# CONTENTS OF SUPPLEMENT 10.5

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 July 2021 at the latest.

#### **GENERAL CHAPTERS**

2.4.33. Tetrabutylammonium in radiopharmaceutical preparations

5.18. Methods of pretreatment for preparing traditional Chinese drugs: general information

#### **MONOGRAPHS**

### Dosage forms

Intravesical preparations (2811)

Plasters, medicated (3032)

# Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

PSMA-1007 (18F) injection (3116)

### Herbal drugs and herbal drug preparations

Chaenomeles fruit (2713)

#### Monographs

Ethanolamine (2847)

Ibandronate sodium monohydrate (2771) Pemetrexed disodium 2.5-hydrate (3046)

Teriflunomide (3036) Ticagrelor tablets (3097)

# **REVISED TEXTS**

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

# GENERAL CHAPTERS

2.6.27. Microbiological examination of cell-based preparations

2.9.4. Dissolution test for patches

4. Reagents (new, revised, corrected)

5.22. Names of herbal drugs used in traditional Chinese medicine

# **MONOGRAPHS**

# General monographs

Vaccines for human use (0153)

# Dosage forms

Parenteral preparations (0520)

Patches (1011)

Preparations for inhalation (0671)

Semi-solid preparations for cutaneous application (0132)

# Vaccines for veterinary use

Avian infectious bronchitis vaccine (live) (0442) Canine parvovirosis vaccine (live) (0964) Equine herpesvirus vaccine (inactivated) (1613) Herbal drugs and herbal drug preparations

#### merbai drugs and nerbai drug preparations

Bilberry fruit, dried (1588) Bupleurum root (2562) Eucalyptus oil (0390)

Narrow-leaved coneflower root (1821)

Orientvine stem (2450)

Pale coneflower root (1822) Purple coneflower herb (1823)

Purple coneflower root (1824)

# Homoeopathic preparations

Anacardium for homoeopathic preparations (2094)

Magnesium phosphoricum for homoeopathic preparations (2505)

# Monographs

Alfacalcidol (1286)

Bacitracin (0465)

Bacitracin zinc (0466)

Betamethasone sodium phosphate (0810)

Calcium acetate (2128) Calcium stearate (0882)

Captopril (1079)

Castor oil, refined (2367)

Castor oil, virgin (0051)

Clomifone citrate (09)

Clomifene citrate (0997) Clotrimazole (0757)

Codeine phosphate sesquihydrate (0075)

Copper sulfate (0893) Dacarbazine (1691)

Dexamethasone sodium phosphate (0549)

Dihydrostreptomycin sulfate for veterinary use (0485)

Erythropoietin concentrated solution (1316)

Ferrous fumarate (0902)

Ferrous gluconate hydrate (0493) Fludarabine phosphate (1781) Gemcitabine hydrochloride (2306)

Gliclazide (1524) Glipizide (0906) Heparin calcium (0332)

Heparins, low-molecular-mass (0828) Kanamycin acid sulfate (0033) Kanamycin monosulfate (0032)

Lamivudine (2217)

Magnesium carbonate, heavy (0043)

Omeprazole (0942)

Paroxetine hydrochloride hemihydrate (2018)

Penicillamine (0566)

Phosphoric acid, concentrated (0004) Phosphoric acid, dilute (0005)

Ramipril (1368)

Ranitidine hydrochloride (0946)

Sodium bromide (0190) Somatostatin (0949) Sulindac (0864)

Titanium dioxide (0150) Zidovudine (1059) Zinc stearate (0306)

# **CORRECTED TEXTS**

The following texts have been corrected for Supplement 10.5 and specify 'corrected 10.5' above the title. These corrections are to be taken into account as soon as possible and not later than **28 February 2021** (the end of the month following the month of publication of Supplement 10.5).

**GENERAL CHAPTERS** 

2.2.2. Degree of coloration of liquids

2.8.24. Foam index

**MONOGRAPHS** 

Monographs

Ammonium bromide (1389)

Cefuroxime axetil (1300)

Codeine hydrochloride dihydrate (1412)

Codeine monohydrate (0076)

Codeine phosphate hemihydrate (0074)

Indapamide (1108)

Potassium bromide (0184)

# TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed in Supplement 10.5.

#### **GENERAL CHAPTERS**

2.9.4. Dissolution test for patches (previously 2.9.4. Dissolution test for transdermal patches)

# **MONOGRAPHS**

### Dosage forms

Patches (1011) (previously Patches, transdermal)

## Monographs

Ferrous gluconate hydrate (0493) (previously Ferrous gluconate)

# **DELETED TEXTS**

The following texts are deleted as of 1 July 2021.

# MONOGRAPHS

Cholecalciferol concentrate (water-dispersible form) (0598)

Theobromine (0298)

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)

# **ERRATA**

**Monograph on** *Erythromycin* (0179): the inclusion of a limit of  $\leq 1.0$  per cent for impurity M, published in the English print version of Supplement 10.4, was incorrect. This erratum concerns only the English print version of the monograph and not the online, downloadable, or French versions. The corrected text is included in the print version of Supplement 10.5.

**Monograph on** *Danaparoid sodium* (2090): the time from the addition of the chromogenic substrate after which the first measurement of the absorbance in the anti-factor IIa activity test is to be performed was erroneously deleted from the English version of the text published in Supplement 10.3. This erratum concerns the print version of the monograph only, since the online and downloadable versions have already been corrected. It does not concern the French versions of the monograph. The corrected text is included in the print version of Supplement 10.5.