Cos'è European Pharmacopoeia?

È il codice farmaceutico che armonizza i testi delle principali farmacopee ufficiali degli Stati Europei e individua norme comuni riconosciute sulla qualità dei medicinali.
Ha lo scopo di assicurare parametri di qualità omologhi per i medicinali a livello europeo.

NB: ***Farmacopea Ufficiale***: è un complesso di disposizioni tecnico/scientifiche ed amministrative, di cui il farmacista si serve per il controllo della qualità dei medicamenti, delle sostanze e/o dei preparati finali, mediante l'indicazione di metodi di verifica chimico analitici e tecnologici delle specifiche di qualità, dei metodi di preparazione o della formulazione.
Contiene inoltre le disposizioni opportune e necessarie a regolare l'esercizio della farmacia.

Home Page

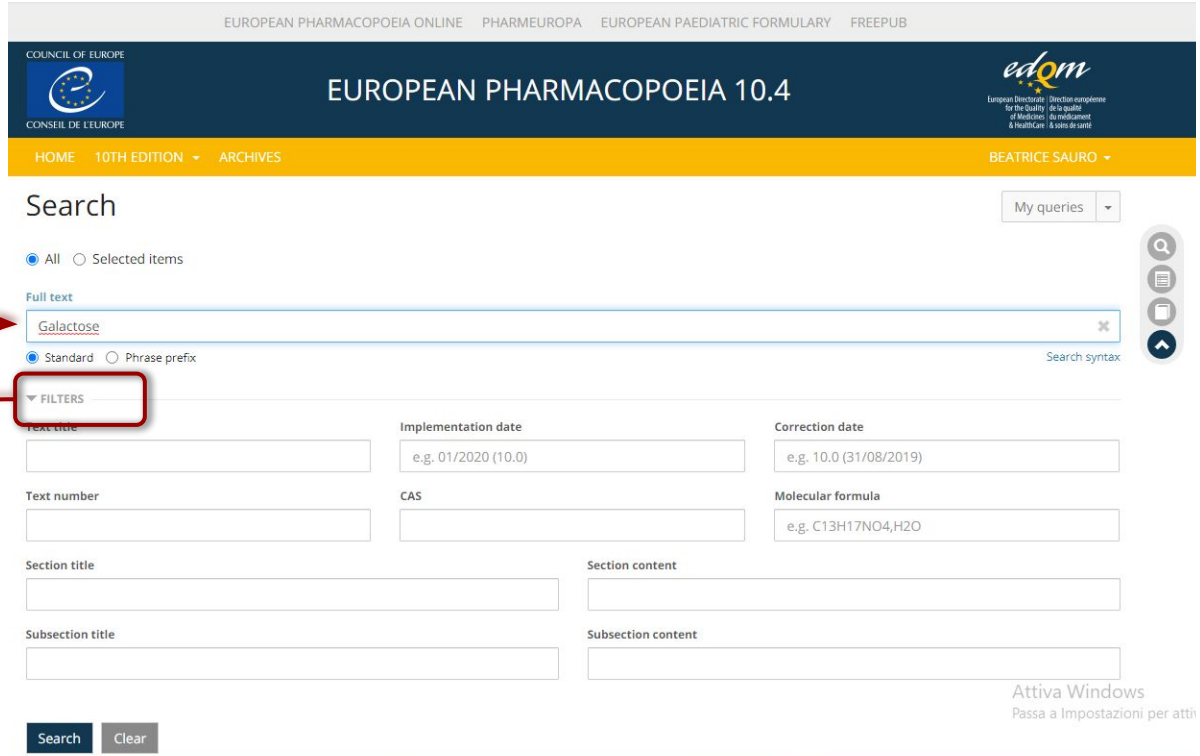
L'Home Page è molto semplice.
In alto è presente il tasto Home, accanto c'è la possibilità di poter accedere alle altre edizioni della European Pharmacopoeia (così come nella colonna a destra) e anche la consultazione degli articoli.

In alto a destra è presente il tasto LOGIN per poter accedere ai contenuti.

Ricerca

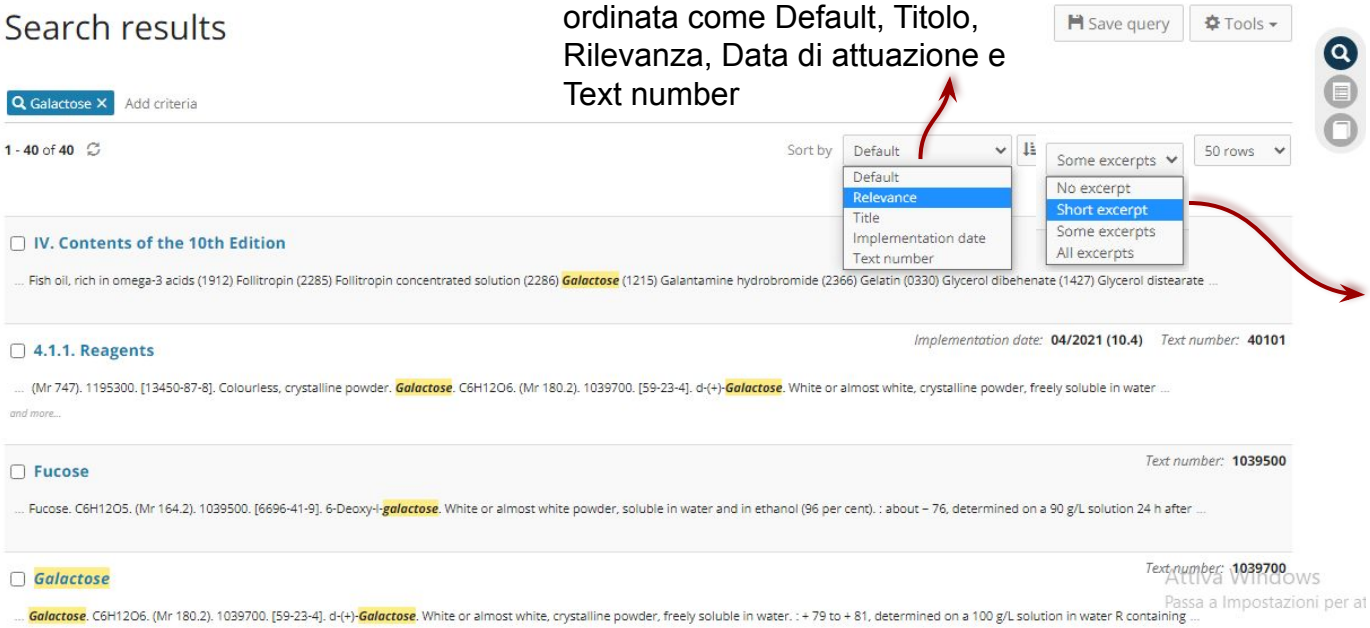
È presente una stringa di ricerca semplice

È possibile inserire dei filtri facendo una ricerca più approfondita: con il CSA, data di attuazione, con la formula molecolare...



Risultati

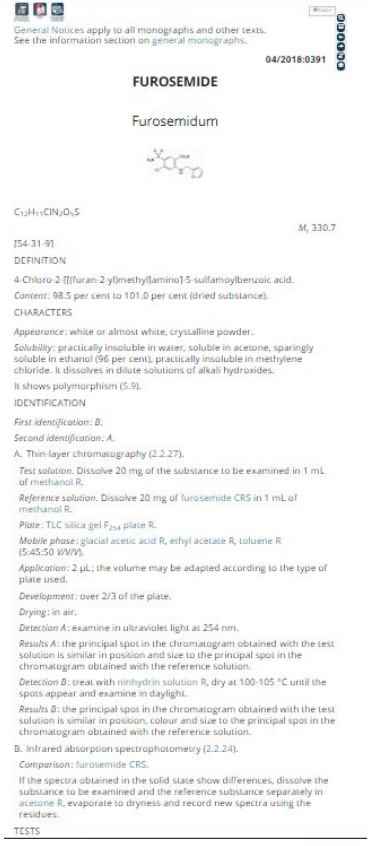
La lista dei risultati può essere ordinata come Default, Titolo, Rilevanza, Data di attuazione e Text number



I risultati possono essere visualizzati con un breve estratto o nessun estratto

Risultati

Cliccando sul risultato di interesse ritroviamo tutta la scheda riferita.
I risultati riportano alle schede dei principi attivi, principali composizioni farmaceutiche e formulazioni, ognuna presenta le caratteristiche comuni alle schede di Farmacopea: formula, caratteristiche, identificazione, analisi chimiche, saggi e impurità.



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

04/2018:0391

FUROSEMIDE

Furosemidum

$C_{12}H_{11}ClN_2O_5S$ *M*, 330.7

[54-31-9]

DEFINITION

4-Chloro-2-[[(furan-2-yl)methyl]amino]-5-sulfamoylbenzoic acid.

Content: 98.5 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance: white or almost white, crystalline powder.

Solubility: practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 per cent), practically insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides.

It shows polymorphism (5.9).

IDENTIFICATION

First identification: B.

Second identification: A.

A. Thin-layer chromatography (2.2.27).

Test solution. Dissolve 20 mg of the substance to be examined in 1 mL of methanol R.

Reference solution. Dissolve 20 mg of furosemide CRS in 1 mL of methanol R.

Plate: TLC silica gel F_{254} plate R.

Mobile phase: glacial acetic acid R, ethyl acetate R, toluene R (5:45:50 *V/V*).

Application: 2 µL; the volume may be adapted according to the type of plate used.

Development: over 2/3 of the plate.

Drying: in air.

Detection A: examine in ultraviolet light at 254 nm.

Results A: the principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.

Detection B: treat with ninhydrin solution R, dry at 100-105 °C until the spots appear and examine in daylight.

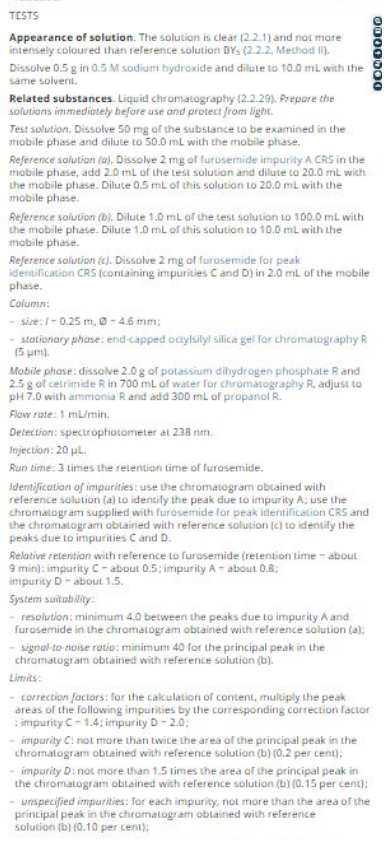
Results B: the principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.

B. Infrared absorption spectrophotometry (2.2.24).

Comparison: furosemide CRS.

If the spectra obtained in the solid state show differences, dissolve the substance to be examined and the reference substance separately in acetone R, evaporate to dryness and record new spectra using the residues.

TESTS



TESTS

Appearance of solution. The solution is clear (2.2.1) and not more intensely coloured than reference solution BY_5 (2.2.2, Method II).

Dissolve 0.5 g in 0.5 M sodium hydroxide and dilute to 10.0 mL with the same solvent.

Related substances. Liquid chromatography (2.2.29). *Prepare the solutions immediately before use and protect from light.*

Test solution. Dissolve 50 mg of the substance to be examined in the mobile phase and dilute to 50.0 mL with the mobile phase.

Reference solution (a). Dissolve 2 mg of furosemide impurity A CRS in the mobile phase, add 2.0 mL of the test solution and dilute to 20.0 mL with the mobile phase. Dilute 0.5 mL of this solution to 20.0 mL with the mobile phase.

Reference solution (b). Dilute 1.0 mL of the test solution to 100.0 mL with the mobile phase. Dilute 1.0 mL of this solution to 10.0 mL with the mobile phase.

Reference solution (c). Dissolve 2 mg of furosemide for peak identification CRS (containing impurities C and D) in 2.0 mL of the mobile phase.

Column:

- *size*: *l* = 0.25 m, Ø = 4.6 mm;
- *stationary phase*: end-capped octylsilyl silica gel for chromatography R (5 µm).

Mobile phase: dissolve 2.0 g of potassium dihydrogen phosphate R and 2.5 g of cetrimide R in 700 mL of water for chromatography R, adjust to pH 7.0 with ammonia R and add 300 mL of propanol R.

Flow rate: 1 mL/min.

Detection: spectrophotometer at 238 nm.

Injection: 20 µL.

Run time: 3 times the retention time of furosemide.

Identification of impurities: use the chromatogram obtained with reference solution (a) to identify the peak due to impurity A; use the chromatogram supplied with furosemide for peak identification CRS and the chromatogram obtained with reference solution (c) to identify the peaks due to impurities C and D.

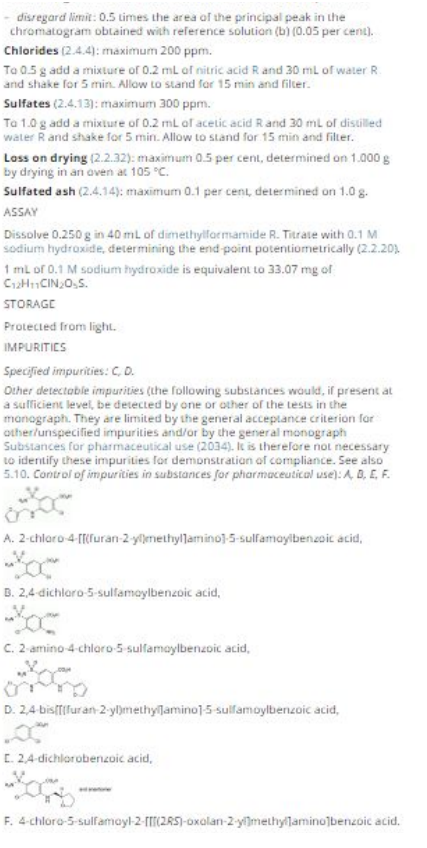
Relative retention with reference to furosemide (retention time = about 9 min): impurity C = about 0.5; impurity A = about 0.8; impurity D = about 1.5.

System suitability:

- *resolution*: minimum 4.0 between the peaks due to impurity A and furosemide in the chromatogram obtained with reference solution (a);
- *signal-to-noise ratio*: minimum 40 for the principal peak in the chromatogram obtained with reference solution (b).

Limits:

- *correction factors*: for the calculation of content, multiply the peak areas of the following impurities by the corresponding correction factor : impurity C = 1.4; impurity D = 2.0;
- *impurity C*: not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (0.2 per cent);
- *impurity D*: not more than 1.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.15 per cent);
- *unspecified impurities*: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.10 per cent);



- *disregard limit*: 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Chlorides (2.4.4): maximum 200 ppm.

To 0.5 g add a mixture of 0.2 mL of nitric acid R and 30 mL of water R and shake for 5 min. Allow to stand for 15 min and filter.

Sulfates (2.4.13): maximum 300 ppm.

To 1.0 g add a mixture of 0.2 mL of acetic acid R and 30 mL of distilled water R and shake for 5 min. Allow to stand for 15 min and filter.

Loss on drying (2.2.32): maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C.

Sulfated ash (2.4.14): maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.250 g in 40 mL of dimethylformamide R. Titrate with 0.1 M sodium hydroxide, determining the end-point potentiometrically (2.2.20).

1 mL of 0.1 M sodium hydroxide is equivalent to 33.07 mg of $C_{12}H_{11}ClN_2O_5S$.

STORAGE

Protected from light.

IMPURITIES

Specified impurities: C, D.

Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph Substances for pharmaceutical use (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. *Control of impurities in substances for pharmaceutical use*): *A, B, E, F.*

A. 2-chloro-4-[[(furan-2-yl)methyl]amino]-5-sulfamoylbenzoic acid,

B. 2,4-dichloro-5-sulfamoylbenzoic acid,

C. 2-amino-4-chloro-5-sulfamoylbenzoic acid,

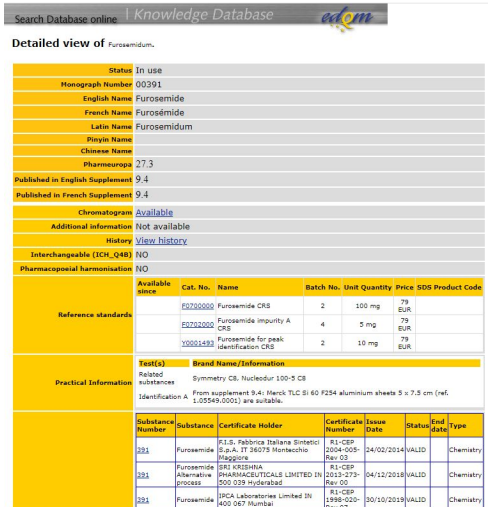
D. 2,4-bis[[(furan-2-yl)methyl]amino]-5-sulfamoylbenzoic acid,

E. 2,4-dichlorobenzoic acid,

F. 4-chloro-5-sulfamoyl-2-[[(2*RS*)-oxolan-2-yl]methyl]amino]benzoic acid.

Risultati

In alto a sinistra si può scaricare il PDF o visionare il documento in un altra lingua.
Cliccando su Knowledge Database dove ci sono i dettagli della monografia



Search Database online | Knowledge Database

Detailed view of Furosemidum.

Status	In use
Monograph Number	00391
English Name	Furosemide
French Name	Furosémide
Latin Name	Furosemidum
Pinyin Name	
Chinese Name	
Pharmeuropa	27.3
Published in English Supplement	9.4
Published in French Supplement	9.4
Chromatogram	Available
Additional information	Not available
History	View history
Interchangeable (ICH_Q4B)	NO
Pharmacopoeial harmonisation	NO

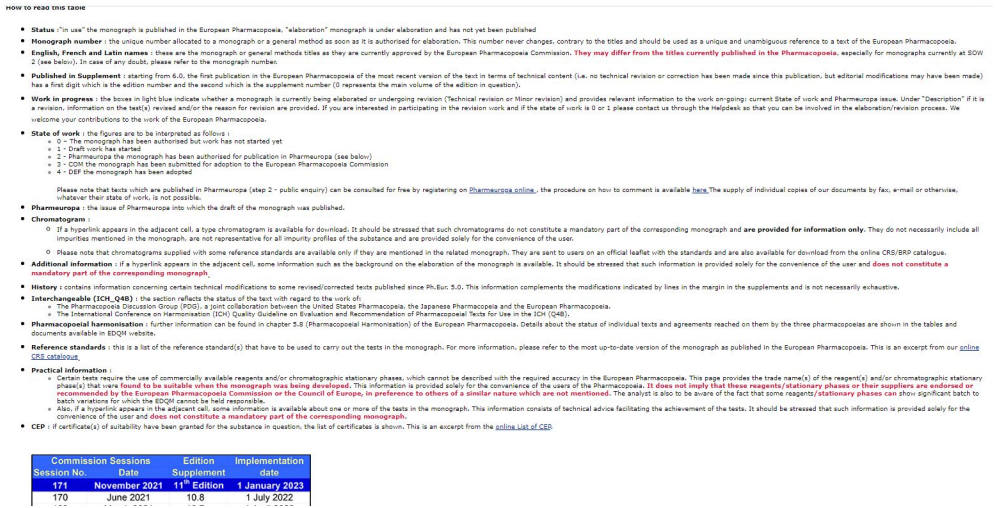
Reference standards

Available since	Cat. No.	Name	Batch No.	Unit Quantity	Price	SDS Product Code
	F0700000	Furosemide CRS	2	100 mg	79 EUR	
	F0702000	Furosemide impurity A CRS	4	5 mg	79 EUR	
	Y0001493	Furosemide for peak identification CRS	2	10 mg	79 EUR	

Practical Information

Test(s)	Brand Name/Information
Related substances	Symmetry C8, Nucleodur 100-5 C8
Identification A	From supplement 9.4: Merck TLC Si 60 F254 aluminium sheets 5 x 7.5 cm (ref. 1.05549.0001) are suitable.

Substance Number	Substance	Certificate Holder	Certificate Number	Issue Date	Status	End date	Type
291	Furosemide	F.I.S. Fabbrica Italiana Sintetici S.p.A. IT 36075 Montecchio Maggiore	R1-CEP 2004-005-Rev 03	24/02/2014	VALID		Chemistry
291	Furosemide Alternative process	SRI KRISHNA PHARMACEUTICALS LIMITED IN 500 039 Hyderabad	R1-CEP 2013-273-Rev 00	04/12/2018	VALID		Chemistry
291	Furosemide	IPCA Laboratories Limited IN 400 067 Mumbai	R1-CEP 1998-020-Rev 02	30/10/2019	VALID		Chemistry



How to read this table

- **Status** : "in use" the monograph is published in the European Pharmacopoeia. "elaboration" monograph is under elaboration and has not yet been published
- **Monograph number** : the unique number allocated to a monograph or a general method as soon as it is authorised for elaboration. This number never changes, contrary to the titles and should be used as a unique and unambiguous reference to a text of the European Pharmacopoeia.
- **English, French and Latin names** : these are the monograph or general methods titles as they are currently approved by the European Pharmacopoeia Commission. **They may differ from the titles currently published in the Pharmacopoeia**, especially for monographs currently at SOW 2 (see below). In case of any doubt, please refer to the monograph number.
- **Published in Supplement** : starting from 6.0, the first publication in the European Pharmacopoeia of the most recent version of the text in terms of technical content (i.e. no technical revision or correction has been made since this publication, but editorial modifications may have been made) has a first digit which is the edition number and the second which is the supplement number (0 represents the main volume of the edition in question).
- **Work in progress** : the boxes in light blue indicate whether a monograph is currently being elaborated or undergoing revision (Technical revision or Minor revision) and provides relevant information to the work on-going: current State of work and Pharmeuropa issue. Under "Description" if it is a revision, information on the text(s) revised and/or the reason for revision are provided. If you are interested in participating in the revision work and if the state of work is 0 or 1 please contact us through the Helpdesk so that you can be involved in the elaboration/revision process. We welcome your contributions to the work of the European Pharmacopoeia.
- **State of work** : the figures are to be interpreted as follows :
  - 0 – The monograph has been authorised but work has not started yet
  - 1 - Draft work has started
  - 2 – Pharmeuropa the monograph has been authorised for publication in Pharmeuropa (see below)
  - 3 - COM the monograph has been submitted for adoption to the European Pharmacopoeia Commission
  - 4 – DEF the monograph has been adopted

  Please note that texts which are published in Pharmeuropa (step 2 - public enquiry) can be consulted for free by registering on Pharmeuropa online , the procedure on how to comment is available here The supply of individual copies of our documents by fax, e-mail or otherwise, whatever their state of work, is not possible.
- **Pharmeuropa** : the issue of Pharmeuropa into which the draft of the monograph was published.
- **Chromatogram** :
  - If a hyperlink appears in the adjacent cell, a type chromatogram is available for download. It should be stressed that such chromatograms do not constitute a mandatory part of the corresponding monograph and **are provided for information only.** They do not necessarily include all impurities mentioned in the monograph, are not representative for all impurity profiles of the substance and are provided solely for the convenience of the user.
  - Please note that chromatograms supplied with some reference standards are available only if they are mentioned in the related monograph. They are sent to users on an official leaflet with the standards and are also available for download from the online CRS/BRP catalogue.
- **Additional information** : if a hyperlink appears in the adjacent cell, some information such as the background on the elaboration of the monograph is available. It should be stressed that such information is provided solely for the convenience of the user and **does not constitute a mandatory part of the corresponding monograph.**
- **History** : contains information concerning certain technical modifications to some revised/corrected texts published since Ph.Eur. 5.0. This information complements the modifications indicated by lines in the margin in the supplements and is not necessarily exhaustive.
- **Interchangeable (ICH_Q4B)** : the section reflects the status of the text with regard to the work of:
  - The Pharmacopoeia Discussion Group (PDG), a joint collaboration between the United States Pharmacopoeia, the Japanese Pharmacopoeia and the European Pharmacopoeia.
  - The International Conference on Harmonisation (ICH) Quality Guideline on Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH (Q4B).
- **Pharmacopoeial harmonisation** : further information can be found in chapter 5.8 (Pharmacopoeial Harmonisation) of the European Pharmacopoeia. Details about the status of individual texts and agreements reached on them by the three pharmacopoeias are shown in the tables and documents available in EDQM website.
- **Reference standards** : this is a list of the reference standard(s) that have to be used to carry out the tests in the monograph. For more information, please refer to the most up-to-date version of the monograph as published in the European Pharmacopoeia. This is an excerpt from our online CRS catalogue
- **Practical information** :
  - Certain tests require the use of commercially available reagents and/or chromatographic stationary phases, which cannot be described with the required accuracy in the European Pharmacopoeia. This page provides the trade name(s) of the reagent(s) and/or chromatographic stationary phase(s) that were found to be suitable when the monograph was being developed. This information is provided solely for the convenience of the users of the Pharmacopoeia. **It does not imply that these reagents/stationary phases or their suppliers are endorsed or recommended by the European Pharmacopoeia Commission or the Council of Europe, in preference to others of a similar nature which are not mentioned.** The analyst is also to be aware of the fact that some reagents/**stationary phases can** show significant batch to batch variations for which the EDQM cannot be held responsible.
  - Also, if a hyperlink appears in the adjacent cell, some information is available about one or more of the tests in the monograph. This information consists of technical advice facilitating the achievement of the tests. It should be stressed that such information is provided solely for the convenience of the user and **does not constitute a mandatory part of the corresponding monograph.**
- **CEP** : if certificate(s) of suitability have been granted for the substance in question, the list of certificates is shown. This is an excerpt from the online List of CEP.

Commission Sessions		Edition	Implementation
Session No.	Date	Supplement	date
171	November 2021	11th Edition	1 January 2023
170	June 2021	10.8	1 July 2022

Ricerca

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

GENERAL MONOGRAPHS

Important notice

The European Pharmacopoeia contains a number of general monographs covering classes of products. These general monographs give requirements that are applicable to all products in the given class or, in some cases, to any product in the given class for which there is a specific monograph in the Pharmacopoeia (see *1. General Notices*, General monographs). Where no restriction on scope of a general monograph is given in a preamble, it is applicable to all products in the class defined, irrespective of whether there is an individual monograph for the product in the Pharmacopoeia.

Whenever a monograph is used, it is essential to ascertain whether there is a general monograph applicable to the product in question. The general monographs listed below are published in the General Monographs section (unless otherwise stated). This list is updated where necessary and republished in each supplement.

Allergen products (1063)

Chemical precursors for radiopharmaceutical preparations (2902)

Dosage Forms monographs
(published in the Dosage Forms section or the Homoeopathic Preparations section, as appropriate)

Essential oils (2098)

Herbal drug extracts (0765)

Herbal drug preparations (1434)

Herbal drugs (1433)

Herbal drugs for homoeopathic preparations (2045)
(published in the Homoeopathic Preparations section)

Herbal teas (1435)

Herbal teas, instant (2620)

Homoeopathic preparations (1038)
(published in the Homoeopathic Preparations section)

Immunosera for human use, animal (0084)

Immunosera for veterinary use (0030)

Live biotherapeutic products for human use (3053)

Methods of preparation of homoeopathic stocks and potentisation (2371)
(published in the Homoeopathic Preparations section)

Monoclonal antibodies for human use (2031)

Mother tinctures for homoeopathic preparations (2029)
(published in the Homoeopathic Preparations section)

Pharmaceutical preparations (2619)

Products of fermentation (1468)

Products with risk of transmitting agents of animal spongiform encephalopathies (1483)

Radiopharmaceutical preparations (0125)

Recombinant DNA technology, products of (0784)

Substances for pharmaceutical use (2034)

Vaccines for human use (0153)

Vaccines for veterinary use (0062)

Vegetable fatty oils (1579)

In ogni scheda dei principi attivi si trova il rimando a “General monograph”, dove c’è l’elenco di tutte le monografie.

Come accedere?

https://pheur.edqm.eu/home

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