THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

edqm

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Herbal curriculum

Content

- The Council of Europe and the EDQM
- The European Pharmacopoeia
- General Notices
- General texts
- General monographs
- Individual monographs
  - For dried herbal drugs
    - Incl. information on reference standards
    - Incl. information on Knowledge database
  - For Herbal drug extracts
  - For Essential oils
- Take-home message

The Council of Europe: the EDQM's parent organisation

- Founded in 1949
- Headquarters in Strasbourg, France
- 46 MEMBER STATES

- The oldest pan-European organisation dedicated to fostering co-operation in Europe
  - Promotes DEMOCRACY
  - Protects THE RULE OF LAW
  - Protects HUMAN RIGHTS

EDQM

The **E**uropean **D**irectorate for the **Q**uality of **M**edicines & HealthCare (EDQM)

- A Directorate of the **Council of Europe**
- Since 1964, work is based on the European Pharmacopoeia Partial Agreement

  ... contributing to public health and access to **good quality medicines and healthcare in Europe**.

European Pharmacopoeia

- 11th Edition contains **2469 monographs (including dosage forms), 386 general texts** (including general monographs and methods of analysis) and more than **2800 descriptions of reagents**.

- Protecting public health – one common compulsory standard
- Applied by all licencing authorities
- Legally binding quality standards for all medicinal products
- Mandatory on the same date for all member states

39 member states and the EU
31 Observers (29 countries, TFDA and WHO)

European Pharmacopoeia Commission

European Pharmacopoeia Commission

Composed of :

- 39 member states
- European Union
- 31 Observers:
  - 5 European countries
  - 24 non European countries
  - Taiwan Food and Drug Administration (TFDA)
  - World Health Organization (WHO)

Presidium

- Chair
- 2 Vice-chairs
- Ph. Eur. Secretariat

Presidium Meetings + Meeting of Chairs of Groups of Experts

Groups of experts

Working parties

- One delegation per member state / Observer
- Three sessions a year
- Texts are adopted by **unanimous** vote
- Composition of groups of experts decided by Ph. Eur. Commission

Groups of Experts and Working Parties

- Composition decided by the Ph. Eur. Commission
- Open to experts from all over the world
- Experts are appointed for 3 years
- Background of experts:
  - National pharmacopoeia authorities
  - Competent authorities
  - University
  - Industry
  - OMCL Network

Work in the field of herbal drugs

- **Groups of experts**
  - 13A (predominantly aromatic herbal drugs and essential oils)
  - 13B
- **Working parties** (specific topics)
  - TCM WP (Traditional Chinese Medicines)
- **“Dormant” Working Parties** (currently inactive, reactivated upon need)
  - PA WP (Pyrrolizidine alkaloids)
  - EXT WP (Extracts)
  - PST WP (Pesticides)
  - MQH WP (Microbiological Quality of Herbal Drugs)
  - WXT WP (Water for Extracts)

Elaboration or revision of a text

Proposed by
Delegation of a member state, expert, EDQM, producer

Request for elaboration / revision

Approval by the Commission

Assignment to a group of experts

Elaboration/ revision of the text by the group

Public enquiry in Pharmeuropa

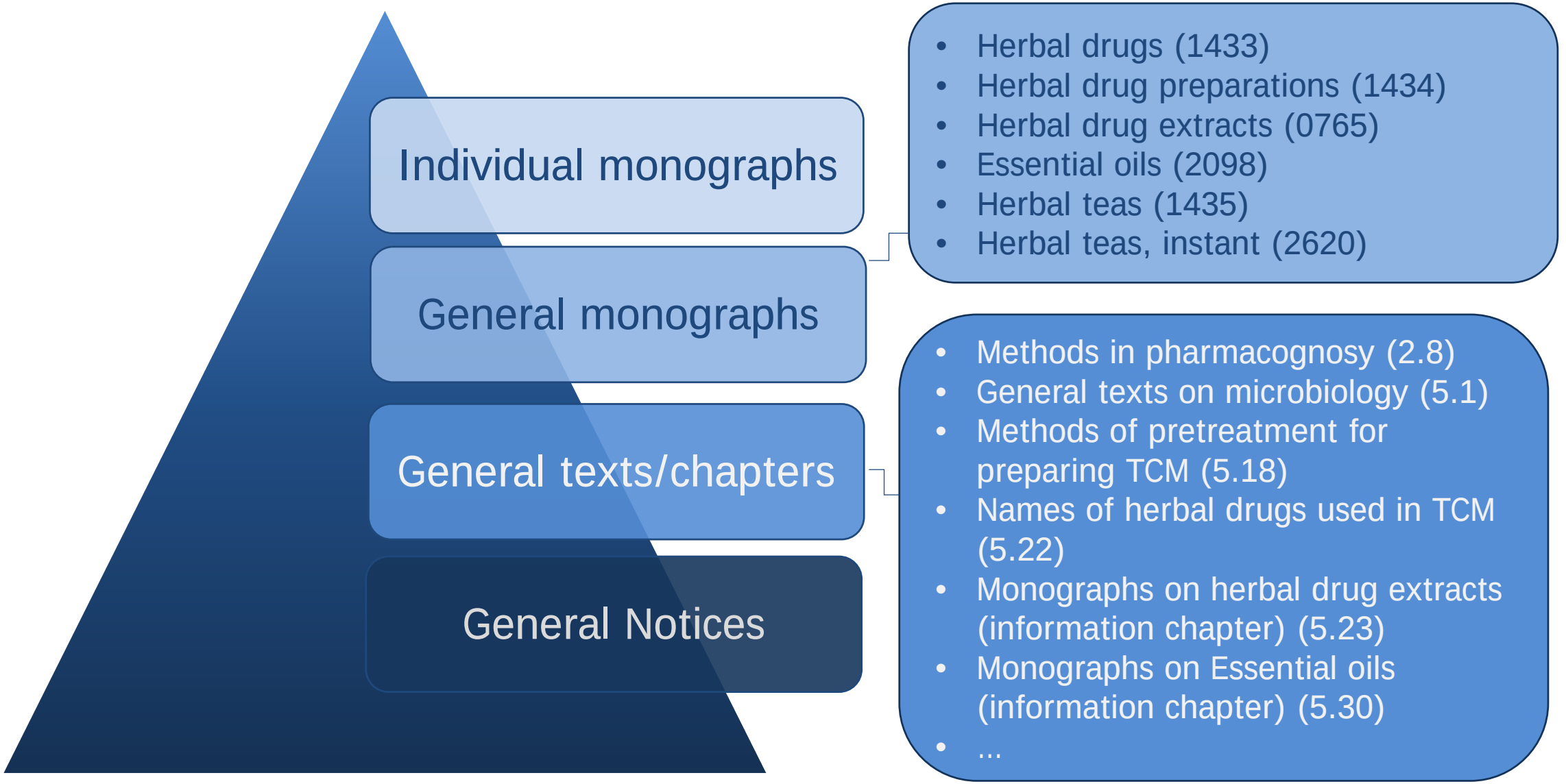
Where necessary

Treatment of comments received during public enquiry

Text adopted by the Commission

Publication

European Pharmacopoeia (Ph. Eur.)



General Notices

General Notices

At the very start of the Ph. Eur.

- address general topics
- aim to provide basic information to the user
- apply to **all** texts incl. general chapters and texts
- include rules to understand texts, conventional expressions, etc.

Essential reading before starting to use monographs and other texts

1.1.1.2 General Notices – Conventional terms

Herbal medicinal product.

Any medicinal product exclusively containing as active ingredients one or more herbal drugs or one or more herbal drug preparations, or one or more such herbal drugs in combination with one or more such herbal drug preparations.

=

Herbal medicinal product

DIRECTIVE 2004/24/EC

1.1.2.1 General Notices – Scope

The use of the title or the Latin subtitle of a monograph implies that the article complies with the requirements of that monograph. Such references to monographs in the texts of the Ph. Eur. are shown using the monograph title and **reference number** in *italics*.

Example: Passionflower herb dry extract (1882)

Definition

Dry extract produced from *Passionflower herb (1459)*.

1.1.2.2. Demonstration of compliance with the Ph. Eur.

"**Unless otherwise indicated** in the General Notices or in the monographs, statements in monographs constitute **mandatory requirements**."

COMPLIANCE = Meets the requirements of all **mandatory** parts of a **monograph**

MANDATORY	INFORMATIVE
➢ Definition ➢ Production ➢ Identification ➢ Tests ➢ Assay	➢ Characters ➢ Storage ➢ Functionality-related characteristics

(1) An article is of **Ph. Eur. quality if it complies with all** of the **requirements** stated in the monograph. This **does not imply that a manufacturer must perform all of the tests** described in a monograph when assessing compliance with the Ph. Eur. before release.

1.1.2.3. Demonstration of suitability of monographs

Manufacturer to evaluate the **suitability of the monograph** for QC of their article. Their choice of analytical procedures may be influenced by:

- the manufacturing process and/or
- the composition of the medicinal product.

When a competent authority considers a specification described in a monograph is **insufficient** to ensure quality of the article, it may **request more appropriate specifications** from the **manufacturer** in line with national or regional regulations.

In such cases, the competent authority informs the Ph. Eur. Commission through either

- the national pharmacopoeia authority or
- the Secretariat of the Ph. Eur. Commission

Details of the alleged insufficiency and the additional specifications: provided by the **manufacturer** to the national pharmacopoeia authority or the EDQM (Helpdesk)

➔ the decision to revise the monograph is taken by the Ph. Eur. Commission.

1.5.1.7 General Notices – Characters

The statements in the Characters section do not constitute Ph. Eur. requirements and are given for information only.

Example: Passionflower herb dry extract (1882)

CHARACTERS

Appearance: greenish-brown amorphous powder.

1.5.1.9 General Notices – Calculation

Example: Arnica flower (1391)
Content:
minimum 0.40 per cent of total sesquiterpene lactones, expressed as dihydrohelenalin tiglate ($C_{20}H_{26}O_5$; M_r 346.4) **(dried drug)**.

Where the result is to be calculated with reference to the dried or anhydrous substance or on another specified basis, the ***determination of loss on drying***, ***water content*** or another test is carried out using the procedure prescribed in the monograph. The words '***dried substance***' or '***anhydrous substance***' etc. appear in parentheses after the result.

1.5.1.9 General Notices - Limits

The prescribed limits are **based on data obtained in routine analytical practice** and are intended to demonstrate that the article being examined complies with the requirements of the monograph. **They take account** of **normal analytical errors, of acceptable variations in manufacture / preparation and of deterioration** to an extent considered acceptable.

No further tolerances are to be applied to the prescribed limits.

1.5.2 General Notices – Monographs on herbal drugs

Tests and Assay

The sulfated ash, total ash, water-soluble matter, alcohol-soluble matter, water content and content of constituents with known therapeutic activity or of markers are **calculated with reference to the drug that has not been specially dried, unless otherwise prescribed in the monograph**.

Content

- The Council of Europe and the EDQM
- The European Pharmacopoeia
- General Notices
- **General texts**
- General monographs
- Individual monographs
  - For dried herbal drugs
    - Incl. information on reference standards
    - Incl. information on Knowledge database
  - For Herbal drug extracts
  - For Essential oils
- Take-home message

General texts

Methods in pharmacognosy (2.8)

- Ash insoluble in HCl (2.8.1)
- Foreign matter (2.8.2)
- Essential oils in herbal drugs (2.8.12)
- Pesticide residues (2.8.13)
- Tannins in herbal drugs (2.8.14)
- Bitterness value (2.8.15)
- Loss on drying of extracts (2.8.17)
- Determination of aflatoxin B1 in herbal drugs (2.8.18)
- Herbal drugs: sampling and sample preparation (2.8.20)
- Microscopic examination of herbal drugs (2.8.23)
- High-performance thin-layer chromatography of herbal drugs and herbal drug preparations (2.8.25)
- Contaminant pyrrolizidine alkaloids (2.8.26)
- ...

General texts (specific for herbals)

- Microbiological quality of herbal medicinal products for oral use and extracts used in their preparation (5.1.8)
- Methods of pretreatment for preparing traditional Chinese drugs: general information (5.18)
- Names of herbal drugs used in Traditional Chinese Medicine (5.22)
- Monographs on herbal drug extracts (information chapter) (5.23)
- Monographs on essential oils (information chapter) (5.30)

Monographs on herbal drug extracts (information chapter) (5.23)

- To be read in conjunction with the general monograph on *Herbal drug extracts (0765)* and individual extract monographs
- Provides more in depth information regarding:
  - **Basis for elaboration of monographs on herbal drug extracts**
  - **Types of extract**
  - **Constituents for assay**
  - **Use of analytical markers in ‘other’ extracts**

Monographs on herbal drug extracts (information chapter) (5.23)

- Table 5.23.-1.-*Classification and principles of production of extracts*

Information available during assessment as regards pharmacological/therapeutic relevance of constituents	Extract type	Extract concept		Extract adjustment
		Quantitative parameters		
		Constituent to be analysed	Quantity of genuine (native) extract that is included in finished products	
Constituents with known therapeutic activity	Standardised	Constituents with known therapeutic activity Constant	Variable	1) By addition of inert excipients (dry extracts) or solvents (liquid extraction preparations or soft extracts) 2) By blending batches
Constituents that are generally accepted to contribute to the therapeutic activity	Quantified	Active marker Range	Constant	By blending batches
Constituents chosen solely for analytical purposes, irrespective of any pharmacological or therapeutic activity they may be reported to possess	Other	Analytical marker Variable	Constant	None

Monographs on essential oils (information chapter)(5.30)

- To be read in conjunction with the general monograph on *Essential oils (2098)* and individual monographs on essential oils
- Provides more in depth information regarding
  - **Basis for elaboration of monographs on essential oils**
  - **Production of essential oils**
  - **Chromatographic profile**
  - **Contaminants in essential oils and skip testing**

General texts (applicable to herbals)

- General texts on microbiology (5.1)
  - *5.1.4 Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use*
- Residual solvents (5.4)
- Reference standards (5.12)
- Implementation of pharmacopoeial procedures (5.26)
- ...

General monographs

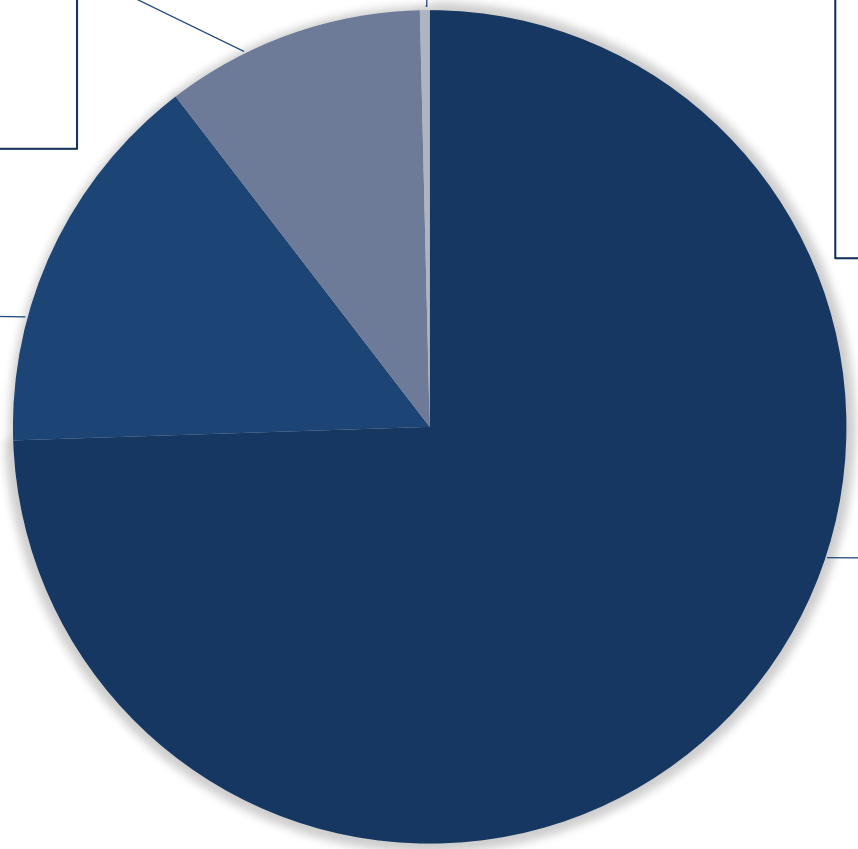
General monographs

- Herbal drugs (1433)
- Herbal drug preparations (1434)
  - Herbal drug extracts (0765)
  - Essential oils (2098)
  - Herbal teas (1435)
  - Herbal teas, instant (2620)

Distribution of monographs by type (Supplement 11.2)

Essential oils
10 %
(32 monographs)

Other herbal drug preparations 3 %
e.g. prepared drugs
(12 monographs)



Herbal drug extracts
15 %
(49 monographs)

Herbal drugs
72 %
(241 monographs)

Herbal drugs

Herbal drugs (1433): Definition I

Herbal drugs are mainly whole, fragmented or broken plants or parts of plants in an unprocessed state, usually in dried form but sometimes fresh. …

= The term ***herbal drug*** is **synonymous** with the term ***herbal substance*** used in European Community legislation on herbal medicinal products.

Herbal drugs (1433): Definition II

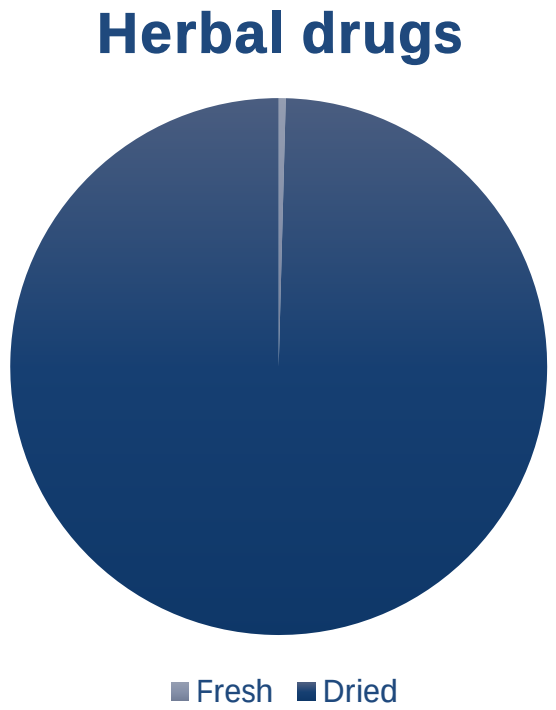
Herbal drug

Cut

Homogeneous
= Herbal drug preparation
e.g. tea

Herbal drugs (1433): dried herbal drugs

- The vast majority of herbal drugs are used in the dried state.
- Practically all herbal drug monographs in the Ph. Eur. are on dried herbal drugs (exemption: Bilberry fruit, fresh).

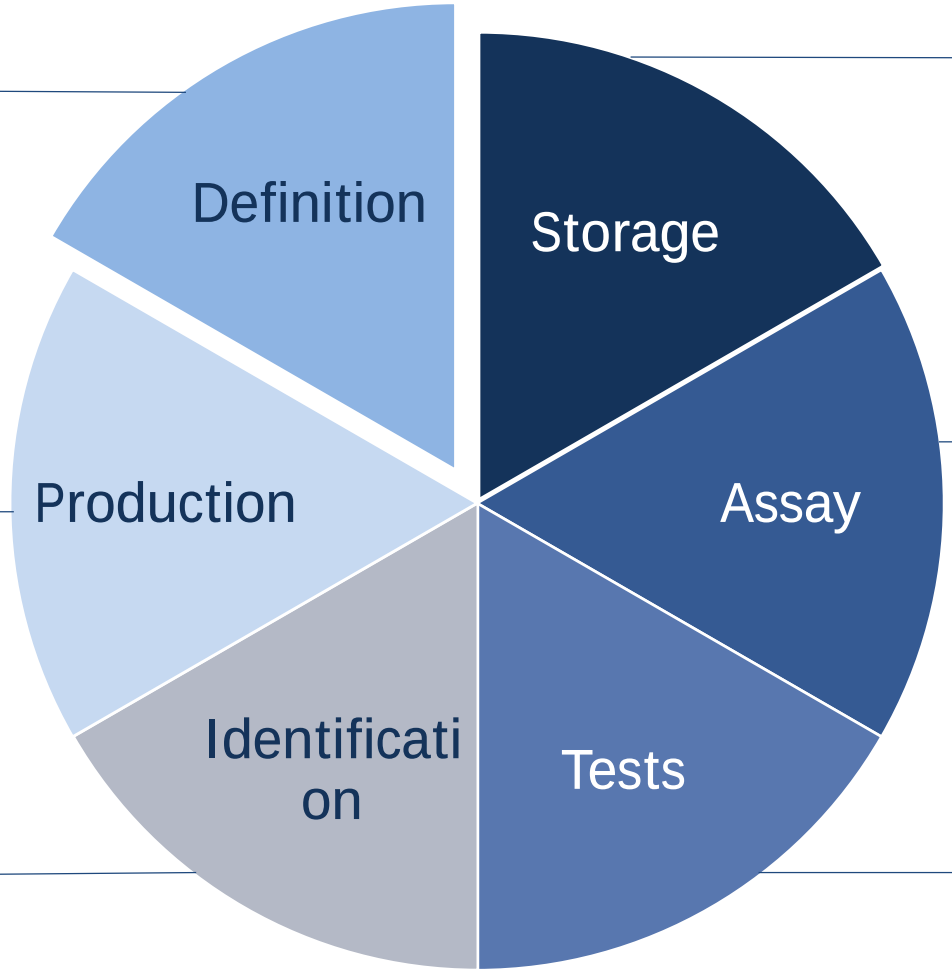


Herbal drugs (1433): Dried herbal drugs

- Whole/fragmented/ broken
- Dried/fresh
- Exact species (binominal name)
- Content

Usually no specific requirements in individual monographs

- Macroscopy
- Microscopy
- (HP)TLC



Protected from light

Usually by LC or UV

- Foreign matter
- Loss on drying
- Total ash
- ...

Herbal drugs (1433): Dried herbal drugs (Tests)

Tests applicable for all herbal drugs:

- Foreign matter
- Loss on drying (2.2.32):

  or Determination of water by distillation (2.2.13) (when high essential oil content)

- Pesticide residues (2.8.13):

  → take into account preparation and complete treatment record

- Heavy metals (2.4.27):

  → unless otherwise stated in an individual monograph or unless otherwise justified and authorised.

Herbal drugs (1433): Dried herbal drugs (Tests)

Foreign matter (2.8.2):

- max 2 per cent m/m (unless otherwise prescribed or justified and authorised)
- A specific test on adulteration may be included

Example: Angelica archangelica root (1857)

Foreign matter (2.8.2): maximum 5 per cent of leaf bases and stem bases, maximum 5 per cent of discoloured pieces and maximum 1 per cent of other foreign matter.

For cut material, the test may be performed prior to cutting.

Herbal drugs (1433): Dried herbal drugs (Tests)

Loss on drying (2.2.32) or Water (2.2.13):

- usually the LoD is performed;
- monographs **commonly** specify drying for a defined period (mostly 2 h) rather than drying to constant mass. Unless otherwise justified, the loss on drying is **not more than 10.0 per cent when drying for 2 h** in an oven at 105 ºC.
- for herbal drugs with a **high essential oil** content (> 1%), **water** is usually determined by distillation;
- The LoD or water content is taken into account for the **content calculation**.

Herbal drugs (1433): Dried herbal drugs (Tests)

Pesticide residues (2.8.13)

- The nature of the plant and the **treatment record** of the batch are taken into account.
- As a minimum, the herbal drug to be examined complies with the limits indicated in **Table 2.8.13.-1.**
- Where there is no limit given in Table 2.8.13.-1, reference is made to regulation **(EC) No. 396/2005**, including annexes and successive updates.

Table 2.8.13.-1.

Substance	Limit (mg/kg)
Acephate	0.1
Alachlor	0.05
Aldrin and dieldrin (sum of)	0.05
Azinphos-ethyl	0.1
Azinphos-methyl	1
Bromophos-ethyl	0.05
Bromophos-methyl	0.05
Bromopropylate	3
Chlordane (sum of *cis*-, *trans* - and oxychlordane)	0.05
Chlorfenvinphos	0.5
Chlorpyriphos-ethyl	0.2
Chlorpyriphos-methyl	0.1
Chlorthal-dimethyl	0.01
Cyfluthrin (sum of)	0.1
λ-Cyhalothrin	1
Cypermethrin and isomers (sum of)	1
DDT (sum of *o,p'*-DDE, *p,p'*-DDE, *o,p'*-DDT, *p,p'*-DDT, *o,p'*-TDE and *p,p'*-TDE)	1
Deltamethrin	0.5
Diazinon	0.5
Dichlofluanid	0.1
Dichlorvos	1
Dicofol	0.5
Dimethoate and omethoate (sum of)	0.1
Dithiocarbamates (expressed as CS2)	2
Endosulfan (sum of isomers and endosulfan sulfate)	3
Endrin	0.05
Ethion	2
Etrimphos	0.05

Herbal drugs (1433): Dried herbal drugs (Tests)

- **Heavy metals (2.4.27)**

  Unless otherwise stated in an individual monograph or unless otherwise justified and authorised:

  - **Cadmium: max. 1.0 ppm**
  - **Lead: max. 5.0 ppm**
  - **Mercury: max. 0.1 ppm**

  Where necessary, limits for other heavy metals may be required.

Example: Kelp (1426)
Arsenic (2.4.27): maximum 90 ppm.
Cadmium (2.4.27): maximum 4 ppm.
Lead (2.4.27): maximum 5 ppm.
Mercury (2.4.27): maximum 0.1 ppm.

Herbal drugs (1433): Dried herbal drugs (Tests)

Where necessary, dried herbal drugs comply with **other tests**.

Depending on the properties of the herbal drug, the introduction of the following tests is considered

- Total ash (2.4.16)
- Ash insoluble in hydrochloric acid (2.8.1)
- Extractable matter
- Swelling index (2.8.4)
- Bitterness value (2.8.15)

Herbal drugs (1433): Dried herbal drugs (Tests)

Total ash (2.4.16)

- Always included in an individual monograph, unless otherwise justified.
- Detects non volatile inorganic compounds like oxalates or calcium pectinat, salts from trace elements

Ash insoluble in HCl (2.8.1)

- May be carried out depending on the nature of the herbal drug e.g. roots
- Detects certain minerals e.g. sand

Herbal drugs (1433): Dried herbal drugs (Tests)

- **Where necessary**, dried herbal drugs comply with **other tests**.
- Aflatoxin B1 (2.8.18)
- Ochratoxin A (2.8.22)
- Radioactive contamination

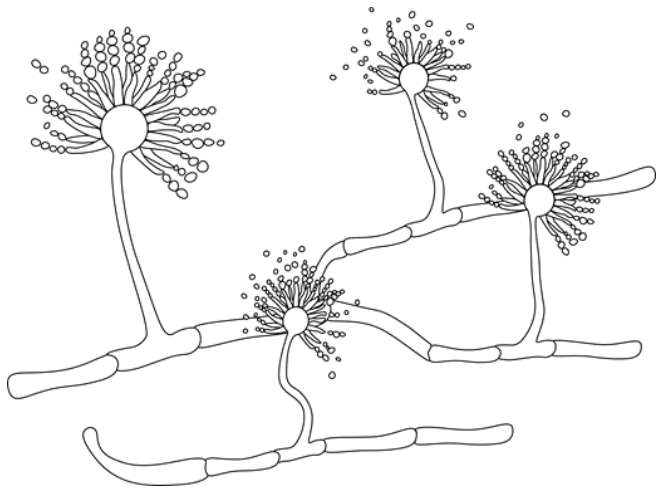
} where necessary/ specific circumstances

- Microbial contamination (5.1.8/5.1.4)

→ testing is applicable for the herbal drug preparation or the herbal medicinal product

Herbal drugs (1433): Dried herbal drugs (Tests)

- **Aflatoxin B1 (2.8.18) and Ochratoxin A (2.8.22)**
  - **harvesting** (e.g. rain)
  - **storage** (too humid)
  - **nature of the herbal drug** (e.g. seeds and nuts with a high oil content)
  - The **suitability of the methods described has been shown for selected drugs**, the **appropriateness for other herbal drugs needs to be shown** or another validated method used.



Herbal drugs (1433): Dried herbal drugs (Tests)

Microbial contamination

The herbal drug as such is not examined directly but the resulting herbal drug preparation or the herbal medicinal product complies with the requirements given in:

- **5.1.4.** Microbiological quality of **non-sterile pharmaceutical preparations** and substances for pharmaceutical use
  - e.g **cutaneous use, inhalation use, oromucosal use**

- **5.1.8.** Microbiological quality of herbal medicinal **products for oral use and extracts** used in their preparation
  - 3 sub categories depending on pre-treatment or use of boiling water

Herbal drugs (1433): Dried herbal drugs (Tests)

- **Swelling index (2.8.4)**

Herbal drugs used for their content in mucilage

→ a test on swelling index may be introduced instead of an assay (e.g. *Fenugreek (1323)*).

- **Bitterness value (2.8.15)**

Herbal drugs used for their content in bitter principles

→ a test on bitterness value may be introduced instead of an assay (e.g. *Gentian root (0392)*).

Herbal drugs (1433): Dried herbal drugs (Tests)

Herbal drugs (1433): Fresh herbal drugs

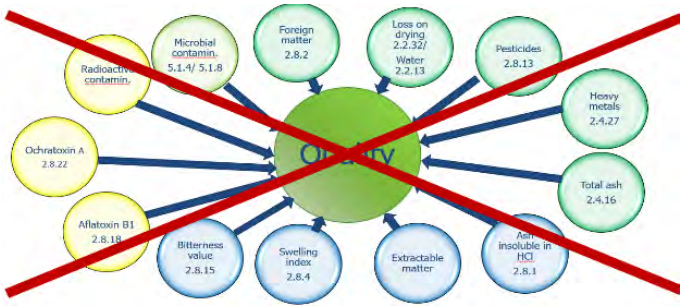
Fresh herbal drug

Processing within a short (validated) period of time

Herbal drug preparation

Testing HDP

Quality



Retained sample

Testing RS

Herbal drug preparations

Herbal drug preparations (1434): Definition I

- DEFINITION
- Herbal drug preparations are **homogeneous** products obtained by:
  - **Extraction**
  - **Distillation**
  - **Expression**
  - **Fractionation**
  - **Purification**
  - **Concentration**
  - **Fermentation**

- **Extracts**
- **Essential oils**
- **Expressed juices**
- **Processed exudates**
- **Herbal drugs that have been subjected to size reduction for specific applications**

Herbal drug preparations (1434)

- General monographs on Herbal drug preparations:
  - Herbal drug extracts (0765)
  - Essential oils (2098)
  - Herbal teas (1435)
  - Instant herbal teas (2620)

Herbal drug preparations (1434): Definition III

Herbal drug preparation

synonymous with

Herbal preparation
(used in European Community Legislation)

NOTE:

The term ***comminuted*** used in European Community legislation on herbal medicinal products describes a herbal drug that has been **either cut or powdered**.

Herbal drug extracts

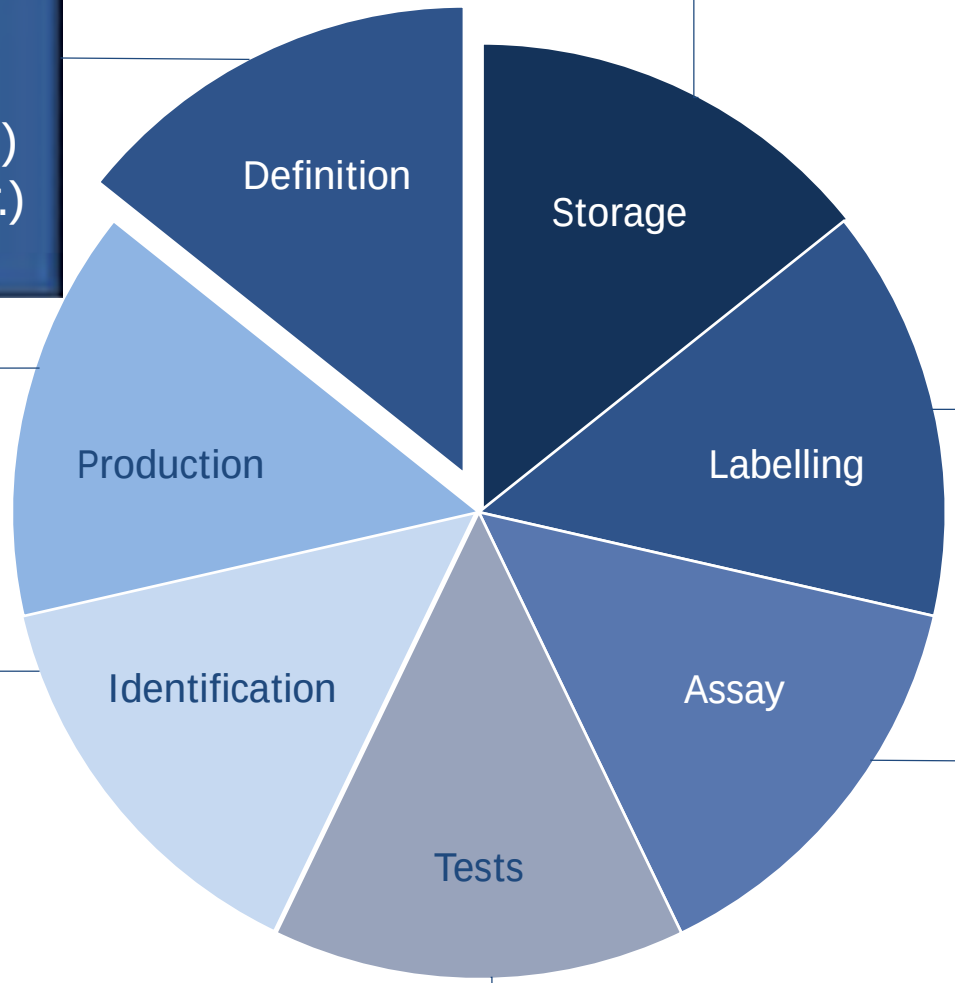
Herbal drug extracts (0765)

- Standardised
- Quantified
- “Other”
- Liquid (tinctures/liquid extracts)
- Semi-solid (oleoresins/soft extr.)
- Solid (dry extracts)

Extraction solvent

- (HP)TLC
- (LC/GC)

- Heavy metals (2.4.27)
- Aflatoxins (2.8.18)
- Ochratoxin A (2.8.22)
- Pesticide residues (2.8.13)
- Microbiological quality (5.1.4 or 5.1.8)
- ...



Protected from light

- Herbal drug
- Form of extract
- Content
- Solvents
- Excipients
- ...

- HPLC
- GC
- UV

Herbal drug extracts (0765): Definition I

Herbal drug extracts are:

- Liquid → Liquid extraction preparations
- Semi-solid → Soft extracts and oleoresins
- Solid → Dry extracts

obtained from *Herbal drugs (1433)* using suitable solvents.

- Essentially defined by:
  - quality of the herbal drug
  - production process (e.g. solvent(s), method of processing)
  - specifications

Ph. Eur. monographs for extracts cover the genuine (native) extract and, where present, excipients.

Herbal drug extracts (0765): Definition II

Different types of extract may be distinguished depending on the constituents assayed:

- **Standardised extracts** (constituents with known therapeutic activity)
  e.g. *Opium tincture, standardised (1841)*

- **Quantified extracts** (active markers)
  e.g. *St. John's wort dry extract, quantified (1874)*

- **Other extracts** (analytical markers)
  e.g. *Hawthorn leaf and flower liquid extract (1865)*

Herbal drug extracts (0765): Production I

Production

- A statement on the **extraction solvent** used, based on medicinal **products licensed in member states,** limits the scope of the monograph:

Example: Boldo leaf dry extract (1816)

The extract is produced from the herbal drug by a suitable procedure using either hot water at not less than 65 °C or a hydroalcoholic solvent equivalent in strength to ethanol (45-75 per cent *V/V*).

Herbal drug extracts (0765): Production II

- Herbal drugs, solvents and other materials used for the preparation of extracts are of suitable quality and where applicable comply with the requirements of any relevant monograph in the Ph. Eur.

Example: Boldo leaf dry extract (1816)
DEFINITION
Extract produced from *Boldo leaf (1396).*

Relevant monograph

- **Herbal drug extracts (0765)**
- **Herbal drug preparations (1434)**
- **Herbal drugs (1433)**
- **Boldo leaf (1396)**

Herbal drug extracts (0765): Production III

Where justified, **herbal drugs** used for the production of extracts **may exceed the limits** for heavy metals specified in the monograph *Herbal drugs (1433)* provided that the resulting **extract satisfies the requirements for heavy metals** (see Tests).

Herbal drug extracts (0765)

- **Identification**
  - Typically using a (HP)TLC similar to that described in the herbal drug monograph.

- **Tests**
  - Heavy metals (2.4.27)
  - Aflatoxins (2.8.18)
  - Ochratoxin A (2.8.22)
  - Pesticide residues (2.8.13)
  - Microbiological quality (5.1.4 or 5.1.8)

Herbal drug extracts (0765)

- **Identification**
  - Typically using a (HP)TLC similar to that described in the herbal drug monograph.

- **Tests**
  - Heavy metals (2.4.27)*
  - Aflatoxins (2.8.18)*
  - Ochratoxin A (2.8.22)*
  - Pesticide residues (2.8.13)*
  - Microbiological quality (5.1.4 or 5.1.8)

* In line with general notices ⟹ testing as such is often performed on the herbal drug.

Herbal drug extracts (0765)

- **Different forms of extracts:**
  - Liquid extraction preparations
    - Liquid (fluid) extracts
    - Tinctures
  - Soft extracts
  - Oleoresins
  - Dry extracts

- **Depending on the form of the extract, different specific tests must be performed in addition to the general tests applicable for all types of extracts.**

Herbal drug extracts (0765)

- **Dry extracts**
  - Loss on drying (2.8.17) (usually not more than 5 per cent m/m)
  - Water (2.5.12) (where a test for loss on drying is not applicable)
  - Residual solvents (5.4)

Essential oils

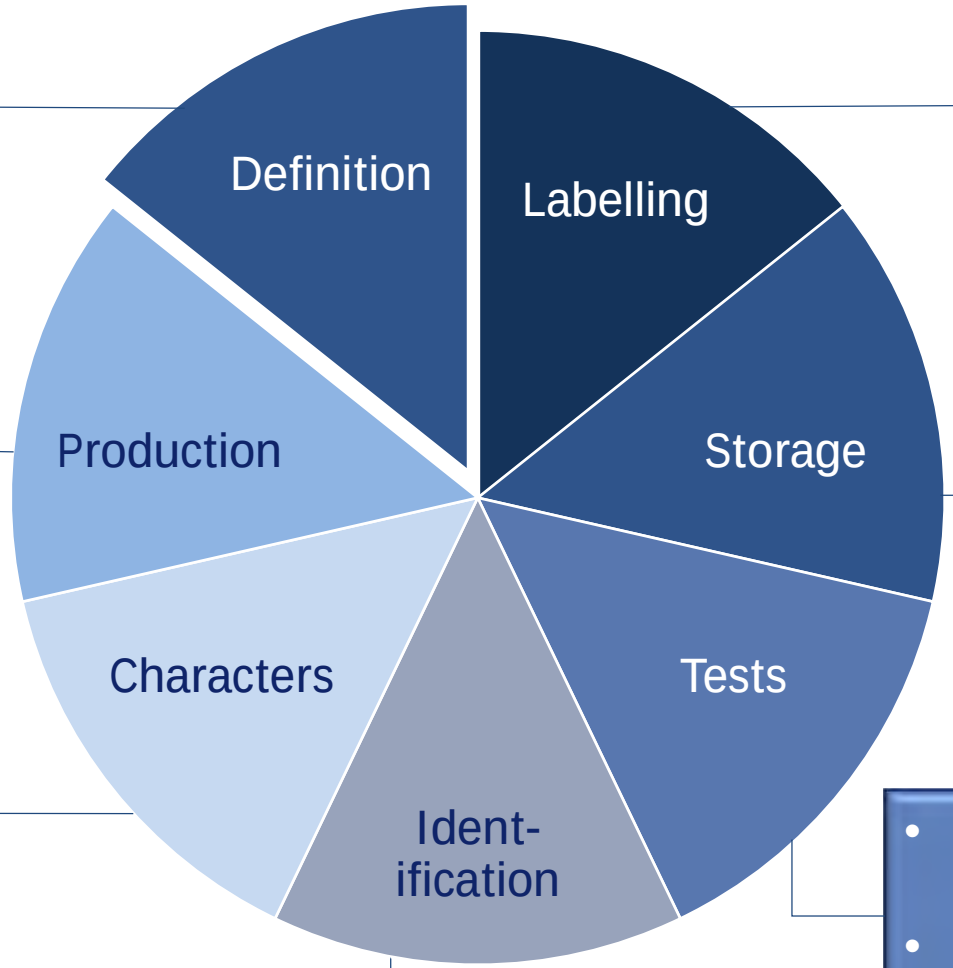
Essential oils (2098)

- Steam distillation
- Dry distillation
- Mechanical process
- + subsequent treatment and/or further processing

- Requirements for the starting materials
  - Herbal drug
  - Water
- Details on the production process
  - Steam/dry/mechanical /rectification

- Appearance and
- Odour

- GC or
- (HP)TLC



- Name according to individual monograph
- Or name of oil and herbal drug used
- Chemotype of oil/antioxidant/additional processing steps

- Well-filled
- Airtight
- Protected from light

- General tests (requirements to be fulfilled by all oils)
- Supplementary tests (where necessary)

Essential oils (2098)

DEFINITION

Odorous product, usually of **complex composition**, obtained from a botanically defined herbal drug by:

- **steam distillation**
- **dry distillation**
- a suitable **mechanical process** without heating.

Any aqueous phase present is separated using a physical process that does not significantly affect the composition.

Essential oils (2098)

Production

- Herbal drugs used for the preparation of essential oils are of suitable quality and, where applicable, comply with the requirements of any **relevant** monograph of the European Pharmacopoeia.

Example: Clove oil (1091)

DEFINITION

Essential oil obtained by steam distillation from the **dried flower buds of *Syzygium aromaticum* (L.) Merr. et L. M. Perry** (syn. *Eugenia caryophyllus* (Spreng.) Bullock et S. G. Harrison).

Relevant monograph

Essential oils (2098)

Herbal drugs (1433)

Herbal drug preparations (1434)

Clove (0376)

Essential oils (2098)

Production

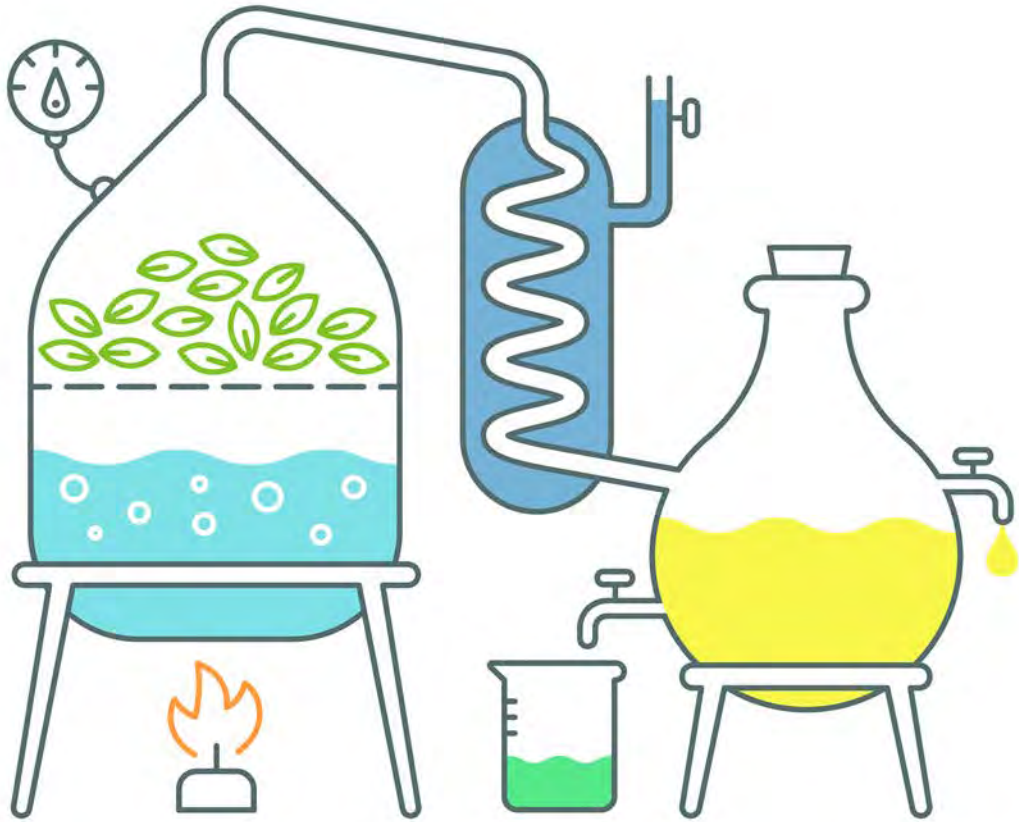
- Different **batches of the herbal drug** may be **combined prior** to **processing**, for example to achieve the quantity required for the production process. The herbal drug may also undergo a preliminary treatment.

- Water: minimum requirement
  - Local drinking water standards
  - World Health Organization drinking water standards
    (unless otherwise justified and authorised)
- A suitable antioxidant may be added to the essential oil.

Essential oils (2098)

Production

- Steam distillation
- Dry distillation
- Mechanical process
- Rectification



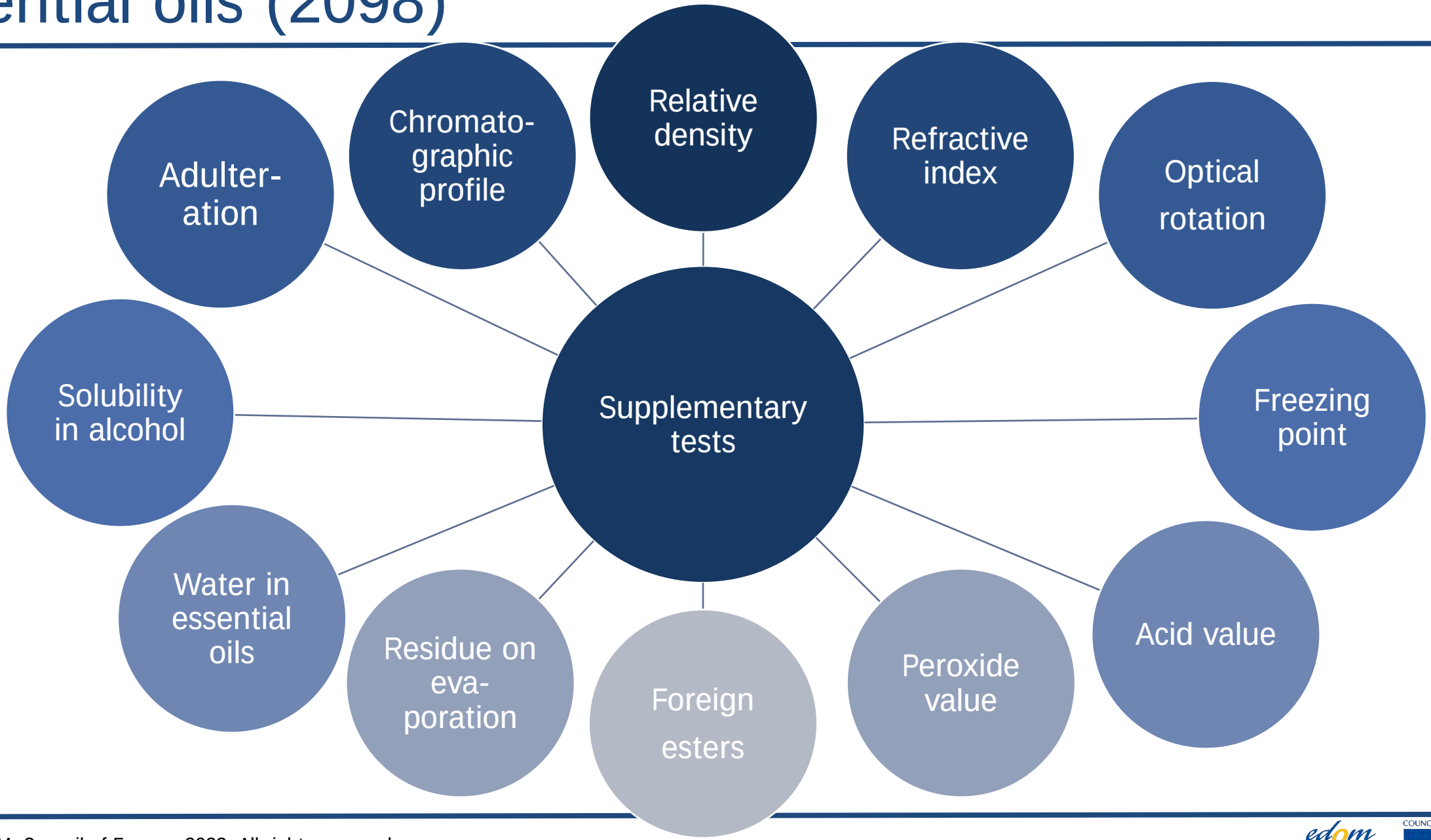
Essential oils (2098)

General Tests

- Fatty oils and resinified essential oils in essential oils (2.8.7)

  The test applies to essential oils obtained by steam distillation or dry distillation.
- Heavy metals (2.4.27)
- Pesticide residues (2.8.13)
- Aflatoxin B1 (2.8.18)
- Microbiological quality (5.1.4 or 5.1.8)

Essential oils (2098)

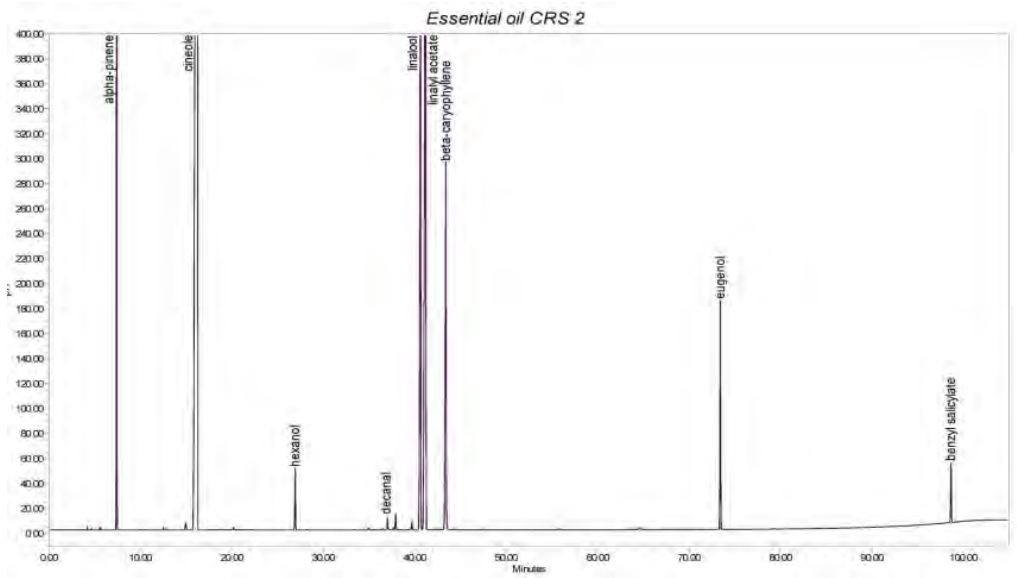


Essential oils (2098)

Chromatographic profile test

To be performed in addition to the system suitability test described in the individual monograph.

- To **periodically check** the **suitability of** the **chromatographic system** (performance qualification).
- Performed using *essential oil CRS*.



Herbal teas / Instant herbal teas

Herbal teas (1435)

- One or more herbal drugs (exclusively)
- Oral aqueous preparations by:
  - Decoction
  - Infusion
  - Maceration
- Supplied in bulk form or in bags for single use.

Relevant monographs

= Herbal teas (1435)

= Herbal drugs (1433)

= Individual Ph. Eur. herbal drug monograph(s)

= Herbal drug preparations (1434)

Herbal teas (1435)

Identification

- botanical examination and/or
- chromatographic profiles [(HP)TLC]

Tests

- Microbiology

  → 5.1.8 taking into account the preparation method (boiling or non-boiling water)

- Herbal teas in bags

  → Uniformity of mass

Instant herbal teas (2620)

- 1 or more **herbal drug <u>preparations</u>** (primarily extracts with or without added essential oils)
- for the preparation of an oral solution
- may contain suitable excipients such as:
  - Maltodextrin
  - Flavourings
- powder or granules (bulk form or sachets)

Relevant monographs

- Instant herbal teas (2620)
- Individual (extract) monograph (where appropriate)
- Herbal drug preparations (1434)
- Other appropriate general monographs
  - Herbal drug extracts (0765)
  - Essential oils (2098)
- Individual excipient monographs

Individual monographs

Individual monographs

- For dried herbal drugs
  - Incl. information on reference standards
  - Incl. information in Knowledge database
- For herbal drug extracts
- For essential oils
- Take-home message

Monographs on dried herbal drugs

Dried herbal drugs: Definition

Example: Passionflower herb (1459)

DEFINITION

Fragmented or **cut**, **dried aerial parts** of ***Passiflora incarnata*** **L.** of the swertisin chemotype or the isovitexin chemotype or a mixture of the two. It may also contain flowers and/or fruits.

Content**:** minimum 1.0 per cent of total flavonoids, expressed as isovitexin ($C_{21}H_{20}O_{10}$; M_r 432.4) (dried drug).

Dried herbal drugs: Identification (1/2)

- Identification is usually done by a combination of:
  - macroscopic botanical description
  - microscopic botanical description (with illustrations)
  - (HP)TLC

IDENTIFICATION
A. The green or greenish-grey or brownish stem is ligneous, hollow, longitudinally striated, glabrous or very slightly pubescent, with a diameter that is generally...
B. Microscopic examination (2.8.23). The powder is light green. Examine under a microscope using chloral hydrate solution R. The powder shows the following diagnostic characters (Figure 1459.-1): fragments of the upper epidermis of the leaf (surface view [A]) consisting of ...

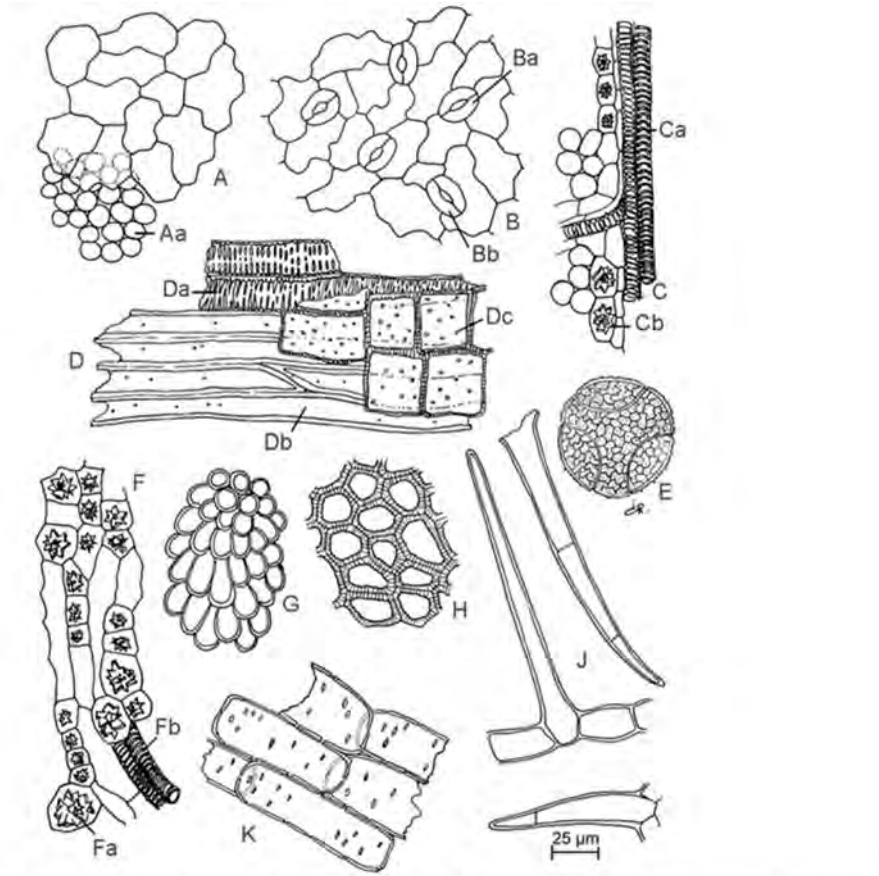


Figure 1459.-1. – *Illustration for identification test B of powdered herbal drug of passionflower herb*

Dried herbal drugs: Identification (2/2)

Example: Passionflower herb (1459)

C. High-performance thin-layer chromatography (2.8.25).

Test solution. To 0.5 g of the powdered herbal drug ...

Reference solution (a). Dissolve 1.5 mg of homoorientin R and...

***Intensity markers*: homoorientin for the yellow fluorescent zones and isovitexin for the green or greenish-blue fluorescent zones.**

Plate: TLC silica gel F_{254} plate R (2-10 µm).

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

Application: 4 µL as bands of 8 mm.

Development: 70 mm from the lower edge of the plate.

Drying: in a current of air at room temperature for 5 min.

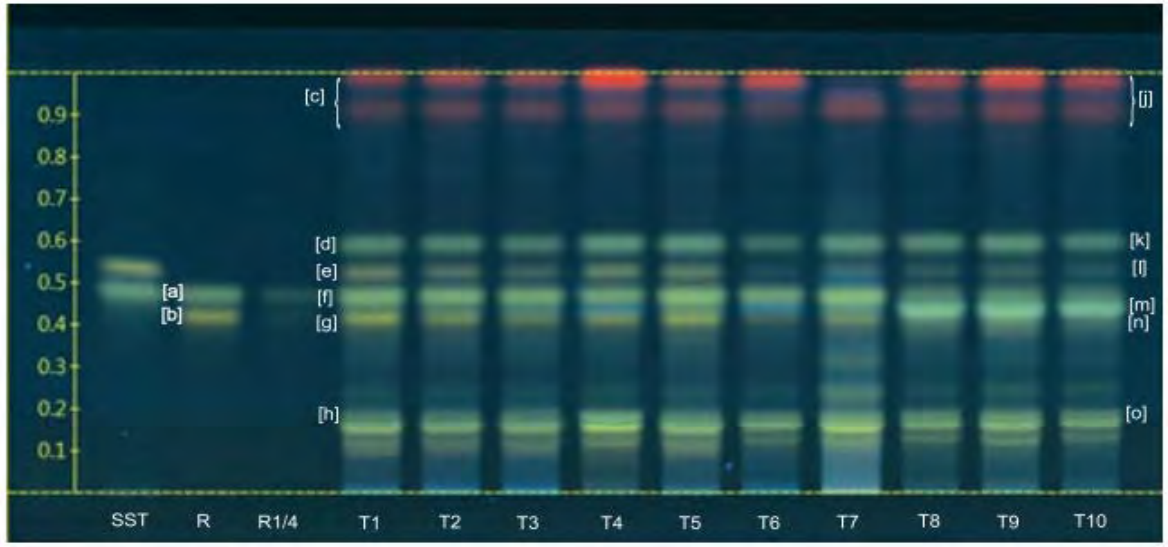
Detection: heat at 100-105 °C for 5 min; spray the warm plate...

***System suitability*: reference solution (c):**

–the chromatogram shows in the middle third 2 distinct zones which may be touching. The lower zone (isovitexin) shows a green ...

Results: see below the sequence of fluorescent zones present in the chromatograms obtained...

Top of the plate		
	[c] 2 red zones, intense	[j] 2 red zones, intense
	[d] A green or greenish-blue zone, faint to equivalent	[k] A green or greenish-blue zone, faint to equivalent
	[e] A yellow zone, faint to equivalent	[l] A yellow zone, faint to equivalent
[a] Isovitexin: a green or greenish-blue zone	[f] A green or greenish-blue zone, faint to equivalent (isovitexin)	
		[m] A bluish-green zone (swertisin)
[b] Homoorientin: a yellow zone	[g] A yellow zone, faint to equivalent (homoorientin)	[n] A yellow zone, faint to equivalent (homoorientin)
	[h] A green or greenish-blue zone, very faint to faint	[o] A green or greenish-blue zone, very faint to faint
Reference solution (a)	**Test solution (isovitexin-type)**	**Test solution (swertisin-type)**



Dried herbal drugs: Tests

- **Foreign matter (2.8.2)**: unless otherwise prescribed or justified and authorised max 2% m/m.
- **Loss on drying (2.2.32)/Water (2.2.13)**
- **Total ash (2.4.16)**
- **Pesticides (2.8.13)**
- **Heavy metals (2.4.27)**
- ...

Example: Passionflower (1459)

TESTS

Total ash (2.4.16): maximum 13.0 per cent.

Loss on drying (2.2.32): maximum 10.0 per cent, determined on 1.000 g of the powdered herbal drug (355) (2.9.12) by drying in an oven at 105 °C for 2 h.

Dried herbal drugs: Tests

In monographs on herbal drugs used for their:

- content in mucilage → test on **Swelling index** (2.8.4)
  e.g. *Fenugreek (1323)*
- content in saponins → test on **Foam index** (2.8.24)
  e.g. *Senega root (0202)*
- content in bitter principles → test on **Bitterness value** (2.8.15)
  e.g. *Gentian root (0392)*

In these cases a formal assay may be omitted.

Dried herbal drugs: Assay

The content is usually determined by:

- LC (preferred)
- UV (e.g flavonoids or tannins)
- GC
- essential oil distillation
- titration

Determination of:

- constituents with known therapeutic activity
- active markers
- analytical markers

(Analytical) markers should be phytochemically typical of the herbal drug and present in sufficient amount for quantitative determination.

Dried herbal drugs: Assay

- Most frequently an LC assay is described:

Example: Passionflower herb (1459)

Liquid chromatography (2.2.29).
Solvent mixture: *water R*, *methanol R* (20:80 *V/V*).
Test solution. Introduce 0.800 g of the powdered herbal drug ...
Reference solution (a). Dissolve 5.0 mg of ***isovitexin CRS*** ...
...
Column:
–*size*: ...
–*Mobile phase*:
–*mobile phase A*: ...

Time[3] (min)	Mobile phase A (per cent *V/V*)	Mobile phase B (per cent *V/V*)	Mobile phase C (per cent *V/V*)
0 - 0.5	95	0	5
0.5 - 26.5	95 → 84	0 → 11	5

Flow rate: 0.7 mL/min.
Detection: spectrophotometer at 338 nm.
Injection: 2 µL.

Identification of peaks: use the chromatogram ...
System suitability: ...
Reporting threshold: ...
Calculate the **percentage content** of the sum of flavonoids, **expressed as isovitexin**, using the following expression:

$$\frac{A_1 \times m_2 \times p}{A_2 \times m_1 \times 2}$$

A_1= sum of the peak areas due to flavonoids which elute with relative retentions between 0.64 and 1.12 with reference to isovitexin in the chromatogram obtained with the test solution;
A_2= area of the peak due to isovitexin in the chromatogram obtained with reference solution (a);
m_1= mass of the herbal drug to be examined used to prepare the test solution, in grams;
m_2= mass of ***isovitexin CRS*** used to prepare reference solution (a), in grams;
p= percentage content of isovitexin in ***isovitexin CRS***.

Dried herbal drugs: Assay

Example: Agnus castus fruit (2147)

Liquid chromatography (2.2.29).

Test solution. Extract 1.000 g of the powdered herbal drug...

Reference solution. Suspend a quantity of ***agnus castus fruit dry extract HRS*** corresponding to 0.10 mg of casticin in 7.5 mL of ...

Column:

–*size*: *l* = 0.125 m, Ø = 4.0 mm;

–*stationary phase*: *end-capped...*

Mobile phase:

–*mobile phase A*: 5.88 g/L solution of ...

Identification of peaks: use the chromatogram supplied with **agnus castus fruit dry extract HRS** and the chromatogram obtained with the reference solution to identify the peaks due to penduletin and casticin.

...

Ph. Eur. chapter 5.12. Reference Standards

Ph. Eur. **chemical reference substance (CRS)**

A **substance or mixture** of substances **intended for use as stated in a monograph** or general chapter of the European Pharmacopoeia. CRSs are in **general primary standards**, except for those (notably antibiotics) that are calibrated in International Units. The latter are secondary standards traceable to the international standard.

Ph. Eur. **herbal reference standard (HRS)**

A **herbal drug preparation** (usually an extract) or a herbal drug **intended for use as stated in a monograph** or general chapter of the European Pharmacopoeia. Unless otherwise specified, HRS are designated as **primary reference standards** for their intended use.

Ph. Eur. reference standards in herbal monographs

Chemical Reference Substance (CRS)

Qualitative CRS

Chemical reference substance used for **peak identification or system suitability** in the (HP)TLC test, LC test or LC assay

Quantitative CRS

Chemical reference substance used as **external standard** for an LC test or an LC assay with an **assigned content**

Ph. Eur. reference standards in herbal monographs

Herbal Reference Standard (HRS)

Qualitative HRS

Herbal reference standard used for **identification or adulteration** in the (HP)TLC test or for **peak identification or system suitability** in the LC test or LC assay

Quantitative HRS

Herbal reference standard used as **external standard** for an LC test or for the LC assay with an **assigned content** of one or more components

Knowledge database

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General Notices apply to all monographs and other texts.
See the information section on general monographs.

PASSIONFLOWER HERB

Passiflorae herba

DEFINITION

Fragmented or cut, dried aerial parts of *Passiflora incarnata* L. of the swertisin chemotype or the isc and/or fruits.

Content: minimum 1.0 per cent of total flavonoids, expressed as isovitexin ($C_{21}H_{20}O_{10}$; M_r 432.4) (dr

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Detailed view of Passiflorae herba.

Status	In use
Monograph Number	01459
English Name	Passionflower herb
French Name	Passiflore
Latin Name	Passiflorae herba
Pinyin Name	
Chinese Name	
Pharmeuropa	30.3
Published in English Supplement	10.3
Published in French Supplement	11.0
Chromatogram	Available
Additional information	Not available
History	View history
Interchangeable (ICH_Q4B)	NO
Pharmacopoeial harmonisation	NO

Reference standards

Available since	Cat. No.	Name	Batch No.	Unit Quantity	Price	SDS Product Code
	Y0002183	Isovitexin HRS	1	15 mg	150 EUR	201700603

Practical Information

Test(s)	Brand Name/Information
HPTLC	Merck HPTLC Si 60 F254 20x10 cm
Assay column	Acquity UPLC HSS T3
Dwell volume	D0 (dwell volume used for development of the method) = 0.7 mL

CEP

Knowledge database

Search Database online | Knowled

Detailed view of Passiflorae herba.

Status	In use
Monograph Number	01459
English Name	Passionflower
French Name	Passiflore
Latin Name	Passiflorae he
Pinyin Name	
Chinese Name	
Pharmeuropa	30.3
Published in English Supplement	10.3
Published in French Supplement	11.0
Chromatogram	Available
Additional information	Not available
History	View history
Interchangeable (ICH_Q4B)	NO
Pharmacopoeial harmonisation	NO

Reference standards

Available since	Cat. No.	Name
	Y0002183	Isovitexin HRS

Practical Information

Test(s)	Brand Name/Informatio
HPTLC	Merck HPTLC Si 60 F254 20
Assay column	Acquity UPLC HSS T3
Dwell volume	D0 (dwell volume used for

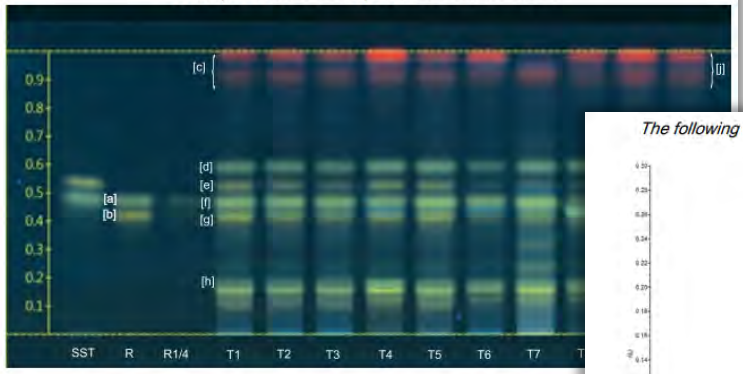
CEP

PASSIONFLOWER HERB

Passiflorae herba

Top of the plate	
[a] Isovitexin: a green or greenish-blue zone	[c] 2 red zones, intense [d] A green or greenish-b faint to equivalent [e] A yellow zone, faint to [f] A green or greenish-bl faint to equivalent (isovite
[b] Homoorientin: a yellow zone	[g] A yellow zone, faint to (homoorientin)
	[h] A green or greenish-b very faint to faint
Reference solution (a)	Test solution (isovitexi

The following chromatogram is shown for information but will not be published in the European Pharmacopoeia. The zones in the chromatogram are identified by letters that correspond to the descriptions in the table above.



SST: reference solution (c)

R: reference solution (a)

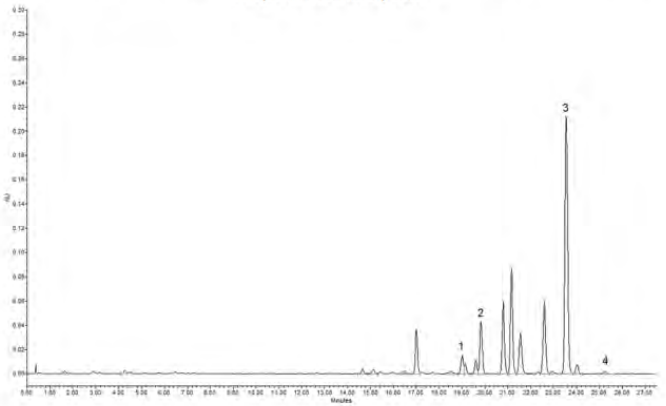
R1/4: reference solution (b)

T1-T7: test solutions pre different batches of pass isovitexin-type

T8-T10: test solutions p different batches of pass swertisin-type

Figure 1459.-2. – *HPTLC chromatogram for different batches of pass*

The following chromatogram is shown for information but will not be published in the European Pharmacopoeia.



1. orientin
2. homoorientin
3. isovitexin
4. swertisin

Figure 1459.-3. – *Chromatogram for the assay of total flavonoids of passionflower herb: test solution, isovitexin-type (full chromatogram)*

EDITION 11.0: French version corrected

SUPPLEMENT 10.3

Identification:

- illustration of powdered herbal drug introduced and its legend integrated into text of identification B;

- TLC replaced by high performance thin-layer chromatography (HPTLC) in accordance with chapter 2.8.25.

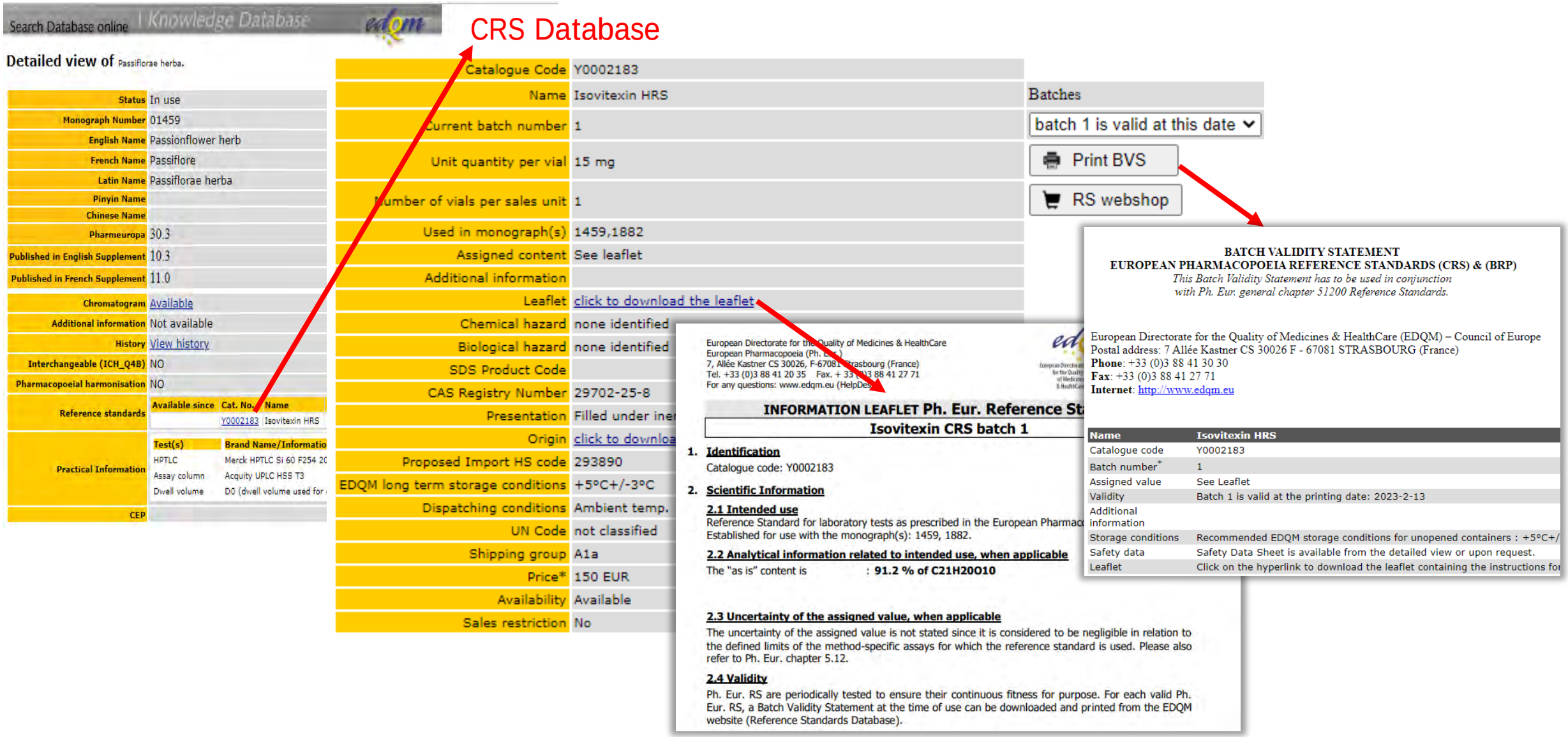
Assay: unspecific photometric assay replaced by LC assay; content limits adapted accordingly.

EDITION 10.0: French version corrected

EDITION 9.2: French version corrected

EDITION 6.0: corrected

Knowledge database



Monographs on herbal drug extracts

Herbal drug extracts: Definition

Example: Passionflower herb dry extract (1882)

DEFINITION

Dry extract produced from ***Passionflower herb (1459)***.

***Content*: minimum 1.5 per cent of total flavonoids, expressed as isovitexin ($C_{21}H_{20}O_{10}$; M_r 432.4) (anhydrous extract)**.

Herbal drug extracts: Production

- A statement on the **extraction solvent** used, based on medicinal products licensed in member states, **limits the scope of the monograph**:

Example: Passionflower herb dry extract (1882)
PRODUCTION
The extract is produced from the herbal drug by a suitable procedure using ethanol (40-90 per cent *V/V*), methanol (60 per cent *V/V*) or acetone (40 per cent *V/V*).

- Extracts produced using other solvents or other concentrations of solvents are not covered by the monograph.

Herbal drug extracts: Characters

Non mandatory requirements for information only.

- Appearance
- (Odour)

Example: Passionflower herb dry extract (1882)
CHARACTERS
Appearance: greenish-brown amorphous powder.

Herbal drug extracts: Identification

- Usually by (HP)TLC
  - Where possible using a similar (HP)TLC as described in the herbal drug monograph.
- Rarely, an additional chemical reaction is described or reference is made to the GC or LC used in the assay
- Reference to the herbal drug in the Definition assures identity

Example: Passionflower herb dry extract (1882)
Definition
Dry extract produced from *Passionflower herb (1459).*

Herbal drug extracts: Tests

Dry extracts

Dry extracts **usually** have a **loss on drying** of **not greater than 5 per cent** *m/m*. Where justified and authorised, a loss on drying with a different limit or a test for water may be prescribed.

Example: Olive leaf dry extract (2313)
Loss on drying *(2.8.17)*: maximum 8.0 per cent.

Example: Passionflower herb dry extract (1882)
Water *(2.5.12)*: maximum 5.0 per cent, determined on 0.500 g.

Herbal drug extracts: Assay

The content is usually determined by:

- LC (preferred)
- UV (e.g. flavonoids or tannins)
- GC
- essential oil determination
- titration

Where possible, the same assay procedure is used for the herbal drug and the extract.

Determination of:

- constituents with known therapeutic activity
- active markers
- analytical markers

(Analytical) markers should be phytochemically typical of the herbal drug and present in sufficient amount for quantitative determination.

Herbal drug extracts: Labelling

- Labelling requirements are provided in the general monograph on *Herbal drug extracts (0765)*.
- Additional requirements may be provided in individual monographs e.g. for stating the content in case of standardised extracts.

Example: Senna fruit dry hydroalcoholic extract, standardised (3127)

DEFINITION

Standardised dry hydroalcoholic extract produced from *Senna pods* (0207).

Content: 14.0 per cent to 22.0 per cent of total hydroxyanthracene glycosides, expressed as sennoside B ($C_{42}H_{38}O_{20}$; M_r 863) (dried extract). The measured content does not deviate from the value stated on the label by more than ± 10 per cent.

LABELLING

The label states the content of total hydroxyanthracene glycosides.

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General Notices apply to all monographs and other texts.
See the information section on general monographs.

PASSIONFLOWER HERB DRY EXTRACT

Passiflorae herbae extractum siccum

DEFINITION

Dry extract produced from Passionflower herb (1459).

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Detailed view of Passiflorae herbae extractum siccum.

Status	In use
Monograph Number	01882
English Name	Passionflower herb dry extract
French Name	Passiflore (extrait sec de)
Latin Name	Passiflorae herbae extractum siccum
Pinyin Name	
Chinese Name	
Pharmeuropa	30.3
Published in English Supplement	10.3
Published in French Supplement	11.0
Chromatogram	Available
Additional information	Not available
History	View history
Interchangeable (ICH_Q4B)	NO
Pharmacopoeial harmonisation	NO

Reference standards

Available since	Cat. No.	Name	Batch No.	Unit Quantity	Price	SDS Product Code
	Y0002183	Isovitexin HRS	1	15 mg	150 EUR	201700603

Practical Information

Test(s)	Brand Name/Information
HPTLC	Merck HPTLC Si60 F254 20x10 cm
Water	Hydranal Composite 5 or Hydranal Methanol dry
Assay column	Aquity UPLC HSS T3
Dwell volume	D0 (dwell volume used for development of the method) = 0.7 mL

CEP

Substance Number	Substance	Certificate Holder	Certificate Number	Issue Date	Status	End date	Type
1882	Passionflower herb dry extract DER: 2-5:1	Gifrer Barbezat Décines-Charpieu FR	R1-CEP 2011-230 - Rev 00	20/11/2018	Valid		Herbal
1882	Passionflower herb dry extract DER: 4-6.5:1	EUROMED S.A. Mollet del Vallès ES	R1-CEP 2015-351 - Rev 00	17/08/2021	Valid		Herbal

Monographs on essential oils

Essential oils: Definition

The following are specified:

- **type of production**
  e.g. dry distillation, steam distillation, mechanical process
- **botanical source**:
  - species
  - plant part
  - state (e.g. fresh, wilted, etc.)

- **If appropriate:**
  - method of subsequent treatment (e.g. re-distillation)
  - Antioxidants

Example: Turpentine oil (1627)
DEFINITION
Essential oil obtained by **steam distillation**, followed by **rectification** at a temperature below 180 °C, from the oleoresin obtained by tapping ***Pinus pinaster*** **Aiton and/or** ***Pinus massoniana*** **D.Don**. A **suitable antioxidant** may be added.

Essential oils: Characters

Non mandatory requirements

- appearance
- odour with reference to single compound
- no reference is made to taste!

Example: Turpentine oil (1627)

CHARACTERS

Appearance: clear, colourless or pale yellow liquid.

Odour reminiscent of α-pinene and β-pinene.

Essential oils: Identification

Example: Turpentine oil (1627)

IDENTIFICATION

First identification: B.

Second identification: A.

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

Test solution. Dilute 1 mL of the oil to be examined...

B. Examine the chromatograms obtained in the test for chromatographic profile.

Results: the peaks in the chromatogram obtained with the test solution are similar in retention time to those in the chromatogram obtained with reference solution (a).

- Usually 2 sets of identification

→ First identification: GC (as in chromatographic profile)

→ Second identification: (HP)TLC

Essential oils: Tests

General test (to be fulfilled by practically all essential oils):

- Fatty oils and resinified essential oils (2.8.7)
- Heavy metals (2.4.27)
- Pesticide residues (2.8.13)
- Aflatoxin B1 (2.8.18)
- Microbiological quality (5.1.4 or 5.1.8)

Monographs on essential oils (**information chapter**) (5.30)

- In general, contaminants such as heavy metals, pesticides, aflatoxins and microbial contaminants are **not considered a critical issue for essential oils** used in medicinal products, but are to be considered on a case by case basis.

Essential oils: Tests

Supplementary tests

If applicable and necessary:

- Relative density (2.2.5).
- Refractive index (2.2.6).
- Optical rotation (2.2.7).
- Freezing point (2.2.18).
- Acid value (2.5.1).
- Peroxide value (2.5.5).
- Foreign esters (2.8.6).
- Residue on evaporation (2.8.9).
- Water in essential oils(2.8.5).
- Solubility in alcohol (2.8.10).
- Adulteration
- Chromatographic profile

Example: Turpentine oil (1627)

TESTS

Relative density *(2.2.5)*: 0.856 to 0.872.

Refractive index *(2.2.6)*: 1.465 to 1.475.

Optical rotation *(2.2.7)*: – 40° to – 28°.

Acid value *(2.5.1)*: maximum 1.0.

Peroxide value (*2.5.5*, Method B): maximum 20.

Fatty oils and resinified essential oils *(2.8.7).* It complies with the test.

Chromatographic profile. Gas chromatography *(2.2.28)*: use the normalisation procedure.

Test solution. Dilute 1.0 mL of the oil ...

Residue on evaporation *(2.8.9)*: maximum 2.5 per cent, determined after heating on a water-bath for 3 h.

Essential oils: Tests

- **Chromatographic profile** instead of assay.
- The composition of the essential oil is determined by gas chromatography using the normalisation procedure.
- Where necessary this may be complemented by a test for chiral purity.

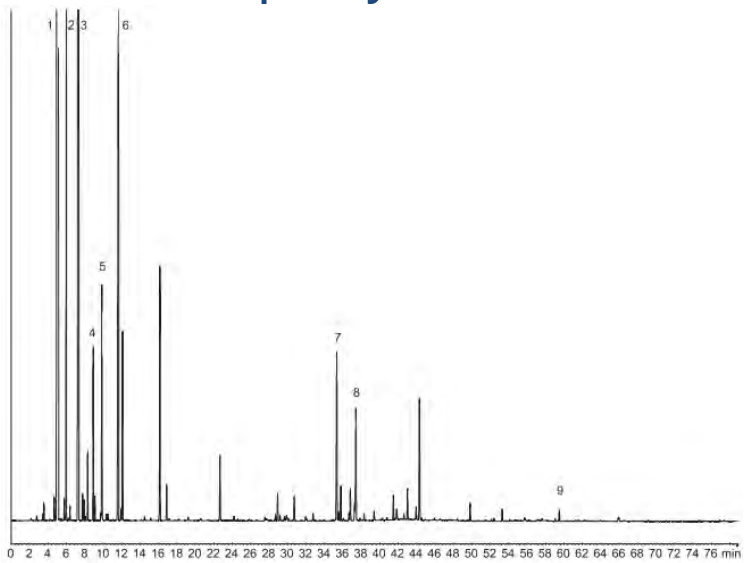


Figure 1627.-1. – *Chromatogram for the test for chromatographic profile of turpentine oil: test solution*

Example: Turpentine oil (1627)

- Determine the percentage content of these components. The limits are within the following ranges:
- –*α-pinene*: 70.0 per cent to 85.0 per cent;
- –*camphene*: 0.5 per cent to 2.0 per cent;
- –*β-pinene*: 5.0 per cent to 20.0 per cent;
- –*car-3-ene*: maximum 1.0 per cent;
- –*β-myrcene*: 0.4 per cent to 1.5 per cent;
- –*limonene*: 1.0 per cent to 7.0 per cent;
- –*longifolene*: 0.2 per cent to 4.0 per cent;
- –*β-caryophyllene*: 0.1 per cent to 3.0 per cent;
- –*caryophyllene oxide*: maximum 1.0 per cent;
- –*disregard limit*: the area of the peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Essential oils: Storage and Labelling

Storage:

- Well-filled
- Airtight container
- Protected from light
- Further conditions may be stated in individual monographs.

Example: Turpentine oil (1627)
STORAGE
At a temperature not exceeding 25 °C.

Labelling:

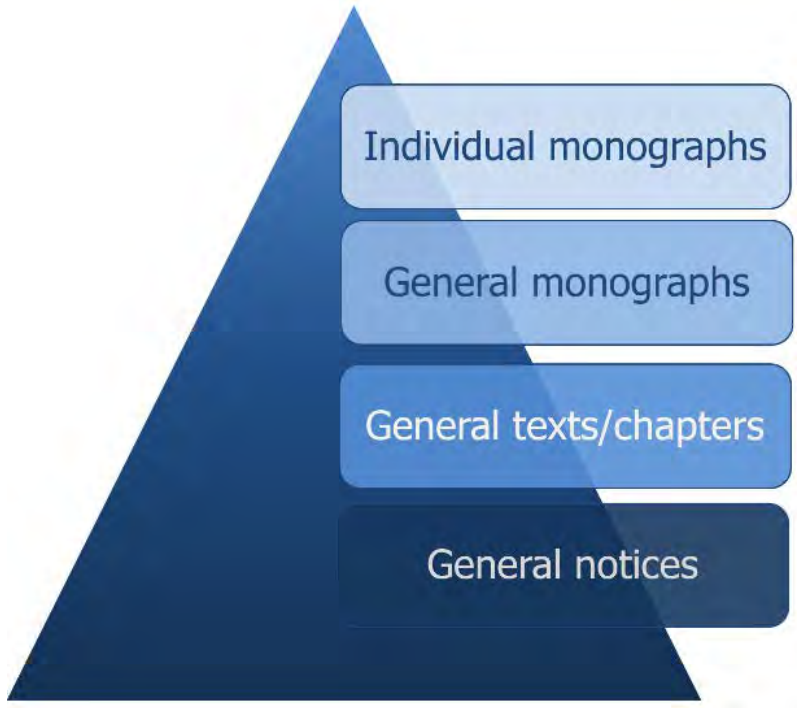
- Type/chemotype of the oil
- Name and concentration of any added antioxidant
- Additional processing steps (not specified in the definition)
- Storage conditions

Example: Rosemary oil (1846)
LABELLING
The label states that the content is Spanish type or Moroccan and Tunisian type.

Take-home message

Take-home message

- Read the **General Notices**!!!
- Pharmacopoeia texts are **not stand-alone texts**, they must be read together:



Take-home message

- Much information found in **General monographs** that are available for:
  - Herbal drugs (1433)
  - Herbal drug preparations (1434)
    - ➢Herbal drug extracts (0765)
    - ➢Essential oils (2098)
    - ➢Herbal teas (1435)
    - ➢Herbal teas, instant (2620)
- Supplementary information is available in the **Knowledge database**

Thank you for your attention

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