



APC- Elaboration of Monographs Technical Guide

v.1.0, 22 June 2023

(according to the Ph.Eur. „Guide for the elaboration of monographs on homoeopathic Preparations“, Edition 2022)

Preface

The IAAP elaborates APC monographs. Based on the “[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)” of the HOM working group (Guide for Homoeopathic Monographs) specific topics to be considered for anthroposophic monographs on preparations in this document.

Individual Monographs should be elaborated for raw materials or preparations used in Anthroposophic Medicine (see Criteria of the adoption of new manufacturing methods and substances in the APC) which are not yet described in any pharmacopoeia or codices.

For the raw material and for the preparation, separate monographs should be prepared with reference to each other. If necessary, different manufacturing processes can be described in the monographs for preparations.

The monograph structure should be in line with the structure defined in the “[Guide for Elaboration of Homoeopathic Monographs](#)”, unless otherwise defined below.

The IAAP board is responsible for the working program of the APC-committee. The responsible board member ensures that the activity is coordinated within the APC-committee. Elaboration of monographs can be initiated by any member of the IAAP and is approved by the IAAP board. If appropriate a project must be put in place and confidentiality agreements should be signed.

Identification and assays should be reproduced by minimum two laboratories and all assays described should be validated.

Reference standards should be described and defined if not described in a pharmacopoeia.



Table of Contents

Preface.....	1
Table of Contents	2
1 Raw material	3
Titles.....	3
Definition	4
Characters.....	4
Identification	5
Tests	5
Assay.....	6
2 Preparations.....	7
2.1 Mother Tinctures / Most Concentrated Homoeopathic Preparation	7
Identification	7
2.2 Compositions	7
Titles.....	7
Definition	7
Production.....	7
Characters.....	7
Identification	8
Tests	8
Storage	8



1 Raw material

For herbals two different cases must be considered: fresh and dried herbal drugs. For the latter the raw material is not subject of the monograph. Testing is performed on the dried herbal drugs because testing in this stage is less affected by the time factor.

Titles

Dried and Fresh Herbal Drugs:

The title consists of the most widely accepted name used traditionally in antroposophic pharmacy. If different parts of the same plant are used, as raw material, the plant parts are named in Latin in parentheses after the name of the plant in the title. The expression “for homoeopathic preparations” or “ad preparationes homoeopathicas, respectively” is not added to the title.

Example: CYDONIA OBLONGA
 Cydonia oblonga

Raw materials of mineral origin (incl. natural waters):

The title consists of the most widely accepted name used traditionally in antroposophic pharmacy. The expression “for homoeopathic preparations” or “ad preparationes homoeopathicas”, respectively is not added to the title.

For minerals the Latin name may be adopted if needed (e.g. quartz rosae).

Example: LEVICO WATER
 Aqua Levici

Chemically described raw materials:

The title consists of the most widely accepted name used traditionally in antroposophic pharmacy. The expression “for homoeopathic preparations” or “ad preparationes homoeopathicas”, respectively is not added to the title.

Example: COPPER
 Cuprum metallicum
 COPPER MIRROR THROUGH REDUCTION
 Cuprum metallicum praeperatum

Raw materials of zoological origin:

The title consists of the most widely accepted name used traditionally in antroposophic pharmacy. The animal species is named in Latin in parentheses after the name of the organ. The expression “for homoeopathic preparations” or “ad preparationes homoeopathicas”, respectively is not added to the title.

Example: DISCI INTERVERTEBRALES (BOVIS)
 Disci intervertebrales bovis
 APIS
 Apis mellifera
 APISINUM

Raw materials that have undergone special treatments (vegetabilised metals):

Binomial name of the plant if available provided in the definition of the monograph followed by the Latin name of the substance used in the cultivation together with the short term for the treatment.

Example: URTICA DIOICA FERRO-CULTA
 Urtica dioica ferro-culta



Definition

Dried and Fresh Herbal Drugs:

See „[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)“.

Raw materials of mineral origin (incl. natural waters):

The chemical composition and if appropriate the minimum content of a characteristic traceable substance.

Raw materials of zoological origin:

Three different types of starting materials of zoological origin can be used in anthroposophic preparations:

- whole animals - definition: the genus of the animal.
- animal organs – definition: the part and the genus of the animal, and if appropriate the age range.
- animal secretions – definition: The genus of the animal and the secretion name.

Chemically described raw materials:

The chemical formula (if applicable including crystal water) and where appropriate the content of the substance or the element.

Raw materials that have undergone special treatments (vegetabilisation methods):

The plant is described as defined in the “[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)” followed by the vegetabilisation method.

Characters

Dried and Fresh Herbal Drugs:

See “[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)”.

Raw materials of mineral origin (incl. natural waters):

Brief description of the physical characters of the mineral. The information given is not to be considered as a mandatory requirement.

- Appearance
- Colour, when characteristic
- Odour, when characteristic

Raw materials of zoological origin:

Brief description of the physical characters of the animal. The information given is not to be considered as a mandatory requirement.

- Appearance
- Colour, when characteristic
- Age, if appropriate

Macroscopic and microscopic characters: The description of zoological characters is included in the identification section. However, some zoological characters that are highly variable and considered not compulsory for the identification of the animal may be described under characters.

Chemically described raw materials:

Brief description of the physical characters of the mineral. The information given is not to be considered as a mandatory requirement.

- Appearance



- Colour, when characteristic
- Solubility

Raw materials that have undergone special treatments (vegetabilisation methods):

See Chapter herbal drugs of the "[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)".

Identification

See "[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)".

Dried and Fresh Herbal Drugs:

- Macroscopic botanical characters (for fresh and dried herbal drugs)
- Microscopic botanical characters (mandatory for dried herbal drugs and if necessary for fresh herbal drugs).
Different than described in the "[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)" microscopic examination of dried herbal drugs can be done without pulverisation.
- Chromatographic methods (dried herbal drugs only, e.g. TLC/ HPTLC / HPLC/GC)
- Chemical reactions

Raw materials of mineral origin (incl. natural waters):

- Specific chemical reactions
- Spectroscopic methods, other instrumental methods (e.g. AAS)

Raw materials of zoological origin:

- Macroscopic and microscopic characters (if applicable)
- instrumental methods (e.g. electrophoresis, SDS-PAGE, Polymerase chain reaction)

Due to immediate further processing of organs and whole animals usually the stock is tested.

Chemically described raw materials:

- Specific chemical reactions
- instrumental methods (e.g. infrared spectroscopy, x-ray structural analysis, raman spectroscopy)

Raw materials that have undergone special treatments (vegetabilisation methods):

Since the metals are not detectable at this stage of process, tests are performed according to chapter herbal drugs of the „[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)“.

Tests

Dried and Fresh Herbal Drugs:

See Chapter herbal drugs of the „[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)“.

Raw materials of mineral origin (incl. natural waters):

According to the nature of the substance, e.g.

- heavy metals (e.g.: AAS, ICP)
- foreign metals and salts
- water content



- acidity or alkalinity
- acidic insoluble impurities
- ash

Raw materials of zoological origin:

According to the nature of the substance. Due to immediate further processing usually the stock is tested.

- Contaminants (e.g. pesticides, heavy metals, aflatoxins), if relevant

Chemically described raw materials:

According to the nature of the substance, e.g.

- related substances
- water content
- acidity or alkalinity

Raw materials that have undergone special treatments (vegetabilisation methods):

See Chapter herbal drugs of the „[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)“.

Assay

Dried and Fresh Herbal Drugs:

Herbal drugs, fresh:

No assay is performed for the fresh plant. When the plant contains toxic components or pharmacologically active substances with a generally known dose/response relationship or relevant for the therapy, an assay is only performed in the preparation.

Herbal drugs, dried:

Only when the plant contains stable toxic components an assay is necessary.

See Chapter herbal drugs of the „[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)“. If no CRS or HRS standards are available the reference standard must be adequately described.

Raw materials of mineral origin (incl. natural waters):

According to the nature of the substance, e.g. metal content (e.g. AAS, ICP)

Raw materials of zoological origin:

Only when the raw material contains stable toxic components an assay is necessary.

Chemically described raw materials:

According to the nature of the substance, e.g. metal content (e.g. AAS, ICP, UV-vis-spectroscopy, titration)

Raw materials that have undergone special treatments (vegetabilisation methods):

No assay is performed for the fresh plant. When the plant contains toxic components or pharmacologically active substances with a generally known dose/response relationship or relevant for the therapy, an assay is only performed in the preparation.



2 Preparations

2.1 Mother Tinctures / Stocks

See chapter mother tinctures in “[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)”.

This chapter is also valid for liquid preparations that are not manufactured according to Ph.Eur. monograph 2371 “methods of preparation of homoeopathic stocks and potentisation” or HAB methods. E.g. company specific manufacturing methods (Sondervorschriften).

Identification

Stocks of zoological origin:

Depending on the nature of the substance SDS-Page polyacrylamide gel electrophoresis or any other characteristic identification reaction (e.g. Cantharidin). Polyacrylamide gel electrophoresis is solely used for qualitative characterisation of proteins in substances of zoological origin.

2.2 Compositions

Titles

Different types of compositions exist. The title contains always the traditionally used name of the composition.

Examples: ANIS-PYRIT
Apis cum Levistico
SOLUM ULIGINOSUM/AESCLUSUS HIPPOCASTANUM L./
EQUISETUM ARVENSE L.

Definition

Reference to the monograph of the starting material if possible (e.g. Ph.Eur., Ph.Fr., GHP, APC) and to the sub-chapter for the specific compositions in the APC (7.1-7.6).

Production

Reference to a manufacturing method (e.g. Ph.Eur., GHP or APC), in special cases description of the preparation in the monograph.

Characters

Brief description of the physical characters of the composition. According to the nature of the Composition, e.g. appearance, odour, bitterness value.



Identification

Depending on the nature of the composition suitable methods, if possible, e.g. chromatographic methods, spectroscopic methods, electrophoresis, specific chemical reactions, other instrumental methods.

Tests

Depending on the nature of the composition suitable methods, e.g. dry residue, ethanol or relative density, pH, osmolality, microbiological quality, if applicable, heavy metals (AAS, ICP), water content, ash, conductivity, water content.

Storage

See chapter mother tinctures in “[Guide for Elaboration of Monographs on Homoeopathic Preparation](#)”.

Version History

Version	Date	
1.0	22 June 2023	New Version: Mm/TS/MeKa Approved by APC Committee 22 June 2023