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FORMULATION AND PHYSICO CHEMICAL EVALUATION OF AN AYURVEDIC POLY HERBAL DRUG MADHURANTAK VATI

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Abstract

Standardization is an important aspect for maintaining and assessing the quality and safety of the polyherbal formulation as these are combinations of more than one herb to attain the desire therapeutic effect.The present paper reports on the standardization of Madhurantakvati a polyherbal formulation indicated in eteric fever. The formulation was prepared as per the reference of Rasatantra Saar evam Sidha prayogaSangraha, a textbook mentioned in the schedule 1 of Drug and Cosmetic act.Analysis of the drug was carried out based on the organoleptic and physicochemical properties.The parameters can be used as a reference standard for the preparation of the polyherbal formulation Madhurantakvati.

Keywords: standardization, polyherbal formulation, Madhurantak Vati

Introduction

Standardization is an important aspect for maintaining and assessing the quality and safety of the polyherbal formulation as these are combinations of more than one herb to attain the desire therapeutic effect. Standardization minimizes batch to batch variation; assure safety, efficacy, quality and acceptability of the polyherbal formulations[1]. Madhurantakvati is a polyherbal formulation mentioned in Rasatantra sara and Sidhaprayogasangraha and is widely prescribed in enteric fever.[2]It contains ingredients like tulasipatra,guduchisatva,ela,dhanyaka,vamshalochana ,lavanga and kasanibeeja and bhavana is given with

[1] Pravin H. Nikam, Joseph Kareparamban, Aruna Jadhav and Vilasrao KadamFuture Trends in Standardization of Herbal Drugs,Journal of AppliedPharmaceutical Science 02 (06); 2012: 38-44

[2]TakurNathusingh,RasaTantra Saar evumSidhaPrayogSangrah Vol. 2,20 th reprint ,Krishna Gopal Ayurveda Bhavan,Kaleda: Jwaradhikar,2017,p. 95.

tulsipatraswarasa. Physico chemical analysis of the formulation was carried out following the guidelines set by WHO for the standardization of herbal drugs.

Materials & Methods

Three batches of madhurantakvati(MVS1,MVS2,MVS3) were prepared as per the classical reference following proper SOP and SMP. All the raw materials except *Guduchi* and *Kasani beeja* were procured from the pharmacy N.I.A., Jaipur. *Kasani beeja* was procured from a local vendor in Jaipur and fresh *Guduchi* stem was collected from in and around the campus of National Institute of Ayurveda ,Jaipur**.**Preparation of *Madhurantakvati* involved the steps likePreparation of *GuduchiSatwa*, Powdering of all other ingredients and mixing in proper ratio and *Bhavana* with *Tulasi Swarasa*.Physicochemical analysis of the sample included parameters like loss on drying,ashvalues,extractive values etc.

Pharmaceutical study

Guduchisatva preparation

*Fresh Guduchi*stem was collected, the physicalimpurities were removed & washed thoroughly with water. Cleaned stem were cut in to small pieces 2-3 inches.(Average dia-2cm average length2.6cm)**.**Five kg of *Guduchi* stem pieces were pounded in *khalwa* until fibers of stem got separated and the material becomes sticky. Four times R O Water (20 litres) was added into it and rubbed well with hands thoroughly and kept overnight for soaking.Next day the material was again well rubbed, until the sliminess disappears into the same water. Then fibers were removed and the remaining material was strained through clean cloth.The strained material was collected in a flat bottom stainless steel container and allowed for the sedimentation. When the solid particles in the materials were sedimented on the bottom of container, the upper liquid portion was decanted carefully. After decantation the starch obtained was again mixed with little quantity of water and allowed again for sedimentation and then liquid portion was removed by decantation process. Repeated washing and decantation were done, for 15 times. Then clear white starch was obtained.Obtained starch was taken in a SS plate and dried.The obtained *Satva* was stored in air tight bottle to avoid moisture absorption of *Satva*.

Powdering

Crude drugs were weighed individually. By careful inspection, foreign matters like dust, sand etc. were removed. Then the entire ingredients were cleaned by cloth dusting. The weightof drugswere noted again to calculate the loss of weight and were stored in separate plastic bags. *Tulasi patra, Lavang, Vanshlochana, Ela, Dhanyak*and *Kasani beej* were powdered separately with the help of grinder and sieved through mesh (80N).Powders were packed separately in air tight container.

Bhavana

For *bhawana* with *Tulasi swarsa*Fresh leaves of *Tulasi* werewas put into mixer grinder along with small quantity of R.O water and smooth Paste (*Kalka*) was prepared.The*kalka* was expressed through the cotton cloth manually. Filtered juice (*swarasa*) was then collected into a steel container.Obtained*swarasa* was

measured by measuring cylinder and then used for *Bhawana* process. Fresh *swarasa*was prepared and used each time.

All the powdered ingredients were weighed as per the requirement. Powdered *Vanslochan* was taken in a*Khalva-yantra* and *Mardana* was carried out for few minutes. Then fine powders of *Lavang* and *Kasani Beej* were added one by one and triturated it for few minutes. The remaining fine powders of *Guduchi Satva, Tulsi Patra ,Dhanyak* , and *Ela* were added and triturated for few minutes till it attained a uniform mixture. Finally this uniform mixture was levigated with required quantity of *Tulsi patraswarasa*till it attained semi solid state. *Bhavana* with *Tulsi Patra Swarasa*was repeated two more times. Then handmade*vati* of size 125 mg. were prepared, dried in shade and stored in airtight container. Similar procedure was adopted for preparation of two more batches of *Madurantakvati*.

Analytical study

Following parameters were selected for the quality assurance of the formulation.

Organoleptic parameters, Loss on drying, Ash value ,Acid Insoluble ash ,Alcohol soluble extractive, Water soluble extractive , pH value ,hardness ,uniformity of weight, Disintegration test, HPTLC ,Microbial contamination, Heavy metal analysis.

Observations and Results

Table No. 1 : Process validation for *Guduchi Satva*(3 batches)

Parameters	Batch
Weight of fresh Guduchi stem	5 kg
Size of Guduchi stem pieces	2.6
Diameter of Guduchi stem pieces	2.1
Quantity of water used	20 lit
Duration(h)	*25*
Yield of Starch (*Satva*) obtained	121.8 g
Yield in %	2.4%

Table No.2: Showing ingredients of*Madhurantak Vati (MVSV)*

S.N.	Ingredients	Ratio of each ingredients	Quantity
1.	*Tulsi Patra*	4Part	40 g
2.	*Guduchisatva*	2Part	20 g
3.	*Vanslochan*	1Part	10 g
4.	*Dhanyaka*	1Part	10 g
5.	*Ela*	1Part	10 g

6.	*Lavang*	1Part	10 g
7	*Kasani beej*	1Part	10 g
8	Total Wt.		110 g

Table No. 3 : Showing removal of foreign matter from crude drugs and their powdering :

S.N.	Ingredients	Total amount	Amount after removing foreign matter	Percentage of foreign matter	Amount after powdering	Yield (%)	Powdering loss(%)
1.	***Tulsi* (Dry)**	300g	280g	6.66%	260 g	92.86%	7.14 %
2.	***Lavang***	250 g	240 g	4 %	210 g	87.5 %	12.5 %
3.	***Vanshlochan***	250 g	245 g	2 %	239 g	97.55 %	2.45 %
4.	***Dhanyak***	250 g	240 g	4 %	230 g	95.83 %	4.17 %
5.	***Kasani Beej***	100 g	80 g	20%	70 g	87.5 %	12.5 %
6.	***Ela (*fruit)**	350 g	260 g(seed)	25.71 %	235 g	90.38 %	9.62 %

Table no.4 Showing various numerical parameters during the preparation of 3 batches of *Tulasi patraswarasa*

Sl.No	Batch	Weight of *Tulshipatra*	Quantity of water Consumed(ml)	Total Quantity of Swarasa obtained(ml)	Mean Value	Colour Of *Swarasa*
1	Batch 1(MVS1)	350 g	100	340	356.7	Light Green
2	Batch 2(MVS2)	350 g	100	360		Light Green
3	Batch 3(MVS3)	350 g	100	370		Light Green

Table No.5 Showing observation and results ofpreparation of 3 batches*Madhurantak Vati* (MVS1,MVS2,MVS3)

Drug	*Bhavana*	Quantity of *Tulsi swarasa*consumed for each *bhawana* (ml)	Total quantity consumed (ml)	Wt. of Sample drug Before *bhavana* (g.)	Wt. of mixture after 3 *bhavana* (g.)	Increase in weight (g.)	Mean Value (g.)
MVS1	1st	210	360	110	124.5	14.5	12.43
	2nd	70					
	3rd	80					
MVS2	1st	200	370	110	122.8	12.8	
	2nd	90					
	3rd	80					
MVS3	1st	210	360	110	120.0	10	
	2nd	70					
	3rd	80					

Table 6 Showing the Organoleptic characters of MVS

SL NO	CHARACTERS	MVS1,MVS2,MVS3
1	Appearance/texture	Round shaped ,smooth surface
2	Colour	Dark green
3	Odour	Characteristic

4	Taste	Katu ,kashaya

Table 7: Showing the Physico chemical parameters of MVS

S. NO	PARAMETER	RESULT			
		MVS1	MVS2	MVS3	MEAN
1.	Loss on Drying at 1050c	9.70%	8.9	9.2	9.26%
2.	Total Ash	15.86%	19.10%	17.85%	17.60%
3.	Acid Insoluble Ash	6.65%	7.55%	6.31%	6.83%
4.	Water Soluble Extractive Value	3.88%	7.44%	5.88%	5.73%
5.	Alcohol Soluble Extractive Value	9.42%	7.45%	8.85%	8.57%
6.	pH value (10%aqueous extract)	5.80%	5.80%	5.30%	5.63
7.	Uniformity of weight (mg)	Avg-150.6 Max-160 .0 Min.-142.0	Avg-128 .0 Max-138 .0 Min.-120.0	Avg-136.8 Max-144 Min.-128.0	138.46 (Uniform)
8.	Hardness	06	03	09	6
9.	Disintegration Time	45min	45min	45min	45 min

Table 8. Showing Heavy metal analysis of MVS1

S. no.	Heavy Metal	Result	Limits
		MVS1	
1.	Lead	7.4 mg/kg	NMT 10 mg/kg
2.	Cadmium	BLQ (LOQ 0.1) mg/kg	NMT 0.3 mg/kg
3.	Mercury	2.27 mg/kg	NMT 1 mg/kg
4.	Arsenic	109.45 mg/kg	NMT 3 mg/kg

Table 9. Showing microbial contamination of MVS1

S. No.	Test parameter	Result	Limits
		MVS1	
1.	Total bacterial count	700 cfu/g	NMT 100000 cfu/g
2.	Total Fungal count	50 cfu/g	NMT 1000 cfu/g
3.	*E. coli*	Absent/g	Should be absent
4.	*Pseudomonas aeruginosa*	Absent/g	Should be absent
5.	*Staphyllococcus aureus*	Absent/g	Should be absent
6.	*Salmonella spp.*	Absent/g	Should be absent

Discussion

Discussion on Pharmaceutical Study

Preparation of *guduchisatva*

According to the A.F.I *Satva'* is aqueous extractable solid substance collected from herbal Plant.Word*"Guduchi Satva"* For the very first time mentioned in *"Rasendra Mangalam"*[3]in context of *"Panchamruta Ras.*" due to its usefulness it is incorporated in the various preparations like *Panchamruta Ras*. *Guduchi satva* preparation is mentioned in *Yoga Ratnakar*[4],*Rasa Yoga Sagar*[5], *SiddhayogaSangraha*[6],

[3] Nagarjuna . Rasendra Mangalam of Nagarjuna. 3\112. In: Sharma HS, editor. Varanasi: Choukhamba Orientalia; 2008. p. 84. [Google Scholar]

[4] Shastri B, editor. 7th ed. Varanasi: Choukhamba Sanskrit Sansthan; 2002. Commentary Vidhyotani of Shastri L on Yogaratnakara of Anonymous; p. 118. [Google Scholar]

[5] Sharma H, Rasa Yoga Sagara. Reprint ed. Varanasi: Chaukhamba Krishnadas Academy; 2004. p. 378. [Google Scholar]

[6] Acharya YT. 13th ed. Ch. 14. Nagpur: Shri BaidhnathAyurved Bhavan Ltd; 2008. Siddha Yoga Sangraha. RajyakshmaUrahkshatadhikar; pp. 83–4. [Google Scholar]

Dravyagunavigyana[7]etc. All these texts have mentioned different methods of preparation…….According to *Yoga RatnakarGuduchi*stem was cut into According to the A.F.I., Satva' is an aqueous extractable solid substance collected from herbal plants. The word "Guduchi Satva" is mentioned for the very first time in "Rasendra Mangalam in the context of "Panchamruta Ras." Due to its usefulness, it is incorporated in the various preparations like Panchamruta Ras. small pieces and triturated well in water then it was filtered through cloth and supernatant liquid is decanted and*shankhanibha*sediment is collected. The quantity of liquid and overnight soaking is not stated, in this reference . *Shankhanibha revealed the color of satva, i.e., the white color. According to Siddha Yoga Sangraha, Guduchi stem is cut into small pieces and pounded well, and then it is kept for overnight soaking in water. The next day it was filtered through cloth, allowed for sedimentation, supernatant liquid was decanted, and sediment was collected. In this reference, soaking was mentioned, but the volume of liquid is not mentioned. The author advised taking the water quantity as sufficient. According to 'Rasa Yoga Sagar, 'Guduchisatva' is called Guduchimodak. 'Rasa Yoga Sagar' has also not mentioned the quantity of water, but it stated that the kalka should be made so fine by trituration & the color of satva is described as Shubhrakhandanibha. In commentary on Bhavaprakash, four times of water for soaking and time of soaking (12-24 hrs) were also mentioned.*In the present study *guduchisatva* was prepared as per the reference of*Dravyagunavigyana* by *YadavjiTrikamji Acharya*.Three batches of*guduchisatva* were prepared.For each batch 5 kg of fresh *guduchi* was utilized.Five kg of Guduchi stem pieces were pounded in khalwa until fibers of the stem got separated and the material became sticky. Four times R O Water (20L) was added into it and rubbed well with hands thoroughly and kept overnight for soaking. The next day the material was again well rubbed until the sliminess disappeared into the same water. Then fibers were removed, and the remaining material was strained through clean cloth.

The strained material was collected in a flat-bottom stainless steel container and allowed for the sedimentation, and then the liquid portion was removed by the decantation process. Repeated washing and decantation were done 15 times. Then clear white starch was obtained. And then the liquid portion was removed by the decantation process. Repeated washing and decantation were done 15 times. Then clear white starch was obtained. The whole process took 7 days for completion. Decantation was done repeatedly to get pure white-colored starch. The percentage yield of guduchisatva of three batches was 2.4%, 1.8%, and 0.61%, respectively. Yield was different for the three batches. Earlier scholars who worked on the pharmaceutical aspect of Guduchisatva reported quantitative variation in the final product.Reported yield of 0.48% satva with fresh stem and 1.20% with dried stem. Preeti Salunke et al. Reported extraction of 0.1% of satva from fresh stem. Sharma Rohit et al., Reported extraction of 1.2%, 2.7%, and 0.76% yield of Satva from thin, medium, and thick stems, respectively..[8]These variations may be due to differences in the species, size of the stem, collection time, and levels of the maturity of the plant. The yield of the Guduchi Satva greatly depends on the

[7]VaidhyaYadav ji TrikamjiAacharya, Dravya Guna Vigyana, Poorvardha&Uttarardh ,Chaukhamba Sanskrit Sansthan; Varanasi:(Uttarardhapratham khanda 2/ 108-109).

[8]Sharma R, Harisha CR, Galib R, Patgiri BJ, Prajapati PK. Quantitative estimation of satva extracted from different stem sizes of Guduchi (*Tinospora cordifolia* (Willd.) Miers. J Pharm Sci Innov. 2012;1(1):38–40

size, environment, association, and cellular activities. In the present study, more yield of guduchisatva was obtained in the practical one, which was carried out in the month of February. The next two batches prepared in the months of March and April yielded less starch.This difference in the yield of Guduchisatva in different seasons is also supported by previous studies, which state that the yield of GS is found to be more in January-February (Shishira) and least in May-June (Grishma). This may be due to the impact of different seasons on cellular proliferation and plant maturity. Maximum metabolic activity of the starch grains in cellular constituents occurs after preliminary development, during which the percentage of starch also increases. Thus, it infers that full maturation of starch grain occurs in Shishira Ritu, which results in maximum yield. The color of the guduchisatva of all three batches was white, and all three samples were tasteless.

Powdering of raw drugs

Ingredients of Madhurantakvati like *Tulasi patra, Lavang, Vanshlochana, Ela, Dhanyak*and *Kasani beej* were cleaned properly, foreign material was removed and powdered separately with the help of grinder and sieved through mesh (80N).Maximum foreign material was observed in *Tulsi patra* (6.66%%) followed by *kasanibeeja*(20%) and *Ela*(25.71 %).In the present study *Tulsi patra*was used, while the raw material was mixed with stem of *Tulsi* and hence loss was more after removal of foreign matter. In case of *Ela* outer covering was removed before powdering which caused the loss.

Preparation of tulsiswarasa

Tulsi swarasa was prepared as per the reference of *Sharangdharasamhiata*.Six batches of*swarasa* was prepared.For each batch 350 g of fresh leaves were used and 100ml of RO water was used to get an average of 358 ml of *swarasa*. Addition of water was necessary for the proper expression of *swarasa*. The expressed*swarasa*was light green in colour.

Preparation of *Madhurantak Vati* (MVS)

The ratio of ingredients of MVS was Tulsi patra 4 parts, *Guduchisatva*2 parts and all other drugs were one part each. In the present study MVS were prepared in three batches. For preparation of*vati*powdered *Vanslochan* was taken in a *Khalva-yantra* and *Mardana* was carried out for few minutes. Then fine powders of *Lavang* and *Kasani Beej* were added one by one and triturated it for few minutes. The remaining fine powders of *GuduchiSatva ,Tulsi Patra , Dhanyak ,* and *Ela* were added and triturated for few minutes till it attained a uniform mixture. Finally this uniform mixture was levigated with required quantity of *Tulsi patraswarasa*till it attained semi solid state. *Bhavana* with *Tulsi Patra Swarasa*was repeated two more times. Similarly, other batches were also prepared. The total weight of powders was 110 g. An average increase in weight of 12.43 g was observed after three Bhavana with Tulsi patra in the case of MVS. The increase in weight can be attributed to the moisture content and addition of solid content from the bhavana dravya.

- In an attempt to assure the quality of the prepared drug a set of physicochemical parameters which include parameters to assess the authenticity and quality of raw drugs used in the preparation of formulation as well as the quality control parameters of *vati*were carried out in the present study. Furthermore, a comparison of the data of the analytical study of both samples, i.e., Madhurantakvati prepared using the classical reference (MVS) and Madhurantakvati, which was prepared by replacing

Guduchisatva with Guduchi Ghana (MVG), was also done to assess the changes in the various parameters. MVS and MVG were prepared in three batches each in an attempt to standardize them; the physicochemical parameters were done in triplicate, and the mean value was calculated.

Organoleptic evalution

Regarding the organoleptic parameters, color samples were dark green in color, probably due to the fresh Tulsi patraswarasa used for Bhavana. They were round in shape and uncoated. The taste of vati was Tikta and kashaya due to the predominance of Tikta and kashaya rasa of individual ingredients.

- **Loss on drying**

Loss on Drying of Sample MVS was 9.7%, 8.9%, and 9.2% for MVS1, MVS2, and MVS3, respectively, and the mean value was 9.26%. Moisture content should be minimum to prevent degradation of product. Excess moisture in drugs encourages microbial growth, the presence of fungi or insects, and leads to deterioration following hydrolysis. Moisture content of both MVS and MVG shows that the tablet should be protected from humid atmosphere, or else water activity would be increased, and it will cause degradation of the tablet.

- **Total ash, Acid insoluble ash**

Ash values are the criteria to judge the identity and purity of crude drugs; MVS contained 17.60 w/w of total ash, respectively. The mean acid insoluble ash of MVS was 6.83% w/w. The residue remaining after the ignition is called ash, which generally contains some inorganic salts derived from the sample, but some adulteration may be added from the sand and soil to the material. Ash value depends on the presence of inorganic substances in the material. Acid Insoluble Ash (AIA) is a part of total ash insoluble in dil. HCl.

- **Extractive values**

In the present work, alcohol and water (distilled water) were used to determine the extractive values. Alcohol-soluble extractives indicate the alcohol-soluble constituents of the formulation, while water-soluble extractive values indicate the water-soluble constituents present in the sample. The alcohol-soluble extractive value of MVS was 8.57%. and water-soluble extractive of MVS was 5.73%

- **pH**

The pH value is one of the main factors influencing the quality of medicine. It always controls many chemical and microbiological reactions. This value conventionally represents the acidity or alkalinity of an aqueous solution and is important from the point of view of the stability or physiological suitability of the drug. The average pH of MVS was 5.63. The values show that the formulations are acidic in nature.

- **Uniformity of weight**

20 tablets of each formulation were weighed individually, and the mean weight was determined. As per the standards the weight variation of tablets having weight ranging from 80-250 mg, Average weight should not exeed the limit of ± 7.5 % for 90% of the tablets and not more than 10% of the tablets exeed a deviation of ± 15% .In the present study, MVS had an average weight of 138.2 mg, the maximum weight of vati was 147.33 mg, and the minimum weight was 128. The vati were found uniform.

- **Hardness**

A hardness of 4 kg/cm² is suitable for handling, and 6 kg/cm² or more would produce a highly compact nature. (Laboratory Guidebook for the Analysis of Ayurveda and Siddha Formulations, CCRAS.). The average hardness of MVS was 6.

- **Disintegration time**

For the medicinal agent in a tablet to become fully available for absorption, the tablet must first disintegrate and dissolve the active part of the drug into the body fluids. Tablets must disintegrate, varying from about 2 minutes to up to 4 hours. Disintegration time (D.T.) is related to the bioavailability of any drug. It is performed to find out how much time the tablet disintegrates at a thermostatically maintained temperature of 370°C. This one is important because the dissolution rate depends upon D.T., which ultimately affects the rate of absorption and physiological availability of the drug in the bloodstream. In the present study, the average D.T. of MVS was 45 min.

Heavy metal analysis

Heavy metals were analyzed by the method of ICP-MS. Results showed lead level as 7.4 ppm, which was within the prescribed limits of 10 ppm. Cadmium level was below the limit of quantification. Mercury and arsenic levels were slightly above the limit. Higher level of arsenic content may be probably attributed to cross contamination in the practical lab where purification etc of mineral drugs are carried out side by side.

- **Microbial contamination**

There is always a chance for herbal drugs to be contaminated with microorganisms from soil, air, and water. Sometimes, microorganisms potentially pathogenic to humans may be present. So it is necessary to estimate the total microbiological count of any pharmaceutical product. Total bacterial MVS was 700 cfu/g, which was below the permissible limits. Total fungal count was 50cfu/g and was within the limits prescribed. In the present study pathogenic bacteria viz E.coli, Pseudomonas aeuruginosa, Staphyllococcus aureus and Salmonella spp. were found absent.The results reveal that the formulations are safe and proper hygiene norms were followed during the preparation of the formulations.

Conclusion

Physicochemical analysis of MVS showed an average moisture content of 9.26%, an ash value of 17.60%, an acid-insoluble ash value of 6.83%, an alcohol-soluble extractive value of 8.57%, a water-soluble extractive value of 5.73%, a pH of 5.63, a hardness of 6, and Disintegration time f 45 minutes. The above parameters can serve as reference values in the pharmaceutical preparation of Madhurantak Vati.