# CONTENTS OF SUPPLEMENT 10.4

All revised or corrected parts of a text are indicated by vertical lines in the margin, while horizontal lines in the margin indicate where parts of a text have been deleted.

Individual copies of texts published in this supplement will not be supplied.

Subscribers to the current version (book or electronic) of the European Pharmacopoeia have access to an online archive version of all obsolete editions and supplements of the European Pharmacopoeia in PDF format.

A list of new reagents published during the course of this edition is available under 'Useful information' in Pharmeuropa Online.

#### **NEW TEXTS**

The following texts appear for the first time in the European Pharmacopoeia. They will be implemented on 1 April 2021 at the latest.

**GENERAL CHAPTERS** 

5.28. Multivariate statistical process control

**MONOGRAPHS** 

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Gallium (<sup>68</sup>Ga) PSMA-11 injection (3044) Herbal drugs and herbal drug preparations

Forsythia fruit (2720)

Morinda root (2977)

Monographs
Regorafenib tablets (3023)

Riociguat (3078)

Riociguat tablets (3079)

Rivaroxaban tablets (3021)

Sorafenib tosilate (2931)

Sorafenib tablets (3022)

Ticagrelor (3087)

#### **REVISED TEXTS**

The following texts have been technically revised since their last publication. They will be implemented on 1 April 2021 at the latest.

#### **GENERAL CHAPTERS**

2.5.29. Sulfur dioxide

4. Reagents (new, revised, corrected)

5.22. Names of herbal drugs used in traditional Chinese medicine

5.25. Process analytical technology

Aprotinin concentrated solution (0579)

Aripiprazole (2617)

Atorvastatin calcium trihydrate (2191) Benserazide hydrochloride (1173)

Benzylpenicillin (procaine) monohydrate (0115)

Calcium lactate monohydrate (2117) Calcium lactate pentahydrate (0468) Calcium lactate trihydrate (0469)

Calcium pantothenate (0470)

Carbomers (1299)

Cellulose, microcrystalline (0316) Cellulose, powdered (0315)

Chlorpromazine hydrochloride (0475)

Cyproheptadine hydrochloride 1.5-hydrate (0817)

Dexamethasone isonicotinate (2237)

Dexpanthenol (0761) Disopyramide (1006)

Dosulepin hydrochloride (1314)

Erythromycin (0179)

Fluticasone propionate (1750) Gadobutrol monohydrate (2735)

Gelatin (0330)

Hypromellose phthalate (0347)

myo-Inositol (1805)

Insulin injection, isophane (0833) Insulin injection, soluble (0834) Insulin preparations, injectable (0854)

## MONOGRAPHS

#### General monographs

Immunosera for human use, animal (0084)

Products of fermentation (1468) Vaccines for veterinary use

Rabies vaccine (inactivated) for veterinary use (0451)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Sodium iodide (131I) solution (0281)

Herbal drugs and herbal drug preparations

Baical skullcap root (2438)

Feverfew (1516)

Sanguisorba root (2385) Zanthoxylum bungeanum pericarp (2656)

Monographs Aciclovir (0968)

Aluminium phosphate, hydrated (1598)

Ammonium chloride (0007)

Aprotinin (0580)

Insulin zinc injectable suspension (0837)

Promazine hydrochloride (1365) Insulin zinc injectable suspension (amorphous) (0835) Promethazine hydrochloride (0524) Insulin zinc injectable suspension (crystalline) (0836)

Levomepromazine hydrochloride (0505)

Lorazepam (1121) Lovastatin (1538)

Magnesium aluminometasilicate (2854)

Mercuric chloride (0120) Norfloxacin (1248)

Paroxetine hydrochloride (2283)

Paroxetine hydrochloride hemihydrate (2018)

Piperacillin monohydrate (1169) Piperacillin sodium (1168)

Piracetam (1733)

Potassium chloride (0185)

Potassium hydrogen tartrate (1984)

Prednicarbate (1467)

Prednisolone (0353)

Propyphenazone (0636)

Sodium aminosalicylate dihydrate (1993)

Sodium chloride (0193) Sodium cromoglicate (0562) Sodium lactate solution (1151) Sodium (S)-lactate solution (2033)

Stearic acid (1474) Tigecycline (2825) Trypsin (0694)

Vancomycin hydrochloride (1058)

Vincamine (1800)

Xylazine hydrochloride for veterinary use (1481)

Zuclopenthixol decanoate (1707)

#### **CORRECTED TEXTS**

The following texts have been corrected for Supplement 10.4 and specify 'corrected 10.4' above the title. These corrections are to be taken into account as soon as possible and not later than 30 November 2020 (the end of the month following the month of publication of Supplement 10.4).

**MONOGRAPHS** Ciclopirox (1407)

Herbal drugs and herbal drug preparations Ciclopirox olamine (1302)

Roselle (1623) Dihydralazine sulfate, hydrated (1310)

Neostigmine bromide (0046) Monographs Amiloride hydrochloride dihydrate (0651) Neostigmine metilsulfate (0626)

Noscapine (0516) Benzalkonium chloride (0372)

Benzalkonium chloride solution (0371) Ondansetron hydrochloride dihydrate (2016)

Pentoxifylline (0851) Carbamazepine (0543)

#### TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed in Supplement 10.4.

#### **MONOGRAPHS**

#### **Monographs**

Piperacillin monohydrate (1169) (previously Piperacillin)

Cyproheptadine hydrochloride 1.5-hydrate (0817) (previously Cyproheptadine hydrochloride)

## **DELETED TEXTS**

The following texts are deleted as of 1 April 2021.

#### **MONOGRAPHS**

Amobarbital (0594)

Amobarbital sodium (0166)

Insulin injection, biphasic (0831)

Metrifonate (1133)

The following texts are deleted as of 1 January 2021.

#### **MONOGRAPHS**

Carisoprodol (1689)

Meprobamate (0407)

Nalidixic acid (0701)

The following texts are deleted as of 1 July 2020.

## **GENERAL CHAPTERS**

2.6.24. Avian viral vaccines: tests for extraneous agents in seed lots

2.6.25. Avian live virus vaccines: tests for extraneous agents in batches of finished product

The following texts are deleted as of 1 April 2020.

## MONOGRAPHS

Herbal drugs and herbal drug preparations

Senna pods, Tinnevelly (0208)

## Monographs

Insulin, bovine (1637)