

This is an unofficial translation of a monograph in the Swiss Pharmacopoeia, published in Supplement 10.2. It is not legally binding.

Anthroposophic Preparations

Definition

Anthroposophic preparations are developed and composed according to the principles of anthroposophic cognition of humans, animals, substances and nature and are appropriate to be used in accordance with these principles.

They are produced according to methods used in anthroposophic pharmacy.

An anthroposophic preparation may contain one or more active substances as well as vehicles and other excipients.

According to anthroposophic principles, active substances may be starting materials which are used as such or starting materials which have been transformed into active substances by a process of anthroposophic pharmacy, including compositions.

Compositions are active substances which are obtained, when two or more starting materials or preparations, with or without excipients, are processed together in a pharmaceutical process of anthroposophic pharmacy (e.g. Ferrum-Quarz).

Vehicles are excipients, which are used to produce active substances (e.g. in the process of potentiation, substances as water, alcohol, whey, lactose, rice starch or glycerine are used). Further excipients are used in the preparation of dosage forms.

Starting Materials

Starting materials for the production of anthroposophic preparations are substances of natural or synthetic origin, in particular :

- Minerals, rocks, metals, natural waters (e.g. sea water)
- Starting materials of botanical origin are usually from certified biodynamic or organic cultivation or sustainable wild plant harvesting: dried or fresh plants or parts of plants, including algae, fungi and lichens; plant secretions, juices, extracts (fractions), oleoresins, essential oils or distillation products (e.g. Pix betulae). Plants may be treated by fertilizing them specially with metal preparations or minerals during cultivation;
- Starting materials of zoological origin: whole animals, parts of animals (e.g. organ preparations), glandular secretions from animals, extracts (e.g. Iecoris oleum), calcareous deposits (e.g. Conchae);

Organ preparations are starting materials taken from healthy warm-blooded animals raised according to adequate and suitable, usually biodynamic standards: fresh or dried organs or parts of organs (including bones, glands), organ extracts, tissue or parts of tissue, preparations from fresh blood;

- Starting materials which can be characterised chemically (e.g. Cuprum metallicum, Aesculinum);

Starting materials used for the production of anthroposophic preparations must comply with the following requirements, where applicable:

- the general requirements for starting materials of the Pharmacopoeia (Ph.Eur. and Ph.Helv.), the German Homoeopathic Pharmacopoeia (GHP/HAB), the French Pharmacopoeia (Ph.F.) or the British Homoeopathic Pharmacopoeia (B.Hom.P.);
- the general requirements for homoeopathic preparations of the Pharmacopoeia, in particular the requirements of the general monograph **Homoeopathic preparations** of the European Pharmacopoeia;
- specific requirements of particular monographs of the Pharmacopoeia, the GHP (HAB), the Ph.F. or, or an appropriate quality monograph of the manufacturer, when there is no particular monograph in a pharmacopoeia. This quality monograph must comply with the requirements listed in Appendix 1 part II C 2 of the Ordinance for complementary and phytochemical Medicines (Komplementär – und Phytoarzneimittelverordnung, KPAV), SR 812.212.24.

For starting materials of zoological origin, adequate measures must be taken to minimise the risk of the presence of agents of infection, including viruses, in the anthroposophic preparation (see Ph.Eur. **Viral safety** (5.1.7)).

For this purpose it must be demonstrated, that

- the method of production includes a step or steps that have been shown to remove or inactivate agents of infection.
- where applicable, starting materials of zoological origin comply with the monograph of the Ph.Eur. **Products with risk of transmitting agents of animal spongiform encephalopathies (Producta cum possibili transmissione vectorium encephalopathiarum spongiformium animalium)**.
- where applicable, the animals and tissues used to obtain raw materials comply with the food law requirements of the competent authorities for animals for human consumption.

In addition, for cells, tissue and organs, it must be demonstrated that the used production methods devitalise the material (devitalisation in the sense according to article 2, paragraph 2, letter a of the law relating to transplantation, SR 810.21).

Starting materials of botanical origin must comply with the monograph of the Ph.Eur. **Herbal drugs for homoeopathic preparations (Plantae medicinales ad praeparationes homoeopathicas)**.

Methods of Preparation

Methods of preparation used in anthroposophic pharmacy include:

- homoeopathic preparation methods of the Pharmacopoeia (Ph.Eur. and Ph.Helv.), the GHP/HAB or the Ph.F.
- anthroposophic methods of preparation described in the GHP/HAB or the B.Hom.P., (methods 1, 2, 3, 4, 5a, 5b, 6, 8a and 12)
- Specific anthroposophic production processes⁽¹⁾

Specific anthroposophic production processes are methods, based on an anthroposophic understanding of medicinal products, such as:

- heat and cold treatments (wet and dry processes, including rhythmic treatments and specific fermentation processes)
- specific methods used for manufacturing products from plants, minerals and metals
- comminuting, dissolving or surface-drying of starting material without further processing
- specific mixing processes

Dilutions and triturations can be produced by potentisation from concentrated preparations by applying an anthroposophic production process.

Anthroposophic pharmacy mainly uses decimal attenuation, rarely centesimal or vicesimal attenuation.

Dosage forms

An anthroposophic preparation may be used in all dosage forms described in the Pharmacopoeia or the GHP/HAB, which correspond to the perception of anthroposophic medicinal products.

All dosage forms of anthroposophic preparations must comply with the monograph of the relevant dosage form of the European Pharmacopoeia, unless otherwise justified.

⁽¹⁾ See for example “Anthroposophic Pharmaceutical Codex” of the International Association of Anthroposophic Pharmacists (IAAP) (www.iaap.org.uk/downloads/codex.pdf)