

## NEW CONTENT, ISSUE 12.3

*Lists of the general chapters and monographs that, for Issue 12.3, 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 12.3, 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 2026** and must be implemented by this date at the latest.*

### GENERAL CHAPTERS

5.38. Quality of data

### MONOGRAPHS

#### Herbal drugs and herbal drug preparations

*Chinese date (3163)*

*Virgate wormwood herb (2633)*

#### Monographs

*Alteplase concentrated solution (3197)*

*Hexylaminolevulinate hydrochloride (3062)*

*Insulin glargine injection (3129)*

*Oxalic acid dihydrate (2963)*

## REVISED TEXTS

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

### GENERAL CHAPTERS

2.2.44. Total organic carbon in water for pharmaceutical use

2.7.23. Numeration of CD34/CD45+ cells in haematopoietic products

2.9.42. Dissolution test for lipophilic solid dosage forms

2.9.43. Apparent dissolution

4. Reagents

5.2.5. Management of extraneous agents in immunological veterinary medicinal products

5.22. Names of herbal drugs used in traditional Chinese medicine

### MONOGRAPHS

#### General monographs

*Methods of preparation of homoeopathic stocks and potentisation (2371)*

**Vaccines for human use**

*Diphtheria vaccine (adsorbed) (0443)*

**Herbal drugs and herbal drug preparations**

*Eleutherococcus (1419)*

**Monographs**

*Alteplase powder for injection (1170)*

*Atomoxetine hydrochloride (2640)*

*Beeswax, white (0069)*

*Beeswax, yellow (0070)*

*Brivaracetam tablets (3140)*

*Calcium gluconate for injection (0979)*

*Chlorhexidine diacetate (0657)*

*Chlorhexidine digluconate solution (0658)*

*Chlorhexidine dihydrochloride (0659)*

*Cholesterol (0993)*

*Citalopram hydrobromide (2288)*

*Clenbuterol hydrochloride (1409)*

*Dihydroergocristine mesilate (1416)*

*Fludrocortisone acetate (0767)*

*Fluorouracil (0611)*

*Hydrocortisone (0335)*

*Insulin aspart (2084)*

*Insulin glargine (2571)*

*Insulin, human (0838)*

*Insulin lispro (2085)*

*Insulin, porcine (1638)*

*Insulin preparations, injectable (0854)*

*Macroglycerol hydroxystearate (1083)*

*Macroglycerol ricinoleate (1082)*

*Malic acid (2080)*

*Oxygen (0417)*

*Oxygen (93 per cent) (2455)*

*Oxygen (98 per cent) (3098)*

*Pergolide mesilate (1555)*

*Pilocarpine hydrochloride (0633)*

*Pilocarpine nitrate (0104)*

*Pregabalin (2777)*

*Ropinirole hydrochloride (2604)*

*Rosuvastatin calcium tablets (3008)*

*Sodium hyaluronate (1472)*

*Tryptophan (1272)*

*Vitamin A concentrate (oily form), synthetic (0219)*

*Vitamin A concentrate (powder form), synthetic (0218)*

*Vitamin A concentrate (solubilisate/emulsion), synthetic (0220)*

*Water for injections (0169)*

*Water, purified (0008)*

*Ziprasidone hydrochloride monohydrate (2421)*

*Ziprasidone mesilate trihydrate (2649)*

## CORRECTED TEXTS

*The following texts have been corrected for Issue 12.3 and specify 'corrected 12.3' below their implementation date. These corrections are to be taken into account as soon as possible and not later than **28 February 2026** (the end of the month following the month of publication of Issue 12.3).*

### GENERAL CHAPTERS

3.1.17. Cyclo-olefin copolymers

### MONOGRAPHS

#### Herbal drugs and herbal preparations

*Narrow-leaved coneflower root (1821)*

*Pale coneflower root (1822)*

*Purple coneflower herb (1823)*

*Purple coneflower root (1824)*

## TEXT WHOSE TITLE HAS CHANGED

*The title of the following text has been changed in Issue 12.3.*

### Monographs

*Alteplase powder for injection (1170) (formerly Alteplase for injection)*

## SUPPRESSED TEXT

*The following text is suppressed as of **1 July 2026**.*

### Monographs

*Dextromoramide tartrate (0021)*

## NEW REAGENTS

*The reagents below have been added to the list of reagents published in chapter 4 of the European Pharmacopoeia for Issue 12.3.*

### Chapter 4.1.1. (Reagents)

*Betulinic acid. 1226000.*

*1,5-Dicaffeoylquinic acid. 1226100.*

*Ethylene-bridged amidosilyl silica gel for chromatography (hybrid material). 1226600.*

*Gallic acid, anhydrous. 1226200.*

*1-Hexanol. 1226300.*

*Periplocin. 1226500.*

## MODIFIED REAGENTS

*The reagents below have been modified for Issue 12.3 (chapter 4 of the European Pharmacopoeia).*

### Chapter 4.1.1. (Reagents)

*Phosphomolybdotungstic reagent. 1065000.*

### Chapter 4.1.3. (Buffer solutions)

*Sulfate buffer solution. 4008900. (Formerly Sulfate buffer solution pH 2.0.)*

## DELETED REAGENT

*The reagent below has been deleted for Issue 12.3 (chapter 4 of the European Pharmacopoeia).*

*Thebaine. 1089200.*