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Original Article

Ayurveda Section

Standardisation and Quality Assessment of *Aragwadhadi* Oil and *Aragwadhadi* Ointment: A Pharmaceutico-analytical Study

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ABSTRACT

Introduction: *Aragwadhadi* oil, a classical Ayurvedic herbomineral formulation containing arsenicals like *Manahshila* (realgar) and *Haratala* (orpiment), is traditionally used for *Shvitra* (vitiligo) and other skin conditions. *Aragwadhadi* ointment is a contemporary adaptation for easier application.

Aim: To establish a Standard Manufacturing Procedure (SMP) for *Aragwadhadi* oil and ointment, and assess their quality through analytical parameters.

Materials and Methods: This pharmaceutico-analytical study was conducted at the Department of *Rasashastra* and *Bhaishajya Kalpana*, MGACHRC, Wardha, Maharashtra, India between January 2024 to December 2024. Ingredients were authenticated and purified using classical *Shodhana* procedures. *Aragwadhadi* oil was prepared via *Sneha Kalpana* and converted into an ointment using white wax. Analytical evaluations included organoleptic, physicochemical, and microbiological studies.

Results: The formulations exhibited stable organoleptic properties (uniform colour, consistency, odour) and acceptable physicochemical parameters: specific gravity (oil: 0.921±0.02; ointment: 0.938±0.03), acid value (3.25±0.14 and 2.98±0.11 mg KOH/g), iodine value (78.4±1.2 and 74.9±1.4 g I_2/100 g), and peroxide value (4.1±0.3 and 3.8±0.2 meq O_2/kg). Microbial contamination was absent {Total Plate Count (TPC)<10 Colony-forming Units /mL; no fungal growth}.

Conclusion: The pharmaceutico-analytical standardisation confirmed the safety, consistency, and potential efficacy of the formulations. This approach integrates traditional Ayurvedic knowledge with modern scientific techniques.

Keywords: Herbomineral formulation, Ointment preparation, Pharmaceutical standardisation, Quality assurance

INTRODUCTION

Aragwadhadi oil is a classical herbomineral formulation containing arsenicals, specifically *Manashila* (realgar) and *Hartala* (orpiment), referenced in the classical text *Chakradatta* and recommended for the treatment of *Shvitra* (vitiligo) [1]. The majority of the ingredients in this medicated oil possess properties that address dermatological issues (*Kushthaghna*), combat parasitic infections (*Krimighna*), and alleviate itching (*Kandughna*) [2]. *Aragvadhadi* ointment is not described in the classical Ayurvedic texts; "rather" it is a modern adaptation for improved usability.

Ayurvedic dosage forms are unique in their pharmaceutical composition and therapeutic applications. Fat-soluble (*Sneha Siddha*) formulations exhibit superior pharmacokinetic properties, including Absorption, Distribution, Metabolism and Excretion (ADME), due to the lipid nature of cell membranes that allow lipid-soluble substances to penetrate cells more effectively [3].

The primary goal of drug standardisation is to guarantee quality, effectiveness, and consistency [4]. Therefore, establishing standardisation and developing dependable quality protocols are essential. In ancient times, physicians prepared drugs in small batches in their own clinics. In the current era, the demand for Ayurvedic drugs has increased significantly, while the availability of raw materials has become limited, increasing the risk of substandard drug production for commercial profit.

Consequently, the establishment of consistent manufacturing standards is vital. The quality of the final products is influenced by raw materials, intermediate processes, and pharmaceutical procedures. A comprehensive understanding of the chemical composition of Ayurvedic formulations is crucial prior to experimental and clinical trials [5,6].

Chemical studies not only identify the chemical constituents but also help establish reference standards. These studies benchmark product quality and indicate areas of improvement when needed. To evaluate finished products, various analytical studies are Mandatory.

The present study presents a pioneering approach to the systematic pharmaceutico-analytical standardisation of both *Aragwadhadi Taila* (oil) and its complementary *Aragwadhadi* Ointment, a notable advancement in the field of Ayurvedic pharmaceutics that has not been documented previously. The dual formulation analysis offers a comprehensive comparative insight into the transformation of traditional lipid-based preparations into contemporary semisolid dosage forms, all while preserving their intrinsic quality and stability. This study aimed to establish a SMP for *Aragwadhadi* oil and its ointment formulation. Additionally, thorough pharmaceutical and quality evaluations were undertaken to ensure reproducibility, safety, and therapeutic efficacy. This meticulous approach underscores the importance of bridging ancient wisdom with modern scientific standards, paving the way for effective and reliable herbal treatments.

MATERIALS AND METHODS

This pharmaceutico-analytical study was conducted at the Department of *Rasashastra and Bhaishajya Kalpana*, MGACHRC, Wardha, Maharashtra, India, with analytical testing performed at the *Dattatraya Rasashala, Wardha* from January 2024 to December 2024. The study further involved animal experimentation with the Animal Institutional Ethics Committee (AEC) was obtained {AEC Letter No: (DMIMS/IEAC/2021/13)}

Study Procedure

Raw materials [Table/Fig-1] were procured locally from Wardha and authenticated by the Department of *Dravyaguna,* MGACHRC, Wardha and the Foundation for Revitalisation of Local Health Traditions (FRLHT), Bengaluru.

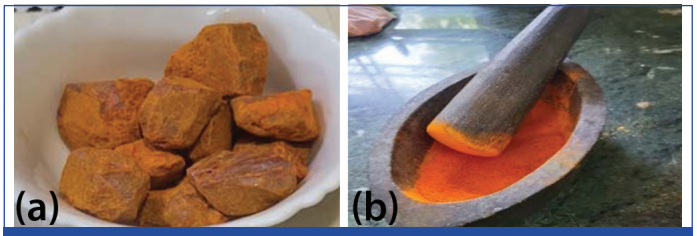
S. No.	Ingredients	Latin/English name	Part used	Proportion	Quantity taken in preparation
1.	*Aargwadha*	Cassia fistula	Fruit pulp	1/4th part	250 gm
2.	*Dhav*	Anogeissus latifolia	Bark	1/4th part	250 gm
3.	*Kushta*	Saussurea lappa	Root	1/4th part	250 gm
4.	*Hartala*	Arsenic trisulfide	-	1/4th part	250 gm
5.	*Manshila*	Realgar	-	1/4th part	250 gm
6.	*Haridra*	Curcuma longa	Rhizome	1/4th part	250 gm
7.	*Daruharidra*	Berberis aristate	Stem	1/4th part	250 gm
8.	*Til Tail*	Sesamum indicum	-	1 part	1 L
9.	Water	-	-	4 part	4 L

[Table/Fig-1]: Ingredients of *Aragwadhadi* oil.

Shodhana (purification)

- ***Manahshila* (Realgar) purification**

Fresh *Ardraka* (ginger) rhizomes were cleaned, peeled, chopped, and ground to extract juice (*Swarasa*). *Ashuddha Manahshila* was powdered using a *Khalva Yantra* and levigated with *Ardraka Swarasa* until dry, completing one *Bhavana* cycle. This process was repeated seven times [7]. The final product was dried, powdered, and stored in an airtight jar [Table/Fig-2a,b].



[Table/Fig-2]: a) Ashuddha Manahshila; b) Bhavana process in progress.

- **Haratala (Orpiment) purification [8]**

Churnodaka (lime water) was prepared by mixing lime powder with water (1:240) and keeping it undisturbed for nine hours. *Ashuddha Haratala* was broken, wrapped in a *Pottali*, and suspended in *Churnodaka* for *Swedana* (steam heating) for three hours. After heating, it was thoroughly washed with hot water, dried, and stored in an airtight container [Table/Fig-3a-c].

Preparation of *Aragwadhadi* oil: All authenticated ingredients were dried and powdered to form *Kalka*. A mixture of *Kalka* (1/4 part), *Tila Taila* (1 part), water (4 parts), and powdered herbs [9] was combined in a stainless steel vessel. The mixture was heated on low flame (*Mandagni*) with continuous stirring until *Snehasiddhi Lakshanas* [10]. Oil readiness indicators) appeared. The oil was then cooled (*Swang Sheeta*), filtered, and stored in airtight bottles [Table/Fig-4a-h].

Preparation of *Aragwadhadi* Ointment: *Aragwadhadi* Oil was gently heated until foaming, then mixed with one-fifth its weight of white wax. After complete melting and homogenisation, the mixture was filtered and stored, yielding a smooth ointment base [Table/Fig-5a-c] [11].

Analytical Evaluation

Analytical evaluation was carried out using standard pharmacopeial methods:

- **Organoleptic parameters** (colour, odour, texture) were evaluated by sensory observation.
- **Physicochemical parameters** were assessed using standard laboratory techniques to ensure quality and stability of the formulation. Specific gravity was determined by the pycnometer

[Table/Fig-3]: a) Ashuddha Haratala; b) During Swedana; c) Shodhita Haratala.

[Table/Fig-4]: a) Aargwadha pulp; b) Heating pulp; c) Herbal powders; d) Mixing ingredients; e) Kalka bolus; f) Oil heating; g) Kalka Paka; h) Final oil.

[Table/Fig-5]: a) White wax; b) Oil-wax mixing; c) Prepared ointment.

method, pH by a digital pH meter, and spreadability by the slip and drag method. The refractive index was measured using an Abbe refractometer. Iodine, acid, and peroxide values were obtained by titrimetric and iodometric methods to evaluate oxidation and purity. Rancidity was detected by the Kreis test, and loss on drying was measured by oven drying at 105°C to assess moisture content. These evaluations followed standard procedures comparable to those described by Liyanage RP and Weerasekara S (2020) [12].

- **Microbiological parameters-**Microbial contamination was assessed using selective culture media for bacterial and fungal growth. Nutrient agar was used for total bacterial count and Sabouraud Dextrose Agar (SDA) for fungal count. The plates were incubated at 37±1°C for 24-48 hours for bacterial cultures and at 25±2°C for 5-7 days for fungal cultures, and the results were expressed as Colony-forming Units per millilitre (CFU/mL) [13].

RESULTS

Both the oil and ointment exhibited acceptable colour, odour, and texture, indicating good quality [Table/Fig-6].

Parameters	Oil (Sample 1)	Ointment (Sample 2)
Colour	Pale yellow	Pale yellow
Odour	Characteristic	Characteristic
Texture	–	Smooth

[Table/Fig-6]: Organoleptic parameters.

The oil demonstrated desirable specific gravity (0.919), refractive index (1.472), and absence of rancidity. The ointment showed acceptable pH (5.3) and spreadability (1.3 g/sec) confirming stability and ease of application. The difference in iodine values between oil and ointment reflected the effect of wax addition, which altered unsaturated fatty acid content. These parameters were consistent with pharmacopeial standards [Table/Fig-7].

Both samples were free from microbial contamination, including pathogenic species (*E. coli, Salmonella, S. aureus, P. aeruginosa*), confirming aseptic manufacturing and storage practices [Table/Fig-8].

DISCUSSION

The classical *Shodhana* (purification) of *Manashila* (realgar) with *Ardraka Swarasa* and *Hartala* (orpiment) with *Churnodaka* ensured detoxification while preserving therapeutic potency, in accordance with *Rasashastra* principles, such purification

Parameters	Oil (S1)	Ointment (S2)
Specific gravity	0.919	–
Refractive index	1.472	–
Acid value	–	2.1
Iodine value	–	114.1
Saponification value	18.29	187.82
Peroxide value	–	2.31
Rancidity	7.2	Absent
Loss on drying (105°C)	Absent	–
pH	–	0.92%
Spreadability	–	1.3 g/sec

[Table/Fig-7]: Physicochemical parameters.
Note: Some values are not applicable (–) for either oil or ointment due to differences in formulation (oil-only or ointment-only characteristics). These have been indicated accordingly instead of leaving blank cells, to avoid confusion.

S. No.	Parameters	Sample 1	Sample 2
1.	Total viable count	Absent	Absent
2.	Total fungus count	Absent	Absent
3.	*Enterobacteriaceae*	Absent	Absent
4.	*E.coli*	Absent	Absent
5.	*Salmonella*	Absent	Absent
6.	*Staphylococcus aureus*	Absent	Absent
7.	*Pseudomonas aueruginosa*	Absent	Absent

[Table/Fig-8]: Microbiological parameters of the samples.

minimises toxicity while maximising efficacy. The *Sneha Kalpana* method ensured lipid solubility and enhanced bioavailability of active compounds. Conversion of the medicated oil into ointment form using white wax improved patient acceptability and convenience without affecting therapeutic potential. The Pharmaceutico-analytical evaluation of *Aragwadhadi Taila* and its conversion into an ointment successfully established a standard manufacturing process and confirmed quality, safety, and therapeutic potential. *Aragwadhadi Taila* (Oil) is a classical Ayurvedic formulation described in *Chakradatta* for *Kustha Roga* (skin diseases) and *Shvitra Roga* (vitiligo). Prepared using mustard oil (*Sarshapa Taila*), cow urine (*Gomutra*), and herbal paste (*Kalka*) [14]. Ointment is a modern adaptation of the oil, formulated for topical use to improve ease of application, reduce messiness, and enhance patient compliance [9].

In the study by Kolhe J et al., Aragvadhadi Taila (ART) was prepared as per *Chakradatta* and evaluated pharmaceutico-analytically, showing characteristic transformation of *Tila Taila* from yellow to reddish brown after *Murchchana* and a final greenish-yellow medicated oil. The formulation exhibited slightly acidic pH (3.59), low moisture content, moderate density (specific gravity 0.9332 g/mL), refractive index of 1.4754, high saponification value (130.90), low acid value (1.329), and an iodine value of 64.9, indicating moderate unsaturation and good absorption potential. These findings emphasised the role of *Murchchana* in enhancing solubility and efficacy of the oil [15].

Similarly, Makwana SM et al., evaluated standardisation process of ART, preparing three batches through classical Sneha Paka and documenting physicochemical parameters such as specific gravity, refractive index, acid value, saponification value, and iodine value. While this established reproducibility of the oil preparation, the scope remained limited to the traditional formulation [16].

In contrast, the present study not only validated the oil but also advanced its application by converting it into an ointment using a modern base, thereby enhancing patient compliance and usability. Moreover, the analytical framework was expanded to include peroxide value and microbiological safety, parameters absent in the earlier work but critical for contemporary quality assurance.

The demonstration of stable organoleptic properties, acceptable physicochemical ranges, and absence of microbial contamination underscores the improved stability and safety profile of the ointment compared to the oil. Thus, the present study is more novel in bridging classical Ayurvedic pharmaceutics with modern pharmaceutical standards, offering a dual-formulation approach that is both scientifically rigorous and clinically relevant.

Further, Makwana S et al., compared ART and Aragvadhadi Gel (ARG) with *Rasayana Churna* in 66 vitiligo patients. Group-A received ART, and Group-B received ARG for two months, both with *Rasayana Churna* internally. Significant improvement was observed in symptoms such as burning sensation, itching, and patch size/number in both groups. Group-B (ARG) showed more consistent results, though intergroup differences were statistically insignificant. Overall, both formulations proved safe and effective with notable pigment regeneration [17].

Parameters like iodine, acid, and peroxide values serve as benchmarks for reproducibility and regulatory validation. Although analytical and pharmaceutical quality has been established, further preclinical and clinical investigations are warranted to confirm therapeutic efficacy.

Overall, the present study strengthens the scientific foundation of ART by validating its stability, safety, and adaptability into a patient-friendly modern dosage form, thereby expanding its relevance in dermatological care.

CONCLUSION(S)

The pharmaceutico-analytical study of *Aragwadhadi Taila* and its ointment formulation demonstrated that the classical methods of ingredient authentication, purification (*Shodhana*), and preparation (*Sneha Kalpana* with subsequent ointment conversion) yielded stable and acceptable products. Both formulations exhibited consistent organoleptic characteristics, including uniform colour, odour, and texture, confirming their sensory stability. Overall, the study validates the pharmaceutico-analytical standards of *Aragwadhadi Taila* and its ointment, supporting their suitability for clinical application and further pharmacological evaluation.

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Authors' contribution: PK: Conceptualisation, Methodology, Data Curation, Analysis, Writing- Original Draft; BR: Review and Supervision.

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