

2.1 Regulatory requirements: the licence to exist

No herbal drug unit may lawfully be set up by decision alone. It must be established under the legal framework that governs drugs in its market, and in India that framework is the Drugs and Cosmetics Act and its Rules, under which manufacturing licences are granted for defined premises, products and categories, with Ayurvedic, Siddha and Unani products licensed under their own provisions and Good Manufacturing Practice requirements, and modern herbal and phytopharmaceutical products handled under the applicable drug provisions. The regulatory requirements for setting up therefore run in a sequence the student should be able to narrate: constitution and registration of the enterprise; selection of premises meeting the factory and drug rules; application for the manufacturing licence with the layout, machinery, personnel and product details the authority examines; provision of the technical staff the rules require; establishment of quality control arrangements, in house or through approved laboratories where permitted; and the collateral licences and registrations, factory, trade, pollution control, tax and, for export, the registrations of Section 2.4. The continuing obligations matter as much as the grant: licences are renewed, premises and products are inspected, records are maintained, and changes of product, process or premises are notified or approved as the rules require. Regulation in this unit is not an obstacle placed in front of the industry; it is the industry operating system, and Units 3 and 4 supply its technical content.

2.2 Global marketing management

Global marketing management is the planning and control of selling herbal products across national markets, and its first lesson is that the world does not classify herbal products uniformly. The same standardised extract product may enter one market as a licensed herbal medicine with efficacy claims, another as a traditional use product with limited claims, another as a dietary or food supplement with no disease claims, and another not at all until locally registered. Marketing management therefore begins with regulatory market selection: which markets accept the product in a category the company can satisfy, with what evidence, labelling and pharmacopoeial standards, Unit 3 supplying the standards map. Product decisions follow: which dosage form, strength, pack and claims suit each market. Pricing and channel decisions must carry the costs of registration, testing, stability data for the destination climate and pharmacovigilance. Promotion is bounded by the claims the category permits. A disciplined global marketer of herbals sells compliance first and product second, because a consignment rejected on documentation, contaminants or labelling destroys more value than a slow registration. The management cycle below organises the topic for examination answers.

```
graph TD; A[Select the market and its herbal product category] --> B[Confirm the evidence, standards and labelling it demands]; B --> C[Adapt product, pack and claims to that category]; C --> D[Register the product and organise compliant supply]; D --> E[Distribute through the chosen channel; monitor response]; E --> F[Handle complaints, adverse reports and renewals]; F --> G[Feed market learning back into product and market selection];
```

2.3 Indian and international patent law as applicable to herbal drugs and natural products

Unit 2 names patent law in its regulatory survey; Unit 5 teaches it in full. The survey position is this. A patent is a time limited exclusive right granted for an invention, and for herbal drugs and natural products its decisive difficulty is that products of nature as found, and traditional knowledge as inherited, are generally not patentable inventions, while genuinely new processes, formulations, extraction methods, standardisation techniques and new uses developed by human ingenuity may be. Indian law states this boundary expressly through its exclusions, including the exclusion of traditional knowledge and of mere aggregation of known properties of traditionally known components, and the international framework of Section 2.5 leaves each country room to draw the line. The regulatory consequence for setting up the industry is practical: before a product is launched, its freedom to operate must be checked against existing patents, and the enterprise must decide what of its own development is worth protecting, by patent or by the other rights of Unit 5. The detail, filing procedure, criteria, cases, opposition and revocation, belongs to Unit 5 and is not duplicated here.

2.4 Export Import (EXIM) policy

The Export Import policy is the government policy framework governing foreign trade: what may be exported or imported, under what conditions, licences, quality requirements and incentives. For the herbal industry it operates on both sides of the factory gate. On the export side, crude drugs, extracts and finished herbal products are exported under the policy classification and conditions in force, with the documentation that importing countries and Indian authorities require: shipping and customs documents, certificates of origin and quality, pharmacopoeial compliance and, where demanded, certificates of free sale and analysis. Conservation enters trade policy directly: plant species threatened by over collection are restricted or prohibited in export in raw form under wildlife and biodiversity controls and international convention commitments, pushing trade toward cultivated material and value added extracts. On the import side, the policy governs import of crude drugs India does not produce, of machinery and of reference standards and instruments, with duties and conditions as notified. EXIM policy also carries the promotional machinery of foreign trade: export promotion councils and boards concerned with medicinal plants and AYUSH products, market development assistance and quality certification support. For examination purposes the policy should be presented as a framework that changes by notification, so principles and machinery are the durable content: classification, licensing and restriction, documentation, quality and conservation conditions, and promotion support.

2.5 TRIPS

TRIPS, the Agreement on Trade Related Aspects of Intellectual Property Rights, is the World Trade Organization agreement that sets minimum standards of intellectual property protection for member

countries, including patents, copyright, trademarks and geographical indications, and requires members to make enforcement available. Its importance for this subject is threefold. First, it obliged member countries, India included, to provide product patent protection in pharmaceuticals, reshaping the legal environment in which herbal and natural product inventions are protected, the background to Unit 5. Second, its patentability standards, inventions that are new, involve an inventive step and are capable of industrial application, with limited permitted exclusions, supply the vocabulary of Unit 5: novelty and non obviousness are the TRIPS era terms. Third, TRIPS is the international forum of the traditional knowledge debate: the patenting abroad of uses long known in Indian traditional medicine, the cases of Unit 5, raised the questions of prior art documentation, benefit sharing and protection of traditional knowledge that India answered in part with its Traditional Knowledge Digital Library and its patent law exclusions. TRIPS does not itself grant patents; national offices grant them under national law built to TRIPS standards. That sentence prevents the commonest error in student answers on this topic.

2.6 Quality assurance in herbal and natural drug products

Quality assurance is the organised whole of arrangements that gives confidence that a product will meet its quality requirements: not testing alone, but the system of which testing is one part. In herbal and natural drug products QA carries extra weight because the starting material is variable, so assurance must extend further back, to supplier approval, authentication of crude drugs, and control of cultivation and collection sources, and further forward, to stability, complaints and recall. The QA functions should be listed as a system: approval of specifications and procedures; vendor qualification; review and release of batches on their complete records; handling of deviations, changes and corrective and preventive actions; validation of processes and methods; stability programme oversight with Unit 4; complaint and recall management; self inspection and audit; and documentation control, the issuing, revision and archiving of every controlled document. QA is independent of production in a sound organisation, with authority to reject material and stop release, because a QA that reports to the production it judges will eventually judge leniently. The three quality systems that follow, TQM, GMP and GLP, together with ISO 9000, are the named frameworks through which QA is implemented, and the comparison table in Section 2.10 fixes their territories.

2.7 TQM: Total Quality Management

Total Quality Management is a management philosophy in which quality is the responsibility of every person and every function, organised around customer satisfaction, continuous improvement and employee involvement. Its concepts, as the syllabus word concepts directs, are the examinable content. Customer focus: quality is defined by the needs of the customer, internal as well as external, each process serving the next. Total involvement: quality cannot be inspected in by a department at the end; it is built by all, which is why TQM trains and empowers operators to own their process quality. Continuous improvement: processes are improved in small, permanent steps, classically by the plan, do, check, act cycle, rather than by occasional campaigns. Process approach: work is managed as processes with inputs, controls and outputs that can be measured. Data based decisions: improvement is directed by measurement, using the basic statistical and problem solving tools, rather than by opinion. Its difference from GMP should be stated: GMP is a regulatory requirement with legal force for defined manufacturing operations; TQM is a voluntary management philosophy that can cover the whole business, and the two reinforce each other.

2.8 GMP: Good Manufacturing Practice

Good Manufacturing Practice is the part of quality assurance that ensures products are consistently produced and controlled to the quality standards appropriate to their intended use. Its elements form the standard list: premises and equipment designed, maintained and cleaned for their purpose; trained personnel with defined responsibilities and hygiene rules; approved, written procedures for every operation,

actually followed and recorded; materials controlled from receipt, through quarantine and testing, to issue; production carried out under batch documentation with in process controls; finished products tested against specification and released by authorised quality personnel; storage and distribution that protect quality; and systems for complaints, recalls and self inspection. For Ayurvedic, Siddha and Unani manufacture in India, GMP is codified in Schedule T of the Drugs and Cosmetics Rules, which sets requirements for factory premises, warehousing, machinery, standard operating procedures, records and quality control for those systems, a point that links this unit to the ISM pharmacopoeias of Unit 3. The herbal emphasis inside GMP is constant: identity of the crude drug is the first GMP act, because all later control is worthless on a misidentified material; segregation and labelling prevent the mix ups that botanical materials, similar in appearance and stored in bulk, invite; and drying, storage and pest control protect constituents that synthetic actives do not lose in the warehouse. GMP checkpoints are drawn in the diagram of Section 2.10.

2.9 GLP: Good Laboratory Practice

Good Laboratory Practice is the quality system for non clinical laboratory studies, concerned with how studies are planned, performed, monitored, recorded, reported and archived, so that the resulting safety data can be trusted and reconstructed by regulators. Its core elements: a defined organisation with a study director responsible for each study; written standard operating procedures for laboratory operations; facilities and equipment suited and maintained for the work; test and reference materials characterised and controlled; a study plan approved before work begins; raw data recorded contemporaneously and traceably; a final report that faithfully reflects the raw data; and archives that preserve the whole for later inspection, with an independent quality assurance unit auditing the system. GLP must be distinguished from ordinary laboratory quality control: the QC laboratory of a factory tests batches for release under GMP, while GLP governs the conduct of safety studies whose data support regulatory decisions. A herbal company meets GLP when the toxicological and safety data on its products are generated for submission; the discipline of traceability it teaches, every result reconstructable to raw data, is the same discipline Unit 4 demands of all testing.

2.10 ISO 9000 and the quality systems compared

ISO 9000 is the family of international standards for quality management systems, published by the International Organization for Standardization, against which an organisation may be certified by an accredited body. The family states requirements for a documented quality management system covering leadership, planning, support, operation, performance evaluation and improvement, in the process and risk based form of the current standards. Certification is voluntary and commercial in motive: it assures customers that a management system exists and is audited, and it is often demanded in trade, which is why a syllabus on industrial technology includes it beside the legal systems. Its limits must be stated as clearly as its value: ISO certification attests the management system, not the quality of any individual product, and it does not replace GMP, which remains the legal condition of manufacture. The table and diagram below fix the four named systems of this unit against each other.

System	What it is	Legal force	Territory	Judged by
TQM	Management philosophy of total involvement and continuous improvement	Voluntary	Whole organisation, customer outward	Results and culture, self driven
GMP	Rules for consistent manufacture and control of products	Mandatory for licensed manufacture	Premises, materials, production, release	Regulatory inspection and batch records
GLP	Rules for planning, conduct, recording and archiving of laboratory safety studies	Required for studies submitted to regulators	Non clinical laboratory studies	Inspection of study traceability and archives

System	What it is	Legal force	Territory	Judged by
ISO 9000	International quality management system standards	Voluntary, certification by accredited bodies	Management system of the whole organisation	External certification audit

The four quality frameworks

GMP: BY LAW	GLP AND TQM	ISO 9000
<ul style="list-style-type: none"> Premises and equipment Materials controlled Batch records kept Release by quality unit Inspection enforced 	<ul style="list-style-type: none"> GLP: study traceability GLP: plans, raw data, archives TQM: everyone owns quality TQM: continuous improvement TQM: customer focus 	<ul style="list-style-type: none"> Management system standard Documented and audited Voluntary certification Covers whole organisation Never replaces GMP

GMP guards manufacture, GLP guards study data, ISO certifies the system, TQM improves all of it

© 2026 PharmacoLearn, pharmacolearn.fyi

Figure: The four quality frameworks of Unit 2 placed on one plant. GMP guards manufacture by law, GLP guards study data, TQM improves everything voluntarily, and ISO 9000 certifies the management system that holds them.

More free M.Pharm notes and unit wise PDFs at pharmacolearn.fyi

Free video lectures on the PharmacoLearn YouTube channel