

List of texts adopted at the November 2018 session of the European Pharmacopoeia Commission

NEW TEXTS

GENERAL CHAPTERS

- 2.6.35. Quantification and characterisation of residual host-cell DNA
- 2.9.49. Powder flow properties by shear cell methods
- 2.9.52. Scanning electron microscopy
- 5.25. Process analytical technology

MONOGRAPHS

Vaccines for veterinary use

Infectious pancreatic necrosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids (3063)

Herbal drugs and herbal drug preparations

- Abelmoschi corolla (2827)
- Serratula coronata herb (2754)

Monographs

- Benzydamine hydrochloride (2759)
- Cocoa butter (2607)
- Dronedarone hydrochloride (3039)
- Prasugrel hydrochloride (3040)
- Squalene (2805)
- Tapentadol hydrochloride (3035)
- Tetracaine (2909)
- Topiramate (2616)
- Vincamine (1800)

REVISED TEXTS

GENERAL CHAPTERS

- 2.2.25. Absorption spectrophotometry, ultraviolet and visible

- 2.6.8. Pyrogens
- 2.6.33. Residual pertussis toxin
- 2.7.2. Microbiological assay of antibiotics
- 2.7.23. Numeration of CD34/CD45+ cells in haematopoietic products
- 2.7.35. Immunonephelometry for vaccine component assay
- 2.8.25. High-performance thin-layer chromatography of herbal drugs and herbal drug preparations
- 2.9.1. Disintegration of tablets and capsules
- 2.9.20. Particulate contamination: visible particles
- 3.1.13. Plastic additives
 - 3.3.1. Materials for containers for human blood and blood components (*previously general chapter 3.1.1*)
 - 3.3.2. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components (*previously general chapter 3.1.1.1*)
 - 3.3.3. Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components (*previously general chapter 3.1.1.2*)
 - 3.3.4. Sterile plastic containers for human blood and blood components (*previously general chapter 3.2.3*)
 - 3.3.5. Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components (*previously general chapter 3.2.4*)
 - 3.3.6. Sterile containers of plasticised poly(vinyl chloride) for human blood containing anticoagulant solution (*previously general chapter 3.2.5*)
 - 3.3.7. Sets for the transfusion of blood and blood components (*previously general chapter 3.2.6*)
 - 3.3.8. Sterile single-use plastic syringes (*previously general chapter 3.2.8*)
- 5.3. Statistical analysis of results of biological assays and tests
- 5.4. ~~Residual solvents~~
 - 5.8. Pharmacopoeial harmonisation
 - 5.21. Chemometric methods applied to analytical data
 - 5.22. Names of herbal drugs used in traditional Chinese medicine
 - 5.24. Chemical imaging

MONOGRAPHS

Dosage forms

Powders, oral (1165)

Vaccines for human use

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

- Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) (2764)
- 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)
- Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) (2149)
- Influenza vaccine (whole virion, inactivated, prepared in cell cultures) (2308)
- Pertussis vaccine (acellular, component, adsorbed) (1356)
- Pertussis vaccine (acellular, co-purified, adsorbed) (1595)
- Poliomyelitis vaccine (oral) (0215)
- Yellow fever vaccine (live) (0537)

Vaccines for veterinary use

- Enteric redmouth disease vaccine (inactivated) for rainbow trout (1950)

Immunosera for human use

- Botulinum antitoxin (0085)

Herbal drugs and herbal drug preparations

- Indigo plant leaf (2727)

Monographs

- Alfacalcidol (1286)
- Aluminium magnesium silicate (1388)
- Anticoagulant and preservative solutions for human blood (0209)
- Apomorphine hydrochloride hemihydrate (0136)
- Arachis oil, hydrogenated (1171)
- Benserazide hydrochloride (1173)
- Biotin (1073)
- Boldine (2971)
- Borage (starflower) oil, refined (2105)

Caffeine (0267)
Caffeine monohydrate (0268)
Candesartan cilexetil (2573)
Carmellose sodium (0472)
Carmellose sodium, low-substituted (1186)
Carmustine (1187)
Castor oil, hydrogenated (1497)
Castor oil, refined (2367)
Castor oil, virgin (0051)
Cellulose, microcrystalline (0316)
Cetyl palmitate (1906)
Chlorpromazine hydrochloride (0475)
Chlortalidone (0546)
Cholesterol for parenteral use (2397)
Cod-liver oil (type A) (1192)
Cod-liver oil (type B) (1193)
Copovidone (0891)
Cottonseed oil, hydrogenated (1305)
Croscarmellose sodium (0985)
Desipramine hydrochloride (0481)
Diacerein (2409)
Diethylene glycol palmitostearate (1415)
Ethylene glycol monopalmitostearate (1421)
Evening primrose oil, refined (2104)
Fenoterol hydrobromide (0901)
Fish oil, rich in omega-3 acids (1912)
Follitropin (2285)
Follitropin concentrated solution (2286)
Galactose (1215)
Galantamine hydrobromide (2366)
Gelatin (0330)
Glycerol dibehenate (1427)
Glycerol distearate (1428)
Glycerol monostearate 40-55 (0495)

Gonadotrophin, chorionic (0498)
Hard fat (0462)
Hard fat with additives (2731)
Heparin calcium (0332)
Heparin sodium (0333)
Human measles immunoglobulin (0397)
Human plasma for fractionation (0853)
Human plasma (pooled and treated for virus inactivation) (1646)
Imidacloprid for veterinary use (2924)
Infliximab concentrated solution (2928)
Irbesartan (2465)
Lauromacrogol 400 (2046)
Levodropizine (1535)
Losartan potassium (2232)
Macrogol 15 hydroxystearate (2052)
Macrogol 30 dipolyhydroxystearate (2584)
Mesterolone (1730)
Olmesartan medoxomil (2600)
Oxytetracycline hydrochloride (0198)
Palmitic acid (1904)
Penicillamine (0566)
Phenylpropanolamine hydrochloride (0683)
Phytomenadione, racemic (3011)
Propranolol hydrochloride (0568)
Propyl gallate (1039)
Propylene glycol monopalmitostearate (1469)
Protamine sulfate (0569)
Pyridoxine hydrochloride (0245)
Safflower oil, refined (2088)
Sodium starch glycolate (type A) (0983)
Sodium starch glycolate (type B) (0984)
Sodium starch glycolate (type C) (1566)
Solutions for organ preservation (1264)
Soya-bean oil, hydrogenated (1265)

Soya-bean oil, refined (1473)
Squalane (1630)
Sucralfate (1796)
Terbutaline sulfate (0690)
Tilidine hydrochloride hemihydrate (1767)
Triglycerides, medium-chain (0868)
Urofollitropin (0958)
Urokinase (0695)
Valsartan (2423)
Vigabatrin (2305)
Vinorelbine tartrate (2107)
Wheat starch (0359)
Wheat-germ oil, refined (1379)
Wheat-germ oil, virgin (1480)