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Original Article

Ayurveda Section

Pharmaco-analytical Characterisation and Quality Control of *Rasapachak Vati*: An Experimental Study

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ABSTRACT

Introduction: In Ayurveda, *Agni* (digestive fire) is fundamental to health and its impairment is considered a primary cause of many gastrointestinal and hepatobiliary disorders. Classical formulations like *Kwatha* (herbal decoction) are effective but face limitations in shelf life, palatability and convenience. To address these challenges, *Rasapachak Vati*, a tablet formulation modified from a classical decoction, was developed to improve patient compliance while retaining therapeutic efficacy.

Aim: To evaluate the *Rasapachak Vati* through comprehensive analytical characterisation using modern techniques.

Materials and Methods: A pharmaceutico-analytical experimental study was conducted in Department of Samhita Siddhanta, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Wardha, Maharashtra, India, with analysis performed at Cotex Laxmi Healthcare Private Limited, MGACHRC, Salod (H), Wardha, from July 2024 to July 2025. The formulation contains *Kalinga* (*Holarrhena pubescens*), *Patola* (*Trichosanthes dioica*) and *Katukrohini* (*Picrorhiza kurroa*), each known for *Deepana* (digestive stimulant), *Pachana* (carminative), *Yakrituttejaka* (liver stimulant) and *Krimighna* (anthelmintic) properties. Analytical evaluation included organoleptic, physicochemical (loss on drying, ash values, pH, extractive values, disintegration time, hardness, friability) and microbiological parameters.

Results: The tablets exhibited a brownish colour, characteristic odour and bitter taste. Physicochemical analysis showed acceptable limits for moisture content (0.52%), total ash (2.44%), acid-insoluble ash (0.05%), alcohol extractive value (28.36%), water extractive value (42.57%) and pH (5.1). The tablets had a disintegration time of four minutes, a hardness of 3.5 kg/cm^2 and friability of 0.5%, indicating good mechanical integrity. Microbiological tests confirmed the absence of pathogenic contaminants, ensuring safety for internal use.

Conclusion: *Rasapachak Vati* is pharmaceutically stable, safe and suitable for therapeutic use. The transformation from decoction to tablet form enhances its shelf life, dosage accuracy and patient acceptability. Analytical validation supports its potential as a standardised, evidence-based Ayurvedic digestive formulation, warranting further pharmacological and clinical investigations.

Keywords: Acid-insoluble ash, Alcohol extractive value, *Deepana*, *Holarrhena pubescens*, *Trichosanthes dioica*

INTRODUCTION

Ayurveda, the ancient system of Indian medicine, has long emphasised the importance of *Agni* (digestive fire) as the cornerstone of health and disease [1]. According to Ayurvedic principles, proper digestion and metabolism are essential for maintaining homeostasis and ensuring the optimal functioning of bodily systems [2]. Weak or disturbed *Agni* is considered the root cause of many disorders, particularly those related to the gastrointestinal and hepatobiliary systems [3]. Therefore, formulations that support and regulate digestive functions are foundational in Ayurvedic therapeutics.

Among the various dosage forms mentioned in classical Ayurvedic texts, *Kwatha* (herbal decoction) holds a significant place due to its ability to extract and deliver the active principles of herbs efficiently [4]. However, the traditional decoction form presents challenges such as difficulty in transportation, poor patient compliance due to taste and volume and inconsistent dosage. These limitations often restrict its widespread use in today's clinical and consumer settings [5].

To overcome these practical issues while preserving the therapeutic potential of *Kwatha*, there is a growing trend of converting such preparations into *Vati* (tablets), a more stable form. This transformation facilitates standardisation, dosage accuracy, ease of administration and improved shelf life, thereby aligning Ayurvedic formulations with modern pharmaceutical practices [6].

In 2019, digestive diseases accounted for 7.32 billion incident cases and 2.86 billion prevalent cases worldwide, causing around eight million deaths and 277 million Disability-adjusted Life Years (DALYs). The global age-standardised incidence and prevalence remained high at 95,582 and 35,106 per 100,000 population, with a death rate of 102 per 100,000. Overall, digestive disorders contributed to a substantial disease burden, representing over one-third of prevalent cases [7].

Rasapachak Vati is a formulation developed by modifying a classical decoction into a tablet form. It contains three essential herbal ingredients, *Kalinga* (*Holarrhena pubescens*), *Patola* (*Trichosanthes dioica*) and *Katukrohini* (*Picrorhiza kurroa*) [8] in a 1:1:1 ratio, each of which is traditionally recognised for its *Deepana* (digestive stimulant), *Pachana* (carminative), *Yakrituttejaka* (liver stimulant) and *Krimighna* (anthelmintic) actions. Collectively, these herbs aim to improve digestion, support liver function and promote detoxification, which are central to managing conditions related to impaired digestion and metabolic imbalance [8].

Holarrhena pubescens has been extensively studied for its metabolic diversity and therapeutic applications. It is widely used in traditional Asian medicine for the management of gastrointestinal disorders, infections, skin diseases and fever. These effects are attributed to its rich phytoconstituents, particularly alkaloids such as conessine, holarrhenine and kurchine, which contribute to its antimicrobial, anti-inflammatory and digestive properties [9].

Similarly, *Trichosanthes dioica* has demonstrated significant antioxidant activity. Studies have shown that its aqueous extract contains phenolic acids, polyphenols and flavonoids, which play a crucial role in scavenging free radicals and preventing oxidative damage. This antioxidant property supports its role in maintaining digestive and hepatic health [10].

Picrorhiza kurroa has also been reported to possess notable pharmacological activities. Phytochemical screening studies indicate that it exhibits strong antioxidant potential and enzyme inhibitory activity. It has been shown to inhibit α-amylase and α-glucosidase enzymes, thereby helping in the regulation of glucose metabolism and reduction of oxidative stress, which further contributes to its hepatoprotective and metabolic benefits [11].

Analytical characterisation using modern techniques and validation of traditional knowledge through measurable parameters. It identifies potential contaminants and determines the pharmacopoeia standards such as organoleptic properties, physicochemical parameters (e.g., loss on drying, ash values, extractive values, pH) and microbiological safety [12].

Vati Kalpana is an important and commonly used formulation in Ayurvedic medicine. It is easy to take, pleasant to taste, has a long shelf life and is convenient to handle and transport. Acharya Sharanghadhara was the first to write a detailed description of it in a dedicated chapter. *Vati*, also known as *Vatak* or *Gutika*, is made by grinding powdered raw materials, which can be herbal or herbo-mineral. These are mixed with binding agents such as water, specific juices, cow urine, cow's milk, jaggery, a type of resin called guggulu, or honey. This mixture is then shaped into small spheres by hand or with machines [13]. The novelty of the study lies in providing a detailed standardisation of *Rasapachak Vati*, ensuring its quality, safety and consistency through thorough tests of its physical and chemical properties, mechanical strength and microbial safety.

To evaluate the pharmaco-analytical characterisation of the *Rasapachak Vati* using modern methods and techniques.

Primary objective: Was to analyse organoleptic, physicochemical and microbiological parameters of *Rasapachak Vati*.

Secondary objective: Was preparation of *Rasapachak Vati* at GMP certified pharmacy.

MATERIALS AND METHODS

This pharmaceutico-analytical study was conducted in the Department of Samhita Siddhanta, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Wardha, Maharashtra, India with analytical evaluation carried out at Cotex Laxmi Healthcare Private Limited, MGACHRC, Salod (H), Wardha, from July 2024 to July 2025 after obtaining approval from the Institutional Ethics Committee (Ref. No. MGACHRC/IEC/Sep2023/746, dated 18/09/2023). The raw drugs required for the preparation of *Rasapachak Vati* were procured from the local market of Wardha, Maharashtra [14]. Authentication of the drugs was carried out by the Department of Dravyaguna, MGACHRC, Wardha.

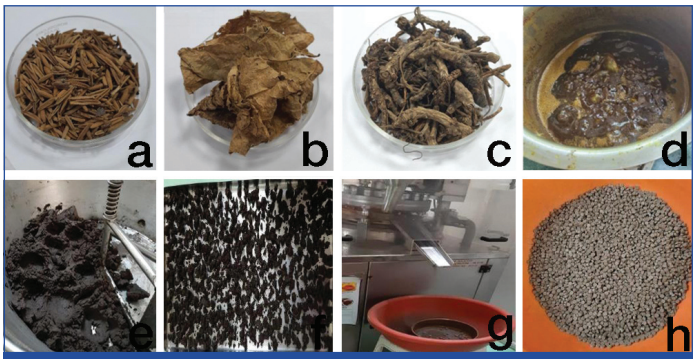
Study Procedure

The authenticated raw materials mentioned in [Table/Fig-1] were taken in a 1:1:1 ratio and thoroughly cleaned to remove extraneous matter and coarsely powdered using a *Khalva Yantra*. The coarse powder was transferred to a clean vessel and 24 litres of water were added. The mixture was boiled over a mild flame and reduced to one-fourth of its original volume (6 litres) to obtain the Kwatha (decoction). The reduced liquid was filtered through a clean muslin cloth to remove solid residues and the filtrate was further heated to obtain a semi-solid extract (*Kwatha Ghana*) [15].

S. No.	Drug name	Botanical name	Part-used	Proportion	Quantity
1.	*Kalinga*	*Holarrhena pubescens Linn.*	Seeds	1 part	1 kg
2.	*Patola*	*Trichosanthes dioica Roxb.*	Leaves	1 part	1 kg
3.	*Katukrohini*	*Picrorhiza kurroa Royle.*	Roots	1 part	1 kg

[Table/Fig-1]: Composition of *Rasapachak Vati* according to classical Ayurvedic references [8].

The preparation of *Rasapachak Vati* was carried out using 3 kg of raw drugs, yielding approximately 4000 tablets of 500 mg each. The *Ghana* was compressed using a single punch tablet machine with a compression force (3-5 kg/cm^2) to achieve acceptable hardness, friability and disintegration time within pharmacopoeial limits. The tablets were packed in airtight, moisture-resistant containers and stored in a cool, dry place [Table/Fig-2a-h].



[Table/Fig-2]: a) *Kalinga* seeds; b) *Patola* leaves; c) *Kutaki* roots; d) *Kwath* preparation; e) *Kwath Ghan* preparation; f) Prepared *Ghan*; g) Tablets in process; h) Prepared tablets.

Analytical evaluation of *Rasapachak Vati* was carried out in accordance with standard guidelines prescribed in the Ayurvedic Pharmacopoeia of India (API) and Ayurvedic Formulary of India (AFI), along with general pharmacopeial procedures [12].

Organoleptic evaluation included assessment of colour, odour and taste.

Physicochemical parameters were analysed using standard methods.

Loss on drying at 105°C was determined by drying the sample in a hot air oven until constant weight. Total ash was obtained by incinerating the sample in a muffle furnace and acid-insoluble ash was measured after treating the ash with dilute hydrochloric acid, followed by filtration and re-incineration. Alcohol and water-soluble extractive values were determined by macerating the sample with respective solvents, filtering, evaporating and weighing the residue. The pH was measured using a digital pH meter after dissolving the sample in distilled water.

The disintegration time was evaluated using a disintegration test apparatus in water maintained at 37±2°C. Tablet hardness was measured using a Monsanto-type hardness tester (Make: Lab India Instruments Pvt., Ltd.,). The instrument was calibrated prior to analysis using standard calibration weights, ensuring accuracy and reliability of readings. Calibration was performed as per the manufacturer's instructions and standard laboratory procedures, with periodic verification to maintain consistency of results.

Friability was determined using a Roche friabilator (Make: Electrolab India Pvt., Ltd.,). The instrument was calibrated before analysis for rotational speed (25±1 rpm) and time (4 minutes/100 revolutions) using a tachometer and standard timer, in accordance with manufacturer guidelines and standard laboratory procedures [12].

Microbiological limit tests were performed as per standard pharmacopoeial and World Health Organisation (WHO) guidelines for herbal formulations [16]. Total aerobic microbial count and total fungal count were determined by the plate count method using nutrient agar and Sabouraud dextrose agar, respectively. The bacterial plates were incubated at 30-35°C for 48 hours, while fungal plates were incubated at 20-25°C for three days. Tests for specific pathogens such as *Escherichia coli*, *Salmonella spp.*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* were carried out using selective media. The acceptable limits were maintained within prescribed standards, i.e., total aerobic count ≤10^5 Colony Forming Unit (CFU)/g, total fungal count ≤10^3 CFU/g and absence of specified pathogens, ensuring safety for internal use.

RESULTS

The formulation was observed to have a brownish colour, a mildly aromatic odour and a bitter taste [Table/Fig-3].

S. No.	Parameters	Result
1.	Colour	Brownish
2.	Odour	Mildly aromatic
3.	Taste	Bitter

[Table/Fig-3]: Showing organoleptic characteristics of *Rasapachak Vati*.

Rasapachak Vati showed low moisture content (loss on drying 0.52%) and minimal inorganic impurities (total ash 2.44%, acid-insoluble ash 0.05%). Extractive values were higher in water (42.57%) than in alcohol (28.36%), indicating greater aqueous solubility. The formulation had a mildly acidic pH (5.1). Tablet evaluation revealed rapid disintegration (4 minutes), adequate hardness (3.5 kg/cm^2) and acceptable friability (0.5%), confirming good mechanical strength and quality compliance [Table/Fig-4].

S. No.	Parameters	Result
1.	Loss of drying at 105°C	0.52%
2.	Total ash	2.44%
3.	Acid-insoluble ash	0.05%
4.	Alcohol extractive value	28.36%
5.	Water extractive value	42.57%
6.	pH	5.1
7.	Disintegration time	4 min
8.	Hardness test	3.5 kg/cm^2
9.	Friability test	0.5%

[Table/Fig-4]: Showing physicochemical parameters of *Rasapachak Vati*.

On microbiological evaluation, the formulation showed no viable microorganisms, with negative results for *Enterobacteriaceae*, *fungi*, *escherichia coli*, *salmonella*, *staphylococcus aureus* and *pseudomonas aeruginosa* [Table/Fig-5].

S. No.	Parameters	Result
1.	Total viable count	Absent
2.	*Enterobacteriaceae*	Absent
3.	Total fungus count	Absent
4.	*Escherichia coli*	Absent
5.	*Salmonella*	Absent
6.	*Staphylococcus aureus*	Absent
7.	*Pseudomonas aeruginosa*	Absent

[Table/Fig-5]: Showing microbiological parameters of *Rasapachak Vati*.

DISCUSSION

Ghana represents a secondary dosage form derived from a decoction, in which water-soluble phytoconstituents are extracted through the decoction process and subsequently concentrated by reheating to yield a thick, semi-solid mass.

The organoleptic evaluation provides the initial qualitative assessment of the formulation. *Rasapachak Vati* was found to have a brownish colour, mildly aromatic odour and a bitter taste, which are consistent with the known properties of its constituent herbs, particularly *Kalinga* and *Katukrohini*, both of which possess bitter principles. These attributes also reflect the formulation's authenticity and palatability, which is essential for patient compliance.

Physicochemical evaluation offers critical insights into the stability, quality and purity of the drug. Loss on drying T 105° was 0.52%, which showed minimal moisture content, suggesting that the samples are likely to have a good shelf life and remain stable during storage. The lack of moisture helps prevent both deterioration of the formulation and the growth of microorganisms.

Similarly, Maddesiya S et al., (2024) highlighted that formulations derived from *Kwatha Ghana* generally maintain stability when the moisture content remains below 2%, affirming the quality control achieved in the present formulation [4].

The low values of total ash (2.44%) and acid-insoluble ash (0.05%) reflect minimal inorganic and silica content. These results imply the absence of adulteration or substitution, confirming the purity of the raw materials and the hygienic nature of the preparation process. Since these values fall within the acceptable range, the sample is considered suitable for internal use. Similarly, Chaudhary P et al., (2024) highlighted low ash values in formulations derived from *Kwath Ghana* [17].

The pH of the formulation falls in the slightly acidic range (5.1), which is within acceptable limits for oral Ayurvedic formulations. A mildly acidic pH is also aligned with gastric pH, potentially enhancing bioavailability and digestive efficacy, especially since *Rasapachak Vati* is meant to aid digestion and detoxification. Similarly, Anjali U et al., (2025) showed slightly acidic value in formulations derived from *Kwath Ghana* [18].

Disintegration time is vital for evaluating the onset of action. The quick disintegration within four minutes indicates that the tablet will rapidly break down in the stomach, ensuring timely release and absorption of active constituents. This supports the therapeutic utility of the formulation in managing digestive disturbances where prompt action is desirable.

Alcohol and water extractive values (28.36% and 42.57% respectively), these values indicate the presence of alcohol and water-soluble phytoconstituents in adequate quantities. The high water extractive value reflects the richness of aqueous-soluble active components, which is significant considering the original formulation is a *Kwatha*. A good alcohol extractive value shows the presence of resins, alkaloids and other non-polar compounds, suggesting a broad spectrum of bioactive constituents in the final product. Similarly, Bhati H et al., (2017) showed approx similar alcohol and water extractive value in formulations derived from *Kwath Ghana* [19].

The hardness test confirms that the tablets are mechanically stable and can withstand handling, packaging and transport without breakage. The friability value (0.5%) is well within the permissible limit (<1%), indicating good compactness and durability of the tablets without affecting disintegration or dissolution.

The microbiological evaluation is crucial for assessing the safety of herbal formulations, especially when administered orally over extended durations. The absence of microbial contaminants, including *E. coli, Salmonella, Staphylococcus aureus, Pseudomonas aeruginosa* and other pathogenic organisms, along with no total viable or fungal count, confirms that *Rasapachak Vati* is microbiologically safe. This is an important finding, especially in the context of herbal preparations, where improper drying, storage, or contamination during processing can lead to microbial proliferation.

These results also reflect strict GMP adherence during the manufacturing process, particularly with regard to sanitation, raw drug handling and post-preparation storage [20].

The present study provides a more comprehensive pharmaco-analytical evaluation of *Rasapachak Vati* compared to the previously published study (Ambadkar S et al., 2017), reported pharmaceutical parameters and High-Performance Thin-Layer Chromatography (HPLC) profiling, focusing on tablet dimensions, hardness, friability and disintegration time (10-12 minutes) [21]. They did not include detailed physicochemical or microbiological safety assessments.

In contrast, the present study provides a comprehensive pharmacokinetic evaluation, covering organoleptic, physicochemical and microbiological parameters. The formulation showed rapid disintegration (4 minutes), acceptable hardness and friability and

complete absence of microbial contaminants, confirming safety and quality. Preparation under Good Manufacturing Practice (GMP) certified conditions further strengthens reproducibility and compliance.

Limitation(s)

The present study was limited to pharmaceutico-analytical evaluation and did not include pharmacological or clinical assessment to establish therapeutic efficacy. Raw drugs were procured from the local market and variation in geographical source may influence phytochemical composition and standardisation. Advanced analytical techniques such as HPTLC, HPLC, or marker-based standardisation were not performed, which could provide more precise chemical profiling. Stability studies under different environmental conditions were not conducted, limiting conclusions regarding long-term shelf life. The analysis was performed on a single batch, which may limit reproducibility; however, strict standard operating procedures were followed during preparation to maintain uniformity.

CONCLUSION(S)

The comprehensive analysis of *Rasapachak Vati* establishes that the formulation is pharmaceutically robust, safe and suitable for internal administration. The scientific validation of this classical Ayurvedic preparation, now in modern tablet form, not only improves its acceptability and convenience but also ensures therapeutic reliability through standardisation. These findings reaffirm the potential of integrating traditional knowledge with contemporary analytical practices, thereby contributing to the evidence-based development of Ayurvedic formulations. Further studies such as pharmacological and clinical evaluations would help substantiate its therapeutic claims and expand its applicability in clinical practice.

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