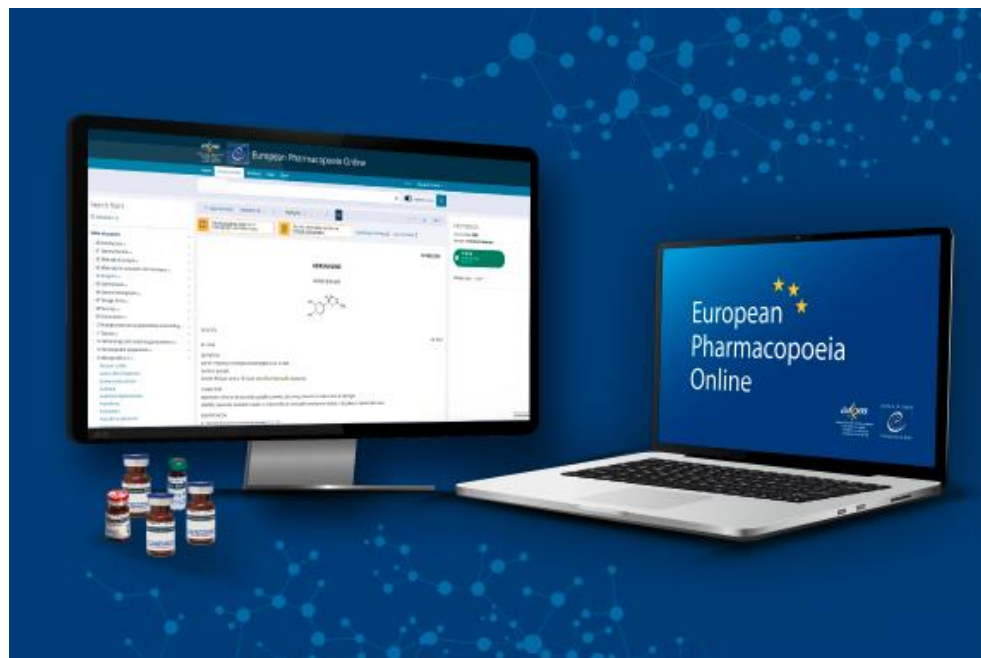
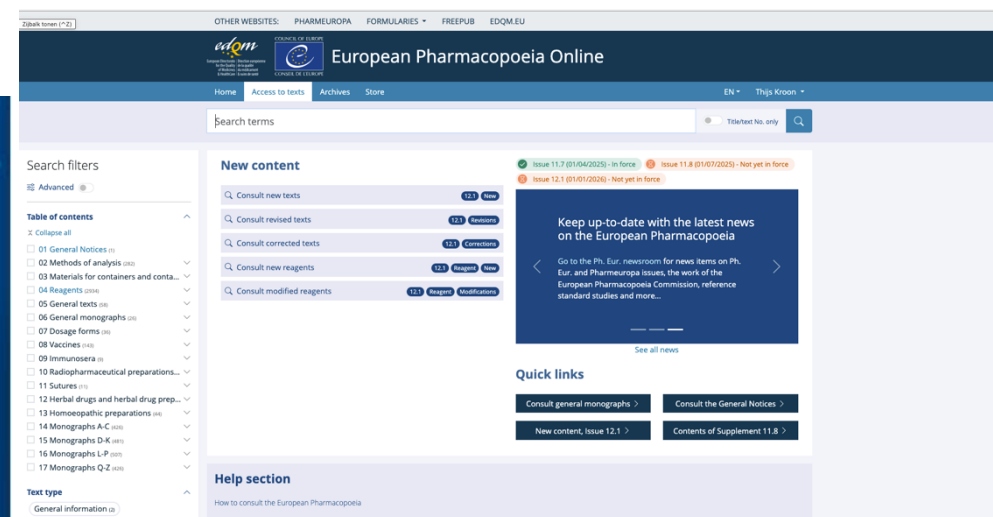


# European Pharmacopoeia update

April 2026  
Thijs Kroon

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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

Keep up-to-date with the latest news on the European Pharmacopoeia

Go to the Ph. Eur. newroom for news items on Ph. Eur. and Pharmeuropa issues, the work of the European Pharmacopoeia Commission, reference standard studies and more...

See all news

Quick links

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How to consult the European Pharmacopoeia

# European Pharmacopoeia

Ed 11.6-12.3

## **NEW**

*Ed 11.6:*

- Ioflupane ( $^{123}\text{I}$ ) injection (3144)

*Ed 11.7:*

- Lutetium ( $^{177}\text{Lu}$ ) Zavadotide guraxetan ( $^{177}\text{Lu}$  PSMA I&T injection: 1<sup>st</sup> therapeutic PSMA monograph)

*Ed 12.2:*

- JK-PSMA-7 ( $^{18}\text{F}$ ) injection (3205)

*No new radiopharmaceutical monographs in Ed 11.8, 12.1 and 12.3*

# European Pharmacopoeia

## Ed 11.6-12.3

### Changes

#### Ed 11.7:

*Gallium (<sup>68</sup>Ga) chloride (accelerator-produced) solution for radiolabelling:* Identification test D has been deleted as it served no purpose.

*Technetium (<sup>99m</sup>Tc) oxidronate injection:* Radiochemical purity test impurity B: replacement of TLC test by paper chromatography test (replacement of MEK). Additionally <sup>99m</sup>Tc pertechnetate cyclotron produced is allowed to be used in the labelling

#### Ed 11.8:

*Gallium (<sup>68</sup>Ga) chloride (generator-produced) solution for radiolabelling:*

- 1) Title changed
- 2) Identification test D has been deleted as it served no purpose.
- 3) Endotoxin limit per batch

*Technetium (<sup>99m</sup>Tc) human albumin injection:*

Updated production section to allow the use of <sup>99m</sup>Tc pertechnetate cyclotron produced

*Tetra-O-acetyl-mannose triflate for radiopharmaceutical preparations:* Statement on hygroscopicity has been removed

# Work in Progress

To be submitted to the Commission

- Multiple technetium ( $^{99m}\text{Tc}$ ) monographs: inclusion of accelerator produced technetium ( $^{99m}\text{Tc}$ ) and updated definitions etc.
- Almost all  $^{18}\text{F}$ -Fluoride monographs: deletion of the radionuclidic purity test A and some textual updates.
- $^{89}\text{Zr}$ -Zirconium oxalate: first monograph with an AMR test, no requirement for individual metals to be tested
- Fluoride ( $^{18}\text{F}$ ) solution for radiolabelling: pH test removed



Published in Pharmeuropa

- Gallium ( $^{68}\text{Ga}$ ) chloride (accelerator-produced) solution for radiolabelling: AMR test for the cyclotron produced material introduced (to be republished in Pharmeuropa)

# Other work in Progress

- Ammonia ( $^{13}\text{N}$ ) injection: Testing done on a “new” column. Further work is needed
- Water ( $^{15}\text{O}$ ) injection: new radiochemical purity test is in development
- $^{15}\text{O}$  gas: work on update halted due out lack of known producers
- Actinium ( $^{225}\text{Ac}$ ) nitrate (generator-produced) solution for radiolabelling: draft version of non-binding text being discussed
- Fluoride ( $^{18}\text{F}$ ) Fluoroestradiol draft monograph completed for publication in Pharmeuropa
- Revision of the Lutetium ( $^{177}\text{Lu}$ ) chloride for radiolabelling monograph
- New monograph on Copper ( $^{64}\text{Cu}$ ) for radiolabelling in preparation
- General monograph on Apparent Molar Radioactivity (AMR): to replace metal testing in radiometal monographs with a test using ligand labelling. To be published in Pharmeuropa
- $^{18}\text{F}$ -Fludeoxyglucose: Chemical purity test to be expanded to cover other related substances



# Other relevant changes to the European Pharmacopoeia

## 5.1.13. Pyrogenicity (new)

- Needed to allow the deletion of the Rabbit Pyrogen Test (deleted as per 01 January 2026)
- Provides guidance on what choice of test (Endotoxin/Monocyte Activation Test)
- Risk Assessment required to select the need for a Monocyte Activation Test or an Endotoxin test for new preparations.

*Note: No requirement to do a Risk Assessment for already approved and accepted endotoxin tests.*

- *Many monographs are affected that deal with/mention the pyrogen test.*

# CHANGES FROM EDITION 11.8 TO EDITION 12.1

Ed 11.8 and earlier: edition + supplements

Ed 12.1 One edition + issues

One edition + issues have one implementation year, but still different implementation dates (edition + supplements had different implementation years)

Ed 12.1 onwards: only on-line

- From Ed 12.1 onwards there is direct access to previous versions of the texts and adapted but not yet in force versions
- Colour indicates status (**green**: current version, **orange**: not yet in force, **red**: no longer in force)
- Archives for Ed 10 and earlier versions are available
- 365 days licensing

For the full training on Ed 12 new features see: <https://www.edqm.eu/en/-/unlocking-the-potential-of-the-european-pharmacopoeia-online>

# QUESTIONS ON THE EUROPEAN PHARMACOPOEIA

When you experience issues with monographs or have feedback on monographs, please contact

***the EDQM helpdesk***

***Helps to improve the quality of the monographs!***

