



Original Article

Quality Control Parameters of Herbo Mineral Formulation: *Sarivadi vati*

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Background: *Sarivadi Vati* has been prepared according to *Bhaishajya Ratnavali* and is indicated under heading of *Karnaroga Adhikara*. In present study, it has been used in *Badhira* (SNHL) *Roga*. **Objective:** Present study is aimed to look out on herbal drugs used in the preparation of *Sarivadi Vati* and standardization of Pharmacognostical, Physicochemical parameters, Microbiological study. **Methods:** Raw drugs identification and authentication was done by pharmacognostical study i.e. morphological features, organoleptic characters and powder microscopy. Physicochemical evaluation was carried out of final product. **Results:** Pharmacognostical Study of raw drugs showed presence of cork cells and bordered pitted vessels of *Guduchi*, Prismatic crystals and Starch grains of *Sariva*, Stone cells & Scleroids of *Twaka*, Oil Globule of *Lavanga* etc. Pharmaceutical evaluation showed results PH 5.5, loss on drying 10.25%w/w, Ash value 10%w/w, Acid insoluble ash 0.18%w/w, Water soluble extract 28.72%w/w, Hardness 1.8 kg, Disintegration time 35.15. Microbiological study of the *Sarivadi Vati* showed that there were no growth of microorganisms (bacterial or fungal) found, till date. i.e 6 month from the date of preparation.

Keywords: *Badhira*, Pharmacognosy, Physicochemical, *Sarivadi Vati*, Standardization.

1. INTRODUCTION

Acharya Sushruta has mentioned 28 *Karna roga* and *Badhira* is one among them. ¹ This condition is mainly characterized by *srotorodha* due to predominance of *vata* or *vatakaphadosha*. Parallel to this *Badhira*, is condition

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which has presentation of hearing loss. Hearing impairment is the most frequent sensory deficit in human populations, over 5% of the world's population – 360 million people has disabling hearing loss (328 million adults and 32 million children).² Hearing impairment is one such condition that has not much treatment modality. In India itself, 63 million people (6.3%) suffer from significant hearing loss. *Sarivadi Vati* is an Ayurvedic tablet form which is used in treating hearing problems such as tinnitus, ear infection etc. This formulation having twelve ingredients and two *Bhasmas* i.e. *Abhraka Bhasma*, *Loha Bhasma*. *Sarivadi vati* is prepared with *Bhavana* by five *Bhavana dravya*. *SarivadiVati* is an Ayurvedic tablet used in treating hearing problems such as tinnitus, ear infection etc. Antimicrobial action of this formulation fights against the bacterial infection in ear. Majority of drugs are having *vata kaphashamak* action. So, it is more effective in *vata kaphaj Karnaroga*. Standardization of drug means confirmation of its identity and determination of its quality and purity. The quality assessment of herbal formulations is of paramount importance in order to justify their acceptability in modern system of medicines.

OBJECTIVE OF STUDY:

Present study, is aimed to look out on herbal drugs used in the preparation of *Sarivadi Vati* and Standardization of Pharmacognostical, Physicochemical parameters, Microbiological study. The purpose of Standardization of raw drugs and final product is to ensure therapeutic efficacy. Therefore, maintaining the quality of this product is an essential factor.

2. MATERIALS & METHODS

Collection, identification, authentication of raw drugs

Collection of raw materials

Herbal *Dravya* procured from the pharmacy of Gujarat Ayurveda University, Jamnagar. The ingredients of *Sarivadi Vati* and its part used are given at Table No 1. The raw drugs were identified and authenticated by Pharmacognosy Laboratory, IPGT & RA, Gujarat Ayurved University, Jamnagar. Identification was done on basis of organoleptic characters [Table No 2], morphological features and powder microscopy of raw drugs as per API standards for authentication. Powder of raw drugs and *Sarivadi Vati* stored in well filled closed glass containers away from the light.

Table 1: Formulation composition: Sarivadi Vati

No	Ingredients	Latin / English name	Part used	Proportion
Herbal Drugs				
1	<i>Dalchini</i>	<i>Cinamomum Zeylanicum</i> .Blume	<i>Twaka</i>	1/4 part
2	<i>Ela</i>	<i>Elettaria cardamomum</i> .Maton	Fruit	1/4 part
3	<i>Guduchi</i>	<i>Tinospora cardifolia</i> Hook thoms	Stem	1 part
4	<i>Kustha</i>	<i>Saussurealappa</i> .C.B.clark	Root	1 part

5	<i>Madhuyasti</i>	<i>Glycyrrhiza glabra</i> .Linn	Root	1 part
6	<i>Nagakerasa</i>	<i>MesuaFerrea</i> Linn	<i>Punkesara</i>	1/4 part
7	<i>Nilotpala</i>	<i>Nymphaea Nouchaliburm</i>	<i>Panchanga</i>	1 part
8	<i>Priyangu</i>	<i>Callicarpa Macrophylla</i> Vahl.	<i>Puspa</i>	1part
9	<i>Sariva</i>	<i>Hemidesmus indicus</i> .R.Br	Root	1 part
10	<i>Tejpatra</i>	<i>Cinamomumtamala</i> .Nees&Eberm	<i>Leaves</i>	1/4 part
11	<i>Lavanga</i>	<i>Syzygiumaromaticum</i> . Linn	<i>Puspakalika</i>	1 part
12	<i>Haritaki</i>	<i>TerminaliaChebula</i> . Retz	<i>Fruit</i>	1/3 part
13	<i>Vibhitaki</i>	<i>TermanaliaBelerica</i>	<i>Fruit</i>	1/3 part
14	<i>Amalaki</i>	<i>Emblicaofficinalis</i> .Gaertn	<i>Fruit</i>	1/3 part

Bhasma

15	<i>AbhrakaBhasma</i>	<i>Calcined biotite mica</i>	<i>Bhasma</i>	9 part
16	<i>Lauhahbhasma</i>	<i>Calcined iron</i>	<i>Bhasma</i>	9 part

Bhavana dravya

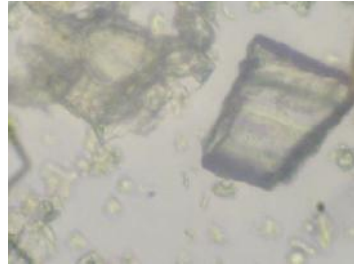
1	<i>KeshrajAmbu</i>	<i>Wedelia Calendulacea</i>	<i>Svarasa</i>	Q.S
2	<i>Arjunatvaka Kwatha</i>	<i>Terminalia Arjuna</i>	<i>Kwatha</i>	Q.S
3	<i>Yavkshara Drava</i>	-	<i>Solution</i>	Q.S
4	<i>Kakmachi</i>	<i>Solanum Nigrum</i>	<i>Swarasa</i>	Q.S
5	<i>Gunjamula</i>	<i>AbrusPrecatorius</i>	<i>Decoction</i>	Q.S

Preparation of Sarivadi Vati in pharmacy of Gujarat Ayurveda University, Jamnagar.

Take fine powder (#120) of the all ingredients in the proportion which mentioned earlier .(Table-1).Then *Bhavana* should be done separately with *Bhringaraja Svarasa*, *Arjuna Kwath*, *Yavakshara jala*, *Kakamachi Svarasa* and *Gunjamoola Kwatha* one by one for one day each. Then *Vati* of 250mg were prepared .Then after it was stored in airtight container. The whole process of *Vati* preparation was done at the Pharmacy under sterile environment.

Pharmacognostical Study

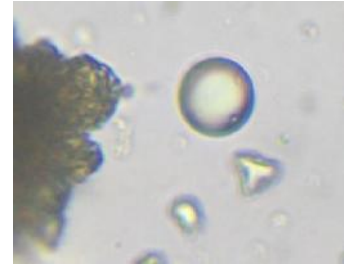
Herbal Drugs used in *Sarivadi Vati* was identified and authenticated by pharmacognosy department, IPGT & RA, Gujarat Ayurved University, Jamnagar. The identification was carried out on raw drugs. Various characters like colour, odour, taste and touch are recorded by using sensory organs.³ Powder microscopy of the finished product was done without stain and after staining with Phloroglucinol+HCl micro photographs were taken under Carl- Zeiss Trinocular microscope attached with camera⁴ By Powder microscopy observed the characters, determined the chemical nature of the cell wall along with the form and chemical nature of the content of the cells.^{5,6}



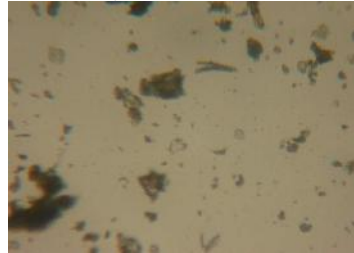
Prismatic crystal of *Sariva*



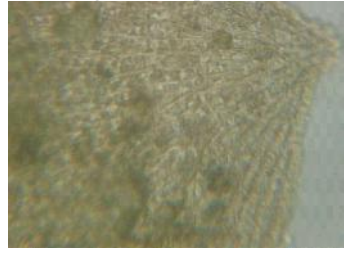
Gudu - frg of border pitted



Oil globule of *lavanga*



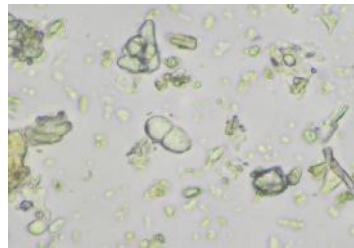
Starch grains of *Nagakesara*



Aleurone grain of *Tamala*



Sclerieds of *Twak*



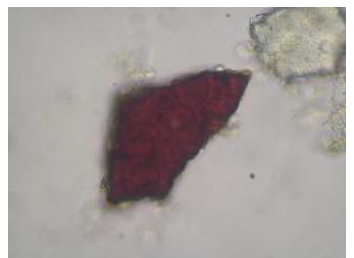
Compound starch grain of *Yashti*



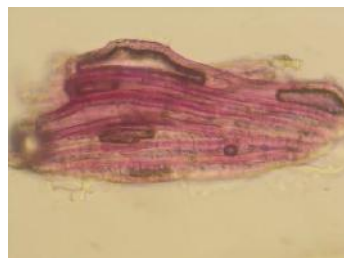
Trichome of *Vibhitaki*



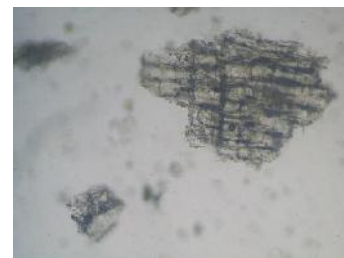
***Amalaki* sclera**



Pericarp cell of *Ela*



Lignified sclera *Haritaki*



***Kushta* cork cells**



***Nilotpala* trichome**



***Priyangu* lignified fibers**

Fig 1: Microphotographs of *Sarivadi vati*

Pharmaceutical Evaluation

Physicochemical Parameters

Sarivadi Vati was analyzed by using qualitative and quantitative parameters at Pharmaceutical Laboratory, IPGT & RA, Gujarat Ayurved University, Jamnagar. *Sarivadi Vati* was analyzed through relevant physicochemical parameters. Physical tests like average weight of *Vati*, average hardness, disintegration time, loss on drying, ash value, acid insoluble ash, PH, and chemical tests like water-soluble extractive were taken^{7, 8}

Microbiological study:

Sample of *Sarivadi Vati* were prepared and studied to check microbial contamination at different climatic conditions. The study was conducted at Microbiology Laboratory, I.P.G.T & R.A., Jamnagar, Gujarat, India. The present Study was carried out to observe the stability study of *Sarivadi Vati* with respect to Microbial Contamination of sample prepared and preserved in different climatic and temperature conditions. Thus, a baseline Microbial profile was studied at regular interval of 15 days for 3 month (table 4).

3. OBSERVATION & RESULTS

Organoleptic characters:

Table 2: Organoleptic characters of *Sarivadi vati*

J	CHARACTERS	OBSERVED CHARACTERS
1	Colour	Reddish brown
2	Odour	Slightly aromatic
3	Taste	Salty
4	Touch	Hard

Microscopic Characters of *Sarivadi Vati*:

Diagnostic characters of *Sarivadi Vati* were observed under the microscope cork cells and bordered pitted vessels of *Guduchi*, Prismatic crystals and Starch grains of *Sariva*, Stone cells & Scleroids of *Twaka*, Oil Globule of *Lavanga*, Starch grain of *Nagakesara*, Compound Starch grains of *Yashti*, Trichome of *Vibhitaki*, Sclera of *Amlaki*, Pericarp cell of *Ela*, Cork cells of *Kushta*, Trichome of *Nilotpala*, Lignified fibres of *Priyangu*. Details of which are depicted in plate no: 1

Physicochemical analysis:

Results of physicochemical analysis i.e. PH, loss on drying, ash value, acid insoluble ash, water soluble extract, hardness, disintegration time shown in Table 3.

Table 3: Results of Physicochemical Evaluation of *Sarivadi Vati*

SR NO	PARAMETERS	RESULTS
01.	pH	5.5
02.	Loss on drying	10.25% w/w
03.	Ash value	10% w/w
04.	Acid insoluble ash	0.18% w/w
05.	Water Soluble extract	28.72% w/w
06.	Hardness	1.8kg/cm ² by Monsanto hardness tester
07.	Disintegration time	35.15 minute

Table 4: Observations of sample preserved at room temperature

Sr. No	Observations of samples				
	Gram's Stain	Aerobic culture	Wet mount/ 10% KOH Preparation	Fungal culture	
1	1st day	not seen Microorganisms isolated	No organisms isolated	Fungal filaments not seen.	No fungal pathogen isolated
2	15th day	Microorganisms not seen	No organisms isolated	Fungal filaments not seen.	No fungal pathogen isolated
3	30 th day	Microorganisms not seen	No organisms isolated	Fungal filaments not seen.	No fungal pathogen isolated
4	45 th day	Microorganisms not seen	No organisms isolated	Fungal filaments not seen.	No fungal pathogen isolated
5	60 th day	Microorganisms not seen	No organisms isolated	Fungal filaments not seen.	No fungal pathogen isolated
6	75 th day	Microorganisms not seen	No organisms isolated	Fungal filaments not seen.	No fungal pathogen isolated

4. DISCUSSION

Pharmacognostical evaluation showed that organoleptic characters of the sample was reddish brown in color, aromatic odor, salty in taste, hard in touch and soft in texture. Microscopically study showed that cork cells and bordered pitted vessels of *Guduchi*, Prismatic crystals and Starch grains of *Sariva*, Stone cells & Scleroids of *Twaka*, Oil Globule of *Lavanga*, Starch grain of *Nagakesara*, Compound Starch grains of *Yashtimadhu*, Trichome of *Vibhitaki*, Sclera of *Amlaki*, Pericarp cell of *Ela*, Cork cells of *Kushta*, Trichome of *Nilotpala*, Lignified fibres of *Priyangu* shows that all the ingredients were present in the finished product and also proven that the purity of the finished product.

The physicochemical parameters plays an important role in the standardization of formulation. According to present study, the total ash is particularly important in the evaluation of purity of drugs, i.e. the presence or absence of foreign matter such as metallic salts or silica^{9, 10} Analytical results showed Total Ash value i.e. 10% w/w. The amount of Acid-insoluble siliceous matter present in product i.e. 0.18% w/w. The water soluble extractive values (28.72% w/w) indicated the presence of sugar, acids etc. The loss on drying at 105°C was 10.25w/w. The pH from 10% w/v solution revealed that pH of formulation was comparable and was slightly acidic. This may be because of acidic salts present in the crude drugs used for preparation of formulation. The Hardness (1.8 kg/cm²) of a *Vati* is a function of how much pressure has been exerted in making it and it varies with the composition, thickness, shape and diameter of tablets¹¹ The disintegration test is a measure of the time required under a given set of conditions for a group of *Vati* to disintegrate into particles. This was found to be 35.15 minutes.

Microbiological study of the *Sarivadi Vati* showed that the quality of *Vati* in standard condition. There were no growth

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of microorganisms (bacterial or fungal) found, till date. i.e. 6
month from the date of preparation in case of *Sarivadi Vati*,
which shows their good shelf life.

Conflict of Interest: None

Source of Funding: Nil

5. CONCLUSION

From the present investigation various standardization parameters such as Physicochemical standards, Pharmacognostical Evaluation and Microbiological study were carried out, it can be concluded that the formulation of *Sarivadi Vati* contains all good characters of an ideal *vati* and it was found to be more effective and economic. The study shows that the contents of formulation are of good quality and purity. The result of present study will also serve as reference standards in the preparation of drug formulation and also helpful in further clinical researches.

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