LECTURE 9

Standardisation of medicines of plant and animal origin. Medicines from medicinal plants of Kazakhstan

From collection and drying to pharmacopoeial quality indicators, storage and the development of domestic herbal products

Standardisation of Medicines and Raw Materials
Educational programme 6B10102 – Pharmacy · 4th year · Department of Fundamental Medicine, Al-Farabi Kazakh National University

OUTLINE

Lecture plan

1. Raw materials of plant and animal origin
2. Collection rules (WHO GACP) and primary processing
3. Animal raw materials: source, TSE, preservation
4. Quality indicators of herbal drugs (ГФ РК / Ph. Eur.)
5. Herbal extracts and their types
6. Medicinal plants of Kazakhstan and product development; storage

DEFINITIONS

Raw materials of natural origin

Plant origin

- **Herbal drugs:** whole, fragmented or cut plants, parts, algae, fungi, lichens, usually dried
- **Herbal drug preparations:** extracts, tinctures, essential oils, powders
- **Herbal teas:** one or more herbal drugs for infusion or decoction

Animal origin

- **Organs and tissues:** pancreas (pancreatin), intestinal mucosa (heparin), bile
- **Secretions:** wool fat (lanolin); bee products: honey, propolis, wax
- **Regional example:** antlers of maral deer, East Kazakhstan

Common problem: natural variability; quality depends on origin, harvest time, processing and storage

Right plant, right part, right time

Plant part	Time of collection	Example
Buds	Early spring, when swelling	Birch, pine buds
Bark	Spring, during sap flow	Oak, buckthorn bark
Leaves	Budding to flowering	Nettle, bilberry leaves
Flowers	Beginning of flowering	Chamomile, calendula
Herb (aerial parts)	Flowering	St John’s wort, yarrow
Fruits, seeds	Full ripeness	Rose hips, sea buckthorn
Roots, rhizomes	Autumn, or early spring	Dandelion, burdock, liquorice

General rules

- Correct botanical identity
- Dry weather, after dew
- Away from roads, industry, treated fields
- Leave part of the population
- No Red Book species
- Breathable containers; record place and date

Drying temperature depends on what we protect

30–35 °C

Essential-oil plants
mint, chamomile: volatile oils are lost at higher temperature

50–60 °C

Glycosides, alkaloids
fast inactivation of enzymes that destroy them

80–90 °C

Vitamin C-rich fruits
rose hips: rapid drying protects ascorbic acid

Good practice: start drying within hours of collection; thin layer, air flow; leaves in shade; end point: leaves brittle, roots snap; confirmed by loss on drying

Healthy source, fast preservation, full traceability

Source

- Healthy animals under veterinary control
- Veterinary certificate
- TSE risk minimised (Ph. Eur. 5.2.8)

Collection

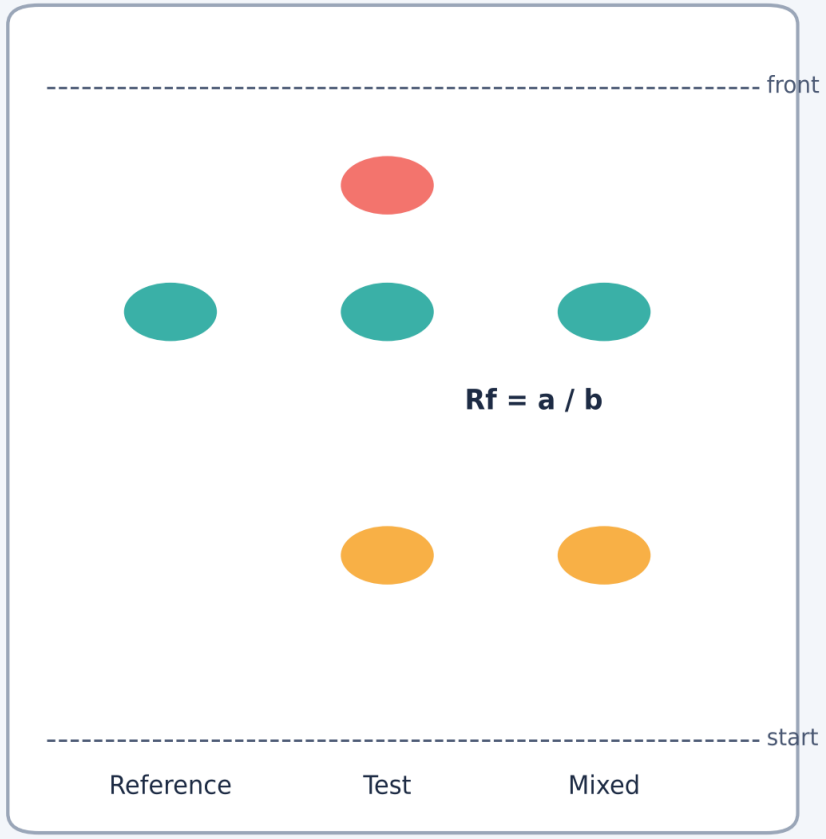
- Organs removed immediately after slaughter
- No contact with gut contents
- Antlers cut at the velvet stage

Preservation

- Rapid chilling or freezing, or drying and defatting
- Unbroken cold chain
- Batch records from animal to raw material

Bee products: apiaries in clean areas, no residues of veterinary drugs, propolis cleaned of wax and debris

Is this the right plant?



Three identification tests

- **A. Macroscopy:** shape, size, colour, surface, fracture, odour
- **B. Microscopy:** diagnostic features of the powder: hairs, stomata, crystals, vessels
- **C. TLC (or HPLC):** chromatographic fingerprint compared with a reference
- **Why all three:** they detect the wrong species, adulteration with a similar plant, the wrong part, exhausted material

Is it clean and safe?

Indicator	Method	Requirement
Foreign matter	2.8.2	≤ 2% unless the monograph states otherwise
Loss on drying / water	2.2.32 / 2.2.13	Limit in the individual monograph
Total ash; ash insoluble in HCl	2.4.16; 2.8.1	Limits in the monograph (minerals; soil and sand)
Heavy metals	2.4.27	Pb ≤ 5.0 ppm, Cd ≤ 1.0 ppm, Hg ≤ 0.1 ppm (unless otherwise stated)
Pesticide residues	2.8.13	Limits listed in 2.8.13
Aflatoxins	2.8.18	B1 ≤ 2 µg/kg; sum B1+B2+G1+G2 ≤ 4 µg/kg, where required
Microbial quality	5.1.8	Category depends on use (e.g. with boiling water)

Marker assay and types of extracts

Assay of herbal drugs

- **Tannins** (bilberry leaves): spectrophotometry
- **Flavonoids** (nettle, bean husks): $AlCl_3$ spectrophotometry or HPLC
- **Ascorbic acid** (rose hips): titration with 2,6-dichlorophenolindophenol
- **Essential oil** (mint, chamomile): distillation, 2.8.12
- **Extractable matter** for teas

Types of extracts

- **Standardised:** adjusted to constituents with known therapeutic activity (e.g. senna, sennosides)
- **Quantified:** adjusted to a range of marker constituents
- **Other:** defined by process and raw material
- **DER:** drug-to-extract ratio, e.g. 5:1

RESOURCE BASE

Medicinal plants of Kazakhstan: antidiabetic example

Plant	Part	Main constituents	In Kazakhstan
Bilberry, Vaccinium myrtillus	Leaves	Tannins, flavonoids	Altai forests, East KZ
Common bean, Phaseolus vulgaris	Pod husks	Flavonoids, amino acids	Cultivated in the south
Dandelion, Taraxacum officinale	Root	Inulin, triterpenes	Widespread
Burdock, Arctium lappa	Root	Inulin	Widespread
Chicory, Cichorium intybus	Root	Inulin, bitter substances	Wild and cultivated
Liquorice, Glycyrrhiza glabra / uralensis	Root	Glycyrrhizin, flavonoids	South KZ, Syr Darya valley
Wild rose, Rosa spp.	Hips	Ascorbic acid, carotenoids	Mountains, river valleys

Technological scheme of an antidiabetic herbal tea

1 Incoming control	2 Cleaning	3 Cutting, sieving	4 Weighing, mixing	5 Filter bags	6 Release
Quarantine, full monograph testing	Remove foreign matter	Particle size by sieve analysis, dust removal	By recipe, second-person check; uniformity	2.0 g per bag; mass of bags checked	Identity of each component, LOD, assay, microbiology

Storage: dry, ventilated, dark; on racks; quarantine / approved / rejected zones; FEFO; aromatic, poisonous and animal raw materials stored separately

Key take-aways

1. **Quality of natural medicines starts in the field:** right plant, part, time, place and drying
2. **Animal raw materials need** veterinary control, TSE risk minimisation and a cold chain
3. **Identity:** macroscopy, microscopy, TLC; purity: foreign matter, ash, heavy metals, pesticides, aflatoxins, microbes
4. **Extracts** are standardised, quantified or other; markers link quality and activity
5. **Kazakhstan’s plant resources** support domestic herbal products when standardised and stored correctly

SELF-CHECK

Control questions and literature

Questions

1. When are roots, leaves and flowers collected?
2. Why are rose hips dried at 80–90 °C and mint at 30–35 °C?
3. Which rules apply to collecting animal raw materials?
4. Name the three identification tests for herbal drugs.
5. Give the heavy metal and aflatoxin limits for herbal drugs.
6. What is the difference between standardised and quantified extracts?
7. Draw the technological scheme of a herbal tea with control points.
8. How must aromatic and animal raw materials be stored?

Sources

- Ph. Eur. 1433 Herbal drugs; 0765 Herbal extracts; 1435 Herbal teas
- Ph. Eur. 2.8.2, 2.4.27, 2.8.13, 2.8.18, 5.1.8, 5.2.8
- WHO guidelines on GACP for medicinal plants (2003)
- State Pharmacopoeia RK, Vols 1–3