

IV. CONTENTS OF THE 5th EDITION

The 5th Edition consists of all texts published in the 4th 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 5th Edition.

The version date (01/2005 for volume 5.0) and the reference number (four digits for monographs and five digits for general chapters) are specified above the title of each text (monographs and general chapters). The version date makes it possible to identify the successive versions of revised texts in different volumes of the 5th Edition. Corrections that are indicated by the word “corrected” under the version date are to be taken into account from the publication date of the volume.

For the 5th Edition, the following systematic modifications have been made to the texts of the Pharmacopoeia.

- The term “specified impurities” has replaced “qualified impurities” in the Impurities section of monographs

in accordance with the texts on *Substances for pharmaceutical use (2034)* and *5.10. Control of impurities in substances for pharmaceutical use*. This term, which is compliant with the ICH guidelines, applies to impurities for which a specific acceptance criterion has been defined.

- In cases covered by the general monograph on *Substances for pharmaceutical use (2034)*, the test for sterility and the corresponding information in the Labelling section are no longer included in specific monographs.
- Chromatograms published for information no longer appear in the Pharmacopoeia; they are now available on the Internet site: www.pheur.org.
- A reference to available biological reference preparations has been added to the monographs concerned.
- The solubility in ether has been deleted from the Characters section and from the reagent descriptions.
- The reference to storage in a cool place has been deleted from the monographs and reagent descriptions.

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. It is to be emphasized that 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.

Individual copies of texts will not be supplied.

NEW TEXTS INCLUDED IN THE 5th EDITION

GENERAL CHAPTERS

- 2.4.30. Ethylene glycol and diethylene glycol in ethoxylated substances
- 2.6.24. Avian viral vaccines: tests for extraneous agents in seed lots (*previously texts 2.6.3, 2.6.4, 2.6.5 and 2.6.6*)
- 2.6.25. Avian live virus vaccines: tests for extraneous agents in batches of finished product (*previously texts 2.6.3, 2.6.4, 2.6.5 and 2.6.6*)
- 5.9. Polymorphism
- 5.10. Control of impurities in substances for pharmaceutical use
- 5.11. Characters section in monographs

MONOGRAPHS

The monographs below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 January 2005 at the latest.

Monographs

- Botulinum toxin type A for injection (2113)
- Ciprofibrate (2013)
- Clioquinol (2111)

- Clofazimine (2054)
- Closantel sodium dihydrate for veterinary use (1716)
- Colestyramine (1775)
- Coriander oil (1820)
- Dipivefrine hydrochloride (1719)
- Dodecyl gallate (2078)
- Edrophonium chloride (2106)
- Formoterol fumarate dihydrate (1724)
- Human coagulation factor VIII (rDNA) (1643)
- Hydromorphone hydrochloride (2099)
- Insulin aspart (2084)
- Insulin lispro (2085)
- Isradipine (2110)
- Lactobionic acid (1647)
- Lysine acetate (2114)
- Mitomycin (1655)
- Octyl gallate (2057)
- Oleyl alcohol (2073)
- Oxeladin hydrogen citrate (1761)
- Propylene glycol dicaprylocaprate (2122)

Pyrantel embonate (1680)
 Ribavirin (2109)
 Salmon oil, farmed (1910)
 Tiamulin for veterinary use (1660)
 Tiamulin hydrogen fumarate for veterinary use (1659)
 Vinorelbine tartrate (2107)

Vaccines for human use

Meningococcal group C conjugate vaccine (2112)

Vaccines for veterinary use

Avian viral tenosynovitis vaccine (live) (1956)
 Bovine leptospirosis vaccine (inactivated) (1939)
 Infectious chicken anaemia vaccine (live) (2038)

Radiopharmaceutical preparations

Sodium fluoride (¹⁸F) injection (2100)
 Sodium iodide (¹³¹I) solution for radiolabelling (2121)

REVISED TEXTS IN THE 5th EDITION**GENERAL CHAPTERS**

1. General notices
- 2.2.1. Clarity and degree of opalescence of liquids
- 2.2.3. Potentiometric determination of pH
- 2.2.5. Relative density
- 2.2.24. Absorption spectrophotometry, infrared
- 2.2.34. Thermal analysis
- 2.2.40. Near-infrared spectrophotometry
- 2.2.46. Chromatographic separation techniques
- 2.4.8. Heavy metals
- 2.6.9. Abnormal toxicity
- 2.6.14. Bacterial endotoxins
- 2.7.16. Assay of pertussis vaccine (acellular)
- 2.9.11. Test for methanol and 2-propanol
- 3.2.1. Glass containers for pharmaceutical use
4. Reagents
- 5.2.8. Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products

MONOGRAPHS

The monographs below have been technically revised since their last publication. They will be implemented on 1 January 2005.

General monographs

Substances for pharmaceutical use (2034)

Monographs

Adrenaline tartrate (0254)
 Ammonium glycyrrhizate (1772)
 Bitter-fennel fruit oil (1826)
 Buserelin (1077)
 Cefapirin sodium (1650)
 Codergocrine mesilate (2060)
 Dexpanthenol (0761)
 Doxycycline hyclate (0272)
 Epirubicin hydrochloride (1590)
 Estradiol benzoate (0139)

Etilefrine hydrochloride (1205)
 Eucalyptus oil (0390)
 Famotidine (1012)
 Goserelin (1636)
 Human anti-D immunoglobulin (0557)
 Hyoscine butylbromide (0737)
 Hyoscine hydrobromide (0106)
 Hyoscyamine sulphate (0501)
 Insulin, human (0838)
 Iohexol (1114)
 Iopamidol (1115)
 Josamycin propionate (1982)
 Ketoprofen (0922)
 Lactose, anhydrous (1061)
 Lactose monohydrate (0187)
 Lavender oil (1338)
 Paraffin, light liquid (0240)
 Paraffin, liquid (0239)
 Penbutolol sulphate (1461)
 Povidone, iodinated (1142)
 Primidone (0584)
 Propyl gallate (1039)
 Propylene glycol (0430)
 Protirelin (1144)
 Risperidone (1559)
 Sulfamethoxazole (0108)
 Thiamazole (1706)

Vaccines for human use

BCG for immunotherapy (1929)
 BCG vaccine, freeze-dried (0163)
 Diphtheria and tetanus vaccine (adsorbed) (0444)
 Diphtheria and tetanus vaccine (adsorbed) for adults and adolescents (0647)
 Diphtheria, tetanus and hepatitis B (rDNA) vaccine (adsorbed) (2062)
 Diphtheria, tetanus and pertussis vaccine (adsorbed) (0445)

Diphtheria, tetanus, pertussis and poliomyelitis (inactivated) vaccine (adsorbed) (2061)
 Diphtheria, tetanus, pertussis, poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2066)
 Diphtheria vaccine (adsorbed) (0443)
 Diphtheria vaccine (adsorbed) for adults and adolescents (0646)
 Haemophilus type b conjugate vaccine (1219)
 Meningococcal polysaccharide vaccine (0250)
 Tetanus vaccine (adsorbed) (0452)
 Typhoid polysaccharide vaccine (1160)

Vaccines for veterinary use

Avian infectious bronchitis vaccine (live) (0442)
 Avian infectious bursal disease vaccine (live) (0587)
 Avian infectious encephalomyelitis vaccine (live) (0588)
 Avian infectious laryngotracheitis vaccine (live) (1068)
 Canine leptospirosis vaccine (inactivated) (0447)
 Duck viral hepatitis type I vaccine (live) (1315)
 Fowl-pox vaccine (live) (0649)
 Marek's disease vaccine (live) (0589)
 Newcastle disease vaccine (live) (0450)

CORRECTED TEXTS IN THE 5th EDITION

The texts below from the 4th Edition have been modified and specify "01/2005:XXXX-corrected" above the title. These modifications are to be taken into account from the publication date of the 5th Edition.

GENERAL CHAPTERS

2.4.18. Free formaldehyde
 2.4.24. Identification and control of residual solvents
 2.5.34. Acetic acid in synthetic peptides
 2.6.15. Prekallikrein activator
 2.6.21. Nucleic acid amplification techniques
 2.7.6. Assay of diphtheria vaccine (adsorbed)
 2.7.11. Assay of human coagulation factor IX
 2.7.14. Assay of hepatitis A vaccine
 2.7.15. Assay of hepatitis B vaccine (rDNA)
 5.3. Statistical analysis of results of biological assays and tests

MONOGRAPHS**General monographs**

Vaccines for veterinary use (0062)

Monographs

Acetylcholine chloride (1485)
 Acetylcystein (0967)
 Acitretin (1385)
 Air, medicinal (1238)
 Almagate (2010)
 Alteplase for injection (1170)
 Amantadine hydrochloride (0463)
 Amikacin sulphate (1290)
 Amoxicillin sodium (0577)
 Ampicillin sodium (0578)
 Anise oil (0804)
 Aspartame (0973)
 Azelastine hydrochloride (1633)

Azithromycin (1649)
 Benfluorex hydrochloride (1601)
 Benzyl alcohol (0256)
 Calcium hydrogen phosphate, anhydrous (0981)
 Calcium hydroxide (1078)
 Carbidopa (0755)
 Castor oil, hydrogenated (1497)
 Castor oil, virgin (0051)
 Cefaclor (0986)
 Cefadroxil monohydrate (0813)
 Cefamandole nafate (1402)
 Cefixime (1188)
 Cefotaxime sodium (0989)
 Cefradine (0814)
 Chlorhexidine digluconate solution (0658)
 Ciclosporin (0994)
 Cilazapril (1499)
 Ciprofloxacin (1089)
 Clarithromycin (1651)
 Clobazam (1974)
 Clobetasone butyrate (1090)
 Detomidine hydrochloride for veterinary use (1414)
 Dihydralazine sulphate, hydrated (1310)
 Diphenhydramine hydrochloride (0023)
 Disodium phosphate, anhydrous (1509)
 Domperidone maleate (1008)
 Doxepin hydrochloride (1096)
 Ebastine (2015)
 Econazole (2049)
 Econazole nitrate (0665)

- Eleutherococcus (1419)
Erythropoietin concentrated solution (1316)
Fibrin sealant kit (0903)
Fish oil, rich in omega-3-acids (1912)
Foscarnet sodium hexahydrate (1520)
Framycetin sulphate (0180)
Gentamicin sulphate (0331)
Glycerol (0496)
Glycerol (85 per cent) (0497)
Glycine (0614)
Goldenrod (1892)
Goldenrod, European (1893)
Gonadorelin acetate (0827)
Guaifenesin (0615)
Halofantrine hydrochloride (1979)
Heparins, low-molecular-mass (0828)
Heptaminol hydrochloride (1980)
Human anti-D immunoglobulin for intravenous administration (1527)
Human plasma for fractionation (0853)
Human plasma (pooled and treated for virus inactivation) (1646)
Hyaluronidase (0912)
Hydroxycarbamide (1616)
Ifosfamide (1529)
Imipramine hydrochloride (0029)
Insulin, bovine (1637)
Insulin, porcine (1638)
Interferon alfa-2 concentrated solution (1110)
Interferon gamma-1b concentrated solution (1440)
Ioxaglic acid (2009)
Isoflurane (1673)
Ivermectin (1336)
Lemon oil (0620)
Lisinopril dihydrate (1120)
Lobeline hydrochloride (1988)
Lomustine (0928)
Magaldrate (1539)
Maltitol, liquid (1236)
Methylprednisolone hydrogen succinate (1131)
Methylthioninium chloride (1132)
Minoxidil (0937)
Mometasone furoate (1449)
Netilmicin sulphate (1351)
Nifedipine (0627)
Nifuroxazide (1999)
Omega-3-acid ethyl esters 60 (2063)
Papaverine hydrochloride (0102)
Pefloxacin mesilate dihydrate (1460)
Pepsin powder (0682)
Phenoxymethylpenicillin (0148)
Phenoxymethylpenicillin potassium (0149)
Piroxicam (0944)
Polymyxin B sulphate (0203)
Polysorbate 20 (0426)
Potassium acetate (1139)
Potassium clavulanate, diluted (1653)
Povidone (0685)
Pravastatin sodium (2059)
Primaquine diphosphate (0635)
Propanol (2036)
Propranolol hydrochloride (0568)
Propylene glycol dilaurate (2087)
Propylene glycol monolaurate (1915)
Pseudoephedrine hydrochloride (1367)
Rifabutin (1657)
Sodium alendronate (1564)
Sodium hyaluronate (1472)
Sodium polystyrene sulphonate (1909)
Somatropin (0951)
Somatropin bulk solution (0950)
Somatropin for injection (0952)
Sorbitol, liquid (crystallising) (0436)
Sorbitol, liquid (non-crystallising) (0437)
Spiramycin (0293)
Star anise oil (2108)
Sucrose (0204)
Tamoxifen citrate (1046)
Thiamine hydrochloride (0303)
Ticlopidine hydrochloride (1050)
DL- α -Tocopheryl hydrogen succinate (1258)
RRR- α -Tocopheryl hydrogen succinate (1259)
Tramazoline hydrochloride monohydrate (1597)
Triacetin (1106)
Vancomycin hydrochloride (1058)
Vinblastine sulphate (0748)
Vincristine sulphate (0749)
Water for injections (0169)
Water, highly purified (1927)
Water, purified (0008)
Willow bark (1583)
Xylose (1278)
Zopiclone (1060)

Vaccines for human use

- Measles, mumps and rubella vaccine (live) (1057)
 Measles vaccine (live) (0213)
 Mumps vaccine (live) (0538)
 Pertussis vaccine (acellular, co-purified, adsorbed) (1595)
 Rubella vaccine (live) (0162)

Vaccines for veterinary use

- Clostridium novyi (type B) vaccine for veterinary use (0362)
 Clostridium perfringens vaccine for veterinary use (0363)
 Clostridium septicum vaccine for veterinary use (0364)

- Equine influenza vaccine (inactivated) (0249)
 Foot-and-mouth disease (ruminants) vaccine (inactivated) (0063)
 Swine erysipelas vaccine (inactivated) (0064)
 Tetanus vaccine for veterinary use (0697)

Radiopharmaceutical preparations

- Iobenguane (¹²³I) injection (1113)
 L-Methionine ([¹¹C]methyl) injection (1617)

Homoeopathic preparations

- Iron for homoeopathic preparations (2026)

TEXTS WHOSE TITLE HAS CHANGED FOR THE 5th EDITION

The titles of the following texts have been changed in the 5th Edition.

GENERAL CHAPTERS

- 2.2.34. Thermal analysis (*previously Thermogravimetry*)
 2.7.4. Assay of human coagulation factor VIII (*previously Assay of blood coagulation factor VIII*)
 3.1.4. Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations (*previously Polyethylene without additives for containers for preparations for parenteral use and for ophthalmic preparations*)
 3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations (*previously Polyethylene with additives for containers for preparations for parenteral use and for ophthalmic preparations*)
 3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations (*previously Polypropylene for containers and closures for preparations for parenteral and ophthalmic use*)
 5.2.8. Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (*previously Minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products*)

MONOGRAPHS**Monographs**

- Amphetamine sulphate (0368) (*previously Amphetamine sulphate*)
 Riboflavin (0292) (*previously Riboflavine*)
 Riboflavin sodium phosphate (0786) (*previously Riboflavine sodium phosphate*)
 Tosylchloramide sodium (0381) (*previously Chloramine*)
 Triacetin (1106) (*previously Glycerol triacetate*)

Vaccines for veterinary use

- Avian infectious bronchitis vaccine (live) (0442) (*previously Avian infectious bronchitis vaccine (live), freeze-dried*)
 Avian infectious bursal disease vaccine (live) (0587) (*previously Avian infectious bursal disease (Gumboro disease) vaccine (live), freeze-dried*)
 Avian infectious laryngotracheitis vaccine (live) (1068) (*previously Avian infectious laryngotracheitis vaccine (live) for chickens*)
 Canine leptospirosis vaccine (inactivated) (0447) (*previously Leptospira vaccine for veterinary use*)
 Duck viral hepatitis type I vaccine (live) (1315) (*previously Duck viral hepatitis vaccine (live)*)
 Fowl-pox vaccine (live) (0649) (*previously Fowl-pox vaccine (live), freeze-dried*)
 Newcastle disease vaccine (live) (0450) (*previously Newcastle disease vaccine (live), freeze-dried*)

TEXTS DELETED FOR THE 5th EDITION

The following texts were deleted on 1 January 2005.

GENERAL CHAPTERS

- 2.6.3. Tests for extraneous viruses using fertilised eggs
 2.6.4. Test for leucosis viruses
 2.6.5. Test for extraneous viruses using cell cultures
 2.6.6. Test for extraneous agents using chicks

MONOGRAPHS

- Carbenicillin sodium (0812)