

CONTENTS OF SUPPLEMENT 11.7

Lists of the monographs and general chapters that, for Supplement 11.7, are new, revised or corrected or have had their titles changed, are given below.

As of the 11th Edition, all revised, corrected or deleted parts of a text published in the online version of the European Pharmacopoeia are indicated by change marks in the form of triangles. For reasons of readability, these triangles are not shown in the print version.

Corrected texts are to be taken into account as soon as possible and not later than the end of the month following the month of publication of the edition or supplement. New and revised texts are to be taken into account not later than the implementation date.

A QR code is included at the start of each text, providing a link to further information on the text (stored in the Knowledge database) for smartphones and tablets with a camera and a compatible app.

Individual copies of texts published in this edition will not be supplied.

Subscribers to the current version (print or online) of the European Pharmacopoeia have access to an online archive version of all obsolete editions and supplements of the European Pharmacopoeia in PDF format.

NEW TEXTS

The following texts appear for the first time in the European Pharmacopoeia. They will be implemented on 1 April 2025 at the latest.

GENERAL CHAPTERS

- 2.4.35. Extractable elements in plastic materials for pharmaceutical use
- 5.33. Design of experiments
- 5.34. Additional information on gene therapy medicinal products for human use

MONOGRAPHS

General monographs

Gene therapy medicinal products for human use (3186)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Lutetium (¹⁷⁷Lu) zovavotide guraxetan injection (3170)

Herbal drugs and herbal drug preparations

- Australian dodder seed (3189)
- California poppy (3088)
- Cypress oil (3003)
- Grapevine leaf (2667)
- Phyllanthus emblica fruit (3160)
- Walnut leaf (2946)

Monographs

- Enoxaparin sodium injection (3131)
- Etravirine tablets (3122)
- Pirfenidone tablets (3155)

REVISED TEXTS

The following texts have been technically revised since their last publication. They will be implemented on 1 April 2025 at the latest.

GENERAL CHAPTERS

- 4. Reagents
- 5.2.12. Raw materials of biological origin for the production of cell-based and gene therapy medicinal products
- 5.22. Names of herbal drugs used in traditional Chinese medicine

MONOGRAPHS

General monographs

Recombinant DNA technology, products of (0784)

Radiopharmaceutical preparations

Gallium (⁶⁸Ga) chloride (accelerator-produced) solution for radiolabelling (3109)

Technetium (^{99m}Tc) oxidronate injection (2376)

Herbal drugs and herbal drug preparations

- Hop strobile (1222)
- Platycodon root (2660)
- Quillaia bark (1843)

Monographs

Amiodarone hydrochloride (0803)

- Aprotinin concentrated solution (0579)
- Baclofen (0653)
- Brivaracetam (3139)
- Calcium ascorbate dihydrate (1182)
- Carmellose sodium, low-substituted (1186)
- Cefamandole nafate (1402)
- Ciclopirox olamine (1302)
- Cinnarizine (0816)
- Dexamfetamine sulfate (2752)
- Dextromethorphan hydrobromide monohydrate (0020)
- Doxylamine hydrogen succinate (1589)
- Dronedaronone hydrochloride tablets (3038)
- Fludrocortisone acetate (0767)
- Hydroxypropylcellulose, low-substituted (2083)
- Naloxone hydrochloride dihydrate (0729)
- Phenylalanine (0782)
- Rosuvastatin calcium tablets (3008)
- Sitagliptin phosphate tablets (2927)
- Sorafenib tosilate tablets (3022)
- Sorbitol, liquid, partially dehydrated (2048)

CORRECTED TEXTS

The following texts have been corrected for Supplement 11.7 and specify 'corrected 11.7' above the title. These corrections are to be taken into account as soon as possible and not later than **30 November 2024** (the end of the month following the month of publication of Supplement 11.7).

GENERAL CHAPTERS

2.6.16. Tests for extraneous agents in viral vaccines for human use

MONOGRAPHS

Herbal drugs and herbal preparations

Rose flower (2949)

Shepherd's purse (2947)

Monographs

Erythritol (1803)

Ipratropium bromide (0919)

Pimozide (1254)

Pirfenidone capsules (3154)

Vanillin (0747)

TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed in Supplement 11.7.

MONOGRAPHS

Dronedarone hydrochloride tablets (3038) (previously *Dronedarone tablets*)

Rosuvastatin calcium tablets (3008) (previously *Rosuvastatin tablets*)

Sitagliptin phosphate tablets (2927) (previously *Sitagliptin tablets*)

Sorafenib tosylate tablets (3022) (previously *Sorafenib tablets*)

SUSPENDED TEXT

The following text is suspended as of **1 July 2022**.

MONOGRAPHS

Gonadotrophin, equine serum, for veterinary use (0719)

SUPPRESSED TEXTS

The following text is suppressed as of **1 April 2025**.

GENERAL CHAPTERS

5.14. Gene transfer medicinal products for human use

The following text is suppressed as of **1 January 2025**.

MONOGRAPHS

Vaccines for human use

Hepatitis A vaccine (inactivated, virosome) (1935)

Influenza vaccine (whole virion, inactivated, prepared in cell cultures) (2308)

Monographs

Fluphenazine enantate (1015)

Isoprenaline sulfate (0502)

Phenylmercuric borate (0103)

The following text is suppressed as of **1 July 2024**.

MONOGRAPHS

Hydroxocobalamin sulfate (0915)

The following text is suppressed as of **1 January 2024**.

MONOGRAPHS

Donepezil hydrochloride monohydrate (3067)

The following texts are suppressed as of 1 July 2023.

MONOGRAPHS

Vaccines for human use

Diphtheria, tetanus and hepatitis B (rDNA) vaccine (adsorbed) (2062)

Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) (1933)

Diphtheria, tetanus, pertussis (whole cell), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2066)

Monographs

Ether, anaesthetic (0367)

The following text is suppressed as of 1 April 2023.

MONOGRAPHS

Diethylstilbestrol (0484)