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INTRODUCTION

All general texts and other monographs of the European Pharmacopoeia that are relevant to homoeopathy are applicable.

The 'Homoeopathy' chapter of the European Pharmacopoeia contains general monographs and individual monographs describing starting materials and preparations used virtually exclusively for homoeopathic medicines. Reference to these monographs for other purposes may be authorised by licensing authorities.

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HOMOEOPATHIC PREPARATIONS

Praeparationes homoeopathicae

DEFINITION

Homoeopathic preparations are prepared from substances, products or preparations called stocks, in accordance with a homoeopathic manufacturing procedure. A homoeopathic preparation is usually designated by the Latin name of the stock, followed by an indication of the degree of dilution and/or potentisation, if applicable.

Raw materials

Raw materials for the production of homoeopathic preparations may be of natural or synthetic origin.

For raw materials of zoological or human origin, adequate measures are taken to minimise the risk of agents of infection, including viruses (*5.1.7*), in the homoeopathic preparations. For this purpose, it is demonstrated that:

- the method of production includes a step or steps that have been shown to remove or inactivate agents of infection;
- where applicable, raw materials of zoological origin comply with the monograph *Products with risk of transmitting agents of animal spongiform encephalopathies (1483)*;
- where applicable, the animals and the tissues used to obtain the raw materials comply with the health requirements of the competent authorities for animals for human consumption;
- for materials of human origin, the donor follows the recommendations applicable to human blood donors and to donated blood (see *Human plasma for fractionation (0853)*), unless otherwise justified and authorised.

A raw material of botanical, zoological or human origin may be used either in the fresh state or in the dried state. Where appropriate, fresh material may be kept deep-frozen. Raw materials of botanical origin comply with the requirements of the monograph *Herbal drugs for homoeopathic preparations (2045)*.

Where justified and authorised for transportation or storage purposes, fresh plant material may be kept in ethanol (96 per cent) or in ethanol of a suitable concentration, provided the whole material including the storage medium is used for processing.

Raw materials comply with any requirements of the relevant monographs of the European Pharmacopoeia.

Vehicles

Vehicles are excipients used for the preparation of certain stocks or for the potentisation process. They may include, for example: purified water, ethanol of a suitable concentration, glycerol and lactose.

Vehicles comply with any requirements of the relevant monographs of the European Pharmacopoeia.

Stocks

Stocks are substances, products or preparations used as starting materials for the production of homoeopathic preparations. A stock is usually one of the following: a mother tincture or a glycerol macerate, for raw materials of botanical, zoological or human origin, or the substance itself, for raw materials of chemical or mineral origin.

Mother tinctures comply with the requirements of the monograph *Mother tinctures for homoeopathic preparations (2029)*.

Glycerol macerates are liquid preparations obtained from raw materials of botanical, zoological or human origin by using glycerol or a mixture of glycerol and either ethanol of a suitable concentration or a solution of sodium chloride of a suitable concentration.

Potentisation

Dilutions and triturations are obtained from stocks by a process of potentisation in accordance with a homoeopathic manufacturing procedure: this means successive dilutions and succussions, or successive appropriate triturations, or a combination of the 2 processes.

The potentisation steps are usually one of the following:

- 1 part of the stock plus 9 parts of the vehicle; they may be designated as 'D', 'DH' or 'X' (decimal);
- 1 part of the stock plus 99 parts of the vehicle; they may be designated as 'C' or 'CH' (centesimal).

The number of potentisation steps defines the degree of dilution; for example, 'D3', '3 DH' or '3X' means 3 decimal potentisation steps, and 'C3', '3 CH' or '3C' means 3 centesimal potentisation steps.

'LM' potencies are manufactured according to a specific procedure with a 50 000 dilution factor by alternate steps of liquid dilution and impregnation of pillules. The number of potentisation steps defines the degree of dilution, for example, 3rd LM means 3 successive LM dilutions.

Dosage forms

A dosage form of a homoeopathic preparation complies with any relevant dosage form monograph in the European Pharmacopoeia, and with the following:

- for the purpose of dosage forms for homoeopathic use, 'active substances' are considered to be 'dilutions or triturations of homoeopathic stocks' or 'homoeopathic stocks' (in case of a mother tincture or a glycerol macerate);
- these dosage forms can contain one or more 'active substances';
- they are prepared using appropriate excipients.

Homoeopathic dosage form 'pillule'

Pillules for homoeopathic use are solid preparations obtained from sucrose, lactose or other suitable excipients. *Pillules for homoeopathic preparations (2153)* are intended for impregnation or coating with one or more homoeopathic preparations. The impregnated pillules comply with the requirements of the monograph *Homoeopathic pillules, impregnated (2079)*. The coated pillules comply with the requirements of the monograph *Homoeopathic pillules, coated (2786)*. Both are intended for sublingual or oral use.

Homoeopathic dosage form 'tablet'

Tablets for homoeopathic use are solid preparations obtained from sucrose, lactose or other suitable excipients according to the monograph *Tablets (0478)*. They may be prepared either by compressing one or more 'active substances' with the excipients or by impregnating preformed tablets with one or more liquid 'active substances'. The preformed tablets for impregnation are obtained from sucrose, lactose or other

suitable excipients according to the monograph *Tablets (0478)*. Tablets for homoeopathic use are intended for sublingual or oral use.

Homoeopathic dosage forms 'parenteral preparation', 'eye preparation', 'nasal preparation'

For the last potentisation step(s), an ethanol-free vehicle is used to minimise the content of ethanol in the final preparation.

The residual ethanol content (*2.9.10*) is not greater than 1 per cent *V/V* unless otherwise justified and authorised.

Manufacturing methods

Homoeopathic preparations are manufactured using a range of methods of preparation and are presented in various dosage forms (covered by general dosage form monographs). The methods of preparation are described in the monograph *Methods of preparation of homoeopathic stocks and potentisation (2371)*. The use of certain preparations obtained using the methods listed below is restricted to certain dosage forms as indicated in Table 1038.-1.

Table 1038.-1.

Manufacturing methods	Dosage forms
2.1.2	Eye drops Solutions for injection Nasal preparations
2.2.1, 2.2.2, 2.2.3	Eye drops Coated homoeopathic pillules Solutions for injection Nasal preparations Ointments, creams and gels Oral powders (triturations) Suppositories
2.2.4	Solutions for injection
3.1.2, 3.2.2	Eye drops Coated homoeopathic pillules Solutions for injection Nasal preparations Ointments, creams and gels Suppositories

The competent authority has the right to accept or reject particular combinations of manufacturing method and substance.

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HERBAL DRUGS FOR HOMOEOPATHIC PREPARATIONS

Plantae medicinales ad praeparationes homoeopathicas

DEFINITION

Herbal drugs for homoeopathic preparations are mainly whole plants or parts of plants, fragmented or broken, and include algae, fungi or lichens, in an unprocessed state, usually in fresh form. The state, fresh or dried, in which the drug is used, is defined in the individual monograph of the European Pharmacopoeia or, in its absence, in the individual monograph of an official national pharmacopoeia of a member state. In the absence of such a monograph, the state in which the herbal drug is used has to be defined. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal drugs for homoeopathic preparations. Herbal drugs for homoeopathic preparations are precisely defined by the botanical scientific name of the source species according to the binomial system (genus, species, variety and author).

Whole describes a herbal drug for homoeopathic preparations that has not been reduced in size and is presented, dried or undried, as harvested.

Fragmented describes a herbal drug for homoeopathic preparations that has been reduced in size after harvesting to permit ease of handling, drying and/or packaging.

Broken describes a herbal drug for homoeopathic preparations in which the more fragile parts of the plant have broken during drying, packaging or transportation.

For dried herbal drugs for homoeopathic preparations, *cut* describes size reduction, other than powdering, that reduces the particle size below that which is described in the macroscopic identity of the herbal drug for homoeopathic preparations.

PRODUCTION

Herbal drugs for homoeopathic preparations are obtained from cultivated or wild plants. Suitable collection, cultivation, harvesting, sorting, drying, fragmentation and storage conditions are essential to guarantee the quality of herbal drugs for homoeopathic preparations.

Herbal drugs for homoeopathic preparations are, as far as possible, free from impurities such as soil, dust, dirt and other contaminants such as fungal, insect and other animal contaminants. They do not present signs of decay.

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 for homoeopathic preparations.

Fresh herbal drugs are processed as rapidly as possible after harvesting. Where justified and authorised for transportation or storage purposes, fresh plant material may be deep-frozen; it may also be kept in ethanol (96 per cent) or in ethanol of a suitable concentration, provided the whole material including the storage medium is used for processing.

Adequate measures have to be taken in order to ensure that the microbiological quality of homoeopathic preparations containing 1 or more herbal drugs comply with the recommendations given in general chapter *5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use.*

IDENTIFICATION

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

TESTS

The tests for foreign matter and loss on drying should be performed before any further processing of the fresh plant.

Foreign matter (*2.8.2*). Where a fresh plant is used as a starting material for the manufacture of homoeopathic preparations, the content of foreign matter is as low as possible; if necessary, the maximum content of foreign matter is indicated in the individual monograph.

Where a dried plant is used as a starting material for the manufacture of homoeopathic preparations, carry out a test for foreign matter, unless otherwise prescribed in the individual monograph. The content of foreign matter is not more than 2 per cent *m/m*, unless otherwise prescribed or justified and authorised.

Adulteration. A specific appropriate test may apply to herbal drugs for homoeopathic preparations liable to be falsified.

Loss on drying (*2.2.32*). Carry out a test for loss on drying on dried herbal drugs for homoeopathic preparations.

If a fresh plant is processed more than 24 h after harvesting, a test for loss on drying should be carried out. The minimum limit is indicated in the individual monograph.