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# "MONOGRAPHS OF THE AYURVEDIC PHARMACOPOEIA OF INDIA FOR COMPOUND FORMULATIONS: A CRITICAL REVIEW OF GAPS IN QUALITY STANDARDS"

**Dr. Jalpa Gandhi**[1]

**AFFILIATIONS:**
1. CEO, IRA Consultancy and Research Organisation, Bhosari MIDC, Pune, Maharashtra, India

**CORRESPONDENCE:**
Dr. Jalpa Gandhi
**EMAILID:**
ceo@icro.co.in

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**ABSTRACT**

**Background:** The Ayurvedic Pharmacopoeia of India (API) is the legal book of standards for Ayurvedic drugs. Part I covers single drugs, and Part II covers selected compound formulations from classical texts. Most Ayurvedic medicines in commerce are compound formulations, yet their quality standards are less developed than those for single drugs. **Objective:** To review the structure of API standards, and to identify gaps in standards for compound formulations, using published evidence on product quality. **Methods:** A critical narrative review of literature on the development of the API, quality surveys and standardisation studies of compound formulations, and international guidance on herbal quality control. **Results:** Part I of the API comprises nine volumes with about 645 monographs on single drugs. For compound formulations, monographs typically specify composition, method of preparation, description, identity by thin-layer chromatography and general physicochemical parameters, but quantitative assays of active markers, dissolution and stability requirements are generally lacking. Evidence from the literature shows the consequences: commercial products of the same formulation differ in marker profiles and in metal content (gold 32–98 wt% in five *Suvarna bhasma* products), preservatives are sometimes present at high levels, heavy metals are frequently detected in over-the-counter products, and calculated shelf lives often fall short of regulatory norms. **Conclusion:** Compound formulation monographs should progressively include quantitative marker assays, fingerprint acceptance criteria, product-specific limits for metals and contaminants, dissolution or disintegration tests where relevant, and stability-linked specifications.

**KEYWORDS:** Ayurvedic Pharmacopoeia of India; Monographs; Compound formulations; Quality standards; Marker compounds; Heavy metals; Regulation

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## INTRODUCTION

A pharmacopoeia defines the identity, purity and strength that a medicine must meet to be sold legally. The Ayurvedic Pharmacopoeia of India, developed under the Drugs and Cosmetics Act, is the official compendium for Ayurvedic drugs. It has two parts: Part I contains monographs on single substances of natural origin, and Part II contains monographs on selected compound formulations drawn from classical texts and the Ayurvedic Formulary of India[1].

Part I has developed into nine volumes with about 645 monographs covering plant, mineral and processed single drugs, including powders and extracts in the later volumes[2,3]. In practice, however, most Ayurvedic medicines sold are multi-ingredient formulations, ranging from simple *churna* to complex *rasa* preparations. The quality of these products depends on the quality of each ingredient, the fidelity of the process and the composition of the finished product. This review examines how well current monographs address these dimensions and where gaps remain.

## METHODS OF THE REVIEW

This is a critical narrative review. Literature on the development and content of the API, quality surveys of commercial Ayurvedic formulations, standardisation studies and international guidance on herbal quality control was identified through PubMed, PubMed Central, DOAJ, Crossref-indexed records and journal archives. Findings were organised according to the elements of a typical pharmacopoeial monograph.

## STRUCTURE OF FORMULATION MONOGRAPHS

A typical API monograph for a compound formulation includes:

- **Definition and formulation composition:** the ingredients, plant parts and proportions, with reference to the classical source.
- **Method of preparation:** a brief description of the classical process.
- **Description:** colour, odour, taste and texture.
- **Identification:** microscopic features of herbal ingredients and thin-layer chromatographic profiles.
- **Physicochemical parameters:** loss on drying, ash values, extractive values, pH and, depending on the dosage form, parameters such as hardness or disintegration time.
- **Other requirements:** general limits for contaminants, storage conditions, therapeutic uses and dose.

This structure establishes identity and broad consistency. It is less effective at ensuring that a product contains a defined amount of its active constituents, that each batch is equivalent to the previous one, or that the product remains within specification throughout its shelf life.

## GAPS IDENTIFIED IN THE LITERATURE

**Table 1. Gaps in compound formulation standards and evidence of their consequences**

| Gap | Consequence reported in the literature |
|---|---|
| Few quantitative marker assays | Marker profiles differ between freshly prepared and commercial *kashaya*; protocols with HPTLC and HPLC have had to be developed by researchers |
| No content assay for metals in *bhasmas* | Gold content of five *Suvarna bhasma* products ranged from 32 to 98 wt%; one contained 5.4 wt% arsenic |
| General rather than product-specific contaminant limits | Heavy metals detected in all 42 over-the-counter products tested in one survey; metals detected in about one in five products sold online |
| No limits for preservatives and undeclared sugar | Preservative levels varied among commercial *Sahacharadi kwatha* brands; very high sodium benzoate and undeclared sugar reported |
| Shelf life not linked to stability data | Calculated shelf lives were shorter than regulatory norms in 54.7% of studies; most studies were single-batch and accelerated |
| Dosage-form tests not always defined | Tablets from classical formulations show variable friability and disintegration |

**1. Quantitative assay of actives**

For single drugs, monographs increasingly specify assays of marker constituents. For compound formulations, identification by thin-layer chromatography is common, but quantitative assays are much less so. Researchers have had to develop their own HPTLC and HPLC methods to standardise formulations such as *Nayopayam kwatha* and *Pathyashadangam kwatha*[5,6]. Without assay limits, products can pass identity tests while containing very different amounts of key constituents, as shown by differences between fresh and commercial *Cirivilvadi kashaya*[4].

**2. Mineral and metal content**

For *bhasmas* and *rasa* preparations, the most important quality attribute is the content and chemical form of the metal. A comparison of five commercial *Suvarna bhasma* products found gold contents from 32 to 98 wt% and arsenic in one product[7]. Monographs that do not specify the assay range of the principal metal, its phase identity and limits for unintended metals cannot detect such variation.

**3. Contaminants and additives**

Contaminant limits for heavy metals, microbial load, aflatoxins and pesticide residues are often set generally rather than by product. Surveys have found heavy metals in all 42 over-the-counter products in one study[8] and in about one in five products sold online[9]. For liquid formulations, preservatives and sugar are added in manufacturing; a comparison of commercial *Sahacharadi kwatha* brands found variable preservative levels[10], and a review highlighted very high sodium benzoate in such products and undeclared sugar in a *Dashamoola kwatha* sample[11]. Monographs should set limits for these additives and require them to be declared.

**4. Stability**

Shelf life is set by regulation for dosage form categories, but monographs rarely include stability-indicating parameters. A systematic appraisal of stability studies found that calculated shelf lives were frequently shorter than the regulatory norm[12]. Linking monograph specifications to stability testing following recognised principles[15] would make expiry dates meaningful.

**5. Dosage-form performance**

For tablets and pills, tests such as hardness, friability, disintegration and, where possible, dissolution ensure that the product releases its contents. Studies of tablets from classical formulations report variable results[13,14]. Dosage-form-specific tests should be included in monographs with appropriate limits.

**INTERNATIONAL CONTEXT**

International guidance for herbal medicines emphasises identity, purity and content, supported by validated methods for contaminants[16]. Comparisons of Ayurvedic and Chinese botanical drugs show both shared challenges and opportunities to harmonise standards[17]. Monographs that meet such expectations are also important for the acceptance of Ayurvedic products in international markets.

**RECOMMENDATIONS**

**Table 2. Proposed additions to API monographs for compound formulations**

| Element | Proposal |
|---|---|
| Marker assays | Quantitative assay of at least one marker for each major ingredient group, with acceptance ranges |
| Fingerprints | HPTLC or HPLC fingerprints with defined acceptance criteria against a reference standard |
| Metal content | Assay of principal metal and phase identity for *bhasma* and *rasa* preparations |
| Contaminants | Product-specific limits for unintended heavy metals, microbial load, aflatoxins and pesticides |
| Additives | Limits and declaration requirements for preservatives, sugar and other excipients |
| Dosage-form tests | Disintegration or dissolution for tablets and capsules; viscosity and microbial limits for liquids |
| Stability | Stability-indicating parameters to support shelf life |
| Reference standards | Development of reference standards for markers and of reference formulations |

## RESEARCH GAPS

Systematic surveys comparing marketed products with existing monographs are needed, along with development of reference standards, validated methods suitable for routine laboratories, and inter-laboratory studies to set realistic acceptance ranges.

## CONCLUSION

The API provides an essential legal framework, and its single-drug monographs are well developed. Monographs for compound formulations, which make up most of the market, rely largely on identity and general physicochemical tests. Evidence of variability in marker content, metal content, contaminants, additives and stability shows the consequences of these gaps. Progressive addition of quantitative, product-specific specifications would strengthen quality assurance and support wider acceptance of Ayurvedic medicines.

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