

# CONTENTS OF SUPPLEMENT 9.6

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 2019** at the latest.

### MONOGRAPHS

#### Herbal drugs and herbal drug preparations

Gastrodia rhizome (2721)

Lightyellow sophora root (2440)

#### Homoeopathic preparations

Digitalis for homoeopathic preparations (2705)

#### Monographs

Haemofiltration and haemodiafiltration, concentrated solutions for (2770)

Imidacloprid for veterinary use (2924)

Infliximab concentrated solution (2928)

Phenoxymethylpenicillin (benzathine) tetrahydrate (2636)

Phytomenadione, racemic (3011)

Podophyllotoxin (2750)

Rotigotine (3014)

Sulfobutylbetadex sodium (2804)

Zoledronic acid monohydrate (2743)

## REVISED TEXTS

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

### GENERAL CHAPTERS

2.2.9. Capillary viscometer method

2.2.17. Drop point

2.2.28. Gas chromatography

2.2.29. Liquid chromatography

2.2.30. Size-exclusion chromatography

2.2.38. Conductivity

2.3.2. Identification of fatty oils by thin-layer chromatography

2.8.13. Pesticide residues

3.1.1.1. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components

3.1.1.2. Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components

3.1.13. Plastic additives

3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion

3.2.1. Glass containers for pharmaceutical use

3.2.3. Sterile plastic containers for human blood and blood components

3.2.4. Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components

3.2.5. Sterile containers of plasticised poly(vinyl chloride) for human blood containing anticoagulant solution

4. Reagents (*new, revised, corrected*)

5.8. Pharmacopoeial harmonisation

5.22. Names of herbal drugs used in traditional Chinese medicine

### MONOGRAPHS

#### General monographs

Allergen products (1063)

Immunosera for human use, animal (0084)

Products of fermentation (1468)<sup>(1)</sup>

#### Dosage forms

Granules (0499)

Pressurised pharmaceutical preparations (0523)

Sticks (1154)

#### Vaccines for human use

Anthrax vaccine for human use (adsorbed, prepared from culture filtrates) (2188)

Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed) (1932)

Haemophilus type b conjugate vaccine (1219)

Hepatitis A (inactivated, adsorbed) and typhoid polysaccharide vaccine (2597)

Hepatitis A (inactivated) and hepatitis B (rDNA) vaccine (adsorbed) (1526)

(1) This text was implemented on 1 April 2018.

- Hepatitis A vaccine (inactivated, adsorbed) (1107)  
 Hepatitis A vaccine (inactivated, virosome) (1935)  
 Hepatitis B vaccine (rDNA) (1056)  
 Human papillomavirus vaccine (rDNA) (2441)  
 Influenza vaccine (split virion, inactivated) (0158)  
 Influenza vaccine (surface antigen, inactivated) (0869)  
 Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) (2149)  
 Influenza vaccine (surface antigen, inactivated, virosome) (2053)  
 Influenza vaccine (whole virion, inactivated) (0159)  
 Influenza vaccine (whole virion, inactivated, prepared in cell cultures) (2308)  
 Measles, mumps and rubella vaccine (live) (1057)  
 Measles, mumps, rubella and varicella vaccine (live) (2442)  
 Measles vaccine (live) (0213)  
 Meningococcal group C conjugate vaccine (2112)  
 Meningococcal polysaccharide vaccine (0250)  
 Mumps vaccine (live) (0538)  
 Pneumococcal polysaccharide conjugate vaccine (adsorbed) (2150)  
 Pneumococcal polysaccharide vaccine (0966)  
 Poliomyelitis vaccine (inactivated) (0214)  
 Rabies vaccine for human use prepared in cell cultures (0216)  
 Rubella vaccine (live) (0162)  
 Shingles (herpes zoster) vaccine (live) (2418)  
 Smallpox vaccine (live) (0164)  
 Tick-borne encephalitis vaccine (inactivated) (1375)  
 Typhoid polysaccharide vaccine (1160)  
 Typhoid vaccine (0156)  
 Varicella vaccine (live) (0648)  
 Yellow fever vaccine (live) (0537)
- Herbal drugs and herbal drug preparations**
- Akebia stem (2472)  
 Bilberry fruit, dried (1588)  
 Bilberry fruit, fresh (1602)  
 Fenugreek (1323)  
 Garlic powder (1216)  
 Isatis root (2566)  
 Milk thistle dry extract, refined and standardised (2071)  
 White horehound (1835)
- Monographs**
- Amikacin sulfate (1290)  
 Amisulpride (1490)  
 Ammonio methacrylate copolymer (type A) (2081)  
 Ammonio methacrylate copolymer (type B) (2082)  
 Aprotinin (0580)  
 Aprotinin concentrated solution (0579)  
 Arachis oil, hydrogenated (1171)  
 Arachis oil, refined (0263)  
 Benzylpenicillin (benzathine) tetrahydrate (0373)  
 Botulinum toxin type A for injection (2113)  
 Botulinum toxin type B for injection (2581)  
 Calcifediol monohydrate (1295)  
 Calcipotriol (2011)  
 Calcipotriol monohydrate (2284)  
 Calcium hydrogen phosphate (0981)  
 Cellulose, microcrystalline (0316)  
 Chlorobutanol (0382)  
 Chlorobutanol hemihydrate (0383)  
 Cholecalciferol concentrate (oily form) (0575)  
 Cinchocaine hydrochloride (1088)  
 Colistin sulfate (0320)  
 Cystine (0998)  
 Cytarabine (0760)  
 Dihydrostreptomycin sulfate for veterinary use (0485)  
 Dihydrotachysterol (2014)  
 Disodium phosphate dodecahydrate (0118)  
 Ebastine (2015)  
 Erythropoietin concentrated solution (1316)  
 Ethosuximide (0764)  
 Glycerol (0496)  
 Glycerol (85 per cent) (0497)  
 Granisetron hydrochloride (1695)  
 Griseofulvin (0182)  
 Haemodialysis, solutions for (0128)  
 Haemofiltration and haemodiafiltration, solutions for (0861)  
 Hypromellose (0348)  
 Kanamycin acid sulfate (0033)  
 Kanamycin monosulfate (0032)  
 Levocarnitine (1339)  
 Lidocaine hydrochloride monohydrate (0227)  
 Mepivacaine hydrochloride (1242)  
 Methacrylic acid - ethyl acrylate copolymer (1:1) (1128)  
 Methylcellulose (0345)  
 Nystatin (0517)  
 Pantoprazole sodium sesquihydrate (2296)  
 Pentobarbital (0200)  
 Pentobarbital sodium (0419)  
 Peritoneal dialysis, solutions for (0862)  
 Phenytoin (1253)  
 Phenytoin sodium (0521)  
 Potassium sulfate (1622)  
 Primaquine diphosphate (0635)  
 Protamine sulfate (0569)  
 Rifamycin sodium (0432)  
 Ropinirole hydrochloride (2604)  
 Sodium sulfate, anhydrous (0099)  
 Sodium sulfate decahydrate (0100)  
 Starches, hydroxyethyl (1785)  
 Streptokinase concentrated solution (0356)  
 Streptomycin sulfate (0053)  
 Tigecycline (2825)

## CORRECTED TEXTS

The following texts have been corrected for Supplement 9.6 and specify 'corrected 9.6' above the title. These corrections are to be taken into account as soon as possible and not later than **31 August 2018** (the end of the month following the month of publication of Supplement 9.6).

### GENERAL CHAPTERS

2.4.20. Determination of elemental impurities

5.24. Chemical imaging

### MONOGRAPHS

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

Gallium (<sup>68</sup>Ga) edotreotide injection (2482)

#### Herbal drugs and herbal drug preparations

Devil's claw root (1095)

Evodia fruit (2718)

Platycodon root (2660)

#### Monographs

Albendazole (1386)

Azithromycin (1649)

Bacitracin (0465)

Bacitracin zinc (0466)

Dextrin (1507)

Follitropin (2285)

Follitropin concentrated solution (2286)

Galantamine hydrobromide (2366)

Goserelin (1636)

Guaifenesin (0615)

Hyoscine butylbromide (0737)

Ibuprofen (0721)

Imatinib mesilate (2736)

Ipratropium bromide (0919)

Mesalazine (1699)

Milbemycin oxime for veterinary use (2536)

Quetiapine fumarate (2541)

Ranitidine hydrochloride (0946)

## HARMONISED TEXTS

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

### GENERAL CHAPTERS

2.2.38. Conductivity

### MONOGRAPHS

#### Monographs

Calcium hydrogen phosphate (0981)

## TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed in Supplement 9.6.

### MONOGRAPHS

#### Monographs

Benzylpenicillin (benzathine) tetrahydrate (0373) (previously *Benzylpenicillin, benzathine*)

Calcifediol monohydrate (1295) (previously *Calcifediol*)

Lidocaine hydrochloride monohydrate (0227) (previously *Lidocaine hydrochloride*)

## DELETED TEXTS

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