

# List of texts adopted at the March 2024 session of the European Pharmacopoeia Commission

## NEW TEXTS

### GENERAL CHAPTERS

- 2.4.35. Extractable elements in plastic materials for pharmaceutical use
- 5.31. Phage therapy medicinal products\*
- 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 (<sup>177</sup>Lu) zadavotide 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 (2496)

#### Monographs

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

## REVISED TEXTS

### GENERAL CHAPTERS

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 and starting materials for radiopharmaceutical preparations

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

Technetium (<sup>99m</sup>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)

Dronedarone 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)

## SUPPRESSED TEXTS

*The following text will be deleted from the European Pharmacopoeia as of 1<sup>st</sup> April 2025.*

### GENERAL CHAPTER

5.14. Gene transfer medicinal products for human use

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\* Given its usefulness in the context of antimicrobial resistance, one of the top threats to global public health, the European Pharmacopoeia Commission decided to make this general chapter available as soon as possible and hence to publish it in Supplement 11.6.