

List of texts adopted at the June 2024 session of the European Pharmacopoeia Commission

NEW TEXTS

GENERAL CHAPTERS

- 2.5.44. Capillary isoelectric focusing for recombinant therapeutic monoclonal antibodies
- 5.1.13. Pyrogenicity

MONOGRAPHS

Dosage forms

- Orodispersible films (3195)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

- Defluorotrimethylammonium-PSMA-1007 for radiopharmaceutical preparations (3158)*
- Edotreotide acetate for radiopharmaceutical preparations (2544)*
- Gozetotide for radiopharmaceutical preparations (3042)*
- Oxodotreotide acetate for radiopharmaceutical preparations (3157)*

Herbal drugs and herbal drug preparations

- White mulberry leaf (3164)

Homoeopathic preparations

- Iberis amara for homoeopathic preparations (2838)

Monographs

- Dapagliflozin propylene glycol monohydrate (3137)
- Dapagliflozin propylene glycol tablets (3175)
- Memantine hydrochloride (2773)
- Olodaterol hydrochloride (3174)
- Rosuvastatin zinc tetrahydrate (3135)

REVISED TEXTS

GENERAL CHAPTERS

- 2.4.20. Determination of elemental impurities
- 2.6.30. Monocyte-activation test
- 2.6.40. Monocyte-activation test for vaccines containing inherently pyrogenic components
- 2.7.24. Flow cytometry
- 3.1.3. Polyolefins
- 3.1.4. Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations
- 3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations
- 3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations
- 3.1.7. Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations
- 3.3.4. Sterile plastic containers for human blood and blood components
- 3.3.7. Sets for the transfusion of blood and blood components
- 5.1.10. Guidelines for using the test for bacterial endotoxins
- 5.2.6. Evaluation of safety of veterinary vaccines and immunosera
- 5.2.7. Evaluation of efficacy of veterinary vaccines and immunosera
- 5.2.11. Carrier proteins for the production of conjugated polysaccharide vaccines for human use
- 5.22. Names of herbal drugs used in traditional Chinese medicine
- 5.31. Phage therapy medicinal products
- 5.34. Additional information on gene therapy medicinal products for human use

MONOGRAPHS

General monographs

- Immunosera for human use, animal (0084)
- Pharmaceutical preparations (2619)
- Radiopharmaceutical preparations (0125)
- Substances for pharmaceutical use (2034)
- Vaccines for human use (0153)
- Vaccines for veterinary use (0062)

Dosage forms

- Intravesical preparations (2811)
- Oromucosal preparations (1807)
- Parenteral preparations (0520)
- Preparations for irrigation (1116)

Vaccines for human use

- Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed) (1932)
- Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2067)
- Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2065)
- Haemophilus type b and meningococcal group C conjugate vaccine (2622)
- Haemophilus type b conjugate vaccine (1219)
- Hepatitis B vaccine (rDNA) (1056)
- Meningococcal group A, C, W135 and Y conjugate vaccine (3066)
- Meningococcal group C conjugate vaccine (2112)
- Meningococcal polysaccharide vaccine (0250)
- Pneumococcal polysaccharide conjugate vaccine (adsorbed) (2150)
- Pneumococcal polysaccharide vaccine (0966)
- Rabies vaccine for human use prepared in cell cultures (0216)
- Tick-borne encephalitis vaccine (inactivated) (1375)

Vaccines for veterinary use

- Salmonella Enteritidis vaccine (live, oral) for chickens (2520)
- Salmonella Typhimurium vaccine (live, oral) for chickens (2521)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

- Gallium (^{68}Ga) chloride solution for radiolabelling (2464)
- Technetium ($^{99\text{m}}\text{Tc}$) human albumin injection (0640)
- Tetra-O-acetyl-mannose triflate for radiopharmaceutical preparations (2294)

Herbal drugs and herbal drug preparations

- Ash leaf (1600)
- Black horehound (1858)
- Burdock root (2943)

Horse-chestnut bark (2945)
Moutan bark (2474)
Narrow-leaved coneflower root (1821)
Pale coneflower root (1822)
Pumpkin seed (2941)
Purple coneflower herb (1823)
Purple coneflower root (1824)
Ribwort plantain (1884)
Rosemary leaf (1560)

Homoeopathic preparations

Cuprum aceticum for homoeopathic preparations (2146)

Monographs

Amikacin sulfate (1290)
Anticoagulant and preservative solutions for human blood (0209)
Anti-T lymphocyte immunoglobulin for human use, animal (1928)
Atropine sulfate (0068)
Bovine serum (2262)
Calcium levulinate dihydrate (1296)
Chloramphenicol sodium succinate (0709)
Chlorhexidine digluconate solution (0658)
Colistimethate sodium (0319)
3-O-Desacyl-4'-monophosphoryl lipid A (2537)
Dicloxacillin sodium (0663)
Doxapram hydrochloride (1201)
Flucloxacillin sodium monohydrate (0668)
Flumetasone pivalate (1327)
Glucose (0177)
Glucose monohydrate (0178)
Haemodialysis, solutions for (0128)
Haemofiltration and haemodiafiltration, solutions for (0861)
Human albumin solution (0255)
Human alpha-1-proteinase inhibitor (2387)
Human antithrombin III concentrate (0878)
Human C1-esterase inhibitor (2818)

Human coagulation factor VII (1224)
Human coagulation factor VIII (0275)
Human coagulation factor IX (1223)
Human coagulation factor XI (1644)
Human fibrinogen (0024)
Human normal immunoglobulin for intramuscular administration (0338)
Human normal immunoglobulin for intravenous administration (0918)
Human normal immunoglobulin for subcutaneous administration (2788)
Human plasma (pooled and treated for virus inactivation) (1646)
Human prothrombin complex (0554)
Human von Willebrand factor (2298)
Kanamycin acid sulfate (0033)
Kanamycin monosulfate (0032)
Methylene chloride (0932)
Peritoneal dialysis, solutions for (0862)
Polymyxin B sulfate (0203)
Procainamide hydrochloride (0567)
Propylthiouracil (0525)
Simeticone (1470)
Sodium citrate (0412)
Sodium molybdate dihydrate (1565)
Solutions for organ preservation (1264)
Sorafenib tosilate (2931)
Thiamazole (1706)

* The publication of these four monographs, adopted at the June 2024 session of the European Pharmacopoeia Commission, will be postponed until chemical reference standards have been established.