

# CONTENTS OF SUPPLEMENT 10.3

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 January 2021** at the latest.

### GENERAL CHAPTERS

- 2.6.32. Test for bacterial endotoxins using recombinant factor C
- 5.1.12. Depyrogenation of items used in the production of parenteral preparations
- 5.17.2. Recommendations on testing of particulate contamination: visible particles

### MONOGRAPHS

#### Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

- Betiotide for radiopharmaceutical preparations (2551)
- Gallium (<sup>68</sup>Ga) chloride (accelerator-produced) solution for radiolabelling (3109)

### Herbal drugs and herbal drug preparations

- Cyathula root (2998)
- Ganoderma (3001)

### Monographs

- Amprolium hydrochloride for veterinary use (3010)
- Deferasirox (2933)
- Dronedarone tablets (3038)
- Latanoprost (2230)
- DL-Lysine acetylsalicylate (2812)
- Rivaroxaban (2932)
- Trifluridine (2910)

## REVISED TEXTS

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

### GENERAL CHAPTERS

- 2.2.2. Degree of coloration of liquids
- 2.2.24. Absorption spectrophotometry, infrared
- 2.2.29. Liquid chromatography
- 2.2.38. Conductivity
- 2.2.49. Falling ball and automatic rolling ball viscometer methods
- 2.6.12. Microbiological examination of non-sterile products: microbial enumeration tests
- 2.6.13. Microbiological examination of non-sterile products: test for specified micro-organisms
- 2.6.27. Microbiological examination of cell-based preparations
- 2.7.14. Assay of hepatitis A vaccine
- 2.9.19. Particulate contamination: sub-visible particles
- 3.3.4. Sterile plastic containers for human blood and blood components
- 3.3.8. Sterile single-use plastic syringes
- 4. Reagents (*new, revised, corrected*)
- 5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use

- 5.1.5. Application of the *F* concepts to heat sterilisation processes
- 5.1.10. Guidelines for using the test for bacterial endotoxins
- 5.22. Names of herbal drugs used in traditional Chinese medicine

### MONOGRAPHS

#### General monographs

- Substances for pharmaceutical use (2034)

#### Dosage forms

- Nasal preparations (0676)
- Oromucosal preparations (1807)

#### Vaccines for human use

- Diphtheria and tetanus vaccine (adsorbed) (0444)
- Diphtheria and tetanus vaccine (adsorbed, reduced antigen(s) content) (0647)
- Diphtheria, tetanus and hepatitis B (rDNA) vaccine (adsorbed) (2062)
- Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) (1931)
- Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) (2764)

- Diphtheria, tetanus and pertussis (whole cell) vaccine (adsorbed) (0445)  
Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (2328)  
Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed) (1932)  
Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) (1933)  
Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed) (1934)  
Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (2329)  
Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2067)  
Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2065)  
Diphtheria, tetanus, pertussis (whole cell) and poliomyelitis (inactivated) vaccine (adsorbed) (2061)  
Diphtheria, tetanus, pertussis (whole cell), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2066)  
Tetanus vaccine (adsorbed) (0452)
- Vaccines for veterinary use**  
Tetanus vaccine for veterinary use (0697)
- Herbal drugs and herbal drug preparations**  
Belamcanda chinensis rhizome (2561)  
Caraway fruit (1080)  
Clove (0376)  
Hawthorn leaf and flower (1432)  
Hawthorn leaf and flower dry extract (1865)  
Hawthorn leaf and flower liquid extract (1864)  
Lime flower (0957)  
Lovage root (1233)  
Opium dry extract, standardised (1839)  
Passionflower herb (1459)  
Passionflower herb dry extract (1882)
- Homoeopathic preparations**  
Homoeopathic preparations (1038)  
Pillules for homoeopathic preparations (2153)
- Monographs**  
Acamprosate calcium (1585)  
Acetylcysteine (0967)  
Adrenaline (2303)  
Ascorbyl palmitate (0807)  
Bambuterol hydrochloride (1293)  
Betamethasone (0312)  
Betamethasone acetate (0975)  
Betamethasone dipropionate (0809)  
Bleomycin sulfate (0976)  
Borax (0013)  
Calcium carbonate (0014)  
Calcium chloride dihydrate (0015)  
Calcium sulfate dihydrate (0982)  
Celiprolol hydrochloride (1632)  
Cetostearyl alcohol (0702)  
Codeine monohydrate (0076)  
Codeine phosphate hemihydrate (0074)  
Cod-liver oil, farmed (2398)  
Cyanocobalamin (0547)  
Danaparoid sodium (2090)  
Deferiprone oral solution (2987)  
Deferiprone tablets (2986)  
Dexamethasone (0388)  
Dexamethasone acetate (0548)  
Dipotassium phosphate (1003)  
Disodium phosphate (1509)  
Disodium phosphate dihydrate (0602)  
Disodium phosphate dodecahydrate (0118)  
Epinastine hydrochloride (2411)  
Epirubicin hydrochloride (1590)  
Ergotamine tartrate (0224)  
Etanercept (2895)  
Everolimus (2918)  
Fluoxetine hydrochloride (1104)  
Human coagulation factor IX (rDNA) concentrated solution (2522)  
Human coagulation factor IX (rDNA) powder for solution for injection (2994)  
Infliximab concentrated solution (2928)  
Isoconazole (1018)  
Isoconazole nitrate (1017)  
Ketoconazole (0921)  
Labetalol hydrochloride (0923)  
Lacosamide infusion (2991)  
Lacosamide oral solution (2990)  
Lacosamide tablets (2989)  
Lactose (1061)  
Lactose monohydrate (0187)  
Letrozole (2334)  
Magnesium chloride hexahydrate (0402)  
Magnesium hydroxide (0039)  
Magnesium oxide, heavy (0041)  
Magnesium oxide, light (0040)  
Magnesium sulfate heptahydrate (0044)  
Mexiletine hydrochloride (1029)  
Minocycline hydrochloride dihydrate (1030)  
Moxifloxacin hydrochloride (2254)  
Mupirocin (1450)  
Mupirocin calcium (1451)  
Mycophenolate sodium (2813)  
Ofloxacin (1455)  
Omega-3-acid triglycerides (1352)  
Pentobarbital (0200)  
Pentobarbital sodium (0419)  
Potassium chloride (0185)  
Potassium clavulanate (1140)  
Potassium clavulanate, diluted (1653)  
Prednisolone acetate (0734)  
Prednisone (0354)  
Primidone (0584)  
Raltegravir chewable tablets (2939)  
Raltegravir tablets (2938)  
Rosuvastatin tablets (3008)  
Salmon oil, farmed (1910)  
Silver, colloidal (2281)  
Sitagliptin tablets (2927)  
Sodium acetate trihydrate (0411)  
Sodium carbonate (0773)  
Sodium carbonate decahydrate (0191)  
Sodium carbonate monohydrate (0192)  
Sodium dihydrogen phosphate dihydrate (0194)

Sodium hydrogen carbonate (0195)	Sulfuric acid (1572)
Sodium laurilsulfate (0098)	Tramadol hydrochloride (1681)
Sodium metabisulfite (0849)	Tramazoline hydrochloride monohydrate (1597)
Solutions for organ preservation (1264)	Vitamin A concentrate (oily form), synthetic (0219)
Sotalol hydrochloride (2004)	Wheat starch (0359)
Streptomycin sulfate (0053)	Wool alcohols (0593)
Sulfobutylbetadex sodium (2804)	Zinc acexamate (1279)
Sulfur (0953)	

## CORRECTED TEXTS

*The following texts have been corrected for Supplement 10.3 and specify 'corrected 10.3' above the title. These corrections are to be taken into account as soon as possible and not later than 31 August 2020 (the end of the month following the month of publication of Supplement 10.3).*

### GENERAL CHAPTERS

- 2.2.39. Molecular mass distribution in dextrans  
2.6.37. Principles for the detection of extraneous viruses in immunological veterinary medicinal products using culture methods

### MONOGRAPHS

#### Herbal drugs and herbal drug preparations

Chinese goldthread rhizome (2715)

#### Monographs

- Alfentanil hydrochloride hydrate (1062)  
Amphotericin B (1292)  
Azathioprine (0369)  
Bacitracin zinc (0466)  
Colistimethate sodium (0319)  
Colistin sulfate (0320)  
Copovidone (0891)  
Cyclizine hydrochloride (1092)  
Dimethyl sulfoxide (0763)  
Ergometrine maleate (0223)  
Fingolimod hydrochloride (2988)  
Fluphenazine enantate (1015)

- Galantamine hydrobromide (2366)  
Gentamicin sulfate (0331)  
Glycine (0614)  
Indapamide (1108)  
Josamycin (1983)  
Josamycin propionate (1982)  
Lactitol monohydrate (1337)  
Levocabastine hydrochloride (1484)  
Neomycin sulfate (0197)  
Nevirapine hemihydrate (2479)  
Paclitaxel (1794)  
Phenylephrine (1035)  
Phenylephrine hydrochloride (0632)  
Pimobendan for veterinary use (2179)  
Polymyxin B sulfate (0203)  
Raltegravir potassium (2887)  
Rifamycin sodium (0432)  
Rivastigmine (2629)  
Spiramycin (0293)  
Stanozolol (1568)  
Tilidine hydrochloride hemihydrate (1767)

## TEXTS WHOSE TITLE HAS CHANGED

*The titles of the following texts have been changed in Supplement 10.3.*

### GENERAL CHAPTERS

- 5.1.5. Application of the *F* concepts to heat sterilisation processes (*previously Application of the  $F_0$  concept to steam sterilisation of aqueous preparations*)

**MONOGRAPHS****Herbal drugs and herbal drug preparations**

Hawthorn leaf and flower liquid extract (1864) (*previously Hawthorn leaf and flower liquid extract, quantified*)

Passionflower herb (1459) (*previously Passion flower*)

Passionflower herb dry extract (1882) (*previously Passion flower dry extract*)

**Monographs**

Silver, colloidal (2281) (*previously Silver, colloidal, for external use*)

Sulfur (0953) (*previously Sulfur for external use*)

**DELETED TEXTS**

*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, Tinnevely (0208)

**Monographs**

Insulin, bovine (1637)