

Pharmaceutical and Analytical Study of the Modified Form of *Pathyadi Lepa* as an Ointment

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ABSTRACT

Introduction: *Pathyadi Lepa* is an Ayurvedic topical treatment described in Bharat Bhaishajya Ratnakar. It contains *Haritaki*, *Karanjbeeja*, *Sarshap*, *Haridra*, *Bakuchi*, *Saindhava Lavan*, and *Vidang*. Traditionally prepared *Lepa* formulations are not convenient to use due to their time-consuming preparation and application. Staining of clothing is another hurdle associated with *Lepa* application.

Aim: To develop a modified ointment formulation that minimises oiliness and improves packaging to address patient concerns.

Materials and Methods: A pharmaceutical analytical study was conducted at the Dattatraya Ayurveda Rasashala Laboratory

of Mahatma Gandhi Ayurved College, Wardha, Maharashtra, from July 2023 to August 2023. The *Pathyadi* ointment was prepared at *Rasashala*, and its organoleptic, physicochemical, and microbiological parameters were assessed.

Results: The analytical study results showed pH 5.5; rancidity was absent; iodine value 19.77; peroxide value 11.32. No microbiological growth was detected.

Conclusion: The analytical parameters were within the normal range for use in skin disorders. Therefore, the modified *Pathyadi Lepa* ointment can be used in *Vicharchika*.

Keywords: *Bahya kalpana*, Decoction, *Kushtha*, Skin disorder, *Taila siddhi lakshana*

INTRODUCTION

Acharya Sharangadhara, in his book *Sharangadhara Samhita*, describes various types of formulations for external application, known as '*Bahya Kalpana*', with *Lepa Kalpana* being a significant subtype due to its localised action [1]. *Lepa* is further classified as *Pralepa*, *Aalepa*, and *Pradeha* [2]. *Doshaghna*, *Vishaghna*, and *Varnya Lepa* are also described in Ayurveda classical books [3]. *Lepa* is widely used for external treatment of various skin disorders. *Pathyadi Lepa*, detailed in Bharat Bhaishajya Ratnakar, is specifically used for treating skin diseases [4]. All sorts of skin illnesses are discussed in Ayurveda under the umbrella of *Kushtha*, which is further classified into *Mahakushtha* and *Kshudrakushtha*. *Vicharchika* is regarded as *Kshudrakushtha* by the Acharyas. It is a disease that coats or covers the skin in a specific manner, leading to cracking, primarily affecting the skin on the hands and feet (*Shabdhakalpa-druma*) [5].

Yoga Ratnakar describes *Pathyadi Lepa* (local application) for managing *Vicharchika*. This formulation primarily includes *Haritaki* (*Terminalia chebula*), *Karanjbeeja* (*Piper nigrum* Linn.), *Safed Sarso* (*Brassica campestris* Linn.), *Haridra* (*Curcuma longa* Linn.), *Bakuchi* (*Psoralea corylifolia*), *Saindhava Lavan* (*Sodiumchloridum*), and *Vidang* (*Embelia robusta*) [4]. These ingredients are generally recognised for their actions as *Kaphaghna* (*Kapha* alleviating), *Pittarechak* (*Pitta* eliminating), *Kushtaghna* (anti-leproptic), *Kandughna* (anti-itching), and *Shothahara* (anti-inflammatory) [6]. They are designed to offer therapeutic effects through topical use. Ointments are applied topically for a variety of purposes, such as providing protection, antiseptic action, moisturising the skin, relieving itching, and serving as astringents. These ointment bases are typically anhydrous and may contain one or more active ingredients in the form of a suspension, solution, or dispersion. Bases can vary in composition, including hydrocarbon (oleaginous), absorption, and water-soluble bases. Transdermal drug delivery has long been regarded as promising due to the skin's easy accessibility, large surface area, extensive connection to the circulatory and lymphatic systems, and the non invasive nature of the treatment [7].

The transformation of this formulation into an ointment facilitates easier use by patients. The ointment form allows convenient packaging, enabling patients to carry and apply it with ease. This modification involved employing suitable bases and emulsifiers to achieve the desired consistency and properties. In the development and assessment of such ointments, organoleptic studies are crucial. These studies evaluate sensory characteristics such as colour, odour and texture, which play a significant role in determining the product's acceptability and effectiveness [8].

Therefore, the present study aimed to develop a modified ointment formulation that minimises oiliness and enhances packaging to address patient concerns. The clinical study of *Pathyadi* ointment aims to evaluate the efficacy of *Pathyadi* ointment in *Vicharchika*. The results of the clinical study will be published upon completion.

MATERIALS AND METHODS

A pharmaceutical analytical study was conducted in the Dattatraya Ayurveda Rasashala Laboratory of Mahatma Gandhi Ayurved College, Wardha, Maharashtra, India, from July 2023 to August 2023.

Collection of raw drugs: The raw drugs were sourced from the herbal garden of Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod Wardha, and verified by the Department of Dravya Guna.

1. *Haritaki* (*Terminalia chebula*)
2. *Karanj beeja* (*Piper nigrum* Linn.)
3. *Haridra* (*Curcuma longa* Linn.)
4. *Sarso* (*Brassica campestris* Linn.)
5. *Bakuchi* (*Psoralea corylifolia*)
6. *Saindhava* (*Sodiumchloridum*)
7. *Vidang* (*Embelia robusta*)

Pharmaceutical study: *Pathyadi Lepa* is a traditional medicine that has been modified into an ointment form to standardise its preparation for clinical applications. Initially, a trial batch of five bottles

was prepared. This initial trial batch served as the foundation for establishing specific parameters regarding ingredients, proportions, and preparation techniques. Results were tested at the Dattatraya Ayurveda Rasashala of Mahatma Gandhi Ayurved College, Wardha, Maharashtra, India.

Following the successful formulation of the initial batch, five additional batches of *Pathyadi Lepa* were produced. These batches were created to facilitate further studies and evaluations in clinical settings. Each subsequent batch was meticulously prepared under standardised conditions to ensure reliability and reproducibility of results.

The primary objective of producing these additional batches was to conduct a thorough clinical study to assess the ointment's effectiveness and safety for potential therapeutic uses. This approach not only helps in establishing quality control measures but also ensures that the therapeutic benefits of the ointment are well documented and validated through scientific research.

Method of preparation:

- Kwath preparation:** Equal quantities of all the drugs listed in [Table/Fig-1] were used in the preparation [2]. The purified powders of *Haritaki*, *Karanj beeja*, *Haridra*, *Sarso*, *Bakuchi*, *Saindhava Lavan*, and *Vidang* were finely ground using a pestle. A decoction, or *kwath*, was prepared by adding 64 liters of water to this powder mixture and subsequently reducing it to 16 liters by boiling [9]. To achieve the desired consistency, the *kwath* was filtered twice and set aside to cool [Table/Fig-2].

S. No.	Drug	Part
1	<i>Haritaki (Terminalia chebula)</i>	1
2	<i>Karanj beeja (Piper nigrum Linn.)</i>	1
3	<i>Haridra (Curcuma Longa. Linn.)</i>	1
4	<i>Sarso (Brassica campestris Linn.)</i>	1
5	<i>Bakuchi (Psoralea Corylifolia)</i>	1
6	<i>Saindhava (Sodiichloridum)</i>	1
7	<i>Vidang (Embelia robusta)</i>	1

[Table/Fig-1]: List of raw drugs with proportion.



[Table/Fig-2]: Kwath preparation.

- Oil preparation:** The *churna* of *Haritaki*, *Karanj beeja*, *Haridra*, *Sarso*, *Bakuchi*, *Saindhava*, and *Vidang* was used to make the *Kalka* for oil preparation. To prepare the oil, one liter of *Tila Taila* was boiled, and the previously prepared *Kalka* along with the *Kwath* was added to it. The mixture was then allowed to cook for approximately eight hours to achieve the *Taila Siddhi Lakshana*. After reaching the desired consistency, the oil mixture was carefully filtered and left to cool [Table/Fig-3] [9].
- Ointment preparation:** Paraffin wax was added to the oil mixture in a 1:5 ratio (Paraffin wax to oil). This combination was thoroughly mixed until it emulsified into a uniform mixture with the consistency of an ointment. The prepared ointment was then packed into airtight 20 mL containers [Table/Fig-4] [10].



[Table/Fig-3]: Oil preparation.



[Table/Fig-4]: Ointment preparation.

Physicochemical analysis: The physicochemical analysis was performed according to the methods specified in the Ayurvedic Pharmacopoeia of India (API) for ointment testing [11]. The following parameters were assessed: loss on drying, pH (10% w/v aqueous solution), spreadability, rancidity, iodine value, and peroxide value.

Loss on drying: The loss on drying of *Pathyadi* ointment was determined by drying 10 g of the ointment at 105°C [12].

pH: The normal pH range of human skin is generally between 4.5 and 6.5, creating a mildly acidic environment known as the "acid mantle." This acidity is maintained by the activity of sebaceous glands, sweat glands, and the skin's natural microbiota [13].

Spreadability: The spreadability of the formulations was evaluated by measuring the spreading diameter of 1 g of the sample placed between two horizontal glass plates (10×20 cm) after one minute, with a standard weight of 25 g applied to the upper plate. Each formulation was tested in triplicate. Spreadability refers to the ability of an ointment to spread evenly on the skin, which is essential for delivering a consistent dose of the medicated product and ensuring the effectiveness of topical treatment [14].

Rancidity: Rancidity refers to the development of an unpleasant odour in fats and oils and is indicative of whether the formulation will be well accepted by patients and will have an extended shelf life [15].

Iodine value: The iodine value reflects the presence of double bonds, which react with iodine compounds. A higher iodine value signifies a greater number of unsaturated fatty acid bonds in the fat [16].

Peroxide value: The peroxide value is used to assess the primary products of oxidative degradation. Oxidation, which can affect the ointment's stability, should be minimised to prevent reactions with atmospheric conditions [17].

Microbiological analysis: Total bacterial and fungal counts were performed following standard procedures [18].

RESULTS

Analytical study: Organoleptic characteristics, including colour, odour, texture, and taste, were carefully noted [Table/Fig-5]. The analytical results presented are the average values obtained from testing six samples of the modified ointment. The pH of the *Pathyadi* ointment formulation was 5.5, which falls within the normal skin pH range, with a low loss on drying of only 0.27%. The spreadability value obtained was 1.3 gm-cm/sec. The iodine value of *Pathyadi* ointment was measured at 19.77. The peroxide value obtained was 11.32 Meq KOH/g, falling within the acceptable range. The microbiological analysis showed the absence of microorganisms in the ointment [Table/Fig-5].

Organoleptic parameter		
1	Colour	Yellowish colour
2	Odour	Predominantly of characteristic
3	Texture	Smooth
Physicochemical parameter		
4	Loss on drying at 105°C	0.27%
5	pH	5.5
6	Spreadability test	1.3 gm/sec
7	Rancidity	Absent
8	Iodine value	19.77 Meq KOH/g
9	Peroxide value	11.32
Microbiological contamination		
10	Total viable count	Absent
11	Enterobacteriaceae	Absent
12	Total fungus count	Absent
13	<i>Escherichia coli</i>	Absent
14	<i>Salmonella</i>	Absent
15	<i>Staphylococcus aureus</i>	Absent
16	<i>Pseudomonas aeruginosa</i>	Absent

[Table/Fig-5]: Physicochemical analytical report.

DISCUSSION

According to *Acharya Sushruta*, the efficacy of *Lepas* is illustrated through the analogy of extinguishing a fire with water poured over a burning house, which results in immediate suppression of the flames. Similarly, the application of *Lepa* effectively reduces the aggravated local *Doshas* through localised treatment. The therapeutic actions of *Lepa* encompass *Shodhana*, *Utsadana*, *Ropana*, and *Pralhadana* [5]. *Pathyadi Lepa* is utilised as *Bahya chikitsa* (external therapy), specifically for the treatment of *Kitibhakushta*, a type of skin disorder, by means of local application. This formulation possesses properties such as *Vranashodhana* (wound purification), *Vranaropana* (wound healing), *Vranahara* (wound soothing), and *Kushtahara* (anti-skin disease) [19].

An organoleptic study is a scientific methodology used to evaluate the sensory attributes of substances, particularly in Ayurvedic drugs. It assesses qualities such as taste, colour, odour, and texture to determine the quality and authenticity of herbal formulations. Such analyses are integral to pharmacognostic studies, ensuring that herbal drugs adhere to established standards through thorough sensory evaluations [8].

In the present investigation, the pH of the *Pathyadi* ointment formulation was measured at 5.5, which is consistent with the ideal skin pH range of 4.5 to 5.5 as reported in dermatological research [13], thereby ensuring compatibility with the skin's natural barrier functions. Furthermore, the observed minimal moisture content of 0.27% contributes to the product's shelf life while inhibiting microbial proliferation. The spreadability value of 1.3 gm-cm/sec indicates a favourable viscosity that promotes efficient application and absorption. This value aligns with

parameters documented in the literature concerning optimal topical formulations [14].

The absence of rancidity, along with a low peroxide value of 11.32 Meq KOH/g, indicates the stability of the ointment and confirms the absence of primary oxidation. These findings are corroborated by previous studies, which have demonstrated that herbal formulations can exhibit substantial resistance to oxidative degradation due to the presence of natural antioxidants within their composition. Additionally, the iodine value of 19.77, indicative of unsaturation, suggests the presence of unsaturated fatty acids that can aid skin absorption and may contribute to anti-inflammatory properties [20].

Microbiological testing confirmed the absence of microorganisms, thereby validating the ointment's safety for patient application and ensuring microbial safety in formulations, particularly those intended for the treatment of inflammatory skin conditions. Notably, a study by Naik K and Dongre N, on the anti-inflammatory activity of *Pathyadi Lepa* in the carrageenan-induced paw oedema model demonstrated its effectiveness in reducing inflammation, underscoring the potential therapeutic properties of comparable herbal ointments [21].

Limitation(s)

Variability in the quality, potency, and concentration of herbal ingredients due to environmental and seasonal factors can impact the formulation's consistency. The analytical study indicates potential effectiveness when applied locally for managing *Vicharchika*; however, local application alone may not be sufficient for all patients. Variability in individual responses, disease severity, and underlying systemic conditions may necessitate a more comprehensive treatment approach, incorporating both topical and systemic therapies to achieve optimal outcomes.

CONCLUSION(S)

The modification of *Pathyadi Lepa* into an ointment form addresses contemporary needs such as improved shelf life, convenient packaging, and enhanced patient acceptability. Through rigorous analytical testing, the ointment has demonstrated its suitability to replace the traditional *Lepa* form in current times.

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