

List of texts adopted at the November 2019 session of the European Pharmacopoeia Commission

NEW TEXTS

GENERAL CHAPTERS

- 2.6.32. Test for bacterial endotoxins using recombinant factor C
- 5.1.12. Depyrogenation of items used in the production of parenteral preparations
- 5.17.2. Recommendations on testing of particulate contamination: visible particles

MONOGRAPHS

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

- Betatide for radiopharmaceutical preparations (2551)
- Gallium (⁶⁸Ga) chloride (accelerator-produced) solution for radiolabelling (3109)

Herbal drugs and herbal drug preparations

- Cyathula root (2998)
- Ganoderma (3001)

Monographs

- Amprolium hydrochloride for veterinary use (3010)
- Deferasirox (2933)
- Dronedarone tablets (3038)
- Latanoprost (2230)
- DL-Lysine acetylsalicylate (2812)
- Rivaroxaban (2932)
- Trifluridine (2910)

REVISED TEXTS

GENERAL CHAPTERS

- 2.2.2. Degree of coloration of liquids
- 2.2.24. Absorption spectrophotometry, infrared

- 2.2.29. Liquid chromatography
- 2.2.38. Conductivity
- 2.2.49. Falling ball and automatic rolling ball viscometer methods
- 2.6.12. Microbiological examination of non-sterile products: microbial enumeration tests
- 2.6.13. Microbiological examination of non-sterile products: test for specified micro-organisms
- 2.6.27. Microbiological examination of cell-based preparations
- 2.7.14. Assay of hepatitis A vaccine
- 2.9.19. Particulate contamination: sub-visible particles
- 3.3.4. Sterile plastic containers for human blood and blood components
- 3.3.8. Sterile single-use plastic syringes
- 5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use
- 5.1.5. Application of the F concepts to heat sterilisation processes
- 5.1.10. Guidelines for using the test for bacterial endotoxins
- 5.22. Names of herbal drugs used in traditional Chinese medicine

MONOGRAPHS

General monographs

Substances for pharmaceutical use (2034)

Dosage forms

Nasal preparations (0676)

Oromucosal preparations (1807)

Vaccines for human use

Diphtheria and tetanus vaccine (adsorbed) (0444)

Diphtheria and tetanus vaccine (adsorbed, reduced antigen(s) content) (0647)

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

Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) (1931)

Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) (2764)

Diphtheria, tetanus and pertussis (whole cell) vaccine (adsorbed) (0445)

Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (2328)

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

- Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) (1933)
- Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed) (1934)
- Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (2329)
- 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)
- Diphtheria, tetanus, pertussis (whole cell) and poliomyelitis (inactivated) vaccine (adsorbed) (2061)
- Diphtheria, tetanus, pertussis (whole cell), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2066)
- Tetanus vaccine (adsorbed) (0452)

Vaccines for veterinary use

Tetanus vaccine for veterinary use (0697)

Herbal drugs and drug preparations

- Belamcanda chinensis rhizome (2561)
- Caraway fruit (1080)
- Clove (0376)
- Hawthorn leaf and flower (1432)
- Hawthorn leaf and flower dry extract (1865)
- Hawthorn leaf and flower liquid extract (1864)
- Lime flower (0957)
- Lovage root (1233)
- Opium dry extract, standardised (1839)
- Passionflower herb (1459)
- Passionflower herb dry extract (1882)

Homoeopathic preparations

- Homoeopathic preparations (1038)
- Pillules for homoeopathic preparations (2153)

Monographs

- Acamprostate calcium (1585)
- Acetylcysteine (0967)

Adrenaline (2303)
Ascorbyl palmitate (0807)
Bambuterol hydrochloride (1293)
Betamethasone (0312)
Betamethasone acetate (0975)
Betamethasone dipropionate (0809)
Bleomycin sulfate (0976)
Borax (0013)
Calcium carbonate (0014)
Calcium chloride dihydrate (0015)
Calcium sulfate dihydrate (0982)
Celiprolol hydrochloride (1632)
Cetostearyl alcohol (0702)
Codeine monohydrate (0076)
Codeine phosphate hemihydrate (0074)
Cod-liver oil, farmed (2398)
Cyanocobalamin (0547)
Danaparoid sodium (2090)
Deferiprone oral solution (2987)
Deferiprone tablets (2986)
Dexamethasone (0388)
Dexamethasone acetate (0548)
Dipotassium phosphate (1003)
Disodium phosphate (1509)
Disodium phosphate dihydrate (0602)
Disodium phosphate dodecahydrate (0118)
Epinastine hydrochloride (2411)
Epirubicin hydrochloride (1590)
Ergotamine tartrate (0224)
Etanercept (2895)
Everolimus (2918)
Fluoxetine hydrochloride (1104)
Human coagulation factor IX (rDNA) concentrated solution (2522)
Human coagulation factor IX (rDNA) powder for solution for injection (2994)

Infliximab concentrated solution (2928)
Isoconazole (1018)
Isoconazole nitrate (1017)
Ketoconazole (0921)
Labetalol hydrochloride (0923)
Lacosamide infusion (2991)
Lacosamide oral solution (2990)
Lacosamide tablets (2989)
Lactose (1061)
Lactose monohydrate (0187)
Letrozole (2334)
Magnesium chloride hexahydrate (0402)
Magnesium hydroxide (0039)
Magnesium oxide, heavy (0041)
Magnesium oxide, light (0040)
Magnesium sulfate heptahydrate (0044)
Mexiletine hydrochloride (1029)
Minocycline hydrochloride dihydrate (1030)
Moxifloxacin hydrochloride (2254)
Mupirocin (1450)
Mupirocin calcium (1451)
Mycophenolate sodium (2813)
Ofloxacin (1455)
Omega-3-acid triglycerides (1352)
Pentobarbital (0200)
Pentobarbital sodium (0419)
Potassium chloride (0185)
Potassium clavulanate (1140)
Potassium clavulanate, diluted (1653)
Prednisolone acetate (0734)
Prednisone (0354)
Primidone (0584)
Raltegravir chewable tablets (2939)
Raltegravir tablets (2938)

Rosuvastatin tablets (3008)
Salmon oil, farmed (1910)
Silver, colloidal (2281)
Sitagliptin tablets (2927)
Sodium acetate trihydrate (0411)
Sodium carbonate (0773)
Sodium carbonate decahydrate (0191)
Sodium carbonate monohydrate (0192)
Sodium dihydrogen phosphate dihydrate (0194)
Sodium hydrogen carbonate (0195)
Sodium laurilsulfate (0098)
Sodium metabisulfite (0849)
Solutions for organ preservation (1264)
Sotalol hydrochloride (2004)
Streptomycin sulfate (0053)
Sulfbutylbetadex sodium (2804)
Sulfur (0953)
Sulfuric acid (1572)
Tramadol hydrochloride (1681)
Tramazoline hydrochloride monohydrate (1597)
Vitamin A concentrate (oily form), synthetic (0219)
Wheat starch (0359)
Wool alcohols (0593)

DELETED TEXTS

The following texts will be deleted from the European Pharmacopoeia as of 1 January 2021.

MONOGRAPHS

Carisoprodol (1689)
Meprobamate (0407)
Nalidixic acid (0701)