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Pharmaceutical Analytical Standardization of *Mahanilvarti*

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Abstract

Mahanilvarti is the drug of choice in the management of *Avranashukla*(Corneal opacity) according to AcharyaVagabhata. In this Article the main aim is to study Pharmaceutical analytical standardization of Mahanilvarti. Drugs required for this *varti*are*Bruhatimula,Yashtimadhu,Tamrabhasma,Saindhava,SunthiAmalakirasa, Amalaki leaves, Yava,* Copper vessel. Method used for preparation is scientific,granthokta method, under all aseptic precaution. Pharmaceutical preparation and analytical study of *Mahanilavarti* was carried out atDattatrayaAyurvedRasashala, Mahatma Gandhi Ayurveda college Hospital and Research center Salod (H) WardhaMaharastra. The formulation was first tasted for Organoleptic parameters such ascolour and odour, Physico chemical analysis and microbial specification testings were performed.*Mahanilvarti* had black and charactersticodour, average weight gain 7.73gm.Analytical standards for *Mahnilavarti*such as loss on drying at 105oC, total ash value, total insoluble ash, water soluble extractive, alcohol soluble extractives, pH, are 1.98%, 4.73 %, 0.5%, 28.15%, 11.37%, 7.33 respectively..

Keywords-Corneal opacity**,** *AvranaShukla, Bruhatimula, Amalaki ,YashtimadhuTamrabhasma.*

INTRODUCTION

Corneal opacity is a problem of the cornea. Corneal opacity happens when the cornea gets scarred. This stops light beams going through the cornea to the retina and may make the cornea seem white or blurred i.e eye issue causes vision misfortune. Modern medicines differ contingent upon the most probable reason and seriousness of the scarring. Alternatives incorporate Eye drops containing steroids anti-infection agents, or both, orally orlocaly laser medical procedure, Phototherapeutic keratectomy (PTK), , Cornea transplant [1]

Vision impairment may be reduced by spectacle or contact lens correction. Contact lenses are good option for treatment of corneal scaring[2]. Corneal tattooing/cosmetic contact lens

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can be an option for rehabilitation, especially in patients where there was no alternative of useful improvement by different treatments [3,4].Careful Treatment Selection of the surgery is controlled by the profundity and area of the obscurity [5]. The proposed medical procedure should have a satisfactory danger/advantage proportion with the possibility to diminish the patient's handicap fundamentally.

In Ayurveda *AvranaShukla*[6] or *Shuddha Shukla* [7] is a disease of *Krishna Mandala* exhibits whitish dots or patches, single or multiple, stationary or diffused spreads from *PrathamaPatala* to *TrityaPatala*. Blind life is miserable hence advised to protect the eyes from diseases and injuries. Due to *Abhishyanda* and other external causes, white opacities develop on the *Krishna Mandala* that is known as *AvranaShukla* or *Shuddha Shukla*.

It is characterized by *AlpaVedana* and *Ashrusrava*. In some cases it associates with visual impairment if *Shukla* arises at the *Drishti Mandala*. It can be correlated to corneal opacity, due to the similarity in *lakshnas, Samprapti* and stages of the disease and becomes complicated. Non-spreading, superficial lesion of *PrathamaPatala* is said to be curable. It can be correlated to Corneal Opacity or non ulcerative keratitis. *AvranaShukla* is a disease affecting *Krishna Mandala* which may ultimately lead to disfi-gurement of cornea and blindness. *AvranaShukla* is a disease of *Krishna Mandala* exhibits whitish dots or patches on cornea due to scarring or clouding of the corneal tissue which decreases vision. The incidence is very common in economically backward and skilled labourers of rock cutting trade, among persons employed in various processes of thrashing, husking and pounding of paddy and also highly prevalent among the working class.corneal opacityprevalence shown 2.35% among the study population.Corneal opacity is one of the majorcauses of blindness. Out of total blind people 1.52% is blind only because of corneal opacity[8,9]. Any opacity in the refractive media causes blurriness of vision to blindness and cosmetic problem. Cornea being the first refractive media of eye has greater importance in refraction

MATERIAL & METHOD

Raw Material Such as *Bruhatimula* (Solanumindicum-Large Egg Plant), *Yashtimadhu*(Glycyrrhizaglabra-Liquorice),*TamraBhasma* (Cuprum-Copper),*Sunth*i (Zingiberofficinale Roscoe)*Saindhava*(Rock salt), *Amalakirasa* and leaves(Emblicofficinalis-Indian gooseberry),*Yava*(Carumcopticum).

Bruhatimula collected from ManasAyurved, Nagpur. *TamraBhasma*PurchesedFrom Uma Ayurvedics Pvt. Ltd, Aligarh.*Yastimadhu, Saindhava,* and *sunthi* were collected from DattatrayaAyurvedRasashalaSawngi Wardha . *Amalaki* Fruit and *Yava*collected from local market, *Amalaki* leaves collected Dattatraya Herbal Garden.(figure 1)Identification and authentication done by Taxonomist. Pharmaceutical preparation of *Mahanilvarti* wascarried out at DattatrayaAyurvedRasashala, MGAC Hospital &Research center Salod (H) WardhaMaharastra. Organoleptic,characters, Physico chemical analysis,microbial contamination was studied in analytical Lab as per API standards.

Table-1: Ingredients of *Mahanilvarti* for each batch

S. N.	Name of ingredients	Part used	Quantity
1.	*Bruhatimula*-Solanumindicum	Root	25gm

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2.	*Yashtimadhu*-Glycyrrhizaglbra,	Stem	25gm
3.	*Tamrabhasma*-Cuprum-,	Bhasma	25gm
4.	*Saindhava*,- Rock salt	-	25gm
5.	*Sunthi*-Zingiberofficinale Roscoe	Root	25gm
6.	*Amalakirasa*-Emblicofficinalis	Fruit	As per requirement
7.	*Amalaki l*eaves-Emblicofficinalis	Leaves	100gm
8.	*Yava*-Carumcopticum	Fruit	50gm

Preparation of *MahanilVarti*

MahanilaVartiAnjana contains *bruhatimulayashtimadhu* ,*tamrachurna*, *saindhava* and *sunthi* after triturin*g* in *amalaki* juice is applied internally to copper vessel. Smoke of the leaves of *amalaki* and yava is given. When dried , prepare varti triturating in water according to Vagbhatuttarkhand adhaya11/39,40,41.

Analytical Study

Analytical study was done to establish the basic standards for *Mahanilvarti*as there is no pharmacopeia standard guidelines. The formulation was first tasted for organoleptic parameters such as odour and colour(Table 4). Physicochemical analysis includes loss on dryingat 105^0C, , Water soluble extractive ,Acid insoluble ash, total ash, Alcoholssolubles Extractive, pH(Table 5) Microbial specifications were tasted to validate its safety for external use. Enterobacteriaceae, Total fungus count, E-coil, Salmonella, Staphylococusaureus, Pseudomonas aueruginosa were performed as per CCRAS Parameters(Table 6) Analysis of samples were conducted as per API Standards in Quality Analysis and Quality Control lab of MGAC Hospital and Research Center, Salod (H) Wardha, Maharastra.

Table- 2: Pharmacological properties of *MahanilVarti*

S. N.	Name of drug	Rasa	Guna	Virya	Vipaka	Doshghnata/karma	Reference
1.	*Bruhatimula* Solanum Indicum-	*Katu, Tikta*	*Laghu, Ruksha, Tikshna*	*Ushna*	*Katu*	*Kaphavataghna/Dipan, Pacha,Swashhar*	BP-N/275 [10]
2.	*Yashtimadhu* Glycyrrhiza glabra	*Madhur*	*Guru, Snighdha*	*Sheet*	*Madhur*	*Tridoshhar, Rasayana,Vajikarana*	BP-N 62/145-146[11]
3.	*TamraBhasma* Cuprum-	*TiktaMadur/Kashaya*	*Sarak,PittaNashakRopan,Laghu,Lekan*	*Sheet*	*Katu-*	*Timir,abhisyand,* to improvevision, Eye diseases	Cha.chi.17/125-

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		AmalaRas					Ch.chi.26/254-255
4.	*Saindhava* Rock salt	*Lavana*	*Laghu,snigdha,*	*Sheet*	-	*Chakshusya,vrushya,Dipana,Rochana*	Cha.Su1/88, Cha.Sam 27 [10]
5.	*Sunthi*Zingiberofficinale Roscoe,	*Katu*	*Laghu, Snigdha,*	*Usna*	*Madhura,*	*Kaphvatahar*	BP-N-p13
5.	*Amalaki* rasa Emblicofficinalis-	*Panchrasa*	*Laghu,ruksha, Sheeta*	*Sheeta*	*Madhur*	*Rasayana,Chakshushya,Vrushyam,Kasahar,Dipana,Kandughna,Raktapittaghna*	BP-N/10[11]
6.	*Amalaki l*eaves Emblicofficinalis-	*Panchrasa*	*Laghu,ruksha, Sheeta*	*Sheeta*	*Madhur*	*Rasayana,Chakshushya,Vrushyam,Kasahar,Dipana,Kandughna,Raktapittaghna*	BP-N/10 [10] [12]
7.	*Yava* Carumcopticum	*Katu*	*Laghu,Ruksha, Tikshna*	*Ushna*	*Katu*	*Kaphavatahar,Shulahar,Shothar,Udarroga,Dipan,Pachana, Sukrahar*	BP-N/627 [10]

Abbreviations used : Ch. – Charaka, Cha. – Charaka, Chi. – Chikitsasthana, Su. – Sutrasthana. Sam. – Samhita, BH-N-BhavaprakashaNighantu, ,

Observation & Results:

*MahanilavartiAnjana*is advicedin the management of corneal opacity as per Vagbhata. In corneal opacity mild pain, mild discharge and visual impairment are cardinal features due to formation of white patches on Cornea by vitiation of *Kapha* and *Rakta*.. This is " *Mahanilavarti"* will help in removing the corneal opacity or only does tattooing.

Table- 3: Quantity of ingredients and yield obtained in preparation of *Mahanilvarti*

Batch No	Name of Drug	Quantity	BhavanaDravya	Frequency	Duration of Bhavana	Quantity obtained	% weight gain
M1	*MahanilaVarti*	125gm	*Aamalaki*juice	3 times	2 hours	135 gm	8gm
M2	*MahanilaVar*	125gm	*Aamalaki*juice	3 times	2 hours	133 gm	6.4gm

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M3	*MahanilaVarti*	125gm	*Aamalaki* juice	3 times	2 hours	136 gm	8.8gm
	Average	125gm		3 times	2 hours	134.66gm	7.73gm

Table-4:Average result of organoleptic parameters of *MahanilVarti*

Parameters	Pharmacopoeia standard	Committee standard	Observations	Inference
Colour	Not available	Not available	Black	Acceptable
Odour	Not available	Not available	Characteristic	Acceptable
Taste	Not available	Not available	-	Acceptable

Table-5: Average result of physico-chemical Parameters of *MahanilVarti*

Parameters	Pharmacopoeia standard	Committee standard	Observations(Average result of three batches)	Inference
Loss on Drying At 105^0C	Not available	Not more than 6%	1.98%	Acceptable
Total ash value	Not available	Not more than 6%	4.73%	Acceptable
Total Insoluble Ash	Not available	Not more than 0.5%	0.5%	Acceptable
Water soluble Extractive	Not available	Not less than 50%	28.15%	Acceptable
Alcohol soluble Extractive	Not available	Not less than 20%	11.37%	Acceptable
pH	Not available	--	7.33	Acceptable

Table-6: Average results of Microbiological specification of Mahanilvarti

Specification	Parameters as per CCRAS	Observations	Inference
Total viable count	Maximum10^5/gm	Absent	Acceptable
Enterobacteriaceae	Maximum10^3/gm	Absent	Acceptable
Total fungus count	Maximum10^3/gm	Absent	Acceptable
E-coil	Maximum10/gm	Absent	Acceptable
Salmonella	None	Absent	Acceptable
Staphylococus.aureus	Absent	Absent	Acceptable
Pseudomonas aueruginosa	Absent	Absent	Acceptable

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Fig 1: Shows Raw marterial use for *MahanilVarti.*

Fig 2: Shows *MahanilVarti*

DISCUSSION

Different pharmaceutical preparations are scientifically designed by ancient Ayurvedic seers. Ample examples of preparations suggest the advancement of Ayurvedic pharmaceutical science and may explore new horizon for finding newer formulations Present formulation is used in the form of Varti. Fine powder of *Bruhatimula, Yashtimadhu, Tamrachurna, Saindhava, sunth*i, obtained after thoroughly pounding a dry drug and filtering it through a clean cloth. Herbal powders preserve their potency up to six months if kept in air tight containers. Moreover there is a possibility of deterioration of powder if the powder is exposed to the moisture conditions. *MahanilaVartiAnjana* contains *bruhatimulayashtimadhu, sunthitamrabhasma,saindhava* after triturin*g* in *amalakirasa* is applied internally to copper vessel. Dhurii.e smoke of the leaves of *amalaki* and *yava* is given many times. When dried , prepare varti triturating in water.*Vartis*can be preserved for two years if kept in airtight container Thus it is having the advantages of long shelf life, portability, and global

acceptance.[13].*Vartis*were prepared in three batches by standard manufacturing procedure, to check its reproducibility and pharmaceutical variability. *Bhavana* is the process by which powders of drugs are ground to a soft mass with liquid media (*Amalki*juice)and allowed to dry. *Bhavana* is an important *Samskara* (processing) mentioned in classics and can be helpful in developing pharmaco-therapeutically potent new molecules. It is a specific procedure in which the material (powder) is thoroughly mixed with the liquid media (decoction, herbal juice -*Amalaki*juiceetc.) and levigation is carried out till complete absorption of liquid into the powder [14]. It helps transformation of the coarse powder into finer state by particle size reduction and impregnation of properties of *BhavanaDravya* and homogenization leading to modification of properties of the end product. Most important feature of *Bhavana* process is that, even a small dose of a drug may be made to produce a very maximum bioavailability. The potency of the single or compound drugs may be further potentiated by conducting the *Bhavana* process, using their own *Swarasa* (juice) [15]. As a rule, *Bhavana* is advocated to be carried out in sunlight.Ultraviolet rays in sunbeam are photo chemically active and said to be responsible to initiate chemical reactions for loss on drying at 105^0 C indicates presence of moisture content. If moisture content is more than permissible limit, then the formulation is more likely to get infected by fungal growth. Moreover, unwanted changes can also occur due to presence of more moisture. In the prepared batches moisture content is much less i.e. this formulation has more stability. Acid insoluble ash represents presence of inorganic content which is not expected in herbal formulation. The obtained value of Acid insoluble ash in all the batches is negligible. Insignificant difference is observed in alcohol soluble extractives. Water soluble extractive value is also nearly same in all three batches. This value is related with assimilation of Varti with liquid media such as water. The physical parameter such as pH was determined to determine basic nature of sample as the action of enzymes is affected by pH and pH is an important factor in taste and safety"Tear pH was measured in 44 normal subjects by immersing the lip of a micro combination glass pH probe in the tear fluid in the inferior cul-de-sac. The normal pH range was 6.5 to 7.6; the mean value was 7.0 [16]".and *MahanilVarti* pH was measured range is also 7.6,which indicates *mahanilvartianjana* is easily acceptable by ophthalmic tissues.

Use of metals in therapeutics was initiated in ancient period. In CharakaSamhita, *Tamra* is described as one of six metals and also quoted as poison. *Tamra* is indicated for the removal of diseases, its powder is indicated for internal use as *Rasayana* (rejuvenation) Its *Anjana* (collyrium) is used for the treatment of *Abhishyanda*and*Timira*.Anjana of *ShankhaVarti* and *DrishtipradaVarti* are prepared with the powder of *Tamra* in combination of other drugs, to cure all eye diseases and also to improve the vision of the patient. [17]. *'Amala'*is an Indian traditional Ayurvedic drug used as a rejuvenating medicine in aging conditions. The fruits of *Amala*commonly used in Ayurveda are assumed to enhance defense against diseases. *Amalaki*rasayanahas immunomodulatory ,antioxidant,[18] , analgesic, antipyretic, , gastroprotective antitussive and cytoprotective actions*Amla* has rejuvenating property help to healing the tissue in eye damage due to corneal opacity [19]. Ginger (Zingiber officinale Roscoe) in the Prevention of Ageing and Degenerative Diseases.Ginger is composed of several bioactive compounds, including 6-gingerol, 6-shogaol, 10-gingerol, gingerdiones, gingerdiols, paradols, 6-dehydrogingerols, 5-acetoxy-6-gingerol, 3,5-diacetoxy-6-

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gingerdioal, and 12-gingerol, that contribute to many biological activities of ginger [20,21]".Few of the cornea related studies from modern medicine were reviewed [22-25].

CONCLUSION

Prepared *Mahanilvarti*isblack in color with characteristicsmell. Analytical standards for *Mahanilvarti*such as loss on drying at 105^{o}C, total ash value, total insoluble ash, water soluble extractive, alcohol soluble extractives, pH, are 1.98%, 4.73 %, 0.5%, 28.15%, 11.37%, 7.33 respectively. Analytical findingsof present study can be considered as reference standard for *Mahanilvarti*.

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