

NEW CONTENT, ISSUE 12.2

Lists of the general chapters and monographs that, for Issue 12.2, 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.

On the European Pharmacopoeia Online, 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 12.2, are new, modified or deleted are given below.

NEW TEXTS

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

GENERAL CHAPTERS

2.6.41. High-throughput sequencing for the detection of viral extraneous agents

5.32. Cell-based preparations for human use

5.37. Recombinant viral vectored vaccines for human use

MONOGRAPHS

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

JK-PSMA-7 (¹⁸F) injection (3205)

Herbal drugs and herbal drug preparations

Cedarwood oil (3002)

Ribwort plantain liquid extract (2961)

Monographs

Golimumab injection (3187)

REVISED TEXTS

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

GENERAL CHAPTERS

2.5.25. Carbon monoxide in gases

2.6.7. Mycoplasmas

3.1.8. Silicone oil used as a lubricant

3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion

4. Reagents

MONOGRAPHS

General monographs

Vaccines for human use (0153)

Vaccines for veterinary use (0062)

Vaccines for human use

Hepatitis A vaccine (inactivated, adsorbed) (1107)
Influenza vaccine (split virion, inactivated) (0158)
Influenza vaccine (surface antigen, inactivated) (0869)
Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) (2149)
Influenza vaccine (surface antigen, inactivated, virosome) (2053)
Influenza vaccine (whole virion, inactivated) (0159)
Poliomyelitis vaccine (inactivated) (0214)
Smallpox vaccine (live) (0164)
Tick-borne encephalitis vaccine (inactivated) (1375)
Yellow fever vaccine (live) (0537)

Herbal drugs and herbal drug preparations

Clary sage oil (1850)
Clove (0376)
Clove oil (1091)
Ispaghula husk (1334)
Ispaghula seed (1333)
Ligusticum root and rhizome (2431)
Liquorice dry extract for flavouring purposes (2378)
Liquorice root (0277)
Psyllium seed (0858)
Szechwan lovage rhizome (2634)

Homoeopathic preparations

Cadmium sulfuricum for homoeopathic preparations (2143)
Cuprum metallicum for homoeopathic preparations (1610)
Ferrum metallicum for homoeopathic preparations (2026)
Magnesium phosphoricum for homoeopathic preparations (2505)

Monographs

Amphotericin B (1292)
Carboprost trometamol (1712)
Cellulose acetate butyrate (1406)
Cysteine hydrochloride monohydrate (0895)
Erlotinib hydrochloride (3094)
Flunitrazepam (0717)
Folic acid hydrate (0067)
Gabapentin (2173)
Glycerol monostearate 40-55 (0495)
Golimumab concentrated solution (3103)
Human albumin solution (0255)
Hydroxyzine hydrochloride (0916)
Metronidazole benzoate (0934)
Midazolam (0936)
Nifedipine (0627)
Oleyl alcohol (2073)
Procaine hydrochloride (0050)
Sorafenib tosylate tablets (3022)
Testosterone enantate (1048)

CORRECTED TEXTS

The following texts have been corrected for Issue 12.2 and specify ‘corrected 12.2’ below their implementation date. These corrections are to be taken into account as soon as possible and not later than 30 November 2025 (the end of the month following the month of publication of Issue 12.2).

GENERAL CHAPTERS

2.9.50. Particle size analysis by dynamic light scattering

MONOGRAPHS

Herbal drugs and herbal preparations

Notopterygium rhizome and root (2662)

Rehmannia root (2569)

Monographs

Dapagliflozin propylene glycol monohydrate (3137)

Dapagliflozin propylene glycol tablets (3175)

Fluoxetine hydrochloride (1104)

Flupentixol dihydrochloride (1693)

Methylphenidate hydrochloride (2235)

Phenoxybenzamine hydrochloride (2983)

Povidone (0685)

Propylene glycol (0430)

Rupatadine fumarate (2888)

Sodium propionate (2041)

Troxerutin (2133)

NEW REAGENTS

The reagents below have been added to the list of reagents published in chapter 4 of the European Pharmacopoeia for Issue 12.2.

Chapter 4.1.1. (Reagents)

n-Dodecane. 1225800.

JK-PSMA-7. 1225900.

MODIFIED REAGENTS

The reagents below have been modified for Issue 12.2 (chapter 4 of the European Pharmacopoeia).

Chapter 4.1.1. (Reagents)

Acid blue 92 solution. 1001401.

Argon. 1008200.

Haemoglobin solution. 1041701.

γ -Linolenyl alcohol. 1156200. (Formerly α -Linolenyl alcohol.)