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ii. Āyurvedic Formulary of India (AFI) - Introduction, development and importance

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The **Āyurvedic Formulary of India (AFI)** is the **official compilation** of **Ayurvedic compound formulations** recognized by India's Ministry of AYUSH. Published under the auspices of the **Ayurvedic Pharmacopoeia Committee (APC)**, it provides **standardized recipes** and **manufacturing guidelines** for multi-herb (and multi-mineral) preparations detailed in classical Ayurvedic texts. Below is a **doctoral-level** exposition of the AFI's **history, structure, volumes, and relevance** to modern Ayurvedic research, industry, and regulation.

Introduction to AFI and the Concept of Formulation

1. Definition of Formulation

- In Ayurveda, a "formulation" (*kalpanā*) is a **multi-drug compound**—“**the use of more than one drug in a medicinal preparation**”—often leveraging synergy among varied ingredients (plant, mineral, animal origin).

2. Context and Need

- Previously, data on **compound formulations** was scattered across multiple classical treatises (*Caraka Saṃhitā, Suśruta Saṃhitā, Bhaiṣajya Ratnāvalī*, etc.).
- The AFI organizes these references in a **systematic**, easy-to-consult format for researchers, manufacturers, regulators, and practitioners.

3. First Official Publication

- **Part I** of the AFI was published in **1976** (English version recognized in **1978**).
- Marked the **APC's** inaugural attempt at compiling classical formulations to aid in **pharmacopoeial standard** development under the **Drugs and Cosmetics Act** (1940).

Development of the AFI

Role of the Ayurvedic Pharmacopoeia Committee (APC)

1. Foundational Efforts

- The APC first compiled the **Ayurvedic Pharmacopoeia of India (API)** (for single drugs) and then expanded to produce **AFI** for compound formulations.
- This synergy ensures both **raw materials** (API monographs) and **final formulations** (AFI) are standardized.

2. Aim and Objectives

- **Consolidate** classical references in a uniform manner, bridging textual synonyms and variant recipe listings.
- Provide a basis for **pharmacopoeial standards** (identity, purity, potency) and to **fulfill** the legal requirements of the **Drug and Cosmetics Act** and **Schedule T (GMP)**.

3. Single Drugs Listing

- An auxiliary step: the **APC** prepared a comprehensive roster of single herbs and minerals (with correct botanical/mineral identification) used in these compound formulations, minimizing confusion over synonyms or adulterants.

Structure and Classification of Formulations

1. Kasthaushadhi vs. Rasaushadhi

- **Kasthaushadhi:** Predominantly **plant-based** preparations (e.g., *āsava, ariṣṭa, avaleha, ghṛta, cūrṇa, taila*).
- **Rasaushadhi:** *Metals and minerals* (e.g., *bhasma, pisti, lauha, mandūra, kupipākva rasāyana*).

2. Volumes

- **Part I** (1976): 444 formulations.
- **Part II** (2000): 192 formulations.
- **Part III** (2011): 350 formulations.
- **Composition:**
 - Parts I & II emphasize **classical** formulations widely manufactured.
 - Part III includes **hospital pharmacy** formulations (in use > 50 years) and lesser-known but clinically relevant recipes.

3. General Format

- **Title:** Name of the formulation (Sanskrit, sometimes cross-referenced with vernacular).
- **Method of Preparation:** Step-by-step instructions (proportions, processing, cooking).
- **Dose:** E.g., 5-10 g or ml, typically referencing classical units converted to metric.
- **Anupāna:** Vehicle or adjuvant (milk, honey, ghee, water).
- **Therapeutic Uses:** Indicated diseases, doṣa imbalances, general conditions.
- **Storage:** Guidelines for container type (glass vs. plastic), shelf-life references.

Overview of AFI Publications and Contents

AFI Part Year Number of Monographs (Compound Formulations)

Part I 1976 444 (predominantly classical, widely used formulations)

Part II 2000 192

Part III 2011 350 (hospital pharmacy formulations in use >50 yrs)

Note: These three parts collectively capture a **majority** of classical formulations, along with their expansions for modern contexts.

Importance and Impact of the AFI

Standardization and Quality Assurance

1. Legal Mandate

- Manufacturers must conform to **AFI** guidelines to claim authenticity and meet **AYUSH licensing**.
- Minimizes risk of inter-manufacturer variability, ensuring safer, reproducible final products.

2. Research and Development

- Pharmaceutical labs or academic centers rely on AFI monographs for standard recipes to test efficacy or synergy.
- Facilitates multicentric clinical trials for widely used formulations (e.g., *Chyawanprash*, *Dantī harītakī*, *Aśvagandhā-Gṛīta*) with uniform compositions.

Preservation of Classical Heritage

1. Consolidation of Classical Recipes

- AFI references root texts (e.g., *Bhaiṣajya Ratnāvalī*, *Śārṅgadhara Saṃhitā*, *Caraka*, *Suśruta*) harmonizing variant readings or synonyms.
- Ensures the textual continuum is not lost or diluted in mass manufacturing settings.

2. Regulatory Consistency

- Regulators, inspectors, and licensing authorities uniformly reference AFI for composition checks, especially in litigation or complaint scenarios.
- Encourages honest labeling (exact ingredients, ratio) and controls unscrupulous adulteration.

Industry Expansion and Global Reach

1. Export Validation

- Many big Ayurvedic houses (Dabur, Himalaya, Charak) rely on AFI for documenting classical formulas in their product portfolios, essential for **export** compliance.
- Lays the foundation for bridging with WHO guidelines on herbal products, enabling mutual recognition or GMP alignment.

2. Innovation

- Hybrid or “proprietary” formulations often partially reference classical compositions from AFI, adapting them with new delivery forms (capsules, syrups).
- Encourages modernization while maintaining classical ethos.

Summation

1. Historical First

- **AFI Part I (1976)** was the earliest consolidated official attempt to unify scattered references on classical **compound** Ayurvedic formulations.

2. Content

- Each monograph indicates **title, ingredients, dosage, anupāna, therapeutic uses, storage** guidelines.

3. Future Prospects

- Ongoing expansions or new volumes may include advanced analytical standards (HPTLC, HPLC) for each compound formula, bridging with the **Ayurvedic Pharmacopoeia of India (API)** single-drug references.
- Potential for e-version or AI-based formula cross-referencing to streamline large-scale R&D and supply chain integrity.

In essence, the **Āyurvedic Formulary of India (AFI)** offers a **structured blueprint for compound formulations**, safeguarding **classical authenticity** and **scientific rigor**—thereby enabling uniform production, consistent clinical efficacy, and global acceptance of **Ayurvedic** medicine.