

Unit 3: Standards

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3.1 Why standards are law in India

A licence promises that a product is what it claims to be; a **standard** is the public text against which that promise is tested. Indian drug law makes the connection explicit: the Drugs and Cosmetics Act names the standards with which drugs must comply, its **Second Schedule** designates the book whose monographs govern each class of drug, and a product that falls below its designated standard is not of standard quality (section 1.4), whatever its licence says. Three standards families do the work for this syllabus: the **Indian Pharmacopoeia** for medicines themselves, the standards of the **Bureau of Indian Standards (BIS)** for the materials, devices, packaging and finished product categories to which BIS standards apply, and the international system of **ISO** and kindred standards for management systems, device quality, laboratory competence and methods. The regulatory skill is designation: for any product, identify which standard governs which attribute, because a monograph, a BIS standard and an ISO certificate answer different questions and none substitutes for another.

The Three Standards Families: IP, BIS and ISO



A monograph, a BIS standard and an ISO certificate answer different questions

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Figure: The standards families of Unit 3: the Indian Pharmacopoeia governs the medicine, BIS standards govern products and materials, and the ISO family governs systems and competence (Unit 3, section 3.1).

3.2 Indian Pharmacopoeial standards

The **Indian Pharmacopoeia (IP)** is the official book of standards for drugs in India, published by the **Indian Pharmacopoeia Commission (IPC)**, an autonomous body of the Ministry of Health and Family Welfare at Ghaziabad, and designated in the Second Schedule to the Act as the standard for drugs manufactured, sold and distributed in India. Its authority was completed in stages: the first edition appeared in 1955, and the Commission now issues successive editions and addenda in a regular cycle, the current generation being the modern, multi volume editions. A monograph in the IP fixes identity, purity, strength and quality: the definition of the substance or preparation, its identification tests, assay and limits for impurities and related parameters, with general chapters supplying the methods. The IP's standards have statutory force: the government analyst tests against them, the courts read them, and where a drug is not in the IP, the Act looks to other designated pharmacopoeias. The Commission also prepares and supplies **Indian Pharmacopoeia Reference Substances**, the physical standards against which assays are run, and issues

the pharmacopoeias for the ASU systems (the Ayurvedic, Siddha and Unani pharmacopoeias), so that the classical medicines of section 2.7 also have a statutory quality text. Related national compendia round out the picture: the National Formulary of India for prescribing information at the primary care level, and the Homoeopathic Pharmacopoeia for its system. For the student, the examination point is the chain: Act, Second Schedule, IP monograph, analyst's report, NSQ prosecution.

3.3 BIS standards

The **Bureau of Indian Standards**, the national standards body under the Ministry of Consumer Affairs, Food and Public Distribution, writes Indian Standards (IS numbers) across every sector of the economy, working under the BIS Act 2016, which strengthened its powers and its conformity assessment schemes. Its certification mark scheme (the familiar **ISI mark**) licenses manufacturers to mark products that conform to an Indian Standard, and the government can make BIS certification compulsory for notified products through Quality Control Orders. Pharmaceuticals meet BIS at four interfaces. **Cosmetics**: the Cosmetics Rules adopt BIS standards for finished cosmetic products, so a lipstick or a shampoo in India is tested to a BIS text as well as licensed under the drug statute. **Devices and materials**: standards for medical devices, surgical dressings, hospital equipment and sterilisation overlap with the Medical Devices Rules, which read BIS and international standards together. **Packaging and inputs**: containers, closures and water and sterilisation standards govern the plant's inputs. And **food**: FSSAI standards incorporate BIS style specifications for packaged drinking water and other categories, which must carry BIS certification as a condition of sale. The lesson mirrors section 3.1: BIS answers whether a product or material conforms to the national specification for its class, a different question from whether a medicine meets its pharmacopoeial monograph.

3.4 ISO and other relevant standards

The international layer is the **International Organization for Standardization (ISO)** and its sister bodies, whose standards India adopts, often as dual numbered IS/ISO texts. The set that a regulatory professional actually cites is short. **ISO 9001** certifies a quality management system in general industry. **ISO 13485** is the quality management standard written for medical devices, and device regulation in India and abroad reads it as the QMS grammar of section 2.6 (the Medical Devices Rules' Schedule V is built in its image). **ISO 14971** governs risk management for medical devices; **ISO 14155** the clinical investigation of devices in human subjects. **ISO/IEC 17025** accredits testing and calibration laboratories, the competence basis on which India's National Accreditation Board for Testing and Calibration Laboratories (NABL) accredits the laboratories whose reports regulators accept, and **ISO 15189** does the same for medical laboratories. Beyond ISO stand the other relevant families the syllabus gestures at: the WHO's standards and international pharmacopoeia for the global market; IEC standards for electro medical equipment; ASTM standards for materials and devices; and the Codex Alimentarius standards that frame food trade and feed into the FSS system of section 2.8. Certification to these standards is voluntary in form but structural in effect: procurement, exports, device licensing and laboratory recognition all price it in, so the syllabus studies them as part of the working law.

Standard family	Custodian	What it standardises	Where it bites in this subject
Indian Pharmacopoeia	Indian Pharmacopoeia Commission	Identity, purity, strength and quality of medicines	Second Schedule standards; NSQ testing; reference substances
BIS Indian Standards	Bureau of Indian Standards	Products, materials, packaging, cosmetics, water, equipment	Cosmetics Rules; QCOs; ISI certification; FSS interfaces

Standard family	Custodian	What it standardises	Where it bites in this subject
ISO 9001 / 13485	ISO	Quality management systems; the device QMS	Device licensing; supplier audits; plant certification
ISO 14971 / 14155	ISO	Device risk management; device clinical investigation	Device files and investigations under the MDR
ISO/IEC 17025, ISO 15189	ISO and IEC	Competence of testing, calibration and medical laboratories	NABL accreditation; regulator accepted test reports
WHO, IEC, ASTM, Codex	Respective bodies	Global health, electrical, materials and food standards	Exports; electro medical devices; food standards

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