IAAP

International Association of Anthroposophic Pharmacists

ANTHROPOSOPHIC PHARMACEUTICAL CODEX APC

EDITION 4.1
2018

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Introductory Note APC edition 4.1, 2018

International Association of Anthroposophic Pharmacists, IAAP

The IAAP is the international umbrella organisation of the national associations of Anthroposophic Pharmacists.
Its purpose, objective and tasks are, in detail:

- To represent anthroposophic pharmacy in the anthroposophic-medical movement and in public life on an international level: Anthroposophic pharmacy is understood as an extension of conventional pharmacy.
- To establish standards regarding further education and training as well as practice in anthroposophic pharmacy (including but not limited to retail pharmacy).
- To set quality standards regarding manufacturing methods and substances used for anthroposophic medicinal products.
- To promote research in anthroposophic pharmacy.
- To achieve international recognition by specialised publications and training material for anthroposophic pharmacists.
- To certify national training programmes in anthroposophic pharmacy.
- To certify individuals as anthroposophic pharmacists.
- To establish a cooperative network between anthroposophic pharmacists to exchange information and best practice throughout the world.
- To award the quality label "Anthromed® Pharmacy" to pharmacies which have competence in advice and manufacture of anthroposophic medicines.
- To initiate / coordinate international activities.

It is in respect of setting and maintaining the quality standards that the Board is pleased to publish edition 4.1 of the Anthroposophic Pharmaceutical Codex (APC). This edition will, as the 4th edition, only be presented in an electronic version.

Only minor changes to the 4th edition have been done. The monographs and requirements of the current version of the European Pharmacopoeia (Ph. Eur.) 9.5 have been taken into account. All references to the British Homoeopathic Pharmacopoeia have been deleted since the relevant manufacturing methods are now integrated in the Swiss Pharmacopoeia or in the APC itself. Some references for use have been added. All substantive amendments are marked by a line to the side of the text.

In addition, two new substances, missing in the 4th edition has been added.

The APC is reviewed and updated by an anthropo¬sophic pharmaceutical committee reporting to the IAAP board.

The changes in summary:

NEW TEXTS

Appendix 2.3
Corpus striatum from the calf

Appendix 2.7
Equisetum arvense, Fermentatio cum Sero Lactis 1:4

REVISED TEXTS

Part IIa:
Introduction
Survey of general methods for the manufacturing of anthroposophic medicinal products and related specific production methods in pharmacopoeias

3. Tinctures
Method 3.13

Part IV: Appendices
IVAA Statement concerning starting materials of animal origin
Appendix 2.4
Ammonium carbonicum
Appendix 2.7
Carex arenaria, ethanol. Decoctum 1:4

Members of the APC committee

Gabriele Jones, pharmacist, Germany, member of the Further Education Committee of GAPiD.

Peter Pedersen, pharmacist, Denmark, former member of the Committee on Manufacturing Methods of the German Homoeopathic Pharmacopoeia (GHP/HAB).

René Schwarz, biology technician, former head of production Weleda Switzerland, Board member of VAEPS.

Responsible person of the IAAP:

Mónica Mennet-von Eiff, pharmacist, Switzerland, President of the Swiss association VAEPS, Board member of the IAAP; member of the Working Group HOM on Homoeopathic Raw Materials and Stocks of the European Pharmacopoeia (Ph. Eur. HOM WP).

The APC is recognised by the following national anthroposophic pharmaceutical associations:

the **French** Association **AFERPA** (Association Française d'étude et de recherche sur la pharmacie anthroposophique – French Association for Studies and Research on Anthroposophic Pharmacy);
the **Brazilian** Association **Farmantropo** (Associação Brasileira de Farmácia Antroposófica – Brazilian Anthroposophic Pharmacy Association);
the **German** Association **GAPiD** (Gesellschaft Anthroposophischer Apotheker in Deutschland – Society of Anthroposophic Pharmacists in Germany);
the **Austrian** Association **ÖGAPh** (Österreichische Gesellschaft anthroposophischer Pharmazeuten – Austrian Society of Anthroposophic Pharmacists);
the **Italian** Association **SOFAI** (Società di farmacisti antroposofi in Italia – Society of Anthroposophic Pharmacists in Italy);
the pharmacist section of the **Swiss** association **VAEPS** (Verband für Anthroposophisch Erweiterte Pharmazie in der Schweiz – Association for Anthroposophically Extended Pharmacy in Switzerland);
the Japanese Association AAPJ (Japanese Association of anthroposophic oriented pharmacists).

Dr. Manfred Kohlhase, President IAAP 28.3.2018

Dr. Mónica Mennet-von Eiff, Responsible person of the IAAP

Foreword

Pharmacy extended by the principles of anthroposophy began to be developed at the beginning of the 20th century by Rudolf Steiner (founder of anthroposophy, 1861 – 1925) and Oskar Schmiedel (Austrian chemist, 1887 – 1959), in collaboration with a number of physicians. Their aim was to reinterpret and complement the results of pharmaceutical and medical research with insights gained from anthroposophic research of the human being and nature.
The basis of the anthroposophic approach to pharmacy is the "holistic" knowledge of mankind and nature, which recognizes the notion that human beings and the kingdoms of nature are related through a common evolution[1].
This perception leads to a comprehensive view of substances in their relationship to health, illness and to a specific approach to pharmacy.

Therefore anthroposophic pharmacy uses substances from the mineral, plant and animal kingdoms[2,3].

Anthroposophic medicinal products have been on the market world-wide and prescribed by qualified medical practitioners since 1921.

The range of anthroposophic medicinal products is partially determined by the physical characteristics of substances, whereby allopathic, phytotherapeutic and homoeopathic criteria are taken into consideration. Most particularly, anthroposophic medicinal products are characterised by their manufacturing processes involving specific anthroposophic and typical homoeopathic pharmaceutical procedures. The range of anthroposophic medicinal products includes potentised medicinal products, manufactured by using the methods of the official homoeopathic pharmacopoeias, as well as concentrated mineral, herbal or animal substances or preparations and compounded medicinal products. Considering this diversity, anthroposophic medicinal products, cannot be defined under a single substance classification.

[1] Jos Verhulst: „Der Erstgeborene" (The first-born), publisher Verlag Freies Geistesleben, Stuttgart, D 2001.
[2] Rudolf Steiner/Ita Wegman: „Grundlegendes für eine Erweiterung der Heilkunst nach geisteswissenschaftlichen Erkenntnissen." GA 27, publisher Rudolf Steiner Verlag, Dornach, CH, 1992.
In English: „Extending Practical Medicine – Fundamental Principles based on the Science of the Spirit". Rudolf Steiner Press , London, GB, 1996.
[3] Rudolf Steiner: „Geisteswissenschaft und Medizin", 20 Vorträge für Ärzte (1920), Rudolf Steiner Verlag, Dornach, CH 1985.
In English: „Introducing Anthroposophical Medicine" (previously published as: Spiritual Science and Medicine). Twenty lectures to doctors. Dornach 21 March – 9 April 1920, GA 312. Anthroposophic Press, Hudson, NY, USA, 1999.

The *Anthroposophic Pharmaceutical Codex APC* gives an overview of substances and methods used in the manufacture of anthroposophic medicinal products as well as of the related quality parameters.

Legal Situation
Today the European Union Directive 2001/83/EEC and amendments contain the main legislation concerning medicinal products. The legal status of anthroposophic medicinal products in the EU is closely related to that of homoeopathic medicinal products (see below).

Preamble of Directive 2001/83/EEC n° (22) refers to anthroposophic medicinal products as follows:
"Anthroposophic medicinal products, which are described in an official pharmacopoeia and prepared by a homoeopathic method are to be considered, as regards to registration and marketing authorization, as homeopathic medicinal products."

From a regulatory point of view anthroposophic medicinal products can be devided into two categories:
- anthroposophic medicinal products manufactured according to a homoeopathic manufacturing method within the meaning of Directive 2001/83/EEC, article 1, 5.:
  "Any medicinal product prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States. (...)"
- anthroposophic medicinal products other than those manufactured by a homoeopathic manufacturing method.

These are equally important and have never been included in any pharmacopoeia.

The definitions of anthroposophic medicinal products given in the Swiss and German Drug Laws take both categories into account (translations by APC Committee):

Switzerland: Regulation of Swissmedic concerning the simplified Authorisation of Complementary and Herbal Medicinal Products (Verordnung des Schweizerischen Heilmittelinstituts über die vereinfachte Zulassung von Komplementär- und Phytoarzneimitteln)
Art. 4,2 f: Anthroposophic medicinal product: Medicinal product, whose active substances are manufactured by a homoeopathic manufacturing procedure, or according to an anthroposophic manufacturing procedure described in the German Homoeopathic Pharmacopoeia or in the British

Homoeopathic Pharmacopoeia or according to a special anthroposophic manufacturing procedure and that is formulated and developed according to the anthroposophic knowledge of man, animal, substance and nature and is meant to be used according to these principles.

Germany: Medicinal Products Act (Gesetz über den Verkehr mit Arzneimitteln)
Art. 4, (33) An anthroposophic medicinal product is a medicinal product that has been developed according to the anthroposophic knowledge of man and nature and that is manufactured according to a homoeopathic manufacturing procedure described in the European Pharmacopoeia or in absence thereof in a pharmacopoeia officially used in the Member States or according to a special anthroposophic manufacturing procedure and that is meant to be used according to the anthroposophic principles concerning man and nature.

In many EU countries, and also world-wide, medicinal products used for the anthroposophic therapeutics are thus partially integrated in legislation.

In Brazil as well as in Australia the APC has been officially recognised as quality standard and reference for anthroposophic medicinal products (RESOLUÇÃO RDC No – 26, DE 30 DE MARÇO DE 2007; amendments to the Australian Therapeutic Goods Act, 2009).

In summary anthroposophic medicinal products as a whole are step by step gaining legal recognition in the EU as well as world-wide, and among other things this requires comprehensive publication of their pharmaceutical quality.

The publication of the *Anthroposophic Pharmaceutical Codex* is to provide transparency of anthroposophic pharmaceutical quality for pharmacists and bodies requiring an appreciation of anthroposophic medicinal products and pharmacy. Furthermore it provides a basis for the maintenance of existing and development of new anthroposophic medicinal products.

The relationship of the APC to the European Pharmacopoeia, to other existing official Pharmacopoeias and non official pharmacopoeias

The APC is published by the IAAP, an independent association of professional pharmacists, within the context of official existing pharmacopoeias. It is the intention of the APC to refer where possible to existing pharmacopoeias. In fact anthroposophic medicinal products are often manufactured and controlled according to existing specifications and standards.
A part of the reference pharmacopoeias for the APC are published by official Authorities, in particular
The European Pharmacopoeia
The French Pharmacopoeia
The German Homoeopathic Pharmacopoeia (which is a part of the German Pharmacopoeia);
The Swiss Pharmacopoiea has implemented two texts concerning anthroposophic pharmacy in the last eight years:

- in 2009 (Suppl. 10.1) with the general Ph.Helv.-monograph "Praeparationes anthroposophicae (Anthroposophic Preparations)" (Ph.Helv. CH 306); it was the first time that anthroposophic preparations appeared as a monograph in an official pharmacopeia. This monograph includes the paragraphs definitions, starting materials, methods of preparation and dosage forms, by analogy with the Ph.Eur.-monograph Homoeopathic preparations Ph.Eur. 1038.
- in September 2013 (Suppl. 11.1) the new Ph.Helv.-chapter "17.7 Manufacturing methods for anthroposophic preparations" came into force. This chapter gives an overview on the general manufacturing processes and describes in more detail some manufacturing methods which are more frequently used in anthroposophic pharmacy and had not been described in an official pharmacopoeia before.

The APC served as important basis to establish both of these Ph.Helv.-texts. Therefore it can be concluded, that the continuing work of the APC supports the establishment of the pharmaceutical quality standards and the regulation of anthroposophic medicinal products in Switzerland.

Further official pharmacopoeias of reference:
The Austrian Pharmacopoeia
The British Pharmacopoeia

In particular the *European Pharmacopoeia* today represents and for the future will represent a reference of paramount importance for the APC.

Therefore in part IV of the APC containing the lists of the various substances used in anthroposophic pharmacy reference is made where possible to the European Pharmacopoeia and other official pharmacopoeias.

Particularly important Ph.Eur. monographs are:
Herbal drugs for homoeopathic preparations (2045)
Homoeopathic preparations (1038)
Methods of preparation of homoeopathic stocks and potentisation (2371)
Minimising the risk of transmitting animal spongiform

encephalopathy agents via human and veterinary medicinal products (50208)
Mother tinctures for homoeopathic preparations (2029)
Tinctures (chapter in 0765 Extracts)
Viral safety (50107)
Other pharmacopoeias referred to in the APC are not officially recognised. Nevertheless they provide reliable standards accepted e.g. by regulatory authorities.

The IAAP understands its task to sustain anthroposophic pharmaceutical activities at any level (e.g. manufacturing, quality control, regulatory affairs), **worldwide**, that is, beyond the countries of the European Pharmacopoeia Convention. Therefore during the evolution of the APC other official pharmacopoeias (or reliable private pharmacopoeias) will possibly be referred to, e.g. the Brazilian Pharmacopoeia.

Table of Content

Structure of the Anthroposophic Pharmaceutical Codex, APC

Part I "Definitions" provides definitions and describes quality aspects as well as parameters related to anthroposophic medicinal products. The different stages incurred in the obtaining of a medicinal product, from the starting material to the dosage form, are described in this part.

Part IIa "General Monographs of specific production methods (Pharmaceutical processes)" contains general monographs concerning the types of preparations/ active substances that are prepared by specified procedures. Beneath the relevant general monograph(s), different specific production methods by which a particular type of a starting material can be prepared are either quoted from other pharmacopoeias or an APC production method is set out.

In this way, the relationship between the APC and other pharmacopoeias, as well as the option to define substances through their production methods are outlined.

Schematically the following order is applied:

General monographs

Definition, Identification, Tests, Assay, Storage, Recommended Designation

Specific production methods related to the particular general monograph

Ph.Eur. Methods	*HAB Methods*	*Ph.fr. Methods*	*APC Methods*

Part IIb "Monographs of starting materials and preparations" sets standards for specific starting materials and preparations. In their last section the monographs of the starting materials list
a) Some existing anthroposophic preparations that utilise the starting material and/ or
b) Manufacturing methods, described in the Ph.Eur., the HAB or the APC commonly used for the processing of the particular starting material. That list is not meant to be exhaustive.

Part III, information about dosage forms in anthroposophic pharmacy as well as production methods of specific dosage forms for anthroposophic medicinal products.

Part IV "Appendices"

In **appendix I** starting materials for the preparation of anthroposophic medicinal products are listed (not excipients and vehicles). The appendices are numbered according to the related chapter in part I: 2.1., 2.2., 2.3., 2.4., 2.5., 2.6.

In **appendix II** a link to the HPUS is given:
- Correlation table: Ph.Eur./HAB manufacturing methods used in anthroposophic pharmacy and corresponding manufacturing in the HPUS.

List of Abbreviations and Symbols

*	see p. 63
1 CH	Symbol for the first centesimal potency, see also C1 and 1C
1 DH	Symbol for the first decimal potency, see also D1 and 1X
1C	Symbol for the first centesimal potency, see also 1 CH and C1
1X	Symbol for the first decimal potency, see also 1 DH and D1
ABMA-Vademecum	Gardin NE, Schleier R: Medicamentos Antroposóficos: Vademecum. Associação Brasileira de Medicina Antroposófica. São Paolo: Editor João de Barro; 2009
APC	Anthroposophic Pharmaceutical Codex
aph	ad preparationes homoeopathicae
API	Active Pharmaceutical Ingredient
B.P.	British Pharmacopoeia
C1	Symbol for the first centesimal potency, see also 1 CH and 1C
CVD	Chemical Vapour Decomposition
D1	Symbol for the first decimal potency, see also 1 DH and 1X
DAB	Deutsches Arzneibuch (German Pharmacopoeia)
DAC	Deutscher Arzneimittel-Codex (German Codex of Medicinal Products)
DER	Drug extract ratio
EU	European Union
fhp	for homoeopathic preparations
GHP	German Homoeopathic Pharmacopoeia. Unauthorized translation of the HAB. In case of differences between the GHP and the HAB the latter is decisive
Gl	Symbol for mother tinctures prepared by HAB method 41 using glycerol
H 2.2.6	Analytical method specified in the HAB
HAB	Deutsches Homöopathisches Arzneibuch (German Homoeopathic Pharmacopoeia)
HPUS	The Homœopathic Pharmacopœia of the United States
IAAP	International Association of Anthroposophic Pharmacists
IVAA statement 2013	see p. 65
KC Monograph	Monograph of the "Kommission C" (Commission of the German Ministry of Health for the anthroposophic therapeutic system and substances), published in the official Gazette of the German government (in German: "Bundesanzeiger")
Liste HAS	Liste der Homöopathischen und Anthroposophischen Stoffe (Anhang 4 zurVerordnung des Schweizerischen Heilmittelinstituts über die vereinfachte Zulassung von Komplementär- und Phytoarzneimitteln (List of Homoeopathic and Anthroposophic Subtances (Appendix 4 in the Regulation of the Swissmedic concerning the simplified Authorisation of Complementary and Herbal Medicinal Products in Switzerland))
LM	Symbol for potencies prepared according to Ph.Eur. (2371) 5.2
MT	Mother tincture
Ph.Eur.	European Pharmacopoeia
Ph.Eur. (2371)	Ph.Eur. Monograph 2371 "Methods of preparation of homoeopathic stocks and potentisation"
Ph.fr.	Pharmacopée Française (french Pharmacopoeia), including monographies de souches pour préparations homéopathiques (monographs of the stocks for homoeopathic preparations)
Ph.Helv.	Pharmacopoea Helvetica (Swiss Pharmacopoeia)
pph	pour préparation homöopathiques
Q	Symbol for potencies diluted by the ratio 1: 50 000
Rh	Symbol for mother tinctures prepared by HAB methods 21 and 22 (rhythmic procedure)

Vade-mecum	Gesellschaft Anthroposophischer Ärzte in Deutschland (ed.) Vademecum Anthroposophische Arzneimittel 3.erg. Aufl. Der Merkurstab 2013; 66 (Suppl.)

Glossary

In this glossary only those terms are referred to, that need extra clarification prior to the definitions given in part I.

Composition	Definition given in the monograph "Anthroposophische Zubereitungen", (Anthroposophic preparations), Swiss Pharmacopoeia, Supplement 10.2, (translation by Swissmedic): "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)."
Excipient	Excipients are auxiliary substances, which may be used for the production of pharmaceutical dosage forms. Excipients may be used in the production of mixtures.
Pharmaceutical process	General term for substance transformations at different stages to obtain starting materials for medicinal products or a medicinal product.
Preparation/active substance	A class of processed starting material specified in the monographs of part II.
Production method	A general manufacturing procedure specified in a pharmacopoeia (see e.g. HAB).
Raw material	Substance which has not undergone any pharmaceutical process and meets a general quality characterisation, e.g. an optical identification.
Starting material	A substance or a composition that meets a specification and can be used as active substance or can be further processed.
Vehicle	Vehicles are auxiliary substances which may be used to produce an active substance. Vehicles may be used in the production of mixtures.

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PART I

Definitions

Table of Content
Part I

1. Anthroposophic medicinal product

DEFINITION

An anthroposophic medicinal product is conceived, developed and produced in accordance with the anthroposophic knowledge of man, nature, substance and pharmaceutical processing[1]. The application within anthroposophic medicine results from that knowledge[2].

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.

An anthroposophic medicinal product can contain one or more active substances (see also part I, chapter 4).

An anthroposophic medicinal product can fundamentally be employed in every dosage form, including external (topical), internal and parenteral dosage forms (see also part III).

PRODUCTION

The active substances or dosage forms of anthroposophic medicinal products are produced:

- in accordance with classical homoeopathic or anthroposophic-homoeopathic manufacturing methods as described in the Ph.Eur., HAB, Ph.fr., and B.Hom.P. (Methods 1, 2, 3, 4, 5a, 5b, 6, 8a, 12)
- in accordance with anthroposophic pharmaceutical codex production methods, i.e. "APC Methods"

and/or

- in accordance with anthroposophic manufacturing methods described in the individual monograph.

An anthroposophic medicinal product complies with the relevant specifications/ monographs set out in parts I and II.

RECOMMENDED DESIGNATION

Concerning the *designation* of anthroposophic medicinal products a reference to the APC is recommended.

2. Starting materials, general information

Starting materials for the production of anthroposophic medicinal products are:

2.1. Minerals, rocks, including natural waters

2.2. Starting materials of botanical origin
Dried or fresh plants or parts of plants, including algae, fungi and lichens;
Plant secretions, juices, extracts, oleoresins, essential oils or distillation products.

2.3. Starting materials of zoological origin
Whole animals, organs, parts of organs dried or fresh;
Animal secretions, extracts, blood products, calcareous products.

2.4. Starting materials that can be described chemically

2.5. Starting materials that have undergone special treatment

2.6. Compositions (for further information see "Glossary"

Starting materials for the production of anthroposophic medicinal products comply with any relevant monograph in the European Pharmacopoeia or in the absence thereof, with the relevant monographs in national pharmacopoeias used in the Member States, or in absence thereof with the individual monograph.

Starting materials can be active substances themselves or can be processed into preparations (see also Part I, chapter 4).

[1] See IAAP brochure: "Basic Information on the Working Principles of Anthroposophic Pharmacy", 2005, http://www.iaap.org.uk/downloads/principles.pdf

[2] For clarification it has to be mentioned here, that anthroposophic medicine from the beginning includes "Over the Counter" products (OTC). A part of its medicinal products had been conceived right from the start for broad use for typical health disorders; see Chapter XX, "Typical Remedies", in Rudolf Steiner/Ita Wegman: "Grundlegendes für eine Erweiterung der Heilkunst nach geisteswissenschaftlichen Erkenntnissen." GA 27, publisher Rudolf Steiner Verlag, Dornach, CH, 1992.
In English: "Extending Practical Medicine – Fundamental Principles based on the Science of the Spirit". Rudolf Steiner Press , London, GB, 1996.

2.1. Minerals, rocks, including natural waters
Minerals are solid, crystalline components of natural origin belonging to the earth's crust and other celestial bodies. A mineral has a defined crystal system and crystal class. Minerals are chemically and physically homogeneous to a significant extent. In reality, however, there are always deviations from the theoretical mineral formula. Many minerals may show differences in their colours. Form and habitus may be significantly different within the same type.

Rocks are composed of one or more minerals having a geological definition and distribution in their natural deposit with a certain statistical homogeneity.

Pieces that will be used for production should be big enough to allow mineralogical identification. If a powdered mineral is used, adequate documentation should ensure the quality and natural origin. In fact pieces used for production must be free from visible foreign matter. They have not undergone any unwanted mechanical or chemical treatment: in particular any chemical reaction, colouring, varnishing, heating and artificial radiation must be excluded. The amount of foreign matter accepted after chemical analysis is specified in the respective monograph.

Natural waters can come from a natural source (e.g. Levico), from the sea (e.g. aqua maris) or from mineral cavities (e.g. agate water).

List of minerals, rocks, including natural waters: see part IV, appendix 2.1.

2.2. Starting materials of botanical origin
Starting materials of botanical origin are:
- Dried or fresh plants or parts of plants, including algae, fungi and lichens;
- Plant secretions, juices, extracts, oleoresins, essential oils or distillation products.

Fresh plants should be used shortly after harvest. If this is not possible, the quality is guaranteed by appropriate measures, e.g. freezing.

If material from cultivated plants is used preference should be given to materials from plants cultivated by biodynamic cultivation ("Demeter" certified) or by other certified organic cultivation methods in accordance to the relevant European regulations ruling organic agricultural products (see also Council Directive (EEC) n° 2092/91).
If wild plants are harvested protection of species according to relevant regulations is granted and special care is taken of the eco-system concerned.

Plants or parts of plants 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 decayed.

Harvested plants or the mother tinctures made thereof are analysed for content of heavy metals and pesticides. The range and frequency of this testing can occur according to a monitoring plan based on risk assessment.

Unless otherwise stated, the collecting or harvesting times are generally:

Whole plants with underground parts and plants without underground parts	at flowering time
Leaves and shoots	when fully developed
Flowers	shortly after opening
Bark	throughout the year
Underground parts of annual plants	at seed ripening time
Underground parts of biennial and perennial plants	in spring
Fruits and seeds	at the time of ripening
Fungi	when the fruiting bodies are fully developed

Particle size: according to Ph.Eur. 2.1.4 Sieves.

Starting materials of botanical origin see part IV, appendix 2.2.

2.3. Starting materials of zoological origin
Starting materials of zoological origin are:
- Whole animals, organs, parts of organs dried or fresh;
- Animal secretions, extracts, blood products, calcareous products.

Lower animals as well as warm-blooded animals are used.

Animal husbandry and keeping must be adequate for the animal species (see also Council Directive (EEC) n° 2092/91). In particular in the case of warm-blooded species animals from well-monitored "Demeter" or biodynamic herds are preferentially used.

The starting materials of zoological origin must meet the requirements of the European and/ or relevant national pharmacopoeias regarding the preparation of medicinal products from materials of animal origin and with EU directives and/or national guidelines of the appropriate regulatory authorities.
In particular the Ph.Eur. monographs on TSE safety (Ph.Eur. 50208), and viral safety (Ph.Eur. 50107) apply.

Animals must be healthy and in good hygienic condition. The intervals given in legislation after the administration of drugs to animals must be observed before the animals are used.

Health requirements, animal keeping, protection of species and processing of animals must comply with the relevant guidelines of responsible national authorities and those of the European Union, where applicable.

List of starting materials of zoological origin see part IV, appendix 2.3.

2.4. Starting materials that can be described chemically
Starting materials that can be described chemically are inorganic and organic substances.
Organic substances are generally of natural origin, e.g. purified fractions.

Preference should be given to clearly traceable substances, that comply with the quality standards in 2.1, 2.2, 2.3.

List of starting materials that can be described chemically see part IV, appendix 2.4.

2.5. Starting materials that have undergone special treatment
Starting materials that have undergone a special treatment are: e.g. plants, parts of plants cultivated by special treatment (see part IIa, chapter 1.1. Vegetabilisation methods of substances used for mother tinctures).

List of starting materials that have undergone special treatment see part IV appendix 2.5.

2.6. Compositions
Different starting materials described in 2.1, 2.2, 2.3, 2.4, 2.5 undergo one or more pharmaceutical processes that will lead to a substance that cannot be described as an addition of its ingredients. The rationale for the synthesis is an anthroposophic formula, in accordance with the anthroposophic understanding of man and nature[1].

List of compositions see part IV, appendix 2.6.

3. Vehicles and excipients

Vehicles are auxiliary substances, which may be used for the production of active substances (e.g. ethanol to obtain an extract or lactose monohydrate to obtain a potentised preparation). Vehicles are also used in the production of mixtures (see part IIa, chapter 9).

Excipients are auxiliary substances, which may be used for the production of the pharmaceutical dosage forms (e.g. NaCl to obtain an isotonic solution for parenteral preparations). Excipients are also used in the production of mixtures (see part IIa, chapter 9).

Vehicles and excipients used in the manufacture of anthroposophic medicinal products comply with the relevant requirements of the European Pharmacopoeia or of the national pharmacopoeias used in the EU Member States.

4. Active substances

4.1. Starting materials
Active substances can be starting materials themselves or preparations.
Starting material used directly as active substances may be the final dosage form, e.g. a herbal tea.

4.2. Preparations
Preparations are obtained from one or more starting materials.

Preparations comply with the specifications described in part II or in the individual monograph.

Preparations can be the final dosage form or can be processed further, e.g. to obtain mixtures.

[1] As an example see: "Biodoron/Kephalodoron" , in Persephone N° 12, M. Kohlhase editor; publisher Verlag am Goetheanum, Dornach, CH, 1998.

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PART IIa

General monographs of preparations and specific production methods (Pharmaceutical processes)

Table of Content Part IIa

Introduction

Brief description of the main pharmaceutical processes applied in anthroposophic pharmacy

Several pharmaceutical processes are described in existing homoeopathic pharmacopoeias as "production methods". These homoeopathic pharmacopoeial production methods can be seen as examples of the general anthroposophic pharmaceutical principle described in the general APC monographs of part IIa.

In anthroposophic pharmacy the treatment of the raw or starting materials can already be part of the pharmaceutical processing, e.g. a plant can be cultivated under treatment with a metal or mineral preparation.

Metals can either be used as a concentrated starting material or undergo a pharmaceutical process depending on the rationale of the anthroposophic therapeutics.

Preparations can be differentiated according to the thermal condition or treatment in the pharmaceutical process. Hereby follows a scheme concerning the related pharmaceutical processes applied to plant material and the main sphere of action.

Preparations may be the final dosage form, be incorporated into the final dosage form or be processed further, e.g. by potentisation.

Treatments in liquid phase

Pharmaceutical process	Heat/cold degree	Starting material	Main sphere of therapeutic action [1, 2]
Cold maceration	2 – 8 °C	fresh or dried plants, all parts	System of nerves and senses throughout the whole organism
Maceration	15 – 25 °C	fresh plants, all parts	system of nerves and senses throughout the whole organism
Rhythmic processing	4/37 °C	fresh plants, all parts	rhythmic system
Digestion	37 °C	fresh plants, leaves, flowers	rhythmic system, circulation
Infusion	60 – 90 °C	dried leaves, flowers	metabolic system, any type of gland
Decoction	ca 100 °C	dried roots, barks, seeds	metabolic system, digestive tract (stomach, intestine)
Distillation	steam, ca 100 °C	fresh or dried plants, all parts	metabolic system, digestion

Treatments in dry phase

Pharmaceutical process	Heat degree	Starting material	Main sphere of therapeutic action [1, 2]
Toasting	170 – 250 °C	dried plants, all parts, dried zoological starting material	metabolic system, digestion (liver)
Carbonisation	above 200 °C	dried plants, all parts, zoological starting material	metabolic system, kidney organisation
Ash process	above 500 °C	dried plants, all parts, zoological starting material	region of the lungs (respiration)

A crucially important pharmaceutical process is potentisation:

- Potentised preparations are gradually diluted substances, whereby at each diluting step a rhythmic succussion (liquid potencies) or trituration (solid potencies) has been carried out.
- During this process the surface of the vehicle and the substance to be potentised are expanded and the mixing is thorough. The potentising time differs for solid and liquid potentised preparations. Astronomical aspects may be considered (e.g. solar or lunar eclipse). Anthroposophic pharmacy mainly uses decimal attenuations. For co-potentised preparations the ratio between active substances to vehicle may vary, differing from 1:10 for homoeopathic co-potentising methods (see also Part IIa, 8 "Potentised Preparations").

[1]General scheme for the correlation between spheres of therapeutic action/ degree of potentisation:

Mother tincture – D10	Metabolic system
D11-D20	Rhythmic system
>D20	System of nerves and senses

See also:
International Federation of Anthroposophic Medical Associations, "The System of Anthroposophic Medicine", pp. 26-28 at ***http://www.ivaa.info/userfiles/file/SystemAnthroposMedicine2011_Interaktiv.pdf***

[2] See IAAP brochure: "Basic Information on the Working Principles of Anthroposophic Pharmacy", 2005, http://www.iaap.org.uk/downloads/principles.pdf
Meyer U. & Pedersen P.A. (ed.): Anthroposophische Pharmazie, Salumed Verlag Berlin 2016.

Survey of general methods for the manufacturing of anthroposophic medicinal products and related specific production methods in pharmacopoeias

General method of the APC	Related specific production method			
	Ph.Eur. (2371)	**HAB**	**Ph.Helv.**	**APC**
1. Special treatment of raw materials				
1.1. Vegetabilisation methods of substances used for mother tinctures			17.7.1.1, 17.7.1.2	1.1.1, 1.1.2
2. Metal preparations				
2.1. Metal mirrors			17.7.2.1 – 17.7.2.4	2.1.1, 2.1.2, 2.1.3, 2.1.4
3. Tinctures and oil extracts				
3.1. Cold treated mother tinctures and liquid preparations thereof		38	17.7.6	
3.2. Tinctures made by maceration with water or ethanol/water	1.1.1 – 1.1.11 1.3.1	12b, c, m, n, o, p, q	17.7.7.1	3.2.1, 3.2.2
3.3. Tinctures made by maceration with glycerol	2.1.1 – 2.1.3 2.2.1 – 2.2.4			3.3.1, 3.3.2, 3.3.3
3.4. Liquid preparations made by maceration with oil				3.4.1
3.5. Tinctures made by percolation	1.1.8 – 1.1.9		17.7.7.2	3.5.1
3.6. Buffered aqueous mother tinctures under exclusion of oxidative influence		32		
3.7. Fermented tinctures		53	17.7.7.3	3.7.1
3.8. Tinctures made by digestion (Digestio)	1.2.1 – 1.2.6 1.4.1		17.7.8.1	3.8.1, 3.8.2
3.9. Tinctures made by infusion (Infusum)	1.2.13, 1.4.4		17.7.8.3	3.9.1, 3.9.2, 3.9.3
3.10. Tinctures made by decoction (Decoction)	1.2.7 – 1.2.12 1.4.2 – 1.4.3	12k, l	17.7.8.4	3.10.1
3.11. Oil extracts with heat treatment		12d – g, 57		

General method of the APC	Related specific production method			
	Ph.Eur. (2371)	**HAB**	**Ph.Helv.**	**APC**
3.12. Preparations made by distillation		52	17.7.8.5	3.12.1, 3.12.2
3.13. Tinctures obtained with rhythmic application of heat and cold		21 – 22, 33 – 37, 51	17.7.9	3.13.1, 3.13.2.
4. Solid starting materials obtained by heat				
4.1. Toasted preparations (Tosta)			17.7.4.1	4.1
4.2. Carbons (Carbo)			17.7.4.2	4.2
4.3. Ashes (Cinis)			17.7.4.3	4.3
5. Solid preparations from plants and liquids (drying onto a vehicle)				
5.1. Solid preparations from fresh plants	4.1.1 − 4.1.2		17.7.5.1	5.1.1
5.2. Solid preparations from liquids, plant juices or aqueous extracts	4.2.1 − 4.2.2		17.7.5.2	5.2.1, 5.2.2, 5.2.3
6. Liquid dilutions	3.1.1 – 3.1.3			
7. Compositions			17.7.3	7.2.1 − 7.2.4
8. Potentised preparations Potentising specifications in:	1 – 5	12j 11, 15, 32 – 38, 39a, 39b, 45, 51, 53		8.1.1, 8.1.2, 8.2.1, 8.2.2 Other APC Methods 8.3
9. Mixtures		12a, 12h, 12i, 16		

Note: How to read the table: Specific production methods are published in different pharmacopoeias e.g. in the Ph.Eur. or in the HAB; it is not a correlation table. If a method (e.g. HAB 49), has been transferred into the Ph.Eur. (2371, 1.3.1), the number is no longer listed in the HAB column. Anthroposophic medicinal products may also be manufactured in accordance with individual specifications or monographs, see also Part I, chapter 1.

1. SPECIAL TREATMENTS OF RAW MATERIALS

In anthroposophic pharmacy treatment of the raw materials can be part of the pharmaceutically relevant processing, e.g. a plant can be cultivated under treatment with a preparation of a mineral, normally containing a specific metal.

1.1. Vegetabilisation methods ("vegetabilised metals")

DEFINITION

Vegetabilisation of substances can be considered as a particular kind of potentising process of metals or minerals taking place through nature. The potentising process is carried out with plants and normally goes through three life cycles. The life cycle means one vegetation period (growing season) for annual, and two growing seasons for biennial plants. The substance and appropriate plant are chosen in accordance with the rationale of anthroposophic understanding of man and nature.

PREPARATION OF MINERAL SUBSTANCES

See APC Method 1.1.1 and 1.1.2.

CULTIVATION

The cultivation of vegetabilised metals is a three years process (for biennial plants 6 years), meaning three generations of plants are grown until the final plant can be further processed, for example to a mother tincture. This process is basically the same for each specific metal (mineral)-plant combination.
Important for the cultivation process is, that each plant grows in the cultivation substrate and field soil specifically prepared for each vegetation period.
The following is a cultivation description for each of the three growing seasons or life cycles.
Exemptions have to be prescribed in individual monographs (e.g. Bryophyllum, Equisetum arvense and Thuja occidentalis).

1st life cycle:
The seeds are sown in soil, which has been treated with a diluted preparation of the concerned inorganic substance (approximately 50 – 200 g/m^2). Alternatively, jars with cultivation substrate, mixed with 5 – 20 g diluted preparation/L can be used. In this case, the young growing plants are transferred to soil, which has been treated as mentioned above.
When the plants reach their full development, i.e. in the flowering stage, compost is made from these plants. For preparing that compost, the upper aerial parts of the specific plant are used as prescribed in the individual monograph; the flowers or/and the leaves with petioles, possibly with stalks, but no woody parts are included. The plant material is mixed together with neutral plant-compost which activates the first composting processes. This metal plant-compost mixture is stored in terracotta pots which are buried almost completely in the soil in the same field used in that growing season. The composting process is continued during the whole winter until the next spring.
In spring the compost is completed and ready to be used to treat the plants of the next growing season, the second life cycle.

2nd life cycle:
Seeds of the same species are sown in cultivation substrate or soil, which was treated with the compost, made from the plant of the 1st growing season. These plants (of the second life cycle) are also grown to their specific plant development stage (i.e. flowering). Compost is made from these plants, which is prepared in a way similar to the compost of the plants of the first life cycle. This compost is stored in terracotta pots, buried in the soil, in the field of the plants of the second life cycle.

3rd life cycle:
Seeds of the same species are sown in cultivation substrate or soil which was treated with compost made from the plants of the second vegetation period. The plants of the third growing season (third vegetation period) are cultivated to their specified harvest stage.

FURTHER PROCESSING

The harvested plants are processed into a mother tincture according to a manufacturing method of the Ph.Eur., HAB or the APC or are otherwise processed.

IDENTIFICATION, TESTS, ASSAY

According to the relevant tincture monograph (See Part IIa, chapters in section 3) or dried herbal drug.

RECOMMENDED DESIGNATION

The designation states:
- the fertilised plant,
- the substance used,
- the designation "cultum", "culta",
- the reference pharmacopoeia/codex.

Examples: Tabacum Cupro cultum APC, Equisetum arvense Silicea cultum APC

Specific pharmacopoeia/APC production methods to produce vegetabilised substances
APC Method 1.1.1 Vegetabilisation of substances of metallic origin ("vegetabilised metals")

For the vegetabilisation of substances of metallic origin plants are treated with a diluted substance, prepared from either a naturally occurring metal or a metal containing mineral (ore).

PREPARATION OF METALLIC SUBSTANCE

The raw material for the manufacturing of the mineral substance is a naturally occurring metal or a metal containing mineral (ore). This is treated during several steps with mineral acids and other substances, containing the chemical elements C, H, N, O and S, to a complex composition containing the metal in a form whose chemical structure is not clearly defined. It is triturated with lactose monohydrate, the result being the metal substance D1: the content of the metal is 8 – 12 %. The metal substance D1 is diluted with a neutral material, e.g. cellulose or sucrose, to form the diluted metal substance that is ready for use. The calculated metal content of this diluted metal substance differs, according to the toxicity and natural abundance of the metal in the soil:

Au, Ag, Pb, Sn, Hg:	max. 100 ppm
Fe, Cu:	max. 1000 ppm

APC Method 1.1.2 Vegetabilisation of silicates

For the vegetabilisation of silicates plants are treated with appropriate mineral containing silica.

PREPARATION OF MINERAL SUBSTANCE

The raw material for the manufacturing of the mineral substance is a pulverised mineral silicate. This is treated during several steps with mineral acids and other substances, containing the chemical elements C, H, N, O and S, to a complex composition containing silicium in a form whose chemical structure is not clearly defined. It is triturated with lactose monohydrate; the result is the silica, particularly quartz substance D1: the content of silicium is 8 – 12 %, calculated as silicium dioxide .

The silica, particularly quartz substance D1 is diluted with a neutral material, e.g. cellulose or sucrose, to form the diluted silica, particularly quartz substance that is ready for use. The calculated content is max. 1 % silicium dioxide.

2. METAL PREPARATIONS

Metals can either be used as a concentrated starting material or undergo a pharmaceutical process depending on the rationale of the anthroposophic therapeutics.

2.1. Metal mirrors

DEFINITION

By producing metal mirrors the metal is transformed through different states of aggregation.The metals or metal salts can be brought through a liquid state (melted or as solution), gas state or plasmatic state to be subsequently (obtained again) condensed in solid state as the pure metal.

Metal mirrors are deposits of metals in reduced state onto a surface by a specific method of production.

Metal mirrors, produced according to APC methods 2.1.1, 2.1.2 and 2.1.3 can be removed from the surface and may be potentised according to Ph.Eur. method 4.1.1 and 4.1.2 and HAB method 48.

TESTS

The following analytical tests are always carried out for the metal which is used as starting material to produce the mirror. The metal mirror itself is only tested when it is produced by the method of reduction of metal salts (2.1.3), the method of chemical vapour decomposition (2.1.2) or the method of sputtering (2.1.4). The metal mirror produced by the method of distillation (2.1.1) is tested after further processing as the first or second produced dilution.

IDENTIFICATION

At least one suitable identification test is carried out.

TESTS

see the individual monograph.

ASSAY

Content according to the individual monograph.

STORAGE

Store in a well-closed container.

RECOMMENDED DESIGNATION

The designation states:

- the metal used,
- the designation ”metallicum praeparatum” or in the case of metal mirror foil the name of the metal followed of the word “foil”,
- the reference pharmacopoeia/codex,

Examples: Argentum metallicum praeparatum APC Cuprum mirror foil APC.

Specific pharmacopoeial/APC production methods to prepare metal mirrors

APC Method 2.1.1 Metal mirrors obtained by distillation
Metal mirrors prepared by distillation are obtained from the pure metal.
The pure metal is heated in appropriate equipment under vacuum until it evaporates. The temperature and the vacuum are to be chosen in such a way, that the metal is distilled. The metal vapour condenses onto the surface of the cooler parts of the distillation equipment, producing a metal mirror. The metal mirror is removed after cooling from the surface.
The exact conditions of the distillation are described in the individual monograph.

APC Method 2.1.2. Metal mirrors obtained by Chemical Vapour Decomposition, CVD
Metal mirrors prepared by chemical vapour decomposition are obtained from a volatile metal compound.
A volatile metal compound is distilled under vacuum in appropriate equipment. The temperature and the vacuum are to be chosen in such a way, that the metal compound is distilled. The vapour is further heated until decomposition of the metal compound. As a result, the pure metal condenses onto the surface of the distillation equipment, producing a metal mirror. After cooling the metal mirror is removed from the surface.

APC Method 2.1.3. Metal mirrors obtained by reduction
Metal mirrors prepared by reduction are obtained from an appropriate metal salt.
To a solution of a metal salt an appropriate reducing agent and reagents are added. The pure metal precipitates onto the surface of the reaction vessel producing the metal mirror. The metal mirror is removed from the surface, filtered from the solution, washed with purified water and ethanol (the concentration of ethanol depending of the nature of the used reagents), until foreign matters are no longer detectable in the rinsing water and then dried.

APC Method 2.1.4. Metal mirror foil
Metal mirror foils are prepared by a process which transforms the processed metal into a plasma aggregation and finally condenses as an approximate 55 – 65 nm thick metal mirror on to the substrate.
To produce a metal mirror foil a process known as sputtering is used. In this vapour phase technique there is no melting of the metal. The sputtering process is most commonly used for thin-film deposition of many different metals. High energy ions impacting on the target can liberate sputtered atoms of the metal as well as positive ions and electrons.
A metal target is put under the effect of a magnetrom. A magnetrom is comprised of a cathode (electron source) an anode (electron collector) and a combined electric and magnetic field. Vacuum conditions ($0.5 – 5 \times 10^{-3}$ mbar) are generated and an inert gas (e.g. Argon Ph.Eur.) is used as medium. The process begins as a result of a collision and momentum transfer from an incoming particle which impacts the inert gas molecules. Ions of the inert gas impact then the surface of the metal and the result is an ejection of metal atoms from the surface. The electric field leads to an ionisation of the metal which goes into a plasma aggregation state (at 30 – 45 °C) and condensates as a metal mirror on the substrate, in this case a plastic foil (e.g. PET). After this process the metal mirror foil is stitched to a special cotton tissue directly over the metal mirror.
The metal mirror foils must not be further processed.

TESTS
Thickness of the mirror.

RECOMMENDED DESIGNATION
the reference pharmacopoeia/codex,
for external use only.

3. TINCTURES, MOTHER TINCTURES, GLYCEROL MACERATES AND VISCOUS EXTRACTS

Tinctures, mother tinctures, glycerol macerates and viscous extracts are obtained from starting materials from botanical or zoological origin by pharmaceutical processes under cold condition (2 – 8 °C), at ambient temperature (15 – 25 °C), with heat treatment at different temperatures, by rhythmic application of heat and cold, by fermentation as well as by distillation. If applicable, vehicles e.g. water, ethanol, water/ethanol mixtures, glycerol, oils may be used. They may be processed further.

3.1. Cold treated mother tinctures and liquid preparations thereof

DEFINITION
Cold treated mother tinctures are prepared from fresh (frozen) or dried herbal drugs. The maceration is carried out at a temperature of 2 – 8 °C using purified water, water for injections or isotonic solution.

PRODUCTION
If necessary, comminute the matter to be extracted.
The prescribed quantity of extraction solvent according to the individual monograph is added to the starting

material. Mix thoroughly and allow to stand in a closed container, where applicable protected from light, for an appropriate time (at least 7 days). Shake or stir occasionally. Express and filter.

IDENTIFICATION

At least one chromatographic identification test is carried out.

TESTS

pH *(Ph.Eur. 2.2.3)*. Where applicable, the preparation complies with the limits prescribed in the individual monograph.

Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6).* The preparation complies with the limits prescribed in the individual monograph.

Relative density *(Ph.Eur. 2.2.5).* Where applicable, the preparation complies with the limits prescribed in the individual monograph.

Methanol *(Ph.Eur. 2.9.11)*. Maximum 0.05 per cent *V/V* of methanol, unless otherwise authorised by a national official Pharmacopoeia, or another limit is justified and authorised.

ASSAY

An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

RECOMMENDED DESIGNATION

The designation states:

- the herbal drug used,
- where applicable, the fresh herbal drug used,
- where applicable, the ethanol content in the preparation,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce mother tinctures obtained under cold conditions (2 – 8 °C)

HAB Method 38

3.2. Tinctures and mother tinctures made by macerations with water or ethanol/water

DEFINITION

Tinctures and mother tinctures made by maceration with water or ethanol/water are liquids and are obtained from fresh (frozen) or dried matter of botanical or zoological origin. The maceration is carried out at a temperature not above 25 °C by using ethanol of a
suitable concentration or purified water.

PRODUCTION

If necessary, comminute the matter to be extracted; animals are processed immediately after killing. The prescribed quantity of extraction solvent according to the individual monograph is added to the starting material. Mix thoroughly and allow to stand in a closed container at the required temperature, where applicable protected from light for an appropriate time. If necessary shake or stir occasionally. Express and filter, if necessary. Adjustment of the content of constituents may be carried out, if necessary, either by adding the extraction solvent of suitable concentration or by adding another macerate of the herbal or animal starting material used. If prescribed in the individual monograph, the tincture can be adjusted to the specified content by concentration, carried out generally under vacuum.

IDENTIFICATION

At least one chromatographic identification test is carried out.

TESTS

Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6).* The preparation complies with the limits prescribed in the individual monograph.

Relative density *(Ph.Eur. 2.2.5).* Where applicable, the preparation complies with the limits prescribed in the individual monograph.

Ethanol content *(Ph.Eur. 2.9.10)*. Where applicable, the ethanol content complies with that prescribed in the individual monograph.

Methanol *(Ph.Eur. 2.9.11)*. Maximum 0.05 per cent *V/V* of methanol, unless otherwise authorised by a national official Pharmacopoeia, or another limit is justified and authorised.

ASSAY

An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE

Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION

The designation states:

- the herbal or animal matter used,
- where applicable, the fresh herbal or animal matter used,
- where applicable, the ethanol content in the preparation,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,

the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce tinctures and mother tinctures made by macerations with water or ethanol/water

Ph.Eur. (2371) Methods
1.1.1 – 11
HAB Methods
1 – 4
Ph.Eur. 1.3.1 (prev. HAB Method 49)
12b, c, m, n, o

APC Method 3.2.1 (related to Ph.Eur. (2371) Method 1.1.8)
Mother tinctures according to APC Method 3.2.1 are prepared using the maceration methods given in the Ph.Eur. monograph "Extracts" (0765). Use 1 part of dried plant or parts of plants to 20 parts of ethanol in suitable concentration (see HAB H 5.3), unless otherwise prescribed in the individual monograph. If adjustment to a given concentration is necessary, calculate the amount of ethanol required to obtain the concentration specified or used for production from the equation given in Ph.Eur. (2371) Method 1.1.1. Mix the calculated amount of ethanol with the filtrate. Allow to stand for not less than 5 days at a temperature not exceeding 20 °C, then filter if necessary.

POTENTISATION
The 2nd decimal dilution (D2) is made from
2 parts of the mother tincture and
8 parts of ethanol of the same concentration.

The 3rd decimal dilution (D3) is made from
1 part of 2nd decimal dilution and
9 parts of ethanol of the same concentration.

Unless a different ethanol concentration is specified, use ethanol 36 per cent *(V/V)* for D4 and then 18 per cent (*V/V*) for subsequent dilutions from D5 onwards and proceed accordingly.

APC Method 3.2.2 (related to HAB Method 12a)
Preparations according to APC Method 3.2.2 are tinctures for external use. They are prepared as follows: Use 1 part of dried plant or parts of plants to 10 parts of ethanol in suitable concentration
(see HAB H 5.3), unless otherwise prescribed in the individual monograph.
Glycerol may be added up to 10 per cent.

3.3. Glycerol macerates

DEFINITION
Glycerol macerates comply with the definition in Ph.Eur. monograph 1038. They are prepared from fresh (frozen) or dried matter of botanical or zoological origin. The maceration is carried out at the required temperature (not above 25 °C) using glycerol of a suitable concentration or a glycerol solution containing sodium chloride.

PRODUCTION
Lower animals are killed immediately before processing; the parts of warm-blooded animals are processed immediately after being killed. Killing is carried out with respect for the animal suffering. Comminute the matter to be extracted. Add the prescribed quantity of extraction solvent according to the individual monograph to the raw material. Mix thoroughly and allow to stand in a closed container at a temperature not above 25 °C, protected from light for an appropriate time. If necessary shake or stir occasionally. Express and filter, if necessary.
Adjustment of the content of constituents may be carried out, if necessary, either by adding the extraction solvent of suitable concentration or by adding another macerate of the starting material of botanical or animal origin used.

IDENTIFICATION
At least one chromatographic or electrophoretic (animal matter) identification test is carried out.

TESTS
Conductivity *(Ph.Eur. 2.2.38).* Where applicable, the preparation complies with the limits prescribed in the individual monograph.
Relative density *(Ph.Eur. 2.2.5).* The preparation complies with the limits prescribed in the individual monograph. Alternatively, the refractive index can be used.
Refractive index (*Ph.Eur. 2.2.6*). Where applicable (preparations according to APC Methods 3.3.1 and 3.3.2), the refractive index of the preparation is measured in appropriate equipment, this measure indicates the water content in the glycerol[1], and this value is called η_m indicating the refractive index of the macerate. This

[1] Miner, Carl S.& Dalton, N.N: (ed.). *Glycerol*, American Chemical Society, Monograph Series, n^0 117. Reinhold Publishing Corp., New York 1953.

measure is used to calculate the proportion of glycerol of the macerate. This calculation is made based on the following equation:

$$\%\ Glycerol\ {}^{m}/_{m} = \frac{\eta_m - 1.3195}{0.0016} \quad \text{(eq.1)}^{1}$$

Electrophoresis *(Ph.Eur. 2.2.31).* Where applicable, the preparation complies with the characteristics prescribed in the individual monograph.
Microbiological examination *(Ph.Eur. 2.6.12, 2.6.13)*. Where applicable, the macerate complies with the limits prescribed.

ASSAY

An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE

Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION

The designation states:

- the dried herbal drug or animal matter used,
- where applicable, the fresh herbal drug or animal matter used,
- the glycerol content of the solvent used for the preparation,
- where applicable, the ratio of starting material to extraction liquid or of starting material to macerate,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce glycerol macerates

Ph.Eur. (2371) Methods
2.1.1 – 2.1.3 (prev. HAB Methods 42)
2.2.1 – 2.2.4 (prev. HAB Methods 41)

APC Method 3.3.1

Glycerol macerates according to APC Method 3.3.1 are prepared from 3 parts of fresh (frozen) matter of botanical or zoological origin and 7 parts of glycerol by maceration.
The prescribed quantity of glycerol is added to the starting material. Mix thoroughly and allow to stand in a closed container for an appropriate time according to the individual monograph. If necessary, shake or stir occasionally. Express and filter, if necessary.
The content of glycerol is determined using measurement of refractive index and should be 70–85 % *(m/m)* of the total mass, calculated based on the equation above (refractive index). Adjustment of the final content of glycerol to 85 % is carried out using measurement of refractive index, and adding glycerol. Adjustment of the content of constituents may be carried out, if necessary by adding another macerate of the herbal or animal starting material used.

APC Method 3.3.2

Glycerol macerates according to APC Method 3.3.2 are prepared from 1 part of dried plants or parts of plants, 2 parts of purified water and 7 parts of glycerol by maceration.
The prescribed quantity of purified water is added to the starting material. Allow standing in a closed container for 6 hours. After that, the prescribed quantity of glycerol is added to the mixture. Mix thoroughly and allow to stand in a closed container for an appropriate time according to the individual monograph. If necessary, shake or stir occasionally. Express and filter, if necessary.
The content of glycerol is determined using measurement of refractive index and should be 75–85 % *(m/m)* of the total mass, calculated based on the equation above (refractive index). Adjustment of the final content of glycerol to 85 % is carried out using measurement of refractive index, and adding glycerol. Adjustment of the content of constituents may be carried out, if necessary by adding another macerate of the herbal or animal starting material used.

APC Method 3.3.3

Mother tinctures according to APC Method 3.3.3 are prepared from killed or freshly slaughtered animals or parts thereof by maceration with glycerol as vehicle (glycerol macerates).

To produce the first decimal dilution (D1), disperse 1 part of finely minced animal material in 9 parts of glycerol (85 per cent), allow to macerate for at least 2 h, then succuss. Where justified, the addition of 1 part of glycerol (85 per cent) to 1 part of animal material before the mincing is accepted. Filter when necessary. In the case of very small amounts of animal material, it is allowed to prepare the 2nd or the 3rd decimal dilution by dispersing 1 part of finely minced animal material in 99 resp. 999 parts (= D2 resp. D3) of glycerol (85 per cent).

POTENTISATION

Where the mother tincture corresponds to the 1st decimal dilution (Ø = D1), the 2nd decimal dilution (D2) is produced from:
1 part of the mother tincture (D1);
9 parts of glycerol (85 per cent) or ethanol (18 per cent *V/V*).

The 3rd decimal dilution (D3) is produced from:
1 part of the 2nd decimal dilution;
9 parts of ethanol (18 per cent *V/V*).
Subsequent dilutions are produced as stated for D3.

Where the mother tincture corresponds to the 2nd or 3rd decimal dilution (Ø = D1), the 3rd or the 4th decimal dilution, respectively (D3 or D4) is produced from:
1 part of the mother tincture (D2 or D3)
9 parts of ethanol (18 per cent *V/V*).
Subsequent dilutions are produced accordingly.

3.4. Liquid preparations made by maceration with oil

DEFINITION
Liquid preparations prepared by maceration with oil are prepared from fresh (frozen) or dried matter of botanical or zoological origin. The maceration is carried out at the required temperature (not above 25 °C) mostly by using arachis oil or olive oil.

PRODUCTION
If necessary, comminute the matter to be extracted. When animal matter is used, lower animals are killed immediately before processing, the parts of warm-blooded animals being processed immediately after killing. Killing is carried out with respect for the animal suffering, e.g. according to HAB H 5.2.4.The prescribed quantity of extraction solvent according to the individual monograph is added to the starting material. Mix thoroughly and allow to stand in a closed container at the required temperature, protected from light for an appropriate time. If necessary shake or stir occasionally. Express and filter, if necessary.
Adjustment of the content of constituents may be carried out, if necessary, either by adding the extraction solvent of suitable concentration or by adding another macerate of the herbal or animal starting material used.

IDENTIFICATION
At least one chromatographic identification test is carried out.

TESTS
Relative density *(Ph.Eur. 2.2.5)*. The preparation complies with the limits prescribed in the individual monograph.
Refractive index *(Ph.Eur. 2.2.6)*. The preparation complies with the limits prescribed in the individual monograph.
Peroxide value *(Ph.Eur. 2.5.5)*. Where applicable, the preparation complies with the limits prescribed in the individual monograph.

ASSAY
An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE
Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION
The designation states:
- the dried herbal drug or animal matter used,
- where applicable, the fresh herbal drug or animal matter used,
- where applicable, the solvent used for the preparation,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce liquid preparations made by maceration with oil

APC Method 3.4.1
Preparations made according to APC Method 3.4.1 are oil extracts for external use prepared from 1 part of lower animals and 10 parts of arachis oil, refined (Ph.Eur.) as follows:

After having killed the animals with CO_2, the animals are minced and mixed thoroughly with 10 parts of arachis oil, refined (Ph.Eur.). Protect the mixture from light. The extraction time should not exceed 8 hours. Then filter.

3.5. Mother tinctures made by percolation

DEFINITION
Mother tinctures made by percolation are prepared from fresh (frozen) or dried herbal drugs.
The percolation is carried out at room temperature using ethanol of suitable concentration or purified water.

PRODUCTION
If necessary, comminute the herbal drug to be extracted to pieces of suitable size. Mix thoroughly with a potion of the prescribed extraction solvent and allow to stand for an appropriate time. Transfer to a percolator and allow the percolate to flow slowly making sure that the 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.

Adjustment of the content of constituents may be carried out, if necessary, either by adding the extraction solvent of suitable concentration or by adding another percolate of the herbal drug used for the preparation.

IDENTIFICATION
At least one chromatographic identification test is carried out.

TESTS
Relative density *(Ph.Eur. 2.2.5).* Where applicable, the preparation complies with the limits prescribed in the individual monograph.
Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6).* The preparation complies with the limits prescribed in the individual monograph.
Methanol *(Ph.Eur. 2.9.11)*. Maximum 0.05 per cent *V/V* of methanol, unless otherwise authorised by a national official Pharmacopoeia, or another limit is justified and authorised.

ASSAY
An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE
Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION
The designation states:
- the fresh herbal drug used,
- where applicable, the dried herbal drug used,
- where applicable, the ethanol content in the preparation,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce mother tinctures made by percolation

Ph.Eur. (2371), Methods 1.1.8, 1.1.9
HAB Methods 4

APC Method 3.5.1 (related to Ph.Eur. (2371) Method 1.1.8)

Mother tinctures according to APC Method 3.5.1 are prepared using the percolation methods given in the Ph.Eur. monograph "Extracts" (0765). Use 1 part of dried plant or parts of plants to 20 parts of ethanol in suitable concentration (see HAB H 5.3), unless otherwise prescribed in the individual monograph. If adjustment to a given concentration is necessary, calculate the amount of ethanol required to obtain the concentration specified or used for production from the equation given in Ph.Eur. (2371) Method 1.1.1. Mix the calculated amount of ethanol with the filtrate. Allow to stand for not less than 5 days at a temperature not exceeding 20 °C, then filter if necessary.

The 2nd decimal dilution (D2) is made from
2 parts of the mother tincture and
8 parts of ethanol of the same concentration.

The 3rd decimal dilution (D3) is made from
1 part of 2nd decimal dilution and
9 parts of ethanol of the same concentration.

Unless a different ethanol concentration is specified, use ethanol 50 per cent (*V/V*) for subsequent dilutions from D4 onwards and proceed accordingly.

3.6. Buffered aqueous mother tinctures manufactured under exclusion of oxidative influence

DEFINITION
Buffered aqueous mother tinctures manufactured under exclusion of oxidative influence are produced by exhaustive extraction of fresh (frozen) plants or parts of plants under the exclusion of atmospheric oxygen with a buffer.

If the fresh plant material is not processed immediately, it must be stored in liquid nitrogen. The loss on drying *(H 2.8.1)* must be determined before it is placed in liquid nitrogen.
From 1 part of the plant material an amount of mother tincture, prescribed in the individual monograph, is produced according to HAB Method 32. This amount is determined in a validation and depends on the loss on drying of the harvested plant material.The mother tincture corresponds to the 2nd decimal dilution (mother tincture = D2).
At first add a defined amount of ascorbate phosphate buffer solution to the plant material and then finely reduce this mixture to a slurry. Under further size reduction, add a quantity of ascorbate phosphate buffer solution, sufficient for achieving the required amount of extract. Express, filter and adjust to the required volume with ascorbate phosphate buffer solution.

According to the individual monograph the production of the mother tincture may require the addition of a second extract from material of the same plant species harvested at a different season. In this case mix the extracts in an appropriate apparatus to a composition (see Chapter 7) and then dilute in a defined proportion with ascorbate phosphate buffer solution. This composition is the mother tincture (=D2).
Potentisation is generally carried out according to HAB Method 32.

Buffered aqueous mother tinctures and their liquid dilutions are exclusively intended for parenteral dosage forms. Before they are processed to finished products, the mother tincture (D2) and the liquid dilution D3 must be stored for between 6 weeks and 1 year. Any eventual sediment must be excluded from the further processing.

IDENTIFICATION

At least one chromatographic identification test is carried out.

TESTS

Loss on drying *(H 2.8.1)*. Loss on drying of the residue after filtration.
Sterility *(Ph.Eur. 2.6.1)*. If buffered aqueous mother tinctures and their liquid dilutions are stored before further processing, they must comply with the test.
Proportion of original extracts: Where applicable, the proportion of both extracts in the composition is determined e.g. by HPLC or by other suitable methods.
Methanol and 2-propanol *(Ph.Eur. 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 authorised by a national official Pharmacopoeia or another limit is justified and authorised.

ASSAY

An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE

Store in a well-closed, airtight container.

RECOMMENDED DESIGNATION

The designation states:
- the herbal drug used,
- the amount of herbal drug used,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce buffered aqueous mother tinctures manufactured under exclusion of oxidative influence

HAB Method 32

3.7. Fermented mother tinctures

DEFINITION

Fermented mother tinctures are aqueous preparations from fresh (frozen) or dried herbal drugs prepared by fermentation at room temperature.

PRODUCTION

If necessary, comminute the herbal drug. Add purified water according to the individual monograph and mix thoroughly. If stated in the individual monograph, add the prescribed fermenting agent. Allow to stand at room temperature for the time prescribed in the individual monograph protected from air, from light and, if necessary, from oxidation. Hereafter express and filter, if necessary.

Adjustment of the content of constituents may be carried out with purified water or by adding purified water to the residue and expressing again.

IDENTIFICATION

At least one chromatographic identification test is carried out.

TESTS

pH *(Ph.Eur. 2.2.3)*. The preparation complies with the limits prescribed in the individual monograph.
Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6).* The preparation complies with the limits prescribed in the individual monograph.
Relative density *(Ph.Eur. 2.2.5).* The preparation complies with the limits prescribed in the individual monograph.
Methanol *(Ph.Eur. 2.9.11)*. Maximum 0.05 per cent *V/V* of methanol, unless otherwise authorised by a national official Pharmacopoeia, or another limit is justified and authorised.

ASSAY

An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE

Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION

The designation states:
- the fresh herbal drug used,
- where applicable, the dried herbal drug used,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce fermented mother tinctures

HAB Method 53
APC Methods 7.2.1, 7.2.3, 7.2.4

APC Method 3.7.1 (see also Compositions 7.2.1)
Mother tinctures according to APC Method 3.7.1 are prepared from fresh plants or parts of plants following the procedure given below.
Finely comminute the plants or parts of plants and mix 1 part of the plant mass with 1 part of purified water. Leave to ferment at 20 to 24 °C with the exclusion of air, ending the fermentation when the pH of the fermentation liquid has fallen to between 4 and 5.
Then express and weigh the expressed liquid. The weight of the expressed liquid is equal to 2 parts and is mixed with 1 part of a mixture of 0.95 parts of ethanol 96 per cent (*V/V*) and 0.05 parts of purified water.
This tincture can together with another tincture of the same plant undergo a special pharmaceutical process leading to a composition according to method 7.2.1.

This procedure is followed for plants harvested in the summer and for plants of the same species, harvested in the winter. The mother tincture is produced by composing equal parts of the two tinctures.

POTENTISATION

The 1st decimal dilution (D1) is made from
3 parts of the mother tincture and
7 parts of ethanol 36 per cent (*V/V*).

The 2nd decimal dilution (D2) is made from
1 part of the 1st decimal dilution and
9 parts of ethanol 18 per cent (*V/V*).

Subsequent dilutions are produced as stated for D2.

RECOMMENDED DESIGNATION

Preparations according to APC Method 3.7.1 carry the designation „ferm APC 3.7.1".

3.8. Tinctures and mother tinctures made by digestion (Digestio)

DEFINITION

Tinctures and mother tinctures made by digestion are liquids prepared from fresh (frozen) or dried plants or parts of plants by heat treatment usually at 37 °C and additional maceration. The digestion is carried out using ethanol of a suitable concentration or purified water.

PRODUCTION

If necessary, comminute the plant or parts of plants to be extracted. The quantity of extraction liquid is added according to the individual monograph. Mix thoroughly and warm to 35 – 39 °C. Then keep at 35 – 39 °C in a covered container. Allow to stand at this temperature for the time prescribed in the individual monograph, stirring occasionally. After cooling, allow to stand at room temperature in a well-closed container, protected from light for the time described in the individual monograph. Add ethanol of appropriate concentration if prescribed. If necessary shake or stir occasionally. Express and filter, if necessary.
Adjustment of the content of constituents may be carried out by diluting, either with the same liquid used for the digestion or with another digestion of the same raw material.
If prescribed in the individual monograph, the tincture can be adjusted to the specified content by concentration, carried out carefully and generally under vacuum.

IDENTIFICATION

At least one chromatographic identification test is carried out.

TESTS

pH *(Ph.Eur. 2.2.3)*. Where applicable the preparation complies with the limits prescribed in the individual monograph.
Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6)*. The preparation complies with the limits prescribed in the individual monograph.
Relative density *(Ph.Eur. 2.2.5)*. The preparation complies with the limits prescribed in the individual monograph.
Methanol *(Ph.Eur. 2.9.11)*. Maximum 0.05 per cent *V/V* of methanol, unless otherwise authorised by a national official pharmacopoeia, or another limit is justified and authorised.

ASSAY

An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE

Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION

The designation states:
- the dried herbal drug used,
- where applicable, the fresh herbal drug used,
- where applicable, the ethanol content in the preparation,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,
- the designation "Digestio" or "ethanol. Digestio" if ethanol is used,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce tinctures and mother tinctures made by digestion

Ph.Eur. (2371) 1.2.1 – 6 (prev. HAB Methods 18)
Ph.Eur. (2371) 1.4.1 (prev. HAB Method 24b)

APC Method 3.8.1
Tinctures according to APC Method 3.8.1 are prepared from fresh plants with purified water as follows:
Comminute the plants or parts of plants unless otherwise prescribed in the monograph. The amount of plants or parts of plants and purified water are defined by the monograph. Introduce the amount of purified water into a round-bottomed flask, place in a water bath and heat up to 48 – 52 °C. Add the plants or parts of plants whereby the flask should be a half to three quarters full, mix thoroughly. Close the flask hermetically. Keep the mixture at 48 – 52 °C for 6 hours. Allow to cool to 35 – 39 °C in the course of 20 – 24 hours and maintain this temperature for 64 – 72 hours with occasional stirring. Allow to cool. If prescribed in the individual monograph add the amount of ethanol 96 per cent *(V/V)* prescribed then express and filter.
Tinctures according to APC Method 3.8.1 which are prepared with purified water only, are generally processed immediately to solid preparations (see method 5.2 "Solid preparations from liquids, plant juices or aqueous extracts").

RECOMMENDED DESIGNATION
Preparations made according to APC Method 3.8.1 carry the designation "Digestio APC 3.8.1". The same applies to preparations made from them. Preparations made according to APC Method 3.8.1 with addition of ethanol carry the designation "ethanol. stab. digestio APC 3.8.1".

APC Method 3.8.2
Method 3.8.2 is used for fresh plants.
Mother tinctures prepared according to APC Method 3.8.2 are ethanolic digestions prepared by heat treatment with additional maceration as described below.
Comminute appropriately the plant or the parts of plants. To 1 part of the comminuted plant add 3.1 parts of ethanol 24 per cent *V/V*. Warm the mixture in a well-closed container to 37 °C and maintain this temperature for 1 h. Cool, allow to stand for not less than 10 days, stirring the mixture or swirling the container from time to time, then express the mixture and filter the resulting liquid. The filtrate is the mother tincture.

3.9. Tinctures and mother tinctures made by infusion (Infusum)

DEFINITION
Tinctures and mother tinctures made by infusion are prepared from adequately prepared dried plant material by adding boiling purified water. If ethanol (of the prescribed concentration) is used, the quantities of ethanol and purified water are added separately.

PRODUCTION
If necessary, comminute the plant material. Boiling purified water is used for extraction. If ethanol of suitable concentration is used, the quantity of ethanol is either used prior to extraction for moistening the dried plant material for the time prescribed or added to the mixture after cooling. Allow to stand in a well-closed container for the time prescribed. If only purified water is used as solvent, it is also used for moistening and to make up the final mass if prescribed. Express and filter, if necessary. If only purified water is used as solvent the preparation is processed further immediately.

IDENTIFICATION
At least one chromatographic identification test is carried out.

TESTS
Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6).* The preparation complies with the limits prescribed in the individual monograph.
Relative density *(Ph.Eur. 2.2.5).* The preparation complies with the limits prescribed in the individual monograph.
Methanol *(Ph.Eur. 2.9.11)*. Maximum 0.05 per cent *V/V* of methanol, unless otherwise authorised by a national official Pharmacopoeia , or another limit is justified and authorised.
Sterility *(Ph.Eur. 2.6.1)*. Applicable only if the infusion is a stored aqueous preparation.

ASSAY
An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE
Store in a well-closed container, protected from light, if the tincture contains ethanol.
If aqueous tinctures made by infusion are stored they must meet the requirements of sterility (Ph.Eur. 2.6.1).

RECOMMENDED DESIGNATION

The designation states:
- the herbal drug used,
- where applicable, the ethanol content in the preparation,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,
- the designation "Infusum" or "ethanol. Infusum", if ethanol is used,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce tinctures and mother tinctures made by infusion

Ph.Eur. (2371) 1.2.13 (prev. HAB Method 20)
Ph. Eur. (2371) 1.4.4 (prev. HAB Method 24a)

APC Method 3.9.1 (related to Ph.Eur. Method 1.12.13)
Mother tinctures according to APC Method 3.9.1 are prepared from dried plants or parts of plants, using 1 part of the plant material and 10 parts of ethanol of the concentration, prescribed in the individual monograph as follows:
Add the amounts of ethanol and purified water required to obtain the prescribed ethanol concentration separately.
Unless a degree of comminution is specified in the monograph, comminute the herbal drug appropriately, add the total amount of boiling purified water, cover and allow to stand until room temperature is reached, for not more than 12 h. Compensate any water loss by evaporation and add the required amount of ethanol. Allow to stand in a well-closed container for 24 – 36 h, stirring occasionally. Express and filter.

POTENTISATION

The mother tincture corresponds to the 1st decimal dilution (Ø = D1).
The 2nd decimal dilution (D2) is made from
1 part of the mother tincture and
9 parts of ethanol of the same concentration as calculated for the mother tincture.

Subsequent decimal dilutions are produced accordingly; in this process the ethanol concentration is reduced with each step in the succession – 50 – 36 – 18 per cent (*V/V*) until the 18 per cent level is reached.

RECOMMENDED DESIGNATION

Preparations made according to APC Method 3.9.1 carry the designation "ethanol. stab. infusum". The same applies to preparations made from them.

APC Method 3.9.2 (related to HAB Method 20)
deleted

APC Method 3.9.3
Mother tinctures according to APC Method 3.9.3 are prepared from fresh or dried plants or parts of plants, using 1 part of the plant material and 10 parts of water *(m/m)* or according to the individual monograph. Comminute the starting material and add the total amount of boiling purified water, cover and allow to stand until room temperature is reached, for not more than 12 h. Compensate any water loss. Allow to stand in a well-closed container for 24 – 36 h, stirring occasionally. Express and filter.

POTENTISATION

The mother tincture corresponds to the 1st decimal dilution (Ø= D1).
The 2nd decimal dilution (D2) is made from
1 part of the mother tincture and
9 parts of glycerol 85 % *(m/m)*.

Subsequent dilutions are produced as stated for D2.

3.10. Tinctures and mother tinctures made by decoction (Decoction)

DEFINITION

Tinctures and mother tinctures made by decoction are prepared from fresh or dried plants or parts of plants that have been allowed to boil with ethanol of a suitable concentration or purified water or extracted with glycerol 85 % at 100°C.

PRODUCTION

If necessary, comminute the plants or parts of plants, add the prescribed quantity of extraction solvent according to the individual monograph and mix thoroughly. Heat the mixture to boiling (in the case of glycerol 85 % to 100°C), if necessary under reflux, maintaining at boiling temperature (in the case of glycerol 85 % at 100°C) for the time prescribed, usually 30 min. After cooling allow to stand in a well-closed container protected from light at room temperature for the time described in the individual monograph. If necessary, shake or stir occasionally. Express and filter, if necessary.

Adjustment of the content of constituents may be carried out by diluting, either with the same liquid used for the decoction or with another decoction of the same raw material.
If prescribed in the individual monograph, the tincture

can be adjusted to the specified content by concentration, carried out carefully and generally under vacuum.

IDENTIFICATION
At least one chromatographic identification test is carried out.

TESTS
Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6).* The preparation complies with the limits prescribed in the individual monograph.
Relative density *(Ph.Eur. 2.2.5).* The preparation complies with the limits prescribed in the individual monograph.
Methanol *(Ph.Eur. 2.9.11)*. Maximum 0.05 per cent *V/V* of methanol, unless otherwise authorised by a national official pharmacopoeia, or another limit is justified and authorised.

ASSAY
An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE
Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION
The designation states:
- the herbal substance used,
- where applicable, the fresh or dried herbal drug used,
- where applicable, the ethanol content in the preparation,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,
- the designation "Decoctum" or "ethanol. Decoctum", if ethanol is used,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce tinctures and mother tinctures made by decoction

HAB Methods 12k, 12l, 12q
Ph.Eur. (2371) 1.2.7 – 12 (prev. HAB Methods 19)
Ph.Eur. (2371) 1.4.2 – 3 (prev. HAB Methods 23)

APC Method 3.10.1 (related to Ph.Eur. Method 1.2.12)
APC Method 3.10.1. is used for dried herbal drugs. Mother tinctures according to APC Method 3.10.1 are ethanolic decoction prepared by heat treatment with ethanol of an appropriate concentration as specified in the individual monograph with additional maceration as described below.
1 part of dried herbal drug is macerated with 20 parts of ethanol of the appropriate concentration (anhydrous,
96 per cent *V/V* – 94 per cent *m/m*,
90 per cent *V/V* – 86 per cent *m/m*,
80 per cent *V/V* – 73 per cent *m/m*,
70 per cent *V/V* – 62 per cent *m/m*,
50 per cent *V/V* – 43 per cent *m/m*,
36 per cent *V/V* – 30 per cent *m/m*,
18 per cent *V/V* – 15 per cent *m/m*),
unless otherwise prescribed in the individual monograph.

Unless otherwise prescribed, comminute the herbal drug, mix thoroughly with the total amount of ethanol of the appropriate concentration and heat to boiling under reflux, maintaining at boiling temperature for 30 min unless otherwise specified in the individual monograph. Cool or allow to cool and leave the mixture to stand in a closed container for 12 – 36 h. Separate the residue from the ethanol and, if necessary, press out. In the latter case, combine the 2 liquids obtained.
Adjust to the concentrations required in the individual monograph in accordance with Ph.Eur. (2371) Method 1.1.8.

POTENTISATION
The 2nd decimal dilution (D2) is made from
2 parts of the mother tincture and
8 parts of ethanol of the same concentration.

The 3rd decimal dilution (D3) is made from
1 part of the 2nd decimal dilution and
9 parts of ethanol of a reduced concentration as given below.

Subsequent decimal dilutions are produced accordingly; in this process the ethanol concentration is reduced with each step in the succession 96 – 90 – 80 – 70 – 50 – 36 – 18 per cent (*V/V*) until the 18 per cent level is reached.

3.11. Viscous extracts with heat treatment

DEFINITION
Viscous extracts with heat treatment are prepared from fresh or dried herbal drugs using a fatty or mineral oil or glycerol 85 % as extraction liquid with heat.

PRODUCTION
If necessary, comminute the herbal drug. Ethanol 96 per cent *(V/V)* may be added to moisten the plant material. The prescribed quantity of the extraction liquid (mostly peanut, olive, sesame or sunflower oil, liquid paraffin, or glycerol 85 %) is added and mixed thoroughly with the herbal drug. The mixture is heated at the prescribed temperature and allowed to stand in a closed container for an appropriate time. Extraction temperature and

time are prescribed in the individual monograph. Finally express and filter. If necessary, the empty space of the container is filled with a protecting gas.

IDENTIFICATION
At least one chromatographic identification test is carried out.

TESTS
Relative density *(Ph.Eur. 2.2.5)*. The preparation complies with the limits prescribed in the individual monograph.
Refractive index *(Ph.Eur. 2.2.6)*. The preparation complies with the limits prescribed in the individual monograph.
Peroxide value *(Ph.Eur. 2.5.5)*. Where applicable, the preparation made with a vegetable oil complies with the limits prescribed in the individual monograph.

ASSAY
An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE
Store in a well-filled, airtight container, protected from light and heat. If necessary, the empty space in the container of oil extracts is filled with an inert gas.

RECOMMENDED DESIGNATION
The designation states:
- the fresh herbal drug used,
- where applicable, the dried herbal drug used,
- the extraction liquid used,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,
- an indication of the extraction temperature,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce viscous extracts with heat treatment

HAB Methods 12 d-g
HAB Method 57

Individual Monographs:
Cydonia oblonga, fruit, glycerol extract with heat treatment 1:2.1.

3.12. Preparations made by distillation (Distillates)

DEFINITION
Distillates are prepared from fresh plants or parts of plants or dried plants, organic or inorganic substances by steam distillation or water-and-steam distillation. The distillation can be done in the presence of other substances that will not interfere with the final composition of the distillate. This process can be repeated several times in a rhythmic sequence of evaporation/condensation. Distillated preparations can be part of a more complex formulation that is composed by several fractions. Distillated preparations can be used as starting materials or finished products and can be potentised.

PRODUCTION
According to the specific methods or the individual monograph.

IDENTIFICATION
At least one chromatographic identification test is carried out.

TESTS
Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6).* The preparation complies with the limits prescribed in the individual monograph.
Relative density *(Ph.Eur. 2.2.5).* Where applicable, the preparation complies with the limits prescribed in the individual monograph.
Methanol *(Ph.Eur. 2.9.11)*. Maximum 0.05 per cent *V/V* of methanol, unless otherwise authorised by a national official pharmacopoeia or another limit is justified and authorised.

RECOMMENDED DESIGNATION
Distillates and derived dosage forms carry the designation „destillata“.

Specific pharmacopoeial/APC production methods to produce preparations made by distillation

APC Method 3.12.1 Preparations made by ethanolic distillation (related to HAB Method 52)

Distillates according to APC method 3.12.1 are prepared from fresh plants or parts of plants following the procedure given below.
Comminute the plant material. Pour 8 parts of ethanol 90 per cent (*V/V*) over 100 parts of plant mass. Leave to stand in a closed container for at least 24 h, then steam distil, ending the steam distillation when 50 parts of distillate have been collected.

The mother tincture is made from
1 part of distillate and
1 part of ethanol 18 per cent (*V/V*).

POTENTISATION

The 1st decimal dilution (D1) is made from
1 part of the mother tincture and
9 parts of ethanol 18 per cent (*V/V*).
Subsequent dilutions are produced as stated for D1.

APC Method 3.12.2 Preparations made by aqueous distillation

Distillates according to APC Method 3.12.2 are preparations of fresh or dried starting materials from mineral, vegetal and animal source, obtained by aqueous distillation.
Comminute the material. To 1 part of material add water according to the individual monograph, then heat with flame source, ending the distillation when 50 parts of distillated have been collected or according to the individual monograph.

The aqueous distillation can be done in the presence of other substances that will not interfere with the final composition of the final distillate.

3.13. Mother tinctures obtained by rhythmic application of heat and cold

DEFINITION

Mother tinctures obtained by rhythmic application of heat and cold are aqueous preparations from fresh or dried herbal drugs or saps from fresh herbal drugs, obtained by fermentation under cold and heat application.

PRODUCTION

Comminute the herbal drug appropriately. Add purified water. If stated in the individual monograph, add the prescribed fermenting agent.
It is also possible to ferment the expressed plant sap or the finely minced fresh plant without addition of purified water. Treat rhythmically with application of heat (generally 37 °C) and cold (generally 4 °C). Where required, express and filter after the time prescribed in the individual monograph. Salts, specific plant ashes, metals or minerals may be added according to the individual monograph.

IDENTIFICATION

At least one chromatographic identification test is carried out.

TESTS

pH *(Ph.Eur. 2.2.3)*. The preparation complies with the limits prescribed in the individual monograph.
Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6).* The preparation complies with the limits prescribed in the individual monograph.
Relative density *(Ph.Eur. 2.2.5).* Where applicable, the preparation complies with the limits prescribed in the individual monograph.
Methanol *(Ph.Eur. 2.9.11)*. Maximum 0.05 per cent *V/V* of methanol, unless otherwise authorised by a national official pharmacopoeia, or another limit is justified and authorised.

ASSAY

An assay with quantitative limits is performed when starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE

Store in a well-closed container, protected from light, at 8 – 15 °C.

RECOMMENDED DESIGNATION

The designation states:
- the herbal drug used,
- where applicable, the fresh herbal drug used,
- where applicable, the name of the salt, metal or mineral added,
- where applicable, the ratio of starting material to extraction liquid or of starting material to preparation,
- the designation „ferm“ (with water and fermenting agents) or „Rh“ (fermented plant sap without fermenting agents),
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce mother tinctures obtained with rhythmic application of heat and cold

HAB Method 21
HAB Method 22
HAB Methods 33
HAB Methods 34
HAB Methods 35
HAB Method 36
HAB Methods 37
HAB Methods 51

APC Method 3.13.1 (related to HAB Method 21)
Rh mother tinctures according to APC Method 3.13.1 are prepared from fresh plants generally yielding more than 50 per cent of expressed liquid, as follows:

Comminute the plants immediately after harvesting and express. Transfer the expressed juice to containers and subject to the diurnal hot-cold rhythm (“Rh”) described below until fermentation is complete.
Each morning, warm the expressed liquid to 35 – 39 °C over a period of 30 – 90 min and maintain

at this temperature. Each evening, cool the expressed liquid to 2 – 6 °C over a period of 30 – 90 min and maintain at this temperature.
Stir the liquid for 60 – 200 min during both temperature phases at the beginning, gradually decreasing to 10 min at the end of the fermentation process. Filter as soon as fermentation has ceased.

POTENTISATION
Aqueous dilutions

The 1st decimal dilution (D1) is made from
1 part of Rh mother tincture and
9 parts of water for injections.

Subsequent decimal dilutions are produced as stated for D1.

Ethanolic dilutions
The 1st decimal dilution (D1) is made from
1 part of Rh mother tincture and
9 parts of ethanol 18 per cent (*V/V*).

Subsequent decimal dilutions are produced as stated for D1.

RECOMMENDED DESIGNATION
Preparations made according to APC Method 3.13.1 carry the designation "Rh"; the same applies to preparations made from them. If ethanol 18 per cent (*V/V*) is used from the 1st decimal dilution onwards, state this on the label.

APC Method 3.13.2 (related to HAB Method 22)
Rh mother tinctures according to APC Method 3.13.2 are prepared from fresh plants, generally yielding distinctly less than 50 per cent of expressed liquid, as follows:

Comminute the plants immediately after harvesting. Subject the plant material to the diurnal hot-cold rhythm ("Rh") for 7 – 10 days. Each morning, warm the plant material to approximately 35 – 39 °C and maintain at this temperature. Each evening, cool the plant material to 2 – 6 °C and maintain at this temperature.
Then express. Transfer the expressed juice to containers and subject to the diurnal hot-cold rhythm ("Rh") as described under method 3.13.1.

POTENTISATION
Aqueous dilutions
The 1st decimal dilution (D1) is made from
1 part of Rh mother tincture and
9 parts of water for injections.

Subsequent decimal dilutions are produced as stated for D1.

Ethanolic dilutions
The 1st decimal dilution (D1) is made from
1 part of Rh mother tincture and
9 parts of ethanol 18 per cent (*V/V*).

Subsequent decimal dilutions are produced as stated for D1.

RECOMMENDED DESIGNATION
Mother tinctures made according to APC Method 3.13.2 carry the designation "Rh"; the same applies to preparations made from them. If ethanol 18 per cent *(V/V)* is used from the 1st decimal dilution onwards, state this on the label.

4. SOLID STARTING MATERIALS OBTAINED BY HEAT

Heat treatment can be applied directly to solid starting materials from botanical or zoological origin without addition of a vehicle. The heat treatment may be performed under presence or reduced presence of oxygen.
Solid starting materials obtained by heat include toasted preparations (Tosta), carbons (Carbo) and ashes (Cinis).

4.1. Toasted preparations – Tosta

DEFINITION
Toasted preparations are obtained from dried plants or parts of plants or solid, dried animal matter by toasting. Toasted preparations are dry, usually brownish and have an intense and characteristic odour.

The substances to be toasted are crushed, if necessary, and are exposed to a heat source for the prescribed time. During the process water evaporates and the matter becomes brown or brownish. This is achieved through control of the heat supply, usually 170 – 250 °C and by tossing the material during this procedure. The toasted substance is powdered.
Particle size of the raw material, temperature and heating time are prescribed in the individual monograph.

Toasted substances may be potentised according to Ph.Eur. 4.1.1.

IDENTIFICATION
According to the individual monograph.

TESTS
The tests are carried out according to the individual monograph, where applicable.

ASSAY
An assay is carried out according to the individual monograph, where applicable.

STORAGE
Store in a well-closed container.

RECOMMENDED DESIGNATION
The designation states:
- the name of herbal or animal matter used,
- the designation "tostus/a/um/", example: Spongia tosta,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce toasted preparations.

According to the individual monograph.
Ph.Helv 17.7.4.1

4.2. Carbons – Carbo

DEFINITION
Carbons are obtained from dried plants or parts of plants or dried animal matter. They are dry, brittle, and generally black substances.
The plant or animal matter is heated to a temperature usually above 200 °C under reduced presence of oxygen to produce the carbonised deposit. The carbonised substance is powdered.
Carbons may be potentised according to Ph.Eur 4.1.1.

IDENTIFICATION
The identification is carried out according to the individual monograph.

TESTS
The tests are carried out according to the individual monograph, where applicable:
- Acidity or Alkalinity,
- Acid-soluble substances,
- Adsorption power,
- Alkali-soluble coloured matter,
- Cyanide,
- Ethanol-soluble substances,
- Fluorescent substances,
- Heavy metals *(e.g. Ph.Eur. 2.4.8)*,
- Loss on drying *(Ph.Eur. 2.2.32)*,
- Sulfated ash *(Ph.Eur. 2.4.14)*,
- Sulfide,
- Total ash *(Ph.Eur. 2.4.16)*,
- Zinc.

ASSAY
An assay is carried out according to the individual monograph, where applicable.

STORAGE
Store in a well-closed container.

RECOMMENDED DESIGNATION
The designation states:
- the name of the herbal or animal matter used,
- the designation "Carbo", example: Carbo Gentianae,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce carbons

Ph.Helv. 17.7.4.2

4.3. Ashes – Cinis

DEFINITION
Ashes are obtained from dried plants or parts of plants or dried animal matter. They are generally fine, amorphous, white, grey, beige or brown powders.

The herbal or animal matter is incinerated generally at a temperature above 500 °C.

Ashes may be potentised according to Ph.Eur. 4.1.1.

IDENTIFICATION
The identification is carried out according to the individual monograph.

TESTS
The tests are carried out according to the individual monograph, where applicable:
- Acid insoluble substances,
- Arsenic *(e.g. Ph.Eur. 2.4.2)*,
- Heavy metals *(e.g. Ph.Eur. 2.4.8)*,
- Loss on drying *(Ph.Eur. 2.2.32)*.

ASSAY
Where applicable the Cinis complies with the individual monograph.

STORAGE
Store in a well-closed container with a desiccant if necessary.

RECOMMENDED DESIGNATION
The designation states:
- the name of the herbal or animal substance used,
- the designation "Cinis", example: Cinis Tabaci,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce ashes

Ph. Helv. 17.7.4.3

5. SOLID PREPARATIONS FROM PLANTS (DRYING ONTO A VEHICLE)

Solid preparations from plants are obtained either by drying fresh plants, plant juices or aqueous extracts onto a vehicle.

5.1. Solid preparations from fresh plants

DEFINITION
Solid preparations of fresh plants are prepared by drying fresh plant material onto suitable vehicles e.g. lactose monohydrate.

PRODUCTION
Comminute the fresh plant material, and mix thoroughly with the vehicle in order to adsorb its liquid part. Dry the mixture gently and mill if necessary.
The preparation can be potentised according to Ph.Eur. (2371) Methods 4.1.1 and 4.1.2.

IDENTIFICATION
At least one chromatographic test is carried out.

TESTS
Loss on drying *(Ph.Eur. 2.2.32):* The solid preparation complies with the limits prescribed in the individual monograph.
Microbiological quality *(Ph.Eur. 5.1.4)*: (Non-aqueous preparations for oral use).

ASSAY
An assay with quantitative limits is performed when raw materials with toxicologically or therapeutically relevant substances are used.

STORAGE
Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION
The designation states:
- the name of the plant material used,
- the quantity used,
- the vehicle used,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce solid preparations from fresh plants

Ph.Eur. (2371) Method
4.1.1

APC Method 5.1.1
Preparations according to APC Method 5.1.1 are solid preparations of fresh plants prepared by drying fresh herbal drugs onto lactose monohydrate.
Comminute the plants or parts of plants. To 1 part of the plant material add the required amount of lactose monohydrate, usually 2.9 parts unless otherwise prescribed in the individual monograph. Mix thoroughly. Dry the moist mixture gently until it reaches the dryness required. Mill, if necessary, then sieve as specified in the individual monograph and remix thoroughly.

POTENTISATION
The preparation can be potentised according to Ph.Eur. (2371) Methods 4.1.1 and 4.1.2.
The 1st decimal dilution (D1) is made from
3 parts of the solid preparation and
7 parts of lactose monohydrate

5.2. Solid preparations from liquids, plant juices or aqueous extracts

DEFINITION
Solid preparations of liquids are prepared by drying plant juices, tinctures, aqueous extracts or solutions or their dilutions onto suitable vehicles e.g. lactose monohydrate.
The expressed juice or the tincture from the fresh plant material or the solution is mixed thoroughly with the vehicle. The mixture is dried gently and milled if necessary.
The preparation can be potentised according to Ph.Eur. (2371) Methods 4.1.1 and 4.1.2.

PRODUCTION
According to the specific methods or the individual monograph.

IDENTIFICATION
At least one chromatographic test is carried out.

TESTS

Loss on drying *(Ph.Eur. 2.2.32).* The solid preparation complies with the limits prescribed in the individual monograph.
Microbiological quality *(Ph.Eur. 5.1.4)*. (Non-aqueous preparations for oral use)

ASSAY

An assay with quantitative limits is performed when raw or starting materials with toxicologically or therapeutically relevant substances are used.

STORAGE

Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION

The designation states:
- the name of the plant material used,
- the quantity used,
- the vehicle used,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce solid preparations from liquid extracts/ plant juices
Ph.Eur. (2371) Methods (refer to potentisation)
4.1.1
4.1.2

APC Method 5.2.1
Preparations according to APC Method 5.2.1 are solid preparations from fresh plant juices prepared by drying the fresh plant juice onto lactose monohydrate or another excipient.
Add 1 part of the expressed plant juice or aqueous extract to 1.9 parts of lactose monohydrate unless otherwise prescribed in the individual monograph to obtain a wet granulate. Dry the wet granulate gently until it reaches the dryness required. Mill, if necessary, then sieve as specified in the individual monograph and remix thoroughly. For granulation it may be necessary to concentrate the plant juice under reduced pressure.

APC Method 5.2.2
Preparations according to APC Method 5.2.2 are solid preparations from fresh plant juices prepared by drying the fresh plant juice onto lactose monohydrate or another excipient.
The expressed plant juice of 1 part of the fresh plant is added to 3 parts of lactose monohydrate unless otherwise prescribed in the individual monograph to obtain a wet granulate. Dry the wet granulate gently until it reaches the dryness required. Mill, if necessary, then sieve as specified in the individual monograph and remix thoroughly. Before granulation it may be necessary to concentrate the plant juice under reduced pressure.

APC Method 5.2.3
Preparations according to APC Method 5.2.3 are solid preparations from aqueous extracts prepared by drying aqueous extracts of fresh plants onto lactose monohydrate or another excipient.
Mix 1 part of the comminuted fresh plants with 0.15 parts of purified water. Then express the mixture.
The expressed aqueous extract is added to 4 parts of lactose monohydrate unless otherwise prescribed in the individual monograph to obtain a wet granulate. Dry the wet granulate gently until it reaches the dryness required. Mill, if necessary, then sieve as specified in the individual monograph and remix thoroughly. Before granulation it may be necessary to concentrate the aqueous extract under reduced pressure.

6. LIQUID DILUTIONS

DEFINITION

Liquid dilutions are prepared by dissolving one or more starting materials in an appropriate vehicle. The liquid obtained may be directly potentised.

PRODUCTION

The starting material is dissolved in the appropriate vehicle. Dissolution may require heating or stirring. The separation of a residue may be necessary.

Where necessary, immediately after the dissolution the first potentisation step is carried out in accordance with the individual monograph.

IDENTIFICATION

Liquid dilutions are identified using a suitable method.

TESTS

Appearance *(Ph.Eur. 2.2.1, 2.2.2)*. Where applicable, the preparation complies with the limits described in the individual monograph.
pH *(Ph.Eur. 2.2.3)*. Where applicable, the preparation complies with the limits prescribed in the individual monograph.
Dry residue *(Ph.Eur. 2.8.16 or H 2.2.6).* Where applicable, the liquid solution complies with the limits prescribed in the individual monograph.
Relative density *(Ph.Eur. 2.2.5)*. The preparation complies with the limits prescribed in the individual monograph.

ASSAY

Where applicable, liquid solutions of chemically

defined starting materials are assayed.

STORAGE
Store in a well-closed container, protected from light.

RECOMMENDED DESIGNATION
The designation states:
- the name of the substance dissolved,
- the quantity dissolved,
- where applicable, the degree of potentisation,
- the reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce liquid dilutions

Ph.Eur. (2371) Methods
3.1.1
3.1.2

HAB Methods 5

7. COMPOSITIONS

Compositions are active substances which are obtained when two or more starting materials and/or preparations with or without excipients and/or vehicles are processed together in a pharmaceutical process that will lead to a new substance (unit). The rationale for composing is the anthroposophic understanding of man, nature, substance and processing. Compositions may be directly used as an active substance or can be potentised or diluted for any dosage form.

7.1. Compositions made by treating two or more starting materials by one or more pharmaceutical processes

DEFINITION
Compositions made by treating two or more starting materials or preparations by one or more pharmaceutical processes are prepared by combining starting materials in a defined ratio according to the individual monograph using a specified process (e.g. specified mixing, heat treatment, chemical process).

PRODUCTION
According to the specific methods or the individual monograph.

IDENTIFICATION/TESTS
According to the nature of the composition. The components of the composition comply with the requirements of the relevant monographs.

RECOMMENDED DESIGNATION
The designation states:
- the name of the composition,
- the composition of the product (quantity of the ingredients),
- reference pharmacopoeia/codex.

Specific APC production methods to produce compositions according to 7.1

Examples (see appendix 2.6): Anis-Pyrit, Ferrum-Quarz, Hepar-Magnesium, Hepar sulfuris, Kalium aceticum comp., Plumbum mellitum, Solutio Sacchari comp. (mineral compositions according to the model of a plant).

7.2. Compositions made by treating two or more extracts or mother tinctures of one plant by one or more pharmaceutical processes

DEFINITION
Compositions made by treating two or more mother tinctures of one plant by pharmaceutical processes are prepared from extracts (mother tinctures) of the same plant species harvested at different seasons, i.e. at different stages of development. According to the individual monograph the extracts are combined in a defined ratio by a specific pharmaceutical process possibly using specific equipment. Adjustment of concentration, of pH, and of osmolality may be carried out.

PRODUCTION
According to the specific methods or the individual monograph.

IDENTIFICATION/TESTS
According to the nature of the composition. The components of the composition comply with the requirements of the relevant monographs.

RECOMMENDED DESIGNATION
The designation states:
- the name of the composition,
- the composition of the product (quantity of the ingredients),
- reference pharmacopoeia/codex.

Specific pharmacopoeial APC production methods to produce compositions according to 7.2

HAB Method 32
HAB Method 38

See appendix 2.6, for example Viscum album compositions.

APC Method 7.2.1 (see also APC Method 3.7.1)
Compositions according to APC Method 7.2.1 are produced from fresh plants or parts of plants by the following procedure:
Finely comminute the plants or parts of plants and mix 1 part of the plant mass with 1 part of purified water. Leave to ferment at 20 to 24 °C with the exclusion of air, ending the fermentation when the pH of the fermentation liquid has fallen to between 4 and 5. Then express and weigh the expressed liquid. The weight of the expressed liquid is equal to 2 parts and is mixed with 1 part of a mixture of 0.95 parts of ethanol 96 per cent (*V/V*) and 0.05 parts of purified water. This tincture is stored until it will undergo another pharmaceutical process with a second tincture of the same plant.
This procedure is followed for plants harvested in summer and for plants of the same species, harvested in winter.
The mother tincture is a composition, produced by unifying equal parts of the two tinctures.

The mother tincture can be potentised as follows:

The 1st decimal dilution (D1) is made from
3 parts of the mother tincture and
7 parts of ethanol 36 per cent (*V/V*).

The 2nd decimal dilution (D2) is made from
1 part of the 1st decimal dilution and
9 parts of ethanol 18 per cent (*V/V*).
Subsequent dilutions are produced as stated for D2.

RECOMMENDED DESIGNATION
Preparations according to APC Method 7.2.1 carry the designation „ferm APC 7.2.1".

APC Method 7.2.2 Compositions of aqueous extracts and liquid preparations thereof
Compositions according to APC Method 7.2.2 are mother tinctures produced from fresh (frozen) plants or parts of plants by the following procedure.
The plants or parts of plants are comminuted in a grinder, pressed in appropriate boxes and frozen at – 10 °C to – 30 °C. The plants or parts of plants are combined to a specific formulation: Plants and parts of plants from winter harvest with plants from spring harvest to give the so called winter formulation. Plants from summer harvest with plants from autumn harvest to give the so called summer formulation.
5 parts of frozen plants are extracted for 1 – 4 h at 10 – 20 °C with 95 parts of 0.09 % sodium chloride solution in a container with stirring. The coarse plants or plant parts are separated by centrifugation. The centrifugate is filled up to 100 parts with 0.09 percent sodium chloride solution and filtered. The winter formulation produces the so called winter extract, the summer formulation the so called summer extract. If the extract is to be stored, sterile filtration must take place.
The composition is produced by composing three parts of winter extract and one part of summer extract as described below.
The winter extract is stirred in a specially constructed gilded mixing vessel. The summer extract is allowed to drop from the top of the vessel into the vortex of the winter extract. The osmolality is adjusted by adding sodium chloride and the pH is adjusted to 6.1 – 6.3 by adding sodium hydroxide solution. If the composition is to be stored, sterile filtration must take place. The composition (mother tincture) can be used directly or can be used for further dilutions. The addition of antioxidants or substances for pH adjustment is allowed.

Dilutions are obtained by diluting the composition. At a temperature between 10 °C and 25 °C the necessary amount of 0.9 percent sodium chloride solution is stirred in a vessel; the composition is dropped from the top into the vortex. The dilution series is: (Composition + sodium chloride solution) e.g. 3+2 (30 mg), 2+3 (20 mg), 1+4 (10 mg), 1+9 (5 mg), 1+49 (1mg), 1+499 (0.1 mg); 1+4999 (0.01 mg). If the dilution is to be stored, sterile filtration must take place.

RECOMMENDED DESIGNATION
The amount of herbal drug (fresh plant) which was extracted to achieve 1 mL/2 mL of the final preparation.

APC Method 7.2.3 and 7.2.4 Compositions of fermented aqueous extracts and liquid preparations thereof
Compositions according to APC Method 7.2.3 and 7.2.4 are mother tinctures produced from fresh plants or parts of plants by the following procedure.
Finely comminute the plants or parts of plants and mix 1 part of the plant mass with 1.318 parts of purified water, 0.03 parts of sucrose, and 0.002 parts of a Lactobacillus plantarum suspension, 10^9 – 10^{10} cfu/mL and mix thoroughly. Leave to ferment for 3 days at 20 to 27 °C with the exclusion of air. Then express and weigh the expressed liquid. If (except for the berries) gentle pressure applied to the plant residue does not achieve a final mass of extract equal to 2 parts, pour a sufficient amount of purified water over the plant residue and express gently. Use the resulting extract to make the extract up to 2 parts. If prescribed in the

individual monograph, adjust the pH to 5.0 – 6.5 by adding sodium hydroxide.
Follow the same procedure for plant material harvested in the summer and for plant material of the same species, harvested in the winter. However, for the winter harvest, process the berries and the other plant parts separately according to the method described above and use 1.328 parts of purified water and 0.02 parts of sucrose. Also, leave the berry mixture to ferment for 4 days.
If the extracts are stored for further processing, they must comply with the test for sterility (Ph.Eur. 2.6.1).

The composition is produced by composing equal parts of the summer and the combined winter extracts as described below.

Method 7.2.3
Mix two parts of summer extract with 3 parts of water for injections.
Mix one part of winter extract of plant material and one part of extract of berries with 3 parts of water for injections.

Method 7.2.4
Mix two parts of summer extract with 3 parts of water for injections. Mix one part of winter extract of plant material and one part of extract of berries with a mixture of 0.002 parts of a metal salt trituration from the D4 potentisation step and 2.998 parts of water for injections.

Methods 7.2.3 and 7.2.4
Feed the mixture of the winter extracts continuously onto the centre of a rotating disk. At the same time, feed the summer extracts continuously onto the slightly raised edge of the disk. The blended mixture flows continually off over the edge of the disk. Filter the mixture; the filtrate is the mother tincture. If the mother tincture is stored for further processing, it must comply with the test for sterility (Ph.Eur. 2.6.1).
The dilution series is (composition or dilution + water for injections): 1+9 (20 mg), 1+19 (10 mg, corresponding to a 1:20 dilution); 1+39 (5 mg); 1 + 99 (2 mg);
1 part 1:20 dilution + 9 parts water for injections (1:200 or 1 mg); 1 part 1:200 dilution + 9 parts water for injections (1:2,000 or 0.1 mg); 1 part 1:2,000 dilution + 9 parts water for injections (1:20,000 or 0.01 mg); 1 part 1:20,000 dilution + 9 parts water for injections (1:200,000 or 0.001 mg); 1 part 1:200,000 dilution + 9 parts water for injections (0.0001 mg). To prepare the final preparation, add sodium chloride to the water for injections to obtain an isotonic solution.

Compositions produced according to methods 7.2.3 and 7.2.4 may be potentised according to chapter 8.

RECOMMENDED DESIGNATION
The amount of herbal drug (fresh plant) which was extracted to achieve 1 mL of the final preparation.

STORAGE
Store the mother tincture in a well-closed container at 2 – 8 °C.

7.3. Compositions made by treating one or more starting materials with one or more mother tinctures which undergo one or more pharmaceutical processes together

DEFINITION
Compositions made by treating one or more starting materials with one or more mother tinctures are obtained by combining one or more starting materials with one or more stocks in a defined ratio according to the individual monograph.

PRODUCTION
According to the specific methods or the individual monograph.

IDENTIFICATION/TESTS
According to the nature of the composition. The components of the composition comply with the requirements of the relevant monographs.

RECOMMENDED DESIGNATION
The designation states:
- the name of the composition,
- the composition of the product (quantity of the ingredients),
- reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce compositions according to 7.3

Examples (see appendix 2.6): Cinis e fructibus Avenae sativae cum Magnesio phosphorico (1:1), Cissus-Ossa.

7.4. Compositions made by treating two or more extracts or mother tinctures and/or dilutions by one or more pharmaceutical processes

DEFINITION
Composition made by treating two or more extracts or mother tinctures and/or dilutions by pharmaceutical

processes are prepared according to an individual monograph prescribing the combination of the ingredients in a defined ratio by a specific pharmaceutical process using specific equipment.

PRODUCTION
According to the individual monograph.

IDENTIFICATION/TESTS
According to the nature of the composition. The components of the composition comply with the requirements of the relevant monographs.

RECOMMENDED DESIGNATION
The designation states:
- the name of the preparation,
- the composition of the product (quantity of the ingredients),
- reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce compositions according to 7.4

Examples (see appendix 2.6): Onopordum acanthium, Folium rec., ethanol. Digestio (1:3.1) with 1 – 2 % Hyoscyamus niger, Herba rec. Ø, see also Plantago lanceolata and Primula.

7.5. Compositions made by co-potentising

DEFINITION
Compositions made by co-potentising are prepared from two or more starting materials and/or preparations (e.g. mother tinctures, potencies) by co-potentising over one or more steps.

PRODUCTION
According to APC Method 8.1 or the individual monograph.

IDENTIFICATION/TESTS
According to the nature of the composition. The components of the composition comply with the requirements of the relevant monographs.

RECOMMENDED DESIGNATION
The designation states:
- the name, quantity and potency degree of each ingredient,
- how many potentising steps were carried out on the mixture as a whole,
- reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce compositions according to 7.5
Ph.Eur. (2371) Methods
5.1.1
5.1.2
5.1.5

8. POTENTISED PREPARATIONS

Potentised preparations are gradually diluted substances, whereby at each diluting step a rhythmic succussion (liquid potencies) or trituration (solid or semi-solid potencies) has been carried out for a defined time. The potentising time differs for solid and liquid potentised preparations. Astronomical aspects may be considered (e.g. solar or lunar eclipse).The preparations are defined by the number of liquid potentising or trituration steps respectively and by the ratio between the vehicle (diluting agent) and the substance to be potentised.

The potentising ratio is usually:
1 part of substance
9 parts of vehicle.

The potentising ratio for co-potentised preparations is usually:
1 part of a mixture of equal parts of active substances
9 parts of vehicle.

LIQUID POTENCIES:
The substance or mixture to be potentised is dissolved in the vehicle in the chosen ratio. Usual vehicles for liquid potencies are water (purified or water for injections), ethanol of various concentrations, glycerol or vegetable oils. Excipients might be necessary, for example to emulsify an aqueous substance into oil. After dissolution, rhythmic succussion is carried out. For the next potentising step one part of the first potency and the prescribed amount of vehicle are brought together and succussed. Further potentising is carried out in likewise manner.

SOLID POTENCIES (TRITURATIONS):
Potencies of solid substances are prepared by trituration of the substance to be potentised usually with lactose monohydrate in the prescribed ratio in a mortar with a pestle or in an adequate trituration machine.
Solid potencies can be further potentised in liquid phase, if they are soluble in a vehicle.

SEMI-SOLID POTENCIES:
Semi-solid potencies are prepared by trituration of a liquid or a solid substance to be potentised with an

ointment base in the prescribed ratio in a mortar with a pestle or in an adequate trituration machine.

Specific pharmacopoeial/APC production methods to produce potentised preparations
Ph.Eur. (2371) Methods
3.2.1 – 3
4.1.1 – 2
4.2.1 – 2
5.1.1 – 5
5.2

HAB Method 12j

The potentising specifications in Ph.Eur. monograph 2371 of Methods 1.1.1 – 1.1.11, 2.1.1, 2.1.2, 2.2.1 – 2.2.4 and 5.1.1 – 5.1.5.

The potentising specifications in HAB methods 5, 11, 15, 32, 33, 34, 35, 36, 37, 38, 39a, 39b, 45, 51, 53.

The potentising specifications in APC Methods.

8.1. Co-potentised preparations

DEFINITION
Method 8.1 is used for preparing dilutions by co-potentising two or more stocks and/or dilutions thereof, where co-potentisation consists of mixing several stocks or dilutions of stocks then potentising them together in one or more potentisation steps.

PRODUCTION
Co-potentised compositions according to APC Method 8.1 may be prepared from starting materials and/or solutions, potentised preparations and mother tinctures whose method of production is specified by a ratio of 1 part of starting material and 10 parts of extraction solvent.
When a solid potency D4 shall be potentised with liquids, it can be potentised one step according to Ph.Eur. (2371) Methods 3.2, and then be used as D5 for co-potentisation or dilution to a final concentration of 1 ppm.

Co-potentised compositions may be used to produce all types of dosage forms. Co-potentisation of mixtures according to APC Method 8.1 to produce parenteral preparations or eye drops is carried out with water for injections or an isotonic solution as diluting agent.

IDENTIFICATION, TEST, ASSAY
are carried out according to the individual monograph.

STORAGE
Store in a well-closed container.

RECOMMENDED DESIGNATION
The designation states:
- the name of the potentised substance(s),
- where applicable, the ethanol content,
- the potentising ratio; decimal potencies may be designated as D or DH or X,
- the potency degree, example: D3 or 3 DH or 3X,
- the reference pharmacopoeia/codex.

APC Method 8.1.1 (Ph.Eur. (2371) Method 5.1.5)
Co-potentised preparations according to APC Method 8.1.1 are liquid dilutions potentised with a suitable vehicle from two or more (n) preparations, each making up 1 part of the final 10 parts. Consequently the vehicle is 10 minus n parts.

POTENTISATION
For the first co-potentisation step combine and succuss 1 part of each of the n preparations with 10 minus n parts of water or ethanol of the appropriate concentration specified under HAB H 5.3. For each further co-potentisation step the ratio is 1 part of the given composed potency and 9 parts of vehicle.

RECOMMENDED DESIGNATION
The designation of co-potentised compositions according to APC Method 8.1.1 and derived dosage forms states how many potentising steps were carried out on the mixture as a whole adding the expressions “rhythmically diluted”.

APC Method 8.1.2 (related to Ph.Eur. (2371) Methods 5.1.1 and 5.1.2)

Co-potentised preparations according to APC Method 8.1.2. are liquid dilutions potentised with a suitable vehicle from two or more (n) preparations, each making up 1/n part of the final 10 parts. Consequently the vehicle is 9 parts.

POTENTISATION
For the first co-potentisation step combine and succuss 1/n part of each of the n preparations with 9 parts of water or ethanol of the appropriate concentration specified under HAB H 5.3. For each further co-potentisation step the ratio is 1 part of the given composed potency and 9 parts of vehicle.

RECOMMENDED DESIGNATION
The designation of co-potentised compositions according to APC Method 8.1.2. and derived dosage

forms states how many potentising steps were carried out on the mixture as a whole.

8.2. Potentising in an ointment base

DEFINITION
Liquid and solid starting materials can be potentised within an ointment base.

PRODUCTION
According to the specific methods or the individual monograph.
IDENTIFICATION, TESTS, ASSAY
are carried out according to the individual monograph.

STORAGE
Store in a well-closed container.

RECOMMENDED DESIGNATION
The designation states:
- the name of the potentised substance(s),
- the potentising ratio; decimal potencies may be designated as D or DH or X,
- the potency degree in the ointment,
- the reference pharmacopoeia/codex.

APC Method 8.2.1 (Ointments containing powdered solid starting materials, related to HAB Method 48)
Ointments containing powdered solid starting materials are produced with 1 part of a powdered metal, powdered mineral or a composition containing minerals and 9 parts of an ointment base leading to a homogeneous ointment. This potentising step in an ointment base results in the first decimal dilution (D1). The particle size of the powdered solid starting material must be smaller than 100 µm.
Ointments according to APC Method 8.2.1 must meet the requirements of the Ph.Eur. monograph "Semi-solid preparations for cutaneous application" (0132).
Ointments according to APC Method 8.2.1 can be used further to produce ointments according to HAB Method 13.

RECOMMENDED DESIGNATION
Ointments according to APC Method 8.2.1 carry the designation "APC M" and the resulting decimal dilution "D1".

APC-Method 8.2.2 Ointments containing solid or liquid dilutions
Ointments containing solid or liquid dilutions are produced with 1 part of a decimal solid or liquid dilution (Dn) and 9 parts of an ointment base leading to a homogeneous ointment. The resulting decimal dilution degree is (Dn+1).
Ointments according to APC Method 8.2.2. must meet the requirements of the Ph.Eur. monograph "Semi-solid preparations for cutaneous application" (0132).

RECOMMENDED DESIGNATION
Ointments according to APC Method 8.2.2 carry the designation of the resulting degree of decimal dilution. Example: D3 or 3 DH or 3X APC 8.2.2.

8.3. Triturations

DEFINITION
Preparations according to APC Method 8.3 are triturations of solid substances with lactose monohydrate as potentising vehicle unless otherwise specified in a ratio of 1:10.

PRODUCTION
Triturate using a machine that ensures even trituration. Suitable machines include mixers with rhythmic, pulsating spatial inversion (e.g. "Turbula"), in combination with a sealable mixing vessel and appropriate grinding balls as well as other machines with rotating movements such as the ball mill.
Triturate the whole amount of vehicle with the substance to be potentised.
The trituration time depends on the machine and the chosen parameters. Trituration must be between 15 and 60 minutes. It has to be ensured, that the trituration is homogeneous and that particle size reduction is achieved.

TESTS
are carried out according to the individual monograph.

RECOMMENDED DESIGNATION
Preparations according to APC Method 8.3 carry the designation of the resulting degree of decimal dilution. Example: D3 or 3 DH or 3X APC 8.3.

9. MIXTURES

DEFINITION
Mixtures are produced from usually two or more active substances.Vehicles and/or excipients may be added. Mixtures contain the sum of the active substances mixed together. Mixtures can also be produced from one active substance and a vehicle. A special manufacturing method is not needed (cf. compositions). Mixtures are used to facilitate the administration of more than one active substance in one single finished product. The mixture itself may be the final dosage form.

Mixtures can be classified into four categories:
9.1. Mixtures of preparations without a vehicle
9.1a. Mixtures of liquid preparations produced according to Ph.Eur., HAB or APC Methods.
9.1b. Mixtures of solid preparations produced according to Ph.Eur., HAB or APC Methods.
9.1c. Liquid and solid preparations, produced according to Ph.Eur., HAB or APC Methods, resulting in a liquid preparation.

9.2. Mixtures of preparations with a vehicle
9.2a. Liquid preparations produced according to Ph.Eur., HAB or APC Methods in which the vehicle is added in a ratio other than 1 to 10 or 1 to 100.
9.2b. Solid preparations produced according to Ph.Eur., HAB or APC Methods in which the vehicle is added in a ratio other than 1 to 10 or 1 to 100.
9.2c. Liquid and solid preparations, produced according to Ph.Eur., HAB or APC Methods, resulting in a liquid preparation, in which the vehicle is added in a ratio other than 1 to 10 or 1 to 100.
9.3. Mixtures of preparations with excipients and vehicles.
9.3a. Liquid preparations produced according to Ph.Eur., HAB or APC Methods with an excipient(s). Vehicles may be added.
9.3b. Liquid and solid preparations, produced according to Ph.Eur., HAB or APC Methods, resulting in a liquid preparation with an excipient(s). Vehicles may be added.
9.4. Mixtures of starting materials used as active substances and mother tinctures or preparations with or without vehicles and/or excipients.

RECOMMENDED LABELLING

- the ingredients mixed and their quantity,
- reference pharmacopoeia/codex.

Specific pharmacopoeial/APC production methods to produce mixtures
HAB Method 12
HAB Method 16

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PART IIb

Individual monographs of starting materials and preparations

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Part IIb

CYDONIA OBLONGATA, FRUIT

Cydonia oblonga, Fructus
Cydonia

DEFINITION

Fresh, ripe fruit of *Cydonia oblonga* Mill. collected during late summer and autumn.

CHARACTERS

The odour is characterised by a typical flowery scent.

IDENTIFICATION

The pear-shaped variety (var. *pyriformis*) is yellow, fragrant, fuzzy, 7 – 15 cm in diameter. The gentle soft pulp is golden yellow.
The apple-shaped variety (var. *maliformis*) is yellow to greenish yellow, fuzzy, 7-15 cm in diameter and less fragrant. The pulp is characterised by stone cells.
Both varieties obtain five oblong-ovate sepals with serrate margins which are located in a depression. They are completely adnate with the 5 carpels. The 5 loculi of the core generally each contain 5 to 15 or sometimes more brown, cuneate seeds arranged in 2 vertical rows and stuck together with a mucilaginous coat.

TESTS

Foreign matter (*Ph.Eur. 2.8.2*).
As low as possible. The whole batch is checked during manufacture. Foreign matter is sorted out.

Adulteration.
Fruits from Japanese quince [*Choenomeles japonica* (Thunb.) Lindl. ex Spach, syn. *Cydonia japonica* Pers., Rosaceae] and Chinese quince [*Choenomeles speciosa* (Sweet) Nakai, Rosaceae] are 4 to 5 cm in diameter with a smooth peel and being devoid of stone cells.

PREPARATIONS

1. Heat treated aqueous preparation according to the individual monograph,
2. Heat treated preparation with glycerol according to the individual monograph,
3. Tincture obtained by rhythmic application of heat and cold according to APC method 3.13 and method HAB 33b.

CYDONIA OBLONGA, FRUIT, HEAT TREATED AQUEOUS TINCTURE 1:2.1

DEFINITION

The heat treated aqueous tincture is prepared from the fresh cut fruit of *Cydonia oblonga* Mill., see Cydonia oblonga, Fruit (Cydonia oblonga, Fructus; Cydonia) APC

PRODUCTION

The heat treated aqueous tincture is prepared in a ratio of fresh fruits to purified water 1:2.1 and by heat treatment at 65 – 70 °C as follows:

The whole fresh ripe fruit are cut into pieces (2 – 4 cm). To 1 part of the cut fruit add 2.1 parts of purified water and mix thoroughly. Heat to 65 – 70 °C in a closed container and keep at this temperature for one hour swirling repeatedly. After cooling to 40 – 45 °C separate by straining the mixture through gauze, filter the resulting liquid and process immediately.

CHARACTERS

Appearance: light yellow, slightly turbid liquid.
Odour: fruity.

IDENTIFICATION

Thin-layer chromatography *(Ph.Eur. 2.2.27)*.

Test solution. Apply 10 mL onto a cartridge filled with octadecylsilylated silica gel *RH* (particle size 55 – 110 µm, 360 mg), preconditioned sequentially with 10 mL of methanol *R* and 10 mL of water *R*. Wash the cartridge with 10 mL of water *R*. Elute with 10 mL of methanol *R*. Evaporate the eluate to dryness under reduced pressure. Dissolve the residue in 1 mL of methanol *R*.

Reference solution. Dissolve 5 mg of rutin *R*, 5 mg of hyperoside *R* and 5 mg of scopoletin *R* in 10 mL of methanol *R*.

Plate: TLC silica gel plate *R*.

Mobile phase: anhydrous formic acid *R*, water *R*, ethyl acetate *R* (15:15:70 *V/V/V*).

Application: 20 µL as bands.

Development: over a path of 10 cm.

Drying: at 105 °C for 5 min.

Detection: spray the plate while still warm with a 10 g/L solution of diphenylboric acid aminoethyl ester *R* in methanol *R*. Subsequently spray with a 50 mL/L solution of macrogol 400 *R*. Examine in ultraviolet light at 365 nm within 30 min.

Results: see below the sequence of the zones present in the chromatograms obtained with the reference solution and the test solution. Other faint zones may be present in the chromatogram obtained with the test solution.

Top of the plate	
Scopoletin: a blue zone	A blue zone A blue zone
Hyperoside: an orange zone	A strong light blue zone
Rutin: an orange zone	An orange zone
Reference solution	**Test solution**

TESTS
Relative density *(Ph.Eur. 2.2.5)*: 1.002 to 1.022.
pH *(Ph.Eur. 2.2.3)*: 3.0 to 4.0.
Dry residue *(Ph.Eur. 2.8.16)*: min. 2.5 % (3 g initial weight and dry at 105 °C for 2 hours).

STORAGE
If stored it must meet the requirements of sterility, store in well closed containers, protected from light.

CYDONIA OBLONGATA, FRUIT, GLYCEROL EXTRACT WITH HEAT TREATMENT 1:2.1

DEFINITION
The glycerol extract with heat treatment is prepared from the fresh cut fruit of *Cydonia oblonga* Mill., see Cydonia oblonga, Fruit (Cydonia oblonga, Fructus; Cydonia) APC.

PRODUCTION
The glycerol extract with heat treatment is prepared in a ratio of fresh fruits to glycerol (85 per cent) 1:2.1 and by heat treatment at 65 – 70 °C as follows:

The whole fresh ripe fruit is cut into pieces (2 – 4 cm). To 1 part of the cut fruit add 2.1 parts of glycerol (85 per cent) and mix thoroughly. Heat to 60 – 70 °C in a closed container and keep at this temperature for one hour swirling repeatedly. After cooling to 40 – 45 °C separate the mixture by straining through gauze, then filter if necessary.

CHARACTERS
Appearance: light yellow, slightly turbid, viscous liquid.
Odour: fruity.

IDENTIFICATION
Thin-layer chromatography *(Ph.Eur. 2.2.27)*.

Test solution. To 5 mL add 15 mL of water *R*. Apply the mixture onto a cartridge filled with octadecylsilylated silica gel *RH* (particle size 55 – 110 µm, 360 mg), preconditioned sequentially with 10 mL of methanol *R* and 10 mL of water *R*. Wash the cartridge with 10 mL of water *R*. Elute with 10 mL of methanol *R*. Evaporate the eluate to dryness under reduced pressure. Dissolve the residue in 0.5 mL of methanol *R*.

Reference solution. Dissolve 10 mg of rutin *R*, 10 mg of hyperoside *R* and 2 mg of scopoletin *R* in 10 mL of methanol *R*.

Plate: TLC silica gel plate *R*.

Mobile phase: anhydrous formic acid *R*, water *R*, ethylacetate *R* (15:15:70 *V/V/V*).

Application: 20 µL as bands.

Development: over a path of 10 cm.

Drying: at 105 °C for 5 min.

Detection: spray the plate while still warm with a 10 g/L solution of diphenylboric acid aminoethyl ester *R* in methanol *R*. Subsequently spray with a 50 mL/L solution of macrogol 400 *R*. Examine in ultraviolet light at 365 nm within 30 min.

Results: see below the sequence of the zones present in the chromatograms obtained with the reference solution and the test solution. Other faint zones may be present in the chromatogram obtained with the test solution.

Top of the plate	
Scopoletin: a blue zone	A blue zone
	A blue zone
Hyperoside: an orange zone	A strong light blue zone
Rutin: an orange zone	An orange zone
Reference solution	**Test solution**

TESTS

Relative density *(Ph.Eur. 2.2.5)*: 1.170 to 1.185.
pH *(Ph.Eur. 2.2.3)*: 3.5 to 5.0.

STORAGE

Protected from light.

CYDONIA OBLONGATA, FRUIT, MOTHERTINCTURE OBTAIND BY RHYTHMIC APPLICATION OF HEAT AND COLD CYDONIA OBLONGATA E FRUCTIBUS FERM 33B

DEFINITION

The tincture obtained by rhythmic application of heat and cold is prepared from the fresh minced fruit of *Cydonia oblonga* Mill., see Cydonia oblonga, Fruit (Cydonia oblonga, Fructus; Cydonia) APC.

PRODUCTION

The tincture obtained by rhythmic application of heat and cold is prepared according to HAB method 33b (APC method 3.13).

CHARACTERS

Appearance: slightly yellow liquid.
Odour: sour, fruity.

IDENTIFICATION

Thin-layer chromatography (*Ph.Eur. 2.2.27*)
Test solution. Apply 2 mL of the tincture onto a cartridge filled with octadecylsilylated silica gel *RH* (sorbens mass 500 mg, 3 mL reservoir) preconditioned sequentially with 2 mL of methanol *R* and 2 mL of water *R*. Wash the cartridge with 10 mL of water *R*. Elute with 10 mL of ether *R*. The eluate is evaporated to dryness. Dissolve the residue in 0.5 mL of methanol *R*.

Reference solution. Dissolve 10 mg of caffeic acid *R* and 10 mg of hyperoside *R* in 10 mL of methanol *R*.

Plate: TLC silica gel plate *R*.

Mobile phase: anhydrous formic acid *R*, water *R*, ethyl acetate *R* (10:10:80 *V/V/V*).

Application: 60 µL of test solution and 10 µL of reference solution, as bands.

Development: over a path of 8 cm.

Drying: in air.

Detection: spray with a 10 g/L solution of diphenylboric acid aminoethyl ester *R* in methanol *R*. Subsequently spray with a 50 g/L solution of macrogol 400 *R* in methanol *R*. Examine in ultraviolet light at 365 nm after 30 min.

Results: See below the sequence of the zones present in the chromatograms obtained with the reference solution and the test solution. Other faint zones may be present in the chromatogram obtained with the test solution.

Top of the plate	
Caffeic acid: a light blue zone	A light blue zone
Hyperoside: an orange yellow zone	A light blue zone
Reference solution	**Test solution**

TESTS

Relative density (*Ph.Eur. 2.2.5*): 1.001 to 1.013.

Dry residue (*based on Ph.Eur. 2.2.32 d*): minimum 1.0 per cent, determined on 1.000 g of mother tincture by drying for 4 to 5 hours at 105 °C.

Calculate the dry residue (per cent *m/m*) from the expression:

$$\frac{(m_3 - m_1)}{m_2} \cdot 100$$

m_1 = mass of the crucible used, in grams;
m_2 = mass of the mother tincture used, in grams;
m_3 = mass of the crucible containing the mother tincture after drying, in grams.

pH (*Ph.Eur. 2.2.3*): 3.0 to 4.2.

STORAGE

In a well closed container at a temperature of max 15 °C.

LEVICO WATER

Aqua Levici
Levico

DEFINITION

Naturally occurring spring water from the source Levico (Italy).
Content:
- *Arsenic*: 4 – 8 ppm
- *Iron*: 1000 – 2500 ppm

CHARACTERS

Appearance: colourless to yellowish-brown liquid, usually clear, a slight sediment may occur.
Odour: almost odourless.

IDENTIFICATION

A. Identification of arsenic by atomic absorption spectrometry (*Ph.Eur. 2.2.23*), see Assay.
Results: the absorbance obtained with the test solution is not below the absorbance obtained with the reference solution with the lowest concentration.
B. Identification of iron by atomic absorption spectrometry (*Ph.Eur. 2.2.23*), see Assay.
Results: the absorbance obtained with the test solution is not below the absorbance obtained with the reference solution with the lowest concentration.
C. Identification of copper by atomic absorption spectrometry (*Ph.Eur. 2.2.23*, Method I).
Test solution. To 1.0 mL add 0.200 mL nitric acid *R* and dilute to 10.0 mL with water *R*.
Reference solution. Prepare the reference solutions (0.5, 1.0, 2.0 and 4.0 ppm Cu) using copper standard solution *R*, diluted as necessary with a 5 per cent *(V/V)* solution of nitric acid *R*. Alternatively, commercially available copper standard solutions for atomic absorption spectrometry can be used.
Source: copper hollow-cathode lamp using a transmission band preferably of 0.5 nm.
Wavelength: 324.8 nm.
Flame: air-acetylene.
Results: the absorbance obtained with the test solution is not below the absorbance obtained with the reference solution with the lowest concentration.
D. To 0.5 mL add 4.5 mL of water *R*. The solution gives reaction a on sulfates (*Ph.Eur. 2.3.1*).

TESTS

Relative density (*Ph.Eur. 2.2.5*): 1.004 to 1.015.
pH (*Ph.Eur. 2.2.3*): 1.5 to 2.5.

ASSAY

Arsenic: 4 ppm to 8 ppm.
Atomic absorption spectrometry (*Ph.Eur. 2.2.23*, Method I).

Test solution. To 0.200 mL add 2.00 mL nitric acid *R* and dilute to 100 mL with water *R*.
Reference solutions. Prepare the reference solutions (5.0, 10.0, 15.0 and 20.0 ppb As) using arsenic standard solution *R*, diluted as necessary with a 5 per cent *(V/V)* solution of nitric acid *R*. Alternatively, commercially available arsenic standard solutions for atomic absorption spectrometry can be used.
Source: arsenic hollow-cathode lamp using a trans-miss$ion band preferably of 0.5 nm.
Wavelength: 193.7 nm.
Atomisation device: graphite furnace.
Calculate the content of arsenic in mg/kg from the expression:

$$X\,[ppm] = \left(\frac{A_1 \cdot F_1}{F_2 \cdot}\right) / 1000$$

A_1: measured concentration of arsenic in µg/L
F_1: 100 mL (dilution factor)
F_2: 0.200 mL

Iron: 1000 ppm to 2500 ppm.
Atomic absorption spectrometry (*Ph.Eur. 2.2.23*, Method I).
Test solution. To 0.500 mL add 2.00 mL nitric acid *R* and dilute to 100 mL with water *R*.
Reference solutions. Prepare the reference solutions (5.0, 10.0, 15.0 and 20.0 ppm Fe) using iron standard solution *R*, diluted as necessary with a 5 per cent *(V/V)* solution of nitric acid *R*. Alternatively, commercially available iron standard solutions for atomic absorption spectrometry can be used.
Source: iron hollow-cathode lamp using a transmission band preferably of 0.2 nm.
Wavelength: 372.0 nm.
Flame: air-acetylene.
Calculate the content of iron in mg/kg from the expression:

$$X\,[ppm] = \frac{A_2 \cdot F_1}{F_2 \cdot}$$

A_2: measured concentration of iron in mg/L
F_1: 100 mL (dilution factor)
F_2: 0.500 mL

STORAGE
Store in a well-closed container, protected from light.

PREPARATIONS
According to Ph.Eur., monograph 2371 Methods 3.1.1, 3.1.2.

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PART III

Dosage forms

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Part III

Dosage forms
Principally an anthroposophic medicinal product can be administered in every dosage form, including external (topical), internal and parenteral dosage forms, with or without excipients.
A dosage form of an anthroposophic medicinal product complies with any relevant dosage form monograph and any relevant test for that dosage form as described in the European Pharmacopoeia or in pharmacopoeias currently used officially in the EU Member States.

Main dosage forms for anthroposophic medicinal products and concerning references to official pharmacopoeias:

Main dosage forms for oral use		**Relevant monograph(s) in (*Monograph number*):**
Standard term	**Traditional name**	
Capsules	Capsules	Ph.Eur. (*0016*)
Granules	Granules	Ph.Eur. (*0499*)
Homoeopathic Pillules, coated	Globuli velati	Ph.Eur. (*1038, 2786*), HAB Method 39
Homoeopathic Pillules, impregnated	Pillules	Ph.Eur. (*1038*, *2079*), HAB Method 10
Tablets	Tablets	Ph.Eur. (*1038*, *0478*), HAB Method 9
Powders, oral	Trituration	Ph.Eur. (*1165*)
Oral drops	Oral drops	Ph.Eur. (*0672*)
Syrups	Syrups	Ph.Eur. (*0672*)
Oral solution	Mother tincture, Dilution	Ph.Eur. (*0672*)

Main dosage forms for cutaneous use		**Relevant monograph(s) in (*Monograph number*):**
Standard term	**Traditional name**	
Creams	Creams	Ph.Eur. (*0132*)
Ointments	Ointments	Ph.Eur. (*0132*), HAB Methods 13 and 48
Gels	Gels	Ph.Eur. (*0132*), HAB Method 13
Lotions	Lotions	B.P., Ph.Eur. (*0927*)
Oils	Oils	HAB Methods 12, Ph.Eur. (*0927*)

Main dosage forms for cutaneous use		**Relevant monograph(s) in (*Monograph number*):**
Liquid preparations (other)	Tinctures for external use, external emulsions, suspensions	Ph.Eur. (*0927*), HAB Methods 12
Powders	Powders	Ph.Eur. (*1166*)

Main dosage forms for auricular use		**Relevant monograph(s) in (*Monograph number*):**
Standard term	**Traditional name**	
Ear drops	Ear drops	Ph.Eur. (*0652*)

Main dosage forms for ophthalmic use		**Relevant monograph(s) in (*Monograph number*):**
Standard term	**Traditional name**	
Eye drops	Eye drops	Ph.Eur. (*1163*), HAB Method 15
Semi-solid eye preparations	Eye ointments	Ph.Eur. (*1163*)

Main dosage forms for nasal use		**Relevant monograph(s) in (*Monograph number*):**
Standard term	**Traditional name**	
Nasal drops, solution	Nasal drops	Ph.Eur. (*0676*), HAB Method 45
Nasal spray, solution	Nasal spray	Ph.Eur. (*0676*)

Main dosage forms for oromucosal use		**Relevant monograph(s) in (*Monograph number*):**
Standard term	**Traditional name**	
Gels	Gels	Ph.Eur. (*1807*)
Solutions	Solutions	Ph.Eur. (*1807*)
Sprays	Sprays	Ph.Eur. (*1807*)
Pillules	Pillules	Ph.Eur. (*1038, 2079, 2786*), HAB Methods 10 and 39

Main dosage forms for vaginal use		**Relevant monograph(s) in (*Monograph number*):**
Standard term	**Traditional name**	
Gels	Gels	Ph.Eur. (*1164*)
Semi-solid vaginal preparations	Globules	Ph.Eur. (*1164*)
Vaginal tablets	Vagitories	Ph.Eur. (*1164*)

Main dosage forms for rectal use		**Relevant monograph(s) in (*Monograph number*):**
Standard term	**Traditional name**	
Suppositories	Suppositories	Ph.Eur. (*1145*), HAB Method 14

Main dosage forms for parenteral use		**Relevant monograph(s) in (*Monograph number*):**
Standard term	**Traditional name**	
Injections	Liquid dilutions for injection, ampoules, Solutions for injection	Ph.Eur. (*0520*), HAB Method 11

APC Pillules containing lactose
(related to HAB Method 10)
APC Pillules containing lactose are pillules made by applying one or more potentised liquid preparations to saccharose pillules, which may contain up to 5 per cent of lactose. The potentising ratio usually is 1:100 (*v/m* or *m/m)*. The ethanol concentration of the potentised liquid preparation(s) is at least 70 per cent (*V/V*). If this is not the case and interactions are excluded, the last potentisation step for decimal potentised preparations must be carried out with ethanol of at least 70 per cent (*V/V*). In case incompatibilities are expected, use ethanol of lower concentration.
Preformed pillule sizes Ph.Eur. 3 and 6:
Ph.Eur. size 3: 110 to 130 pillules weigh 1 g
Ph.Eur. size 6: 20 to 28 pillules weigh 1 g.
Dry the pillules after impregnation in air.

RECOMMENDED DESIGNATION
the designation states:
the amount of potentised preparation(s),
the potency degree,
the potentising ratio in case other than 1:100.

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PART IV
Appendices

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Note concerning appendix 2.3.
Animal substances marked with "*" belong to category A materials according to "Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" if sourced e.g. from cattle *Bos taurus* L. Though sourcing from animals below 6 months of age from herds not fed with meat bone meal has been practice up to now in the field of concerning anthroposophic quality management, pharmaceutical manufacturers must continuously adapt their sourcing to the requirements of the Note for guidance, such as changing the donor animal. The APC Committee needs to reflect the existing practice and will adapt to implemented changes.

References concerning nomenclature in appendices 2.1. to 2.7.

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Note concerning the references for use in anthroposophic medicine in appendices 2.1. to 2.7.
The references given in the columns to the right in the appendices 2.1 to 2.6 aim to provide evidence, that the particular starting material is known and has been part of the medicinal tradition in anthroposophic medicine.

Where available, the monographs of the Commission C for medicinal products for human use dealing with the anthroposophic therapeutic direction (according to §25 of the German Drug Law) published in the German Federal Gazette (Bundesanzeiger) have been referred to. Some starting materials are mentioned in monographs of combined products only (e.g. Amethyst in Tropaeolum comp.)
Not all starting materials are mentioned in the Commission C monographs, because on the one hand its work stopped in 1994 after the 5th amendment of the German Drug law prior to completion work. On the other hand a number of starting materials in the lists are only known in the anthroposophic medicine tradition in countries other than Germany. The Commission C monographs also refer to specific and composed active substances as well as existing pharmaceutical products. A number of references from other sources may refer generically to particular raw or starting materials, sometimes without linking to specific active substances. The latter references show that the raw or starting material has been considered in therapeutic and pharmaceutical grounds in anthroposophic medicine. They may however also refer to specific active substances.

Where there is no reference, the particular starting material has not yet been presented or discussed in publications. However anthroposophic pharmaceutical manufacturers place medicinal products on the market obtained from those starting materials. The IAAP sees it as its task to promote the writing of publications, to support the relevance of the starting material in anthroposophic medicine. Much work still needs to be done.

References concerning the use in anthroposophic medicine in appendices 2.1. to 2.7.

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IVAA Internationale Vereinigung Anthroposophischer Ärztegesellschaften
International Federation of Anthroposophic Medical Associations
Fédération Internationale des Associations Médicales Anthroposophiques

IVAA Statement concerning starting materials of animal origin
Statement concerning starting materials of animal origin not yet mentioned in published anthroposophic medical literature or in published official regulatory documents concerning anthroposophic medicinal products

Anthroposophic medicinal products containing preparations from starting materials of animal origin belong to the range of anthroposophic therapeutics.1

Most of these starting materials and/or the anthroposophic medicinal products concerned are mentioned in anthroposophic medical literature or in official regulatory documents. A certain number of these however are not mentioned in such references, although belonging to the range
of anthroposophically used starting materials of animal origin. The anthroposophic medicinal products concerned are available to doctors.2

This statement confirms the anthroposophic therapeutic usage and relevance of these starting materials.3

The starting materials of animal origin are listed on the following papers.4

For the IVAA

Dr. Peter Zimmermann
Dr. Andreas Arendt

15.02.2013

List updated 1.03.2018
Starting materials with specific references published since 15.02.2013 have been deleted from the following addendum to the IVVA statement.

[1] Girke M. Internal Medicine. 1st edition. Berlin: Salumed Verlag; 2016.
[2] Jütte R. Organpräparate in der Geschichte der „Schulmedizin", der Homöopathie und der Anthroposophischen Medizin. Der Merkurstab 2009; 1: 49–60.
[3] Roemer F. Sommer M. Zur Bedeutung der potenzierten Organpräparate in der anthroposophischen Therapierichtung. Der Merkurstab 1998; Sonderheft Organpräparate.
[4] Gesellschaft Anthroposophischer Ärzte in Deutschland e.V. and Medizinische Sektion der Freien Hochschule für Geisteswissenschaft Dornach. Vademecum Anthroposophische Arzneimittel. 4. edition. Filderstadt (Germany); 2017

Scientific name	Scientific name of the animal	Abbreviated definition
Aorta	*Oryctolagus cuniculus L.*	Aorta from the rabbit
Aranea avicularis	*Avicularia avicularia L*	Whole bird spider
Arteria basilaris	*Bos taurus L.*	Arteria basilaris from the calf
Arteria brachialis	*Bos taurus L.*	Arteria brachialis from the calf
Arteria coeliaca	*see Truncus coeliacus*	
Arteria pulmonalis	*Bos taurus L.*	Arteria pulmonalis from the calf
Arteria renalis	*Bos taurus L.*	Arteria renalis from the calf
Articulatio cubiti	*Bos taurus L.*	Elbow joint with parts from the bones that form the joint, joint cartilage, parts of joint capsule, synovia and parts of the ligaments from the calf
Articulatio radiocarpea	*Bos taurus L.*	Radiocarpal joint with parts of the bones, cartilage, ligaments and joint capsule that form the proximal carpal joint from the calf
Articulatio temporomandibularis	*Bos taurus L.*	Parts of the os mandibulare and of the os temporale in the joint area, of the joint capsule, of the ligaments, of cartilage, as well as synovia from the calf
Articulationes intercarpeae	*Bos taurus L.*	Parts of the bones forming the joint, of the cartilage like surface of the articulation, as well as synovia from the calf
Articulationes intervertebrales cervicales	*Bos taurus L.*	Region of the cervix: Parts of the bone process that participate to the intervertebral joints, cartilage and joint capsules, as well as synovia from the calf
Articulationes intervertebrales lumbales	*Bos taurus L.*	Region of the loin: Parts of the bone process that participate to the intervertebral joints, cartilage and joint capsules, as well as synovia from the calf
Atlas	*Bos taurus L.*	Parts of the Atlas (1. cervical) from the calf
Axis	*Bos taurus L.*	Parts of the Axis (2. cervical) from the calf
Cartilago articularis coxae	*Bos taurus L.*	Cartilage of the hip joint from the calf
Cervix uteri	*Bos taurus L.*	Parts of the neck of the womb from the cow
Circulus arteriosus cerebri	*Bos taurus L.*	Circulus arteriosus cerebri of the pituitary shaft from the calf
Coccus cacti	*Dactylopius coccus Costa*	The dried, fertilized, female of Dactylopius coccus Costa
Columna anterior	*Bos taurus L.*	Parts of the columna anterior of the spinal chord from the calf
Columna posterior	*Bos taurus L.*	Parts of the columna posterior of different parts of the spinal chord from the calf
Cornu Caprae ibecis	*Capra ibex L.*	Horn from the ibex
Dactylopius coccus	see *Coccus cacti*	
Dens	*Bos taurus L.*	Teeth from the calf
Diencephalon	*Bos taurus L.*	Diencephalon from the calf

Scientific name	Scientific name of the animal	Abbreviated definition
Dura mater encephali	*Bos taurus L.*	Dura mater encephali from the calf
Endocardium	*Bos taurus L.*	Endocardium from the calf
Epididymis	*Bos taurus L.*	Left epididymis from the bull
Erytrocytes	*Equus przewalskii f. caballus Poliakov*	Erythrocytes from the blood of the horse
Galea aponeurotica	*Bos taurus L.*	Parts of the superficial fascia of the forehead from the calf
Glandula parotis	*Bos taurus L.*	Glandular tissue of the body of the parotid gland from the calf
Glandula suprarenalis (Cortex)	*Bos taurus L.*	Glandula suprarenalis (cortex) from the calf
Glandula suprarenalis (Medulla)	*Bos taurus L.*	Medulla glandulae suprarenalis of both adrenal glands from the calf
Gyrus cinguli	*Bos taurus L.*	Gyrus cinguli from the calf
Hepar	*Oryctolagus cuniculus L.*	Liver from the rabbit
Ligamentum longitudinale anterius	*Bos taurus L.*	Parts of the ligamentum longitudinale anterius of thoracic and lumbar regions of the spine from the calf
Lingua	*Bos taurus L.*	Parts of the tongue muscles, mucous membrane and papillae from the calf
Liquor cerebrospinalis	*Bos taurus L.*	Liquor cerebrospinalis from the calf
Mephitis putorius	*Mephitis mephitis Schreb.*	Liquid secretion of anal glands from Mephitis mephitis Schreb.
Moschus	*Moschus moschiferus L.*	Secretion of bursa from male Moschus moschiferus L.
Musculi glutaei	*Bos taurus L.*	Gluteal muscles from the calf
Musculus soleus-Komplex	*Bos taurus L.*	Parts of the musculus soleus-complex, musculus soleus, musculus fibularis (peronaeus) longus, musculus gastrocnemius from the calf
Mygale avicularis	*see Aranea avicularis*	
Nervus abducens	*Bos taurus L.*	Nervus abducens from the calf
Nervus accessorius	*Bos taurus L.*	Nervus accessorius from the calf
Nervus femoralis	*Bos taurus L.*	Nervus femoralis from the calf
Nervus hypoglossus	*Bos taurus L.*	Nervus hypoglossus from the calf
Nervus pudendus	*Bos taurus L.*	Nervus pudendus from the calf
Nervus radialis	*Bos taurus L.*	Nervus radialis from the calf
Nervus tibialis	*Bos taurus L.*	Nervus tibialis from the calf
Nervus ulnaris	*Bos taurus L.*	Nervus ulnaris from the calf

Scientific name	Scientific name of the animal	Abbreviated definition
Oesophagus	*Sus scrofa domestica L.*	Oesophagus from the pig
Ossicula auditus	*Bos taurus L.*	Auditory bones from the calf
Papillae duodeni	*Sus scrofa domestica L.*	Papilla duodeni region of the small intestine from the pig
Pars pallida	*Bos taurus L.*	Parts of the base of the brain from the calf
Patella	*Bos taurus L.*	Patella from the calf
Penis	*Bos taurus L.*	Penis from the bull
Pia mater encephali	*Bos taurus L.*	Pia mater encephali from the calf
Plexus lumbalis	*Bos taurus L.*	Plexus lumbalis from the calf
Plexus rectalis	*see Plexus haemorrhoidalis*	
Renes, regio pyelorenalis	*Bos taurus L.*	Parts of tissue from the pelvis renalis and medulla renalis from the calf
Sclera	*Bos taurus L.*	Sclera from the calf
Sinus cavernosus-Komplex	*Bos taurus L.*	Parts of the sinus cavernosus-complex; sinus cavernosus, nervus opticus, nervus oculomotorius, nervus trochlearis, nervus trigeminus and nervus abducens from the calf
Thrombocytes	*Equus przewalskii f. caballus Poliakov*	Thrombocytes from the blood of the horse
Tonsilla pharyngea	*Bos taurus L.*	Tonsilla pharyngea from the calf
Trachea	*Bos taurus L.*	Trachea from the calf
Truncus coeliacus	*Bos taurus L.*	Arteria coeliaca (Truncus coeliacus) from the calf
Tunica mucosa intestini tenuis	*Sus scrofa domestica L.*	Mucosa from the different regions of the small intestine from the pig
Tunica mucosa recti	*Sus scrofa domestica L.*	Tunica mucosa recti from the pig
Ureter	*Bos taurus L.*	Ureter from the calf
Vagina	*Bos taurus L.*	Vagina from the cow
Valva trunci pulmonalis	*Bos taurus L.*	Valva trunci pulmonalis from the calf
Valvula mitralis	*Bos taurus L.*	Valva mitralis from the calf
Vena cava	*Bos taurus L.*	Parts of the vena cava cranialis and vena cava caudalis from the calf
Vena portae	*Bos taurus L.*	Vena portae from the calf
Vertebra cervicalis	*Bos taurus L.*	Vertebra cervicalis from the calf
Vertebra coccygea	*Bos taurus L.*	Vertebra coccygea from the calf
Vertebra lumbalis	*Bos taurus L.*	Vertebra lumbalis from the calf