Extracts

DEFINITION
Extracts are preparations of liquid (liquid extracts and tinctures), semi-solid (soft extracts) or solid (dry extracts) consistency, obtained from herbal drugs or animal matter, which are usually in a dry state.

Where medicinal products are manufactured using extracts of animal origin, the requirements of chapter 5.1.7. Viral safety apply.

Different types of extract may be distinguished. Standardised extracts are adjusted within an acceptable tolerance to a given content of constituents with known therapeutic activity; standardisation is achieved by adjustment of the extract with inert material or by blending batches of extracts. Quantified extracts are adjusted to a defined range of constituents; adjustments are made by blending batches of extracts. Other extracts are essentially defined by their production process (state of the herbal drug or animal matter to be extracted, solvent, extraction conditions) and their specifications.

PRODUCTION
Extracts are prepared by suitable methods using ethanol or other suitable solvents. Different batches of the herbal drug or animal matter may be blended prior to extraction. The herbal drug or animal matter to be extracted may undergo a preliminary treatment, for example, inactivation of enzymes, grinding or defatting. In addition, unwanted matter may be removed after extraction.

Herbal drugs, animal matter and organic solvents used for the preparation of extracts comply with any relevant monograph of the Pharmacopoeia. For soft and dry extracts where the organic solvent is removed by evaporation, recovered or recycled solvent may be used, provided that the recovery procedures are controlled and monitored to ensure that solvents meet appropriate standards before re-use or admixture with other approved materials. Water used for the preparation of extracts is of a suitable quality. Except for the test for bacterial endotoxins, water complying with the section on Purified water in bulk in the monograph on Purified water (0008) is suitable. Potable water may be suitable if it complies with a defined specification that allows the consistent production of a suitable extract.

Where applicable, concentration to the intended consistency is carried out using suitable methods, usually under reduced pressure and at a temperature at which deterioration of the constituents is reduced to a minimum. Essential oils that have been separated during processing may be restored to the extracts at an appropriate stage in the manufacturing process. Suitable excipients may be added at various stages of the manufacturing process, for example to improve technological qualities such as homogeneity or consistency. Suitable stabilisers and antimicrobial preservatives may also be added.
Extraction with a given solvent leads to typical proportions of characterised constituents in the extractable matter; during production of standardised and quantified extracts, purification procedures may be applied that increase these proportions with respect to the expected values; such extracts are referred to as ‘refined’.

**IDENTIFICATION**

Extracts are identified using a suitable method.

**TESTS**

Where applicable, as a result of analysis of the herbal drug or animal matter used for production and in view of the production process, tests for microbiological quality (5.1.4), heavy metals, aflatoxins and pesticide residues (2.8.13) in the extracts may be necessary.

**ASSAY**

Wherever possible, extracts are assayed by a suitable method.

**LABELLING**

The label states:

- the herbal drug or animal matter used;
- whether the extract is liquid, soft or dry, or whether it is a tincture;
- for standardised extracts, the content of constituents with known therapeutic activity;
- for quantified extracts, the content of constituents (markers) used for quantification;
- the ratio of the starting material to the genuine extract (DER);
- the solvent or solvents used for extraction;
- where applicable, that a fresh herbal drug or fresh animal matter has been used;
- where applicable, that the extract is ‘refined’;
- the name and amount of any excipient used including stabilisers and antimicrobial preservatives;
- where applicable, the percentage of dry residue.

**Liquid extracts — extracta fluida**

**DEFINITION**

Liquid extracts are liquid preparations of which, in general, 1 part by mass or volume is equivalent to 1 part by mass of the dried herbal drug or animal matter. These preparations are adjusted, if necessary, so that they satisfy the requirements for content of solvent, and, where applicable, for constituents.

**PRODUCTION**

Liquid extracts are prepared by using ethanol of a suitable concentration or water to extract the herbal drug or animal matter, or by dissolving a soft or dry extract (which has been produced using the same strength of extraction solvent as is used in preparing the liquid extract by direct extraction) of the herbal drug or animal matter to be extracted, to pieces of suitable size. Mix thoroughly with a portion of the prescribed extraction solvent and allow to stand for an appropriate time. The residue is separated from the extraction solvent and, if necessary, pressed out. In the latter case, the 2 liquids obtained are combined.

A slight sediment may form on standing, which is acceptable as long as the composition of the liquid extract is not changed significantly.

**TESTS**

- **Relative density** (2.2.5). Where applicable, the liquid extract complies with the limits prescribed in the monograph.
- **Ethanol** (2.9.10). For alcoholic liquid extracts, carry out the determination of ethanol content. The ethanol content complies with that prescribed.

**Methanol and 2-propanol** (2.9.11): maximum 0.05 per cent V/V of methanol and maximum 0.05 per cent V/V of 2-propanol for alcoholic liquid extracts, unless otherwise prescribed.

**Dry residue** (2.8.16). Where applicable, the liquid extract complies with the limits prescribed in the monograph, corrected if necessary, taking into account any excipient used.

**Tinctures — tincturae**

**DEFINITION**

Tinctures are liquid preparations that are usually obtained using either 1 part of herbal drug or animal matter and 10 parts of extraction solvent, or 1 part of herbal drug or animal matter and 5 parts of extraction solvent.

**PRODUCTION**

Tinctures are prepared by maceration or percolation (outline methodology is given below) using only ethanol of a suitable concentration for extraction of the herbal drug or animal matter, or by dissolving a soft or dry extract (which has been produced using the same strength of extraction solvent as is used in preparing the tincture by direct extraction) of the herbal drug or animal matter in ethanol of a suitable concentration. Tinctures are filtered, if necessary. Tinctures are usually clear. A slight sediment may form on standing, which is acceptable as long as the composition of the tincture is not changed significantly.

**Production by maceration.** Unless otherwise prescribed, reduce the herbal drug or animal matter to be extracted to pieces of suitable size, mix thoroughly with the prescribed extraction solvent and allow to stand in a closed container for an appropriate time. The residue is separated from the extraction solvent and, if necessary, pressed out. In the latter case, the 2 liquids obtained are combined.

**Production by percolation.** If necessary, reduce the herbal drug or animal matter to be extracted to pieces of suitable size. Mix thoroughly with a portion of the prescribed extraction solvent and allow to stand for an appropriate time. Transfer to a percolator and allow the percolate to flow at room temperature slowly making sure that the herbal drug or animal matter to be extracted is always covered with the remaining extraction solvent. The residue may be pressed out and the expressed liquid combined with the percolate.

**TESTS**

- **Relative density** (2.2.5). Where applicable, the tincture complies with the limits prescribed in the monograph.
- **Ethanol** (2.9.10). The ethanol content complies with that prescribed.
- **Methanol and 2-propanol** (2.9.11): maximum 0.05 per cent V/V of methanol and maximum 0.05 per cent V/V of 2-propanol, unless otherwise prescribed.
- **Dry residue** (2.8.16). Where applicable, the tincture complies with the limits prescribed in the monograph, corrected if necessary, taking into account any excipient used.
HERBAL DRUG PREPARATIONS

Plantae medicinales praeparatae

DEFINITION
Herbal drug preparations are obtained by subjecting herbal drugs to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal drugs, tinctures, extracts, essential oils, expressed juices and processed exudates. Herbal teas comply with the monograph on Herbal teas (1435). Instant herbal teas consist of powder or granules of one or more herbal drug preparation(s) intended for the preparation of an oral solution immediately before use.

STORAGE
Protected from light.

LABELLING
The label states in addition to the requirements listed above:
- for tinctures other than standardised and quantified tinctures, the ratio of starting material to extraction liquid or of starting material to final tincture;
- the ethanol content in per cent V/V in the final tincture.

Soft extracts — extracta spissa

DEFINITION
Soft extracts are semi-solid preparations obtained by evaporation or partial evaporation of the solvent used for extraction.

TESTS
Dry residue (2.8.16). The soft extract complies with the limits prescribed in the monograph.
Solvents. Where applicable, a monograph on a soft extract prescribes a limit test for the solvent used for extraction.

STORAGE
Protected from light.

Dry extracts — extracta sicca

DEFINITION
Dry extracts are solid preparations obtained by evaporation of the solvent used for their production. Dry extracts usually have a loss on drying or a water content of not greater than 5 per cent m/m.

TESTS
Water (2.2.13). Where applicable, the dry extract complies with the limits prescribed in the monograph.
Loss on drying (2.8.17). Where applicable, the dry extract complies with the limits prescribed in the monograph.
Solvents. Where applicable, a monograph on a dry extract prescribes a limit test for the solvent used for extraction.

STORAGE
In an airtight container, protected from light.

HERBAL DRUGS

Plantae medicinales

DEFINITION
Herbal drugs are mainly whole, fragmented, or cut plants, parts of plants, algae, fungi or lichen, in an unprocessed state, usually in dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal drugs. Herbal drugs are precisely defined by the botanical scientific name according to the binominal system (genus, species, variety and author).

PRODUCTION
Herbal drugs are obtained from cultivated or wild plants. Suitable collection, cultivation, harvesting, drying, fragmentation and storage conditions are essential to guarantee the quality of herbal drugs. Herbal drugs are, as far as possible, free from impurities such as soil, dust, dirt and other contaminants such as fungal, insect and other animal contaminations. They are not rotten. If a decontaminating treatment has been used, it is necessary to demonstrate that the constituents of the plant are not affected and that no harmful residues remain. The use of ethylene oxide is prohibited for the decontamination of herbal drugs.

IDENTIFICATION
Herbal drugs are identified using their macroscopic and microscopic descriptions and any further tests that may be required (for example, thin-layer chromatography).

TESTS
Foreign matter (2.8.2). Carry out a test for foreign matter, unless otherwise prescribed or justified and authorised. The content of foreign matter is not more than 2 per cent m/m, unless otherwise prescribed or justified and authorised. A specific appropriate test may apply to herbal drugs liable to be adulterated.
Loss on drying (2.2.32). Carry out a test for loss on drying, unless otherwise prescribed or justified and authorised.
Water (2.2.13). A determination of water may be carried out instead of a test for loss on drying for herbal drugs with a high essential-oil content.
Pesticides (2.8.13). Herbal drugs comply with the requirements for pesticide residues. The requirements take into account the nature of the plant, where necessary the preparation in which the plant might be used, and where available the knowledge of the complete record of treatment of the batch of the plant.
Microbial contamination. Recommendations on the microbiological quality of herbal medicinal products consisting solely of one or more herbal drugs are given in the text 5.1.4. Microbiological quality of pharmaceutical preparations.
Where necessary, herbal drugs comply with other tests, such as the following, for example.
Total ash (2.4.16).
Ash insoluble in hydrochloric acid (2.8.1).
Extractable matter.
Swelling index (2.8.4).