CONTENTS OF SUPPLEMENT 9.7

A vertical line in the margin indicates where part of a text has been revised or corrected. A horizontal line in the margin indicates where part of a text has been deleted. However, these indications, which are not necessarily exhaustive, are given for information and do not form an official part of the texts. Editorial changes are not indicated.

Subscribers to the current version (printed or electronic) of the European Pharmacopoeia have access to an online archive version of all previous editions of the European Pharmacopoeia.

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 2019 at the latest.

GENERAL CHAPTERS

2.2.63. Direct amperometric and pulsed electrochemical detection
2.6.36. Microbiological examination of live biotherapeutic products: tests for enumeration of microbial contaminants
2.6.38. Microbiological examination of live biotherapeutic products: tests for specified micro-organisms

MONOGRAPHS

General monographs
Live biotherapeutic products for human use (3053)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations
Fluorodopa (18F) (prepared by nucleophilic substitution) injection (2481)
Yttrium (90Y) chloride solution for radiolabelling (2803)

Herbal drugs and herbal drug preparations
Achyranthes bidentata root (2999)
Corydalis rhizome (2976)
Ligusticum root and rhizome (2431)
Typhae pollen (2937)

Monographs
Atazanavir sulfate (2898)
Boldine (2971)
Deferiprone oral solution (2987)
Dexamfetamine sulfate (2752)
Esomeprazole sodium (2923)
Everolimus (2918)
Fingolimod hydrochloride (2988)
Lacosamide infusion (2991)
Lacosamide oral solution (2990)
Magnesium aluminometasilicate (2854)
Terpin monohydrate (2940)

REVISED TEXTS

The following texts have been technically revised since their last publication. They will be implemented on 1 April 2019.

GENERAL CHAPTERS

2.2.24. Absorption spectrophotometry, infrared
2.4.29. Composition of fatty acids in oils rich in omega-3 acids
2.9.23. Gas pycnometric density of solids
2.9.31. Particle size analysis by laser light diffraction
2.9.33. Characterisation of crystalline and partially crystalline solids by X-ray powder diffraction (XRPD)
2.9.34. Bulk density and tapped density of powders
2.9.35. Powder fineness
2.9.39. Water-solid interactions: determination of sorption-desorption isotherms and of water activity

4. Reagents
5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use
5.1.8. Microbiological quality of herbal medicinal products for oral use and extracts used in their preparation
5.8. Pharmacopoeial harmonisation
5.14. Gene transfer medicinal products for human use
5.22. Names of herbal medicinal products used in traditional Chinese medicine
5.23. Monographs on herbal drug extracts (information chapter)

MONOGRAPHS

General monographs
Herbal drug extracts (0765)
Pharmaceutical preparations (2619)
Recombinant DNA technology, products of (0784)

Herbal drugs and herbal drug preparations
Atractylodes lancea rhizome (2559)
Atractylodes rhizome, largehead (2560)
Fresh bilberry fruit dry extract, refined and standardised (2394)
Kudzuvine root (2434)
Peppermint oil (0405)
Saw palmetto fruit (1848)
Thomson kudzuvine root (2483)
Monographs
Acetone (0872)
Alfentanil hydrochloride hydrate (1062)
Amefetamine sulfate (0368)
Amiloride hydrochloride dihydrate (0651)
Amorolfine hydrochloride (2756)
Betacarotene (1069)
Calcium folinate hydrate (0978)
Calcium levofolinate hydrate (1606)
Castor oil, refined (2367)
Cefazolin sodium (0988)
Cellulose acetate (0887)
Chloramphenicol (0071)
Closantel sodium dihydrate for veterinary use (1716)
Dipotassium clorazepate monohydrate (0898)
Entecavir monohydrate (2815)
Ergocalciferol (0082)
Ethylcellulose (0822)
Fibrin sealant kit (0903)
Glipizide (0906)
Griseofulvin (0182)
Human haematopoietic stem cells (2323)
Indometacin (0092)
Miconazole (0935)
Miconazole nitrate (0513)
Mupirocin (1450)
Mupirocin calcium (1451)
Nicergoline (1998)
Norfloxacin (1248)
Nortripyline hydrochloride (0941)
Poloxamers (1464)
Polymyxin B sulfate (0203)
Proguanil hydrochloride (2002)
Pyrimethamine (0288)
Saccharin (0947)
Saccharin sodium (0787)
Sertraline hydrochloride (1705)
Simvastatin (1563)
Sodium molybdate dihydrate (1565)
Telmisartan (2154)
Temozolomide (2780)
CORRECTED TEXTS
The following texts have been corrected for Supplement 9.7 and specify 'corrected 9.7' above the title. These corrections are to be taken into account as soon as possible and not later than 30 November 2018 (the end of the month following the month of publication of Supplement 9.7).

GENERAL CHAPTERS
2.7.2. Microbiological assay of antibiotics

MONOGRAPHS
Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations
Choline ([11C]methyl) injection (2462)
Fluorocholine ([18F] injection (2793)

CORRECTED TEXTS

HARMONISED TEXTS
The following texts have undergone pharmacopoeial harmonisation (see chapter 5.8. Pharmacopoeial harmonisation).

GENERAL CHAPTERS
2.9.23. Gas pycnometric density of solids
2.9.31. Particle size analysis by laser light diffraction
2.9.33. Characterisation of crystalline and partially crystalline solids by X-ray powder diffraction (XRPD)
2.9.34. Bulk density and tapped density of powders
2.9.35. Powder fineness
2.9.39. Water-solid interactions: determination of sorption-desorption isotherms and of water activity

HARMONISED TEXTS

The following texts have been deleted from the work programme of the Pharmacopoeial Discussion Group.

MONOGRAPHS
Cellulose acetate (0887)
Saccharin (0947)
Saccharin sodium (0787)

TEXTS WHOSE TITLE HAS CHANGED
The titles of the following texts have been changed in Supplement 9.7.

MONOGRAPHS
Alfentanil hydrochloride hydrate (1062) (previously Alfentanil hydrochloride)
Calcium folinate hydrate (0978) (previously Calcium folinate)
Calcium levofolinate hydrate (1606) (previously Calcium levofolinate pentahydrate)
Dipotassium clorazepate monohydrate (0898) (previously Dipotassium clorazepate)

DELETED TEXTS

The following texts are deleted as of 1 April 2019.

MONOGRAPHS
Monographs
Chlorpropamide (1087)
Oxrenolol hydrochloride (0628)
Water, highly purified (1927)

The following texts are deleted as of 1 January 2019.

GENERAL CHAPTERS
2.6.9. Abnormal toxicity

MONOGRAPHS
Monographs
Desoxycortone acetate (0322)
Emetine hydrochloride pentahydrate (0081)
Phytomenadione (1036)

The following texts are deleted as of 1 January 2018.

MONOGRAPHS
Vaccines for human use
Cholera vaccine (0154)
Cholera vaccine, freeze-dried (0155)
Typhoid vaccine, freeze-dried (0157)

The following text is deleted as of 1 July 2017.

GENERAL CHAPTERS
2.6.19. Test for neurovirulence of poliomyelitis vaccine (oral)

The following text is deleted as of 1 April 2017.

GENERAL CHAPTERS
2.2.60. Melting point - instrumental method