

Medicinal plant production

BSc

Minimum questions

(without proper answer to them, the exam can not be accepted and no further question would be set)

1./ What is a medicinal plant in general and in rational (use oriented) term?

In general, all plants may be called medicinal plants which have been used for curing purposes, based on traditions or any literature source.

As a rational, narrower term, medicinal plants are only the species registered as such in official documents. The regulation may be different in each country but in most of them, the Pharmacopoeia consists also plant drugs.

2./ What is a plant drug and how the names of them should be created? (with examples)

A plant drug is the plant part registered in Pharmacopoeias or other official documents. It may be:

- The plant part containing the highest amount of active compounds preserved mostly by drying and having not been processed further on except eventual cutting, chopping, cleaning or other mechanical handlings;
- Primarily product gained directly from the plant raw, like essential oil, fatty oil, balm, resin;
- Material gained from plant raw by simple processes like medical coal, tar

The name is created from the scientific name of the genus and denomination of the drug type (e.g. *Foeniculi fructus*, *Aetheroleum rosmarini*) but in some cases traditional and specific denominations also may exist (e.g. *Liquiritae radix*). The names are written in *italics* like species names.

3./ What is a "Traditional Herbal Medicinal Product" as EU product category?

Based on an EU directive of 2003 a medicinal plant product can be registered simpler than synthetic medicines, if it:

- is appropriate for use without a medical doctor supervision;
- has a well defined efficacy and dosage;
- can be taken orally or externally;
- there are evidences about its use in an EU country for at least 15 years;
- there are enough scientific evidence about its efficacy and safety.

4./ What is a dietary supplement?

A food product which contains special effective compounds in a concentrated form. These products may contain vitamins, minerals, medicinal plants and other natural materials. Officially it is prohibited to announce any health claim on the product. They are subjects of the national food regulation where safety and not efficacy is important.

5./ What do we call effective materials/active compounds of the drugs?

They are chemical compounds or groups of compounds which have justified biological effects (e.g. thymol, apigenin, morphine, etc.).

Other related terms of phytotherapy are:

- marker compound: used primarily for quality check, is well measurable and representing the activity of the drug; (pl. hypericin, gallic acid)
- chaperon compound: supporting absorbance and utilisation of the effective materials in the human body (e.g. oils)

6./ Which are the 5 compound classes and their precursors according to the biogenetical system?

Saccharides – primer products of the photosynthesis (e.g. mucilages, starch)

Phenoloids – containing phenol ring and their formation is going on mostly through the shikimic acid pathway (e.g. tannins, coumarines, flavonoids)

Polyketids – they belong or are derivatives of poly-beta-keto acids and are formed through the malonate/acetate pathway (e.g. pumpkin oil, gamma-linoleic acid, hypericin, stb.)

Terpenoids – derived from mevalonic acid or deoxy-xilulose. Their basic unit is the five carbon atom isoprene and their grouping is made according to the number of these units: C10 = monoterpene, C15 = sesquiterpene, C20 = diterpene, C30 = triterpene, C40= tetraterpene (e.g. essential oils, bitter substances, steroids, carotinoids)
Azotoids – nitrogen containing compounds derived from amino acid precursors (e.g. alkaloids, cyanogenic glycosides)

7./ Where do the active compounds accumulate in the plants and in which average concentrations ?

Active compounds are usually accumulating in exogenous or endogenous storage places in the plant tissues. E.g. essential oils accumulate in oil glands or cavities, alkaloids in milk vessels, mucilages or flavonoids in vacuoles. Most compounds are accumulated in some percentages, fatty oils and saccharides up to 40-50% while alkaloids usually only below 1%.

8./ What do the terms "efficacy", "safety" and "quality" refer to ?

- Efficacy: the physiological effect must be proved either by reliable literature data or by pharmacological investigations. Important measures of this latter are the ED50 value (Effectiv dosage) showing the amount of the target compound (pro kg body mass) which can assure the desired effect at least in 50% of the experimental animals.
- Safety: other important measure is the LD50 value (Lethal dosage) showing the amount of the target compound (pro kg body mass) which would kill 50% of the experimental animals. It means that materials for medical purposes may be used only if they are not toxic, have only limited adverse effects and the conditions and contraindications of their use must be known.
- Quality: means that a product is appropriate for use and fits to the desired parameters. It can be assured among others by the quality assurance arrangements during the production.

9./ What does the „dosage- effect” connection mean?

By elevated dosages of the target compound the physiological effect is increasing. In pharmacological tests usually the values ED1, followed by ED50 and ED99 are set which is followed again by LD1, LD50 and LD 99 (see question 8). Between the ED50 and LD1 the „therapeutical range” is defined. The wider this range is, the more safe the compound is.

10./ What kind of quality assurance (QA) systems are applied during the production of medicinal plant products?

GAP (Good Agricultural Practice): QA system applied during field production, the principles have been fixed by the WHO and EUROPAM (association of European MAP growers).

GMP (Good Manufacturing Practice): QA system applied during preparation of medicines and is guided by the Health authority.

GLP (Good Laboratory Practice): QA applied e.g. during quality test of medicinal plant drugs, basic principles are fixed by international accreditation guidelines.

11./ What is the difference among quality test, quality assurance and quality certification?

- In case of MAPs the quality test is the measuring of the parameters of the target product (drug) and comparing them to the requirements set in the Pharmacopoeia or specific standards.
- Quality assurance is a control process during production of the drug and its primarily and secondary processing.
- certificate is provided by independent accredited partners based on the required documents and certifying its excellent quality. Still rare in MAP sector.

12./ What does the „cereal agrotechnology” cover ? (with examples!)

Applying cereal agrotechnology, the MAP growers use the same equipments and machinery as for the large scale cultivation of cereals crops. These are e.g. machines for the soil preparation, sowing, weeding or harvesting equipments. Frequent in case of coriander, milk thistle or poppy among others.

13./ What is primarily and secondary processing in MAP production?

Primarily processing is all the processes which goal is the production of the drug of required quality. It may include the steps after harvesting like washing, cleaning, sorting, drying, chopping, cutting, etc. Their place is characteristically the agricultural firm.

Secondary processing is all the processes when products ready to consume (e.g. pills, tea mixtures, extracts, syrups, dragees, etc.).

14./ What is the difference between essential (volatile) oils and fatty oils?

Essential oil (Aetheroleum) are mixtures of compounds belonging mostly to the terpenoid group of active compounds (mono- and sesquiterpenes) and less frequently other volatile compounds of small molecular mass. They quickly evaporate at room temperature and are produced by distillation, extraction or pressing.

Fatty oils (Oleum) compounds belong to the group of polyketides, contain saturated or unsaturated fatty acids and/or their esthers. Usually they are thick fluids, non volatile and easy to dry. They are produced by pressing.