

IV. CONTENTS OF THE 11th EDITION

The 11th Edition consists of new texts as well as all current texts from the 10th Edition, some of which have been revised or corrected.

Lists of the monographs and general chapters that, for the 11th Edition, are new, revised or corrected or have had their titles changed, are given below.

The version date (for example 01/2023 for a text that is new or has been revised for the 11th Edition), completed by 'corrected X.X' if a corrected version of the text has subsequently been published in Supplement X.X, is specified above the title of each monograph and general chapter. The version date makes it possible to identify the successive versions of texts in different editions. The reference number (4 digits for monographs and 5 digits for general chapters) is also specified.

The edition or supplement in which the current version was first published is stated in the Knowledge database on the EDQM website.

As of the 11th Edition, all revised, corrected or deleted parts of a text published in the online version of the European Pharmacopoeia are indicated by change marks in the form of triangles. For reasons of readability, these triangles are not shown in the print version, but users will still be able to determine if a text has been corrected or revised as indicated above.

Change marks 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 edition or supplement. New and revised texts are to be taken into account not later than the implementation date.

A QR code is included at the start of each text, providing a link to further information on the text (stored in the Knowledge database) for smartphones and tablets with a camera and a compatible app.

In addition to corrections made to individual texts, systematic corrections have been made to the texts of the European Pharmacopoeia for the 11th Edition. A list of these corrections is available on *Pharmeuropa Online*.

Individual copies of texts published in this edition will not be supplied.

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

NEW TEXTS

The following texts appear for the first time in the European Pharmacopoeia. They will be implemented on 1 January 2023 at the latest.

GENERAL CHAPTERS

- 2.6.39. Microbiological examination of human tissues
- 2.7.36. Assay of Bet v 1 allergen
- 5.26. Implementation of pharmacopoeial procedures

MONOGRAPHS

Herbal drugs and herbal drug preparations

Shepherd's purse (2947)

Toadflax herb (2962)

Homoeopathic preparations

- Bryonia for homoeopathic preparations (2490)
- Ephedra vulgaris for homoeopathic preparations (2710)
- Mandragora for homoeopathic preparations (2840)
- Stramonium for homoeopathic preparations (2734)

Monographs

Melatonin (3059)

REVISED TEXTS

The following texts have been technically revised since their last publication. They will be implemented on 1 January 2023 at the latest.

GENERAL CHAPTERS

- 1. General notices
- 2.1.3. Ultraviolet ray lamps for analytical purposes
- 2.2.46. Chromatographic separation techniques
- 2.9.2. Disintegration test for solid rectal and vaginal dosage forms
- 2.9.3. Dissolution test for solid dosage forms
- 4. Reagents
- 5.17.1. Recommendations on dissolution testing

MONOGRAPHS

General monographs

Vaccines for veterinary use (0062)

Dosage forms

Glossary (1502)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Tetra-*O*-acetyl-mannose triflate for radiopharmaceutical preparations (2294)

Herbal drugs and herbal drug preparations

Codonopsis root (2714)

Platycodon root (2660)

Homoeopathic preparations

Ferrum metallicum for homoeopathic preparations (2026)
Hyoscyamus for homoeopathic preparations (2091)

Monographs

Acitretin (1385)
Adrenaline (2303)
Argon (2407)
Calcium chloride hexahydrate (0707)
Carprofen for veterinary use (2201)
Cefoxitin sodium (0990)
Cellulose acetate phthalate (0314)
Cholecalciferol (0072)
Cholecalciferol concentrate (oily form) (0575)
Cholecalciferol concentrate (powder form) (0574)
Cholesterol for parenteral use (2397)
Ciclopirox olamine (1302)
Ciprofibrate (2013)
Ciprofloxacin hydrochloride (0888)
Codergocrine mesilate (2060)
Colchicine (0758)
Cyclophosphamide monohydrate (0711)
Cytarabine (0760)
Daunorubicin hydrochloride (0662)
Dequalinium chloride (1413)
Difloxacin hydrochloride trihydrate for veterinary use (2239)
Dihydroergotamine mesilate (0551)
Dihydrostreptomycin sulfate for veterinary use (0485)
Enrofloxacin for veterinary use (2229)
Erythromycin (0179)
Erythromycin estolate (0552)
Erythromycin ethylsuccinate (0274)
Erythromycin lactobionate (1098)
Erythromycin stearate (0490)
Etodolac (1422)

Febantel for veterinary use (2176)
Fenbendazole for veterinary use (1208)
Fish oil, rich in omega-3 acids (1912)
Follitropin (2285)
Follitropin concentrated solution (2286)
Hydroxyethyl salicylate (1225)
Isradipine (2110)
Levocarnitine (1339)
Levomepromazine maleate (0925)
Lufenuron for veterinary use (2177)
Magnesium chloride 4.5-hydrate (1341)
Mannitol (0559)
Marbofloxacin for veterinary use (2233)
Mesna (1674)
Methylene chloride (0932)
Morantel hydrogen tartrate for veterinary use (1546)
Moxidectin for veterinary use (1656)
Nitrogen (1247)
Paraffin, white soft (1799)
Paraffin, yellow soft (1554)
Pimobendan for veterinary use (2179)
Potassium iodide (0186)
Selamectin for veterinary use (2268)
Sodium hyaluronate (1472)
Sodium iodide (0196)
Spiramycin (0293)
Stearic acid (1474)
Sucrose (0204)
Sulfadimethoxine sodium for veterinary use (2745)
Sulfamethoxyipyridazine for veterinary use (0638)
Thioridazine hydrochloride (0586)
Tinidazole (1051)
Tretinoin (0693)
Vedaprofen for veterinary use (2248)
Xylazine hydrochloride for veterinary use (1481)

CORRECTED TEXTS

The following texts have been corrected for the 11th Edition and specify 'corrected 11.0' above the title. These corrections are to be taken into account as soon as possible and not later than 31 August 2022 (the end of the month following the month of publication of the 11th Edition).

GENERAL CHAPTERS

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| 2.2.59. Glycan analysis of glycoproteins | 2.7.12. Assay of heparin in coagulation factors |
| 2.3.1. Identification reactions of ions and functional groups | 2.7.13. Assay of human anti-D immunoglobulin |
| 2.5.11. Complexometric titrations | 2.7.16. Assay of pertussis vaccine (acellular) |
| 2.5.15. Phenol in immunosera and vaccines | 2.7.18. Assay of human coagulation factor II |
| 2.5.23. Sialic acid in polysaccharide vaccines | 2.7.19. Assay of human coagulation factor X |
| 2.5.42. <i>N</i> -Nitrosamines in active substances | 2.7.21. Assay of human von Willebrand factor |
| 2.6.14. Bacterial endotoxins | 2.7.25. Assay of human plasmin inhibitor |
| 2.6.15. Prekallikrein activator | 2.7.30. Assay of human protein C |
| 2.6.20. Anti-A and anti-B haemagglutinins | 2.7.32. Assay of human α -1-proteinase inhibitor |
| 2.6.26. Test for anti-D antibodies in human immunoglobulin | 2.7.34. Assay of human C1-esterase inhibitor |
| 2.6.30. Monocyte-activation test | 2.9.53. Particulate contamination: sub-visible particles in non-injectable liquid preparations |
| 2.6.32. Test for bacterial endotoxins using recombinant factor C | 3.2.2. Plastic containers and closures for pharmaceutical use |
| 2.7.8. Assay of tetanus vaccine (adsorbed) | 5.1.6. Alternative methods for control of microbiological quality |
| 2.7.9. Test for Fc function of immunoglobulin | 5.4. Residual solvents |

- 5.6. Assay of interferons
 5.12. Reference standards
 5.18. Methods of pretreatment for preparing traditional Chinese drugs: general information

MONOGRAPHS

General monographs

- Immunosera for human use, animal (0084)
 Monoclonal antibodies for human use (2031)

Dosage forms

- Intrauterine preparations for veterinary use (1806)

Vaccines for human use

- Poliomyelitis vaccine (oral) (0215)
 Rotavirus vaccine (live, oral) (2417)

Vaccines for veterinary use

- Newcastle disease vaccine (inactivated) (0870)

Herbal drugs and herbal drug preparations

- Agnus castus fruit (2147)
 Cascara dry extract, standardised (1844)
 Chinese motherwort (2785)
 Couch grass rhizome (1306)
 Digitalis leaf (0117)
 Ginkgo dry extract, refined and quantified (1827)
 Green tea (2668)
 Houttuynia herb (2722)
 Indian frankincense (2310)
 Lycopodium lucidus herb (2723)
 Mullein flower (1853)
 Scrophularia root (2973)
 Tolu balsam (1596)
 Tragacanth (0532)

Homoeopathic preparations

- Cadmium sulfuricum for homoeopathic preparations (2143)

Monographs

- Acetylcholine chloride (1485)
 Adenine (0800)
 Allantoin (1288)
 Alteplase for injection (1170)
 Aminocaproic acid (0874)
 Ammonio methacrylate copolymer (type A) (2081)
 Ammonio methacrylate copolymer (type B) (2082)
 Antazoline hydrochloride (0972)
 Anti-T lymphocyte immunoglobulin for human use, animal (1928)
 Arginine aspartate (2096)
 Bismuth subnitrate, heavy (1494)
 Bismuth subsalicylate (1495)
 Bromocriptine mesilate (0596)
 Butylhydroxyanisole (0880)
 Butylhydroxytoluene (0581)
 Calcium glucoheptonate (1399)
 D-Camphor (1400)
 Carbachol (1971)
 Carbocysteine (0885)
 Carbomers (1299)
 Cetrimide (0378)
 Cetylpyridinium chloride (0379)
 Chloral hydrate (0265)
 Chlorcyclizine hydrochloride (1086)
 Chloroquine phosphate (0544)

- Cineole (1973)
 Clebopride malate (1303)
 Clobazam (1974)
 Clonazepam (0890)
 Cocaine hydrochloride (0073)
 Coconut oil, refined (1410)
 Cresol, crude (1628)
 Croscarmellose sodium (0985)
 Danaparoid sodium (2090)
 Demeclocycline hydrochloride (0176)
 Deptropine citrate (1308)
 Deslanoside (0482)
 Dexamethasone (0388)
 Dextromoramide tartrate (0021)
 Diazoxide (0550)
 Diclazuril for veterinary use (1718)
 Diethylene glycol monoethyl ether (1198)
 Diethylstilbestrol (0484)
 Digitoxin (0078)
 Dihydrocodeine hydrogen tartrate (1776)
 Dinoprostone (1311)
 Disopyramide phosphate (1005)
 Disulfiram (0603)
 Enoxolone (1511)
 Ephedrine (0488)
 Ephedrine hemihydrate (0489)
 Ethylcellulose (0822)
 Ethylmorphine hydrochloride (0491)
 Fibrin sealant kit (0903)
 Filgrastim concentrated solution (2206)
 Filgrastim injection (2848)
 Finasteride (1615)
 Flubendazole (1721)
 Flunarizine dihydrochloride (1722)
 Flunitrazepam (0717)
 Flurazepam monohydrochloride (0905)
 Framycetin sulfate (0180)
 Gadodiamide hydrate (2225)
 Glutamic Acid (0750)
 Gramicidin (0907)
 Halofantrine hydrochloride (1979)
 Heptaminol hydrochloride (1980)
 Hexetidine (1221)
 Histamine dihydrochloride (0143)
 Homatropine hydrobromide (0500)
 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 IX (rDNA) powder for solution for injection (2994)
 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 α -1-proteinase inhibitor (2387)
 Human prothrombin complex (0554)
 Human tetanus immunoglobulin (0398)
 Human von Willebrand factor (2298)
 Hydroxyethylcellulose (0336)
 Hydroxypropylcellulose, low-substituted (2083)
 Hypromellose (0348)
 Interferon alfa-2 concentrated solution (1110)
 Interferon beta-1a concentrated solution (1639)
 Interferon gamma-1b concentrated solution (1440)
 Irinotecan hydrochloride trihydrate (2675)
 Loperamide oxide monohydrate (1729)
 Macrogol oleyl ether (1125)
 Macrogols (1444)
 Magnesium trisilicate (0403)
 Maize starch (0344)
 Maleic Acid (0365)
 Malic acid (2080)
 Menadione (0507)
 Mestranol (0509)
 DL-Methionine (0624)
 Methylcellulose (0345)
 N-Methylpyrrolidone (1675)
 Metixene hydrochloride (1347)
 Metronidazole (0675)
 Metronidazole benzoate (0934)
 Molgramostim concentrated solution (1641)
 Neomycin sulfate (0197)
 Nifedipine (0627)
 Nikethamide (0233)
 Nitrogen, low-oxygen (1685)
 Norgestrel (0940)
 Nortriptyline hydrochloride (0941)
 Oleic acid (0799)
 Olsalazine sodium (1457)
 Oxacillin sodium monohydrate (2260)
 Oxytocin concentrated solution (0779)
 Pentoxyverine hydrogen citrate (1621)
 Pethidine hydrochloride (0420)
 Phenolphthalein (1584)
 Phenolsulfonphthalein (0242)
 Phenylbutazone (0422)
 Phenylmercuric acetate (2042)
 Physostigmine salicylate (0286)
 Picotamide monohydrate (1358)
 Piperazine adipate (0423)
 Pirenzepine dihydrochloride monohydrate (2001)
 Polysorbate 80 (0428)
 Poly(vinyl alcohol) (1961)
 Potassium hydrogen aspartate hemihydrate (2076)
 Potassium sulfate (1622)
 Potato starch (0355)
 Procainamide hydrochloride (0567)
 Propacetamol hydrochloride (1366)
 Propanol (2036)
 Propylthiouracil (0525)
 Proxyphylline (0526)
 Resorcinol (0290)
 Rice starch (0349)
 Rifabutin (1657)
 Rilmenidine dihydrogen phosphate (2020)
 Riociguat tablets (3079)
 Roxithromycin (1146)
 Sodium aurothiomalate (1994)
 Somatropin (0951)
 Somatropin concentrated solution (0950)
 Somatropin for injection (0952)
 Somatropin solution for injection (2370)
 Streptokinase concentrated solution (0356)
 Sulfadoxine (0740)
 Sulfafurazole (0741)
 Sulfamerazine (0358)
 Sulfanilamide (1571)
 Sulfathiazole (0742)
 Sultamicillin (2211)
 Sultamicillin tosilate dihydrate (2212)
 Suxamethonium chloride (0248)
 Tiabendazole (0866)
 Tioconazole (2074)
 Trapidil (1576)
 Trifluoperazine hydrochloride (0059)
 Trimetazidine dihydrochloride (1741)
 Trometamol (1053)
 Vanillin (0747)
 Vinblastine sulfate (0748)
 Vincristine sulfate (0749)
 Vitamin A concentrate (powder form), synthetic (0218)
 Water for injections (0169)

TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed in the 11th Edition.

GENERAL CHAPTERS

- 2.9.2. Disintegration test for solid rectal and vaginal dosage forms (*previously 2.9.2. Disintegration of suppositories and pessaries*)

MONOGRAPHS

- Cyclophosphamide monohydrate (0711) (*previously Cyclophosphamide*)

SUSPENDED TEXTS

The following text is suspended as of 1 July 2022.

MONOGRAPHS

- Gonadotrophin, equine serum, for veterinary use (0719)