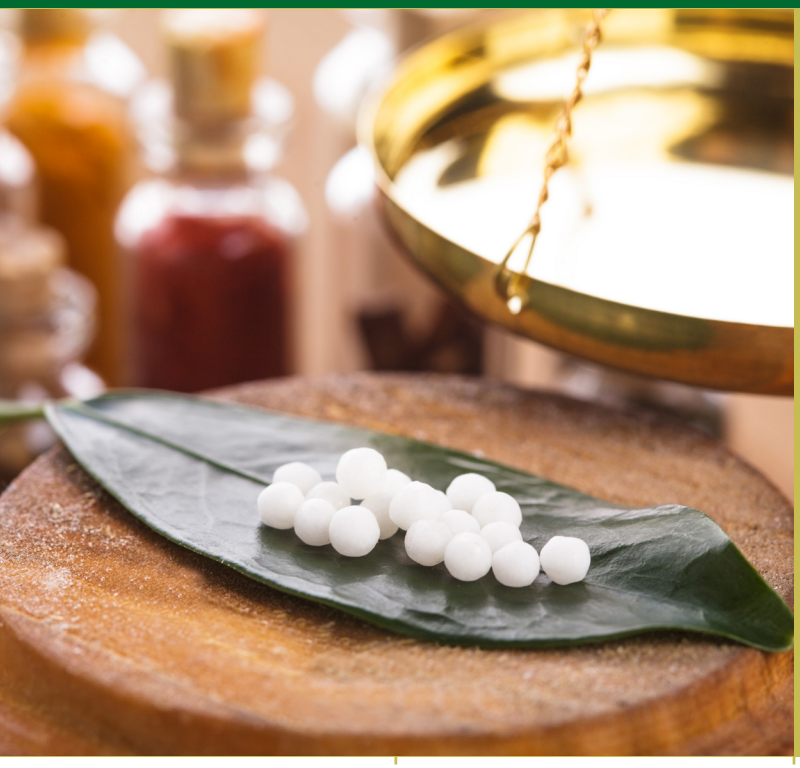
Guide
for the elaboration of monographs on **homoeopathic preparations**



> Stocks for homoeopathic preparations may be of mineral, chemical, botanical, zoological or human origin

European Pharmacopoeia

Homoeopathic preparations

European Directorate for the Quality of Medicines & HealthCare

Edition 2022

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Guide
for the elaboration of monographs on homoeopathic preparations

Edition 2022

European Directorate for the Quality of Medicines & HealthCare

English version
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CONTENTS

NOTE ON THE GUIDE

The guide has been revised:

- To add an **introduction** and the **scope of the guide**.

- **English title:** to delete any reference to scientific names because there is always a traditional name; this is therefore only theoretical.

- **Definition**: to include chemotypes (Lamiaceae, Asteraceae) for essential oil-containing plants.

- **Production** (mother tincture): the example of a mother tincture prepared using a cut drug (2800) has been replaced by an example of a mother tincture prepared from a fresh herbal drug (*Belladonna for homoeopathic preparations (2489*)) and an example of a mother tincture prepared from a dried herbal drug (*Nux-vomica for homoeopathic preparations (2514)*).

- **Characters**: to give more details/examples.

- **Identification**: to delete the reference to stomatal index (*2.8.3*) as this test is used to distinguish between the two species of Senna which are currently described in the same monograph.
To add a reference to HPTLC (*2.2.27*) for identification purposes. Examples have been added for the dried herbal drug (*Ignatia for homoeopathic preparations (2513)*) and for the mother tincture (*Digitalis for homoeopathic preparations (2705))*.

- **Tests**: to have the same order of tests as in the corresponding general monographs. Furthermore, the distinction between typical tests and other tests has been deleted.
  - **Foreign matter** (*2.8.2*)**:** for fresh herbal material, the maximum permissible limit should be based in particular on the type of plant material in question and the harvesting method (manual or mechanical); the general maximum of 5 per cent can therefore be replaced by a lower limit when possible.
  - **Test for adulteration**: examples of well-known adulterations are included.
  - **Extractable matter**: updated to take into account the new Ph. Eur. policy on assays.
  - **Gas chromatography** (*2.2.28*) **or liquid chromatography** (*2.2.29*)**:** moved to the end of the test section.
  - **Contaminant pyrrolizidine alkaloids** (*2.8.26*)**:** added.

  - **Ultraviolet and visible absorption spectrophotometry** (*2.2.25*)**:** The example of *Cinchona bark (0174)* has been replaced by 'Total phenol derivatives expressed as eugenol in the monograph *Anacardium for homoeopathic preparations (2094)'.*
  - **Volumetric titration**: The example of *Ipecacuanha root (0094)* has been replaced by *Staphysagria for homoeopathic preparations (2289).* The example of *Kelp (1426)* has been kept.

- **Assay**: updated to include the new Ph. Eur. policy.
    - For dried raw materials, no change where **toxic compounds** are present. **Assay and qualitative identification to beperformed**. Where **unstable toxic compounds** are present, to perform a **limit test** and to keep the current qualitative identification.
    - For fresh raw materials, **no change** from the current testing scheme (i.e. botanical identification).
    - For stocks (whether prepared from fresh or dried raw material), **no change** where **toxic compounds** are present; assay and qualitative identification to be performed (as for dried stable toxic raw materials). For **unstable toxic compounds**, to perform **a limit test** and also to keep the current qualitative identification (as for dried unstable toxic raw materials).
    - For homoeopathic preparations containing non-toxic compounds, a semi quantitative fingerprint based for example on HPTLC method (2.8.25) should be performed (pilot phase ongoing).

Indeed, the HOM Working Party has started a **pilot phase on a semi-quantitative fingerprint approach** for homoeopathic preparations containing non-toxic compounds. The result of the pilot phase will be included in this guide as soon as available.

- **Storage**: a reference to the terminology given in the General Notices and in general chapter *3.2 Containers* has been added.

GUIDE FOR THE ELABORATION

OF MONOGRAPHS ON HOMOEOPATHIC PREPARATIONS

INTRODUCTION

PURPOSE OF THE GUIDE

The Guide is intended to provide guidance to authors (and contributors) and users of European Pharmacopoeia (Ph. Eur.) monographs on homoeopathic preparations. This applies in particular to:

1. the Homoeopathy Working Party in the preparation of Ph. Eur. monographs,
2. authorities responsible for granting marketing authorisations/registration for homoeopathic medicinal products,
3. manufacturers of homoeopathic preparations and homoeopathic medicinal products,
4. public and private analytical laboratories working for one of the above,
5. the Secretariat of the European Pharmacopoeia and any other departments of the
   European Directorate for the Quality of Medicines & HealthCare (EDQM).

STATUS AND SCOPE OF THE GUIDE

The monographs and general chapters of the European Pharmacopoeia set out the official standards for medicinal products. This guide provides information on the elaboration and use of these standards but has **no official status**. In the event of doubt or dispute, the text of the European Pharmacopoeia alone is authoritative.

Scope: monographs on raw materials and the homoeopathic preparations produced thereof with a focus on monographs on herbal stocks.

Ph. Eur. monographs and general chapters must be interpreted with reference to the General Notices. All users of the Ph. Eur. must be familiar with this text.

All users of the Ph. Eur. must also be familiar with the following guides which are available for free on the EDQM website and regularly updated (https://www.edqm.eu/en/technical-guides)

- European Pharmacopoeia Style Guide (2017)
- Technical guide for the elaboration of monographs on medicinal products containing chemically defined active substances (2020)
- Recommendations for the layout of monographs on substances of human and animal origin (under Additional information)

Stocks for homoeopathic preparations may be of mineral, chemical, botanical, zoological or human origin.

A monograph on a stock for homoeopathic preparations is drafted with the same overall structure as other monographs of the European Pharmacopoeia and both the latest versions of the *Technical Guide for the Elaboration of Monographs* (referred to as the *Technical Guide*) and of the *European Pharmacopoeia Style Guide* apply to monographs on these homoeopathic preparations. This Guide develops the specific points which are appropriate to monographs for homoeopathic preparations and which are not presented in the two general Guides above.

The title of a monograph on a stock for homoeopathic preparations consists of the most widely accepted name of the stock used traditionally in homoeopathy followed by the expression 'for homoeopathic preparations'. Where there is no traditional name, the title is derived from the scientific name. The Latin title is derived from the scientific name of the material (herbal, chemical, human or zoological). The English, French and Latin titles may be different. The only exception is for monograph titles for chemical substances that are based on recommended International Nonproprietary Names (INN). In this case, the INN is used for the titles as described in the *European Pharmacopoeia Style Guide* under 'Monograph titles'. The traditional name is mentioned as footnote in the monograph title.

It is recalled that all tests and assays described in a monograph must be validated according to the procedures stated in the *Technical Guide*. The complete data for validation according to the ICH guidelines are supplied to the Secretariat and examined by the rapporteur.

The general monographs covering herbal drugs for homoeopathic preparations in the Ph. Eur. are *Herbal drugs for homoeopathic preparations (2045), Homoeopathic preparations (1038), Methods of preparation of homoeopathic stocks and potentisation (2371)* and *Mother tinctures for homoeopathic preparations (2029)*. These general monographs, as appropriate, apply to all preparations for homoeopathic use, and their provisions must be taken into account when elaborating specific monographs. Individual monographs include only specific requirements for the quality of the respective herbal drug and mother tincture.

There are three different types of monographs covering homoeopathic products in the Ph. Eur.:

Monographs on **stocks of chemical origin** (including minerals) are drafted according to the same rules as the other monographs, and both the *European Pharmacopoeia Style Guide* and the *Technical Guide for the Elaboration of Monographs* apply.

For stocks of human or zoological origin, there are two parts to the monograph: the first describes the raw material and the second describes the mother tincture.

For monographs on herbal stocks, the *Style Guide* and the *Technical Guide for the Elaboration of Monographs* also apply. Descriptions of the raw material and of the mother tincture prepared from this raw material are included in the same monograph.

The aspects specific to monographs on herbal drugs for homoeopathic preparations are described below.

The general monograph *Herbal drugs for homoeopathic preparations (2045)* applies to all herbal drugs for homoeopathic use and its provisions must be taken into account when elaborating specific monographs.

ELABORATION OF MONOGRAPHS ON HERBAL DRUGS FOR HOMOEOPATHIC PREPARATIONS

TITLES

ENGLISH TITLE

The English name is given in capitals.

The title consists of the most widely accepted name used traditionally in homoeopathy, followed by the expression 'for homoeopathic preparations'.

Examples: Belladonna for homoeopathic preparations

Cocculus for homoeopathic preparations

Ignatia for homoeopathic preparations

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.

Example: Crataegus (fructus) for homoeopathic preparations / crataegus (fructus et folium cum flore) for homoeopathic preparations.

The plant part (e.g. leaf, root, bark) is written in the singular and only in the plural in the case of aerial parts, since aerial parts may cover different plant parts (e.g. stem, leaf, flower, fruit).

Example: Arnica (radix) for homoeopathic preparations

The state of the plant may be indicated in the title, in particular when the same part may be used in the fresh or dried state and when there is a specific monograph on each state. In such cases the state is mentioned at the end of the title.

Example: Gelsemium for homoeopathic preparations, fresh

Gelsemium for homoeopathic preparations, dried

LATIN TITLE

The Latin title consists of the scientific name of the plant (genus, species according to the *Kew Index*) followed by 'ad preparationes homoeopathicas'.

Examples: Atropa belladonna ad preparationes homoeopathicas

Anamirta paniculata ad preparationes homoeopathicas

Strychnos ignatii ad praeparationes homoeopathicas

Where necessary, the plant part is mentioned in the Latin title, which in such cases consists of the species name (genitive) followed by the name of the organ used (nominative and singular) followed by 'ad preparationes homoeopathicas'.

Example: Arnicae montanae radix ad preparationes homoeopathicas

Similarly, where necessary, the state of the herbal drug is mentioned in the Latin title, which in such cases consists of the species name (nominative) followed by the state of freshness of the herbal drug (nominative and singular) followed by 'ad preparationes homoeopathicas'.

Example: Gelsemium sempervirens recens ad preparationes homoeopathicas

RAW MATERIAL OR HERBAL DRUG

Two cases:

The raw material is the subject of a Ph. Eur. monograph.

There is only a cross-reference to the existing monograph.

Example*:* The herbal drug complies with the requirements of the monograph *Goldenseal rhizome (1831)*.

The raw material is not the subject of a Ph. Eur. monograph.

Herbal drugs used in the dried state must be distinguished from herbal drugs used in the fresh state. Certain tests are not performed on fresh herbal drugs owing to the short time between harvesting and the preparation of the mother tincture. The testing of dried herbal drugs is less affected by the time factor.

A. DRIED HERBAL DRUGS

In the absence of available examples in monographs on homoeopathic preparations, the definitions are found in the corresponding monographs in the Ph. Eur. section on Herbal drugs.

DEFINITION

Some or all of the following are usually included in the definition of a herbal drug:

— The state of the herbal drug: dried.

  The herbal drugs are mainly whole plants or plant parts, fragmented, broken or cut.

— The complete scientific name of the plant (genus, species, subspecies, variety, author) as obtained from the *Kew Index* and its supplements (*International Plant Names Index IPNI*).

— The part or parts of the plant used, written in the singular and only in the plural in the case of aerial parts (same as for the title) ; several plant parts may be mentioned if necessary.

— Where appropriate, the stage in the growth cycle when harvesting takes place, the time of collection or other necessary information.

— Where appropriate, for stable toxic compounds, the minimum content of one or more **quantified constituents** is stated. Dried herbal drugs very often contain a mixture of related substances. In such cases, the **total content of quantified constituents** may be determined and expressed as one of the constituents, usually the major constituent.

— Where appropriate, chemotypes should be mentioned.

The statements '(dried drug)' or '(anhydrous drug)' imply that the monograph prescribes respectively a test for loss on drying (*2.2.32*) or a determination of water by distillation (*2.2.13)*. In practice, the dried drug is dried again when the loss on drying test is performed (*2.2.32*).

The title is not repeated in the definition.

Example: refer to the monograph on *Goldenseal rhizome (1831)*.

CHARACTERS

This section contains a brief description of the physical characters of the dried herbal drug. The information given is not to be regarded as mandatory requirements.

ORGANOLEPTIC CHARACTERS

The colour of the herbal drug is indicated where this is characteristic.

Only highly characteristic odours should be described. Terms such as ‘aromatic’ and ‘characteristic’ are not used.

Appearance: hard, friable, brownish to reddish-brown mass; thin fragments are brownish-yellow when examined against the light.

Reminiscent odour of vanillin.

No reference is made to taste unless there is a test for bitterness value (*2.8.15*) in the monograph or the taste is highly characteristic and not toxic.

MACROSCOPIC AND MICROSCOPIC BOTANICAL CHARACTERS

The description of botanical characters is included in the Identification section. However, some botanical characters that are highly variable and considered not compulsory for the identification of the plant may be described under Characters.

IDENTIFICATION

This section provides all the tests performed to identify the dried herbal drug including its colour.

All the identifications mentioned below are not necessarily included; some may be absent when they are not feasible or are not significant for the purpose of identification.

The monograph may have a First identification and a simpler Second identification that is suitable for use where the equipment required for the main (First) identification tests is not available, or the tests are not otherwise feasible, or for any other reason, such as where the pharmacist, in some Member States, may have an obligation to identify a herbal drug, for example in a community pharmacy. Some tests may be specified in both the First and Second identifications. Application of the First and Second identifications is defined in the General Notices. The identification section is introduced by a statement of the two identification series:

Example:

First identification: A, B, C, E

Second identification: B, D

MACROSCOPIC BOTANICAL CHARACTERS

When applicable, referred to as identification A.

The important macroscopic botanical characters of the dried herbal drug are specified to permit a clear identification. When two species/subspecies of the same plant are included in the definition, the individual differences between the two are indicated. Further information for rapid identification of the drug is provided if necessary. When

the definition states that the herbal drug can be either whole or fragmented, both the whole drug and the fragmented drug are described.

Example: refer to the monograph on *Nux-vomica for homoeopathic preparations (2514)*.

MICROSCOPIC EXAMINATION

When applicable, referred to as identification B.

The *microscopic examination of herbal drugs* (*2.8.23*) reduced to a powder describes the dominant or the most specific characters, including, if necessary, examination of the stomata. The colour of the powder, and the reagents used for the microscopic examination are specified. The sieve number needs to be stated if the fineness of the powder diverges from sieve number 355 (*2.1.4*) as described in the general method (*2.8.23*). It may be necessary to perform the microscopic examination using more than one reagent in order to identify the specific characters. A specific stain may be prescribed for particular characters. Negative statements should be avoided since they usually refer to adulteration rather than to identification.

Illustrations of the main microscopic features of powders may be included.

Example: refer to the monograph on *Nux-vomica for homoeopathic preparations (2514)*.

THIN-LAYER CHROMATOGRAPHY (TLC) AND HIGH PERFORMANCE THIN-LAYER CHROMATOGRAPHY (HPTLC) FOR IDENTIFICATION

When applicable, referred to as identification C.

Two types of presentation are possible.

TLC or HPTLC PRESCRIBED FOR THE IDENTIFICATION OF THE DRIED HERBAL DRUG

Manufacturers may choose between classical TLC and HPTLC (*2.2.27*) for identification purposes.

The process steps of HPTLC are identical to classical TLC. The main difference between them is the particle size which is usually 2 µm to 10 µm for fine particle size (High Performance Thin-Layer Chromatography, HPTLC) plates and 5 µm to 40 µm for normal TLC plates and the degree of standardisation.

TLC and HPTLC are described under Identification, even if other chromatographic methods, such as gas chromatography (GC) and liquid chromatography (LC) are subsequently used in the monograph. In this context, the TLC/HPTLC is aimed at defining the typical profile of the herbal drug with respect to selected reference substances which are described for inclusion as reagents (e.g. *rutin R*). The choice of

reference compound should be characteristic for the herbal drug and should be commercially available. Markers not present in the plant can be used to describe the profile. Wherever possible, existing reagents described in general chapter *4.1.1. Reagents* of the European Pharmacopoeia are used as reference compounds. Where necessary, a description of a new reagent (name, molecular formula, relative molecular mass, CAS Registry Number, chemical nomenclature) is appended to the draft monograph for subsequent inclusion in general chapter *4.1.1.* The availability of reference substances as commercial reagents must be verified during monograph elaboration. Where they are not readily available, a chemical reference substance (CRS) or herbal reference substance (HRS) will have to be established and the availability of a suitable quantity must be verified during monograph elaboration.

If the test has been developed both for TLC and HPTLC and equivalent results are obtained, HPTLC conditions (plates, application volume and development distance) are given in square brackets after those for TLC.

The commercial name of the TLC or HPTLC plate used during monograph development is included as a footnote to the monograph and after adoption by the Ph. Eur. Commission, it is transferred to the EDQM *Knowledge* database at the time of publication of the monograph in the European Pharmacopoeia.

For methods following chapter *2.2.27*, a minimum of two reference compounds must be used to validate the separation and spacing between the zones, otherwise a resolution test is necessary. For methods following chapter *2.8.25,* a system suitability test is described.

All the information concerning the preparation of the reference solution and the test solution and the chromatographic conditions is clearly stated. The methodology used, where possible, must be such that the same application volume is used for the reference solution and the test solution.

For TLC (2.2.27), the width of the applied bands is indicated in the monograph.

The chromatograms are described in the form of a table, which shows the upper, middle and lower third of the plate.

Only the characteristic zone(s) in the chromatogram obtained with the test solution are described in the table in relation to the position of the zones due to the reference compounds in the chromatogram obtained with the reference solution. Indication of very faint zones that may not be visible in all batches should be avoided. The reference compounds serve to indicate the position and separation between zones; they do not necessarily need to be constituents of the herbal drug (analytical marker).

The names of the constituents detected in the chromatogram obtained with the reference solution are always given. The names of the constituents detected in the chromatogram obtained with the test solution are given only if these constituents are present in the reference solution, if there is evidence that such a constituent occurs naturally in the herbal drug and if its presence is well established.

Example: *Ignatia for homoeopathic preparations (2513)*

C. Thin-layer chromatography (*2.2.27*).

Test solution. To 2.0 g of the powdered herbal drug (710) (*2.9.12*) add 20 mL of *ethanol (70 per cent V/V) R*, allow to macerate for 15 min at room temperature, with stirring, and centrifuge. Use the supernatant.

Reference solution. Dissolve 10 mg of *brucine R* and 10 mg of *strychnine R* in 10 mL of *ethanol (96 per cent) R*.

Plate: *TLC silica gel plate R* (5-40 µm) [or *TLC silica gel plate R* (2-10 µm)][1].

Mobile phase: *concentrated ammonia R*, *methanol R*, *methylene chloride R* (1:5:95 *V/V/V*) ; use the lower layer.

Application: 10 µL [or 5 µL] as bands.

Development: over a path of 15 cm [or 6 cm].

Drying: in air, then in an oven at 105-110 °C for 15 min ; allow to cool.

Detection: spray with *iodoplatinate reagent R* and examine immediately in daylight.

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

Top of the plate	
_____ _____ Strychnine : a violet zone Brucine : a blue zone	_____ _____ A violet zone (strychnine) A blue zone (brucine)
Reference solution	**Test solution**

[1] Merck Si 60 is suitable. Normally, chromatograms are not described in terms of R_f values (retardation factors).

It is usually necessary to indicate when faint zones other than those described are also present in the chromatogram of the test solution.

Zones may be detected by examination in daylight, ultraviolet light, with or without using a reagent.

A copy in colour of a suitable chromatogram has to be provided to the Secretariat. The chromatogram is included in the draft monograph from the Pharmeuropa to the Commission stage. After publication of the monograph in the Ph. Eur., the picture of the chromatogram is included in the EDQM *Knowledge* database but not in the Ph. Eur.

Example: refer to the monograph on *Nux-vomica for homoeopathic preparations (2514)*.

TLC PRESCRIBED UNDER TESTS AND IDENTIFICATION

If a TLC test is used both for the detection of adulterations and for identification, the method is described entirely under Tests with a cross-reference under Identification. The table is always included in the Identification section.

LIQUID OR GAS CHROMATOGRAPHY

Where LC or GC is used in a test or assay, it may also be referred to under Identification.

Example: - For LC, refer to *Cocculus for homoeopathic preparations (2486)*
- For GC, refer to *Juniper oil (1832)*

CHEMICAL REACTIONS FOR IDENTIFICATION

Chemical reactions are included only if the chromatographic methods do not give sufficient identification and if the reaction is particularly characteristic of a constituent or a group of constituents. They must allow rapid identification without the use of complex equipment and not be so sensitive as to give a false positive result.

TESTS

Specific tests are performed as prescribed in the general monograph *Herbal drugs for homoeopathic preparations (2045)*, such as:

FOREIGN MATTER (*2.8.2*)

The general monograph *Herbal drugs for homoeopathic preparations (2045)* imposes for dried plants a limit of not more than 2 per cent *m/m* for foreign matter, unless otherwise prescribed in an individual monograph or otherwise justified and authorised. The test is prescribed in the individual monograph only where a limit for foreign matter is other than 2 per cent. The type of foreign matter is indicated where appropriate. Where necessary, the monograph indicates how the foreign matter is identified.

Example:

> **Foreign matter** (*2.8.2*): maximum 8 per cent of lignified branches with a diameter greater than 2.5 mm and maximum 2 per cent of other foreign matter.

TEST FOR ADULTERATION

As stated in the general monograph *Herbal drugs for homoeopathic preparations (2045)*, a specific appropriate test may apply to herbal drugs or mushrooms for homoeopathic preparations liable to be falsified.

As stated in the *General Notices*, section 1.5.1.6, information on adulteration may be made available to users of the Ph. Eur. to help them detect adulterated articles. For homoeopathic products, this covers usually substances for which an incident has

occurred and for which incidental adulteration is a known risk (for example contamination during collection in the wild).

The manner in which this test is carried out depends on the knowledge available on possible adulterations.

Macroscopic and/or microscopic examinations and/or chromatographic or other tests can be used to detect plant species that are not part of the definition. Microscopic examination is done particularly to detect adulteration by herbal drugs that have a similar morphological appearance but which come from totally different species to demonstrate for example that a given herbal drug is free of toxic substances, such as alkaloids and cardiotonic steroids.

The title of the test is "Other [genus] species" or the name of the unwanted species – there may be more than one plant species (the complete scientific name of the adulterant (genus, species, subspecies, variety, author) is usually obtained from the *Kew Index (International Plant Names Index IPNI))* or their constituent(s). This title is written in bold, the unwanted plant species are written in bold italics.

Known examples of common adulterations are mentioned (see *Ignatia for homoeopathic preparations (2513)*, *Nux-vomica for homoeopathic preparations (2514)*).

Where the method is either TLC or HPTLC, it is described entirely under Tests and wherever feasible it is also used to identify the dried herbal drug. In the chromatogram obtained with the test solution only the position and colour of the zone(s) of the constituent(s) that must be absent are described by comparison with the chromatogram obtained with the reference solution. The zones present in the chromatogram obtained with the test solution are not described under Tests but under Identification in the form of a table.

Examples: refer to the monograph on *Verbena herb (1854), Ash leaf (1600).*

LOSS ON DRYING (2.2.32)

The words '(dried substance)' imply that the monograph prescribes a test for loss on drying and that the substance is dried under the prescribed conditions.

Herbal drugs are dried for preservation purposes: if they are insufficiently dried, growth of yeasts or moulds may occur. This test determines the maximum amount of water that may be present in the dried drug under the stated conditions. The limit should be specified on the basis of the results obtained on a reasonable number of varied samples of acceptable quality. Monographs usually specify drying for a defined period (usually 2 h) rather than drying to constant mass.

The monograph indicates the amount of herbal drug necessary for the determination and the degree of size reduction of the drug or the fineness of the powder using the sieve number (*2.1.4*).

Example:

Loss on drying (*2.2.32*): maximum 10.0 per cent, determined on 1.00 g of the powdered drug (710) (*2.9.12*) by drying in an oven at 105 °C for 2 h.

WATER (2.2.13)

For herbal drugs containing more than 10 mL/kg (1 per cent) of essential oil, the determination of water by distillation (*2.2.13*) is carried out instead of the test for loss on drying. The degree of size reduction of the drug or the fineness of the powder using a sieve number (*2.1.4*) is indicated if required.

Example:

Water (*2.2.13*): maximum 120 mL/kg, determined on 20.0 g of the crushed herbal drug.

TOTAL ASH (2.4.16)

This test is included unless otherwise justified. It is to be carried out on the powdered drug. It is not necessary to state the sieve number.

Example:

Total ash (*2.4.16*): maximum 14.0 per cent.

ASH INSOLUBLE IN HYDROCHLORIC ACID (2.8.1)

This test may be carried out depending on the nature of the particular herbal drug and is used to detect unacceptable quantities of certain minerals.

Example:

Ash insoluble in hydrochloric acid (*2.8.1*): maximum 2.0 per cent.

BITTERNESS VALUE (2.8.15)

This test is applicable to dried herbal drugs containing bitter substances.

Example:

Bitterness value (*2.8.15*): minimum 4000.

SWELLING INDEX (2.8.4)

This test is applicable to certain dried hydrocolloid-containing herbal drugs, for example herbal drugs containing mucilage such as *Iceland moss (1439)*.

Example:

Swelling index (*2.8.4*): minimum 12, determined on the powdered drug (710).

HEAVY METALS (2.4.27)

A general method *Heavy metals in herbal drugs and fatty oils (2.4.27)* is included in the Ph. Eur. It is applicable to herbal drugs for homoeopathic preparations.

A test for a specific heavy metal may be needed where a particular herbal drug is known to accumulate that metal. This is indicated in the general monograph *Herbal drugs for homoeopathic preparations (2045)*. Furthermore, limits for heavy metals (cadmium, lead and mercury) may be given in the specific monograph if these are different from those stated in this general monograph.

EXTRACTABLE MATTER

This test is applicable to dried herbal drugs such as *Hop strobile (1222)*. In general, extraction may be performed with water or ethanol.

Example:

> **Matter extractable by ethanol (70 per cent *V/V*)**: minimum 25.0 per cent.
> To 10.0 g of the powdered drug (355) (*2.9.12*) add 300 mL of *ethanol (70 per cent V/V) R* and heat for 10 min on a water-bath under a reflux condenser. Allow to cool, filter and discard the first 10 mL of the filtrate. Evaporate 30.0 mL of the filtrate to dryness on a water-bath and dry in an oven at 100-105 °C for 2 h. The residue weighs a minimum of 0.250 g.

CONTAMINANT PYRROLIZIDINE ALKALOIDS (2.8.26)

Herbal drugs that are contaminated with common weeds containing pyrrolizidine alkaloids (PAs) can be tested as described in the general chapter *Contaminant pyrrolizidine alkaloids (2.8.26)*. The general chapter permits the use of any procedure consisting of chromatography coupled with MS/MS or high resolution MS that meets the validation requirements specified in the chapter. As an example, it describes an analytical procedure that has been shown to be suitable for the determination of PAs in a number of matrices. Specific limits may be included in the Ph. Eur. in future. When appropriate and in agreement with the competent authority, a risk based approach may be performed using an adequate risk management concept for appropriate measures for controlling the risk of PA contamination.

AFLATOXINS B_1 (*2.8.18*)

The use of this test is considered depending on the nature, geographical origin and production of the plant. It is also usually performed when the water content / loss on drying of the starting dried herbal drug is greater than 12 per cent. Herbal drugs that are subject to contamination by aflatoxins are tested by a validated method. The competent authority may also require that the sum of aflatoxins B_1, B_2, G_1 and G_2 are determined.

OCHRATOXINS (*2.8.22*)

This test is carried out where necessary on herbal drugs (e.g. seeds, roots or fruits) that are subject to contamination by ochratoxin A, using a validated method. It is also usually performed when the water content / loss on drying of the starting dried herbal drug is greater than 12 per cent.

In certain special circumstances, the risk of RADIOACTIVE CONTAMINATION should be considered (e.g. mushrooms).

For herbal drugs containing saponins, the FOAM INDEX (*2.8.24*) may be given.

GAS CHROMATOGRAPHY (*2.2.28*) OR LIQUID CHROMATOGRAPHY (*2.2.29*)

The use of GC or LC is indicated under Tests to detect plant species that are not part of the definition (e.g. essential oils), to limit certain constituents (e.g. estragole in *Bitter fennel (0824)*) or to control the possible degradation or evaporation of any constituents that must be present in the dried herbal drug at a certain level.

Substances used for quantification are established as chemical reference substances (CRSs). Where those compounds are not readily available a surrogate CRS or a herbal reference standard (HRS) may be established. The use of HRSs for quantitative purposes is discouraged unless the former option is unfeasible.

Where reagents are not readily available or too expensive, the establishment of a CRS or HRS may be envisaged, the availability of a suitable quantity must be verified during monograph elaboration.

Identification of peaks and system suitability (e.g. resolution) can be assessed using an HRS or the pure compounds as reagents. For the establishment of CRSs or HRSs, a sufficient quantity of a batch of suitable quality must be available.

A system suitability criterion should be included in the monograph. The commercial name of the column or columns found suitable during elaboration of the monograph are included in a footnote and transferred to the EDQM *Knowledge* database after publication of the monograph. A typical chromatogram is included in the draft monograph published in Pharmeuropa and transferred to the EDQM *Knowledge* database after publication of the monograph.

When the same GC or LC method is used both for an assay and for a test, the method is described entirely under Tests with a cross-reference under Assay.

For unstable toxic compounds, a limit test should be performed and a maximum value for the content is given in the Definition section.

For non-toxic compounds, a semi-quantitative method based for example on HPTLC fingerprint (2.8.25) may be performed (pilot phase ongoing).

ASSAY

For toxic stable components, an assay has to be performed and a minimum value for the content is given in the Definition section.

Quantification is performed using the corresponding pure chemical compounds as CRSs. If a pure compound is not available, a readily available substance may be used as a 'surrogate' chemical reference standard and a correction factor shall be described in the monograph.

Standards used for quantification are established as CRSs or as HRSs; the availability of a sufficient quantity of a batch of suitable quality must be verified during monograph elaboration. Substances used for quantification are established as CRSs. Where those compounds are not readily available, a surrogate CRS or an HRS may be established.

Identification of peaks and system suitability (e.g. resolution) can be assessed using an HRS or the pure compounds as reagents. For the establishment of CRSs or HRSs, a sufficient quantity of a batch of suitable quality must be available.

The complete data for validation according to the ICH guidelines are supplied to the Secretariat and examined by the rapporteur. The constituent chosen must be suitable for a determination of the quality of the drug or relevant to its toxicity.

Wherever possible, LC or GC are the methods of choice to determine the content of specific constituents rather than a global determination by spectrophotometry.

LIQUID CHROMATOGRAPHY (*2.2.29*) AND GAS CHROMATOGRAPHY (*2.2.28*)

For the technical and editorial content of these analytical methods, see the *Technical Guide* and the *Style Guide*. The general methods on *Chromatographic separation techniques* (*2.2.46*), *Liquid chromatography* (*2.2.29*) and *Gas chromatography* (*2.2.28*) must also be consulted.

A system suitability criterion should be included in the monograph. The commercial name(s) of the column(s) found suitable during elaboration of the monograph are included in a footnote and transferred to the EDQM *Knowledge* database after publication of the monograph in the *European Pharmacopoeia*. A representative chromatogram is included in the draft monograph published in Pharmeuropa and transferred to the EDQM *Knowledge* database after publication of the monograph.

The expression used to calculate the result of the assay is given.

Example: refer to the monograph on *Goldenseal rhizome (1831).*

ULTRAVIOLET AND VISIBLE ABSORPTION SPECTROPHOTOMETRY (*2.2.25*)

Spectrophotometry allows a global determination of constituents that are very often a group or classes of constituents that are characterised by a maximum absorption in the same range of wavelengths. It may be used for the quantification of constituents when these are a mixture of related substances.

Example: Refer to 'Total phenol derivatives' expressed as eugenol in the monograph on *Anacardium for homoeopathic preparations (2094)*.

VOLUMETRIC TITRATION

Examples: volumetric titration is used for the total alkaloids expressed as delphinine ($C_{33}H_{45}NO_9$; M_r 599.7) (dried drug) in the monograph on *Staphysagria for homoeopathic preparations (2289)* and for the determination of total iodine in the monograph on *Kelp* (*1426*).

DETERMINATION OF TANNINS IN HERBAL DRUGS (*2.8.14*)

This assay is described as a general method.

Examples: refer to the monographs on *Hamamelis leaf (0909)* or *Rhatany root (0289)*.

DETERMINATION OF ESSENTIAL OILS IN HERBAL DRUGS (*2.8.12*)

When a minimum content of essential oil is required in the Definition, the assay is carried out on the drug, reduced in size, if necessary, as prescribed in the monograph.

Example: refer to the monograph on *Eucalyptus leaf* (1320)

STORAGE

The storage conditions described in the general monograph on *Herbal drugs for homoeopathic preparations (2045)* are applicable unless otherwise specified.

Where applicable, specific additional conditions are given in the individual monograph.

The terminology given in the General Notices and in general chapter *3.2 Containers* should be used.

Example: Do not store in powdered form.

B. FRESH HERBAL DRUGS

DEFINITION

Some or all of the following are usually included in the definition:

—The state of the herbal drug: fresh.

— The complete scientific name of the plant (genus, species, subspecies, variety, author) as obtained from the *Kew Index* and its supplements (*International Plant Names Index IPNI*).

—The part or parts of the plant used (written in the singular) and only in the plural in the case of aerial parts (same as for the title); several plant parts may be mentioned if necessary,

— Where appropriate, the stage in the growth cycle when harvesting takes place, the time of collection or other necessary information.

— Where appropriate, chemotypes should be mentioned.

The title is not repeated in the definition.

Examples

Whole, fresh mushroom (fruiting body) *Amanita phalloides* (Vaill.: ex Fr.) Link.
Fresh bulb, with roots removed, of the garden onion, *Allium cepa* var. *cepa* L.

CHARACTERS

This section contains a brief description of the physical characters of the fresh herbal drug. The information given is not to be regarded as mandatory requirements.

ORGANOLEPTIC CHARACTERS

The colour of the herbal drug is indicated where this is characteristic.

Only highly characteristic odours should be described. Terms such as ‘aromatic’ and ‘characteristic’ are not used.

Example:

The cut drug has a strong lachrymatory effect.

MACROSCOPIC AND MICROSCOPIC BOTANICAL CHARACTERS

The description of botanical characters is included in the Identification section. However, some botanical characters that are highly variable and considered not compulsory for the identification of the plant may be described under Characters.

IDENTIFICATION

This section includes tests performed to identify the fresh herbal drug including its colour.

All the identifications mentioned below are not necessarily included, some may be absent when they are not feasible or are not significant for the purpose of identification.

MACROSCOPIC BOTANICAL CHARACTERS

When applicable, referred to as identification A.
The important macroscopic botanical characters of the fresh herbal drug are specified to permit a clear identification.

Example: refer to the monograph on *Hypericum for homoeopathic preparations (2028).*

When two species/subspecies of the same plant are included in the definition, the individual differences between the two are indicated.

Further useful information for rapid identification of the fresh herbal drug is described where necessary such as examination under a lens (x magnification) or examination in ultraviolet light.

Example:

> Examine under a lens (x10). The upper surface is shiny, dry, appearing somewhat uneven, with no remains of the veil.

MICROSCOPIC EXAMINATION

When applicable, referred to as identification B.
In some cases, when two similar species are used to produce two different preparations and/or when there may be confusion between two fresh herbal drugs, identification by microscopic examination of the fresh herbal drug may be needed. This is done by examining a significant tissue or organ, for example, the lower epidermis of a leaf or the spores of a fungus.

The dominant or the most specific characters of the epidermis, including, if necessary, the stomata are described based on an examination of a sample. The reagents used for the microscopic examination are specified as described in general method *2.8.23*. It may be necessary to perform the microscopic examination using more than one reagent in order to identify the specific characters. A specific stain may be prescribed for particular characters. Negative statements should be avoided since they usually refer to adulteration rather than to identification.

Example:

Examine under a microscope using a solution containing 1.5 g of *iodine R*, 5 g of *potassium iodide R* and 100 g of *chloral hydrate R* in 100 mL of *distilled water R*. The spores are bluish-black (starch reaction), short elliptical to subspherical, 8-11 µm long and 7-9 µm in diameter.

TESTS

Specific tests are performed as prescribed in the general monograph *Herbal drugs for homoeopathic preparations (2045)*, such as:

FOREIGN MATTER (2.8.2)

For fresh plants, the content of foreign matter is as low as possible, taking into consideration the type of plant material in question and the harvesting method (manual or mechanical). A maximum limit is given on a case by case basis, followed by 'unless otherwise justified and authorised'. An acceptable maximum content of foreign matter could be 5 per cent *m/m* if a lower content cannot be achieved. Whenever possible, an indication of the type of foreign matter is given in the individual monograph. Where necessary, the monograph indicates how the foreign matter is identified.

Example:

Foreign matter (*2.8.2*): maximum 5 per cent.

Foreign matter (*2.8.2*): maximum 4 per cent of fruits and maximum 1 per cent of other foreign matter.

TEST FOR ADULTERATION

In certain cases, botanical examinations (macroscopic and/or microscopic) and/or additional chemical reactions are carried out. In particular, this is done to detect adulteration by herbal drugs with similar characteristics but which originate from different species.

The title of the test is 'Other [genus] species' or the name(s) of the unwanted species – there may be more than one plant species [the complete scientific name of the adulterant (genus, species, subspecies, variety, author) is usually obtained from the *Kew Index (International Plant Names Index IPNI)*]. The title is written in bold, the unwanted plant species are written in bold italics.

Example: refer to the monograph on *Agaricus phalloides for homoeopathic preparations (2290)*.

LOSS ON DRYING (2.2.32)

Such a test is performed when fresh plants are processed more than 24 h after harvesting. The temperature and drying period should be specified in the monograph. A minimum limit should be specified on the basis of the results obtained on a reasonable number of varied samples of acceptable quality. The monograph indicates the amount of fresh herbal drug needed to perform the test.

Example: **Digitalis for homoeopathic preparations (2705)**

Loss on drying (*2.2.32*): minimum 70.0 per cent, determined on 5.0 g of the communited herbal drug by drying in an oven at 105 °C for 2 h.

MOTHER TINCTURE

Mother tinctures must comply with the requirements of the general monograph on *Mother tinctures for homoeopathic preparations (2029).* The provisions of the general monograph are not repeated in individual monographs but any specific information required for application of the general monograph is included.

When a method used for the mother tincture is the same as the one used for the herbal drug and when the herbal drug and the mother tincture are part of the same monograph, the method is not repeated but simply referred to.

DEFINITION

Reference is made to the monograph on the herbal drug to be used as the homoeopathic raw material from which the mother tincture is prepared. The preparation method is specified in the Production section and is not described in the Definition.

Assay limits are included for mother tinctures that are toxic. Here upper and lower assay limits should be given. The limits depend on the preparation method defined in the general monograph *Methods of preparation of homoeopathic stocks and potentisation (2371)* or in the Production section of the relevant monograph; where necessary, the preparation method is mentioned in parentheses, after the specified value.

Examples: refer to the monographs on *Hydrastis for homoeopathic preparations (2500), Hyoscyamus for homoeopathic preparations (2091)*, *Nux-vomica for homoeopathic preparations (2514)* and *Cocculus for homoeopathic preparations (2486)*.

PRODUCTION

This section mentions the preparation method(s) defined in the general monograph *Methods of preparation of homoeopathic stocks and potentisation (2371)*. Other methods described in an official national pharmacopoeia of a Member State may be considered when drafting the monograph. Such methods are then described in detail in the Production section of the individual monograph. Specific aspects of the production methods (such as the degree of size reduction of the drug, the extraction solvent and the duration of maceration) are taken into consideration, if necessary, and described in the individual monograph. Prior to extraction, the size of dried herbal drugs is reduced and, if applicable, related to sieve numbers, for the different plant parts: e.g. wood, bark and roots should be cut (2800). For a dried herbal drug used in the production of a mother tincture, the degree of size reduction is described (like cut,

powder). Whether a reference to a sieve number is also given depends on the manufacturing method used.

Examples: refer to the monographs on *Ignatia for homoeopathic preparations (2513)* and *Nux-vomica for homoeopathic preparations (2514)*:

- reference to a sieve is included for method 1.1.8;
- reference to a sieve is not included for method 1.1.10.

Example (for mother tinctures prepared from fresh herbal drugs):

Belladonna for homoeopathic preparations (2489):

Production: The mother tincture is prepared according to the following methods prescribed in the general monograph *Methods of preparation of homoeopathic stocks and potentisation (2371):*

- **method 1.1.3;**

- **method 1.1.10**, using ethanol (45 per cent *V/V*).

Example (for mother tinctures prepared from dried herbal drugs):

Nux-vomica for homoeopathic preparations (2514):

Production: The mother tincture is prepared according to the following methods prescribed in the general monograph *Methods of preparation of homoeopathic stocks and potentisation (2371)*:

- **method 1.1.8**; using the **powdered herbal drug (710) (*2.9.12*)** and ethanol (70 per cent *V/V*);

- **method 1.1.10**, using the **powdered herbal drug** and ethanol (65 per cent *V/V)*.

CHARACTERS

This section contains a brief description of the physical characters of the mother tincture. The information given is not to be regarded as mandatory requirements.

ORGANOLEPTIC CHARACTERS

The colour of the mother tincture is indicated where this is characteristic.

Example:

CHARACTERS
Appearance: brown liquid.

Only highly characteristic odours should be described. Terms such as ‘aromatic’ and ‘characteristic’ are not used.

No reference is made to taste unless there is a test for bitterness value (2.8.15) in the monograph. The bitterness value (2.8.15) should be performed unless toxic. The taste is described.

Example: Gentian tincture (1870)

CHARACTERS
It has a strong bitter taste.

IDENTIFICATION

If two methods of preparation produce different products, the identification tests to be carried out in each case are specified at the beginning of the section.

Example: refer to the monograph on *Agaricus phalloides for homoeopathic preparations (2290).*

THIN-LAYER CHROMATOGRAPHY (TLC) AND HIGH PERFORMANCE THIN-LAYER CHROMATOGRAPHY (HPTLC) FOR IDENTIFICATION

Where applicable, refer to as method A.

Where it exists, the preferred method is that used for the herbal drug. In this case, the method is usually described entirely in the section on the herbal drug with a cross-reference in the section on the mother tincture.

Example: refer to the monograph on *Nux-vomica for homoeopathic preparations (2514).*

Two types of presentation are possible.

TLC or HPTLC PRESCRIBED FOR THE IDENTIFICATION OF THE MOTHER TINCTURE

Manufacturers may choose between TLC and HPTLC (*2.2.27*) for identification purposes.

The process steps of HPTLC are identical to classical TLC. The main difference between them is the particle size which is usually 2 µm to 10 µm for fine particle size (HPTLC plates) and 5 µm to 40 µm for normal TLC plates and the degree of standardisation.

TLC and HPTLC are described under Identification, even if other chromatographic methods, such as gas chromatography (GC) and liquid chromatography (LC) are subsequently used in the monograph. In this context the TLC/HPTLC is aimed at defining the typical profile of the mother tincture with respect to selected reference compounds which are described for inclusion as reagents (e.g. *rutin R*). The choice of reference compound should be characteristic of the mother tincture and should be commercially available. Markers not present in the mother tincture can be used to

describe the profile. Wherever possible, existing reagents described in general chapter *4.1.1. Reagents* of the European Pharmacopoeia are used as reference compounds. Where necessary, a description of a new reagent (name, molecular formula, relative molecular mass, CAS Registry Number, chemical nomenclature) is appended to the draft monograph for subsequent inclusion in general chapter *4.1.1.* The availability of reference compounds as commercial reagents must be verified during monograph elaboration. Where they are not readily available, a CRS or HRS will have to be established and the availability of a suitable quantity must be verified during monograph elaboration.

If the test has been developed both for TLC and HPTLC and equivalent results are obtained, HPTLC conditions (plates, application volume and development distance) are given in square brackets after those for TLC.

The commercial name of the TLC or HPTLC plate used during monograph development is included as a footnote to the monograph and after adoption by the Ph. Eur. Commission, it is transferred to the EDQM *Knowledge* database at the time of publication of the monograph in the European Pharmacopoeia.

For methods following chapter *2.2.27*, a minimum of two reference compounds must be used to validate the separation and spacing between the zones, otherwise a resolution test is necessary.

All the information concerning the preparation of the reference solution and the test solution and the chromatographic conditions is clearly stated. The methodology used, where possible, must be such that the same application volume is used for the reference solution and the test solution.

For TLC (2.2.27), the width of the applied bands is indicated in the monograph. The chromatograms are described in the form of a table, which shows the upper, middle and lower third of the plate.

Only the characteristic zone(s) in the chromatogram obtained with the test solution are described in the table in relation to the position of the zones due to the reference compounds in the chromatogram obtained with the reference solution. Indication of very faint zones that may not be visible in all batches should be avoided. The reference compounds serve to indicate the position and separation between zones; they do not necessarily need to be constituents of the mother tincture (analytical marker).

The names of the constituents detected in the chromatogram obtained with the reference solution are always given. The names of the constituents detected in the chromatogram obtained with the test solution are given only if these constituents are present in the reference solution, if there is evidence that such a constituent occurs naturally in the mother tincture and if its presence is well established.

Example: *Digitalis for homoeopathic preparations (2705).*

Thin-layer chromatography (*2.2.27*).
Test solution. Evaporate 10 mL of the mother tincture to be examined to dryness under

reduced pressure. Take up the residue in 1 mL of a mixture of equal volumes of *ethyl acetate R* and *methanol R*.
Reference solution. Dissolve 5 mg of *digitoxin R* and 2 mg of *gitoxin R* in a mixture of equal volumes of *ethyl acetate R* and *methanol R*, and dilute to 10 mL with the same mixture of solvents.
Plate: *TLC silica gel plate R* (5-40 µm) [or *TLC silica gel plate R* (2-10 µm)].
Mobile phase: *water R*, *methanol R*, *ethyl acetate R* (7.5:10:75 *V/V/V*).
Application: 20 µL [or 10 µL] as bands.
Development: over a path of 10 cm [or 6 cm].
Drying: in air.
Detection: treat with a mixture of 2 volumes of a 10 g/L solution of *chloramine R* and 8 volumes of a 250 g/L solution of *trichloroacetic acid R* in *ethanol (96 per cent) R*, then heat at 100-105 °C for 10 min ; examine in ultraviolet light at 365 nm.

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

Top of the plate	
_____ Digitoxin : a bluish-green fluorescent zone Gitoxin : a light blue fluorescent zone _____	_____ A bluish-green fluorescent zone (digitoxin) A light blue fluorescent zone (gitoxin) _____ A faint brownish-yellow fluorescent zone may be present A faint light blue fluorescent zone may be present
Reference solution	**Test solution**

Normally, chromatograms are not described in terms of R_f values (retardation factors).

It is usually necessary to indicate when faint zones other than those described are also present in the chromatogram of the test solution.

Zones may be detected by examination in daylight, ultraviolet light, with or without using a reagent.

A copy in colour of a suitable chromatogram has to be provided to the Secretariat. The chromatogram is included in the draft monograph from the Pharmeuropa to the Commission stage. After publication of the monograph in the Ph. Eur., the picture of the chromatogram is included in the EDQM *Knowledge* database but not in the Ph. Eur.

Example: refer to monograph on *Hydrastis for homoeopathic preparations (2500)*.

TLC PRESCRIBED UNDER TESTS AND IDENTIFICATION
If a TLC test is used both for the detection of adulterations and for identification, the method is described entirely under Tests with a cross-reference under Identification. The table is included in the Identification section of the mother tincture or if the

mother tincture is prepared from dried herbal material and shows the same zones as the herbal drug, a reference is made to the table for the herbal drug.

LIQUID OR GAS CHROMATOGRAPHY

Where LC or GC is used in a test or assay, it may also be referred to under Identification.

Example:

Refer to the monograph on *Cocculus for homoeopathic preparations (2486)*.

CHEMICAL REACTIONS FOR IDENTIFICATION

Chemical reactions are included only if chromatographic methods do not give sufficient identification and if the reaction is particularly characteristic of a constituent or a group of constituents. They must allow rapid identification without the use of complex equipment and not be so sensitive as to give a false positive result.

TESTS

Standard tests are covered by the general monograph *Mother tinctures for homoeopathic preparations (2029)*. Specific tests are described in the monograph on the mother tincture. The limits in individual monographs take the production method into account.

RELATIVE DENSITY

The relative density is measured according to method *2.2.5*. The method of preparation of the mother tincture is mentioned.

Example:

Relative density (*2.2.5*): 0.900 to 0.920 when method 1.1.3 is used.

ETHANOL

The ethanol content is measured according to method *2.9.10*. It is expressed as a range of + or - 5 per cent around the value for the content specified for the method of preparation.

Example:

Ethanol (*2.9.10*): 40 per cent *V/V* to 50 per cent *V/V* when method 1.1.10 is used.

METHANOL

Where justified, the limit may be given in the individual monograph if this is different from that stated in the general monograph *Mother tinctures for homoeopathic preparations (2029)*.

Example:

Methanol (*2.9.11*): maximum 0.10 per cent *V/V*.

DRY RESIDUE

The dry residue is measured according to method *2.8.16* and is expressed as a minimum value. If two methods of preparation produce two mother tinctures with different dry residues, the two minimum values are indicated, each followed by the number for the method of preparation in parentheses.

Example:

Dry residue (*2.8.16*): minimum 1.4 per cent.

LIMIT TEST

If the mother tincture contains unstable toxic components, a limit test for the unstable toxic components is described in the monograph and the maximum upper limit for these components is specified in the Definition section (refer to the Note on the Guide, paragraphs on the 'Assay' for 'Dried Herbal Drugs' and 'Mother tincture').

***Example*:** refer to the monograph *Sanguinaria for homoeopathic preparations (2687).*

For non-toxic compounds, a semi-quantitative method based for example on HPTLC fingerprint (2.8.25) may be performed (pilot phase ongoing).

BITTERNESS VALUE (2.8.15)

This test is applicable to mother tinctures originating from herbal drugs containing bitter substances.

ASSAY

Where applicable, for stable toxic components, an assay has to be performed.
The method should be the same as that used for the herbal drug, wherever possible.

STORAGE

Storage conditions described in the general monograph on *Mother tinctures for homoeopathic preparations (2029)* are applicable and, unless otherwise specified, state: *'store protected from light'.*

A maximum storage temperature may be specified.

Any additional specific conditions are given in the individual monograph.

LABELLING

Most of the statements required for labelling are covered by the general monograph *Mother tinctures for homoeopathic preparations (2029).*

REAGENTS

For the technical content and the style see both the *Technical Guide* and the *Style Guide*.

The commercial availability of constituents and markers that are described as reagents must be verified during the elaboration of the monograph. Where a reagent may be difficult to obtain, the names and addresses of suppliers are included in footnotes and transferred to the EDQM *Knowledge* database after publication of the monograph.

The description of the reagents consists of their name, molecular formula, relative molecular mass, CAS Registry Number and chemical nomenclature. The EDQM adds a unique identifier (seven-digit number in italics) when the reagent is included in the reagents list.

CHEMICAL REFERENCE SUBSTANCES / HERBAL REFERENCE STANDARDS

Reference standards, which may be qualitatively and quantitatively used, are established as CRSs or HRSs.

Establishment of CRSs or HRSs is co-ordinated by the EDQM laboratory (DLAB); the Group of Experts should advise on a supplier of a batch of suitable quality. A representative of DLAB is usually present at meetings of the group when draft monographs are discussed.

ENG

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