IV. CONTENTS OF THE 10th EDITION

The 10th Edition consists of new texts as well as all current texts from the 9th Edition, some of which have been revised or corrected.

Lists of the monographs and general chapters that, for the 10th Edition, are new, revised or corrected, or have had their titles or chapter numbers changed, are given below.

The version date (for example 01/2020 for a text that is new or revised for the 10th Edition), completed by 'corrected X.X' if a corrected version of the text has subsequently been published in Supplement X.X, and the reference number (4 digits for monographs and 5 digits for general chapters) are specified above the title of each monograph and general chapter. The version date, completed by 'corrected X.X' if appropriate, makes it possible to identify the successive versions of texts in different editions.

The volume in which the current version was first published is stated in the Knowledge database on the EDQM website. As of the 10th Edition, all revised or corrected parts of a text are indicated by vertical lines in the margin and horizontal lines in the margin indicate where parts of a text have been deleted. Lines in the margin that were present in revised or corrected texts in the previous edition are deleted with each new edition.

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 volume. New and revised texts are to be taken into account not later than the implementation date.

A barcode is included at the start of each text, providing a link to further information on the text (e.g. the Knowledge database) for smartphones and tablets with a camera and a barcode reader app.

In addition to corrections made to individual texts, the following decisions and systematic modifications have been made to the texts of the European Pharmacopoeia for the $10^{\rm th}$ Edition.

- For texts not currently undergoing revision, the wording used in the calculation of percentage contents in the quantitative expression of acceptance criteria in tests for related substances has been modified to specify the full name of the substance (i.e. including counter-ions, hydrates etc.).
- Tests using diphosphorus pentoxide, predominantly tests for loss on drying, have been modified, where possible, to avoid the use of this substance due to its toxicity.
- The names and descriptions of the reagents used to describe stationary phases for gas chromatography have been revised.
- 'Tamper-proof' has been replaced by 'tamper-evident'.
- Reference to general chapter 2.8.23. *Microscopic examination of herbal drugs* has been added when microscopic examination is carried out using a powder with a non-standard sieve size.
- The terms 'coarse' and 'coarsely' have been deleted from 'coarse powder (1400) (2.9.12)' and 'coarsely powdered herbal drug (1400) (2.9.12)'.
- Results are expressed in per cent instead of per cent *m/m* in the tests Dry residue of extracts (2.8.16) and Loss on drying of extracts (2.8.17).
- Individual copies of texts published in this edition will not be supplied.

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

A list of new reagents published during the course of this edition is available under 'Useful information' in Pharmeuropa Online.

NEW TEXTS

The following texts appear for the first time in the European Pharmacopoeia. They will be implemented on **1 January 2020** at the latest.

GENERAL CHAPTERS Serratula coronata herb (2754) 2.6.35. Quantification and characterisation of residual Monographs host-cell DNA Benzydamine hydrochloride (2759) 2.9.49. Powder flow properties by shear cell methods Cocoa butter (2607) 2.9.52. Scanning electron microscopy Dronedarone hydrochloride (3039) 3.3. Containers for human blood and blood components, Octreotide (2414) and materials used in their manufacture; transfusion sets and materials used in their manufacture; syringes Prasugrel hydrochloride (3040) 5.25. Process analytical technology Squalene (2805) Tapentadol hydrochloride (3035) **MONOGRAPHS** Tetracaine (2909) Vaccines for veterinary use Infectious pancreatic necrosis vaccine (inactivated, Topiramate (2616) oil-adjuvanted, injectable) for salmonids (3063) Vincamine (1800) Herbal drugs and herbal drug preparations

Abelmoschi corolla (2827)

REVISED TEXTS

The following texts have been technically revised since their last publication. They will be implemented on **1 January 2020** at the latest.

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
- 3.3.2. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components
- 3.3.3. Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components
- 3.3.4. Sterile plastic containers for human blood and blood components
- 3.3.5. Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components
- 3.3.6. Sterile containers of plasticised poly(vinyl chloride) for human blood containing anticoagulant solution
- 3.3.7. Sets for the transfusion of blood and blood components
- 3.3.8. Sterile single-use plastic syringes
- 4. Reagents
- 5.3. Statistical analysis of results of biological assays and tests
- 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

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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)

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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)

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Castor oil, hydrogenated (1497)

Castor oil, refined (2367)

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Cellulose, microcrystalline (0316)

Cetyl palmitate (1906)

Chlorpromazine hydrochloride (0475)

Chlortalidone (0546)

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Cod-liver oil (type B) (1193)

Copovidone (0891)

Cottonseed oil, hydrogenated (1305)

Croscarmellose sodium (0985)

Desipramine hydrochloride (0481)

Diacerein (2409)

Diethylene glycol palmitostearate (1415)

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Evening primrose oil, refined (2104)

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Fish oil, rich in omega-3 acids (1912)

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CORRECTED TEXTS

The following texts have been corrected for the 10^{th} Edition and specify 'corrected 10.0' above the title. These corrections are to be taken into account as soon as possible and not later than **31** August **2019** (the end of the month following the month of publication of the 10^{th} Edition).

GENERAL CHAPTERS

- 1. General notices
- 2.2.5. Relative density
- 2.2.29. Liquid chromatography
- 2.2.31. Electrophoresis
- 2.4.23. Sterols in fatty oils
- 2.4.25. Ethylene oxide and dioxan
- 2.4.26. N,N-Dimethylaniline
- 2.4.32. Total cholesterol in oils rich in omega-3 acids
- 2.5.19. *O*-Acetyl in polysaccharide vaccines
- 2.5.37. Methyl, ethyl and isopropyl methanesulfonate in methanesulfonic acid
- 2.5.38. Methyl, ethyl and isopropyl methanesulfonate in active substances
- 2.5.39. Methanesulfonyl chloride in methanesulfonic acid
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- 2.5.41. Methyl, ethyl and isopropyl benzenesulfonate in active substances
- 2.7.8. Assay of tetanus vaccine (adsorbed)
- 2.8.9. Residue on evaporation of essential oils
- 2.9.10. Ethanol content
- 2.9.11. Test for methanol and 2-propanol
- 3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion

- 3.2. Containers
- 5.1.2. Biological indicators and related microbial preparations used in the manufacture of sterile products
- 5.1.6. Alternative methods for control of microbiological quality
- 5.2.12. Raw materials of biological origin for the production of cell-based and gene therapy medicinal products
- 5.9. Polymorphism
- 5.10. Control of impurities in substances for pharmaceutical use
- 5.12. Reference standards
- 5.15. Functionality-related characteristics of excipients
- 5.16. Crystallinity

MONOGRAPHS

General monographs

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Immunosera for veterinary use (0030)

Live biotherapeutic products for human use (3053)

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Magnesium aspartate dihydrate (1445) Magnesium stearate (0229) Maize starch (0344) Meldonium dihydrate (2624) Menadione (0507) Mepivacaine hydrochloride (1242) Mepyramine maleate (0278) Meropenem trihydrate (2234) Metacresol (2077) Methadone hydrochloride (0408) Methanol (1989) Methyl salicylate (0230) Methylcellulose (0345) Methylene chloride (0932) N-Methylpyrrolidone (1675) Metoclopramide hydrochloride monohydrate (0674) Mianserin hydrochloride (0846) Minocycline hydrochloride dihydrate (1030) Molgramostim concentrated solution (1641) Naftidrofuryl hydrogen oxalate (1594) Nandrolone decanoate (1992) Naphazoline hydrochloride (0730) Naphazoline nitrate (0147) Neomycin sulfate (0197) Neostigmine bromide (0046) Neostigmine metilsulfate (0626) Netilmicin sulfate (1351) Nevirapine hemihydrate (2479) Nicardipine hydrochloride (2776) Norflurane (2257) Nystatin (0517) Octyldodecanol (1136) Olevl alcohol (2073) Olsalazine sodium (1457) Orphenadrine citrate (1759) Orphenadrine hydrochloride (1760) Oseltamivir phosphate (2422) Oxacillin sodium monohydrate (2260) Oxeladin hydrogen citrate (1761) Oxolinic acid (1353) Oxytetracycline dihydrate (0199) Oxytocin (0780) Oxytocin concentrated solution (0779) Paclitaxel (1794) Papaverine hydrochloride (0102) Pemetrexed disodium heptahydrate (2637) Permethrin (25:75) (1762) Phentolamine mesilate (1138) Phytosterol (1911) Piperacillin sodium (1168) Piperazine hydrate (0425) Poloxamers (1464) Polymyxin B sulfate (0203) Polyoxypropylene stearyl ether (2602) Polysorbate 80 (0428) Poly(vinyl acetate) (1962) Poly(vinyl acetate) dispersion 30 per cent (2152) Potassium clavulanate (1140) Potassium dihydrogen phosphate (0920) Pramipexole dihydrochloride monohydrate (2416) Praziquantel (0855)

Propanol (2036) Propofol (1558) Protirelin (1144) Pyrantel embonate (1680) Pyridostigmine bromide (1255) Pyrrolidone (2180) Rabeprazole sodium (2868) Rabeprazole sodium hydrate (2331) Raltegravir potassium (2887) Ranitidine hydrochloride (0946) Remifentanil hydrochloride (2644) Reserpine (0528) Rifamycin sodium (0432) Rilmenidine dihydrogen phosphate (2020) Rivastigmine hydrogen tartrate (2630) Rupatadine fumarate (2888) Saccharin (0947) Saccharin sodium (0787) Salmeterol xinafoate (1765) Sertraline hydrochloride (1705) Sevoflurane (2269) Sildenafil citrate (2270) Sitagliptin phosphate monohydrate (2778) Sitagliptin tablets (2927) Sodium aminosalicylate dihydrate (1993) Sodium aurothiomalate (1994) Sodium cetostearyl sulfate (0847) Sodium cyclamate (0774) Sodium hyaluronate (1472) Sodium (S)-lactate solution (2033) Sodium phenylbutyrate (2183) Sodium propionate (2041) Sodium stearyl fumarate (1567) Solifenacin succinate (2779) Somatostatin (0949) Somatropin (0951) Somatropin concentrated solution (0950) Somatropin for injection (0952) Somatropin solution for injection (2370) Spectinomycin dihydrochloride pentahydrate (1152) Spectinomycin sulfate tetrahydrate for veterinary use (1658) Spiramycin (0293) Starch, hydroxypropyl (2165) Starch, hydroxypropyl, pregelatinised (2645) Starches, hydroxyethyl (1785) Stearyl alcohol (0753) Streptokinase concentrated solution (0356) Streptomycin sulfate (0053) Sufentanil citrate (1269) Sulbactam sodium (2209) Sulfadimethoxine sodium for veterinary use (2745) Sulfaguanidine (1476) Sulfamerazine (0358) Sulfobutylbetadex sodium (2804) Sultamicillin (2211) Sultamicillin tosilate dihydrate (2212) Sumatriptan succinate (1573)

Tacalcitol monohydrate (2272) Tacrolimus monohydrate (2244) Tadalafil (2606) Tamsulosin hydrochloride (2131) Teriparatide (2829) Terpin monohydrate (2940) Testosterone decanoate (1736) Testosterone enantate (1048) Testosterone isocaproate (1737) Tetracycline hydrochloride (0210) Tetryzoline hydrochloride (2101) Thiamazole (1706) Thiamine hydrochloride (0303) Thiamine nitrate (0531) Thiocolchicoside crystallised from ethanol (2896) Thiocolchicoside hydrate (2814) Thiomersal (1625) Tianeptine sodium (2022) Tiapride hydrochloride (1575) Ticarcillin sodium (0956) Tigecycline (2825) Tizanidine hydrochloride (2578) Tobramycin (0645) all-rac-a-Tocopherol (0692) RRR-a-Tocopherol (1256) all-rac-a-Tocopheryl acetate (0439) RRR-a-Tocopheryl acetate (1257) α -Tocopheryl acetate concentrate (powder form) (0691) DL-a-Tocopheryl hydrogen succinate (1258) RRR-a-Tocopheryl hydrogen succinate (1259) Tolterodine tartrate (2781) Tosylchloramide sodium (0381) Tributyl acetylcitrate (1770) Tri-*n*-butyl phosphate (1682) Triethyl citrate (1479) Trimebutine maleate (2182) Trimetazidine dihydrochloride (1741) Trimethoprim (0060) Trolamine (1577) Troxerutin (2133) Tuberculin purified protein derivative, avian (0535) Tuberculin purified protein derivative, bovine (0536) Tylosin for veterinary use (1273) Tylosin phosphate for veterinary use (2802) Tylosin tartrate for veterinary use (1274) Vancomycin hydrochloride (1058) Vardenafil hydrochloride trihydrate (2782) Vecuronium bromide (1769) Vinblastine sulfate (0748) Vincristine sulfate (0749) Vindesine sulfate (1276) Voriconazole (2576) Wool alcohols (0593) Wool fat (0134) Wool fat, hydrogenated (0969) Xylitol (1381) Ziprasidone mesilate trihydrate (2649)

TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed for the 10th Edition.

GENERAL CHAPTERS

2.6.33. Residual pertussis toxin (previously Residual pertussis toxin and irreversibility of pertussis toxoid)

MONOGRAPHS

Vaccines for veterinary use

Enteric redmouth disease vaccine (inactivated) for rainbow trout (1950) (*previously Yersiniosis vaccine (inactivated) for salmonids*)

Sutures for human use

Sutures for human use: introduction (90004) (*previously Introduction*)

Herbal drugs and herbal drug preparations

Herbal drugs: introduction (90029) (previously Introduction)

Homoeopathic preparations

Homoeopathic preparations: introduction (90006) (*previously Introduction*)

TEXTS WHOSE NUMBERING HAS CHANGED

The numbering of the following texts has been changed for the 10th Edition following the modification of the structure of section 3 and the creation of chapter 3.3. Containers for human blood and blood components, and materials used in their manufacture; transfusion sets and materials used in their manufacture; syringes. Chapter 3.3 contains the following texts, which were previously in chapters 3.1. Materials used for the manufacture of containers and 3.2. Containers.

GENERAL CHAPTERS

- 3.3.1. Materials for containers for human blood and blood components (previously 3.1.1)
- 3.3.2. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components (*previously* 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 3.1.1.2*)
- 3.3.4. Sterile plastic containers for human blood and blood components (*previously 3.2.3*)
- 3.3.5. Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components (previously 3.2.4)
- 3.3.6. Sterile containers of plasticised poly(vinyl chloride) for human blood containing anticoagulant solution (*previously* 3.2.5)
- 3.3.7. Sets for the transfusion of blood and blood components (previously 3.2.6)
- 3.3.8. Sterile single-use plastic syringes (*previously 3.2.8*)