

Unit 3: Monographs of Herbal Drugs

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3.1 General parameters of monographs of herbal drugs

A monograph is the authoritative written standard for a drug: the set of definitions, tests and limits by which a sample is judged to be that drug and to be of acceptable quality. A herbal drug monograph must do more work than a synthetic drug monograph, because its subject is a natural material of variable composition, and its general parameters form the core list of this unit. Title and definition: the official name, botanical name with family, the part used, and, for extracts, the solvent and drug extract ratio, fixing identity before any test. Description: macroscopic characters, colour, odour, taste, size and fracture, the first screen against substitution. Identification: microscopical characters of the whole and powdered drug, chemical identification reactions, and chromatographic identity, typically a TLC or HPTLC fingerprint against reference material. Purity tests: foreign matter, ash values, extractive values, moisture or loss on drying, and the contaminant limits, heavy metals, pesticide residues, microbial limits and aflatoxins where applicable. Assay: quantitative determination of the active or marker constituents by the stated method, with limits. Then the supporting parameters: standards for storage and labelling, and, in the fuller pharmacopoeial style, the reference standards and reagents the tests require. Two parameters carry special teaching weight. Fingerprint identity is the herbal monograph signature test: a whole chromatographic pattern compared, not a single spot, because the drug is a mixture. And the marker assay raises the question the examiner loves: the marker need not be the active, it is the measurable constituent chosen to represent the batch, and a monograph is honest about which it is using. The parameters are collected in the diagram of Section 3.8.

3.2 The Indian Pharmacopoeia (IP)

The Indian Pharmacopoeia is the official book of drug standards for India, published by the Indian Pharmacopoeia Commission under the Drugs and Cosmetics Act, whose monographs carry legal force for drugs manufactured and sold in India. Its herbal coverage has grown across editions from a small set of crude drug monographs to a substantial body of herbal drug, extract and formulation monographs, written in the IP house style: definition with botanical name and part, description, identification including chromatographic fingerprinting, tests for foreign matter, ash, extractives, loss on drying and contaminants, and assay of marker constituents, supported by general chapters on methods. In comparative answers, IP is the home standard for the Indian industry of Units 1 and 2, the book its licences and courts actually enforce, and its herbal monographs draw on Indian drugs and Indian analytical practice. Its relationship with the Ayurvedic Pharmacopoeia of Section 3.4 is complementary: IP governs herbal drugs in the modern drug framework, while the Ayurvedic Pharmacopoeia governs the classical ASU drugs in theirs.

3.3 The United States Pharmacopoeia (USP)

The United States Pharmacopoeia, published with the National Formulary by the United States Pharmacopeial Convention, sets the enforceable standards for drugs and, importantly for this subject, for dietary supplements in the United States. Its herbal monographs appear largely as botanical dietary supplement monographs, in the USP style of definition, identification by macroscopic, microscopic and chromatographic methods, composition or assay of characteristic constituents, and specific tests including limits for contaminants such as heavy metals, pesticides and microbes, backed by an extensive apparatus

of general chapters and physical reference standards that laboratories can purchase and use. The comparative points are its legal setting, standards enforced through the food and drug law for products on the US market, including supplements; its strong reference standard system; and its detailed general chapters on topics such as heavy metals and pesticide residues in botanicals, which laboratories worldwide borrow even when working to other pharmacopoeias.

3.4 The Ayurvedic Pharmacopoeia of India

The Ayurvedic Pharmacopoeia of India, published by the Government of India for the Ayurvedic system, is the official standard book for Ayurvedic drugs: single drugs of plant, mineral and animal origin in its earlier parts and compound formulations in its later parts, with the Ayurvedic Formulary standing beside it as the book of classical formulations. Its monographs combine the classical identity of the drug, Sanskrit name, synonyms, and the properties assigned in the tradition, with modern laboratory parameters: macroscopic and microscopic description, foreign matter, ash and extractive values, chromatographic identification and, where established, assay, together with standards for the finished classical forms. Its legal territory is the ASU industry licensed under the Drugs and Cosmetics Act, and its GMP partner is Schedule T of Section 2.8. In comparison with IP, its monographs serve a system in which the formulation as a whole, prepared by the classical process, is the medicine, so pharmacopoeial control must standardise both the raw drugs and the classical processes, a harder problem than single drug standardisation and the reason its development is a continuing national programme.

3.5 The Siddha and Unani Pharmacopoeias

The Siddha Pharmacopoeia of India and the Unani Pharmacopoeia of India are the parallel official books for the other two codified Indian systems named in the syllabus, published by the Government of India in parts covering single drugs and formulations of each system. Their monograph pattern follows the Ayurvedic model because their regulatory position is the same: definition in the system own terms with botanical or other origin, classical properties and uses, then the laboratory parameters of identity, purity and strength that a modern inspector can test, macroscopy and microscopy, physicochemical constants, chromatographic identity and contaminant limits as developed. The comparative teaching point is unity inside diversity: three traditional systems, three pharmacopoeias, one regulatory Act, one GMP schedule, and one shared scientific apparatus of testing, because a heavy metal or a wrong species is a defect in any system language. Their coverage is younger and less complete than the Ayurvedic book, and monographs are added part by part as standards are developed and validated, which is itself a live example of the modernisation challenge of Unit 1.

3.6 The American Herbal Pharmacopoeia (AHP)

The American Herbal Pharmacopoeia is a non government, expert authored series of monographs on botanicals, produced in the United States, which is not a legally enforceable pharmacopoeia in the USP sense but a scholarly standard widely used by industry and regulators as a reference. Its monographs are distinctive in depth and structure: nomenclature and botany, cultivation and collection, history of use, identification including detailed microscopy and chromatography, constituents, analytical methods, therapeutics and safety information, and a review of the evidence, presented as a monograph and therapeutic compendium together. In comparative answers its position is the expert reference model: no legal force of its own, high scientific authority, monographs developed herb by herb to a depth the official books, covering many drugs at once, rarely match. It shows students what a monograph becomes when it is allowed to teach as well as to test.

3.7 The British Herbal Pharmacopoeia (BHP)

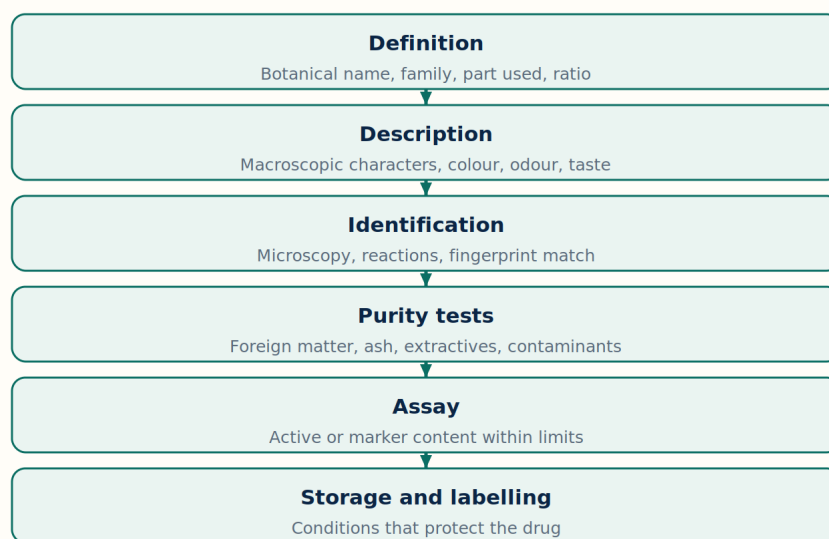
The British Herbal Pharmacopoeia, published by the British Herbal Medicine Association, is the United Kingdom counterpart in the comparison: a herbal profession pharmacopoeia providing monographs for herbal drugs used in British herbal practice, in a concise testing style, definition, macroscopic and microscopic identification, TLC identification, and physicochemical tests such as ash, extractive and moisture values, with assays where suitable. It sits in the British setting in which many herbal products are supplied under traditional herbal registration, whose quality standards refer to pharmacopoeial quality, the European and British Pharmacopoeias carrying the legally enforceable monographs for that market. The comparative point mirrors the American case with a difference: BHP is a practice pharmacopoeia of the herbal profession, valued for its selection and its fit to the drugs herbalists actually use, while legal enforceability in its home market flows through the official pharmacopoeias and the registration system.

3.8 The pharmacopoeias compared

Comparison is the syllabus verb for this unit, so the table collects the seven books on the points an examiner can ask. The diagram after it collects the monograph parameters of Section 3.1.

Pharmacopoeia	Publisher and status	Main territory	Monograph character
Indian Pharmacopoeia (IP)	Indian Pharmacopoeia Commission; official, legally enforceable in India	Herbal drugs, extracts and formulations in the modern drug framework	Definition, description, identification with fingerprinting, purity tests, marker assay
USP	US Pharmacopeial Convention; enforceable in the United States	Drugs and botanical dietary supplements	Identification, composition and assay, contaminant limits, purchasable reference standards, extensive general chapters
Ayurvedic Pharmacopoeia of India	Government of India; official for Ayurvedic drugs	Single Ayurvedic drugs and classical compound formulations	Classical identity and properties with laboratory parameters of identity, purity and strength
Siddha Pharmacopoeia of India	Government of India; official for Siddha drugs	Single Siddha drugs and formulations	Ayurvedic model applied to the Siddha materia medica
Unani Pharmacopoeia of India	Government of India; official for Unani drugs	Single Unani drugs and formulations	Ayurvedic model applied to the Unani materia medica
American Herbal Pharmacopoeia	Expert non profit body; no direct legal force	Botanicals of American herbal practice and trade	Deep scholarly monographs: botany, analysis, therapeutics and safety together
British Herbal Pharmacopoeia	British Herbal Medicine Association; profession pharmacopoeia	Herbal drugs of British herbal practice	Concise testing monographs: identification, TLC, physicochemical tests

Anatomy of a herbal monograph



Identity, purity and assay are the tested core of every monograph

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Figure: The general parameters of a herbal drug monograph. Identity, purity and assay are the tested core; definition, description and storage frame them.

Reading the table as an argument: official pharmacopoeias trade depth for enforceability and coverage, profession and expert books trade enforceability for depth and selection, and the Indian system books carry the extra task of standardising classical formulations and processes. A manufacturer selling in several markets works to several books at once and releases against the strictest applicable limit for each parameter, which is the practical end of the comparative study.

3.9 WHO guidelines in quality assessment of herbal drugs

The World Health Organization guidelines on quality assessment of herbal drugs, part of the WHO programme of guidance on herbal medicines, supply the international reference framework that the pharmacopoeias of this unit implement nationally. Their subject is the whole quality chain, and the guidelines should be presented in that chain order. Identity and quality of the starting material: correct botanical identification, control of cultivation and collection, and attention to the factors, geography, season and processing, that move composition. Quality control parameters for herbal materials and preparations: macroscopic and microscopic examination, foreign matter, ash and extractive values, moisture, chromatographic fingerprinting, assay of actives or markers, and the contaminant battery, heavy metals, pesticide residues, microbial contamination and aflatoxins, with the principle that limits and methods must suit a natural, variable material. Stability and shelf life, assessed by the methods of Unit 4. Good practices in the chain: good agricultural and collection practice at the source and GMP in manufacture, linking this unit back to Unit 2. And assessment in the round: quality cannot be separated from safety and efficacy assessment, so the guidelines sit inside the wider WHO guidance on research and evaluation of traditional medicine. The workflow below states the assessment as an industrial sequence.

WHO quality assessment of herbal drugs



Quality assessment is a chain: every link guarded, no single test decides

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Figure: Quality assessment in the WHO sense is a chain, not a single test: identity, purity, fingerprint and assay, contaminants, stability and good practices each guard one link.

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