

IV. CONTENTS OF THE 7th EDITION

The 7th Edition consists of all texts published in the 6th Edition, which may subsequently have been revised or corrected, and new texts.

For the information of the reader, lists are given below of monographs and general chapters that are new, or that have been revised, corrected or deleted, and texts whose title has been changed for the 7th Edition.

The version date (for example 01/2011 for a text that is new or revised for the 7th 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 text (monographs and general chapters). The version date, completed by 'corrected X.X' if appropriate, makes it possible to identify the successive versions of texts in different editions. From the 7th Edition, if a text has not been revised for a new Edition, the version date published in the previous Edition will be kept in order to improve traceability. The volume in which this version has been published for the first time is stated in the Knowledge database on the EDQM website.

A vertical line in the margin indicates where part of a text has been revised or corrected. A horizontal line in the margin indicates where part of a text has been deleted. However, these indications, which are not necessarily exhaustive, are given for information and do not form an official part of the texts. Editorial changes are not indicated.

Lines in the margin that were present in revised or corrected texts in the previous Edition will be deleted with each new Edition.

Corrections that are indicated by the note 'corrected 7.0' under the version date are to be taken into account from the publication date of the volume.

For the 7th Edition, the following decisions and systematic modifications to the texts of the European Pharmacopoeia have been made.

- Monographs on herbal drugs and herbal drug preparations have been published in a separate chapter in volume 1.
- Where appropriate, monographs on herbal drugs are being progressively revised to incorporate the legend of the illustration of the powdered herbal drug into the text of identification test B.
- In several monographs on essential oils, information that already appears in the general monograph *Essential oils (2098)* has been deleted. The expression of limits of content for components has been modified ('less than' replaced by 'maximum').
- The number of significant figures in the expression of limits has been modified (mainly in atomic emission spectrometry and atomic absorption spectrometry tests).
- Where appropriate, reference to general chapter 2.2.22. *Atomic emission spectrometry* is being progressively replaced by reference to general chapter 2.2.57. *Inductively coupled plasma-atomic emission spectrometry*.
- Information in the gradient tables of liquid chromatography tests is being progressively harmonised (under normal conditions, information concerning the return to initial conditions is being deleted).
- Reference to the new method H for heavy metals has been introduced where appropriate.
- The graphic formulae and nomenclature of impurities that are the subject of a monograph have been introduced in the transparency list.
- The symbol 'l' for litre has been replaced by 'L'.
- The stem 'sulph' has been replaced by 'sulf'.
- The term 'parenteral dosage form' has been replaced by 'parenteral preparation' and the term 'parenteral use' has been replaced by 'parenteral administration', where appropriate.
- The presentation of monographs on materials used for the manufacture of containers, monographs on containers, several monographs on radiopharmaceutical preparations and some other monographs has been harmonised by converting them into the new drafting style, which does not entail any changes to their technical content. The list of monographs concerned is available on the EDQM website. For monographs on radiopharmaceutical preparations, details of the production procedure when various possibilities exist have been moved from the Definition section to the Knowledge database.

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

Subscribers to the current version (printed or electronic) of the European Pharmacopoeia have access to an archive version of all previous editions of the European Pharmacopoeia.

NEW TEXTS INCLUDED IN THE 7th EDITION

The texts below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 January 2011 at the latest.

GENERAL CHAPTERS

2.2.59. Glycan analysis of glycoproteins

2.8.21. Test for aristolochic acids in herbal drugs

MONOGRAPHS

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Fluoride (¹⁸F) solution for radiolabelling (2390)

Herbal drugs and herbal drug preparations

Astragalus mongholicus root (2435)

Fourstamen stephania root (2478)

Monographs

Amylmetacresol (2405)

Carbon monoxide (2408)

Cefpodoxime proxetil (2341)

Entacapone (2574)

Levetiracetam (2535)

Lufenuron (anhydrous) for veterinary use (2177)
 Meropenem trihydrate (2234)
 Starch, hydroxypropyl (2165)
 Starches, hydroxyethyl (1785)

Sucralfate (1796)
 Trimebutine maleate (2182)
 Valaciclovir hydrochloride, anhydrous (1768)
 Ziprasidone hydrochloride monohydrate (2421)

REVISED TEXTS IN THE 7th EDITION

The texts below have been technically revised since their last publication. They will be implemented on 1 January 2011 unless otherwise indicated by a footnote.

GENERAL CHAPTERS

- 2.5.24. Carbon dioxide in gases
- 2.5.25. Carbon monoxide in gases
- 2.5.35. Nitrous oxide in gases
- 2.6.16. Tests for extraneous agents in viral vaccines for human use
- 2.6.27. Microbiological control of cellular products
- 2.7.14. Assay of hepatitis A vaccine
- 5.1.2. Biological indicators of sterilisation
- 5.1.3. Efficacy of antimicrobial preservation
- 5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use
- 5.2.3. Cell substrates for the production of vaccines for human use
- 5.8. Pharmacopoeial harmonisation

MONOGRAPHS

Vaccines for human use

Measles, mumps, rubella and varicella vaccine (live) (2442)
 Varicella vaccine (live) (0648)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

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

Herbal drugs and herbal drug preparations

Agrimony (1587)
 Angelica root (1857)
 Artichoke leaf (1866)
 Butcher's broom (1847)
 Calendula flower (1297)
 Capsicum (1859)
 Cinchona bark (0174)
 Dandelion root (1852)
 Devil's claw root (1095)
 Ginger (1522)
 Ginkgo leaf (1828)
 Goldenseal rhizome (1831)
 Hamamelis leaf (0909)
 Hop strobile (1222)
 Liquorice ethanolic liquid extract, standardised (1536)
 Mallow flower (1541)
 Melissa leaf (1447)
 Mullein flower (1853)
 Nettle leaf (1897)
 Oregano (1880)
 Peppermint leaf (0406)
 Red poppy petals (1881)

Homoeopathic preparations

Homoeopathic preparations (1038)
 Methods of preparation of homoeopathic stocks and potentisation (2371)

Monographs

Acetylsalicylic acid (0309)
 Aciclovir (0968)
 Aluminium oxide, hydrated (0311)
 Ambroxol hydrochloride (1489)
 Aminoglutethimide (1291)
 Aprotinin (0580)
 Aprotinin concentrated solution (0579)
 Ascorbic acid (0253)
 Azithromycin (1649)
 Benazepril hydrochloride (2388)
 Buflomedil hydrochloride (1398)
 Calcium acetate (2128)
 Captopril (1079)
 Carrageenan (2138)
 Chlorocresol (0384)
 Chymotrypsin (0476)
 Cladribine (2174)
 Clebopride malate (1303)
 Codeine phosphate hemihydrate (0074)
 Danaparoid sodium (2090)
 Fish oil, rich in omega-3 acids (1912)
 Flucytosine (0766)
 Fluoxetine hydrochloride (1104)
 Fluspirilene (1723)
 Fosfomycin calcium (1328)
 Fosinopril sodium (1751)
 Ganciclovir (1752)
 Glycerol monocaprylocaprate (2392)
 Gonadotrophin, chorionic (0498)
 Haemodialysis, solutions for (0128)
 Haemofiltration and haemodiafiltration, solutions for (0861)
 Heparin calcium (0332)⁽¹⁾
 Heparin sodium (0333)⁽¹⁾
 Human antithrombin III concentrate (0878)
 Human coagulation factor VII (1224)
 Human coagulation factor IX (1223)
 Human coagulation factor XI (1644)
 Human fibrinogen (0024)
 Human normal immunoglobulin (0338)
 Human plasma (pooled and treated for virus inactivation) (1646)
 Human prothrombin complex (0554)
 Human von Willebrand factor (2298)
 Hydrocortisone (0335)
 Insulin, human (0838)
 Ioxaglic acid (2009)

(1) This text entered into force on 1 August 2010.

Isoprenaline hydrochloride (1332)	Sertraline hydrochloride (1705)
Isotretinoin (1019)	Silica, colloidal anhydrous (0434)
Itraconazole (1335)	Silica, dental type (1562)
Levodropropizine (1535)	Silica, hydrophobic colloidal (2208)
Lisinopril dihydrate (1120)	Sodium ascorbate (1791)
Meclozine dihydrochloride (0622)	Sodium hyaluronate (1472)
Methylphenobarbital (0189)	Sodium lactate solution (1151)
Nicotinic acid (0459)	Sodium propyl parahydroxybenzoate (1263)
Nimesulide (1548)	Somatostatin (0949)
Ofloxacin (1455)	Spironolactone (0688)
Omeprazole sodium (1032)	Sulfinpyrazone (0790)
Pancreas powder (0350)	Talc (0438)
Peritoneal dialysis, solutions for (0862)	Timolol maleate (0572)
Phentolamine mesilate (1138)	Titanium dioxide (0150)
Phloroglucinol, anhydrous (2301)	α -Tocopheryl acetate concentrate (powder form) (0691)
Phloroglucinol dihydrate (2302)	Tolbutamide (0304)
Polysorbate 80 (0428)	Tretinoin (0693)
Protamine hydrochloride (0686)	Triflusal (1377)
Protamine sulfate (0569)	Tropicamide (1159)
Risperidone (1559)	Trypsin (0694)
Salbutamol (0529)	Zolpidem tartrate (1280)

CORRECTED TEXTS IN THE 7th EDITION

The texts below from the 6th Edition have been corrected and specify 'corrected 7.0' above the title. These corrections are to be taken into account from the publication date of the 7th Edition (15 July 2010).

GENERAL CHAPTERS

1. General notices
- 2.4.15. Nickel in polyols
- 2.6.14. Bacterial endotoxins
- 2.7.2. Microbiological assay of antibiotics
- 2.7.30. Assay of human protein C
- 3.1.1.1. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components
- 3.1.1.2. Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components
- 3.1.3. Polyolefines
- 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
- 3.1.10. Materials based on non-plasticised poly(vinyl chloride) for containers for non-injectable, aqueous solutions
- 3.1.11. Materials based on non-plasticised poly(vinyl chloride) for containers for dry dosage forms for oral administration
- 3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion
- 3.1.15. Polyethylene terephthalate for containers for preparations not for parenteral use
- 3.2.9. Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders

MONOGRAPHS

Vaccines for veterinary use

Anthrax spore vaccine (live) for veterinary use (0441)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Ammonia (¹³N) injection (1492)
Chromium (⁵¹Cr) edetate injection (0266)
Cyanocobalamin (⁵⁷Co) capsules (0710)
Cyanocobalamin (⁵⁷Co) solution (0269)
Cyanocobalamin (⁵⁸Co) capsules (1505)
Cyanocobalamin (⁵⁸Co) solution (0270)
Fludeoxyglucose (¹⁸F) injection (1325)
Gallium (⁶⁷Ga) citrate injection (0555)
Indium (¹¹¹In) chloride solution (1227)
Indium (¹¹¹In) oxine solution (1109)
Indium (¹¹¹In) pentetate injection (0670)
Iobenguane (¹²³I) injection (1113)
Iobenguane (¹³¹I) injection for diagnostic use (1111)
Iobenguane (¹³¹I) injection for therapeutic use (1112)
Iodomethylnorcholesterol (¹³¹I) injection (0939)
Sodium chromate (⁵¹Cr) sterile solution (0279)
Sodium iodohippurate (¹²³I) injection (0564)
Sodium iodohippurate (¹³¹I) injection (0282)
Sodium pertechnetate (^{99m}Tc) injection (fission) (0124)
Sodium pertechnetate (^{99m}Tc) injection (non-fission) (0283)
Sodium phosphate (³²P) injection (0284)
Strontium (⁸⁹Sr) chloride injection (1475)
Technetium (^{99m}Tc) colloidal rhenium sulfide injection (0126)
Technetium (^{99m}Tc) colloidal sulfur injection (0131)
Technetium (^{99m}Tc) colloidal tin injection (0689)
Technetium (^{99m}Tc) gluconate injection (1047)
Technetium (^{99m}Tc) human albumin injection (0640)
Technetium (^{99m}Tc) macrosalb injection (0296)
Technetium (^{99m}Tc) medronate injection (0641)
Technetium (^{99m}Tc) mertiatide injection (1372)
Technetium (^{99m}Tc) microspheres injection (0570)

Technetium (^{99m}Tc) pentetate injection (0642)
 Technetium (^{99m}Tc) succimer injection (0643)
 Technetium (^{99m}Tc) tin pyrophosphate injection (0129)
 Thallous (²⁰¹Tl) chloride injection (0571)
 Tritiated (³H) water injection (0112)
 Water (¹⁵O) injection (1582)
 Xenon (¹³³Xe) injection (0133)

Herbal drugs and herbal drug preparations

Anise oil (0804)
 Bitter-fennel herb oil (2380)
 Cassia oil (1496)
 Cinnamon bark oil, Ceylon (1501)
 Cinnamon leaf oil, Ceylon (1608)
 Citronella oil (1609)
 Clary sage oil (1850)
 Eleutherococcus (1419)
 Ivy leaf (2148)
 Juniper oil (1832)
 Liquorice root (0277)
 Mandarin oil (2355)
 Nutmeg oil (1552)
 Safflower flower (2386)
 Spanish sage oil (1849)
 Spike lavender oil (2419)
 Star anise oil (2108)
 Tea tree oil (1837)
 Turpentine oil, Pinus pinaster type (1627)

Homoeopathic preparations

Copper for homoeopathic preparations (1610)
 Iron for homoeopathic preparations (2026)

Monographs

Acebutolol hydrochloride (0871)
 Acemetacin (1686)
 Acetylcysteine (0967)
N-Acetyltryptophan (1383)
 Acitretin (1385)
 Alfentanil hydrochloride (1062)
 Almagate (2010)
 Aluminium magnesium silicate (1388)
 Aluminium sodium silicate (1676)
 Amikacin sulfate (1290)
 Amisulpride (1490)
 Ammonium glycyrrhizate (1772)
 Arachis oil, hydrogenated (1171)
 Ascorbyl palmitate (0807)
 Atropine sulfate (0068)
 Azaperone for veterinary use (1708)
 Azathioprine (0369)
 Barium sulfate (0010)
 Beclometasone dipropionate, anhydrous (0654)
 Beclometasone dipropionate monohydrate (1709)
 Benzalkonium chloride (0372)
 Benzalkonium chloride solution (0371)
 Benzoyl peroxide, hydrous (0704)
 Betadex (1070)
 Bismuth subcarbonate (0012)
 Bismuth subgallate (1493)
 Bismuth subnitrate, heavy (1494)
 Bismuth subsalicylate (1495)
 Bleomycin sulfate (0976)
 Brotizolam (2197)

Buprenorphine (1180)
 Calcipotriol, anhydrous (2011)
 Calcium ascorbate (1182)
 Calcium dobesilate monohydrate (1183)
 Calcium folinate (0978)
 Calcium gluconate for injection (0979)
 Calcium levofolate pentahydrate (1606)
 Calcium stearate (0882)
 D-Camphor (1400)
 Carbasalate calcium (1185)
 Carboplatin (1081)
 Carmellose (2360)
 Carmellose sodium, low-substituted (1186)
 Carprofen for veterinary use (2201)
 Cefadroxil monohydrate (0813)
 Cefalexin monohydrate (0708)
 Cefalotin sodium (0987)
 Cefamandole nafate (1402)
 Cellulose, microcrystalline (0316)
 Charcoal, activated (0313)
 Chlorcyclizine hydrochloride (1086)
 Chlorhexidine diacetate (0657)
 Chlorhexidine digluconate solution (0658)
 Chlorhexidine dihydrochloride (0659)
 Chlorpromazine hydrochloride (0475)
 Cisplatin (0599)
 Clarithromycin (1651)
 Clopamide (1747)
 Closantel sodium dihydrate for veterinary use (1716)
 Codeine (0076)
 Colchicine (0758)
 Copper sulfate, anhydrous (0893)
 Copper sulfate pentahydrate (0894)
 Cotton, absorbent (0036)
 Cottonseed oil, hydrogenated (1305)
 Desflurane (1666)
 Diclazuril for veterinary use (1718)
 Didanosine (2200)
 Digoxin (0079)
 Dihydroergocristine mesilate (1416)
 Dipivefrine hydrochloride (1719)
 Dipotassium phosphate (1003)
 Dopexamine dihydrochloride (1748)
 Doxazosin mesilate (2125)
 Econazole (2049)
 Econazole nitrate (0665)
 Enalaprilat dihydrate (1749)
 Enrofloxacin for veterinary use (2229)
 Epinastine hydrochloride (2411)
 Etomidate (1514)
 Felypressin (1634)
 Fenbendazole for veterinary use (1208)
 Fenbufen (1209)
 Ferrous fumarate (0902)
 Ferrous sulfate, dried (2340)
 Filgrastim concentrated solution (2206)
 Flubendazole (1721)
 Flunarizine dihydrochloride (1722)
 Fluorescein (2348)
 Fluphenazine decanoate (1014)
 Fluphenazine enantate (1015)

Formoterol fumarate dihydrate (1724)	Polysorbate 20 (0426)
Galantamine hydrobromide (2366)	Polysorbate 40 (1914)
Gelatin (0330)	Polysorbate 60 (0427)
Gemfibrozil (1694)	Potassium acetate (1139)
Glibenclamide (0718)	Potassium chloride (0185)
Gonadorelin acetate (0827)	Potassium citrate (0400)
Guaifenesin (0615)	Potassium dihydrogen phosphate (0920)
Haemodialysis solutions, concentrated, water for diluting (1167)	Potassium hydrogen carbonate (1141)
Human albumin solution (0255)	Potassium metabisulfite (2075)
Hydrocodone hydrogen tartrate 2.5-hydrate (1784)	Potassium nitrate (1465)
Ibuprofen (0721)	Povidone (0685)
Imipramine hydrochloride (0029)	Praziquantel (0855)
<i>myo</i> -Inositol (1805)	Prazosin hydrochloride (0856)
Interferon gamma-1b concentrated solution (1440)	Procaine hydrochloride (0050)
Irbesartan (2465)	Propafenone hydrochloride (2103)
Ketobemidone hydrochloride (1746)	Propyl gallate (1039)
Lauromacrogol 400 (2046)	Ramipril (1368)
Levamisole for veterinary use (1728)	Ranitidine hydrochloride (0946)
Levodopa (0038)	Rifamycin sodium (0432)
Lithium carbonate (0228)	Rutoside trihydrate (1795)
Loperamide hydrochloride (0929)	Salbutamol sulfate (0687)
Loperamide oxide monohydrate (1729)	Sodium alginate (0625)
Macrogol 40 sorbitol heptaoleate (2396)	Sodium aminosalicylate dihydrate (1993)
Magnesium acetate tetrahydrate (2035)	Sodium chloride (0193)
Magnesium chloride 4.5-hydrate (1341)	Sodium stearate (2058)
Magnesium chloride hexahydrate (0402)	Sodium sulfite, anhydrous (0775)
Marbofloxacin for veterinary use (2233)	Sodium sulfite heptahydrate (0776)
Mebendazole (0845)	Somatropin (0951)
Mefenamic acid (1240)	Somatropin concentrated solution (0950)
Menthol, racemic (0623)	Somatropin for injection (0952)
Methacrylic acid - ethyl acrylate copolymer (1:1) (1128)	Soya-bean oil, hydrogenated (1265)
Methotrexate (0560)	Spirapril hydrochloride monohydrate (1766)
Methylprednisolone (0561)	Stavudine (2130)
Methyl salicylate (0230)	Sulfaguanidine (1476)
Methylthioninium chloride (1132)	Sulfasalazine (0863)
Metronidazole benzoate (0934)	Testosterone (1373)
Microcrystalline cellulose and carmellose sodium (2050)	Tetrazepam (1738)
Minocycline hydrochloride dihydrate (1030)	Thioridazine (2005)
Naproxen sodium (1702)	Thioridazine hydrochloride (0586)
Nilutamide (2256)	Tilidine hydrochloride hemihydrate (1767)
Nitrofurantoin (0101)	all- <i>rac</i> - α -Tocopherol (0692)
Norethisterone (0234)	Tolfenamic acid (2039)
Orbifloxacin for veterinary use (2259)	Trandolapril (2245)
Orciprenaline sulfate (1033)	Tribenoside (1740)
Oxaliplatin (2017)	Tryptophan (1272)
Oxprenolol hydrochloride (0628)	Vancomycin hydrochloride (1058)
Oxycodone hydrochloride (1793)	Verapamil hydrochloride (0573)
Papaverine hydrochloride (0102)	Vincristine sulfate (0749)
Parnaparin sodium (1252)	Vinorelbine tartrate (2107)
Penicillamine (0566)	Xylometazoline hydrochloride (1162)
Pethidine hydrochloride (0420)	Zinc acetate dihydrate (1482)
Phenylephrine (1035)	Zinc acexamate (1279)
Phenylephrine hydrochloride (0632)	Zinc gluconate (2164)
Pholcodine (0522)	Zinc oxide (0252)
Pirenzepine dihydrochloride monohydrate (2001)	Zinc stearate (0306)

TEXTS WHOSE TITLE HAS CHANGED FOR THE 7th EDITION

The titles of the following texts have been changed in the 7th Edition.

MONOGRAPHS

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Iodomethylnorcholesterol (¹³¹I) injection (0939) (*previously Norcholesterol injection, iodinated (¹³¹I)*)

Monographs

Calcium acetate, anhydrous (2128) (*previously Calcium acetate*)

Meclozine dihydrochloride (0622) (*previously Meclozine hydrochloride*)

TEXTS DELETED FOR THE 7th EDITION

The following text is deleted as of 1 January 2011.

MONOGRAPHS

Monographs

Gallamine triethiodide (0181)

ERRATA

For the following corrected texts published in Supplement 6.3, please read ‘corrected 6.3’ instead of ‘corrected 6.0’. This correction has been taken into account in the 7th Edition.

MONOGRAPHS

Monographs

Glucose, anhydrous (0177)

Glucose monohydrate (0178)