

Unit 1: Herbal Remedies, Toxicity and Regulations

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Advanced Pharmacognosy-II, subject code MPG202T, is the second core theory subject of M.Pharm Pharmacognosy, Semester 2. It carries 4 credits and 60 hours of theory, taught at 4 hours per week, for 100 marks, and its five units are of equal length at 12 hours each. Its scope, as the syllabus states it, is to know and understand the adulteration and deterioration that occurs in herbal and natural drugs and the methods of detection of the same, and to study herbal remedies and their validations, including methods of screening. Where Advanced Pharmacognosy-I taught how herbal drugs are cultivated, collected and turned into standardised products, this subject teaches the other half of professional judgement: how a herbal drug is doubted, tested and proven. Unit 1 sets the standard of proof, comparing herbals with conventional drugs and working through efficacy, validation of therapies, toxicity, regulation, and the pharmacodynamic and pharmacokinetic issues that make herbal products behave differently from single molecule medicines. Unit 2 is the quality unit: adulteration and deterioration, their types, causes and control, sampling and foreign matter, DNA fingerprinting for identity, and the detection of heavy metals, pesticide residues, phytotoxins and microbial contamination. Unit 3 follows knowledge back to its source, ethnobotany and ethnopharmacology, bioprospecting, and reverse pharmacology. Unit 4 applies the analytical discipline to six named drugs, *Andrographis paniculata*, *Boswellia serrata*, *Coleus forskohlii*, *Curcuma longa*, *Embolica officinalis* and *Psoralea corylifolia*, profiling each by its source, markers and methods. Unit 5 closes with biological screening: the in vitro and in vivo evaluation techniques by which a claim of activity is tested, and toxicity studies as per OECD guidelines. One idea holds the subject together: a herbal drug earns trust the same way a synthetic drug does, by identity established, quality measured, activity demonstrated and safety tested, and every unit is one of those four proofs examined closely.

1.1 Herbals versus conventional drugs

The comparison between herbal and conventional medicines is the frame of the whole unit, and it should be made precisely, because the differences are differences of material, not of dignity: both are medicines, but they arrive at the patient by very different routes. A conventional drug is, in the standard case, a single defined chemical entity of known structure, manufactured to a specification, dosed in exact milligrams, and characterised by a pharmacokinetic profile measured for that one molecule. A herbal drug is a whole plant part or an extract of it: a mixture of many constituents in proportions set by genetics, season, soil and processing, of which one or a few are named as markers, while the rest are incompletely characterised. From that single root fact the examinable contrasts grow, and the table states them fairly, giving herbals their genuine strengths as well as their problems.

Point of comparison	Herbal drugs	Conventional drugs
Composition	Mixture of many constituents, markers named	Single defined chemical entity
Standardisation	By marker content and fingerprint	By assay of the active itself
Batch variation	Real, driven by plant and season	Small, controlled by manufacture
Dose precision	Approximate, extract strength varies	Exact, unit dose defined
Evidence base	Long traditional use, fewer trials	Clinical trial led development
Interaction knowledge	Often incomplete, discovered late	Studied before marketing

Point of comparison	Herbal drugs	Conventional drugs
Cost and access	Usually low cost, widely available	Developed at high cost

Herbals versus conventional drugs

HERBAL DRUGS	CONVENTIONAL DRUGS	JUDGED ALIKE
Mixture of many constituents	Single defined molecule	Identity established
Markers named, rest partial	Assayed directly	Quality measured
Batch variation is real	Manufacture controlled	Activity demonstrated
Dose approximate	Exact unit dose	Safety tested
Traditional evidence base	Trial led evidence base	Claims matched to evidence

Different materials, the same four questions of proof

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Figure: Herbals and conventional drugs differ as materials, in composition, variation and evidence base, and are judged alike by the four tests of identity, quality, activity and safety.

Two cautions belong with the table. First, the contrast is a spectrum, not a wall: some conventional drugs began as plant constituents isolated and purified, and some herbal products are standardised to a discipline approaching that of conventional manufacture. Second, the traditional use of a herbal is evidence of a kind, evidence of human exposure over long periods, but it is not the same kind of evidence as a controlled trial, and Section 1.3 takes up exactly what each kind of evidence can and cannot prove. The professional position this subject teaches is neither dismissal nor credulity: a herbal product is judged by the same four questions as any medicine, what is it, how strong is it, does it work, and is it safe, while recognising that the methods for answering them must be adapted to a mixture.

1.2 Efficacy of herbal medicine products

Efficacy, the capacity of a product to produce the claimed effect under controlled conditions, is harder to establish for herbal products than for conventional drugs, and the reasons should be listed rather than merely felt. The product tested must first be defined, yet an extract described only by plant name and solvent is not fully defined: plant part, extraction method, drug extract ratio and marker content all change what the material actually is, so two trials of the same named herb may have tested materially different products. The active principle may be unknown or may be a group of constituents acting together, so dose cannot be tied to a blood level of one molecule. Traditional indications are often broad and symptomatic, which makes trial endpoints harder to fix than the defined endpoints of conventional trials. Against these difficulties stand the genuine assets: a long record of human use that identifies plausible indications and obvious harms, and in the better developed herbal sectors, standardised extracts on which proper trials have in fact been run.

The examination answer should then state what an efficacy claim for a herbal product properly requires: an authenticated starting material, a defined and standardised extract, a stated marker content, a plausible indication drawn from traditional use or pharmacology, and controlled clinical evidence proportionate to the claim. Where such evidence exists, the claim stands on the same footing as any other. Where it does not, the honest label is traditional use, which several regulatory systems recognise as a claim category of its own, Section 1.5, rather than borrowing the authority of proof that has not been performed. Efficacy is therefore not a property of the plant in the field; it is a property of a defined product, made to a standard,

tested for a stated purpose.

1.3 Validation of herbal therapies

Validation of a herbal therapy is the organised process of converting that traditional claim into tested knowledge, and it proceeds in a defensible order. The first step is to fix the material: botanical identity authenticated, part and preparation defined, quality established by the methods of Unit 2 and the profiles of Unit 4, because a therapy cannot be validated if the substance given to patients changes from batch to batch. The second step is the preclinical record: pharmacological screening of the kind taught in Unit 5, which tests whether the claimed activity appears in experimental systems at all, and toxicity testing that sets the first safety boundary. The third step is clinical evaluation in humans, in phases adapted to a product with a history of use: observational and experiential evidence from practice is collected and systematised, then controlled trials test defined outcomes in defined patients. The fourth step is continuing surveillance after marketing, pharmacovigilance of the kind introduced in Semester 1, because herbal harms are characteristically discovered late and reported rarely.

Two design problems deserve explicit mention, since examiners favour them. Blinding is difficult when a herbal preparation has a characteristic taste, smell or colour, so trial design must work harder to keep the comparison honest. Placebo response and the natural course of the mild, self limiting conditions for which herbals are often used can imitate efficacy, which is why uncontrolled observation, however long, cannot substitute for comparison. Validation is complete, in the sense this subject uses the word, when identity, quality, activity, clinical effect and monitored safety have each been addressed by the method appropriate to it; a therapy strong in one and silent in the others is partly validated, and the professional should be able to say which part is missing.

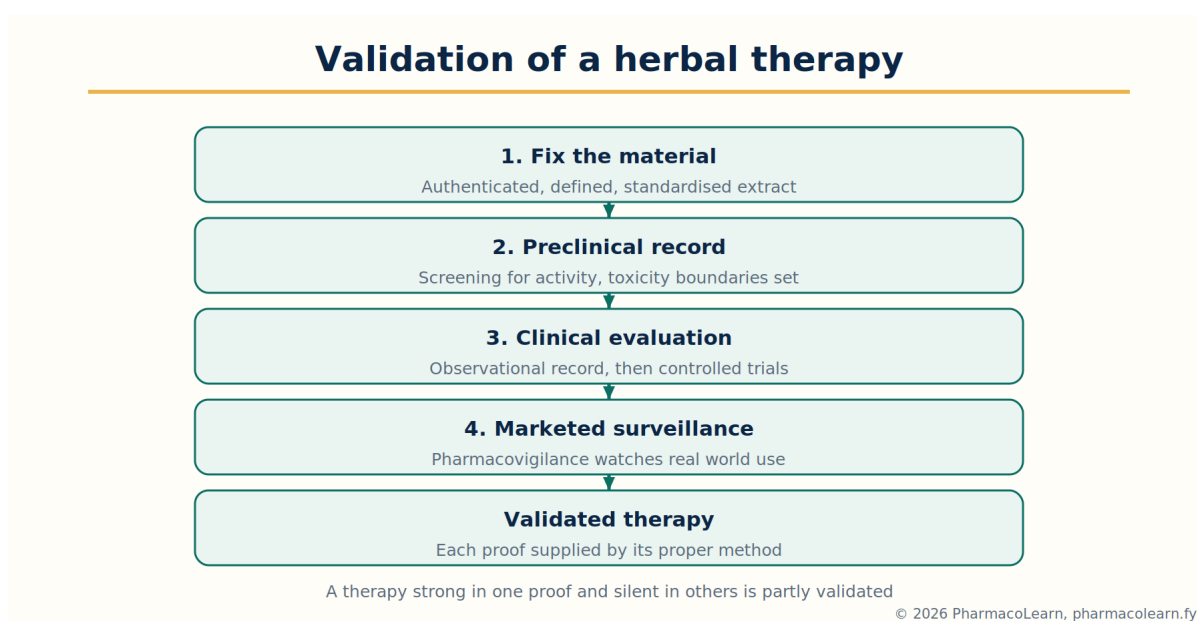


Figure: The validation path. The material is fixed first, the preclinical record and clinical evaluation follow, and surveillance continues after marketing; each proof is supplied by its proper method.

1.4 Toxicity of herbal remedies

The unit title carries toxicity, and the governing idea must be stated plainly: natural origin is not a safety certificate. A plant defends itself with chemistry, and many plant constituents are potent poisons in the wrong dose, the wrong preparation or the wrong patient. The standard teaching examples make the point concretely. Pyrrolizidine alkaloids, present in some traditional herbs and as contaminants from weeds harvested with the crop, injure the liver and can obstruct its veins. Aristolochic acids, from Aristolochia

species substituted or mistaken for other drugs, cause a characteristic kidney failure and urinary tract cancers, one of the clearest lessons in why identity testing of Unit 2 is a safety procedure and not a formality. Ephedra type stimulant herbs act on the heart and blood pressure. Alongside intrinsic toxicity sit the acquired harms: heavy metals, pesticides and microbes carried from field and factory, treated as detection problems in Unit 2, and the deliberate adulteration of some commercial products with undeclared conventional drugs, which converts a quality offence into a poisoning.

Toxicity in herbals also hides better than in conventional medicine. Patients often do not report herbal use to their physicians, adverse events are attributed to the disease rather than the remedy, and under reporting is severe, so the absence of reports is weak evidence of absence of harm. Dose is the final complication: a traditional decoction and a concentrated modern extract of the same plant are exposures of different orders, so a safety record earned by the weak preparation does not automatically transfer to the strong one. The balanced conclusion is the one the subject sustains throughout: herbal toxicity is real, specific and testable, and the correct response is not alarm but the standard apparatus of identification, limits, labelling and surveillance.

1.5 Regulation of herbal medicines

Regulation is society's machinery for making Sections 1.2 to 1.4 compulsory, and the world's systems arrange themselves along one recognisable line: how much proof of efficacy is demanded before a claim may be made. At one end, herbal products are regulated as medicines in full, requiring quality, safety and efficacy dossiers like conventional drugs, the route taken for herbal products that seek therapeutic claims in stringent systems, and for the phytopharmaceutical category recognised in the Indian Drugs and Cosmetics Rules for purified and standardised plant derived fractions. In the middle stand traditional use registration systems, of which the European traditional herbal medicinal products framework is the standard example: quality and safety must be proven in full, while efficacy is accepted on the basis of long standing use, classically thirty years of medicinal use including fifteen within the European Union, and the permitted claims are limited accordingly. At the other end, some systems regulate most herbals as supplements or foods, the United States dietary supplement model being the standard case, where the product may be sold without premarket proof of efficacy, manufacturing quality is still regulated, and claims are confined to structure and function language with the burden of safety action falling largely after marketing.

In India, Ayurvedic, Siddha and Unani medicines are licensed under the Drugs and Cosmetics Act and Rules, manufactured under the good manufacturing practice requirements of Schedule T, and judged against the Ayurvedic and other pharmacopoeias; classical formulations and proprietary medicines follow related but distinct evidential expectations. The World Health Organization runs through all of these as the common reference: its guidelines on the assessment of herbal medicines and its monographs on selected medicinal plants supply the shared vocabulary of quality, safety and efficacy assessment that national systems adapt. For the examination, the systems matter less as lists than as one principle stated three ways: the strength of the claim permitted is matched, in every serious system, to the strength of the evidence supplied.

1.6 Pharmacodynamic issues

Pharmacodynamics, what the drug does to the body, presents three characteristic issues for herbal products. The first is multiplicity: an extract contains many constituents that may act on several targets at once, weakly each and jointly in ways that are difficult to predict from any single constituent, so the pharmacology of the extract is not simply the pharmacology of its marker. The marker itself may not even be the active: a constituent chosen because it is easy to measure may be a passenger while others do the work, which is why Unit 4 profiles name markers as analytical anchors and not automatically as actives. The

second issue is direction of interaction between constituents, described as synergy where the mixture outperforms its parts and antagonism where it underperforms; both are real phenomena in mixture pharmacology, and both are routinely claimed and rarely proven, so the student should treat strong synergy claims as hypotheses requiring the same evidence as any other claim. The third issue is interaction with conventional drugs at the effect level: herbal products with sedative, hypoglycaemic, anticoagulant or stimulant actions add to or oppose prescribed medicines of the same classes, and the classic teaching examples are the bleeding risk when ginkgo, garlic or ginseng preparations meet anticoagulant and antiplatelet therapy, and the additive effect of hypoglycaemic herbs with antidiabetic drugs.

The professional consequences follow directly. A pharmacodynamic claim for a herbal product should be supported at the level of the product, not borrowed from an isolated constituent tested in a different system; dose response, where it exists, should be stated for the preparation actually sold; and interaction potential belongs on the label and in the prescriber's mind, not in the small print of post marketing experience. Unit 5 supplies the experimental methods by which these effect claims are first tested.

1.7 Pharmacokinetic issues

Pharmacokinetics, what the body does to the drug, is where the mixture nature of herbals bites hardest, because absorption, distribution, metabolism and excretion must now be followed for many constituents at once, most of them unmeasured. The characteristic issues should be known as a set. Bioavailability of many plant constituents is low and erratic, limited by poor solubility, degradation in the gut and first pass metabolism, and it varies with the preparation, so the decoction, the dry extract and the isolated constituent of the same plant can deliver very different exposures. Gut bacteria transform many constituents, hydrolysing glycosides to their absorbable aglycones, so the microbiome becomes an unlisted manufacturing step between dose and effect. Plant constituents also change the handling of other drugs: the standard example is St John's wort, whose hyperforin induces the metabolising enzyme CYP3A4 and the transporter P-glycoprotein, lowering blood levels of medicines such as ciclosporin, oral contraceptives and several antivirals, sometimes to the point of treatment failure. Other constituents inhibit metabolic enzymes in vitro, grapefruit type furanocoumarin inhibition being the famous food example of the mechanism, though the step from an in vitro signal to a clinical effect must always be verified in humans before it is taught as fact.

For standardisation the conclusion is practical: since full pharmacokinetic characterisation of a mixture is rarely achievable, control shifts to the input side, a defined extract, a fixed marker range and a consistent process, so that whatever the body does with the product, it does with the same product every time. That is the same discipline Unit 2 enforces analytically and Unit 4 illustrates drug by drug, and it is the realistic answer this subject gives to the pharmacokinetic problem: where exposure cannot be fully measured, manufacture must be fully controlled.

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