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Pharmaceutical and Analytical Study of *Amalakyadigana Vati* an Ayurvedic Formulation for *Netra Roga*

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ABSTRACT

The eye is a highly developed sensory organ that provides humans with their most important and fundamental function of seeing. Ocular diseases are most common condition found in a day to day life. *Acharya Sushrutha* asserts that *Abhishyanda*, one of the *Aupsargic roga*, is the primary cause of all eye diseases. It is one among the *Sarvagata roga*. *Amalakyadi gana* is a combination of herbal and mineral topical formulation cited in sutra sthana by *Acharya Sushrutha .Amalakyadi Gana* consists of four drugs i.e., *Amalaki*, *Haritaki*, *Pippali*, *Chitraka*.The *Chakshushya* effect of *Amalakyadi gana* exhibit beneficial effects in ocular conditions. The current study has been undertaken with the aim to modify *Amalakyadi gana* into *vati* form and to develop the physiochemical profile of the final product. Pharmaceutical testing of the *Amalakyadigana vati* formulation was performed in accordance with the PLIM's API and drug testing protocol. **Material and Method:** The prepared drug was evaluated for organoleptic study, physiochemical study and microbial study. **Result and Discussion:**As the levels of heavy metals were within permissible values and free from any pathogenic microbes, the formulation is safe to use. **Conclusion:** *Amalakyadigana vati* was prepared by following the method described in *Sharangdhar Samhita*. This paper present the analytical study of the formulation.

Key Words *Abhishyanda , Amalakyadigana vati, Analytical Study*

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INTRODUCTION

A pharmaceutical method called *Vati Kalpana* involves triturating raw medication powder with a specific juice, decoctions of several liquid media and the medicines are prepared in the form of pills or tablets after the mixture turns into a fine paste[1].In the field of *Ayurvedic* pharmaceutical research, *Vati Kalpana* is a secondary preparation. *Gutika,Modaka* and *Varti* are the synonyms of *Vati*. These are the names that were given to *Vati kalpana* based on shape, dose and route of administration. In the pharmaceutics of *Ayurveda Vati kalpana* is significant due to its palatability, easy administration, convenient dispensing and transmission form. Due to its accurate dosing,

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longer shelf life and palatability, *Vati kalpana* is well-accepted in present clinical practice[2,3]. The *Amalakyadigana vati* formulation contains four drugs i.e., *Amalaki*, *Haritaki*, *Pippali*, *Chitraka* in all equal amounts. Almost all drugs have *Chakshushya* and *Rasayana Dravyas* properties[4]. By virtue of the above mentioned properties this formulation is believed to have action on *Vataja Abhishyanda* .This paper presents the analytical study of the formulation, which may serve as supporting literature for future studies and to maintain standard quality of the formulation.

AIMS AND OBJECTIVES

A) To Modify *Amalakyadigana* in the form of vati

B) To determine the result of the sterility test and the physicochemical tests of *Amalakyadigana vati*

C) To evaluate the physical or organoleptic character of the manufactured drug.

MATERIALS AND METHODS

Collection of raw materials

The Hans Pharmacy in Premnagar Ashram Haridwar procured the raw medicines for the *Amalakyadigana Vati*. The ingredients were determined by the Dravyaguna PG Department of Rishikul Campus Haridwar. The Hans Pharmacy in Premnagar Ashram Haridwar prepared the final product.The contents of *Amalakyadigana Vati* and details of ingredients shown below in table 1 and figure 1.

Table 1 Ingredients and Composition of *Amalakyadigana*[5]

S.NO	NAME	LATIN NAME	FAMILY	VIRYA VIPAKA	PART USED	RATIO
1	*Amalaki*	Emblica officinalis	Euphorbiaceae	Sheeta Madhura	Fruit	1
2	*Haritki*	Terminalia chebula	Combretaceae	Ushana Madhura	Fruit	1
3	*Pippali*	Piper longumlinn	Piperaceae	Laghu Tikshna Snigdha	Fruit	1
4	*Chitraka*	Plumbago zeylanica	Plumbaginac	Ruksha Laghu Tikshna	Rhizome	1

Method of preparation of *Amalakyadigana Vati*

The *Amalakyadigana Vati* was prepared in GMP-approved Hans Pharmacy, Sidcul, Haridwar, Uttarakhand. The *Amalakyadigana Vati* was prepared as per standard operative procedures of the *Ayurvedic* Pharmacopeia of India for the *Vati* preparation. For the preparation of *Amalakyadigana Vati* of all the raw herbal drugs i.e *Amalaki*, *Haritki*, *Pippali* and *Chitraka* were taken in equal amount and all the drugs were converted into fine powder separately and passed through sieve number 85, weight individually in the required quantities.

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Fine powder of all the dugs was mixed together uniformly. Then the binder solution of 5% gum acacia powder was prepared by adding the required quantity of water.

The obtained damp material is spread in a 5-7 mm thick layer in a stainless steel tray. This tray was kept in a hot air tray dryer at 55 0C. At a multi mill with a sieve sieze of 20 ,this dry mass was passed to prepare granules. Talc and magnesium stearate, the component that act as lubricant were combined thoroughly and sieved through Sieve No.100 and mixed with the dried granules. The final step involved compressing the tablet in a rotating multi-station tablet punching machine with the 250mg punches and die. Store and pack the *Vatis* in an air-tight container for storage. Shield them from moisture and light.

Emblica officinalis

Piper longumlinn

Terminalia chebula

Plumbago zeylanica

Figure 1 Raw drug of *Amalakyadigana Vati* for fine powder

Method of preparation of *Amalakyadigana Vati*

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Powdered of Raw Drugs	Acacia gum powdered (excipient)	Punching of tablets	Prepared Amalakyadigana Vati

Figure 2 Pharmaceutical unit operation of tablet preparation

Method of evaluation of *Amalakyadigana Vati*: The vati were evaluated by employing parameters mentioned in *Ayurvedic* Pharmacopeia of India & protocol of *Ayurvedic* drug testing of PLIM, Ghaziabad, UP, India [6-7]

Heavy Metal Test: Spectrometry of the sample was also carried out for the heavy metals such as cadmium (Cd), lead (Pb), mercury (Hg), arsenic (As). All the metals were present in the ointment in safe range.

Microbial Analysis: *Amalakyadigana vati* was evaluated for total bacterial count and total fungal count count. Total bacterial count was carried out by plate count method, which is mentioned in A.P.I, Part II, Vol-I, Appendices 2.4

Weight variation test: By weighing and calculating the weights of 20 tablets that were randomly chosen from a batch of tablets, The uniformity of weight test is carried out .The individual weights are contrasted with the average weight[8].

Disintegeration Time Test: For a tablet Disintegeration, the process of breaking down tablet into granules, is a crucial first step in the medication dissolution process.The apparatus consists of a basket-rack assembly containing six open-ended transparent tubes held vertically upon a 10- mesh stainless wire screen.A tablet is inserted in each of the six tubes of the basket during testing, and the basket is raised and lowered in a fluid bath at a rate of 30 to 32 cycles per minute for 15 minutes.

RESULT AND DISCUSSION

Table 2 Physical characterization description

Appearance	**A brown coloured round shaped biconvex uncoated**
Colour	Darkish Brown
Odour	Characteristic
Taste	Characteristic
Average weight (mg) of	266.2
Uniformity of weight (%	Within limit
Disintegeration time (m	19-20

Table 3 Physicochemical properties

Parameters	Amalakyadigana Vati
Loss of Drying (%w/w)	4.76
Total Ash (% w/w)	4.68

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Acid insoluble(%w/w)	0.68
Alcohol soluble extraction (% w/w)	39.33
Water soluble extraction(% w/w)	52.76

Table 4 Heavy Metals

Lead (Pb) ppm	5.17
Arsenic (As) ppm	<0.50
Cadmium (Cd) ppm	0.08
Mercury (Hg) ppm	<0.13

Table 5 Microbiological Analysis

Total Bacterial Count	**21400 cfu/g**
Yeast and Mould Count	<100 cfu/g
E.coli	Absent
Salmonella sp.	Absent
P.aeruginosa	Absent
S.aureus	Absent

Analytical report

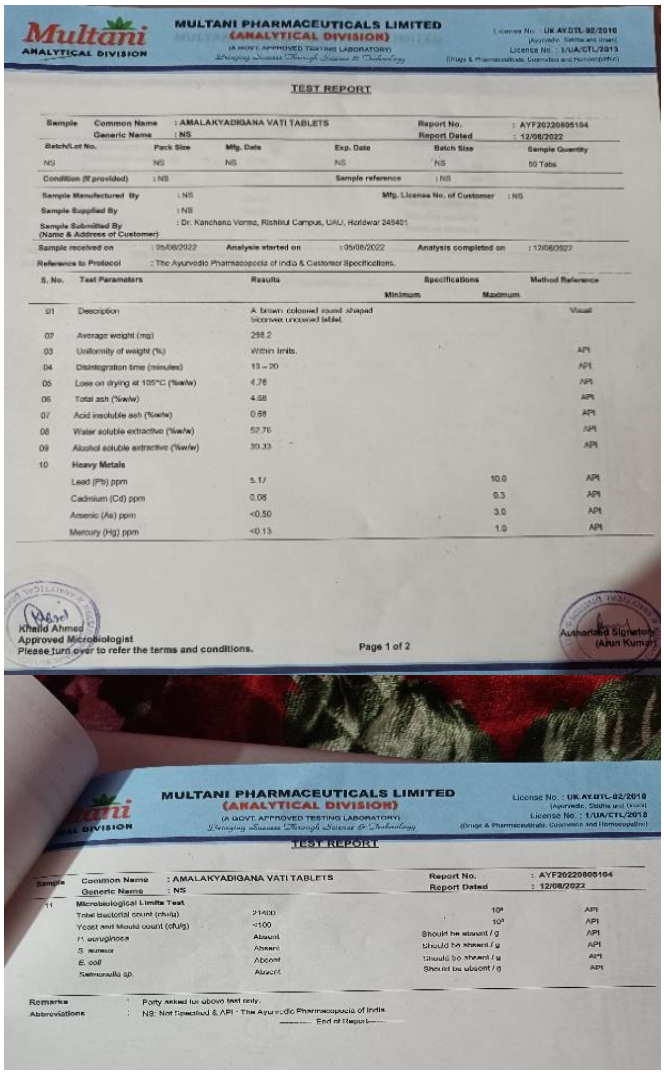
MULTANI PHARMACEUTICALS LIMITED
(ANALYTICAL DIVISION)
TEST REPORT
Common Name : AMALAKYADIGANA VATI TABLETS
Report No. : AYF20220805104
Report Dated : 12/08/2022
Reference to Protocol : The Ayurvedic Pharmacopoeia of India & Customer Specifications.
Page 1 of 2
Please turn over to refer the terms and conditions.

Image 1 Analytical Study

CONCLUSION

Pharmacognostical evaluation of *Amalakyadigana vati* illustrated the distinctive characters of this preparation. To guarantee the safety and quality of the drug, microscopic characteristics, physio-chemical parameters, sterility, heavy metal testing and microbiological analysis are essential parameters. All *Amalakyadigana vati* metrics were discovered to be within the normal range as shown above in table 2,3,4 and 5 and may be applied for standardization and quality evaluation of the drug for future scholars.

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