

NEW CONTENT, ISSUE 13.3

Lists of the general chapters and monographs that, for Issue 13.3, 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 13.3, 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 July 2027 and must be implemented by this date at the latest.

GENERAL CHAPTERS

2.5.46. Phenolic antioxidants in plastic materials

2.6.42. Test for procoagulant activity in immunoglobulin preparations

2.8.27. Determination of estragole

MONOGRAPHS

Vaccines for veterinary use

Bluetongue vaccine (inactivated) (2899)

Herbal drugs and herbal drug preparations

Asparagus cochinchinensis root (3221)

Primula flower (2540)

Sage leaf (Salvia officinalis), cut (3201)

Monographs

Adalimumab concentrated solution (3147)

Olaparib (3238)

Olaparib tablets (3239)

Ropivacaine hydrochloride (2800)

REVISED TEXTS

The following texts have undergone revision of their technical content since their last publication. They will come into force on 1 July 2027 and must be implemented by this date at the latest.

GENERAL CHAPTERS

2.2.40. Near-infrared spectroscopy

2.2.47. Capillary electrophoresis

2.4.24. Identification and control of residual solvents

2.6.27. Microbiological examination of cell-based preparations

2.6.39. Microbiological examination of human tissues

3.1.3. Polyolefins

3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations

3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations

3.1.7. Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations

4. Reagents

5.22. Names of herbal drugs used in traditional Chinese medicine

MONOGRAPHS

Vaccines for human use

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)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Alovudine (^{18}F) injection (2460)

Fludeoxyglucose (^{18}F) injection (1325)

Fluoride (^{18}F) solution for radiolabelling (2390)

Fluorocholine (^{18}F) injection (2793)

Fluorodopa (^{18}F) (prepared by electrophilic substitution) injection (1918)

Fluorodopa (^{18}F) (prepared by nucleophilic substitution) injection (2481)

Fluoroethyl-L-tyrosine (^{18}F) injection (2466)

Fluoromisonidazole (^{18}F) injection (2459)

PSMA-1007 (^{18}F) injection (3116)

Sodium fluoride (^{18}F) injection (2100)

Herbal drugs and herbal drug preparations

Lemon verbena leaf (1834)

*Sage leaf (*Salvia officinalis*) (1370)*

Saw palmetto fruit (1848)

Verbena herb (1854)

Monographs

Almond oil, refined (1064)

Almond oil, virgin (0261)

Arachis oil, hydrogenated (1171)

Arachis oil, refined (0263)

Ascorbyl palmitate (0807)

Borage (starflower) oil, refined (2105)

Calcium hydroxide (1078)

Castor oil, refined (2367)

Chloroquine phosphate (0544)

Cineole (1973)

Coconut oil, refined (1410)

Cottonseed oil, hydrogenated (1305)

Dexamethasone sodium phosphate (0549)

Dihydrocodeine hydrogen tartrate (1776)

Econazole (2049)

Evening primrose oil, refined (2104)

Fluorescein sodium (1213)

Human normal immunoglobulin for intravenous administration (0918)

Human normal immunoglobulin for subcutaneous administration (2788)

Human plasma for fractionation (0853)

Ibandronate sodium monohydrate (2771)
Iopamidol (1115)
Levocetirizine dihydrochloride (3115)
Levomenthol (0619)
Linseed oil, virgin (1908)
Maize oil, refined (1342)
Maltitol, liquid (1236)
Metformin hydrochloride (0931)
Metronidazole (0675)
Naproxen (0731)
Naproxen sodium (1702)
Nikethamide (0233)
Noscapine (0516)
Olive oil, refined (1456)
Prednisolone sodium phosphate (0735)
Procainamide hydrochloride (0567)
Rapeseed oil, refined (1369)
Safflower oil, refined (2088)
Sesame oil, refined (0433)
Sorbitol, liquid (crystallising) (0436)
Sorbitol, liquid (non-crystallising) (0437)
Sorbitol, liquid, partially dehydrated (2048)
Soya-bean oil, hydrogenated (1265)
Soya-bean oil, refined (1473)
Sulfadiazine (0294)
Sulfamethoxazole (0108)
Sulfanilamide (1571)
Sunflower oil, refined (1371)
Valaciclovir hydrochloride (1768)
Wheat-germ oil, refined (1379)
Wheat-germ oil, virgin (1480)

CORRECTED TEXTS

*The following texts have been corrected for Issue 13.3 and specify ‘corrected 13.3’ below their implementation date. These corrections are to be taken into account as soon as possible and not later than **30 November 2026** (the end of the month following the month of publication of Issue 13.3).*

GENERAL CHAPTERS

2.6.21. Nucleic acid amplification techniques
2.9.1. Disintegration of tablets and capsules

MONOGRAPHS

Dosage forms

Nasal preparations (0676)

Herbal drugs and herbal drug preparations

Guar (1218)

Monographs

Alteplase powder for injection (1170)
Atorvastatin calcium (2191)
Calcipotriol (2011)
Calcipotriol monohydrate (2284)

Chloroxylenol (2980)
Ciclopirox olamine (1302)
Macrogol poly(vinyl acetate)-poly(vinylcaprolactam) grafted copolymer (3156)
Oxygen (0417)
Oxygen (93 per cent) (2455)
Oxygen (98 per cent) (3098)
Water for injections (0169)
Water, purified (0008)

SUPPRESSED TEXTS

The following texts are suppressed as of 1 July 2027.

MONOGRAPHS

Aloes, Barbados (0257)
Difloxacin hydrochloride trihydrate for veterinary use (2239)
Pivampicillin (0852)

NEW REAGENTS

The reagents below have been added to the list of reagents published in chapter 4 of the European Pharmacopoeia for Issue 13.3.

Chapter 4.1.1. (Reagents)

Cation-exchange resin, weak R1. 1228400.
Chlorotrimethylsilane R1. 1019301.
2,4-Di-tert-butylphenyl 3,5-di-tert-butyl-4-hydroxybenzoate. 1228800.
Neomenthol. 1228900.
Pseudoprotodioscin. 1228700.
Urea hydrogen peroxide. 1228600.
Verbenalin. 1228000.

MODIFIED REAGENTS

The reagents below have been modified for Issue 13.3 (chapter 4 of the European Pharmacopoeia).

Chapter 4.1.1. (Reagents)

Caffeic acid. 1014300.
Ferulic acid. 1149500.
Geranyl acetate. 1106500.
Linalyl acetate. 1107200.
Methyl anthranilate. 1107300.
trans-Nerolidol. 1107900.
Neryl acetate. 1108000.
 α -Pinene. 1130800.
 β -Pinene. 1109000.
Sabinene. 1109700.

DELETED REAGENTS

The reagents below have been deleted for Issue 13.3 (chapter 4 of the European Pharmacopoeia).

Chapter 4.1.1. (Reagents)

Sarafloxacin hydrochloride. 1181400.
Tetramethyldiaminodiphenylmethane. 1088700.
Tetramethyldiaminodiphenylmethane reagent. 1088701.