

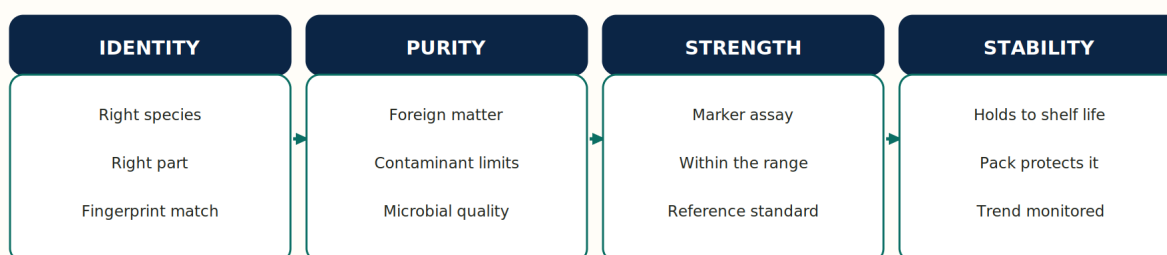
Unit 4: Testing of Natural Products and Drugs

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4.1 Testing of natural products and drugs: what testing must prove

Testing is the laboratory half of quality: the application of defined methods to a sample, against defined limits, to support a decision to accept, reject or release. For natural products the testing programme must prove four things, and organising the unit by them prevents the common error of treating testing as a list of instruments. Identity: the material is the species, part and preparation it claims to be, proved by macroscopic, microscopic, chemical and fingerprint methods of Unit 3. Purity: it is free, within limits, of what should not be there, foreign matter, other species, heavy metals, pesticide residues, microbial load and toxins. Strength: it contains its actives or markers within the specified range, proved by assay. And performance over time: it stays within specification to the end of its shelf life, proved by the stability programme of Sections 4.3 and 4.4. Behind the four proofs stand the disciplines that make any single result believable: sampling that represents the batch, methods validated for the matrix, reference standards of known purity, instruments calibrated, analysts trained and records that allow the result to be reconstructed, the GLP discipline of Unit 2 applied in the QC laboratory. The quality control gate diagram collects the programme.

The four proofs of testing



A batch passes all four gates or it does not pass

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Figure: The four proofs of natural product testing. A batch passes all four gates or it does not pass; strength cannot compensate for failed identity or purity.

4.2 Herbal medicines: clinical laboratory testing

The syllabus places clinical laboratory testing inside the testing unit, and the phrase should be taught in its plain sense: the laboratory testing by which herbal medicines are examined in relation to their clinical use, the testing of the medicine and, where studies are done, of the patient receiving it. On the medicine side, clinical use raises the testing stakes: batches used in clinical evaluation must be fully characterised, authenticated, fingerprinted and assayed, with contaminants excluded, because a clinical result obtained with an uncharacterised product proves nothing and cannot be repeated; the tested, retained batch becomes the chemical definition of what was clinically studied. On the study side, clinical laboratory testing in herbal medicine trials and in safety monitoring covers the standard laboratory safety panel applied to participants, blood counts, liver and kidney function tests and other biochemistry, used to detect organ toxicity, interactions and adverse effects of the herbal product under study, together with testing for the product specific concerns of herbals, such as screening for adulteration with synthetic drugs in products

where that abuse is known. The teaching point that unifies the section: herbal medicines are not exempt from laboratory evidence. The closer a product comes to clinical claims, the more completely it must be characterised chemically and monitored biologically, and the laboratory is where both are done.

4.3 Stability testing of natural products

Stability testing is the programme of studies that shows how the quality of a product varies with time under the influence of environmental factors, and from which shelf life, storage conditions and packing are set. Natural products need the programme in a sharpened form, because their constituents are chemically alive in ways a stable synthetic crystal is not: glycosides hydrolyse, volatile oils evaporate and oxidise, fixed oils turn rancid, enzymes in incompletely dried drugs keep working, pigments and markers fade and degrade in light and heat, and moisture invites microbial growth. The programme therefore tests the attributes that can change: description and physical character, moisture, marker or active assay, fingerprint comparison against the initial profile, degradation products where known, microbial quality, and, for dosage forms, the performance tests of the form such as disintegration and dissolution. The study designs are the standard pair. Long term studies store the product at the storage condition claimed, for the period of the proposed shelf life, testing at planned intervals. Accelerated studies store it under stressed temperature and humidity to reveal the degradation pattern quickly and to predict behaviour, with intermediate conditions used when accelerated results demand them. For herbal products the fingerprint is a stability instrument in its own right: a marker can hold while the wider profile drifts, and the chromatogram comparison catches the drift, which is why Unit 3 fingerprinting returns here as a testing tool.

4.4 Stability protocols

A stability protocol is the written plan that makes a stability study a piece of evidence rather than a set of stored samples. Its contents form a standard list that should be reproduced confidently. Objective and scope: the product, batches and market climate the study serves. Batches: normally production or pilot batches in the marketed pack, identified by number, size and manufacturing date. Storage conditions: the long term, intermediate and accelerated conditions chosen, with the climatic zone reasoning for the intended market stated. Time points: the planned testing intervals across the study. Tests and methods: the stability indicating attributes of Section 4.3, each with its method, and the requirement that assay methods be stability indicating, able to separate and measure the marker in the presence of its degradation products. Acceptance criteria: the specification the product must meet at every time point, shelf life specifications where they differ from release. Packing: the container closure system under test, since stability belongs to product in pack, not product in bulk. Evaluation and conclusions: how trends are assessed, how shelf life is estimated from the data, and what happens on an out of specification or out of trend result, including the effect on the marketed shelf life. The protocol flow below shows a study moving from plan to shelf life decision.

```
Write the protocol: batches, conditions, time points, tests, limits
|
Manufacture and pack the study batches; record time zero results
|
Store under long term and accelerated conditions as planned
|
Withdraw samples at each time point; test against the protocol
|
Compare fingerprint, assay and all attributes with time zero
|
Trend the results: within limits and stable trend?
|
Assign or confirm shelf life, storage statement and pack
|
Continue long term study to confirm the assigned shelf life
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Stability testing: protocol to shelf life



Shelf life is a conclusion from trended data, not a hope on a label

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Figure: The stability workflow. The protocol is written before the first sample is stored; shelf life is a conclusion drawn from trended data, not a hope printed on a label.

4.5 Reading stability results for natural products

The unit closes with the judgement the data demand. Shelf life is assigned from the long term evidence, supported and sometimes shortened by accelerated behaviour; a product whose marker falls steadily is assigned the time at which it is projected to reach its limit, not the time at which it was last seen passing. Storage statements follow the failure mode: protect from light where photodegradation appears, protect from moisture where hydrolysis or microbial risk drives change, store in well closed containers where volatiles escape. Packing changes are a legitimate stability conclusion: a better barrier pack can rescue a product whose chemistry is sound but whose container leaks moisture or oxygen. Retest and expiry language must be used correctly: crude drugs and extracts may carry retest arrangements after which they are re examined before use, while finished products carry expiry dates beyond which they are not used. Stability is where Units 1 to 3 are cashed: the standardised extract, made under GMP to a pharmacopoeial monograph, either holds its specification in its pack for its shelf life or it does not, and the stability file is the proof.

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