

Unit 2: Adulteration and Deterioration

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2.1 Introduction: adulteration and deterioration defined

Adulteration is the practice of substituting the original crude drug, partially or fully, with other similar looking substances that are either free from or inferior in chemical and therapeutic properties, or of adding material that debases the drug's quality. Deterioration is the separate, quieter failure: the genuine drug losing quality over time through moisture uptake, oxidation, light, heat, enzymatic change and attack by insects and microbes, until it no longer meets its standard although nobody has touched it dishonestly. The unit treats them together because the laboratory sees them together, as one question asked of every consignment: is this material what it claims to be, in the condition it should be in? The stakes are those of Unit 1 made concrete. An adulterated drug fails therapeutically at best, since the substituted material lacks the actives, and poisons at worst, when the adulterant is itself toxic or the substitution replaces a safe drug with a dangerous relative. Deteriorated material misleads differently, passing identity tests while its strength has drained away. Quality control of herbal drugs is therefore organised, in this unit's order, as knowledge of the fraud patterns, control of their causes, correct sampling, and then the specific determinations: foreign matter, DNA identity, and the contaminant panel of heavy metals, pesticides, phytotoxins and microbes.

2.2 Types of adulteration and substitution of herbal drugs

The standard classification should be learned as a working list, since each type has its own detection logic.

Substitution with inferior commercial varieties replaces the drug with a cheaper, similar species or grade of lower activity, the classic case being dog senna and other inferior *Cassia* species passed with genuine senna. **Substitution with superficially similar but unrelated drugs** exploits appearance alone, where the substitute may be inert or actively harmful. **Adulteration using artificially manufactured substances** fabricates the drug's form, as with artificial invert sugar imitating honey or moulded and coloured materials imitating structured drugs. **Adulteration using exhausted drugs** returns to the market material from which the valuable constituent has already been removed, volatile oil distilled cloves and extracted ginger being the classical teaching examples: the shape is genuine, the strength is gone.

Adulteration using vegetative parts of the same plant bulks the drug with stems, stalks and other parts of the correct plant that carry little of the active, clove stalks in cloves being the standard case.

Adulteration of powders dilutes ground drugs, where morphology can no longer protect the buyer, with starch, dextrin, chalk, brick powder or exhausted powder of the same drug. **Addition of toxic materials** covers stones and soil added for weight and, in the gravest cases, toxic plant material or undeclared synthetic drugs worked into products. Against deliberate fraud stands unintentional substitution, through confusion of similar names, similar appearance, careless collection and mistaken identity in the field, which produces the same laboratory picture with no fraudster to blame.

One distinction organises the whole list for examination purposes. Some types attack identity, the drug is not the species claimed; some attack strength, the drug is genuine but empty or diluted; and some attack safety, adding what should not be there at all. Detection follows the attack: identity falls to microscopy and DNA, strength to assay and fingerprint, safety to the contaminant determinations of Sections 2.7 to 2.9.

Adulteration: three kinds of attack

IDENTITY ATTACKED	STRENGTH ATTACKED	SAFETY ATTACKED
Inferior varieties substituted	Exhausted drugs resold	Stones and soil for weight
Similar species passed off	Same plant parts as bulk	Toxic plant material added
Wrong plant from the field	Powders diluted	Undeclared synthetic drugs
Detected by microscopy	Deteriorated stock blended	Contaminated collection
Detected by DNA fingerprint	Detected by assay, fingerprint	Detected by contaminant panel

Detection follows the attack: identity, strength and safety each have their tests

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Figure: The types of adulteration grouped by what they attack. Identity frauds, strength frauds and safety frauds each meet a different family of tests.

2.3 Causes and measures of adulteration

The causes divide into the conditions that invite fraud and the failures that permit error. Scarcity is the first cause: a drug in short supply, from a slow growing, over collected or geographically narrow source, commands a price that makes substitution profitable and tempts collectors to stretch the genuine article. High price acts the same way even without scarcity, saffron standing as the permanent example of a drug whose value invites imitation. Seasonal and regional availability leaves gaps that substitutes fill. On the error side, confusion in vernacular names, where one name covers several species across regions, similar morphology between genuine drug and substitute, ignorance or negligence in collection, and faulty storage that deteriorates genuine stock until it is quietly replaced or blended, all feed adulteration without deliberate fraud. Deterioration has its own causes in the same section: excess moisture, heat, light, oxygen, insect infestation and microbial growth during careless storage and transport.

The measures answer the causes in order. Prevention begins in the field and the supply chain, with authenticated source material, good agricultural and collection practices of the kind taught in Semester 1, trained collectors, and purchase from traceable suppliers against specifications. Process control adds correct drying, protected storage and stock rotation, so genuine material is not lost to deterioration and replaced in desperation. Detection is the laboratory programme of the rest of this unit, applied at purchase, at manufacture and in market surveillance, with pharmacopoeial monographs supplying the standards against which material is judged. Enforcement closes the system: licensing of manufacture, inspection, sampling of marketed products and legal consequence for proven fraud, because a detection method without a consequence is merely information. The examination point is that adulteration is controlled as a system, of which the laboratory is one part, not the whole.

2.4 Sampling procedures

Every determination in this unit is performed not on the consignment but on a sample of it, so sampling is the step on which all later evidence stands or falls. The principles are constant across pharmacopoeias and the WHO guidance on quality control of herbal materials. The sample must represent the whole: material is drawn from a spread of containers selected according to the size of the consignment, and from different positions within containers, top, middle and bottom, because settling, moisture and admixture are never evenly distributed. The portions drawn are combined and then reduced by quartering, mixing the bulk, dividing it into quarters, rejecting opposite quarters and repeating until a working sample of manageable size remains, a method that reduces quantity without biasing composition. Samples for different purposes

are kept distinct and labelled with full identity of batch and source: the analytical sample for the laboratory, and a retained reference sample held against future dispute. Sampling itself can contaminate, so clean tools, clean containers and protection from moisture and light during transit are part of the procedure, not courtesies.

Two examination points complete the section. First, sampling intensity responds to risk and history: a trusted supplier with a clean record and a new, unknown or previously failed source are not sampled with the same rigour, and visible heterogeneity of a consignment is itself a finding that widens the sampling. Second, identity work begins at sampling, not in the laboratory: the sampler records appearance, odour and condition of the bulk, because foreign matter, mould and insect damage, Section 2.5, are often visible at the warehouse in a way no extract in a vial will later show.

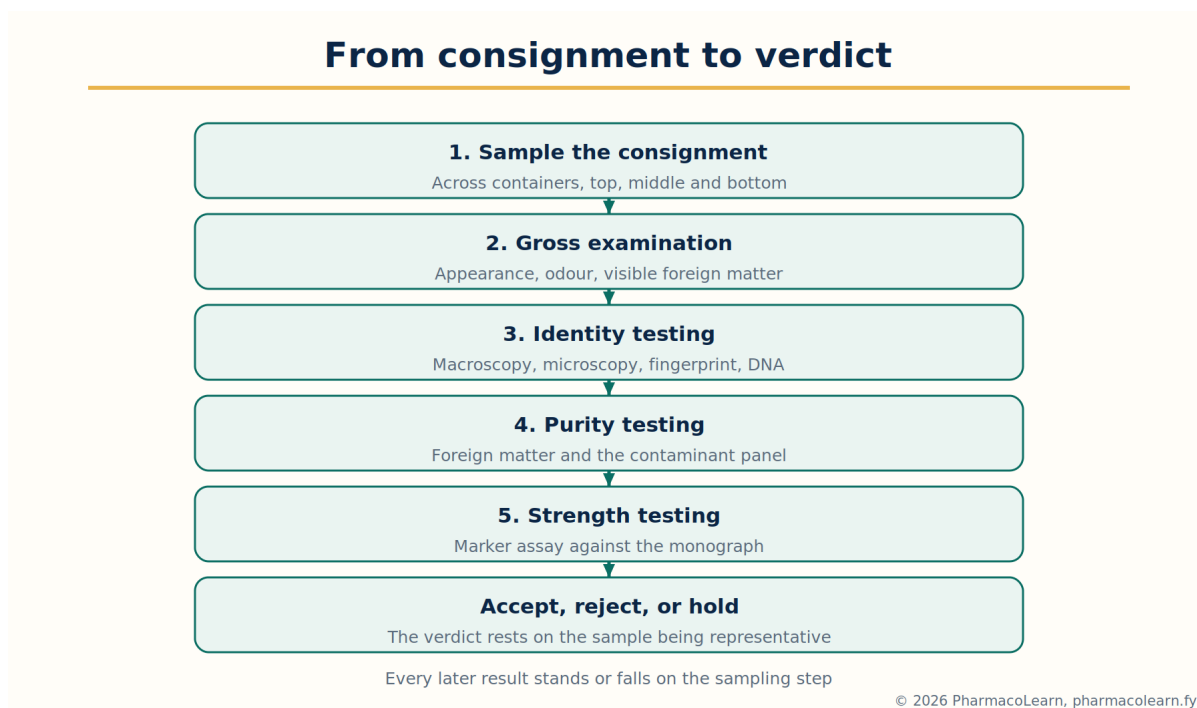


Figure: The detection workflow. Sampling, gross examination, identity, purity and strength determinations lead to the verdict, and every stage rests on the sampling being representative.

The detection workflow of the unit, from consignment to verdict, runs as follows.

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Consignment received and documented
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Sample drawn across containers, positions noted
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Gross examination: appearance, odour, visible foreign matter
|
Identity: macroscopy, microscopy, fingerprint, DNA where needed
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Purity: foreign matter, ash, extractives, contaminant panel
|
Strength: marker assay against the monograph
|
Verdict: accept, reject, or hold for referee testing
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2.5 Determination of foreign matter

Foreign matter is everything in the sample that is not the drug as defined: parts of the plant other than the official part, other plants entirely, soil, stones, sand, animal contamination, mould and insect remains. Its determination is the oldest test in pharmacognosy and remains one of the most informative, because it

measures the care taken at collection and cleaning in a single number. The procedure is direct: a weighed quantity of the sample, taken by the sampling discipline of Section 2.4, is spread and sorted, by eye and under magnification, separating everything foreign, and the separated material is weighed and expressed as a percentage of the sample. For drugs where sorting is impractical the pharmacopoeial methods adapt the principle, using sieving, sedimentation or microscopic estimation as the drug demands.

Pharmacopoeias set a limit for foreign matter in each monograph, and material above the limit fails, however good its assay, because foreign matter is a direct index of the supply chain that produced the batch.

The section connects backward and forward. Backward, foreign matter is where the adulteration types of Section 2.2 first become visible: stalks in a leaf drug, exhausted material mixed with fresh, weed seeds carrying the pyrrolizidine risk of Unit 1. Forward, a high foreign matter result directs the contaminant panel, since material collected carelessly from the ground carries soil borne metals and microbes with it. A low result, conversely, is earned evidence of good practice that no later test can confer retrospectively.

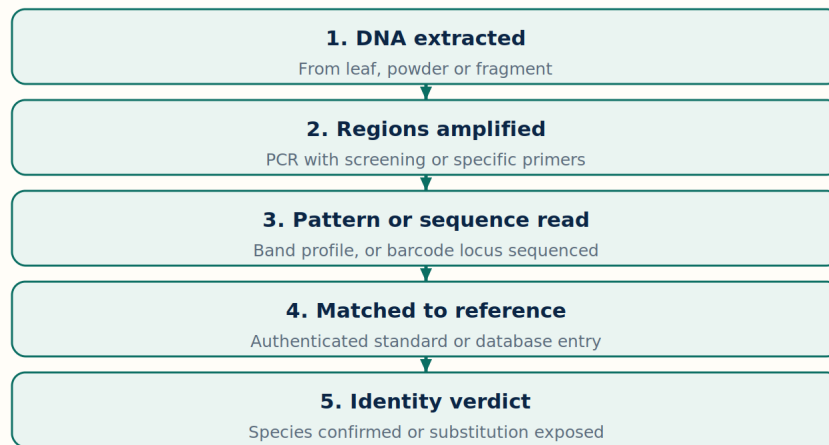
2.6 DNA fingerprinting techniques in identification of drugs of natural origin

Morphology fails exactly where modern trade needs it most: in powders, extracts and fragments, where the structures microscopy reads have been ground away, and between closely related species whose chemistry overlaps. DNA fingerprinting answers by reading identity from the genome itself, which is present in every fragment, unchanged by season, age or growing conditions. The working methods should be known as a family with their logics distinguished. **RAPD**, random amplified polymorphic DNA, amplifies DNA with short arbitrary primers and compares the resulting band patterns; it is fast and needs no prior sequence knowledge, but its reproducibility between laboratories is weak. **AFLP**, amplified fragment length polymorphism, cuts the DNA with restriction enzymes and selectively amplifies fragments, giving many bands and high discrimination at the price of a longer protocol. **ISSR** amplifies the regions between microsatellite repeats, combining simplicity with good polymorphism. **SSR** markers target specific microsatellite loci and are highly reproducible once developed for a species. **SCAR** markers convert a distinctive fragment from a screening method into a single, robust, species specific test, the form in which fingerprinting becomes a routine identity assay. Alongside fingerprinting stands **DNA barcoding**, which sequences a standard short region, the plant core barcode loci *rbcL* and *matK*, with ITS2 widely used for medicinal plants, and matches the sequence against reference databases.

Technique	Basis	Strength	Limitation
RAPD	Arbitrary primer PCR bands	Fast, no sequence data needed	Poor reproducibility
AFLP	Restriction plus selective PCR	Many markers, high discrimination	Long, demanding protocol
ISSR	PCR between microsatellites	Simple, polymorphic	Dominant markers
SCAR	One species specific PCR product	Robust routine identity test	Must be developed per drug
Barcoding	Standard locus sequenced	Database matched, portable	Needs intact DNA, close species may share

The limits must travel with the method, in the examination as in practice. DNA methods prove species identity, not quality: they cannot measure marker content, detect exhaustion, or find chemical contamination, and DNA in highly processed extracts may be too degraded to amplify. DNA fingerprinting therefore takes its place inside the workflow of Section 2.4 as the identity instrument of last resort and highest authority, beside, never instead of, the chemical fingerprint and assay.

DNA fingerprinting for identity



DNA proves species, not strength: chemistry must still be assayed

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Figure: DNA fingerprinting for identity. DNA is extracted, amplified, read as a band pattern or barcode sequence, and matched against an authenticated reference.

2.7 Detection of heavy metals

Heavy metals reach herbal drugs from the ground up and the factory down: contaminated soil and irrigation water where the plant grew, atmospheric deposition near industry and roads, metal contact in processing equipment, and, in some traditional preparations, deliberate mineral ingredients whose control is a separate discipline. The metals of standard concern are lead, cadmium, arsenic and mercury, each with cumulative toxicity at low doses, which is why pharmacopoeias and WHO guidance set limits for them in herbal materials and finished products. Detection is instrumental and follows a fixed logic. The organic matrix is first destroyed, by dry ashing or acid digestion, since the metals must be freed into solution before they can be measured. Measurement is then by atomic spectrometry: flame and graphite furnace **atomic absorption spectrometry** for routine single metal work, **inductively coupled plasma** optical emission or mass spectrometry where many metals are measured together at very low levels, and cold vapour techniques for mercury, which is volatile enough to be measured as a vapour. The examination essentials are the sample preparation, the matching of method sensitivity to the limit being enforced, and the use of reference materials and recovery checks, because a digestion that loses the metal manufactures a false pass.

The contaminant panel

HEAVY METALS	PESTICIDE RESIDUES	TOXINS AND MICROBES
Lead, cadmium	Sprayed crops, stored drugs	Pyrrolizidine alkaloids
Arsenic, mercury	Organochlorine family	Aristolochic acids
From soil, water, plant	Organophosphorus family	Aflatoxins from moulds
Digestion, then AAS	Pyrethroids and others	Microbial limit testing
Or ICP spectrometry	GC and LC with MS	Named pathogen tests

Four contaminant classes, each with its own detection chemistry

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Figure: The contaminant panel of Sections 2.7 to 2.9. Each contaminant class, heavy metals, pesticide residues, phytotoxins and microbes, carries its own detection chemistry.

2.8 Detection of pesticide residues

Medicinal plants are crops, and crops are sprayed; in addition, stored crude drugs have historically been fumigated and protected against insects, so residues of the organochlorine, organophosphorus, carbamate and pyrethroid families can persist into the finished herbal product. Detection is a multi residue problem: dozens of possible compounds at very low levels in a complex plant matrix that interferes at every step. The standard workflow is extraction of the residues from the powdered drug into organic solvent, clean up to remove pigments, oils and other matrix material that would swamp the measurement, and then separation and detection matched to the chemistry of the targets: **gas chromatography** with selective detectors, and increasingly mass spectrometry, for the volatile and heat stable majority, and **liquid chromatography with mass spectrometry** for the polar and heat labile remainder. Results are judged against residue limits set for herbal materials in pharmacopoeial and regulatory lists. Two cautions belong in the answer: a result is only as wide as the panel screened, so the method reports which compounds were sought, and residues concentrate unevenly, which returns the examiner to Section 2.4, since no instrument can correct a sample that never represented the batch.

2.9 Detection of phytotoxins and microbial contamination in herbs and their formulations

The last two items of the contaminant panel concern poisons the plant kingdom and the microbial world contribute themselves. **Phytotoxins** are toxic constituents that arrive with the drug or its adulterants: pyrrolizidine alkaloids from weed contamination of harvested crops, aristolochic acids where Aristolochia species enter the supply, cyanogenic compounds in materials that carry them, and potent cardiac or neurotoxic constituents in substituted species. Their detection is chemical and specific, chromatographic separation with mass spectrometric confirmation being the standard approach, because these toxins act at low levels and cannot be found by general tests. **Microbial contamination** is assessed by the pharmacopoeial microbial limit framework: total aerobic microbial count and total yeast and mould count as the general load, and specified pathogen testing for organisms such as Escherichia coli, Salmonella and Staphylococcus aureus whose presence is unacceptable in oral products. Mycotoxins, above all the aflatoxins produced by Aspergillus moulds on badly stored material, are tested chemically in the same spirit as the phytotoxins, by chromatographic methods after clean up, because their harm is chronic and carcinogenic rather than infectious. Formulations inherit all of it: an extract concentrates whatever the raw material carried, and water based preparations support microbial growth, so the panel is applied to finished

products as well as to crude drugs, with preservative and process controls in manufacture completing what testing begins.

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