

Unit 3: Formulation Development of the Indian Systems

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3.1 The pharmacopoeias and texts as the working sources

Formulation development in the Indian systems does not begin from a blank page; it begins from the books. Every classical formulation a manufacturer may sell traces to a text recognised in the First Schedule of the Drugs and Cosmetics Act, and its working recipe, in the modern statutory sense, is the one printed in the system's formulary: the Ayurvedic Formulary of India for Ayurveda, the Siddha Formulary of India for Siddha, the National Formulary of Unani Medicine for Unani, and the pharmacopoeial directions of the Homoeopathic Pharmacopoeia of India for Homoeopathy, with the pharmacopoeias of Section 1.7 supplying the standards for the ingredients and for those finished products they monograph. The salient feature of ISM formulation work follows directly: development here means faithful realisation of a textual formulation at manufacturing scale, with modern standardisation wrapped around it, and a genuinely new ISM product, a proprietary medicine, must declare its textual or reasoned basis and pass the licensing scrutiny that Unit 4 describes. The classes of formulation in the next four sections are therefore taught as the pharmacopoeias and texts present them: by class, by technique and by the purpose each technique serves, without quantities, which belong to the formulary texts themselves.

3.2 Ayurvedic formulation classes and their preparation techniques

The Ayurvedic classes arrange themselves by the operation that defines them. The aqueous classes come first in classical order: swarasa, the expressed juice of the fresh drug; kalka, the paste; kwatha, the decoction, in which coarse drug is boiled down in water and strained, the base liquid of the whole pharmacy; hima, the cold infusion; and phanta, the hot infusion. These are short lived preparations, and their industrial descendants are the extracts and liquid orals of the modern factory. The powder and pill classes follow: churna, fine sieved powders of one or more drugs, and vati, pills made by rolling a powdered mass with a liquid medium and drying, the class into which much of the mineral containing pharmacy also falls. The lipid classes, sneha kalpana, cook drugs into ghee or oil: the drug paste and decoction are processed into the fat until the classical end points of the cooking are reached, judged by the traditional signs of completion, and the resulting ghrita and taila carry the fat soluble and processed constituents in a stable, dosable form.

The remaining classes are the distinctive technologies. Sandhana kalpana, the fermented class of asava and arishta, sets a decoction or juice with sugar or jaggery and a fermenting flower, classically dhataki, in sealed vessels until fermentation generates its own alcohol, which then extracts and preserves; the manufacturer's art lies in controlling a living process to a consistent alcohol content and character. Rasaushadhi, the herbo mineral pharmacy, works the mineral class through shodhana, purification, the Ayurvedic parallel of Suddhi; bhavana, repeated levigation of the material with prescribed liquids; and puta, controlled incineration in sealed crucibles under measured fuel heat, repeated until the product, a bhasma, passes the classical tests of fineness and quality, tests such as floating on water and filling the lines of the fingertip, which are genuine physical checks of particle fineness whatever else is claimed for them. Parpati, made by pressing a molten mineral preparation between leaves into flakes, and kupipakwa preparations, sublimed in glass bottles under graded heat, complete the classical mineral repertoire. The examination asks for the salient features of these techniques: the operation, its product class and its purpose, at exactly the level given here.

Ayurvedic formulation classes by defining operation

AQUEOUS	Extraction with water	Swarasa, kalka, kwatha, hima, phanta
POWDER AND PILL	Comminution and rolling	Churna and vati
LIPID (SNEHA)	Cooking into fat	Taila (oils) and ghrita (ghees)
FERMENTED (SANDHANA)	Self generated alcohol	Asava and arishta
MINERAL (RASAUSHADHI)	Purify, levigate, incinerate	Bhasma, parpati, kupipakwa

Each class is a technique before it is a product

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Figure: The Ayurvedic formulation classes by their defining operation. Each class is a technique before it is a product: extraction, powdering, lipid cooking, fermentation and the mineral operations.

3.3 Siddha formulation techniques

Siddha formulation technique rests on the Gunapadam classification of Unit 1 and divides by its three drug classes. The herbal preparations parallel the Ayurvedic ones in Tamil dress: chooranam, the powders; kudineer, the decoctions; nei, medicated ghees; and ennai, medicated oils, prepared by processing drugs into the fat as in the sneha method. The mineral pharmacy is where Siddha technique is most itself. Parpam, the white calxes, are produced by grinding the purified metal or mineral with herbal juices and subjecting the cakes to puta, calcination, in sealed earthen vessels, repeatedly, until a fine white powder results. Chenduram, the red preparations, carry the same operations to the red oxide and sulphide type products. Chunnam are the alkaline preparations, kalangu the pill like hardened preparations, and kattu the bound forms in which a processed material is held in a stable lump by treatment with specified juices, each class defined by its operation and end form. Mezhu, the wax like preparations, complete the standard list. Across all of them the doctrine of Section 1.11 governs: no mineral enters these operations unpurified, and the classical tests of the finished calx, fineness above all, are the technique's own quality gate, which modern manufacture supplements with the instrumental analysis of Section 1.8.

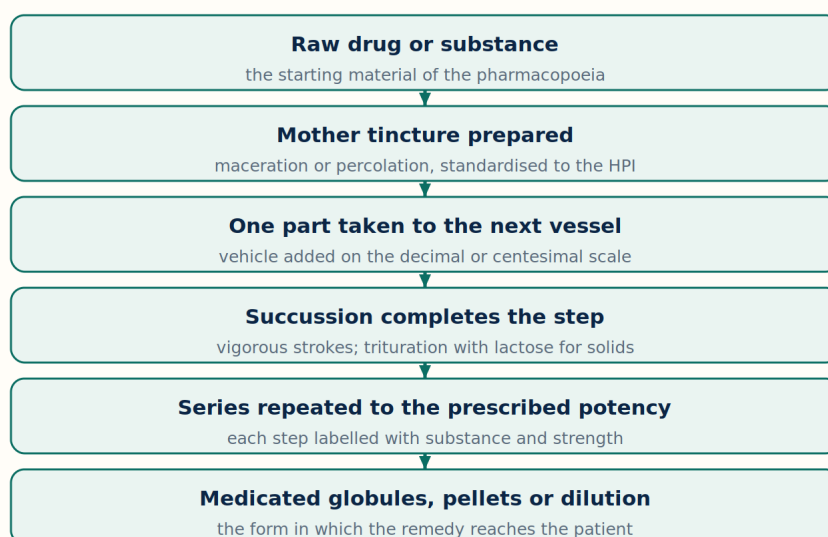
3.4 Unani formulation techniques

Unani pharmacy, the saidala of the classical texts, works with techniques that partly parallel the Ayurvedic and partly reflect its own Greco-Arab inheritance. Its powder class is the safoof; its pill classes habb and qurs; its characteristic semi solids are the majoon, an electuary in which powdered drugs are worked into a honey or sugar base, with jawarish and khamira as its lighter and fermented relations; sharbat carries drugs in syrup; laooq is a linctus like preparation taken slowly; arq, the distillate, is made by distilling aromatic drugs with water, the direct counterpart of the Ayurvedic arka; roghan are the medicated oils; and marham the ointments and qairooti the wax based preparations for external use. The techniques are those of any classical pharmacy: comminution and sieving for the powders, incorporation into the sweet bases at controlled consistency for the electuaries, distillation for the arq, and expression and maceration for the oils. What the Unani Formulary adds is the same architecture as the other systems: named classical formulations with fixed ingredient lists, so that development means standard realisation, exactly as Section 3.1 stated.

3.5 Homoeopathic preparation techniques

Homoeopathic pharmacy is the most procedurally distinctive in this unit, because its preparations are defined by a process with no counterpart elsewhere: potentisation. Manufacture begins from the mother tincture, the starting solution prepared from the raw drug, for plant drugs by maceration or percolation with alcohol of pharmacopoeial strength, and standardised as the Homoeopathic Pharmacopoeia of India directs. From the mother tincture the dilutions are made in series: at each step one part of the previous strength is diluted in the prescribed proportion of vehicle, alcohol and water for liquids, on one of the two pharmacopoeial scales, the decimal scale of one to ten or the centesimal scale of one to a hundred, and the step is completed by succussion, a defined number of vigorous downward strokes of the vial, which the system's doctrine holds to be as essential as the dilution itself. Insoluble substances begin as triturations, ground in series with lactose in mortar by a timed procedure until a soluble strength is reached, from which liquid potencies continue. The finished potencies are delivered as the liquid dilution itself, or medicated onto globules and pellets of cane sugar, or in tablets and external forms such as ointments and liniments prepared from the tinctures. The manufacturer's discipline, examined here as technique, is one of serial accuracy, scrupulous cleaning between remedies, since the same vessels carry many, and exact labelling of name and potency, the two facts on which the whole system turns: a homoeopathic medicine whose substance or potency is wrong is not a weak medicine but the wrong one.

Potentisation: the homoeopathic sequence



Accuracy of the series and of the label is the whole of the manufacture

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Figure: Potentisation as a manufacturing sequence. Each step is a defined dilution completed by succussion or trituration, and the label must carry substance and potency exactly.

3.6 Standardization of ISM formulations

Standardization is the process by which a classical formulation, defined by a text, is made reproducible in a factory and demonstrable in a laboratory, taught here as a chain of controls rather than as a single test. The chain begins with the raw materials, each certified against its pharmacopoeial monograph by the identity, purity and quality work of Section 1.8; a formulation made from uncertified drugs cannot be standardised afterwards, because no finished product test can recover information the batch never had. The second control is the process itself: the classical method translated into a written manufacturing procedure with defined quantities, times, temperatures and end point tests, so that the textual instruction becomes an auditable operation, the same conversion Schedule T demands in Unit 4. The third control is the finished product specification: organoleptic characters, physico-chemical constants, fingerprint against a reference batch, marker assays where characteristic ingredients carry established markers, and the microbial and

contaminant limits of the pharmacopoeias. Where a classical formulation has no established marker, the standard practice is honest about it: fingerprint and process control carry the weight, and consistency with the reference profile, not an invented assay, is the claim.

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Standardization of an ISM formulation
  Classical text and formulary entry identified
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    v
  Every raw material certified to its monograph
    |
    v
  Textual method written as a controlled procedure
    |
    v
  In process end points checked (classical and physical)
    |
    v
  Finished product: fingerprint, markers, constants, limits
    |
    v
  Batch released against the specification

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3.7 Shelf life and stability studies of ISM formulations

A classical text may say that a preparation keeps, but a modern label must print an expiry, and the distance between those two statements is the shelf life and stability work of this section. Shelf life for ISM formulations is assigned from evidence of two kinds. The first is the classical and formulary record itself, which for many classes carries traditional keeping periods, long for the fermented and mineral preparations, short for the aqueous ones, and which the licensing framework respects as the starting position. The second is the modern stability study, adapted from the general pharmaceutical pattern: batches stored under defined conditions of temperature and humidity, long term and accelerated, and tested at intervals for the characters that can fail, appearance, odour and taste, moisture, physico-chemical constants, fingerprint and marker content, alcohol content in the fermented class, and microbial quality, until the point at which the product leaves its specification defines the supported shelf life. The failure modes differ by class and should be known: aqueous liquids spoil microbially; churnas cake, lose volatiles and take up moisture; tailas and ghrilas turn rancid by oxidation; asavas continue to change slowly in the bottle; bhasmas, the most stable class, still demand protection from moisture. Packaging is part of the study, since the container that admits air and damp decides the result as surely as the formula. The conclusion is the standard one of this degree: shelf life is not a property a product has by tradition, it is a period demonstrated by a study and printed as a promise the manufacturer must keep.

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