European Pharmacopoeia update

April 2026

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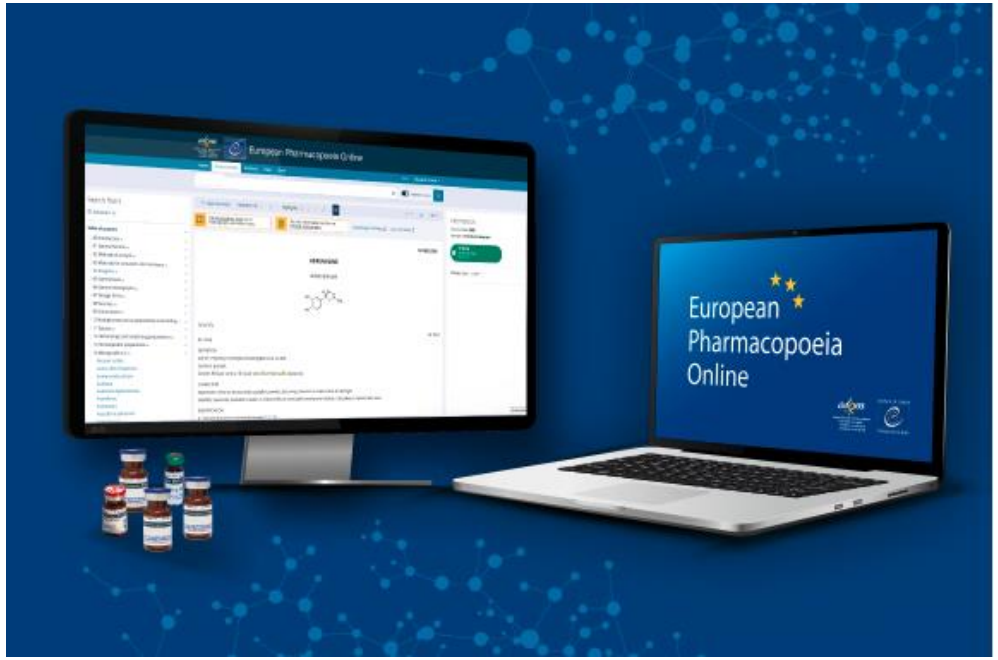

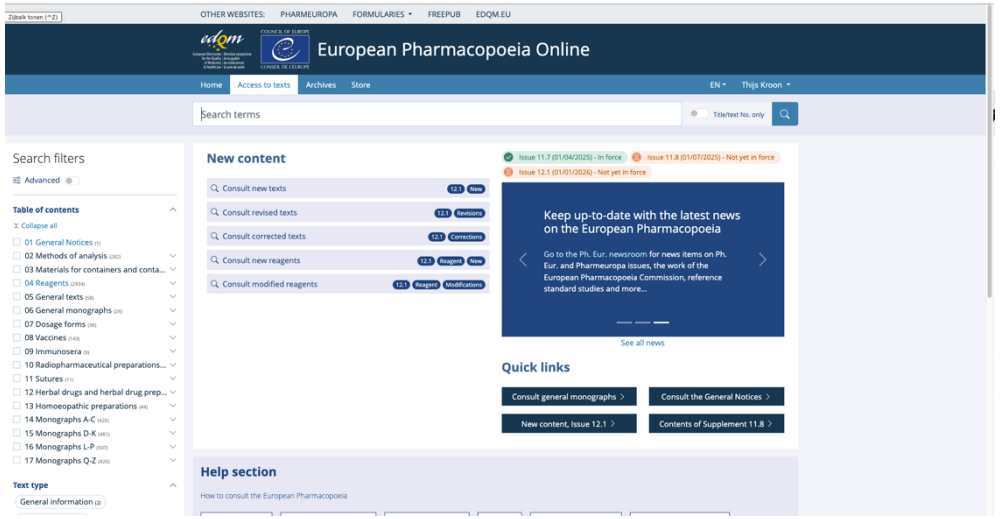

European Pharmacopoeia
Ed 11.6-12.3

NEW

Ed 11.6:

- Ioflupane (123I) injection (3144)

Ed 11.7:

- Lutetium (^{177}Lu) Zadavotide guraxetan (177Lu PSMA I&T injection: 1st therapeutic PSMA monograph)

Ed 12.2:

- JK-PSMA-7 (18F) 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 (^{68}Ga) chloride (accelerator-produced) solution for radiolabelling: Identification test D has been deleted as it served no purpose.

Technetium (99mTc) oxidronate injection: Radiochemical purity test impurity B: replacement of TLC test by paper chromatography test (replacement of MEK). Additionally ^{99m}Tc pertechnetate cyclotron produced is allowed to be used in the labelling

Ed 11.8:

Gallium (68Ga) 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 (99mTc) human albumin injection:

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

Published in Pharmeuropa

- Gallium (68Ga) 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}N) injection: Testing done on a “new” column. Further work is needed
- Water (^{15}O) injection: new radiochemical purity test is in development
- ^{15}O gas: work on update halted due out lack of known producers
- Actinium (^{225}Ac) nitrate (generator-produced) solution for radiolabelling: draft version of non-binding text being discussed
- Fluoride (^{18}F) Fluoroestradiol draft monograph completed for publication in Pharmeuropa
- Revision of the Lutetium (^{177}Lu) chloride for radiolabelling monograph
- New monograph on Copper (^{64}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}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!