The Academic
International Journal of Multidisciplinary Research

An Online Peer Reviewed / Refereed Journal
Volume 3 | Issue 12 | December 2025
ISSN: 2583-973X (Online)
Website: www.theacademic.in

Standardisation of Panchakarma A Review: Initiatives and Developments Advancing Ayurveda through Uniform Practices

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DOI : https://doi.org/10.5281/zenodo.18218989

ARTICLE DETAILS

Research Paper

Accepted: 19-12-2025

Published: 10-01-2026

Keywords:

Standardisation, Panchakarma, Pharmacovigilance, Ayurveda, Evidence-based practice

ABSTRACT

Panchakarma, a cornerstone of Ayurveda, comprises five principal therapies—Vamana, Virechana, Basti, Nasya, and Raktamokshana—aimed at detoxification and restoration of doshic balance. Contemporary practice, however, shows wide procedural diversity, subjective dosing, and regional variations, leading to inconsistent outcomes and occasional complications. These challenges highlight the need for systematic standardisation and pharmacovigilance. This paper synthesises initiatives and research contributions toward standardising Panchakarma procedures, equipment, dosage forms, and efficacy assessment tools, while integrating pharmacovigilance frameworks to enhance patient safety and credibility. A narrative review of government initiatives, classical references, and recent clinical studies was undertaken. Domains included Standard Operating Procedures (SOPs), equipment regulation, dose quantification, and psychometric validation. Pharmacovigilance strategies were analysed with reference to national programmes and institutional frameworks. Validated SOPs reduce procedural variability, equipment standardisation improves safety, and dose quantification bridges classical measures with modern reproducibility. Psychometric tools enable objective efficacy

assessment, while pharmacovigilance systems support early detection of adverse events and rational medicament use. Together, these measures strengthen patient safety, academic rigor, and policy acceptance. Standardisation and pharmacovigilance position Panchakarma as a credible, evidence-based modality. Governmental initiatives and collaborative research provide a framework for harmonising classical wisdom with modern science, paving the way for global integration.

Introduction

Panchakarma, derived from classical Ayurvedic texts, represents five principal therapeutic procedures—Vamana (emesis), Virechana (purgation), Basti (medicated enema), Nasya (nasal therapy), and Raktamokshana (bloodletting). These therapies aim at detoxification, rejuvenation, and restoration of doshic balance. Historically, Panchakarma has been revered for its holistic healing, disease prevention, and wellness promotion.

However, the contemporary practice of Panchakarma faces challenges. Regional variations in procedures, subjective dosing, and lack of uniformity in training have led to inconsistencies in outcomes. Clinical validation is often hindered by the absence of reproducible protocols, while deviations from classical guidelines and modern biomedical standards have occasionally resulted in complications such as diarrhoea, rectal prolapse, skin rashes, etc (Ajanal,2015). These realities underscore the urgent need for standardisation and pharmacovigilance to safeguard tradition while ensuring scientific rigor.

The Need for Standardisation

The diversity of Panchakarma practices across India and globally has created significant variability in therapeutic outcomes. For instance, a review paper even suggested that each and every step of Panchakarma and related upakramas should be standardised to get consistent therapeutic outcomes (Bang,2024). Pilot trials, multi-centric validation, and reproducible Standard Operating Procedures (SOPs) were adopted to a limited extend to ensure consistency. Without standardisation, the evidence base remains fragmented, limiting the credibility of Panchakarma in international healthcare discourse.

Standardisation ensures that procedures are executed in alignment with both classical Ayurvedic texts and modern biomedical safety standards. It involves the creation of validated SOPs, uniform training

modules, and quality assurance mechanisms for medicament preparation. Such harmonisation not only reduces risks but also enhances reproducibility, thereby enabling systematic reviews and meta-analyses that strengthen the scientific foundation of Panchakarma.

Government Initiatives

The Government of India has recognized the importance of standardisation in Ayurveda and has taken proactive steps to institutionalize it. The Bureau of Indian Standards (BIS) has established a dedicated department for AYUSH standardisation, reflecting a policy-level commitment to harmonising traditional practices with international benchmarks (Press Information Bureau, 2024). Seven sectional committees have been formed to address Ayurveda, Yoga, Unani, Siddha, Homeopathy, and Panchakarma, with a focus on developing guidelines for procedures, equipment, and training.

Collaboration with the Ministry of AYUSH and research institutions has further strengthened these efforts. The Central Council for Research in Ayurvedic Sciences (CCRAS) has initiated multi-centric trials and validation studies, ensuring that Panchakarma protocols are scientifically tested and globally credible. These initiatives represent a structural framework that integrates classical wisdom with modern governance, paving the way for international acceptance of Ayurveda.

Research Contributions

Clinical studies and literature reviews have consistently emphasized the significance of standardisation in Panchakarma. The paper (Kadam,2023) emphasizes the need for standardization in Panchakarma therapy to ensure safety, efficacy, and uniformity across clinical practice. It outlines protocols for Purva Karma, Pradhan Karma, and Pashchat Karma, stressing dose fixation, procedural uniformity, and clinical trials as essential steps.

Critical reviews have identified gaps in procedural validation and pharmacovigilance. Devi (2017) underscored the need for systematic research to address these gaps, pointing out that without rigorous validation, Panchakarma risks being marginalized in evidence-based healthcare systems. Together, these contributions demonstrate that research is not only validating the efficacy of Panchakarma but also shaping its future trajectory toward global integration.

Article on standardisation of procedures (Patel J,2017) even highlighted the ways on which we have to proceed for standardisation like protocol design, dosage fixation and procedural uniformity.

Pharmacovigilance Imperative

Pharmacovigilance, traditionally associated with modern medicine, is equally critical in Ayurveda due to its complex formulations and individualized dosing. The integration of pharmacovigilance into Panchakarma practice ensures early detection of risks, rational use of medicaments, and evidence-based refinement of protocols.

Monitoring adverse drug reactions and therapy-related complications is essential, particularly given the individualized nature of Ayurvedic dosing. Establishing structured reporting mechanisms allows practitioners to document complications systematically, creating a feedback loop that informs continuous refinement of therapeutic protocols. The Ministry of AYUSH has initiated a central sector scheme to promote pharmacovigilance of Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) drugs, with the All India Institute of Ayurveda designated as the National Pharmacovigilance Centre (All India Institute of Ayurveda,2025). This program emphasizes documenting adverse drug reactions and monitoring misleading advertisements, thereby strengthening the safety and credibility of traditional medicine practices in public health. By embedding pharmacovigilance within Panchakarma also, Ayurveda aligns itself with global healthcare standards, thereby strengthening patient safety and credibility.

Approaches to standardisation

The approach to standardisation involves the development of uniform dosage schedules, procedural protocols, and validated SOPs for medicament preparation and therapeutic environments. Collaboration with the AYUSH Ministry, CCRAS, and academic institutions enhances credibility, while pilot trials and multi-centric validation studies ensure reproducibility.

The pharmacovigilance framework integrates surveillance systems for monitoring adverse drug reactions and therapy-related complications. Reporting mechanisms are established to capture individualized dosing and complex formulations, while continuous monitoring and feedback loops enable evidence-based refinement of protocols. Together, these methods create a dual framework that harmonises practice and safeguards patient safety.

Standardisation of Procedures

Importance of Procedural Uniformity

Procedural diversity has historically been one of the greatest challenges in Panchakarma. Regional traditions, institutional practices, and individual physician preferences have led to significant variability in therapeutic outcomes. For example, The paper *Good Panchakarma Pharmacovigilance Guidelines (PPV) in Ayurveda w.s.r. to Shiroroga in Ancient Ayurveda* by Shantalapriyadarsini (2019) highlights the importance of pharmacovigilance in Panchakarma procedures, especially in conditions like *Shiroroga*. It demonstrates that adverse effects often arise when rules, regulations, and procedural guidelines are neglected.The text meticulously documents taboos, adverse reactions, and remedial measures during Panchakarma, showing how deviations from prescribed conduct (e.g., speaking loudly, traveling, wrong diet) can lead to serious complications. It emphasizes that ancient treatises already contained SOP-like frameworks—clear inclusion/exclusion criteria, dose fixation, seasonal indications, and remedial measures for adverse reactions. By analyzing these guidelines, the paper underscores that modern Panchakarma practice must adopt SOPs to prevent iatrogenic harm, ensure reproducibility, and maintain patient safety. Thus, this paper serves as a strong example of how SOPs are indispensable in procedural execution, bridging classical wisdom with contemporary pharmacovigilance standards. Without uniformity and strict monitoring, evidence-based validation remains fragmented.

Development of Standard Operating Procedures (SOPs)

The Central Council for Research in Ayurvedic Sciences (CCRAS) and the Ministry of AYUSH have initiated multi-centric trials to create reproducible SOPs for Panchakarma therapies. These SOPs detail patient preparation, therapeutic environments, medicament administration, and post-procedure care.

Research Contributions

Patil et al. (2017) emphasized the clinical significance of standardisation, noting that uniform protocols enhance safety and reproducibility. Devi (2017) provided a critical review of the scope of research in standardisation, identifying gaps in procedural validation. More recently, Kadam R et.al (2023) outlined procedural requirements and the importance of standardisation in Panchakarma therapy, underscoring the need for globally accepted guidelines.

Standardisation of Equipment

The equipment used in Panchakarma procedures—such as Basti yantras, therapeutic tables, and specialized instruments for Vamana or Virechana—has traditionally been region-specific and often lacks regulatory oversight. The absence of uniform standards for medical devices compromises both safety and reproducibility.

Naik et al.,2025 emphasizes that the standardization of Ayurveda medical devices, including Panchakarma equipment, is crucial for ensuring safety, reproducibility, and credibility in clinical practice. By harmonizing design, material quality, and procedural use of instruments, the study highlights how variability in therapeutic outcomes can be minimized. It also underscores the role of standardized devices in facilitating clinical trials, regulatory acceptance, and integration of Ayurveda into modern healthcare systems. Ultimately, the work provides a new perspective on how equipment standardization strengthens both patient safety and global recognition of Panchakarma therapies (Naik, 2025). By regulating equipment through BIS and AYUSH committees, Panchakarma can align with international medical device standards, enhancing credibility and patient safety.

Standardisation of Dosage Forms and Dose of Medicines

Ayurveda's individualized dosing, while therapeutically nuanced, poses challenges for reproducibility and pharmacovigilance. Variability in medicament preparation and administration has led to complications and inconsistent outcomes.

One important aspect is the Bindu dosage unit used in Nasya therapy. In this context, *Bindu* refers to the unit of *taila* (medicated oil) instilled into the nasal passages.

This study underscores the critical need for standardization of doses and dosage forms in Panchakarma administration, particularly Nasya. It demonstrates that the routinely practiced drop method delivers a dose nearly ten times lower than the classical Bindu measurement, leading to suboptimal therapeutic effects. By establishing that one Bindu equals approximately 0.5 ml (10 drops), the paper bridges classical references with modern quantification. Such standardization ensures accuracy, safety, and reproducibility in Panchakarma procedures, preventing Ayoga (under-dosage) and optimizing patient outcomes. Research has emphasized the need to define therapeutic ranges and harmonise medicament preparation to ensure reproducibility (Chippa, 2016). The paper by Bhusal et al. (2022) focuses on the standardization of Antarnakhamusti Pramana for Madanphala Pippali and its Churna, a classical dose measure used in Vamana Karma. Through a study involving 190 volunteers, the authors evaluated purified (Sodhita), raw (Asodhita), and powdered forms, finding average weights of 8.71 g, 9.25 g, and 6.32 g respectively. The research highlights the variability in traditional practice and emphasizes the need for uniform dose determination to ensure safety and efficacy in Panchakarma procedures. This work strengthens the scientific basis of Ayurveda by aligning classical measures with modern quantification methods.

Standardisation of dosage forms therefore involves harmonising medicament preparation, ensuring quality control, and defining therapeutic ranges. These studies emphasized the importance of rational dosing and pharmacovigilance in Ayurveda, particularly in complex formulations. Together, these contributions underscore the need for dosage standardisation to achieve both safety and scientific rigor.

Standardisation of Tools and Parameters to Measure Efficacy

Limitations of Subjective Assessment

The efficacy of Panchakarma therapies has often been assessed subjectively, limiting their acceptance in evidence-based medicine. Without validated tools, outcomes remain anecdotal and lack scientific credibility.

Development of Validated Tools

Recent advances in psychometric validation have led to the creation of tools for assessing Samyak Snigdha Lakshana, a key parameter in Panchakarma therapies. The paper by Kadambari et al. (2023) focuses on the development and validation of a psychometric tool to assess *Samyak Snigdha Lakshana* during Snehapana, a preparatory step in Panchakarma. By systematically applying face, content, and construct validation, the authors identified six key lakshanas—*Vatanulomana, Agni dipti, Snigdha varcha, Asamhata varcha, Anga snigdhata,* and *Klama*—as decisive indicators of proper oleation. The tool was tested on 60 subjects and further clinically assessed in 20 volunteers, showing strong reliability with Cronbach's alpha above 0.8. This work demonstrates how psychometric principles can be integrated into Ayurveda to create standardized, evidence-based assessment instruments, ensuring reproducibility and clinical accuracy in Panchakarma practice. Such instruments, grounded in classical principles and modern psychometrics, enable objective measurement of therapeutic outcomes.

Research Contributions

The development and validation of psychometric tools represent a significant step toward evidence-based Ayurveda. By standardising efficacy parameters, Panchakarma can achieve reproducibility, facilitate clinical trials, and enhance global recognition. This aligns with international healthcare standards, positioning Panchakarma as a credible therapeutic modality.

Key Insights

The implementation of standardisation and pharmacovigilance has led to harmonisation of practices across institutions, improved procedural safety, and reduced variability in outcomes. Alignment with national and international standards has enhanced credibility, while early detection of risks and rational medicament use have strengthened patient safety. These outcomes demonstrate that the integration of standardisation and pharmacovigilance is not merely theoretical but has tangible benefits for clinical practice and global recognition.

Discussion

The dual emphasis on standardisation and pharmacovigilance elevates Panchakarma into a globally recognized, safe, and scientifically validated therapy. Standardisation ensures reproducibility, enabling robust clinical trials and systematic reviews, while pharmacovigilance safeguards patient safety by detecting complications and rationalizing medicament use.

At the academic level, these frameworks foster rigor and credibility, while at the clinical level, they enhance governance and patient trust. Policy-level initiatives, such as those undertaken by BIS and AYUSH, provide structural support for these efforts, ensuring that Panchakarma is integrated into international healthcare systems. Collaborative efforts in designing validated tools, SOPs, and monitoring systems bridge classical wisdom with modern science, creating a holistic framework for global acceptance.

Scope of Development

The scope for development in Panchakarma is vast. Standardisation enhances credibility, facilitating integration into international healthcare systems. Expansion of clinical trials and evidence-based research strengthens scientific validation, while the wellness industry and Ayurveda tourism stand to benefit from globally recognized practices. Integration with modern healthcare systems through collaborative frameworks enables cross-disciplinary acceptance, positioning Panchakarma as a credible and evidence-based therapeutic modality.

Conclusion

Standardisation and pharmacovigilance are imperative for advancing Panchakarma. Together, they ensure credibility, safety, and global recognition. Government initiatives, research contributions, and collaborative frameworks pave the way for evidence-based Ayurveda with international acceptance. By

bridging classical wisdom with modern science, Panchakarma can evolve into a globally recognized therapeutic system that embodies both tradition and innovation.

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