

CONTENTS OF SUPPLEMENT 9.3

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 January 2018** at the latest.

GENERAL CHAPTERS

- 5.2.14. Substitution of *in vivo* method(s) by *in vitro* method(s) for the quality control of vaccines
5.24. Chemical imaging

MONOGRAPHS

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Sodium pertechnetate (^{99m}Tc) injection (accelerator-produced) (2891)

Herbal drugs and herbal drug preparations

Magnolia biondii flower bud (2742)

Homoeopathic preparations

Ammonium carbonicum for homoeopathic preparations (2916)

Monographs

Acetylene intermix (1 per cent) in nitrogen (2903)
Carbon monoxide intermix (5 per cent) in nitrogen (2904)
Human coagulation factor IX (rDNA) powder for solution for injection (2994)
Methane intermix (2 per cent) in nitrogen (2905)
Nicardipine hydrochloride (2776)
Rupatadine fumarate (2888)
Tacrolimus monohydrate (2244)
Tylosin phosphate for veterinary use (2802)

REVISED TEXTS

The following texts have been technically revised since their last publication. They will be implemented on **1 January 2018** unless otherwise indicated by a footnote.

GENERAL CHAPTERS

- 2.1.6. Gas detector tubes
2.2.37. X-ray fluorescence spectrometry
2.2.49. Falling ball and automatic rolling ball viscometer methods
2.4.20. Determination of elemental impurities
2.6.14. Bacterial endotoxins
2.6.16. Tests for extraneous agents in viral vaccines for human use
2.6.17. Test for anticomplementary activity of immunoglobulin
2.7.9. Test for Fc function of immunoglobulin
4. Reagents (*new, revised, corrected*)
5.2.3. Cell substrates for the production of vaccines for human use
5.8. Pharmacopoeial harmonisation
5.20. Elemental impurities
5.22. Names of herbal drugs used in traditional Chinese medicine

MONOGRAPHS

General monographs

Pharmaceutical preparations (2619)
Substances for pharmaceutical use (2034)

Dosage forms

Capsules (0016)
Chewing gums, medicated (1239)
Intraruminal delivery systems (1228)
Liquid preparations for oral use (0672)
Oromucosal preparations (1807)
Tablets (0478)
Veterinary liquid preparations for cutaneous application (1808)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Pentetate sodium calcium for radiopharmaceutical preparations (2353)

Herbal drugs and herbal drug preparations

Angelica dahurica root (2556)
Angelica pubescens root (2557)
Barbary wolfberry fruit (2612)
Clematis armandii stem (2463)
Uncaria stem with hooks (2729)

Monographs

Aceclofenac (1281)
Aluminium magnesium silicate (1388)
Alverine citrate (2156)
Aspartic acid (0797)

Azithromycin (1649)	Lactulose (1230)
Betamethasone dipropionate (0809)	Magnesium aspartate dihydrate (1445)
Ceftazidime pentahydrate (1405)	Naloxone hydrochloride dihydrate (0729)
Ceftazidime pentahydrate with sodium carbonate for injection (2344)	Nortriptyline hydrochloride (0941)
Chlorhexidine diacetate (0657)	Olive oil, refined (1456)
Chlorhexidine digluconate solution (0658)	Olive oil, virgin (0518)
Chlorhexidine dihydrochloride (0659)	Prednisone (0354)
Clindamycin hydrochloride (0582)	Soya-bean oil, refined (1473)
Deferoxamine mesilate (0896)	Tiotropium bromide monohydrate (2420)
Erythromycin ethylsuccinate (0274) ⁽¹⁾	Tylosin for veterinary use (1273)
Gefitinib (2866)	Tylosin phosphate bulk solution for veterinary use (1661)
Heparin calcium (0332)	Tylosin tartrate for veterinary use (1274)
Heparin sodium (0333)	Vindesine sulfate (1276)
Human coagulation factor IX (rDNA) concentrated solution (2522)	Vitamin A concentrate (oily form), synthetic (0219)
Hydroxyethylcellulose (0336)	Vitamin A concentrate (powder form), synthetic (0218)
Lactose (1061)	Vitamin A concentrate (solubilisate/emulsion), synthetic (0220)
Lactose monohydrate (0187)	

CORRECTED TEXTS

The following texts have been corrected for Supplement 9.3 and specify 'corrected 9.3' above the title. These corrections are to be taken into account as soon as possible and not later than 31 August 2017 (the end of the month following the month of publication of Supplement 9.3).

GENERAL CHAPTERS

- 2.2.56. Amino acid analysis
- 2.7.2. Microbiological assay of antibiotics

MONOGRAPHS

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

- Fluoroethyl-L-tyrosine (¹⁸F) injection (2466)
- Lutetium (¹⁷⁷Lu) solution for radiolabelling (2798)

Herbal drugs and herbal drug preparations

- Andrographis herb (2712)
- Codonopsis root (2714)
- Kudzuvine root (2434)
- Magnolia officinalis flower (2568)
- Thomson kudzuvine root (2483)

Homoeopathic preparations

- Ignatia for homoeopathic preparations (2513)
- Nux-vomica for homoeopathic preparations (2514)

Monographs

- Alfadex (1487)
- Anastrozole (2406)
- Ascorbic acid (0253)
- Atropine (2056)
- Atropine sulfate (0068)
- Betadex (1070)
- Citalopram hydrobromide (2288)
- Citalopram hydrochloride (2203)
- Clemastine fumarate (1190)

- Copovidone (0891)
- Esketamine hydrochloride (1742)
- Filgrastim concentrated solution (2206)
- Gadobutrol monohydrate (2735)
- Gelatin (0330)
- Hydroxychloroquine sulfate (2849)
- Insulin, bovine (1637)
- Insulin, porcine (1638)
- Irinotecan hydrochloride trihydrate (2675)
- Lactitol monohydrate (1337)
- Lansoprazole (2219)
- Levocabastine hydrochloride (1484)
- Nevirapine (2255)
- Nicotinic acid (0459)
- Noradrenaline hydrochloride (0732)
- Noradrenaline tartrate (0285)
- Norfloxacin (1248)
- Poly(vinyl acetate) (1962)
- Poly(vinyl acetate) dispersion 30 per cent (2152)
- Poly(vinyl alcohol) (1961)
- Primidone (0584)
- Solifenacin succinate (2779)
- Thiocolchicoside crystallised from ethanol (2896)
- Thiocolchicoside hydrate (2814)
- Trimebutine maleate (2182)
- Troxerutin (2133)
- Valaciclovir hydrochloride (1768)
- Valaciclovir hydrochloride, hydrated (2751)

(1) This text was implemented on 1 May 2017.

HARMONISED TEXTS

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

GENERAL CHAPTERS

2.6.14. Bacterial endotoxins

MONOGRAPHS

Monographs

Hydroxyethylcellulose (0336)

Lactose (1061)

Lactose monohydrate (0187)

TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed in Supplement 9.3.

GENERAL CHAPTERS

2.2.49. Falling ball and automatic rolling ball viscometer methods (*previously Falling ball viscometer method*)

2.4.20. Determination of elemental impurities (*previously Determination of metal catalyst or metal reagent residues*)

5.20. Elemental impurities (*previously Metal catalyst or metal reagent residues*)

MONOGRAPHS

Dosage forms

Intraruminal delivery systems (1228) (*previously Intraruminal devices*)

DELETED TEXTS

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