

CONTENTS OF SUPPLEMENT 10.6

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 2022 at the latest.

GENERAL CHAPTERS

- 2.1.7. Balances for analytical purposes
- 2.5.42. *N*-Nitrosamines in active substances
- 2.8.26. Contaminant pyrrolizidine alkaloids
- 2.9.53. Particulate contamination: sub-visible particles in non-injectable liquid preparations

MONOGRAPHS

Vaccines for veterinary use

Vibriosis vaccine (inactivated) for sea bass (3090)

Herbal drugs and herbal drug preparations

Scrophularia root (2973)

Thunberg fritillary bulb (2588)

Homoeopathic preparations

Sanguinaria for homoeopathic preparations (2687)

Toxicodendron quercifolium for homoeopathic preparations (2519)

Monographs

Fluticasone furoate (2768)

Methylaminolevulinate hydrochloride (3073)

Phenoxybenzamine hydrochloride (2983)

Trazodone hydrochloride (2857)

REVISED TEXTS

The following texts have been technically revised since their last publication. They will be implemented on 1 January 2022 at the latest.

GENERAL CHAPTERS

- 1. General notices
- 2.4.29. Composition of fatty acids in oils rich in omega-3 acids
- 2.8.13. Pesticide residues
- 2.9.1. Disintegration of tablets and capsules
- 2.9.27. Uniformity and accuracy of delivered doses from multidose containers
- 2.9.33. Characterisation of crystalline and partially crystalline solids by X-ray powder diffraction (XRPD)
- 3.2.2. Plastic containers and closures for pharmaceutical use
- 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)

Vaccines for veterinary use (0062)

Dosage forms

Ear preparations (0652)

Eye preparations (1163)

Foams, medicated (1105)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Gallium (⁶⁸Ga) edotreotide injection (2482)

Pentetate sodium calcium hydrate for radiopharmaceutical preparations (2353)

Herbal drugs and herbal drug preparations

Atractylodes lancea rhizome (2559)

Ganoderma (3001)

Milk thistle dry extract, refined and standardised (2071)

Milk thistle fruit (1860)

Nettle root (2538)

Olive leaf (1878)

Monographs

Aluminium stearate (1663)

Aprotinin concentrated solution (0579)

Benzoyl peroxide, hydrous (0704)

Bisacodyl (0595)

Bumetanide (1076)

Butyl parahydroxybenzoate (0881)

Calcium carbonate (0014)

Calcium gluconate (0172)

Calcium gluconate, anhydrous (2364)	Nitrofurural (1135)
Calcium hydrogen phosphate (0981)	Olmesartan medoxomil (2600) ⁽¹⁾
Calcium hydrogen phosphate dihydrate (0116)	Oxybutynin hydrochloride (1354)
Calcium hydroxide (1078)	<i>all-rac</i> -Phytomenadione (3011)
Calcium phosphate (1052)	Potassium metabisulfite (2075)
Candesartan cilexetil (2573) ⁽¹⁾	Povidone (0685)
Carboplatin (1081)	Pravastatin sodium (2059)
Cellulose acetate phthalate (0314)	Propyl parahydroxybenzoate (0431)
Chenodeoxycholic acid (1189)	Raltegravir chewable tablets (2939)
Cholecalciferol concentrate (oily form) (0575)	Raltegravir tablets (2938)
Cholesterol for parenteral use (2397)	Regorafenib tablets (3023)
Copper sulfate pentahydrate (0894)	Riociguat tablets (3079)
Croscarmellose sodium (0985)	Rivaroxaban tablets (3021)
Crospovidone (0892)	Rosuvastatin calcium (2631)
Dapsone (0077)	Rosuvastatin tablets (3008)
Deferiprone tablets (2986)	Salbutamol sulfate (0687)
Dimetindene maleate (1417)	Sertaconazole nitrate (1148)
Dipotassium clorazepate monohydrate (0898)	Sitagliptin tablets (2927)
Dronedarone tablets (3038)	Sodium calcium edetate (0231)
Etacrynic acid (0457)	Sodium starch glycolate (type A) (0983)
Ethyl parahydroxybenzoate (0900)	Sodium starch glycolate (type B) (0984)
Ethylcellulose (0822)	Sodium stearate (2058)
Ferrous sulfate, dried (2340)	Sodium sulfite (0775)
Ferrous sulfate heptahydrate (0083)	Sodium sulfite heptahydrate (0776)
Flurbiprofen (1519)	Sorafenib tablets (3022)
Fosinopril sodium (1751)	Talc (0438)
Human albumin solution (0255)	Terazosin hydrochloride dihydrate (2021)
Hydralazine hydrochloride (0829)	Ticagrelor tablets (3097)
Hydroxyethylcellulose (0336)	Tigecycline (2825)
Hydroxypropylcellulose (0337)	Tobramycin (0645)
Hydroxypropylcellulose, low-substituted (2083)	RRR- <i>alpha</i> -Tocopheryl hydrogen succinate (1259)
Hypromellose (0348)	Valsartan (2423) ⁽¹⁾
Irbesartan (2465) ⁽¹⁾	Verapamil hydrochloride (0573)
Lacosamide tablets (2989)	Wheat starch (0359)
Losartan potassium (2232) ⁽¹⁾	Wheat starch (0359)
Magnesium carbonate, light (0042)	Zinc acetate dihydrate (1482)
Magnesium stearate (0229)	Zinc gluconate (2164)
Methyl parahydroxybenzoate (0409)	Zinc oxide (0252)
Methylcellulose (0345)	

⁽¹⁾ This text was implemented on 1 April 2021.

CORRECTED TEXTS

The following texts have been corrected for Supplement 10.6 and specify 'corrected 10.6' above the title. These corrections are to be taken into account as soon as possible and not later than 31 August 2021 (the end of the month following the month of publication of the Supplement 10.6).

MONOGRAPHS

Herbal drugs and herbal drug preparations

Forsythia fruit (2720)

Monographs

Bacitracin (0465)

Bacitracin zinc (0466)

Cefalexin monohydrate (0708)

Dexpanthenol (0761)

Dipotassium phosphate (1003)

Disodium edetate (0232)

Disodium phosphate (1509)

Disodium phosphate dihydrate (0602)

Disodium phosphate dodecahydrate (0118)

Edetic acid (1612)

Fluorescein (2348)

Moxidectin for veterinary use (1656)

Salbutamol (0529)

Starches, hydroxyethyl (1785)

Sulfadimethoxine (2741)

Sulfadimethoxine sodium for veterinary use (2745)

TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed in Supplement 10.6.

GENERAL CHAPTERS

2.9.27. Uniformity and accuracy of delivered doses from multidose containers (*previously Uniformity of mass of delivered doses from multidose containers*)

preparations (2353) (*previously Pentetate sodium calcium for radiopharmaceutical preparations*)

MONOGRAPHS**Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations**

Pentetate sodium calcium hydrate for radiopharmaceutical

Monographs

all-rac-Phytomenadione (3011) (*previously Phytomenadione, racemic*)

DELETED TEXTS

The following text is deleted as of 1 January 2022.

MONOGRAPHS

Barbital (0170)

The following texts are deleted as of 1 July 2021.

MONOGRAPHS

Cholecalciferol concentrate (water-dispersible form) (0598)

Theobromine (0298)

The following texts are deleted as of 1 April 2021.

MONOGRAPHS

Amobarbital (0594)

Amobarbital sodium (0166)

Insulin injection, biphasic (0831)

Metrifonate (1133)

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)