

# 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.

Individual copies of texts will not be supplied.

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 (<sup>18</sup>F) (prepared by nucleophilic substitution) injection (2481)

Yttrium (<sup>90</sup>Y) 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
- 2.7.14. Assay of hepatitis A vaccine
- 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 drugs 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)	Human haematopoietic stem cells (2323)
Alfentanil hydrochloride hydrate (1062)	Indometacin (0092)
Amfetamine sulfate (0368)	Miconazole (0935)
Amiloride hydrochloride dihydrate (0651)	Miconazole nitrate (0513)
Amorolfine hydrochloride (2756)	Mupirocin (1450)
Betacarotene (1069)	Mupirocin calcium (1451)
Calcium folinate hydrate (0978)	Nicergoline (1998)
Calcium levofolate hydrate (1606)	Norfloxacin (1248)
Castor oil, refined (2367)	Nortriptyline hydrochloride (0941)
Cefazolin sodium (0988)	Poloxamers (1464)
Cellulose acetate (0887)	Polymyxin B sulfate (0203)
Chloramphenicol (0071)	Proguanil hydrochloride (2002)
Closantel sodium dihydrate for veterinary use (1716)	Pyrimethamine (0288)
Dipotassium clorazepate monohydrate (0898)	Saccharin (0947)
Dosulepin hydrochloride (1314)	Saccharin sodium (0787)
Entecavir monohydrate (2815)	Sertraline hydrochloride (1705)
Ergocalciferol (0082)	Simvastatin (1563)
Ethylcellulose (0822)	Sodium molybdate dihydrate (1565)
Fibrin sealant kit (0903)	Telmisartan (2154)
Glipizide (0906)	Temozolomide (2780)
Griseofulvin (0182)	

**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 ( $[^{14}\text{C}]$ methyl) injection (2462)

Fluorocholine ( $^{18}\text{F}$ ) injection (2793)

**Monographs**

Crospovidone (0892)

Paclitaxel (1794)

Phloroglucinol (2301)

Phloroglucinol dihydrate (2302)

**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

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

**MONOGRAPHS****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****Monographs**

Alfentanil hydrochloride hydrate (1062) (previously *Alfentanil hydrochloride*)

Calcium folinate hydrate (0978) (*previously Calcium folinate*)  
Calcium levofolate hydrate (1606) (*previously Calcium levofolate pentahydrate*)  
Dipotassium clorazepate monohydrate (0898) (*previously Dipotassium clorazepate*)

## DELETED TEXTS

*The following texts are deleted as of 1 April 2019.*

### MONOGRAPHS

#### Monographs

Chlorpropamide (1087)  
Oxprenolol 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