

## NEW CONTENT, ISSUE 13.1

*Lists of the general chapters and monographs that, for Issue 13.1, 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.*

*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 13.1, 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 January 2027** and must be implemented by this date at the latest.*

### GENERAL CHAPTERS

2.5.43. Size-exclusion chromatography for recombinant therapeutic monoclonal antibodies

2.9.54. Uniformity of delivered dose of inhalation and nasal preparations

### MONOGRAPHS

#### Herbal drugs and herbal drug preparations

*Cat's claw bark (2530)*

*Chicory root (2948)*

*Geranium oil (3005)*

#### Monographs

*Cabazitaxel (3223)*

*Caspofungin acetate (3029)*

*Linagliptin (3173)*

*Nintedanib esilate (3237)*

## REVISED TEXTS

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

### GENERAL CHAPTERS

2.1.7. Balances for analytical purposes

2.4.35. Extractable elements in plastic materials for pharmaceutical use

2.6.14. Bacterial endotoxins

2.6.39. Microbiological examination of human tissues

2.8.25. High-performance thin-layer chromatography of herbal products

2.9.1. Disintegration of tablets and capsules

2.9.19. Particulate contamination: sub-visible particles

#### 4. Reagents

5.1.10. Guidelines for using the test for bacterial endotoxins

5.1.13. Pyrogenicity

- 5.32. Cell-based preparations for human use
- 5.34. Additional information on gene therapy medicinal products for human use
- 5.36. mRNA vaccines for human use
- 5.37. Recombinant viral vectored 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

### General monographs

*Gene therapy medicinal products for human use (3186)*

*Substances for pharmaceutical use (2034)*

### Dosage forms

*Ear preparations (0652)*

*Nasal preparations (0676)*

*Parenteral preparations (0520)*

*Preparations for inhalation (0671)*

*Pressurised pharmaceutical preparations (0523)*

*Veterinary semi-solid preparations for oral use (2638)*

### Vaccines for human use

*BCG for immunotherapy (1929)*

*BCG vaccine, freeze-dried (0163)*

*Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2067)*

*Tetanus vaccine (adsorbed) (0452)*

### Vaccines for veterinary use

*Tetanus vaccine for veterinary use (0697)*

### Herbal drugs and herbal drug preparations

*Frangula bark (0025)*

*Frangula bark dry extract, standardised (1214)*

*Goldenrod (1892)*

*Guar (1218)*

*Nettle leaf (1897)*

*Nettle root (2538)*

*White mulberry leaf (3164)*

### Monographs

*Amoxicillin sodium (0577)*

*Amoxicillin trihydrate (0260)*

*Betacarotene (1069)*

*Biotin (1073)*

*Carnauba wax (0597)*

*Chlorpromazine hydrochloride (0475)*

*Dextromethorphan hydrobromide monohydrate (0020)*

*2,4-Dichlorobenzyl alcohol (2410)*

*Dodecyl gallate (2078)*

*Doxazosin mesilate (2125)*

*Erythropoietin concentrated solution (1316)*

*Felodipine (1013)*

*Golimumab injection (3187)*

*Haemodialysis solutions, concentrated, water for diluting (1167)*  
*Histamine dihydrochloride (0143)*  
*Hyoscine hydrobromide hydrate (0106)*  
*Isoniazid (0146)*  
*Ivermectin (1336)*  
*Lercanidipine hydrochloride (3052)*  
*Levothyroxine sodium hydrate (0401)*  
*Linseed oil, virgin (1908)*  
*Manganese gluconate (2162)*  
*Methylthioninium chloride hydrate (1132)*  
*Metoclopramide (1348)*  
*Metoclopramide hydrochloride monohydrate (0674)*  
*Nilotinib hydrochloride monohydrate (2993)*  
*Octyl gallate (2057)*  
*Paclitaxel (1794)*  
*Penbutolol sulfate (1461)*  
*Pentamidine diisetonate (1137)*  
*Salbutamol sulfate (0687)*  
*Sitagliptin phosphate tablets (2927)*  
*Sultamicillin (2211)*  
*Thiamazole (1706)*  
*Trimetazidine dihydrochloride (1741)*  
*Water for injections (0169)*  
*Water, purified (0008)*

## CORRECTED TEXTS

*The following texts have been corrected for Issue 13.1 and specify 'corrected 13.1' below their implementation date. These corrections are to be taken into account as soon as possible and not later than **31 May 2026** (the end of the month following the month of publication of Issue 13.1).*

### GENERAL CHAPTERS

- 3.1.10. Materials based on non-plasticised poly(vinyl chloride) for containers for non-injectable, aqueous solutions
- 3.1.11. Materials based on non-plasticised poly(vinyl chloride) for containers for solid dosage forms for oral administration
- 3.1.13. Plastic additives

### MONOGRAPHS

#### General monographs

*Herbal drug extracts (0765)*

#### Herbal drugs and herbal preparations

*Abelmoschi corolla (2827)*  
*Baical skullcap root (2438)*  
*Clematis armandii stem (2463)*  
*Clematis rhizome and root (2527)*  
*Drynaria rhizome (2563)*  
*Houttuynia herb (2722)*  
*Loquat leaf (2978)*  
*Notopterygium rhizome and root (2662)*  
*Safflower flower (2386)*

*Schisandra fruit (2428)*

### **Monographs**

*Hydralazine hydrochloride (0829)*

*Kanamycin monosulfate monohydrate (0032)*

*Piperacillin monohydrate (1169)*

*Valganciclovir hydrochloride (2930)*

## **TEXTS WHOSE TITLE HAS CHANGED**

*The titles of the following texts have been changed in Issue 13.1.*

### **GENERAL CHAPTERS**

2.8.25. High-performance thin-layer chromatography of herbal products (*formerly High-performance thin-layer chromatography of herbal drugs and herbal drug preparations*)

### **MONOGRAPHS**

*Hyoscine hydrobromide hydrate (0106) (formerly Hyoscine hydrobromide)*

*Levothyroxine sodium hydrate (0401) (formerly Levothyroxine sodium)*

## **SUPPRESSED TEXT**

*The following text is suppressed as of 1 January 2027.*

### **GENERAL CHAPTERS**

2.6.32. Test for bacterial endotoxins using recombinant factor C

## **NEW REAGENTS**

*The reagents below have been added to the list of reagents published in chapter 4 of the European Pharmacopoeia for Issue 13.1.*

### **Chapter 4.1.1. (Reagents)**

*N-(4-Aminophenyl)-N-methyl-2-(4-methylpiperazin-1-yl)acetamide. 1227400.*

*Amylose derivative immobilised on silica gel for chiral separation. 1226800.*

*Ethanesulfonic acid. 1226900.*

*Ethylene-bridged diol silica gel for chromatography (hybrid material). 1227000.*

*Ethylene-bridged pentafluorophenylpropylsilyl silica gel for chromatography (hybrid material). 1226700.*

*Frangulin A. 1227100.*

*Glucofrangulin A. 1227200.*

*Uncarine E. 1227300.*

### **Chapter 4.1.3. (Buffer solutions)**

*0.05 M Tris-hydrochloride buffer solution pH 7.2, for BET. 4016700.*

## **MODIFIED REAGENTS**

*The reagents below have been modified for Issue 13.1 (chapter 4 of the European Pharmacopoeia).*

### **Chapter 4.1.1. (Reagents)**

*Butylhydroxytoluene. 1013800.*

*Decanol. 1024700.*

*Dimethylstearamide. 1030800.*

*Emodin. 1034400.*

*Glucose. 1025700.*

*Hyoscine hydrobromide. 1044800.*

*Methyl decanoate. 1054000.*

*Quercitrin. 1138200.*

*Rutoside trihydrate. 1075300.*

*Sodium hydrogen carbonate. 1081300.*

*Sodium laurilsulfate. 1081900.*

*Tetracos-15-enoic acid methyl ester. 1144800.*

## DELETED REAGENTS

*The reagents below have been deleted for Issue 13.1 (chapter 4 of the European Pharmacopoeia).*

### **Chapter 4.1.1. (Reagents)**

*Atropine sulfate. 1159000.*

*N,N-Diethylethane-1,2-diamine. 1028500.*

*Linolenic acid. 1143300.*