



European Directorate for the Quality of Medicines & HealthCare

Council of Europe

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

Unlocking the potential of the Ph. Eur. Online

Module 1: New features, advanced navigation and efficient searching

EDQM Webinar

1 & 3 July 2025



What you can look forward to in this webinar

★ **New features and improvements**

Explore user-friendly upgrades and new functionalities, including text status indicators.

★ **Site navigation**

Learn how to find your way around the new site, from the homepage to the dashboard, archives and help section.

★ **Text page structure**

Take a tour of the new layout to see how each text is presented, with key information, access to other versions, and tools that make navigation easier.

★ **Focus on text statuses and advanced search**

Get acquainted with the statuses of texts and our enhanced search features and filters.

New features and improvements: overview

Main changes

Before



1 edition and 8 supplements – 3 years - e.g. 11.0, 11.1,..., 11.7, 11.8

Now



1 edition composed of 3 issues per year - e.g. 12.1, 12.2 and 12.3

- ✓ The term « **Edition** » will be used for a 1-year package
- ✓ The term « **Issue** » will be used for each of the 3 publications per « Edition »



1 Edition ⇔ 1 implementation year

Main changes

Before

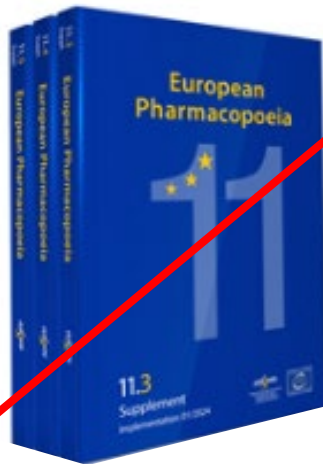


Print + Online versions

Now



Online version only;
No publication of paper version of the Ph. Eur. as in its previous format



Note: the Ph. Eur. website is designed for desktop and laptop computers, but not yet for tablets or smartphones.

Unlocking the potential of the Ph. Eur. Online - Module 1: New features, advanced navigation and efficient searching

Main changes

Before



Legally binding texts were republished in each edition

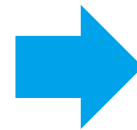
Now



Each issue contains new and updated texts only

- ★ Texts that were changed
- ★ New texts
- +
- ★ Texts that were not changed

Edition



- Only**
- ★ Texts that were changed
 - ★ New texts

Issue

Main changes

Before

⊘ Access to a supplement and then to the version of a specific text in this supplement

Now

✓ Direct access to a text and to all its previous and future versions (each version is linked to an issue) - starting from 11.0

NOW AVAILABLE

11.8
07/2025

ACCESS

11.7
04/2025

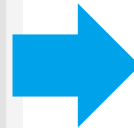
ACCESS

11.6
01/2025

ACCESS

Table of contents

- ☐ European Pharmacopoeia 11.8
 - ☒ European Pharmacopoeia 11.8
 - ☐ 00 Introduction
 - ☐ 01 General notices
 - ☐ 02 Methods of analysis
 - ☐ 03 Materials for containers...
 - ☐ 04 Reagents
 - ☐ 05 General Texts
 - ☐ 06 General Monographs
 - ☐ 07 Dosage forms
 - ☐ 08 Vaccines
 - ☐ 09 Immunosera
 - ☐ 10 Radiopharmaceutical pr...
 - ☐ 11 Sutures
 - ☐ 12 Herbal drugs and herba...
 - ☐ 13 Homoeopathic preparat...
 - ☒ 14 Monographs A-C
 - ☐ Abacavir sulfate
 - ☐ Acacia, dried dispersion



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European Pharmacopoeia Online

Home Access to texts Archives Store

EN Elisabeth Poirier

Daunorubicin

Back to results Results (1/3) Highlights (0/10)

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

01/2023:0662 corrected 11.4

DAUNORUBICIN HYDROCHLORIDE

Daunorubicini hydrochloridum

$C_{27}H_{30}ClNO_{10}$

M. 564.0

Information

Text number: 0662

Text type: Individual monograph

In force

Effective from 01/01/2023 to 31/12/2025

Issue 11.0

Correction date: 30/11/2023

Issue 11.4

New version from 01/01/2026

Change issue 11.4

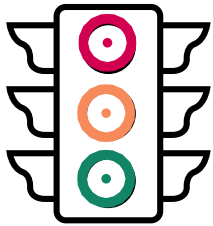
12.1 Not yet in force

11.4 in force

11.0 Pre-correction

Older Go to PDF archives

Main changes



- No longer in force / No longer in use
(for example, superseded)
- Not yet in force / Not yet in use
(published BUT implementation date not yet reached)
- In force / In use **Default**

☐ **Daunorubicin hydrochloride** Correction date **30/11/2023 (11.4)** Implementation date **01/01/2023 (11.0)** Text number **0662**

✓ In force ⌛ New version (1) → Go to Text type **Individual monograph**

...01/2023:0662 corrected 11.4 Daunorubicin...

Result card

Information

Text number: **0662**
Text type: **Individual monograph**

In force
Effective from 01/01/2023 to 31/12/2025
Issue 11.0
Correction date: 30/11/2023
Issue 11.4

⌛ New version from 01/01/2026 ➤

Change issue 11.4 ▼

12.1
Not yet in force

11.4
In force

11.0
Pre-correction

Older
Go to PDF archives 🔗

Text information panel

Main changes

Before



Subscription : included 3 supplements; maximum validity of 18 months

Now



365-day licensing model: access to all the Ph. Eur. content for 1 year

NOW AVAILABLE

11	11.8	07/2025	ACCESS
11	11.7	04/2025	ACCESS
11	11.6	01/2025	ACCESS

Access to a list of supplements



European Pharmacopoeia Online

Webinar: Unlocking the potential of the European Pharmacopoeia Online

Register for our webinar on the 1st of July to discover the new platform. Say goodbye to the "Blue Book" and learn about the Ph. Eur. Online new features and licence management as well as tips for advanced navigation and efficient searching.
Date added due to high demand: 3rd of July.

See all news

Hello Elisabeth Poirier
Welcome to the European Pharmacopoeia.

Access to European Pharmacopoeia texts

About the Ph. Eur. Online

This page provides access to the English and French versions of the European Pharmacopoeia (Ph. Eur.) Online. In the event of any discrepancy between the web (HTML) version and the PDF version, the PDF version shall prevail. If you identify a discrepancy, please contact us via the EDQM HelpDesk.

TERMS AND CONDITIONS: upon the purchase of a licence key for the Ph. Eur., the Licensee acknowledges that he or she has read and agrees to be bound by the following General Terms and Conditions.

PRIVACY NOTICE AND SECURITY POLICY: for information on data

Access to the whole site for 365 days

Main changes

Before



Archives : PDFs

Now



Archives contain PDF versions of the 10th Edition and earlier editions

Home	Access to texts	Archives	Store	EN ▾	Elisabeth Poirier ▾
Archives					
10th Edition ▾					
9th Edition ▾					
8th Edition ▾					
7th Edition ▾					
6th Edition ▾					
5th Edition ▾					
4th Edition ▾					
3rd Edition ▾					
2nd Edition ▾					
1st Edition ▾					

PDF version for editions 1 to 10

Information

Text number: **0662**

Text type: **Individual monograph**

In force



Effective from 01/01/2023 to
31/12/2025
Issue 11.0
Correction date: 30/11/2023
Issue 11.4



New version
from 01/01/2026



Change issue 11.4 ▾

12.1

Not yet in force

11.4

In force

11.0

Pre-correction

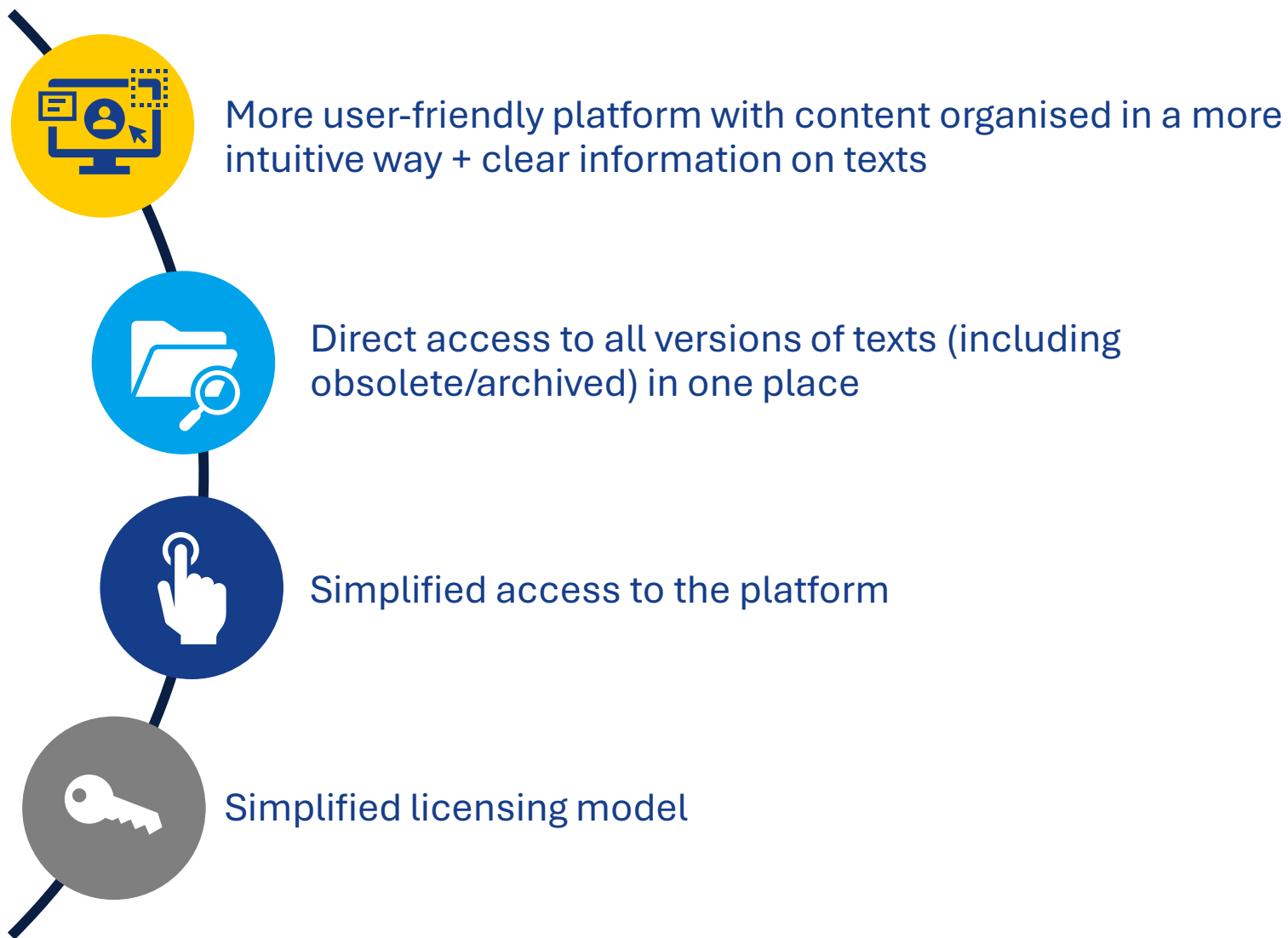
Older

Go to PDF archives



Starting from
the 11th Edition =>
versions added
directly to texts

Improvements



What will it look like?

Previously



Accessible until end 2025 for those who have a licence for Supplements 11.6-11.8



URL: <https://pheur.edqm.eu>

New online version



New 365 licence required – access to all Ph. Eur. content

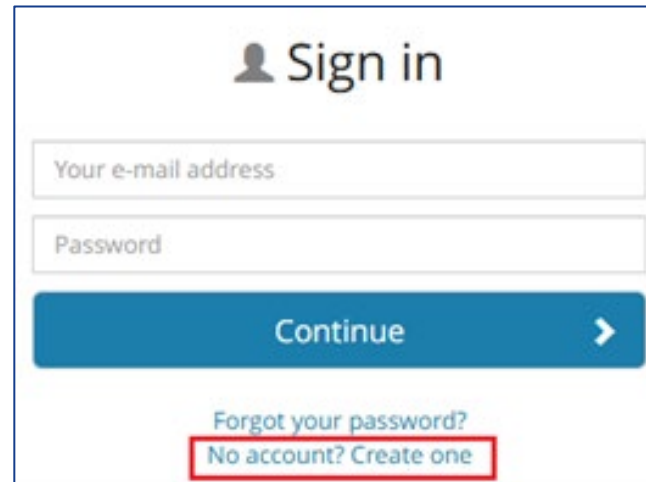


URL: <https://pheur-online.edqm.eu>

Accessing the new Ph. Eur. Online
website (<https://pheur-online.edqm.eu>)

Accessing the Ph. Eur. Online for the first time

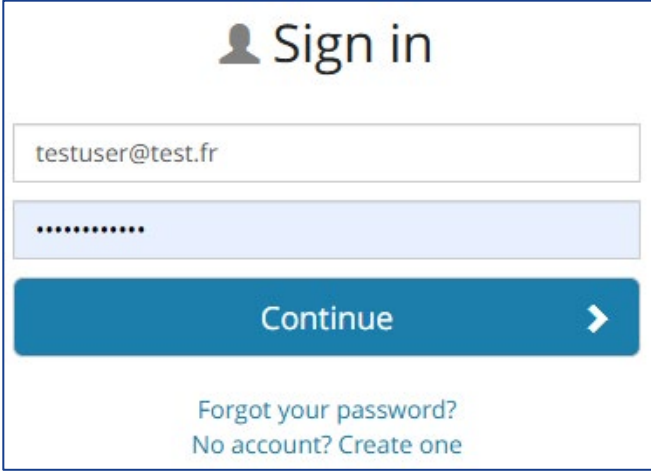
- ★ On the home page, click on **Sign in** on the right side of the menu bar;
- ★ In the authentication window, click on **No account? Create one**;
- ★ To be done whether you already have an EDQM account or not.



The image shows a 'Sign in' form with a title 'Sign in' and a user icon. Below the title are two input fields: 'Your e-mail address' and 'Password'. A blue 'Continue' button with a right arrow is positioned below the password field. At the bottom of the form, there are two links: 'Forgot your password?' and 'No account? Create one'. The 'No account? Create one' link is highlighted with a red rectangular border.

Log in to the Ph. Eur. Online

- ★ Click on **Sign in** on the right side of the menu bar;
- ★ Enter your login credentials (your e-mail address and the password you have set up);
- ★ Click on **Continue**;
- ★ You are now signed in to the site.



The image shows a 'Sign in' form with a title 'Sign in' and a user icon. Below the title are two input fields: the first contains the email address 'testuser@test.fr' and the second contains a masked password '.....'. A blue 'Continue' button with a right-pointing arrow is positioned below the password field. At the bottom of the form, there are two links: 'Forgot your password?' and 'No account? Create one'.

My licence keys

As a user who has been assigned a seat on a 365-licence, you can view your licence details:

- ★ Log in to the Ph. Eur. website
- ★ Click on your username on the right side of the menu bar;
- ★ Select **My licence keys**;

 EPID-ZR9XY-1SYH40TW1L-TT75F-VEF7 

Owner Admin User

Days left 329

✓ Active

Activated on
22 May 2025

Expires on
22 May 2026

Assigned
2 / 200

Available
198

Test User ▾

Sign out

My licence keys

My profile

User manual

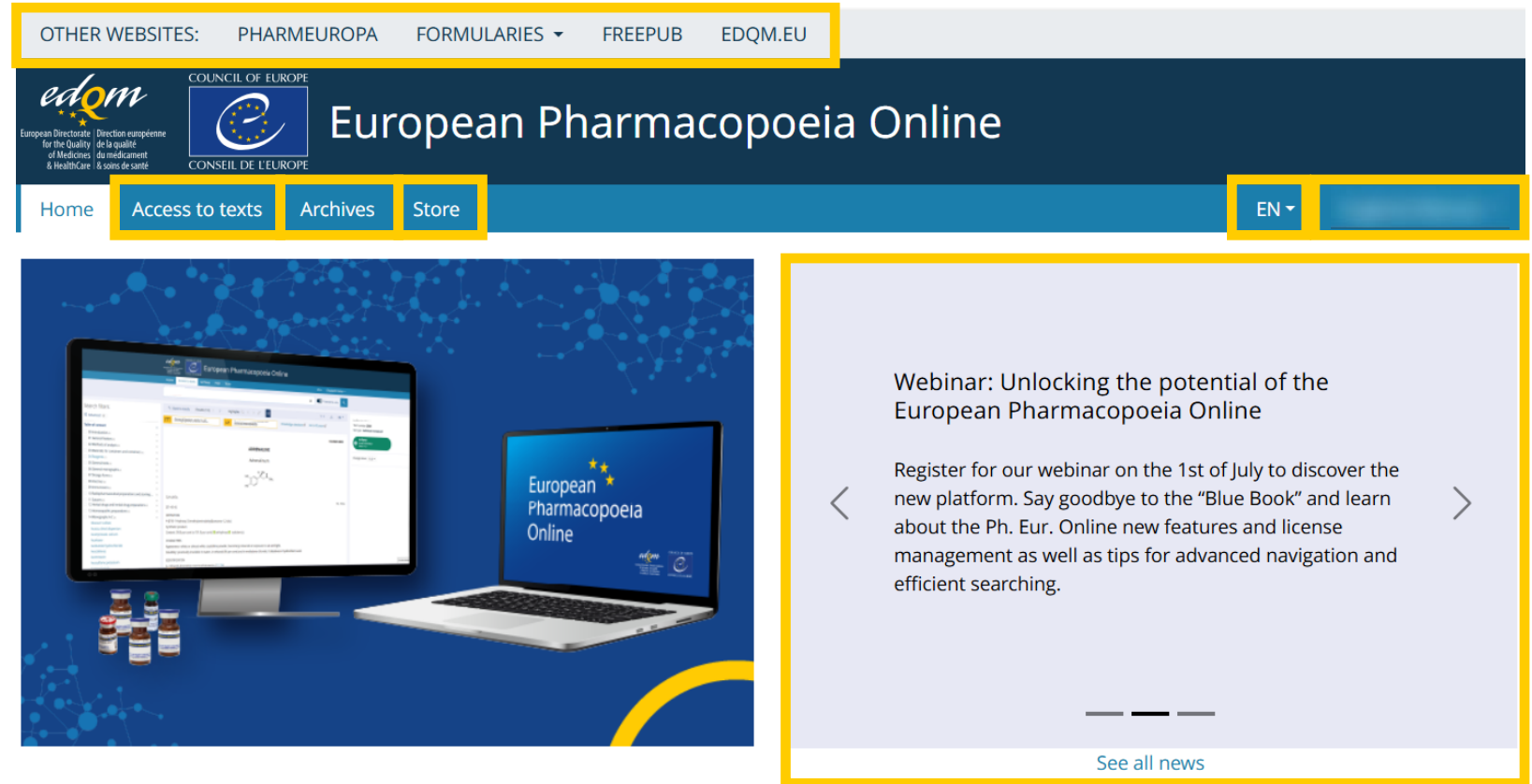
Change password

Site navigation

Homepage

The homepage provides essential information and easy access to key resources (1/3):

- ★ Quick links to other EDQM websites (in the grey banner);
- ★ The Ph. Eur. texts (Access to texts);
- ★ The archives (10th Edition and earlier);
- ★ The EDQM Store;
- ★ Language options (FR or EN);
- ★ Your account;
- ★ The news carousel.



Homepage

The homepage provides essential information and easy access to key resources (2/3):

- ★ The licence information panel;
- ★ The Ph. Eur. publication schedule;
- ★ Direct access to the EDQM Store:
 - ★ To buy a licence for full access to the Ph. Eur.,
 - ★ Or order Ph. Eur. reference standards using the online order form.

Licence needed

A licence is needed to access the European Pharmacopoeia. First-time visitor with a 365-day licence? Please [create an account](#). If you already have a 365-day licence and an account, please click on [Sign-in](#). Need help? Check the [Help section](#) or contact us via the [EDQM HelpDesk](#).

[Access to European Pharmacopoeia texts](#)

ABOUT THE EUROPEAN PHARMACOPOEIA

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TERMS AND CONDITIONS: upon the purchase of a licence key for the Ph. Eur., the Licensee acknowledges that he or she has read and agrees to be bound by the following [General Terms and Conditions](#).

PRIVACY NOTICE AND SECURITY POLICY: for information on data protection and information asset security for this website, please see the [Ph. Eur. Privacy notice](#) and the [EDQM applications security notice](#).

Publication schedule

ISSUE	PUBLICATION DATE	CORRECTION DATE	IMPLEMENTATION DATE
11.6	07/2024	31/08/2024	01/01/2025
11.7	10/2024	30/11/2024	01/04/2025
11.8	01/2025	28/02/2025	01/07/2025
12.1	07/2025	31/08/2025	01/01/2026
12.2	10/2025	30/11/2025	01/04/2026
12.3	01/2026	28/02/2026	01/07/2026

EDQM Store

[Purchase or renew a 365-day licence](#)

[Order reference standards](#)

[Go to the store](#)

[How to order publications](#)

[How to order reference standards](#)

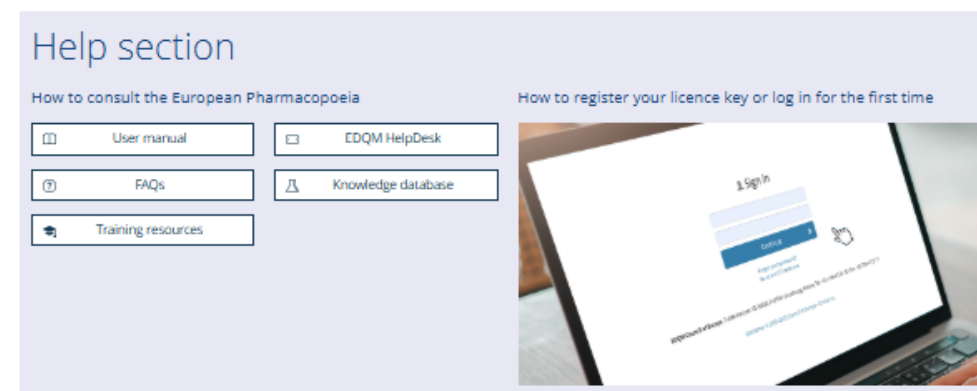
edqm
European Directorate for the Quality of Medicines & Healthcare | Direction européenne de la qualité du médicament & soins de santé

CONSEIL DE L'EUROPE

Homepage

The homepage provides essential information and easy access to key resources (3/3):

- ★ **The Help section.** This area provides quick access to a variety of support tools:
 - The User Manual: a comprehensive guide on how to use the platform effectively;
 - Key to monographs;
 - EDQM HelpDesk and FAQs;
 - Training resources on the Ph. Eur.: a link to the Ph. Eur. training programme (to deepen your understanding of the Ph. Eur.);
- ★ **Useful information:** this section gives you access to a range of resources like Pharmeuropa Online, the Knowledge database,...



Useful information

Pharmeuropa Online

Drafts of new and revised texts proposed for inclusion in the Ph. Eur. are found in Pharmeuropa Online, as well as information on newly adopted texts and pharmacopoeial harmonisation, and access to Pharmeuropa Bio & Scientific Notes.

[Find out more](#)

Knowledge database

The Knowledge database provides additional information on Ph. Eur. texts including their revision history, information on ongoing work, links to reference standards catalogue numbers and access to the list of CEPs.

[Find out more](#)

Standard Terms database

The Standard Terms database contains harmonised terms and definitions to describe pharmaceutical dosage forms, routes and methods of administration, containers, closures, administration devices, units of presentation and agreed combinations of terms.

[Find out more](#)

Join our Experts

The Ph. Eur. welcomes input from experts from all around the world. Whether you are employed by a national authority, industry or academia, your contribution to preparing and maintaining Ph. Eur. texts will be highly valued.

[Find out more](#)

Request new texts or revisions

Users are encouraged to submit draft monographs or general chapters. Proposals for revisions to general chapters or monographs already published in the European Pharmacopoeia are also welcomed.

[Find out more](#)

CombiStats

CombiStats is an online application developed by the EDQM for the statistical analysis of data from biological assays and tests, such as those found in the monographs of the Ph. Eur.

[Find out more](#)

EDQM and health protection

Go to the Medicines section of the EDQM website to find out about our other contributions to medicines regulation, such as the Pharmacopoeial Discussion Group, the European Paediatric Formulary, the Biological Standardisation Programme, the Certificate of Suitability procedure and the OMCL Network.

[Find out more](#)

Ph. Eur. Commission (EPC)

The European Pharmacopoeia Commission assembles at three yearly sessions to adopt the texts to be published in the Ph. Eur. and to make technical decisions by consensus. Information on recent EPC sessions can be found on the EDQM website.

[Find out more](#)

Archives

Users can access PDF versions of texts from the 10th Edition and earlier.



Use CTRL+F to quickly search for a specific Ph. Eur. text within a PDF.


[Home](#) [Access to texts](#) [Archives](#) [Store](#) EN ▾ 🔍

Archives

10th Edition



EUROPEAN PHARMACOPOEIA – 10th Edition



- [2022 10th Edition Supplement 10.8](#)
- [2022 10th Edition Supplement 10.7](#)
- [2022 10th Edition Supplement 10.6](#)
- [2021 10th Edition Supplement 10.5](#)
- [2021 10th Edition Supplement 10.4](#)
- [2021 10th Edition Supplement 10.3](#)
- [2020 10th Edition Supplement 10.2](#)
- [2020 10th Edition Supplement 10.1](#)
- [2020 10th Edition 10.0 Volume 1](#)
- [2020 10th Edition 10.0 Volume 2](#)
- [2020 10th Edition 10.0 Volume 3](#)

**PDF version of Supplements (1st-10th Edition)**

EUROPEAN
PHARMACOPOEIA
TENTH EDITION
Supplement 10.8

*Published in accordance with the
Convention on the Elaboration of a European Pharmacopoeia
(European Treaty Series No. 50)*

Store

Clicking on the Store tab takes you directly to the EDQM store where you can renew your licence and access additional services.



Reference Standards

CATALOGUE

- Consult our complete list of standards:
 - [European Pharmacopoeia Reference Standards](#)
 - [Who International Standards for Antibiotics \(ISA\)](#)
 - [Who International Chemical Reference Substances \(ICRS\)](#)

ORDER / QUOTATION

- Place your order
- Ask for a quotation



Publications & CombiStats

CATALOGUE

- Consult our complete list of publications (including CombiStats)

ORDER / QUOTATION

- Place your order and benefit from free shipping charges for the print versions
- Issue your quotation (quotations issued on the store will have to be transformed into an order on the store)



Payment & Documents

MY ACCOUNT

- PAY online
- Consult all your orders and invoices for any EDQM products (publications, reference standards, conferences, CombiStats etc.)
- Print all documents relevant to your orders

[Need help](#)



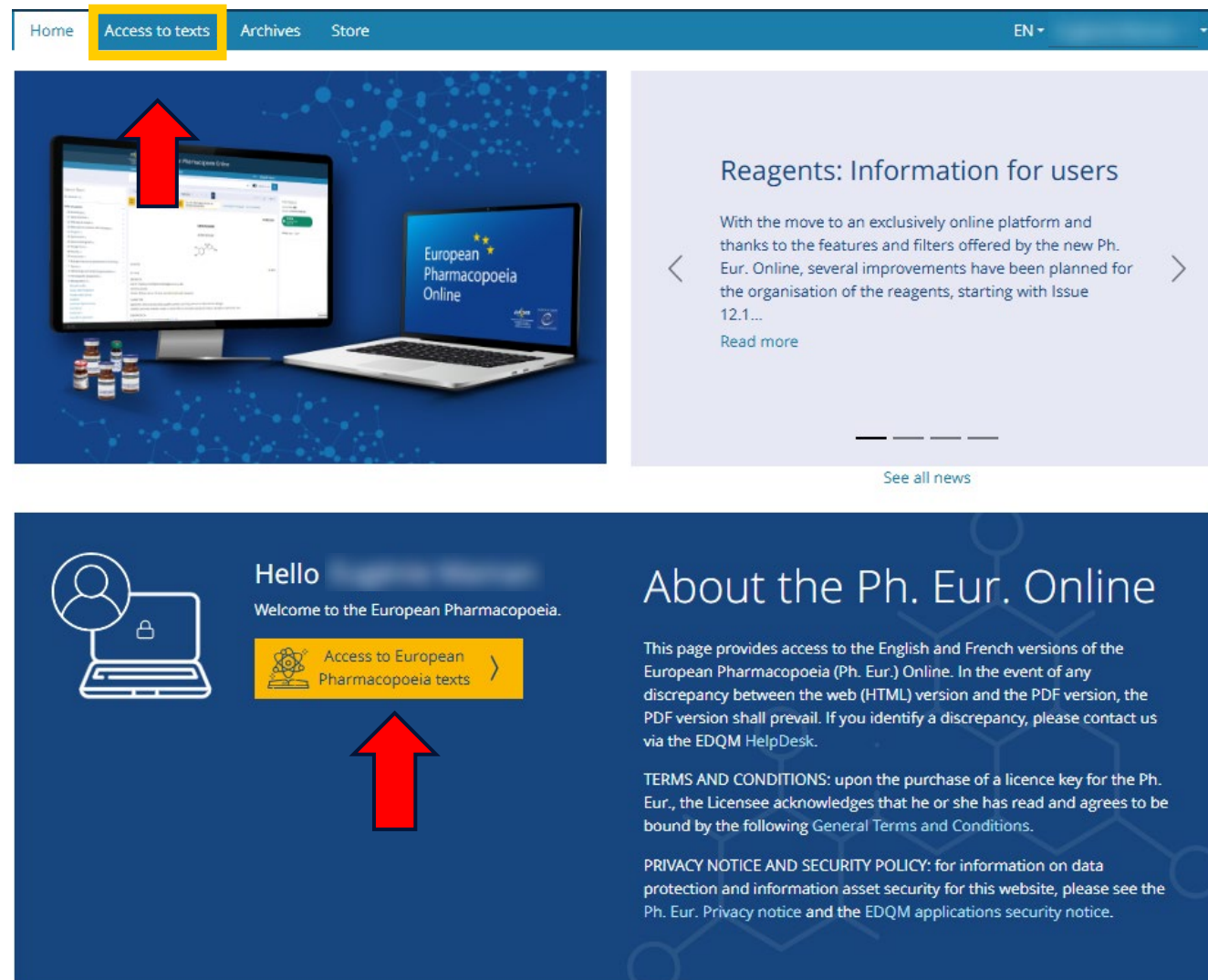
[Download Terms & Conditions](#)

Dashboard

It is the central hub of the platform.

To access it:

- Click on the 'Access to texts' tab in the top navigation bar (blue bar);
- Or click on the yellow box labelled 'Access to Ph. Eur. texts' in the licence information panel.



Dashboard

This page displays:

- ★ The Ph. Eur. issue currently in force and the next one, which has been published but is not yet in force;
- ★ A list of pre-defined searches that offer quick access to the latest updates;
- ★ ‘Quick links’, including the contents (New content) of the in force and more recently published issues. This includes all new, revised, corrected and suppressed texts, as well as new and modified reagents;
- ★ A Help section.

The screenshot shows the Ph. Eur. Online dashboard. At the top, there's a 'New content' section with a list of search options: 'Consult new texts' (12.1 New), 'Consult revised texts' (12.1 Revisions), 'Consult corrected texts' (12.1 Corrections), 'Consult new reagents' (12.1 Reagent New), and 'Consult modified reagents' (12.1 Reagent Modifications). To the right, a banner for 'Issue 11.8 (01/07/2025) - In force' and 'Issue 12.1 (01/01/2026) - Not yet in force' is displayed. Below this, a 'Reagents: Information for users' section contains text about the move to an exclusively online platform and improvements planned for Issue 12.1, with a 'See all news' link. A 'Quick links' section at the bottom right features four buttons: 'Consult general monographs >', 'Consult the General Notices >', 'New content, Issue 12.1 >', and 'Contents of Supplement 11.8 >'. At the very bottom, a 'Help section' titled 'How to consult the European Pharmacopoeia' includes links for 'User manual', 'Key to monographs', 'EDQM HelpDesk', 'FAQs', 'Training resources', and 'Publication schedule'.

Search tools and filters

Search settings

Home Access to texts Archives Store

Search terms

New content

- Consult new texts 12.1 New
- Consult revised texts 12.1 Revisions
- Consult corrected texts 12.1 Corrections
- Consult new reagents 12.1 Reagent New
- Consult modified reagents 12.1 Reagent Modifications

Issue 11.7 (01/04/2025) - In force Issue 11.8 (01/07/2025) - Not yet in force
Issue 12.1 (01/01/2026) - Not yet in force

Reagents: Information for users

With the move to an exclusively online platform and thanks to the features and filters offered by the new Ph. Eur. Online, several improvements have been planned for the organisation of the reagents, starting with Issue 12.1...

Read more

See all news

Quick links

- Consult general monographs >
- Consult the General Notices >
- New content, Issue 12.1 >
- Contents of Supplement 11.8 >

EN

Title/text No. only

By default, search results are provided in the language selected in the interface:

- If your interface is set to English, your search results will include only English texts;
- If it is set to French, you will only see French texts.

New content – quick access

In the ‘New content’ section of the Dashboard, you will find a list of predefined searches for quick access to the latest updates.

Click on the links to launch these predefined searches.

- ★ ‘Consult new texts’: these are new texts published in the latest issue;
- ★ ‘Consult revised texts’: these are revised texts published in the latest issue.
- ★ ‘Consult corrected texts’: these are corrections of existing texts published in the latest issue;
- ★ ‘Consult new reagents’: these are new reagents published in the latest issue;
- ★ ‘Consult modified reagents’: these are reagents modified in the latest issue.

The screenshot displays the Ph. Eur. Online dashboard. The top navigation bar includes 'Home', 'Access to texts', 'Archives', and 'Store'. A search bar is located at the top right. The left sidebar contains 'Search filters' with options for 'Advanced' search, 'Table of contents', 'Text type' (General information, General Notices, General chapter, General monograph, Reagent, Individual monograph), and 'Status' (In force / in use, Upcoming, No longer in force / in use). The main content area features a 'New content' section highlighted with a yellow box, containing links for 'Consult new texts', 'Consult revised texts', 'Consult corrected texts', 'Consult new reagents', and 'Consult modified reagents'. To the right of this section is a 'Reagents: Information for users' box and a 'Quick links' section with buttons for 'Consult general monographs', 'Consult the General Notices', 'New content, Issue 12.1', and 'Contents of Supplement 11.8'. A 'Help section' is located at the bottom left of the main content area.

Search tools & Filters

The platform offers two main tools to help you search and navigate the Ph. Eur.:

- ★ The search box, available on every page when browsing texts;
- ★ The table of contents (TOC).

The screenshot shows the Ph. Eur. Online interface. A yellow box highlights the 'Search filters' section on the left, which includes a 'Table of contents' list. A red arrow points from the text 'TOC' to this section. Another yellow box highlights the 'Search terms' input field at the top, with a red arrow pointing to it from the text 'Search box'. A third yellow box highlights the 'Title/text No. only' toggle switch, with a red arrow pointing to it from the text 'Toggle'. The interface also shows a 'New content' section with links to consult new, revised, corrected, and modified texts, as well as a 'Reagents: Information for users' section.

The platform also includes several search filters to help refine your results:

- ★ The 'Title/Text No. only' toggle switch;
- ★ Additional filters in the left panel.

Search tools & Filters

1. Autocompletion + syntax help

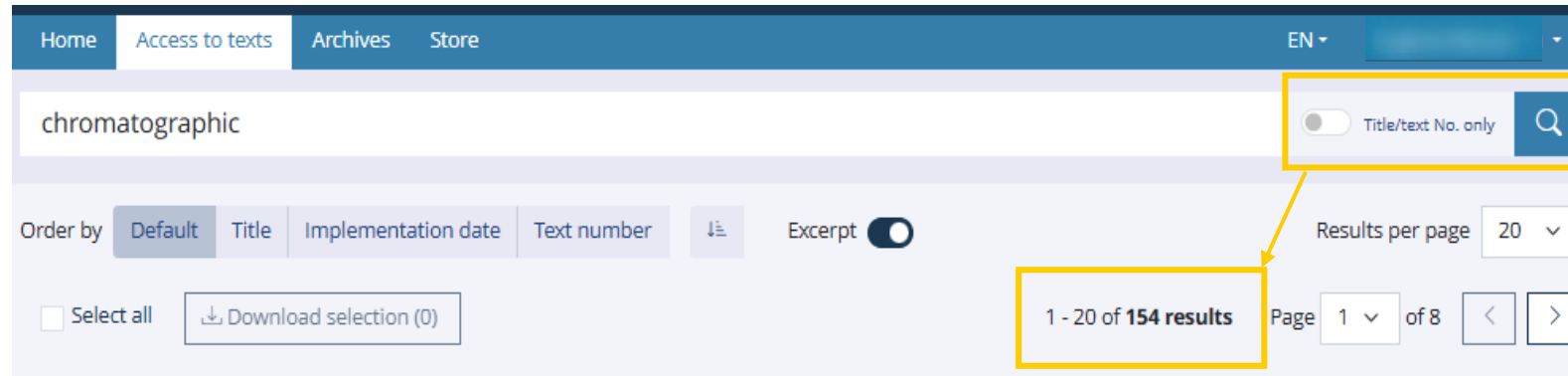
The screenshot displays the Ph. Eur. Online search interface. The top navigation bar includes links for Home, Access to texts, Archives, and Store, along with a language selector set to EN. The search bar contains the text 'chroma'. A dropdown menu labeled '1' shows search suggestions for 'chroma', including 'chroman', 'chromat', 'chromate', 'chromatin', 'chromatis', 'chromatogram', 'chromatograms', 'chromatograph', 'chromatographed', 'chromatographic', 'chromatographies', 'chromatographs', 'chromatography', 'chromatophores', 'chromatogram', and 'chromazurol'. To the right, a 'Search syntax' help box labeled '2' provides instructions on how to refine searches using operators. It includes a table with columns for Operator, To search for..., and Example.

Operator	To search for...	Example
*	A word containing a string of characters	hydro* to find texts containing words that begin with "hydro". *methyl for words that end in "methyl", or hydro*methyl or *droxymeth* to find texts that contain the word "hydroxymethyl".
OR	any of the specified words	virus OR vaccine to find texts containing the word "virus" or "vaccine", or both.
" "	An exact phrase	"crystalline powder" to find texts containing this exact phrase.
partial	A specific string of characters within words or phrases, allowing for word completion at either end	partial:"ly acid" to find texts that contain, for example, "slightly acid" or "highly acidic".

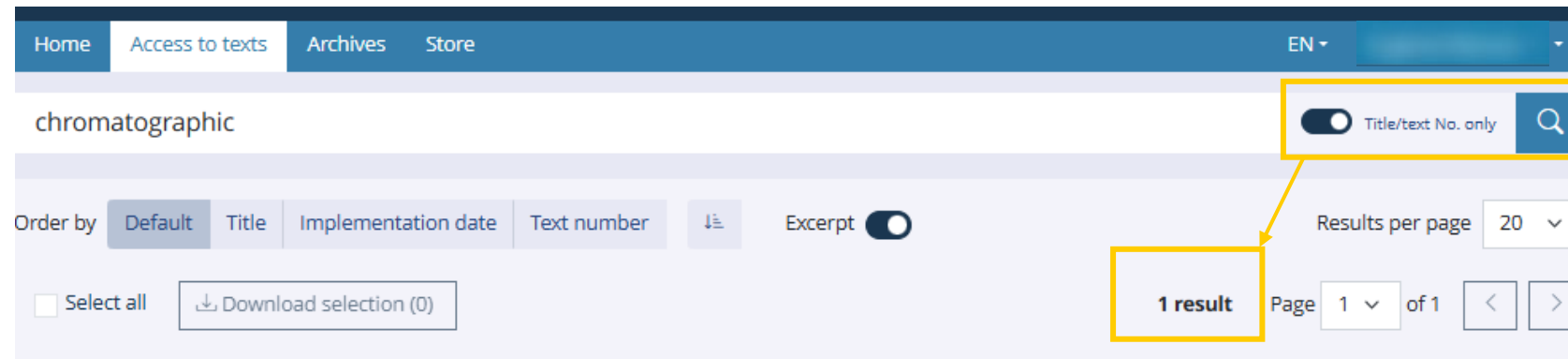
1. Suggestion of words present in the Ph. Eur. contents.
2. Search syntax help: most commonly used operators.

Search tools & Filters

2. 'Title/Text No. only' toggle switch



When this toggle is turned on, the search engine limits your query to titles of texts or text numbers only. This helps you perform a much more precise search, especially when you're looking for a specific document or topic.



Search tools & Filters

3. Filters (left-hand panel)

These filters allow you to narrow your search results, based on additional criteria, making it easier to find exactly what you are looking for.

- You can filter by Text type (e.g., monographs, general chapters, reagents), text status, and more;
- You can combine multiple filters to further refine your results and increase their relevance.

You can also activate the **‘Advanced’ toggle switch** at the top of the filters panel. This reveals **additional advanced filters and search options**.

The screenshot shows the 'Search filters' panel. At the top, there is a toggle switch for 'Advanced' which is currently turned off. Below this is a 'Table of contents' section with a downward arrow. The 'Text type' section is expanded, showing four filter buttons: 'General information (6)', 'General Notices (1)', 'General chapter (369)', and 'General monograph (62)'. Below these are two more buttons: 'Reagent (2934)' and 'Individual monograph (2496)'. The 'Status' section is also expanded, showing a 'Defaults' button and a list of status options. The 'In force / in use' option is checked. Under the 'Upcoming' section, 'New texts' is checked, while 'Corrections', 'Revisions / modifications', 'Suppressions / deletions', and 'Suspensions' are unchecked. Under the 'No longer in force / in use' section, all options ('Pre-correction', 'Superseded / replaced', 'Suppressed / deleted', and 'Suspended') are unchecked.

Search filters

Advanced ☐

Table of contents

Text type

General information (6) General Notices (1)

General chapter (369) General monograph (62)

Reagent (2934) Individual monograph (2496)

Status Defaults

☒ In force / in use

☒ Upcoming

☐ Corrections

☐ Revisions / modifications

☒ New texts

☐ Suppressions / deletions

☐ Suspensions

☐ No longer in force / in use

☐ Pre-correction

☐ Superseded / replaced

☐ Suppressed / deleted

☐ Suspended

Search tools & Filters

3.1. TOC

Each section title in the Table of Contents includes two key elements:

- A checkbox.
You can select checkboxes to launch a search that displays all texts within the selected section (e.g. “07 Dosage forms”)
You can also combine this selection with a keyword search to look for specific terms within the selected content (e.g. “endotoxins”)
- A chevron.
You can expand or collapse section headings and subheadings, revealing or hiding the corresponding content by clicking on a chevron.

For a cleaner view, you can click on ‘Collapse all’ to minimise all sections at once or hide the entire TOC by clicking the top-level chevron.

The screenshot shows a 'Table of contents' section with a list of items. A yellow box highlights the 'Collapse all' link at the top. A blue arrow points from the text 'checkbox' to the checkbox of item '03 Materials for containers and containers (29)'. Another blue arrow points from the text 'chevron' to the chevron of the same item. The list of items is as follows:

Item	Count
<input type="checkbox"/> 01 General Notices	(3)
<input type="checkbox"/> 02 Methods of analysis	(282)
<input type="checkbox"/> 03 Materials for containers and containers	(29)
<input type="checkbox"/> 04 Reagents	(2934)
<input type="checkbox"/> 05 General texts	(58)
<input type="checkbox"/> 06 General monographs	(26)
<input type="checkbox"/> 07 Dosage forms	(36)
<input type="checkbox"/> 08 Vaccines	(143)
<input type="checkbox"/> 09 Immunoser	(9)
<input type="checkbox"/> 10 Radiopharmaceutical preparations and starting materials for radiop...	
<input type="checkbox"/> 11 Sutures	(11)
<input type="checkbox"/> 12 Herbal drugs and herbal drug preparations	(362)
<input type="checkbox"/> 13 Homoeopathic preparations	(44)
<input type="checkbox"/> 14 Monographs A-C	(426)
<input type="checkbox"/> 15 Monographs D-K	(481)
<input type="checkbox"/> 16 Monographs L-P	(507)
<input type="checkbox"/> 17 Monographs Q-Z	(426)

Search tools & Filters

3.2. Text type

The Text type filter allows you to narrow your search results to specific categories of texts. You can apply this filter by clicking on the buttons that correspond to the type of text you are interested in

The available categories are:

- General Notices
- General monograph
- General chapter
- Individual monograph
- Reagent

The screenshot shows the European Pharmacopoeia Online search interface. The 'Text type' filter is highlighted with a yellow box, showing 'General monograph (62)' as the selected category. The search results show 1 - 20 of 62 results. The first result is 'Homoeopathic preparations' with a definition. The second result is 'Herbal drugs for homoeopathic preparations' with a definition. The third result is 'Mother tinctures for homoeopathic preparations' with a definition.

Search tools & Filters

3.3. Status

By default, the platform searches for new or 'in force' texts, which is why these statuses are pre-selected.

Available status filters include:

- In force / in use;
- Upcoming;
- No longer in force / in use.

OTHER WEBSITES: PHARMEUROPA FORMULARIES FREEPUB EDQM.EU

edqm COUNCIL OF EUROPE
European Directorate for the Quality of Medicines & HealthCare

European Pharmacopoeia Online

Home Access to texts Archives Store EN

Search terms Title/text No. only

Search filters

Advanced ☐ Clear all (1)

Table of contents

Text type

General information (6) General Notices (1) General chapter (369)

General monograph (62) Reagent (2934) Individual monograph (2498)

Status

☒ In force / in use

☒ Upcoming

☐ Corrections

☐ Revisions / modifications

☒ New texts

☐ Suppressions / deletions

☐ Suspensions

☐ No longer in force / in use

☐ Pre-correction

☐ Superseded / replaced

☐ Suppressed / deleted

☐ Suspended

Order by Default Title Implementation date Text number Excerpt ☐

Select all Download selection (0)

1 result Page 1 of 1

1. General notices Implementation date 01/01/2023 (11.0) Text number 10000

☒ In force ☒ New version (1) Go to Text type General Notices

1.1 GENERAL STATEMENTS 1.1.1 General principles 1.1.1.1 Quality systems 1.1.1.2 Conventional terms 1.1.1.3 References to regulatory documents 1.1.2 Compliance with the Ph. Eur. 1.1.2.1 Scope 1.1.2.2 Demonstration of compliance with the Ph. Eur. 1.1.2.3 Demonstration of suitability of monographs 1.1.2.4 Validation and implementation of Ph. Eur. analytical procedures 1.1.2.5 Alternative analytical procedures 1.1.2.6 Pharmacopoeial harmonisation 1.2 OTHER PROVISIONS APPLYING TO MONOGRAPHS AND...

Select all Download selection (0)

1 result Page 1 of 1


Help section

How to consult the European Pharmacopoeia


User manual Key to monographs EDQM HelpDesk FAQs Training resources Publication schedule

Search results

Download search results



COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

European Pharmacopoeia

Home

Access to texts

Archives

Store

dicloxacillin

Order by

Default

Title

Implementation date

Text number

Excerpt ☐

☐ Select all

☐ Contents of Supplement 11.8

Text type **General information**

...hosphoryl lipid A (2537)Dicloxacillin sodium monohydrate (0663)Doxapram...

... Dicloxacillin sodium monohydrate (0663) (previously Dicloxacillin sodium)...

☐ Cloxacillin sodium

Correction date **31/08/2019 (10.0)** Implementation date **01/01/2008 (6.0)** Text number **0661**

☒ In force Text type **Individual monograph**

...cloxacillin sodium CRS, 25 mg of dicloxacillin sodium CRS and 25 mg of flucloxacillin...

☐ Dicloxacillin sodium monohydrate

Implementation date **01/07/2025 (11.8)** Text number **0663**

A1		Title							
	A	B	C	D	E	F	G		
1	Title	Text type	Text numb	Issue	Implementat	Correction d	Excerpts		
2	Contents of Supplement 11.8	General	90010	11.8	01/07/2025		...hosphoryl lipid A (2537)Dicloxacillin sodium monohydrate (0663)Doxapram...		
3	Cloxacillin sodium	Individual monograph	0661	6.0	01/01/2008	31/08/2019	...cloxacillin sodium CRS, 25 mg of dicloxacillin sodium CRS and 25 mg of flucloxacillin...		
4	Dicloxacillin sodium monohydrate	Individual monograph	0663	11.8	01/07/2025		...025:0663 Dicloxacillin sodium ... : dicloxacillin sodium CRS.B. Thin-layer...		
5	Flucloxacillin magnesium octahydrate	Individual monograph	2346	6.2	01/07/2008		...nce solution (a). Dissolve 25 mg of dicloxacillin sodium CRS in 5 mL of ...		
6	Flucloxacillin sodium monohydrate	Individual monograph	0668	11.8	01/07/2025		...cloxacillin sodium CRS, 25 mg of dicloxacillin sodium CRS and 25 mg of flucloxacillin...		

You can download the search results (Excel file), by clicking on “select all” and “download”.

Note: The Excel file will list all search results (not just those seen on the first page).

Search results

edqm

European Directorate
for the Quality
of Medicines
& HealthCare

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

European Pharmacopoeia Online

HomeAccess to textsArchivesStore

EN

dicloxacillin

Title/text No. only

Order byDefaultTitleImplementation dateText number

Excerpt

Results per page20

Select allDownload selection (0)

1 resultPage 1 of 1

☐ **Dicloxacillin sodium monohydrate**

In force

New version (1) → Go to

Text type **Individual monograph**

Implementation date **01/07/2025 (11.8)** Text number **0663**

C19 H19 Cl2 N3 NaO5 S, H2 O M r 10.3 [13412-64-1] DEFINITION Sodium (2S,5R,6R)-6-[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-amido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate. Semi-synthetic product derived from a fermentation product. Content : 95.0 per cent to 102.0 per cent (anhydrous substance). CHARACTERS Appearance : white or almost white, hygroscopic, crystalline powder. Solubility : freely soluble in water, soluble in ethanol (96 per cent) and in...

Select allDownload selection (0)

1 resultPage 1 of 1

Status of text

Upcoming version
of text + direct link

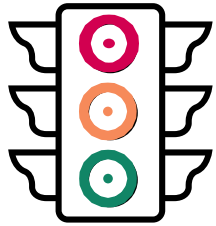
Type of text

Implementation
date and Issue
number

Page display for Ph. Eur. texts: Navigating between versions of texts ("traffic light" system)

Navigating between text versions – traffic light system

New feature introduced: traffic light system for text statuses



- **No longer** in force (for example, superseded)
- **Not yet** in force (published BUT implementation date not yet reached)
- **In force** Default

By default, when you search for a text, only one version is displayed (the in-force version, or the not yet in force version for new texts).

If a text has a newer version pending, you will see an orange bubble with a direct link to access it.

☐ **Dicloxacillin sodium monohydrate**

Implementation date **01/07/2025 (11.8)** Text number **0663**

☒ In force

☒ New version (1) → [Go to](#)

Text type **Individual monograph**

C19 H16 Cl2 N3 NaO5 S₂ H₂ O M r 510.3 [13412-64-1] DEFINITION Sodium (2S,5R,6R)-6-[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-amido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate. Semi-synthetic product derived from a fermentation product. Content : 95.0 per cent to 102.0 per cent (anhydrous substance). CHARACTERS Appearance : white or almost white, hygroscopic, crystalline powder. Solubility : freely soluble in water, soluble in ethanol (96 per cent) and in...

Navigating between text versions – text page information

The information panel (right-hand side) provides:

- General information such as the text number and the type of text;
- The status of the version of the text you are looking at;
- Links to other versions of the same text.

Home Access to texts Archives Store EN

dicloxacillin Title/text No. only

Back to results Results (3/5) Highlights (0/10) T EN

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

07/2025:0663

DICLOXACILLIN SODIUM MONOHYDRATE
Dicloxacillinum natriicum monohydricum

CC1=C(Cl)C(=O)N2C(=O)C(=C(Cl)C=C2O1)C(=O)N[C@@H](C)C[C@H](C)C(=O)O[Na] · H₂O

C₁₉H₁₆Cl₂N₃NaO₅S·H₂O M_r 510.3

[13412-64-1]
DEFINITION

Information
Text number: **0663**
Text type: **Individual monograph**

In force
Effective from 01/07/2025 to 31/12/2025
Issue 11.8

New version from 01/01/2026

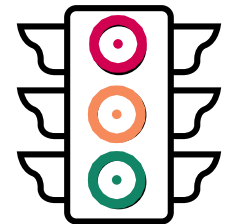
Change issue 11.8

12.1
Not yet in force

11.8
In force

10.0
No longer in force

Older
Go to PDF archives



Navigating between text versions - in force

[Home](#) [Access to texts](#) [Archives](#) [Store](#) EN

Title/text No. only

[Back to results](#) Results (87/131) [Highlights \(0/0\)](#) T EN

General Notices apply to all monographs and other texts.

See the information section on **general monographs**.

Knowledge database

RS store

07/2025:0663

DICLOXACILLIN SODIUM MONOHYDRATE
Dicloxacillinum natricum monohydricum

$C_{19}H_{16}Cl_2N_3NaO_5S \cdot H_2O$ M_r 510.3

[13412-64-1]

DEFINITION
Sodium (2S,5R,6R)-6-[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-amido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate.
Semi-synthetic product derived from a fermentation product.
Content: 95.0 per cent to 102.0 per cent (anhydrous substance).

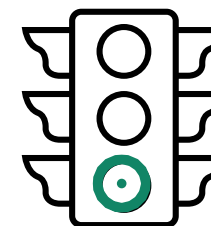
CHARACTERS
Appearance: white or almost white, hygroscopic, crystalline powder.
Solubility: freely soluble in water, soluble in ethanol (96 per cent) and in methanol.

Information
Text number: **0663**
Text type: **Individual monograph**

In force
Effective from 01/07/2025 to 31/12/2025
Issue 11.8

New version from 01/01/2026

Change issue 11.8



Navigating between text versions – not yet in force

Home Access to texts Archives Store EN

Search terms Title/text No. only

Back to results Results (87/131) Highlights (0/0) T EN

General Notices apply to all monographs and other texts.

See the information section on general monographs.

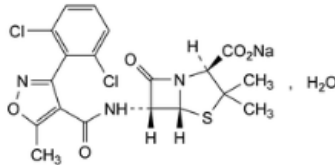
Knowledge database

RS store

01/2026:0663

DICLOXACILLIN SODIUM MONOHYDRATE

Dicloxacillinum natricum monohydricum



$C_{19}H_{16}Cl_2N_3NaO_5S \cdot H_2O$

[13412-64-1]

DEFINITION

Sodium (2S,5R,6R)-6-[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-amido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate.

Semi-synthetic product derived from a fermentation product.

Content: 95.0 per cent to 102.0 per cent (anhydrous substance).

M_r 510.3

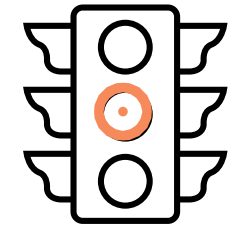
Information

Text number: **0663**
Text type: **Individual monograph**

Not yet in force
Effective as from 01/01/2026
Issue 12.1

Version in force
effective from 01/07/2025 to 31/12/2025

Change issue **12.1**



Navigating between text versions – no longer in force

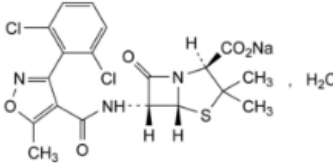
Home Access to texts Archives Store EN

Search terms Title/text No. only

Back to results Results (87/131) Highlights (0/0) T EN

General Notices apply to all monographs and other texts. See the information section on **general monographs**. Knowledge database RS store

DICLOXACILLIN SODIUM
Dicloxacillinum natricum



$C_{19}H_{16}Cl_2N_3NaO_5S \cdot H_2O$ M_r 510.3

[13412-64-1]

DEFINITION
Sodium (2S,5R,6R)-6-[[[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-yl]carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate.
Semi-synthetic product derived from a fermentation product.
Content: 95.0 per cent to 102.0 per cent (anhydrous substance).

01/2008:0663 corrected 10.0

Information
Text number: **0663**
Text type: **Individual monograph**

No longer in force
Published in Issue 6.0
Effective from 01/01/2008 to 30/06/2025
Correction date: 31/08/2019
Issue 10.0

New version from 01/01/2026

Version in force effective from 01/07/2025 to 31/12/2025

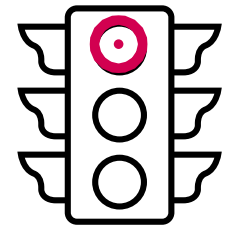
Change issue 10.0

12.1
Not yet in force

11.8
In force

10.0
No longer in force

Older
Go to PDF archives



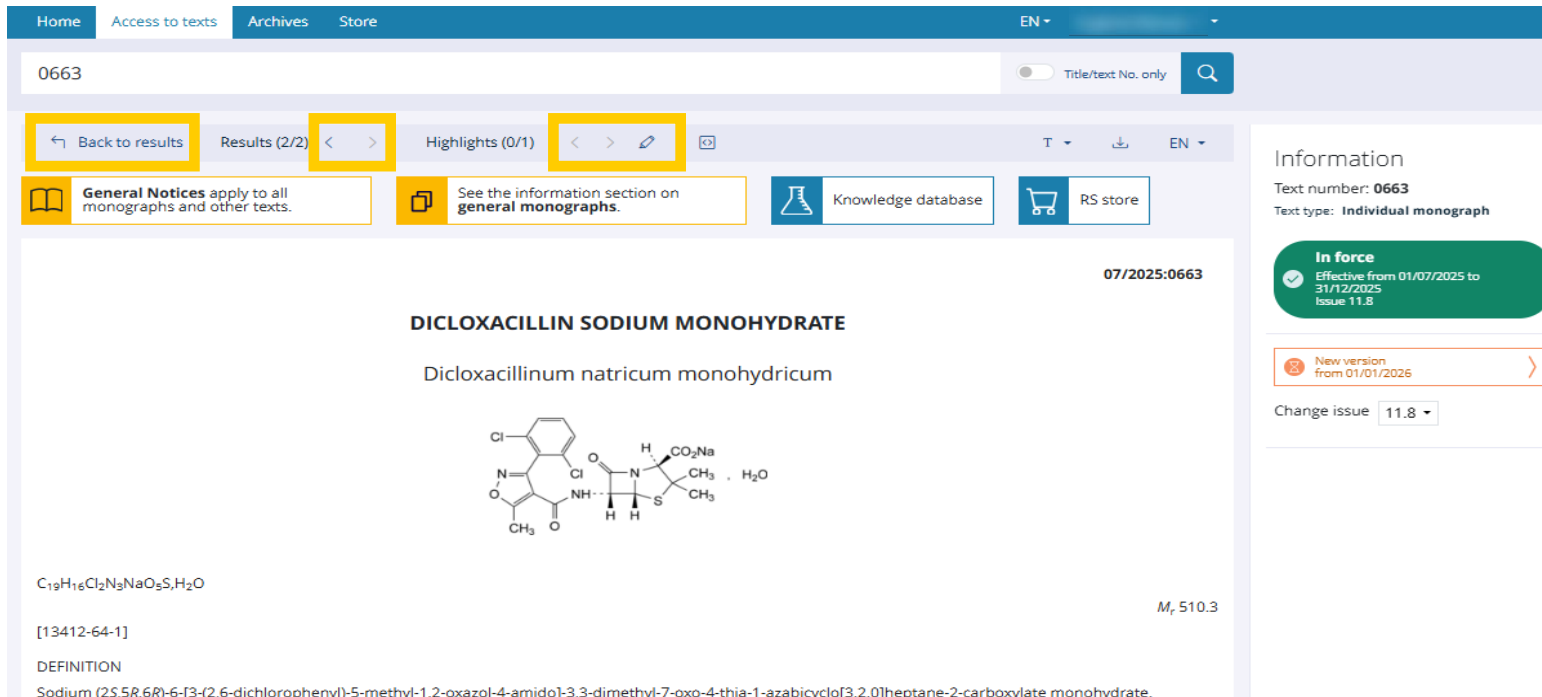
Page display for Ph. Eur. texts: Text page structure

Text page structure – text toolbar (1/3)

On top of each text, a toolbar allows you to:

- Quickly go back to your search results;
- Navigate between the different results of your search;
- Highlight the searched terms found in the text and navigate between the different occurrences.

Click on  to hide or display highlighted terms.



Home Access to texts Archives Store EN

0663 Title/text No. only

Back to results Results (2/2) Highlights (0/1)

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

07/2025:0663

DICLOXACILLIN SODIUM MONOHYDRATE

Dicloxacillinum natriicum monohydricum

CC1(C)SC(=O)N1C(=O)N2C(=O)c3cc(Cl)c(Cl)cc3N2C(=O)O · H₂O

C₁₉H₁₆Cl₂N₃NaO₅·H₂O

[13412-64-1]

DEFINITION

Sodium (2S,5R,6R)-6-[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-amido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate.

M_r 510.3

Information

Text number: 0663

Text type: Individual monograph

In force

Effective from 01/07/2025 to 31/12/2025

Issue 11.8

New version from 01/01/2026

Change issue 11.8

Text page structure – text toolbar (2/3)

- Displaying change marks:

Change marks make it easy to see content added/modified or deleted compared to the previously published version; 

They can be hidden or displayed by clicking on .

Home Access to texts Archives Store

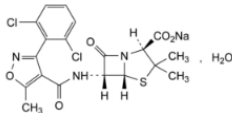
0663

Back to results Results (2/2) Highlights (0/1)

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

DICLOXACILLIN SODIUM MONOHYDRATE


Dicloxacillinum natricum monohydricum



$C_{19}H_{16}Cl_2Na_3O_5S_2H_2O$

[13412-64-1]

Water (2.5.12): 3.0 per cent to 4.5 per cent, determined on 0.300 g.





ASSAY



Liquid chromatography (2.2.29) as described in the test for related substances with the following modifications.

Injection: test solution (b) and reference solution (a).

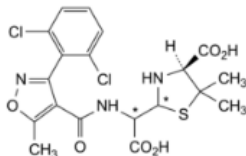
System suitability: reference solution (a):



- *repeatability:* maximum relative standard deviation of 1.0 per cent  determined on  6 injections.

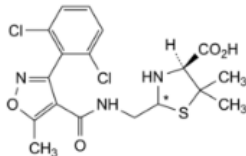
STORAGE



In an airtight container, at a temperature not exceeding 25 °C. If the substance is sterile,  the container is also sterile and tamper-evident .

IMPURITIES




A.  (2E,4S)-2-[(E)-carboxy[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-amido]methyl]-5,5-dimethyl-1,3-thiazolidine-4-carboxylic acid (penicilloic acids of dicloxacillin), 



B.  (2E,4S)-2-[[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-amido]methyl]-5,5-dimethyl-1,3-thiazolidine-4-carboxylic acid (penicilloic acids of cloxacillin), 

Text page structure – text toolbar (3/3)

- Download the PDF version of the text by clicking on  ;
- Switch between the English and the French version of the text.

Home Access to texts Archives Store EN

0663 Title/text No. only

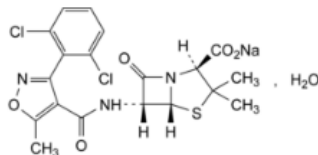
Back to results Results (2/2) Highlights (0/1) T

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

07/2025:0663

DICLOXACILLIN SODIUM MONOHYDRATE

Dicloxacillinum natricum monohydricum



$C_{19}H_{16}Cl_2N_3NaO_5S \cdot H_2O$

[13412-64-1]

DEFINITION

Sodium (2S,5R,6R)-6-[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-amido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate.

Information

Text number: **0663**

Text type: **Individual monograph**

In force

Effective from 01/07/2025 to 31/12/2025 Issue 11.8

New version from 01/01/2026

Change issue 11.8

Text page structure – useful links

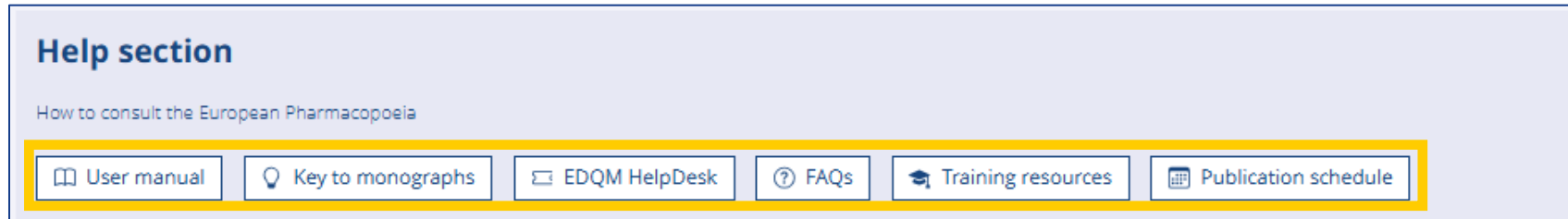
Underneath the text toolbar, you can find:

- A direct link to the General Notices;
As a reminder, General Notices are applicable to all texts and general chapters of the European Pharmacopoeia.
- The list of general monographs;
As a reminder, substances and medicinal products that are the subject of an individual monograph are also required to comply with applicable general monographs.
- The link to the Knowledge database;
- The link to the Reference Standards store.

The screenshot shows the monograph page for Dicloxacillin Sodium Monohydrate. At the top, there is a navigation bar with links: 'Back to results', 'Results (2/2)', 'Highlights (0/1)', and a language dropdown set to 'EN'. Below this is a yellow banner with four icons and text: a book icon for 'General Notices apply to all monographs and other texts.', a document icon for 'See the information section on general monographs.', a flask icon for 'Knowledge database', and a shopping cart icon for 'RS store'. The main content area has a date '07/2025:0663' in the top right. The title 'DICLOXACILLIN SODIUM MONOHYDRATE' is centered, followed by its Latin name 'Dicloxacillinum natriicum monohydricum'. Below this is the chemical structure of the compound. The molecular formula $C_{19}H_{16}Cl_2N_3NaO_5 \cdot H_2O$ is shown on the left, and the relative molecular mass M_r 510.3 is on the right. The identifier '[13412-64-1]' is also present. The 'DEFINITION' section at the bottom provides the full chemical name: 'Sodium (2S,5R,6R)-6-[3-(2,6-dichlorophenyl)-5-methyl-1,2-oxazol-4-amido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate.'

Text page structure

- The Help section can be found at the bottom of each text.



Pharmeuropa link

Texts undergoing public consultation – results card

HomeAccess to textsArchivesStore

EN

tetanus AND veterinary

Title/text No. only

Order byDefaultTitleImplementation dateText number

Excerpt

Results per page20

Select allDownload selection (0)

1 - 2 of 2 resultsPage 1 of 1

Tetanus vaccine for veterinary use

In force

Text type Individual monograph

Implementation date 01/01/2021 (10.3)Text number 0697

Text in Pharmeuropa → Go to

1. DEFINITION Tetanus vaccine for veterinary use is a preparation of the neurotoxin of Clostridium tetani inactivated to eliminate its toxicity while maintaining adequate immunogenic properties. The vaccine may be used to induce active and/or passive immunity. 2. PRODUCTION 2-1. preparation OF the VACCINE C. tetani used for production is grown in an appropriate liquid medium. The toxin is purified and then detoxified or it may be detoxified before purification. The detoxification process is...

Tetanus antitoxin for veterinary use

In force

Text type Individual monograph

Implementation date 01/01/2008 (6.0)Text number 0343

DEFINITION Tetanus antitoxin for veterinary use is a preparation containing principally the globulins that have the power of specifically neutralising the neurotoxin formed by Clostridium tetani . It consists of the serum or a preparation obtained from the serum of animals immunised against tetanus toxin. PRODUCTION CHOice of composition The antitoxin is shown to be satisfactory with respect to safety (5.2.6) and efficacy (5.2.7). For the latter, it shall be demonstrated, for each target...

Select allDownload selection (0)

1 - 2 of 2 resultsPage 1 of 1

Direct link to the version in Pharmeuropa if a text is currently available for public consultation.

Pharmeuropa Texts for Comment

FRDocument en Français

PDFAdobePDF

How to comment

CommentTools

Public deadline: 2025-06-30
NPA deadline: 2025-08-31

Reference: PA/PH/Exp. 15V/T (24) 17 ANP 1

BRIEFING NOTE 2

Absence of tetanus toxin : a section on alternative in vitro methods to the test in guinea pigs has been added. This new section includes a general part on alternative in vitro methods to encourage their use and describe prerequisites for their introduction as a replacement for the test in guinea pigs. It also includes a specific part on the Binding And Cleavage ('BINACLE') method, based on the results of a collaborative study to test its applicability as an alternative to the test in guinea pigs. The BINACLE method mimics essential steps of the mechanism of action of tetanus toxin and may be suitable to replace the test in guinea pigs, after product-specific validation to demonstrate that toxoids from the routine production process do not interfere with sensitive detection of tetanus neurotoxin. 3

For more information, see: 4

– Collaborative study for the characterisation of the BINACLE Assay for in vitro detection of tetanus toxicity in toxoids” - Part 1; 5

– Collaborative study for the characterisation of the BINACLE Assay for in vitro detection of tetanus toxicity in toxoids” - Part 2; 6

published in Pharmeuropa Bio & Scientific Notes in 2024. 7

The same changes have been introduced in the monograph on Tetanus vaccine (adsorbed) (0452), published in the same issue of Pharmeuropa. 8

XXXX:0697 9

TETANUS VACCINE FOR VETERINARY USE 10

Vaccinum tetani ad usum veterinarium 11

Texts undergoing public consultation – text page information

The screenshot displays the Ph. Eur. Online interface for a specific text. At the top, a navigation bar includes links for 'Back to results', 'Results (16/19)', 'Highlights (0/0)', and a language selector set to 'EN'. Below this, a row of four buttons provides quick access: 'General Notices' (applying to all monographs), 'See the information section on general monographs', 'Knowledge database', and 'RS store'. The main content area is titled 'TETANUS VACCINE FOR VETERINARY USE' with the Latin name 'Vaccinum tetani ad usum veterinarium' and the identifier '01/2021:0697'. The 'DEFINITION' section states that the vaccine is a preparation of the neurotoxin of *Clostridium tetani* inactivated to eliminate toxicity while maintaining immunogenic properties. The 'PRODUCTION' section is partially visible. On the right, an 'Information' sidebar shows the text number '0697', type 'Individual monograph', and a green 'In force' status as of 01/01/2021, Issue 10.3. A 'Change issue' dropdown is set to '10.3'. A yellow box highlights a 'Text in Pharmeuropa' notification, stating that a new draft is available for public consultation and that comments should be submitted by 30/06/2025. A blue arrow points from the 'How to comment' link in this notification to the text 'Explanatory note on how to submit comments.'

Back to results Results (16/19) Highlights (0/0) T EN

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

01/2021:0697

TETANUS VACCINE FOR VETERINARY USE

Vaccinum tetani ad usum veterinarium

1. DEFINITION

Tetanus vaccine for veterinary use is a preparation of the neurotoxin of *Clostridium tetani* inactivated to eliminate its toxicity while maintaining adequate immunogenic properties. The vaccine may be used to induce active and/or passive immunity.

2. PRODUCTION

2-1. PREPARATION OF THE VACCINE

Information

Text number: **0697**
Text type: **Individual monograph**

In force
as of 01/01/2021
Issue 10.3

Change issue 10.3

Text in Pharmeuropa
A new draft of this text is available for public consultation.
[Submit comments by 30/06/2025.](#)
[How to comment](#)

Explanatory note on how to submit comments.

Focusing on status filters

Scenario #1: Suppressions

Suppressions

The screenshot displays the European Pharmacopoeia Online interface. The header includes the EDQM logo, the Council of Europe logo, and the text "European Pharmacopoeia Online". The navigation bar contains links for Home, Access to texts, Archives, and Store, along with a language dropdown set to EN.

The search bar is labeled "Search terms" and includes a toggle for "Title/text No. only" and a search icon. Below the search bar, the "Search filters" section is visible, with a "Table of contents" and "Text type" filters. The "Status" filter is highlighted with a red arrow, showing a list of status options: "In force / in use", "Upcoming", "No longer in force / in use", "Pre-correction", "Superseded / replaced", "Suppressed / deleted", and "Suspended". The "Upcoming" section is expanded, showing "Corrections", "Revisions / modifications", "New texts", "Suppressions / deletions" (which is checked), and "Suspensions".

The search results are displayed in a table with columns for "Order by" (Default, Title, Implementation date, Text number), "Excerpt" (toggle), and "Results per page" (20). The results show three items, all marked as "Pending suppression" and "General chapter". The first item is "2.6.8. Pyrogens" (Text number 20608), the second is "2.6.10. Histamine" (Text number 20610), and the third is "2.6.11. Depressor substances" (Text number 20611). Each item includes the implementation date (01/01/2026 (12.1)) and a note stating "This text is suppressed from the European Pharmacopoeia as of 01/2026.".

Suppressions: upcoming suppressions

HomeAccess to textsArchivesHelpStore

EN

2.6.8

Title/text No. only

Order byDefaultTitleImplementation dateText number

Excerpt

Results per page20

Select allDownload selection (0)

1 resultPage 1 of 1

2.6.8. Pyrogens

In force

Suppression upcoming (1) → Go to

Correction date 30/11/2021 (10.7) Implementation date 01/01/2020 (10.0) Text number 20608

Text type General chapter

... corrected 10.7 2.6.8. Pyrogens The test consists of measuring the rise in body temperature...

...If the summed response of the 1st group does not exceed the figure given in the 2nd column of Table 2.6.8.-1, the substance passes the test. If the summed response exceeds the figure given in the 2nd column of the table...

...3rd column of the table, the product fails the test. Table 2.6.8.-1

HomeAccess to textsArchivesStore

EN

2.6.8

Title/text No. only

Back to resultsResults (1/1)Highlights (0/0)

General Notices apply to all monographs and other texts.

See the information section on general monographs.

Knowledge database

RS store

Suppressed:20608

2.6.8. PYROGENS

This text is suppressed from the European Pharmacopoeia as of 01/2026.

Information

Text number: 20608

Text type: General chapter

Pending suppression

Effective from 01/01/2026

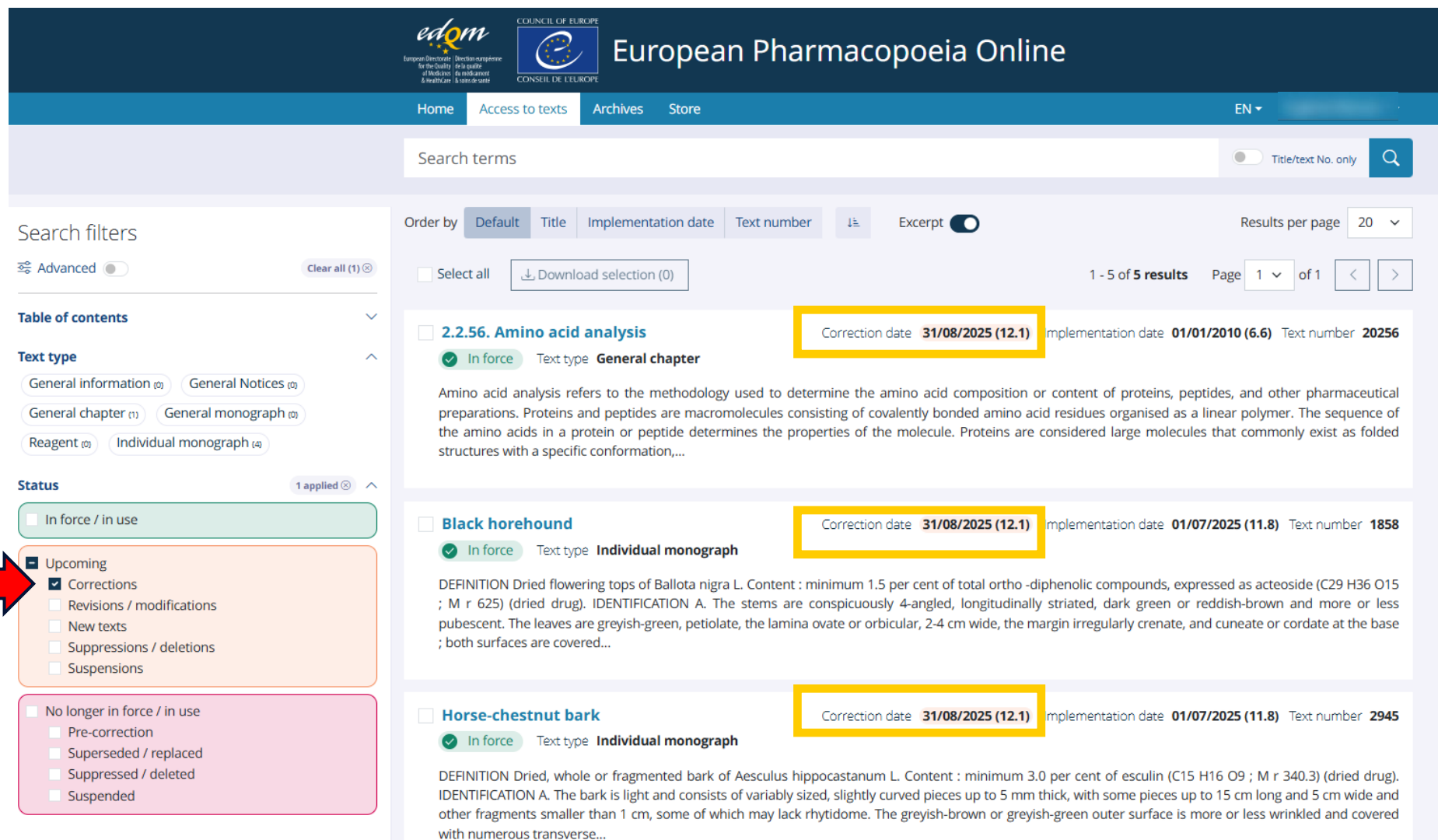
Issue 12.1

Version in force (corrected)

Change issue12.1

Scenario #2: Corrections

Corrections



The screenshot displays the European Pharmacopoeia Online interface. The top navigation bar includes the EDQM logo, the Council of Europe logo, and the text "European Pharmacopoeia Online". Below this, there are tabs for "Home", "Access to texts", "Archives", and "Store". A search bar is located on the right side of the navigation bar.

The main content area is divided into a left sidebar and a main results area. The sidebar contains "Search filters" with a "Table of contents" section and a "Text type" section. The "Text type" section has buttons for "General information (0)", "General Notices (0)", "General chapter (1)", "General monograph (0)", "Reagent (0)", and "Individual monograph (4)". The "Status" section has a "1 applied" filter and a list of status options: "In force / in use", "Upcoming", "Corrections", "Revisions / modifications", "New texts", "Suppressions / deletions", "Suspensions", "No longer in force / in use", "Pre-correction", "Superseded / replaced", "Suppressed / deleted", and "Suspended". A red arrow points to the "Corrections" option in the "Upcoming" section.

The main results area shows a list of search results. The first result is "2.2.56. Amino acid analysis" with a correction date of "31/08/2025 (12.1)", implementation date of "01/01/2010 (6.6)", and text number "20256". The second result is "Black horehound" with a correction date of "31/08/2025 (12.1)", implementation date of "01/07/2025 (11.8)", and text number "1858". The third result is "Horse-chestnut bark" with a correction date of "31/08/2025 (12.1)", implementation date of "01/07/2025 (11.8)", and text number "2945".

Corrections

Home

Access to texts

Archives

Store

EN

20256

Order by

Default

TitleImplementation dateText number

Excerpt

Results per page20

Select allDownload selection (0)

Highlighted

Correction date 31/08/2025 (12.1)

Implementation date 01/01/2010 (6.6)Text number 20256

2.2.56. Amino acid analysis

In force

Text type General chapter

Home

Access to texts

Archives

Store

EN

20256

Back to resultsResults (1/1)Highlights (0/1)

General Notices

apply to all monographs and other texts.

See the information section on

general monographs.

Knowledge database

RS store

01/2010:20256

corrected 12.1

2.2.56. AMINO ACID ANALYSIS⁽¹⁾

(SEE NOTE)

Amino acid analysis refers to the methodology used to determine the amino acid composition or content of proteins, peptides, and other pharmaceutical preparations. Proteins and peptides are macromolecules consisting of covalently bonded amino acid residues organised as a linear polymer. The sequence of the amino acids in a protein or peptide determines the properties of the molecule. Proteins are considered large molecules that commonly exist as folded structures with a specific conformation, while peptides are smaller and may consist of only a few amino acids. Amino acid analysis can be used to quantify proteins and peptides, to determine the identity of proteins or peptides based on their amino acid composition, to support protein and peptide structure analysis, to evaluate fragmentation strategies for peptide mapping, and to detect atypical amino acids that might be present in a protein or peptide. It is necessary to hydrolyse a protein/peptide to its individual amino acid constituents before amino acid analysis. Following protein/peptide hydrolysis, the amino acid analysis procedure can be the same as that practiced for free amino acids in other pharmaceutical preparations. The amino acid constituents of the test sample are typically derivatised for analysis.

In force

as of 01/01/2010 Issue 6.6

Correction date:

31/08/2025 Issue 12.1

Change issue12.1

Scenario #3: Modifications (reagents)

Modifications (reagents)

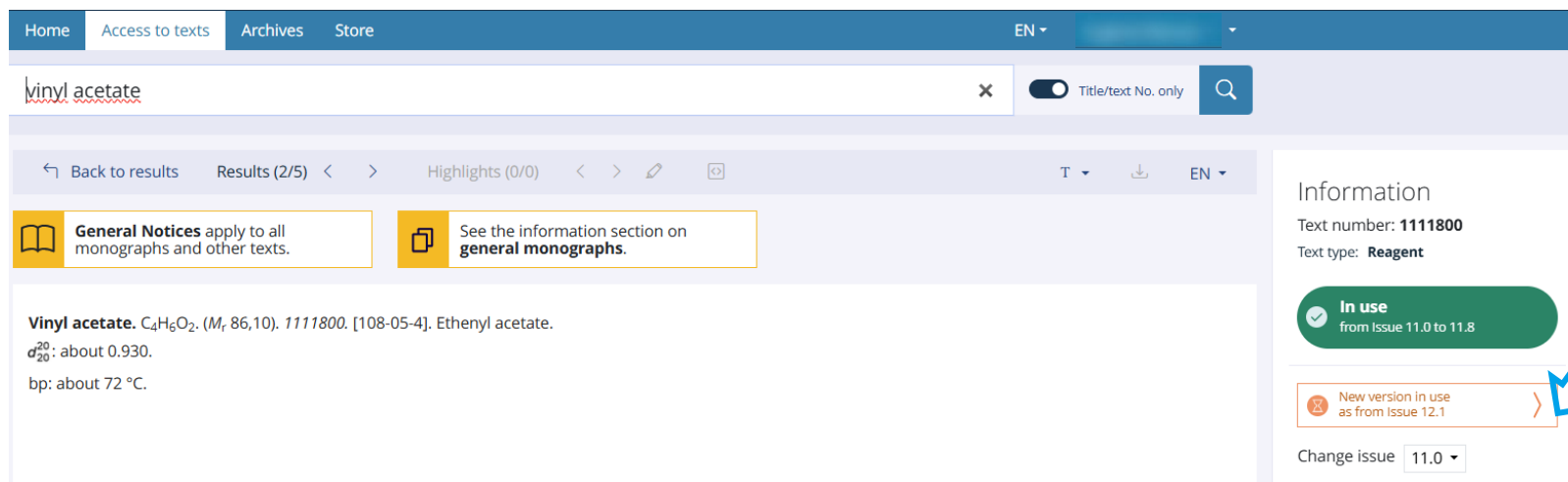
The screenshot displays the European Pharmacopoeia Online interface. The header includes the EDQM logo, the Council of Europe logo, and the title "European Pharmacopoeia Online". The navigation bar contains links for Home, Access to texts, Archives, and Store, along with a language dropdown set to EN.

The search bar is located at the top right, with a search icon and a toggle for "Title/text No. only". Below the search bar, the "Search filters" section is visible on the left. It includes a "Table of contents" section with a "Text type" filter set to "Reagent" (6) and a "Status" filter set to "In force / in use" (1 applied). The "Status" filter is further broken down into "Upcoming" (Revisions / modifications) and "No longer in force / in use" (Pre-correction, Superseded / replaced, Suppressed / deleted, Suspended).

The main content area shows search results for reagents. The results are ordered by "Default" and show 1 - 6 of 6 results. The results list includes:

- ε-Caprolactam** (Text type: Reagent, Not yet in use) In use from 12.1 Text number 1104200. Content: minimum 99 per cent.
- Chlorogenic acid** (Text type: Reagent, Not yet in use) In use from 12.1 Text number 1104700. Content: minimum 97.0 per cent.
- Menthofuran** (Text type: Reagent, Not yet in use) In use from 12.1 Text number 1051500. Content: minimum 95.0 per cent, calculated by the normalisation procedure.
- Pulegone** (Text type: Reagent, Not yet in use) In use from 12.1 Text number 1073100. Content: minimum 95.0 per cent, calculated by the normalisation procedure.

Modifications (reagents)



Home Access to texts Archives Store EN

vinyl acetate

Back to results Results (2/5) Highlights (0/0)

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

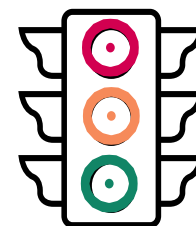
Vinyl acetate. $C_4H_6O_2$ (M_r 86,10). 1111800. [108-05-4]. Ethenyl acetate.
 d_{20}^{20} : about 0,930.
bp: about 72 °C.

Information
Text number: 1111800
Text type: Reagent

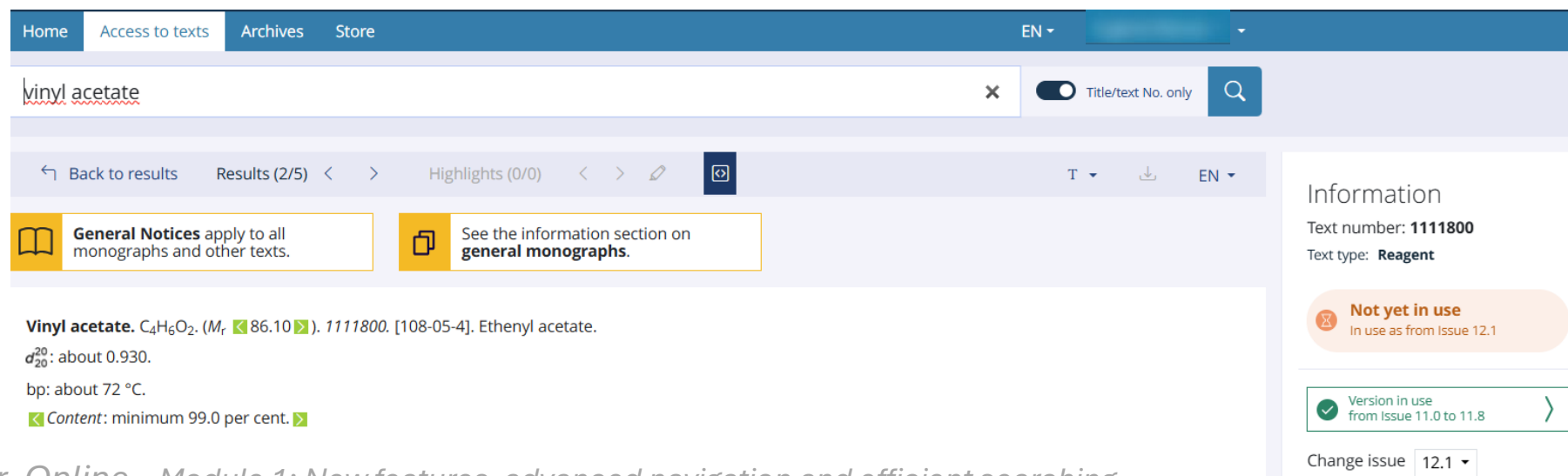
In use
from Issue 11.0 to 11.8

New version in use as from Issue 12.1

Change issue 11.0



- No longer in use
- Not yet in use
- In use



Home Access to texts Archives Store EN

vinyl acetate

Back to results Results (2/5) Highlights (0/0)

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

Vinyl acetate. $C_4H_6O_2$ (M_r 86,10). 1111800. [108-05-4]. Ethenyl acetate.
 d_{20}^{20} : about 0,930.
bp: about 72 °C.
Content: minimum 99.0 per cent.

Information
Text number: 1111800
Text type: Reagent

Not yet in use
In use as from Issue 12.1

Version in use
from Issue 11.0 to 11.8

Change issue 12.1

Advanced text search

Advanced search

Search filters


Advanced 

Table of contents

Text type

Status

Issue

Search language

CAS

Molecular formula

Section

Subsection

Issue

☐ 12th Edition (0)

☐ 12.1 (0)

01/01/2026

Corr. 31/08/2025

☐ 11th Edition (1)

☐ 10th Edition (1)

Show more

Search language

Defaults

☒ English (Default)

☐ French

☐ English + French

CAS

You can use the ? or * wildcards

Molecular formula

You can use the ? or * wildcards

Section

Title

Content

Subsection

Title

Content



Advanced search: search by Ph. Eur. Issue



If you are searching for all texts published in a specific issue, we strongly recommend that you select **all** statuses (In force + Upcoming + No longer in force).

European Pharmacopoeia Online

Search filters

Advanced ☒ Clear all (13)

Table of contents

Text type

Status 12 applied

- ☒ In force / in use
- ☒ Upcoming
 - ☒ Corrections
 - ☒ Revisions / modifications
 - ☒ New texts
 - ☒ Suppressions / deletions
 - ☒ Suspensions
- ☒ No longer in force / in use
 - ☒ Pre-correction
 - ☒ Superseded / replaced
 - ☒ Suppressed / deleted
 - ☒ Suspended

Issue 1 applied

- ☐ 12th Edition (137)
- ☐ 12.1 (137) 01/01/2026 Corr. 31/08/2025
- ☒ 11th Edition (3956)
- ☒ 11.8 (129) 01/07/2025 Corr. 28/02/2025
- ☐ 11.7 (64) 01/04/2025 Corr. 30/11/2024

Order by Default Title Implementation date Text number Excerpt ☐ Select all Download selection (0) 1 - 20 of 129 results Page 1 of 7

Contents of Supplement 11.8 Text number 90010

Text type General information

Lists of the monographs and general chapters that, for Supplement 11.8, are new, revised or corrected or have had their titles changed, are given below. As of the 11th Edition, all revised, corrected or deleted parts of a text published in the online version of the European Pharmacopoeia are indicated by change marks in the form of triangles. For reasons of readability, these triangles are not shown in the print version. Corrected texts are to be taken into account as soon as possible and not...

2.4.20. Determination of elemental impurities Implementation date 01/07/2025 (11.8) Text number 20420

☒ In force Text type General chapter

Introduction This chapter describes two analytical procedures (procedures 1 and 2) and validation criteria for the evaluation of the levels of elemental impurities. The chapter permits the use of any procedure that meets the validation criteria specified in this chapter. As the chemical composition of the considered substances and the specification limits for the target element(s) (see Glossary) of interest vary considerably, it is difficult to describe all suitable sample preparation and...

2.5.44. Capillary isoelectric focusing for recombinant therapeutic monoclonal antibodies Implementation date 01/07/2025 (11.8) Text number 20544

☒ In force Text type General chapter

INTRODUCTION AND SCOPE This general chapter covers general capillary isoelectric focusing (cIEF) and imaged capillary isoelectric focusing (icIEF) procedures (2.2.47) that can be employed for qualitative and quantitative determination of charged variants (isoforms). Charge heterogeneity is an important quality attribute that can impact the safety, efficacy and stability of therapeutic monoclonal antibodies (mAbs). It results from post-translational modifications (e.g. glycation, sialylation...

Advanced search – clear all filters

To clear all filters:

- Click on “Clear all” or;
- Click on “Access to texts”.

The screenshot displays the Ph. Eur. Online interface. At the top, there is a navigation bar with links: Home, Access to texts, Archives, and Store. Below this, a toggle switch for 'Advanced' search is shown. A red arrow points to the 'Clear all (13)' button, which is highlighted with a yellow box. Another red arrow points to the 'Access to texts' link in the navigation bar. The left sidebar contains various filter categories: Table of contents, Text type, Status (12 applied), Issue (1 applied), and Search language (English (Default), French). The main content area shows a list of monographs, including 'Contents of Supplement 11.8' and '2.4.20. Determination of elemental i', with details on their status and text type.

Advanced search – combine filters and syntax to refine your search

Example 1 : searching for texts that describe a chromatographic system

Step 1: typing chrom* will search for all texts containing terms beginning with chrom

=> 2539 results

The screenshot shows the Ph. Eur. Online search interface. The top navigation bar includes 'Home', 'Access to texts', 'Archives', and 'Store'. The search bar contains the text 'chrom*'. Below the search bar, there are search filters on the left and search options on the right. The search filters include 'Advanced' (toggle), 'Table of contents', 'Text type', and 'Status'. The search options include 'Order by' (Default, Title, Implementation date, Text number), 'Excerpt' (toggle), 'Select all', and 'Download selection (0)'. The search results show two items: '1. General notices' and '2.1.3. Ultraviolet ray lamps for analytical purposes'. The first item is highlighted with a yellow box. The text of the first item is: '...ratio of general chapter 2.2.46. Chromatographic separation techniques). 1.3.1 Materials for containers and containersMaterial...of the type 'Carry out either tests A, B or tests C, D'. For example, one test determines enantiomeric purity by chromatogr...specific optical rotation ; the intended...describing a particular enantiomer include a test to confirm enantiomeric purity, either using specific optical rotation or a...for racemic character using optical rotation is included only if there is information on the specific...'. The second item is '2.1.3. Ultraviolet ray lamps for analytical purposes' with the text: '...The distance between the lamp and the chromatographic plate under examination used in a pharmacopoeial test never exce...the above-mentioned...'. The search results are displayed in a table with columns for 'Text type' and 'Implementation date'.

Advanced search – combine filters and syntax to refine your search

Step 2:

- Apply text type filter: general chapter;
- Add key words to the section filter: for example, “equipment” and “detector” to narrow this search to electronic chromatographic systems;
- Activate the ‘Title only’ toggle switch to display general chapters with titles dealing with chromatography only.

=> 4 results

The screenshot displays the Ph. Eur. Online search interface. At the top, a search bar contains the query "chrom*" and a toggle switch is set to "On". Below the search bar, the "Search filters" section is visible. The "Text type" filter is set to "General chapter" (4). The "Section" filter is set to "equipment" and "detector" (2 applied). The "Status" filter is set to "Defaults". The "Issue" filter is set to "Defaults". The "Search language" filter is set to "Defaults". The "CAS" filter is set to "Defaults". The "Molecular formula" filter is set to "Defaults". The "Order by" dropdown is set to "Default". The "Excerpt" toggle switch is set to "On". The results section shows 1 - 4 of 4 results. The first result is "2.2.28. Gas chromatography" (Implementation date: 01/04/2023 (11.1)). The second result is "2.2.29. Liquid chromatography" (Implementation date: 01/04/2023 (11.1)). The third result is "2.2.30. Size-exclusion chromatography" (Implementation date: 01/04/2023 (11.1)).

Advanced search – combine filters and syntax to refine your search

Example 2 : searching for texts containing the words tablets or capsules or both in the title

- Use the 'OR' Boolean operator in the search box to look for texts containing the words 'tablets' or 'capsules', or both.
- Toggle the 'Title only' switch to limit the search to texts containing the words 'tablets' or 'capsules' in their title.
- Apply text type filter: individual monograph.
- Add key words to the section filter: only texts including a dissolution test, for example.

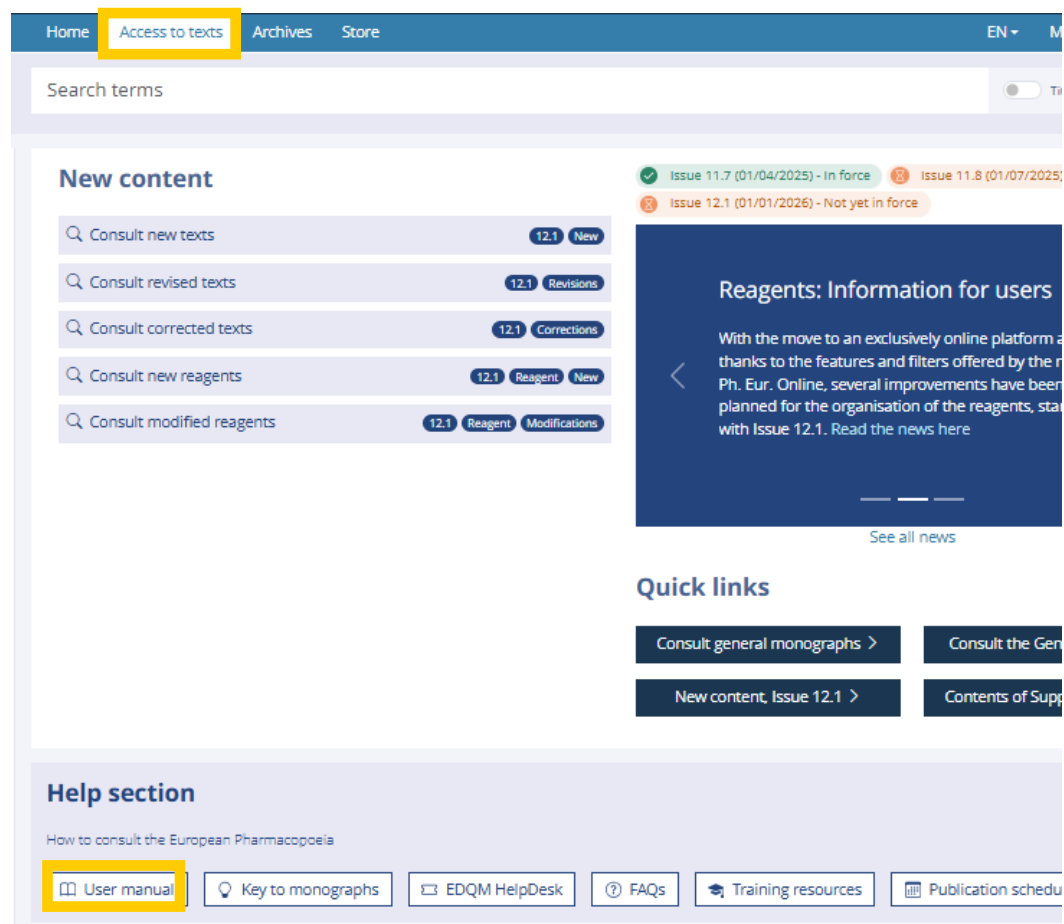
The screenshot displays the European Pharmacopoeia Online search interface. The search bar at the top contains the query "capsules OR tablets". The search filters on the left include:

- Search filters:** Advanced search is toggled on.
- Table of contents:** Individual monograph (16) is selected.
- Status:** Defaults.
- Issue:** Defaults.
- Search language:** Defaults.
- CAS:** Defaults.
- Molecular formula:** Defaults.
- Section:** Title (1 applied).
- Content:** dissolution (1 applied).

The search results on the right show 1 - 16 of 16 results. The first result is "Deferasirox dispersible tablets", which is in force and is an individual monograph. The definition states: "Dispersible tablets containing Deferasirox (2933), for human use. They comply with the monograph Tablets (0478) and with the requirements. Content : 95.0 per cent to 105.0 per cent of the content of deferasirox (C21 H15 N3 O4) stated on the label. IDENTIFICATION A. Record the UV spectrum of the principal peak in the chromatograms obtained with the solutions used in the assay, with a diode array detector in the range of 210-400 nm." The second result is "Deferiprone tablets", which is also in force and is an individual monograph. The definition states: "Tablets containing Deferiprone (2236), for human use. They comply with the monograph Tablets (0478) and the following additional requirements. Content : 95.0 per cent to 105.0 per cent of the content of deferiprone (C7 H9 NO2) stated on the label. IDENTIFICATION A. Record the UV spectrum of the principal peak in the chromatograms obtained with the solutions used in the assay, with a diode array detector in the range of 210-400 nm." The third result is "Dronedarone hydrochloride tablets", which is in force and is an individual monograph. The definition states: "Tablets containing Dronedarone hydrochloride (3039), for human use. They comply with the monograph Tablets (0478) and the following additional requirements. Content : 95.0 per cent to 105.0 per cent of the content of dronedarone (C31 H44 N2 O5 S) stated on the label. IDENTIFICATION A. Record the UV spectrum of the principal peak in the chromatograms obtained with the solutions used in the assay, with a diode array detector in the range of 210-400 nm."

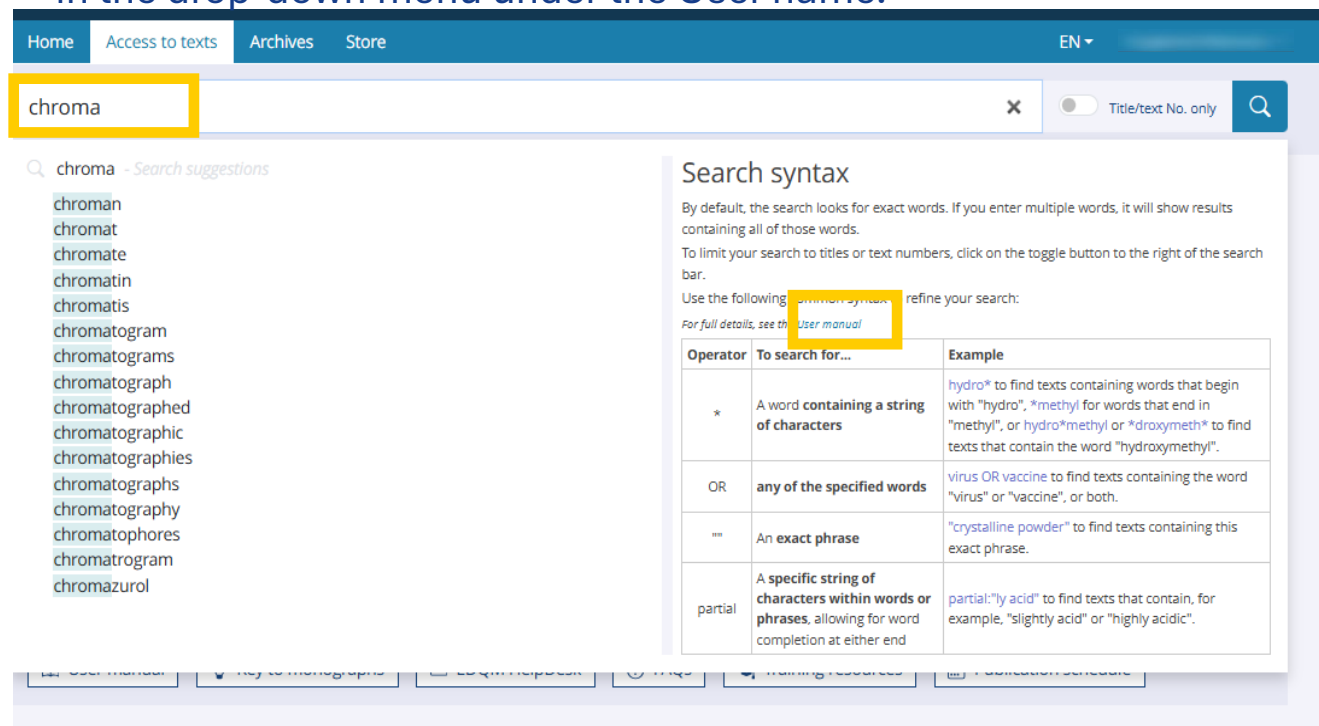
User manual for additional search combinations

More combinations of filters and search syntax are possible depending on your specific advanced search. Please consult our [User manual](#) to find all available search syntax to improve your search efficiency.



The User manual is available:

- **at the bottom of all pages** in the Help section;
- when you start to type **in search bar in the syntax help box** itself;
- in the drop-down menu under the User name.



More information



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du médicament
& soins de santé

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