

NEW CONTENT, ISSUE 12.1

Lists of the general chapters and monographs that, for Issue 12.1, are new, revised, corrected, suppressed or have had their titles changed, are given below.

All revised, corrected or deleted parts of a text published in the European Pharmacopoeia are indicated by change marks in the form of triangles.

New and revised texts are to be taken into account not later than the stated implementation date. Corrected texts are to be taken into account as soon as possible and not later than the end of the month following the month of publication of the issue.

As of 12.1, a panel to the right of each general chapter or monograph provides a summary of the text's implementation status, based on the stated implementation date. New and revised texts for which the implementation date has not yet come into effect are labelled "not yet in force". Corrected texts display the status "in force", with additional information on the correction date.

New reagents, as well as the parts of reagents that have been modified, are indicated by change mark triangles in both their individual entries and in the cumulative lists in general chapter 4. Reagents. Each reagent has a unique 7-digit reference code that is given in italics after the name of the reagent.

Lists of reagents that, for Issue 12.1, are new, modified or deleted are given below.

TEXTS THAT HAVE CHANGED SECTION

The following general monographs were previously found in the Homoeopathic preparations section. As of Issue 12.1, they appear in the sections listed below. This move has no impact on their content or applicability.

General monographs

Herbal drugs for homoeopathic preparations (2045)

Homoeopathic preparations (1038)

Methods of preparation of homoeopathic stocks and potentisation (2371)

Mother tinctures for homoeopathic preparations (2029)

Dosage forms

Homoeopathic pillules, coated (2786)

Homoeopathic pillules, impregnated (2079)

Pillules for homoeopathic preparations (2153)

NEW TEXTS

The following texts appear for the first time in the European Pharmacopoeia. They will come into force on 1 January 2026 and must be implemented by this date at the latest.

GENERAL CHAPTERS

3.1.16. Cyclo-olefin polymers

3.1.17. Cyclo-olefin copolymers

3.1.18. Styrene block copolymers for containers and closures for parenteral preparations and ophthalmic preparations

5.36. mRNA vaccines for human use

5.39. mRNA substances for the production of mRNA vaccines for human use

5.40. DNA templates for the preparation of mRNA substances

MONOGRAPHS

Herbal drugs and herbal drug preparations

Epimedium leaf (3190)

Patchouli herb (3192)

Monographs

Haemodialysis, concentrated solutions for (3206)
Macrogol poly(vinyl acetate)-poly(vinylcaprolactam) grafted copolymer (3156)
L-Malic acid (3143)
Palonosetron hydrochloride (3041)
Tazobactam (2210)
Teriparatide injection (3130)

REVISED TEXTS

The following texts have undergone revision of their technical content since their last publication. They will come into force on 1 January 2026 and must be implemented by this date at the latest.

GENERAL CHAPTERS

1. General Notices
- 2.2.39. Molecular mass distribution in dextrans
- 2.5.42. N-Nitrosamines in active substances and medicinal products
- 2.9.34. Bulk density of powders
4. Reagents
- 5.1.9. Guidelines for using the test for sterility
- 5.22. Names of herbal drugs used in traditional Chinese medicine

MONOGRAPHS

Vaccines for veterinary use

Foot-and-mouth disease (ruminants) vaccine (inactivated) (0063)

Herbal drugs and herbal drug preparations

Adhatoda vasica leaf (2738)
Fleeceflower root (2433)
Fourstamen stephania root (2478)
Wild pansy (flowering aerial parts) (1855)

Monographs

Aluminium hydroxide, hydrated, for adsorption (1664)
Amitriptyline hydrochloride (0464)
Amlodipine besilate (1491)
Aprotinin (0580)
Aprotinin concentrated solution (0579)
Bromperidol decanoate (1397)
Butylhydroxytoluene (0581)
Charcoal, activated (0313)
Chymotrypsin (0476)
Clomipramine hydrochloride (0889)
Clonazepam (0890)
Clopidogrel besilate (2790)
Clopidogrel hydrogen sulfate (2531)
Codergocrine mesilate (2060)
Danaparoid sodium (2090)
Daunorubicin hydrochloride (0662)
Dicloxacillin sodium monohydrate (0663)
Dosulepin hydrochloride (1314)
Escitalopram (2758)

Escitalopram oxalate (2733)
Esomeprazole magnesium dihydrate (2787)
Esomeprazole magnesium trihydrate (2372)
Esomeprazole sodium (2923)
Fluconazole (2287)
Fluticasone propionate (1750)
Follitropin (2285)
Follitropin concentrated solution (2286)
Glycerol dibehenate (1427)
Glycerol distearate (1428)
Glycerol monolinoleate (1429)
Glycerol mono-oleate (1430)
Glycerol monostearate 40-55 (0495)
Gonadotrophin, chorionic (0498)
Haemodialysis solutions, concentrated, water for diluting (1167)
Haemodialysis, solutions for (0128)
Haemofiltration and haemodiafiltration, concentrated solutions for (2770)
Haemofiltration and haemodiafiltration, solutions for (0861)
Hard fat (0462)
Hard fat with additives (2731)
Heparin calcium (0332)
Heparin sodium (0333)
Heparins, low-molecular-mass (0828)
Homatropine hydrobromide (0500)
Hydroxyethylcellulose (0336)
Hydroxypropylcellulose, low-substituted (2083)
Hypromellose (0348)
Indometacin (0092)
Kanamycin acid sulfate (0033)
Kanamycin monosulfate monohydrate (0032)
Lacosamide (2992)
Lamivudine (2217)
Levetiracetam (2535)
Macrogols (1444)
Macrogols, high-molecular-mass (2444)
Maize starch (0344)
Methylcellulose (0345)
Nicotine ditartrate dihydrate (2599)
Nitrendipine (1246)
Oxytetracycline hydrochloride (0198)
Pentobarbital sodium (0419)
Peritoneal dialysis, solutions for (0862)
Pivmecillinam hydrochloride (1359)
Propylene glycol dilaurate (2087)
Propylene glycol monocaprylate (2799)
Propylene glycol monolaurate (1915)
Remifentanil hydrochloride (2644)
Rifamycin sodium (0432)
Rivaroxaban (2932)
Ropivacaine hydrochloride monohydrate (2335)

Rotigotine (3014)
Salicylic acid (0366)
Sitagliptin phosphate monohydrate (2778)
Sodium hydrogen carbonate (0195)
Sodium polystyrene sulfonate (1909)
Starch, hydroxypropyl (2165)
Starches, hydroxyethyl (1785)
Streptomycin sulfate (0053)
Sucrose monopalmitate (2319)
Sucrose stearate (2318)
Tapentadol hydrochloride (3035)
Tobramycin (0645)
Trypsin (0694)
Urofollitropin (0958)
Urokinase (0695)
Ursodeoxycholic acid (1275)
Zanamivir hydrate (2611)

CORRECTED TEXTS

*The following texts have been corrected for Issue 12.1 and specify ‘corrected 12.1’ below their implementation date. These corrections are to be taken into account as soon as possible and not later than **31 August 2025** (the end of the month following the month of publication of Issue 12.1).*

GENERAL CHAPTERS

2.2.56. Amino acid analysis

MONOGRAPHS

Herbal drugs and herbal preparations

Black horehound (1858)

Horse-chestnut bark (2945)

Homoeopathic preparations

Homoeopathic preparations: introduction (90006)

Monographs

Alprazolam (1065)

TEXT WHOSE TITLE HAS CHANGED

The title of the following text has been changed in Issue 12.1

GENERAL CHAPTERS

2.5.42. N-Nitrosamines in active substances and medicinal products (*formerly N-Nitrosamines in active substances*)

SUPPRESSED TEXTS

*The following texts are suppressed as of **1 January 2026**.*

GENERAL CHAPTERS

- 2.6.8. Pyrogens
- 2.6.10. Histamine
- 2.6.11. Depressor substances

NEW REAGENTS

The reagents below have been added to the list of reagents published in chapter 4 of the European Pharmacopoeia for Issue 12.1.

Chapter 4.1.1. (Reagents)

Benzonitrile. 1225100.
2,4-Di-*tert*-butyl-5-methylphenol. 1224800.
2,6-Di-*tert*-butylphenol. 1224900.
Epimedin A. 1225500.
Ergosterol. 1225700.
Fangchinoline. 1225000.
Icariin. 1225400.
Patchoulol. 1225600.
N-Vinylcaprolactam. 1225300.
1-Vinylimidazole. 1225200.

MODIFIED REAGENTS

The reagents below have been modified for Issue 12.1 (chapter 4 of the European Pharmacopoeia).

Chapter 4.1.1. (Reagents)

ϵ -Caprolactam. 1104200.
Chlorogenic acid. 1104700.
Menthofuran. 1051500.
Pulegone. 1073100.
Vinyl acetate. 1111800.