

## CRITICAL APPRAISAL OF AYURVEDIC PHARMACOPOEIAL STANDARDS IN THE LIGHT OF CLASSICAL BHAISHAJYA

KALPANA

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### ABSTRACT

**Background:** Bhaishajya Kalpana constitutes the pharmaceutical foundation of Ayurveda, wherein the quality and efficacy of formulations are governed by meticulous processing methods, dosage-form specificity, and classical quality indicators such as Samskara and Paka Lakshana.<sup>[1,5]</sup> The Ayurvedic Pharmacopoeia of India (API) was developed to ensure quality control and uniformity of Ayurvedic drugs; however, its emphasis predominantly lies on analytical end-product parameters.<sup>[6]</sup> **Objective:** To critically evaluate the gaps in the Ayurvedic Pharmacopoeia of India with reference to classical Bhaishajya Kalpana principles. **Materials and Methods:** A comprehensive literary review was conducted using classical Ayurvedic texts including Charaka Samhita, Sushruta Samhita, Ashtanga Hridaya, and Sharangadhara

Samhita. These principles were compared with standards prescribed in various volumes of the Ayurvedic Pharmacopoeia of India to identify conceptual and pharmaceutical discrepancies. **Results:** The analysis revealed inadequate representation of process-based parameters, limited dosage- form-specific standards, insufficient emphasis on organoleptic assessment, and weak correlation between classical processing methods and stability criteria in API monographs. **Conclusion:** Although the API has significantly contributed to the analytical standardization of Ayurvedic medicines, the exclusion of classical pharmaceutical principles may affect reproducibility and therapeutic consistency. Incorporation of process-oriented standards rooted in Bhaishajya Kalpana is essential for strengthening Ayurvedic pharmacopoeial practices.

**KEYWORDS:** Bhaishajya Kalpana, Ayurvedic Pharmacopoeia of India, Samskara, Standardization, Ayurvedic pharmaceuticals.

## **INTRODUCTION**

Ayurveda accords equal importance to the drug, disease, and pharmaceutical process, recognizing that the method of preparation significantly influences therapeutic efficacy. Bhaishajya Kalpana elaborates systematic principles related to drug collection, processing, formulation, storage, and administration. Classical texts emphasize parameters such as Desha, Kala, Samskara, and Paka Lakshana, which collectively ensure pharmaceutical quality and therapeutic reliability.<sup>[1]</sup>

The Ayurvedic Pharmacopoeia of India was formulated with the objective of establishing quality standards and promoting global acceptance of Ayurvedic medicines. While the API has strengthened analytical quality control, it largely reflects a product-centric approach. This paradigm differs from the classical process-centric approach advocated in Bhaishajya Kalpana. The present review critically examines this divergence and highlights pharmacopeial gaps when viewed through the lens of classical Ayurvedic pharmaceuticals.

## **MATERIALS AND METHODS**

The present study is a narrative review based on literary analysis.

### **Sources of Data**

Classical Ayurvedic texts.

Charaka Samhita, Sushruta Samhita, Ashtanga Hridaya, Sharangadhara Samhita.

### **Standard reference works**

Ayurvedic Pharmacopoeia of India (Part I and II) Ayurvedic Formulary of India.

Relevant published research articles on Ayurvedic standardization.

### **Method of Analysis**

Classical pharmaceutical principles were systematically compared with pharmacopeial standards to identify gaps related to process validation, dosage-form specificity, organoleptic assessment, and stability considerations.

### **Concept of Standardization in Classical Bhaishajya Kalpana**

Classical Ayurveda conceptualizes standardization as a holistic and dynamic process rather

than a static end-product evaluation. Emphasis is placed on Dravya Pariksha for assessing raw material quality, followed by appropriate Samskara to enhance therapeutic attributes and minimize toxicity. The attainment of desired pharmaceutical endpoints is confirmed through Paka Lakshana, which vary according to dosage forms.<sup>[1,4,5]</sup>

Sensory parameters such as Gandha, Varna, Rasa, and Sparsha are integral to quality assessment and are considered reflective of proper processing. These parameters ensure batch-to-batch consistency and serve as practical tools for pharmaceutical validation.<sup>[2,5]</sup>

### **Overview of Ayurvedic Pharmacopoeia of India**

The API prescribes standards primarily based on macroscopic and microscopic evaluation, physicochemical parameters, chromatographic profiling, and, where applicable, assay of active constituents. This approach has enhanced analytical rigor and regulatory compliance. However, the pharmacopeial framework largely evaluates the finished product, with limited consideration of classical manufacturing variables.<sup>[6,7]</sup>

### **Identified Pharmacopeial Gaps**

#### **Absence of Process-Based Parameters**

Classical pharmaceutical processes such as Sneha Paka, Avaleha Siddhi, and Sandhana are not adequately standardized in API monographs. The lack of process markers may lead to inter-batch variability despite analytical conformity.<sup>[4,5]</sup>

#### **Inadequate Dosage-Form-Specific Standards**

Distinct dosage forms in Ayurveda possess unique pharmaceutical characteristics. Uniform analytical parameters across diverse formulations may fail to capture dosage-form-specific quality attributes described in classical texts.

#### **Limited Emphasis on Organoleptic Evaluation**

Although organoleptic characteristics are mentioned in the API, their pharmaceutical relevance as described in classical literature is not fully utilized for quality assessment.<sup>[1,6]</sup>

#### **Weak Correlation with Stability and Shelf-Life**

Shelf-life determination in the API lacks explicit correlation with classical concepts such as Samskara and excipient behavior, particularly in hygroscopic formulations like Avaleha.<sup>[6,9]</sup>

## DISCUSSION

The present review critically examines the Ayurvedic Pharmacopoeia of India (API) through the conceptual framework of classical Bhaishajya Kalpana, highlighting a fundamental divergence between analytical standardization and process-oriented pharmaceutical validation. Classical Ayurvedic pharmaceutics emphasizes that drug quality, safety, and efficacy are inseparably linked to pharmaceutical procedures such as Dravya Shodhana, Samskara, Bhavana, Paka, and Sandhana. These processes are therapeutic determinants rather than auxiliary steps.<sup>[1,2,4]</sup>

Classical texts describe pharmaceutical endpoints through Lakshana, including Sneha Siddhi Lakshana, Avaleha Paka Lakshana, and Sandhana Lakshana, which ensure batch-to-batch reproducibility and therapeutic consistency. The absence of these indicators in API monographs reflects a conceptual shift toward end-product evaluation, potentially compromising pharmaceutical integrity.<sup>[4,5]</sup>

The API's reliance on physicochemical and chromatographic parameters, while essential for regulatory compliance, does not fully capture the pharmaceutical transformations emphasized in Ayurveda. Dosage-form-specific characteristics, organoleptic evaluation, and classical stability concepts remain underutilized.<sup>[6,8]</sup>

## CONCLUSION

The Ayurvedic Pharmacopoeia of India represents a milestone in analytical standardization; however, it requires conceptual enrichment through the integration of classical Bhaishajya Kalpana principles. Incorporation of process-based parameters, dosage-form-specific Lakshana, and organoleptic validation alongside modern analytical tools is essential for true standardization. Such harmonization will preserve the pharmaceutical identity, therapeutic reliability, and scientific credibility of Ayurvedic formulations.<sup>[1,6]</sup>

## Future Perspectives

Development of process-based pharmacopeial appendices  
Inclusion of classical pharmaceutical endpoints in API revisions.

Collaborative involvement of Bhaishajya Kalpana experts in regulatory frameworks.

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