07/2010:1434

HERBAL DRUG PREPARATIONS

Plantae medicinales praeparatae

DEFINITION

Herbal drug preparations are homogeneous products obtained by subjecting herbal drugs to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation.

Herbal drug preparations include, for example, extracts, essential oils, expressed juices, processed exudates, and herbal drugs that have been subjected to size reduction for specific applications, for example herbal drugs cut for herbal teas or powdered for encapsulation.

Herbal teas comply with the monograph *Herbal teas (1435)*.

NOTE: the term *comminuted* used in European Community legislation on herbal medicinal products describes a herbal drug that has been either cut or powdered.

The term *herbal drug preparation* is synonymous with the term *herbal preparation* used in European Community legislation on herbal medicinal products.

07/2017:1433

HERBAL DRUGS

Plantae medicinales

DEFINITION

Herbal drugs are mainly whole, fragmented or broken plants or parts of plants in an unprocessed state, usually in dried form but sometimes fresh. In this general monograph, the word 'plant' is used in the broader sense to also include algae, fungi and lichens. 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).

Whole describes a herbal drug that has not been reduced in size and is presented, dried or undried, as harvested; for example: dog rose, bitter fennel or sweet fennel, Roman chamomile flower.

Fragmented describes a herbal drug that has been reduced in size after harvesting to permit ease of handling, drying and/or packaging; for example: cinchona bark, rhubarb, passion flower.

Broken describes a herbal drug in which the more-fragile parts of the plant have broken during drying, packaging or transportation; for example: belladonna leaf, matricaria flower, hop strobile.

Cut describes a herbal drug that has been reduced in size, other than by powdering, to the extent that the macroscopic description in the monograph of the herbal drug can no longer be applied. When a herbal drug is cut for a specific purpose that results in the cut herbal drug being homogeneous, for example when cut for herbal teas, it is a herbal drug preparation. Certain cut herbal drugs processed in this way may be the subject of an individual monograph.

A herbal drug that complies with its monograph and is subsequently cut for extraction shall comply in its cut form, except for its macroscopic description, with the monograph for that herbal drug, unless otherwise justified.

The term *herbal drug* is synonymous with the term *herbal substance* used in European Community legislation on herbal medicinal products.

DRIED HERBAL DRUGS

PRODUCTION

Dried herbal drugs are obtained from cultivated or wild plants. Suitable collection, cultivation, harvesting, drying, fragmentation and storage conditions are essential to guarantee their quality.

Dried 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 herbal drug are not affected and that no harmful residues remain. The use of ethylene oxide is prohibited for the decontamination of herbal drugs.

IDENTIFICATION

Dried 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. An appropriate specific test may apply to dried herbal drugs liable to be adulterated. It may not be possible to perform the test for foreign matter on a dried herbal drug that is cut, as described under Definition, for either a specific purpose or for extraction. Under these circumstances the cut material is presumed to comply with the test for foreign matter providing that the dried herbal drug prior to cutting was compliant with this test.

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 dried herbal drugs with a high essential-oil content.

Pesticides (*2.8.13*). Dried 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 treatment record of the batch of the plant.

Heavy metals (*2.4.27*). Unless otherwise stated in an individual monograph or unless otherwise justified and authorised:

- *cadmium*: maximum 1.0 ppm;
- *lead*: maximum 5.0 ppm;
- *mercury*: maximum 0.1 ppm.

Where necessary, limits for other heavy metals may be required.

Where necessary, dried 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*).

Bitterness value (*2.8.15*).

Aflatoxin B_1 (*2.8.18*). Where necessary, limits for aflatoxins may be required.

Ochratoxin A (*2.8.22*). Where necessary, a limit for ochratoxin A may be required.

Radioactive contamination. In some specific circumstances, the risk of radioactive contamination is to be considered.

Microbial contamination. Where a dried herbal drug is used whole, cut or powdered as an ingredient in a medicinal product, the microbial contamination is controlled (*5.1.8. Microbiological quality of herbal medicinal products for oral use and extracts used in their preparation* or *5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use* (e.g. for cutaneous use)).

ASSAY

Unless otherwise prescribed or justified and authorised, dried herbal drugs are assayed by an appropriate method.

STORAGE

Protected from light.

Where used for the production of essential oils, some of the tests prescribed for dried herbal drugs may no longer be necessary. This is considered on a case-by-case basis depending on the provenance of the dried herbal drug and the production process. The need for testing (e.g. for potential contaminants) and the stage of testing (herbal drug/essential oil) is to be considered.

FRESH HERBAL DRUGS

A fresh herbal drug is one that is intended to be processed into a herbal drug preparation (e.g. essential oil, juice, tincture) within a relatively short period of time after harvesting. Under these circumstances, the extensive analysis prescribed for dried herbal drugs is not appropriate and the following analytical requirements, based on the provenance of the fresh herbal drug, are considered suitable, provided that processing to the herbal drug preparation takes place within a validated time period after harvesting.

(1) For a fresh herbal drug that has been cultivated from seeds, cuttings, etc., whose origin and traceability can be demonstrated, and where the complete history of the herbal drug from planting to harvesting is documented:

- macroscopic identification of the plant and plant parts to be processed;
- compliance with a suitable limit test for foreign matter.

(2) For a cultivated fresh herbal drug where the information on life cycle from seed to harvesting, as described under (1), is incomplete, the same analytical requirements as described under (1) apply, as well as any additional tests that may be necessary depending on the information available on the herbal drug to be processed and any potential or known quality issues.

(3) For a fresh herbal drug that is wild-crafted, the analytical requirements should be assessed on a case-by-case basis and will depend on the ease of identification or characterisation of the herbal drug/herbal drug preparation and potential adulterants, and the method of processing or type of herbal drug preparation to be manufactured. For example, in the case of essential oils, the majority of the oil composition is determined when it is analysed, whereas for a juice or a tincture, such analytical capabilities are limited. For the processing of plant parts, a wild-crafted fresh flower, easily identifiable by its distinctive appearance and colour, would be expected to require fewer analytical control parameters than a wild-crafted fresh root with few, if any, visually distinctive features. Analytical requirements as described under (1) may be acceptable when fully justified.

For fresh herbal drugs, where the extensive analysis described for dried herbal drugs is not feasible prior to processing into the herbal drug preparation, appropriate tests (e.g. for contaminants) are performed on a suitable retained sample of the fresh herbal drug or on the herbal drug preparation.

Fresh herbal drugs may be frozen for storage purposes. Defined processes for freezing and thawing are required to ensure the quality of the herbal drug. Appropriate testing of the herbal drug, justified on the basis of the freezing and manufacturing processes, is put in place and may include testing prior to freezing and at the time of use.

When handling and processing fresh herbal drugs, it is necessary to ensure, by visual inspection or other suitable means, the absence of unwanted fermentation, the presence of which may alter the quality of the herbal drug preparation, including possible mycotoxin production.

01/2013:1435

HERBAL TEAS

Plantae ad ptisanam

DEFINITION

Herbal teas consist exclusively of one or more herbal drugs intended for oral aqueous preparations by means of decoction, infusion or maceration. The preparation is prepared immediately before use.

Herbal teas are usually supplied in bulk form or in bags for single use.

The herbal drugs used comply with the appropriate individual European Pharmacopoeia monographs or in their absence with the general monograph *Herbal drugs (1433)*.

IDENTIFICATION

The identity of herbal drugs present in herbal teas is checked by suitable methods such as botanical examinations and/or chromatographic profiles.

TESTS

Recommendations on the microbiological quality of herbal teas (*5.1.8*) take into account the prescribed preparation method (use of boiling or non-boiling water).

The proportion of herbal drugs present in herbal teas is checked by appropriate methods.

Herbal teas in bags comply with the following test:

Uniformity of mass. Determine the individual and the average mass of the contents of 20 randomly chosen units as follows: weigh a single full bag of herbal tea, open it without losing any fragments. Empty it completely using a brush. Weigh the empty bag and calculate the mass of the contents by subtraction. Repeat the operation on the 19 remaining bags and calculate the average mass of the contents of the 20 units. Unless otherwise justified, not more than 2 of the 20 individual masses deviate from the average mass by more than the percentage deviation shown in the table below and none deviates by more than twice that percentage.

Average mass	Percentage deviation
less than 1.5 g	15 per cent
1.5 g to 2.0 g included	10 per cent
more than 2.0 g	7.5 per cent

STORAGE

Protected from light.