

Unit 4: Schedule T and Quality Assurance in ISM Manufacture

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4.1 Why ISM manufacture has a GMP of its own

Ayurvedic, Siddha and Unani medicines are drugs in Indian law, manufactured for sale under licence, and a licensed drug industry needs a good manufacturing practice fitted to its materials and methods. The general drug industry works under Schedule M of the Drugs and Cosmetics Rules; the ISM industry works under Schedule T, the schedule of the same Rules that prescribes GMP for Ayurvedic, Siddha and Unani medicines, notified in 2000 and binding as a condition of the manufacturing licence. Its premise is exactly the premise of this subject: a classical formulation is only as good as the factory that realises it, because identity can be lost in a dirty store, strength in a wrong process and safety in a contaminated vessel, in a traditional factory as surely as in a synthetic one. Schedule T therefore translates the classical pharmacy into auditable requirements under the heads the syllabus prints: its objectives and components, infrastructure, working space, storage, machinery, standard operating procedures, health and hygiene, and documentation. This unit teaches it in that order, and the student should note what Schedule T is not: it is not a judgement on the classical systems themselves, and it changes no formulation by a single ingredient; it governs only how faithfully and cleanly the formulation is made.

4.2 Objectives and components of GMP under Schedule T

The objectives of Schedule T, in its own terms, are that the raw materials used are authentic, of prescribed quality and free from contamination; that the manufacturing process is the prescribed process, performed so as to maintain the standards; that adequate quality control measures are adopted; and that the finished drug released for sale is of acceptable quality. Those four objectives, authenticity, prescribed process, quality control and acceptable product, are the whole of GMP in one sentence, and every component that follows is machinery for making them true. The components, as the schedule organises them, fall into two parts. The first part states the general requirements that apply to every unit: factory premises and their situation and construction; the warehousing and storage arrangements; the machinery and equipment; the standard operating procedures; health and hygiene of personnel; documentation and records; and the quality control expectations. The second part works through the categories of Ayurvedic, Siddha and Unani dosage forms, the classes of Unit 1 and Unit 3 grouped for the purpose, and states the minimum working space and the machinery and equipment expected for each category, so that a unit licensed for fermented liquids must show the vessels and space that fermentation honestly needs, and a unit making mineral preparations must show the furnaces and grinding equipment of that pharmacy. Sections 4.3 to 4.8 open each component in turn.

Schedule T: components of GMP for ISM

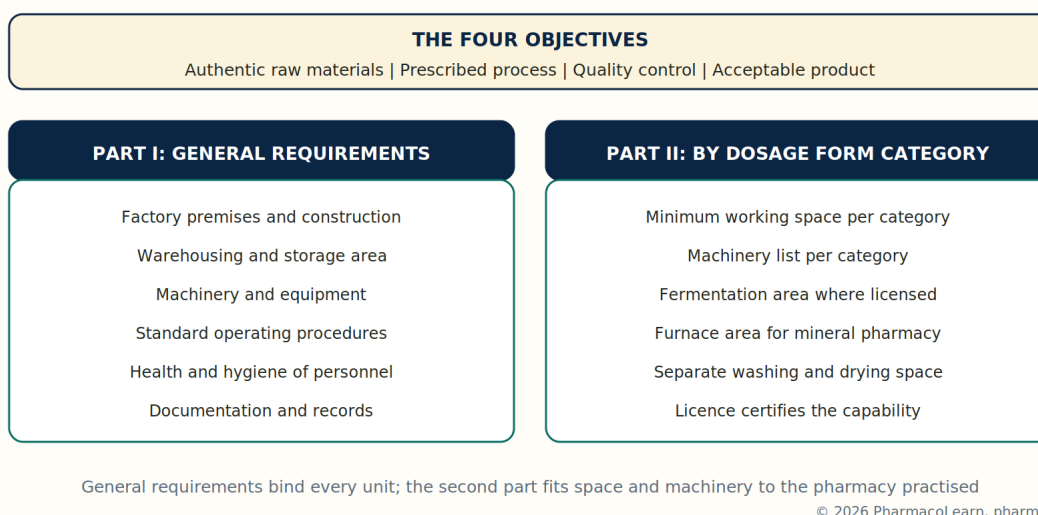


Figure: The components of Schedule T. General requirements bind every unit; the second part sets space and machinery category by category of dosage form.

4.3 Infrastructural requirements: location and building

The infrastructural requirements begin before any machine is installed. The factory premises must be located and constructed so that manufacture is protected from the surroundings and the surroundings from manufacture: sited away from open drains, public lavatories and sources of contamination, in a building designed for the work, with surfaces that can be cleaned and a layout that separates the dirty operations, raw drug washing and grinding, from the clean ones, filling and packing. The schedule expects the manufacturing area to be organised as a flow: raw material enters at one end through its store, passes through processing, and leaves as packed product, without crossing streams in which finished goods meet raw waste. Separate provision is expected for the operations whose character demands it: the furnace area for the mineral pharmacy, the fermentation area for asava and arishta, and space for the washing and drying of crude drugs, which in this industry is a major operation and not a corner of the yard. These are the requirements of any honest factory, restated for a pharmacy whose raw materials arrive as roots, barks and minerals rather than as drums of fine chemicals.

4.4 Working space and storage area

Working space under Schedule T is prescribed as a minimum, and prescribed by category: the schedule's second part assigns to each group of dosage forms the area in square feet that its manufacture requires, so that the licence itself certifies that the factory can physically perform the operations it claims. The principle beneath the numbers, which is what this subject examines, is that each operation must have room to be done properly and separately: grinding without dusting the packing line, fermentation without crowding the boiling vessels, and the mineral operations with their furnaces and repeated calcinations given their own territory. Storage receives equal weight, and in three divisions: the raw material store, where drugs are kept identified, off the floor, protected from moisture, pests and mix up, with the poisonous and mineral drugs under their own control; the in process and quarantine arrangements, by which material waits, labelled, for its quality verdict; and the finished goods store, from which alone released product may leave. In an industry whose materials are seasonal harvests bought in bulk, the store is where quality is first kept or first lost, and Schedule T's insistence on it is the factory echo of the raw drug doctrine of Section 1.10.

4.5 Machinery and equipment

The machinery component of Schedule T lists, by dosage form category, the equipment a unit must possess: the grinders, pulverisers and sieves of the powder pharmacy; the boilers, extraction vessels and strainers of the aqueous classes; the fermentation vessels of sandhana; the furnaces, crucibles and grinding machinery of the mineral classes; the distillation apparatus for arka; the filling, sealing and labelling equipment of the packing end; and the basic quality control instruments by which the factory checks its own work. Two features deserve notice. The list is a floor, not a ceiling: it names the minimum by which the licensed categories can honestly be made, in traditional or modern form, and a factory may exceed it freely. And the schedule admits the traditional implements of the classical pharmacy where they genuinely perform the operation, which is why the ISM factory is a regulated hybrid, classical in method and modern in discipline, exactly as Unit 3 described its formulations.

4.6 Standard operating procedures

Standard operating procedures are the written form of the factory's discipline: a procedure for every recurring operation, stating what is done, by whom, with what, and how it is recorded, covering the receipt and sampling of raw materials, their cleaning and processing, each manufacturing operation, the cleaning of equipment and premises between products, the maintenance of machinery, and the quality control checks at each stage. Their function in the ISM setting is the conversion named in Unit 3: the classical text says what the medicine is, the formulary says how it is classically made, and the SOP says how this factory, with these machines and these workers, makes it the same way every time. An inspector reading the SOPs can walk the factory in paper before walking it in fact, and a deviation discovered in a batch can be traced to the procedure that allowed it, which is what makes the SOP set, rather than any single machine, the real instrument of good manufacturing practice.

4.7 Health and hygiene

The health and hygiene component governs the people, on the standard GMP reasoning that the worker is the most mobile source of contamination in any factory. Schedule T expects the personnel engaged in manufacture to be medically fit and free from infectious disease, to observe personal hygiene, and to wear the protective clothing the work requires; it expects the premises to be kept clean, with arrangements for washing, for the exclusion of pests, and for the separation of the manufacturing areas from eating, drinking and other domestic use. In the ISM factory the component carries an extra weight, because so much of the pharmacy is open handling: drugs washed by hand, pastes ground and levigated, pills rolled, liquids strained and filled, and mineral powders, some of them preparations of toxic starting materials, weighed and ground in quantity. Hygiene here protects the worker as directly as the product, and the examination treats the component with that double sense.

4.8 Documentation and records

Documentation is the final general component and the one that makes all the others provable. The records Schedule T expects a unit to maintain cover the life of every batch: the raw material records, showing each drug received, its identification and quality verdict and its issue to manufacture; the batch manufacturing record, showing the formulation made, the quantities and batch numbers of every ingredient, the operations performed and their dates, the in process checks and the yield; the quality control record of the finished product against its specification; and the distribution record, by which every consignment sold can be traced to the batch it came from, so that a complaint or a recall can find its product. Records must be retained for the period the Rules prescribe beyond the product's shelf life. The principle is the GMP principle of every system in this degree: if it is not recorded, it did not happen, and a classical name on the label is not a record.

The batch documentation chain



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Figure: The documentation chain. Every batch carries its own paper life, from the raw material verdict to the consignment that can be traced back to it.

4.9 Quality assurance in the ISM industry: GAP, GMP and GLP

Quality assurance for an ISM product is a chain of three good practices, each guarding one stage of the product's life, and the syllabus names the chain explicitly. GAP, good agricultural practices, guards the field stage: the cultivation and collection of the medicinal plants themselves, the subject MPG102T taught as good agricultural and collection practice, by which the wild and farmed raw material arrives identified, uncontaminated and of the right part and season. GMP, good manufacturing practice, guards the factory stage, and for this industry it is Schedule T, the whole of Sections 4.1 to 4.8. GLP, good laboratory practice, guards the testing stage: the discipline of the laboratories, the manufacturer's own and the independent ones, in which the identity, purity, quality and safety studies on which release and licensing rest are performed under documented, auditable conditions. The chain's logic is the logic of the whole degree: quality cannot be inspected into a product at the end, it is built at the field, kept at the factory and proven at the laboratory, and a failure at any link reaches the patient through all the links below it.

The quality chain of an ISM product

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graph TD; A[GAP: the field  
(identified, clean, correct raw material)] --> B[GMP: the factory (Schedule T)  
(prescribed process, recorded batches)]; B --> C[GLP: the laboratory  
(auditable testing and safety studies)]; C --> D[A product whose quality can be shown];
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4.10 Documents for new drug application and export registration

An ISM manufacturer placing a new product on the market, or an existing product on a foreign market, must convert the factory's discipline into documents a regulator can judge. For a new drug application in the domestic framework, the dossier assembles the product's identity and basis: the classical textual reference or the rationale for a proprietary formulation, the complete composition, the manufacturing method and its

controls, the raw material and finished product specifications with their test methods, the stability evidence supporting the shelf life of Section 3.7, the safety and, where the category demands it, clinical evidence standing behind the claims, and the draft label with its claims stated exactly as they will be sold. For export registration the same core is re-cut to the importing country's pattern, with the additions foreign regulators characteristically require: the manufacturing licence and the GMP certificate evidencing Schedule T compliance, the free sale certificate from the home authority, pharmacopoeial specifications for the product and its ingredients, and the importing country's own labelling and claim rules, which differ sharply between countries that register traditional medicines and countries that admit them only as supplements or not at all. The professional point is constant: the dossier is not paperwork added to the medicine, it is the medicine's evidence, organised for judgement, and a product whose documents cannot be assembled was never as ready as its factory believed.

4.11 Challenges in monitoring the safety of herbal medicines

The syllabus closes the unit with the safety problem, under its three printed heads: regulation, quality assurance and control, and national and regional pharmacopoeias. Under regulation, the challenge is structural: herbal and ISM products reach the market by routes, classical licensing, traditional use registration, supplement sale, that ask for less premarket safety proof than a new synthetic drug faces, so the safety system leans heavily on monitoring after sale, in populations who often do not tell their physicians they are taking the product, and who attribute harms to their disease; under reporting is therefore not an accident of the system but its predictable state. Under quality assurance and control, the challenge is the material itself: a variable natural product, open to species substitution, contamination and the adulteration of MPG202T, whose harms are quality failures before they are pharmacology, together with the mineral preparations of Units 1 and 3, whose declared ingredients include substances toxic in any other context and whose safety rests wholly on the processing and testing that only audit can verify. Under pharmacopoeias, the challenge is coverage and convergence: national and regional pharmacopoeias, the API and its sister volumes among them, together with the WHO monographs, do not yet cover every drug in commerce, do not always agree in their limits, and leave manufacturer and regulator to judge unlisted material by analogy. The response the subject builds toward is the one its units have assembled piece by piece: authenticate the material, manufacture under Schedule T, test against the pharmacopoeia, label honestly, and monitor after sale with the expectation of finding harm, since a monitoring system that expects nothing will find nothing until the harm is large.

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