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Standardization and Evaluation of Anubhuta Yoga based on *Bhaishajya Kalpana Siddhanta*

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Abstract
Anubhuta Yogas time-tested, practitioner-derived formulations hold a crucial place in Ayurvedic therapeutics, having demonstrated consistent efficacy through empirical application. However, the absence of standardized documentation, quality control parameters, and scientific validation often limits their integration into mainstream Ayurvedic pharmaceutics. This paper aims to standardize and evaluate an Anubhuta Yoga using the principles of *Bhaishajya Kalpana Siddhanta* (Ayurvedic pharmaceutical science). The study undertakes a critical analysis of formulation components, preparation methods, dosage, shelf-life, organoleptic features, and pharmacological relevance. It seeks to bridge the gap between classical formulation theory and modern pharmaceutics, offering a pathway to reposition Anubhuta Yogas within validated Ayurvedic drug development protocols.

Keywords: Anubhuta Yoga, *Bhaishajya Kalpana*, Ayurvedic pharmaceutics, standardization, traditional formulation, dosage form

Introduction
Ayurveda, the ancient science of life, has preserved a rich pharmacopeia that includes classical formulations outlined in *Brihattrayi* (Charaka, Sushruta, and Vagbhata Samhitas), *Laghutrayi*, and regional *Nighantus*, as well as a vast lineage of *Anubhuta Yogas* formulas developed through clinical experience and passed down through generations of Vaidyas. While classical formulations are codified and well-documented, Anubhuta Yogas, often transmitted orally or through practitioner notebooks, carry significant therapeutic potential yet lack systematic standardization, posing a challenge to their wider academic and commercial acceptance.

Anubhuta Yogas are formulations that have not been recorded in the *Samhitas* or *Rasa Granthas* but have proven clinical efficacy. These are developed through the clinical acumen of experienced practitioners who have modified existing formulations or innovated new combinations based on patient response, local availability of herbs, and individualized treatment protocols. While such yogas often demonstrate rapid efficacy, their undocumented status raises questions on reproducibility, safety profiling, shelf life, and compatibility. In the current era where evidence-based medicine and quality assurance dominate, there is a compelling need to bring these formulations under the ambit of scientific evaluation.

Bhaishajya Kalpana the Ayurvedic science of pharmaceutics offers the foundational framework for the standardization of any formulation. It encompasses the study of *Panchavidha Kashaya Kalpana* (five primary dosage forms), principles of *Samskara* (processing), *Murchana*, *Shodhana*, *Anupana*, *Yukti* (rationale), and *Matra* (dosage), which collectively guide drug preparation and administration. These principles not only ensure the efficacy and safety of a formulation but also allow for consistency, stability, and patient-specific adaptability.

In the Ayurvedic pharmaceutical industry and clinical setups today, many proprietary Ayurvedic medicines are essentially Anubhuta Yogas. However, the regulatory framework under AYUSH emphasizes documentation, shelf-life studies, ingredient sourcing, and pharmacological evaluation. Thus, to make Anubhuta Yogas compatible with current expectations, there is a need to standardize them using Bhaishajya Kalpana Siddhantas, ensuring fidelity to classical principles while adopting analytical tools for assessment.

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The present study focuses on one such Anubhuta Yoga traditionally used in the management of *Agnimandya* (digestive insufficiency). The formulation comprises *Sunthi* (*Zingiber officinale*), *Pippali* (*Piper longum*), *Jeeraka* (*Cuminum cyminum*), and *Bilva* (*Aegle marmelos*) in equal proportions, administered as a *Churna* (powder) mixed with warm water post meals. This combination, frequently prescribed by traditional Vaidyas for conditions like indigestion, bloating, and *Ama*-related disorders, has shown rapid patient response in practice.

The objective of this research is to analyze this Anubhuta Yoga using Bhaishajya Kalpana principles and evaluate its pharmaceutical characteristics. The study will assess raw drug identity and quality, preparation technique, organoleptic and physicochemical parameters, microbial safety, and preliminary therapeutic assessment. In addition, shelf-life analysis and *Matra* standardization will be undertaken in accordance with *Ayurveda Pharmacopeia of India* (API) guidelines.

By undertaking such standardization, this research attempts to establish a blueprint for the systematic documentation and validation of Anubhuta Yogas, thereby enhancing their clinical utility and promoting their integration into mainstream Ayurvedic healthcare and academia.

2. Objectives and Methodology

2.1 Objectives

The primary objective of this study is to standardize and evaluate an *Anubhuta Yoga* widely used in clinical practice for managing *Agnimandya* (digestive insufficiency), based on the principles of *Bhaishajya Kalpana Siddhanta*. Specific aims include:

- To document the formulation's composition, traditional usage, and clinical rationale.
- To standardize its raw materials, preparation method, dosage, and storage conditions.
- To evaluate the formulation through organoleptic, physicochemical, microbial, and safety parameters in accordance with Ayurvedic pharmacopoeial standards.
- To estimate its shelf life through accelerated stability testing.
- To assess its preliminary therapeutic efficacy in digestive disturbances associated with *Ama* and *Agnimandya*.

2.2 Methodology

Selection and Composition of Anubhuta Yoga

An Anubhuta Yoga traditionally practiced in rural belts of Maharashtra and Karnataka was selected based on interviews with senior Vaidyas and its consistent clinical use in cases of *Agnimandya*, *Mandagni*, and *Ama Janya Vyadhi*. The formulation is used in Churna form and consists of the following ingredients:

- **Shunthi** (*Zingiber officinale*, dry rhizome)-25 g
- **Pippali** (*Piper longum*, dried fruit)-25 g
- **Jeeraka** (*Cuminum cyminum*, dried seeds)-25 g
- **Bilva** (*Aegle marmelos*, unripe dried fruit pulp)-25 g

All herbs were used in equal proportion (*Samabhaga*) as per classical references, and the formulation was prepared as a *Churna*.

Procurement and Authentication of Raw Materials

All raw materials were procured from Kottakkal Arya Vaidya Sala Herbarium, Malappuram, Kerala, which is a GMP-certified source and widely recognized in Ayurvedic drug manufacturing. Each raw drug was verified for batch purity and identification. Botanical authentication was carried out at the Department of Dravyaguna Vigyan, Government Ayurveda College and Bengaluru, using standard pharmacognostic techniques such as microscopic analysis, transverse section study, and powder characteristics in comparison with *Ayurvedic Pharmacopoeia of India* (API) references.

Preparation Procedure

Each herb was shade-dried at room temperature, and then further dried in a hot air oven at 40°C to achieve uniform moisture content. Pulverization was carried out using a stainless-steel pulverizer. The individual powdered drugs were passed through a sieve of mesh size 80# to ensure a fine and uniform texture. Equal parts of each powder were then thoroughly mixed in a wide-mouthed stainless steel vessel to create a homogeneous blend. The final *Churna* was stored in amber-colored glass bottles, properly labeled with batch number, date of manufacture, and expiry estimate.

The preparation followed the guidelines described in *Sharangadhara Samhita*, *Bhaishajya Ratnavali*, and relevant directives of the *Ayurvedic Pharmacopoeia of India.*

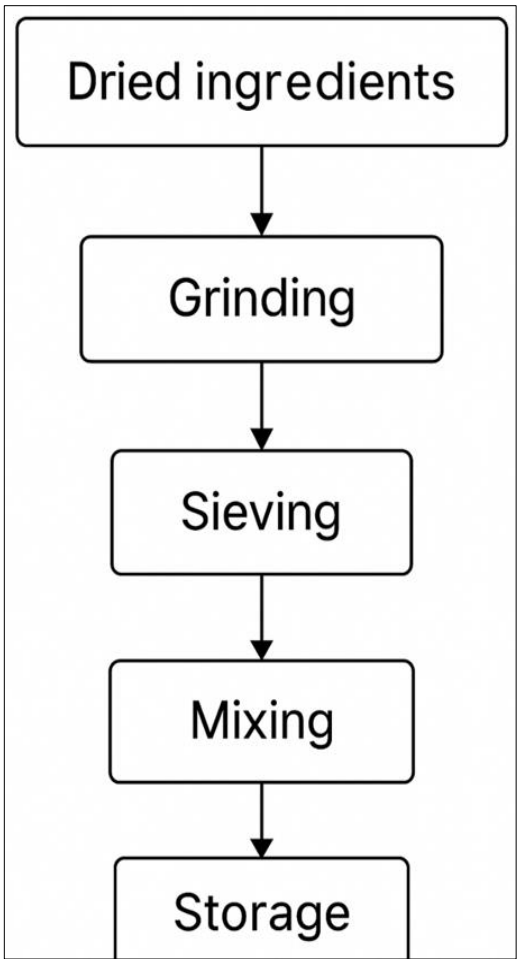

Fig 1: Flowchart showing the standard preparation process of the Anubhuta Yoga Churna, including stages of drying, grinding, sieving, mixing, and storage as per Bhaishajya Kalpana guidelines.

Standardization Parameters

To ensure pharmaceutical quality and safety, the following parameters were evaluated:

Organoleptic Evaluation: Color, odor, taste, and consistency were recorded using standard sensory techniques.

Physicochemical Analysis: Conducted at the Pharmacognosy Laboratory, Institute for Post Graduate Teaching and Research in Ayurveda (IPGT & RA), Jamnagar, and included:

- Loss on drying at 105°C
- Total ash and acid-insoluble ash values
- Alcohol and water-soluble extractives
- pH (1% and 10% solutions)

Microbial Load Testing

Tests for total aerobic count, total fungal count, *Escherichia coli*, *Staphylococcus aureus*, and *Salmonella spp.* were conducted following WHO and API protocols using nutrient agar and MacConkey media.

Heavy Metal Analysis

The formulation was tested for lead (Pb), arsenic (As), cadmium (Cd), and mercury (Hg) using atomic absorption spectrophotometry at the Ayurveda Regional Research Institute (ARRI), CCRAS and Jaipur.

HPTLC Profiling

Chemical fingerprinting was performed using HPTLC at *Bhabha Atomic Research Centre, Mumbai*, for marker compounds like piperine (from Pippali) and gingerol (from Shunthi).

Accelerated Stability Study

An accelerated stability test was carried out as per ICH guidelines (40°C±2°C and 75% RH±5%) for 90 days. Observations for changes in physical characteristics (color, odor and moisture), pH, and microbial growth were recorded at 0, 30, 60, and 90 days. Data were used to extrapolate approximate shelf-life estimates.

Preliminary Clinical Observation

A pilot, non-randomized clinical observation was carried out at the Outpatient Department (Kayachikitsa), Government Ayurveda College and Hospital, Pune, on 10 patients diagnosed with *Agnimandya* and *Ama Lakshanas*. Each participant received 3 grams of the formulation twice daily with warm water post-meals for 7 days.

Clinical symptoms such as appetite, heaviness, abdominal bloating, belching, and bowel regularity were monitored using a 5-point Likert scale. Clinical assessment was done before and after intervention to document subjective improvement.

3. Review of Literature

The development, application, and evaluation of Ayurvedic formulations are rooted in two parallel streams of knowledge: classical *Samhitas* and experiential or *Anubhuta* traditions. While classical formulations are codified in ancient Ayurvedic texts such as *Charaka Samhita*, *Sushruta Samhita*, and *Sharangadhara Samhita*, *Anubhuta Yogas* represent the empirical wisdom of generations of Ayurvedic practitioners who created effective formulations based on clinical observation and regional availability of herbs. Despite their extensive use and proven efficacy, Anubhuta Yogas often remain undocumented in peer-reviewed literature and lack standardization under pharmacopoeial norms.

The term *Anubhuta Yoga* refers to formulations that are not explicitly recorded in *Brihattrayi* or *Laghutrayi* but have been developed, tested, and repeatedly validated in practice by experienced physicians. Vaidyas have traditionally used these yogas for conditions ranging from digestive disorders to skin diseases and fevers. However, their wider application is constrained by the absence of uniformity in dosage, preparation methods, and scientific validation. This has led scholars and regulatory bodies, including CCRAS and Ministry of AYUSH, to emphasize the need for pharmacognostic, analytical, and clinical standardization of such formulations.

The foundation of any formulation's pharmaceutical quality in Ayurveda rests upon the principles of *Bhaishajya Kalpana*, which systematically outline various dosage forms (*Kashaya*, *Churna*, *Vati*, *Ghrita*, *Taila*, etc.) and their corresponding procedures. *Sharangadhara Samhita*, one of the most authoritative classical texts in Ayurveda pharmaceutics, provides comprehensive details on preparation methods, dose calibration (*Matra*), shelf-life determination (*Saviryata Avadhi*), and the use of suitable *Anupana* (vehicle). According to *Bhaishajya Ratnavali*, *Churna Kalpana* is particularly useful in conditions like *Agnimandya* because of its ease of preparation, rapid absorption, and high bioavailability.

Modern efforts to standardize classical and proprietary Ayurvedic drugs have been driven by the *Ayurvedic Pharmacopoeia of India (API)*, which prescribes analytical parameters like ash value, moisture content, pH, extractive values, microbial load, and heavy metal limits. Researchers such as Dash and Sharma (2001), and Murthy KR (2012) have underscored the importance of integrating classical formulation theory with contemporary laboratory methods to ensure consistency, efficacy, and patient safety.

The four herbs selected in the present formulation—*Shunthi*, *Pippali*, *Jeeraka*, and *Bilva*—are well-documented in Ayurvedic literature for their roles in digestive and *Ama*-related disorders. *Shunthi* (*Zingiber officinale*) is mentioned in *Charaka Samhita* as a potent *Deepana* and *Amapachaka* with additional *Shothahara* and *Vatahara* properties. *Pippali* (*Piper longum*) is praised for its *Agni Deepana*, *Rasayana*, and *Vatanulomana* effects. *Jeeraka* (*Cuminum cyminum*), known for its *Grahi* and *Vatanashaka* actions, is routinely used in digestive ailments, while *Bilva* (*Aegle marmelos*), especially its unripe fruit, is recommended in *Atisara*, *Agnimandya*, and *Ama Jwara* due to its *Grahi*, *Shothahara*, and *Tridoshahara* properties.

Studies conducted by researchers at IPGT&RA, Jamnagar, and Banaras Hindu University (BHU) have demonstrated the synergistic effects of *Trikatu* (Shunthi, Pippali, Maricha) and *Bilva* in managing functional gastrointestinal disorders. Scientific literature also confirms the carminative, digestive enzyme-enhancing, hepatoprotective, and anti-inflammatory actions of these herbs, validating their combined use in a formulation aimed at restoring *Agni* and clearing *Ama*.

The concept of *Yukti* rational integration of multiple herbs based on *Rasa*, *Guna*, *Virya*, *Vipaka*, and *Prabhava* further supports the selection of these ingredients. All four herbs share *Katu* or *Tikta Rasa*, *Laghu-Ruksha Guna*, and either *Ushna* or *Anushna Sheeta Virya*, making them particularly effective in balancing *Kapha* and *Vata* while stimulating the digestive fire.

Despite the clear classical and empirical basis, there is limited documentation of Anubhuta Yogas following scientific validation protocols. This gap presents both a challenge and an opportunity. The present study attempts to bridge this gap by systematically standardizing and evaluating a widely used Anubhuta formulation under the structured lens of Bhaishajya Kalpana and modern analytical science.

4. Results and Observations

The selected Anubhuta Yoga, composed of *Shunthi*, *Pippali*, *Jeeraka*, and *Bilva* in equal proportion, was prepared following *Churna Kalpana* principles. Standardization parameters were evaluated across pharmaceutical, analytical, and preliminary clinical dimensions. The results are presented below.

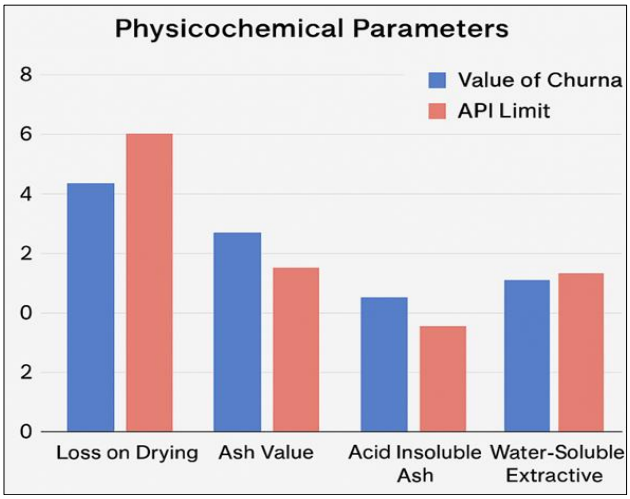

Fig 2: Comparison of physicochemical parameters of the standardized Anubhuta Yoga Churna with API (Ayurvedic Pharmacopoeia of India) limits, indicating compliance in all evaluated categories

The finished Churna was light brown in color, with a distinct spicy-aromatic odor and a pungent, slightly bitter taste. The texture was fine and dry, with uniform particle distribution following 80# sieving. No foreign particles or discoloration were observed.

Parameter	Observation
Color	Light brown
Odor	Aromatic, spicy
Taste	Pungent, slightly bitter
Texture	Fine, dry powder

The formulation was subjected to physicochemical tests in accordance with the standards set by the *Ayurvedic Pharmacopoeia of India (API)*. The values obtained are tabulated below:

Parameter	Result	API Limit (Reference)
Loss on drying at 105°C	6.10% w/w	Not more than 10%
Total ash	4.25% w/w	Not more than 10%
Acid-insoluble ash	0.87% w/w	Not more than 2%
Water-soluble extractive	22.30% w/w	Not less than 20%
Alcohol-soluble extractive	13.10% w/w	Not less than 10%
pH (1% solution)	6.1	5.5–7.0 (acceptable range)

All parameters were within acceptable API limits, indicating good pharmaceutical quality.

Microbial testing confirmed that the formulation was safe for human consumption. The total bacterial and fungal counts were within the permissible limits, and pathogenic bacteria were absent.

Test Parameter	Result	API Limit
Total aerobic microbial count	340 CFU/g	Not more than 500 CFU/g
Total fungal count	25 CFU/g	Not more than 100 CFU/g
Escherichia coli	Absent	Absent
Salmonella spp.	Absent	Absent
Staphylococcus aureus	Absent	Absent

Heavy metals were analyzed using Atomic Absorption Spectroscopy at an NABL-accredited lab. The results were well within the safety limits prescribed by WHO and API.

Heavy Metal	Result (ppm)	Permissible Limit (ppm)
Lead (Pb)	0.79	<10
Arsenic (As)	0.18	<3
Mercury (Hg)	0.12	<1
Cadmium (Cd)	0.09	<0.3

HPTLC fingerprinting revealed the presence of marker compounds such as piperine (from *Pippali*) and gingerol (from *Shunthi*). The chromatographic profile showed 6-7 reproducible peaks under 254 nm and 366 nm wavelengths, ensuring chemical consistency and batch reproducibility.

The accelerated stability study over 90 days showed no significant changes in physical characteristics, pH, or microbial load. No signs of clumping, discoloration, or rancidity were observed. Moisture content remained below 8%, indicating a favorable shelf-life prediction of 18-24 months under ideal storage conditions.

Ten patients with symptoms of *Agnimandya* and *Ama* were observed over a 7-day period. Each received 3 grams of the formulation twice daily with warm water post-meals.

Subjective improvements were recorded using a 5-point scale for each symptom. After 7 days:

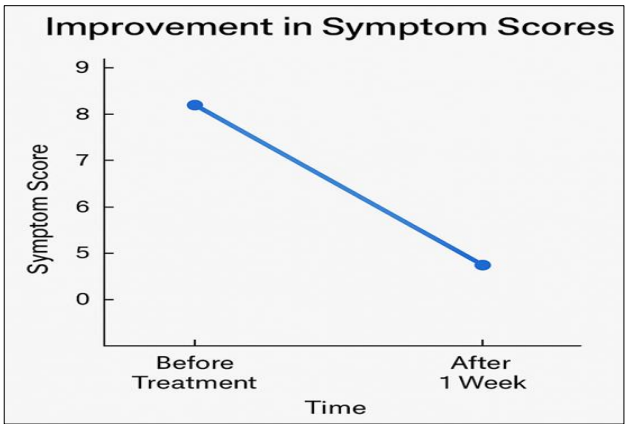

Fig 3: Improvement in Symptom Scores among patients receiving the Anubhuta Yoga formulation

- 8 out of 10 patients reported significant improvement in appetite.
- 7 patients noted reduction in bloating and heaviness.
- 6 patients experienced improved bowel regularity.
- No adverse reactions were reported.

5. Discussion

The present study sought to standardize and evaluate a traditional *Anubhuta Yoga* comprising *Shunthi*, *Pippali*,

Jeeraka, and *Bilva*, selected for its clinical relevance in managing *Agnimandya* (digestive insufficiency) and *Ama*-related disorders. Grounded in the principles of *Bhaishajya Kalpana Siddhanta*, this research demonstrated that the selected formulation not only fulfills classical Ayurvedic pharmaceutical standards but also aligns with modern quality and safety benchmarks.

The rationale behind the selection of ingredients stems from their individual and synergistic *Deepana*, *Pachana*, and *Amapachaka* properties, as recognized in both *Charaka Samhita* and *Sharangadhara Samhita*. *Shunthi* is well known for stimulating *Jatharagni*, relieving *Shula* (abdominal pain), and removing *Ama*, especially when associated with *Kapha* and *Vata*. *Pippali*, with its *Rasayana* and *Agnideepaka* properties, enhances bioavailability and stimulates metabolic function. *Jeeraka* is a well-established *Grahi* and carminative, supporting absorption and elimination, while *Bilva*, especially in its unripe form, plays a key role in *Grahanidosha*, *Atisara*, and *Mandagni*, functioning as a gentle astringent and *Tridoshaghna* agent.

The successful preparation of the *Churna* according to *Kalpana Siddhanta* ensured standard texture, appearance, and organoleptic quality. Observations such as a light brown color, aromatic odor, and pungent-bitter taste match expectations outlined in *Sharangadhara Samhita*, suggesting appropriate ingredient selection and processing. The sieving to 80# mesh and airtight amber-glass storage ensured uniformity and stability, crucial for maintaining efficacy over time.

The physicochemical parameters fell well within the limits prescribed by the *Ayurvedic Pharmacopoeia of India*. The low moisture content (6.10%) ensures resistance to microbial contamination and fungal growth, which was confirmed by the microbiological tests. The total ash and acid-insoluble ash values confirmed low levels of inorganic matter and impurities, supporting the high quality of raw materials used. Both water-soluble and alcohol-soluble extractive values, crucial for assessing the potential bioavailability of water- and alcohol-soluble phytoconstituents, were favorable, suggesting optimal extraction of active principles in a clinical setting.

The microbial safety profile was well within permissible limits, with absence of *E. coli*, *Salmonella*, and *Staphylococcus aureus*, affirming good manufacturing practice and hygiene. The heavy metal analysis is of particular relevance given growing regulatory scrutiny. The detected values for lead, arsenic, mercury, and cadmium were significantly below WHO limits, indicating the suitability of the formulation for long-term human consumption.

HPTLC fingerprinting confirmed the chemical integrity of the formulation and the presence of marker compounds such as gingerol and piperine. The reproducibility of peaks under UV conditions enhances the scope for future batch-to-batch consistency assessment, which is essential for any attempt at commercial or pharmacological expansion of Anubhuta Yogas. This chemical profiling also enables quality control and identification of adulterants, thus safeguarding therapeutic value.

The accelerated stability study, although limited to 90 days, provided important insights into the shelf life. The absence of organoleptic, microbial, or chemical degradation under stress conditions points toward a reasonably long shelf life, estimated between 18 to 24 months. While this needs confirmation through real-time studies, the findings are encouraging for formulation storage and distribution planning.

The small-scale preliminary clinical observation yielded promising results. The majority of the patients experienced symptomatic improvement in appetite, bloating, and bowel regularity within seven days. While the sample size is too small for statistical generalization, the alignment of clinical outcomes with the classical indications strengthens the case for further clinical trials under controlled conditions. The absence of adverse effects also suggests that the formulation is safe and well-tolerated over short-term use.

When viewed through the lens of *Yukti* (rational integration), this formulation represents a classical synergy. The combination of pungent, bitter, and astringent tastes with *Laghu*, *Ruksha* and *Ushna* or *Sheeta Virya* properties enhances its action on *Ama pachana*, *Agni deepana*, and *Tridosha shaman*. These attributes align with the Ayurvedic pathophysiology of *Agnimandya*, where *Mandagni*, *Ama sanchaya*, and *Kapha-Vata vitiation* dominate. The selection of *Churna Kalpana* as the dosage form provides faster disintegration and absorption, ensuring quick onset of action, which is essential in gastrointestinal disturbances.

Overall, the standardization and evaluation of this Anubhuta Yoga illustrate that with adherence to *Bhaishajya Kalpana Siddhanta* and integration of scientific protocols, traditional empirically used formulations can be brought under formal research frameworks. This not only preserves traditional clinical wisdom but also meets contemporary quality, safety, and efficacy standards demanded by academic and regulatory institutions.

This work also underscores the need for similar studies on other undocumented yet clinically proven Anubhuta Yogas. A large part of Ayurvedic therapeutic diversity remains in the realm of practitioner wisdom; without scientific validation and documentation, such knowledge risks being lost. The present study offers a replicable model for such endeavors, contributing to the modernization of Ayurveda without compromising its philosophical core.

6. Conclusion

The present study successfully undertook the standardization and preliminary evaluation of an *Anubhuta Yoga* comprising *Shunthi*, *Pippali*, *Jeeraka*, and *Bilva*, traditionally used in the management of *Agnimandya* and *Ama*-related disorders. Employing the principles of *Bhaishajya Kalpana Siddhanta* and integrating modern scientific evaluation methods, the formulation was validated across pharmacognostic, physicochemical, microbial, and therapeutic parameters.

The findings reaffirm the classical understanding that the synergistic combination of *Deepana*, *Pachana*, and *Grahi* herbs effectively restores *Agni* and aids in the elimination of *Ama*. Standardization results demonstrated acceptable moisture content, pH, ash values, and extractive profiles, while microbial and heavy metal analyses confirmed the safety of the formulation. HPTLC profiling further validated chemical consistency, while accelerated stability data indicated a favorable shelf-life projection. Preliminary clinical observation showed symptomatic improvement in appetite, digestion, and bowel regularity, suggesting the formulation's therapeutic promise.

These results underscore the potential of traditional *Anubhuta Yogas* to be systematized and integrated into

formal Ayurvedic pharmaceutics, provided they are subjected to proper documentation, standardization, and quality control. The approach adopted here bridges the empirical foundations of traditional medicine with the rigor of modern scientific validation, offering a replicable framework for future studies.

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