

## PHARMACEUTICAL AND ANALYTICAL VALIDATION OF YASHDAMRIT MAL-HAR – A HERBOMINERAL AYURVEDIC FORMULATION

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### ABSTRACT

The Ayurvedic Pharma industry is rapidly expanding its demand in national as well as international markets. Due to the lack of pharmaceutical and analytical validation of Ayurvedic products, the quality of Ayurvedic products differs from batch to batch. Pharmaceutical and analytical validation can be achieved, if the herbal products are evaluated and analyzed using both Ayurvedic as well as modern techniques of standardization, in-process and after preparation of the finished product. *Yashdamrit Malhar* herbomineral formulation is traditionally used for wound, burn and eczema disorders. *Yashdamrit Malhar* is developed based on *Malhar Kalpana* (Ointment) process mentioned in *Rasatarangni*, which is very effective in *Vicharchika* (Eczema). Its constituent is, *Yashada* (Zinc), *Murchhita Tila Taila* (Sesame oil) and *Siktha* (Wax). *Siktha Taila* acts as an emollient or as a base in the preparation of *Malhar*. Almost all ingredients are *Kusthaghna*, especially *Yashada*.

**Keywords:** Ayurvedic formulation, *Malhar Kalpana*, Process validation, *Yashdamrit Malhar*.

### INTRODUCTION

Standardization of herbomineral formulations is essential to assess the quality of drugs. It is based on the concentration of their active principles, physical, chemical, Phyto-chemical, In- vitro, and In-vivo

parameters. The quality assessment of herbomineral formulations is important to justify their acceptability & safety. One of the major problems faced by Ayurveda physicians is the unavailability of unique

pharmaceutical and analytical validation procedures for herbal medicines and their formulations. In India, the department of the AYUSH Government of India is now working on the development of standard operating procedures for the manufacturing process of Ayurvedic preparation to avoid batch to batch variations. This can be achieved if the herbal products are evaluated and analyzed using both Ayurvedic as well as modern techniques of standardization during preparation and after preparation of the finished product. There are different techniques to standardize raw drugs & finished products. This can be achieved; if herbal products are evaluated & analyzed using sophisticated modern techniques standardization such as pH, Viscosity, Refractive index, Saponification value, spreadability, etc in this study guidelines prescribed in good manufacturing Practices and Good Laboratory Practices for Ayurvedic medicines are strictly followed during preparation and on finished drug formulation. The term *Malahar* is originated from the root word *Malham* or *Marham*, which is a commercial external use dosage form of the *Unani* system of medicine. This is called *Malhar Kalpana* because it removes *Mala*

(residue etc) from *Vrana*, *Vidhradi*, *Tvakvikar* etc. This is similar to ointments (unguentum) in modern pharmaceuticals. This dosage form is introduced into *Ayurveda* by *Yogaratanakara*. *Yashdamrit Malhar* is a great composition given in *Rasatarangini*, which is described as very effective in *Vicharchika*. Its constituent is *Yashada*, *Murchhita Tila Taila* and *Siktha*. *Tila Taila* acts as an emollient or as a base in the preparation of *Malhar*. Almost all ingredients are *Kusthaghan*, *Vrana Ropana* (Wound Healing), *Vedana Sthapana* (Pain Killer), *Daha Samaka* (Lowering Burning Sensation), *Tridoshahara*.

#### Material and Method:

*Yashdamrit Malhar* is developed based on the *Malhar Kalpana* process mentioned in *Rasatarangni*. *Yashdamrit Malhar* is a Mineral herbal formulation having three ingredients in its composition. The fusion method is applied in the preparation of *Malhar*, clinical trial was done on the patients of Eczema with a random selection method is used, irrespective of their age, sex, religion, occupation etc. A scoring pattern is adopted for the study.

**Table 1:** Showing ingredients with their weight for *Tila Taila Murchhana* and their weights for 16kg of a sample of *Yashdamrit Malhar*

S.N.	Drug	Rasa	Guna	Virya	Vipaka	Doshghnata	Rogaghata	Quantity
01.	<i>Manjistha</i>	<i>Madhur, Kasaya, Tikta</i>	<i>Guru</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kaph pitta</i>	<i>Kustha, Sotha, Prameha, Krimi</i>	1 Kg
02.	<i>Haridra</i>	<i>Tikta, Katu</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Tridosha</i>	<i>Kustha, Krimi, Vrana</i>	350 gm
03.	<i>Haritaki</i>	<i>Pancharasa (except Lavana)</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Madhur a</i>	<i>Tridosha</i>	<i>Kustha, Viband h, Prameha</i>	750 gm
04.	<i>Vibhitaki</i>	<i>Kasaya</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Madhur a</i>	<i>Tridosha</i>	<i>Kustha, Krimi</i>	750gm
05.	<i>Amalaki</i>	<i>Pancharasa (except Lavana)</i>	<i>Sheet, Ruksha</i>	<i>Sheet</i>	<i>Madhur a</i>	<i>Tridosha</i>	<i>Kustha, Visarpa, Raktapitta</i>	750 gm
06.	<i>Lodhra</i>	<i>Kasaya</i>	<i>Laghu, Grahi</i>	<i>Sheet</i>	<i>Katu</i>	<i>Kaph pitta</i>	<i>Raktavikara, Jwara, Atisara</i>	350 gm
07.	<i>Musta</i>	<i>Tikta, Katu</i>	<i>Laghu, Ruksha</i>	<i>Sheet</i>	<i>Katu</i>	<i>Kaph pitta</i>	<i>Krimi, Jwara, Raktavikara</i>	350 gm
08.	<i>Nalika</i>	<i>Madhura, Kasaya</i>	<i>Snigdha, Guru</i>	<i>Sheet</i>	<i>Madhur a</i>	<i>Pitta</i>	<i>Visarpa, Vrana, Daha, Raktavikara</i>	350 gm
09.	<i>Ketaki Pushpa</i>	<i>Tikta, Katu, Madhura</i>	<i>Laghu, Snigdha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kapha</i>	<i>Netraroga, Rakta avikara</i>	350 gm
10.	<i>Vatankur</i>	<i>Kasaya</i>	<i>Guru, Ruks ha</i>	<i>Sheet</i>	<i>Katu</i>	<i>Kaphapitta</i>	<i>Visarpa, Daha, V yanga</i>	350 gm
11.	<i>Hwiber</i>	<i>Katu, Tikta</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kaphavata</i>	<i>Deepana, Gulma, Arsha</i>	350 gm

**Table 2:** Showing ingredients with their weight for 16 Kg Sample of Yashdamrit Malhar

S. N.	Drug	Rasa	Guna	Virya	Vipaka	Doshaghanta	Rogaghanta	Quantity
1.	Yashada	Kashaya, Tikta	Sheeta	Sheeta		Kaphapittasamakama	Kustha, Prameha, Raktavikara	6 Kg
2.	Tila Taila	Madhura	Tiksna, Vyavayi, Suksma, Usna, Visada, Guru, Sara, Vikasi		Madhura	Vatakaphahara	Vataroga, Bhagna, Yoni-karna-siroroga, Kesapata, Vrana.	16 Kg
3.	Siktha	Madhura	Snigdha, Picchila			VataRaktahara	Sandhankar, Vrunaropaka	2.4 Kg

**Procedure:**

Yashdamrit Malhar was prepared by following steps.

1. *Tila Taila Murchhana*: All the processes are done according to the reference given in *Bhaishajya Ratnavali, Jwara Chikitsa*.
2. *Yashada Shodhana*: *Shodhana* of *Yashada* was done according to the reference given in *Rasatarangini (R.T.) 19/98-99*.
3. Preparation of *Yashada Pushpa*: This process was done according to the reference R.T. 19/116-119.

4. Preparation of *Siktha Taila*: This was done according to reference R.T. 4/59-61.
5. Preparation of *Yashdamrit Malhar*: This was done according to the reference R.T. 19/146-147.

**OBSERVATION AND RESULTS:** The analytical studies showed that the drug does not contain any microbes and also comes under the standard parameter of superficial ointment.

**Table 3:** General/ Organoleptic Characters:

Name of The Drug	Colour	Appearance	Odour	Touch
Yashdamrit Malhar	Light Brown	Semi-Solid, Thick Paste	Characteristic odour	Buttery soft, oily

The physicochemical tests, which are mentioned in API and AFI, in standardization of Yashdamrit Malhar had been worked out in ARBRO PHARMACEUTICAL Ltd. Kritinagar, New Delhi (Delhi Govt. approved laboratory).

**Table 4:** Chemical Tests

S.No.	Tests	Result
01.	Saponification Value	150.83
02.	Viscosity(cps)	827000
03.	Acid Value	4.17
04.	Peroxide Value(mg/kg)	0.90
05.	Thermal Stability (at 37°C for 72 hrs)	No Oil Separation observed, passes the test

**Table 5:** Microbiological

01	Total Viable Count	<10cfu/gm
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**Table 6:** Gram-Negative Pathogen:

1.	E. coli	Absent/gm
2.	Pseudomonas aeruginosa	Absent/gm
3.	S. aureus	Absent/gm

(Note: BDL=Below Detection Limit, MDL=Method Detection)

**Table 7:** Heavy Metal Test

01	Mercury (Hg)	Below detection limit
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## DISCUSSION

The therapeutic activity of compound formulation is decided by the action of a major ingredient or by the synergic action of all ingredients. The pharmacodynamic properties of *Yashada bhasma* is *Rasa – Kashaya, Tikta, Guna – Sheeta, Veerya – Sheeta, Doshaghnata – Kapha pitta shamaka, Karma – Vrunaropaka, Vrunas hamaka* the drugs used in the *shodhana* also induce the *kapha pitta* property in the *Yashada bhasma*. In *Vicharchika* main vitiated *dosha* is *Kapha*, which causes itching, *Pidika* (Carbuncle), Inflammation and *Raga* or Fainting of Skin. *Yashdamrit Malhar* is a Herbo mineral formulation. All of its constituents have *Kapha shamaka* property. *Acharya Sushruta* had mentioned *Vicharchika* as *Tridosaja Vyaadhi*. So, the *kapha Shamaka* properties of the drug minimize the symptoms of the disease. Even in modern science also, it is expected to be zinc has a good antiseptic, astringent, local sedative action, it reduces the chronic inflammation it checks the bleeding and secretion from broken skin by precipitating the secretions, it provides a soothing and protective effect to the skin. So, by this *yoga* main dominated *doshas* i.e., *Kapha pitta* in *Sravi Vicharchika*. So, it is best in *Srava, Kandua, Pidika Yukta Vicharchika*. *Tila taila* has *Tikta Rasa, Tikshna, Vyavayi, Sukshma, Vishada, Sara, Vikasi Guna* and *Ushna Virya*. It acts as a soothing agent, demulcent and emollient. It not only acts as a vehicle but also increases drug absorption by the skin through lipophilic pores. Both *Tila taila* as well as *Siktha* act as chemical drug penetration enhancers i.e., fatty acid & alkaline. *Siktha* and *Tila taila* act as an emollient or as a base in the preparation of *Malhar*. The active principle of *Malhar* is to reach the deeper tissues through *Sira Mukha & Swedavahi Srotas* & stain it with their *Sukshma & Tikshna* properties. Due to their *Ushna, Tikshna, Vishada & Sukshma* properties, they unblock the obstruction in *Swedavaha Srotas* & allow the local toxins to flow out through the *Sweda*, thus clearing out the microchannels.

## CONCLUSION

*Yashdamrit Malhar* is developed based on the *Malhar Kalpana* process mentioned in *Rasatarangni*. The *So-dhana* of *Yashada* not only removes the impurities but also improve the quality and therapeutic activity for external administration without producing any harmful effects. The analytical studies showed that the drug does not contain any microbes and also comes under the standard parameter of superficial ointment. The above discussion shows that this *Malhar* is one of the best Ointment for Eczema Disease. This composition should be considered by a pharmaceutical company for curing Skin Disease.

## REFERENCES

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