<i>Salmonella</i>	None	Absent	Acceptable
<i>Staphylococcus aureus</i>	Absent	Absent	Acceptable
<i>Pseudomonas aeruginosa</i>	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 Shiriyate* (not in stand dissolution in water) was observed at 2hr and 5 min (Graph1). Average 11.06 kg of *Shatavari* Granules were obtained in three batches (Table1).

**Figure 2****Figure 3**

5. Conclusions

10.06 kg *Shatavari* granules can be prepared from 1kg *Shatavari* root in average 6.40 hrs at 90-100 °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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