

CONTENTS OF THE 6TH EDITION

NEW TEXTS

GENERAL CHAPTERS

- 2.2.57. Inductively coupled plasma-atomic emission spectrometry
- 2.2.58. Inductively coupled plasma-mass spectrometry
- 2.7.28. Colony-forming cell assay for human haematopoietic progenitor cells
- 2.7.29. Nucleated cell count and viability
- 2.8.20. Herbal drugs: sampling and sample preparation
- 2.9.41. Friability of granules and spheroids

MONOGRAPHS

The monographs below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 January 2008 at the latest.

Vaccines for human use

Cholera vaccine (inactivated, oral) (2327)

Vaccines for veterinary use

Rabbit haemorrhagic disease vaccine (inactivated) (2325)

Radiopharmaceutical preparations

Fluorodopa (¹⁸F) (prepared by electrophilic substitution) injection (1918)

Monographs

Bistort rhizome (2384)
Dacarbazine (1691)
Devil's claw dry extract (1871)
Dextranomer (2238)
Dorzolamide hydrochloride (2359)
Felbinac (2304)
Fexofenadine hydrochloride (2280)
Flavoxate hydrochloride (1692)
Fluorescein (2348)
Glycerol monocaprylate (2213)
Glycerol monocaprylocaprate (2392)
Indinavir sulphate (2214)
Lansoprazole (2219)
Macrogol 40 sorbitol heptaoleate (2396)
Magnesium citrate, anhydrous (2339)
Methylethylamine maleate (1788)
Microcrystalline cellulose and carmellose sodium (2050)
Moxidectin for veterinary use (1656)
Norgestimate (1732)
Notoginseng root (2383)
Ritonavir (2136)
Ropivacaine hydrochloride monohydrate (2335)
Safflower flower (2386)
Vinpocetine (2139)

REVISED TEXTS

GENERAL CHAPTERS

- 1. General notices
- 2.2.17. Drop point
- 2.2.22. Atomic emission spectrometry
- 2.2.23. Atomic absorption spectrometry
- 2.6.9. Abnormal toxicity
- 4. Reagents
- 5.1.4. Microbiological quality of pharmaceutical preparations
- 5.3. Statistical analysis of results of biological assays and tests

MONOGRAPHS

The monographs below have been technically revised since their last publication. They will be implemented on 1 January 2008.

General monographs

Monoclonal antibodies for human use (2031)
Substances for pharmaceutical use (2034)

Dosage forms

Eye preparations (1163)
Rectal preparations (1145)
Vaginal preparations (1164)

Vaccines for human use

Influenza vaccine (surface antigen, inactivated, virosome) (2053)

Vaccines for veterinary use

Avian infectious bursal disease vaccine (inactivated) (0960)

Monographs

Adenosine (1486)
Allopurinol (0576)
Alteplase for injection (1170)
Amitriptyline hydrochloride (0464)
Ascorbyl palmitate (0807)
Benzbromarone (1393)
Boldo leaf (1396)

Calendula flower (1297)
 Castor oil, hydrogenated (1497)
 Cefamandole nafate (1402)
 Cefepime dihydrochloride monohydrate (2126)
 Cetyl palmitate (1906)
 Chlortalidone (0546)
 Cholecalciferol (0072)
 Chondroitin sulphate sodium (2064)
 Chymotrypsin (0476)
 Clonidine hydrochloride (0477)
 Clozapine (1191)
 Copper sulphate, anhydrous (0893)
 Copper sulphate pentahydrate (0894)
 Dalteparin sodium (1195)
 Danaparoid sodium (2090)
 Diclofenac potassium (1508)
 Diclofenac sodium (1002)
 Diethylcarbamazine citrate (0271)
 Dipyrindamole (1199)
 Dopamine hydrochloride (0664)
 Enoxaparin sodium (1097)
 Erythropoietin concentrated solution (1316)
 Etodolac (1422)
 Eucalyptus leaf (1320)
 Fenofibrate (1322)
 Fenoterol hydrobromide (0901)
 Fluorouracil (0611)
 Glucagon, human (1635)
 Glycerol dibehenate (1427)
 Gonadotrophin, chorionic (0498)
 Heparin calcium (0332)
 Heparin sodium (0333)
 Heparins, low-molecular-mass (0828)
 Human albumin solution (0255)
 Human anti-D immunoglobulin (0557)
 Human anti-D immunoglobulin for intravenous administration (1527)
 Human plasma for fractionation (0853)
 Human prothrombin complex (0554)
 Hyaluronidase (0912)
 Hydrochlorothiazide (0394)
 Insulin, bovine (1637)
 Insulin, porcine (1638)
 Ketorolac trometamol (1755)
 Lidocaine hydrochloride (0227)
 Macrogol 15 hydroxystearate (2052)
 Macrogol oleate (1618)
 Matricaria flower (0404)
 Medroxyprogesterone acetate (0673)
 Metamizole sodium (1346)
 Methenamine (1545)
 Nadroparin calcium (1134)
 Nonoxinol 9 (1454)
 Noradrenaline hydrochloride (0732)
 Noradrenaline tartrate (0285)
 Oregano (1880)
 Palmitic acid (1904)
 Pancreas powder (0350)
 Paraffin, hard (1034)
 Parnaparin sodium (1252)
 Paroxetine hydrochloride, anhydrous (2283)
 Paroxetine hydrochloride hemihydrate (2018)
 Pentaerythrityl tetranitrate, diluted (1355)
 Pepsin powder (0682)
 Perindopril *tert*-butylamine (2019)
 Pholcodine (0522)
 Promethazine hydrochloride (0524)
 Riboflavin (0292)
 Ribwort plantain (1884)
 Rice starch (0349)
 Sodium acetate trihydrate (0411)
 Sodium calcium edetate (0231)
 Sodium fluoride (0514)
 Sodium hyaluronate (1472)
 Squalane (1630)
 Tinzaparin sodium (1271)
 Trimipramine maleate (0534)
 Trypsin (0694)
 Urofollitropin (0958)
 Urokinase (0695)
 Warfarin sodium (0698)
 Warfarin sodium clathrate (0699)
 Yohimbine hydrochloride (2172)

CORRECTED TEXTS

The texts below from the 5th Edition have been modified and specify '01/2008:XXXX-corrected 6.0' above the title. These modifications are to be taken into account from the publication date of the 6th Edition.

GENERAL CHAPTERS

- 2.2.20. Potentiometric titration
 2.4.8. Heavy metals
 2.4.15. Nickel in polyols
 2.4.29. Composition of fatty acids in oils rich in omega-3 acids
 2.5.12. Water: semi-micro determination
 2.5.33. Total protein
 2.6.13. Microbiological examination of non-sterile products: test for specified micro-organisms
 2.7.2. Microbiological assay of antibiotics
 2.7.6. Assay of diphtheria vaccine (adsorbed)
 2.7.8. Assay of tetanus vaccine (adsorbed)
 2.8.12. Determination of essential oils in herbal drugs

- 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
- 3.1.4. Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations
- 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
- 3.2.2.1. Plastic containers for aqueous solutions for infusion
- 3.2.9. Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders
- 5.2.1. Terminology used in monographs on biological products
- 5.14. Gene transfer medicinal products for human use

MONOGRAPHS

General monographs

Herbal drugs (1433)

Vaccines for human use

Diphtheria vaccine (adsorbed) (0443)
 Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) (1931)
 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), 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)
 Haemophilus type b conjugate vaccine (1219)
 Meningococcal group C conjugate vaccine (2112)
 Pertussis vaccine (acellular, component, adsorbed) (1356)
 Pertussis vaccine (acellular, co-purified, adsorbed) (1595)
 Smallpox vaccine (live) (0164)
 Tetanus vaccine (adsorbed) (0452)

Vaccines for veterinary use

Aujeszky's disease vaccine (live) for pigs for parenteral administration (0745)
 Bovine parainfluenza virus vaccine (live) (1176)
 Bovine respiratory syncytial virus vaccine (live) (1177)
 Brucellosis vaccine (live) (Brucella melitensis Rev. 1 strain) for veterinary use (0793)
 Canine distemper vaccine (live) (0448)
 Distemper vaccine (live) for mustelids (0449)
 Feline calicivirosis vaccine (live) (1102)
 Infectious bovine rhinotracheitis vaccine (live) (0696)

Radiopharmaceutical preparations

Indium (¹¹¹In) pentetate injection (0670)
 Strontium (⁸⁹Sr) chloride injection (1475)
 Technetium (^{99m}Tc) macrosalb injection (0296)

Homoeopathic preparations

Cadmium sulphate hydrate for homoeopathic preparations (2143)
 Common stinging nettle for homoeopathic preparations (2030)
 Copper acetate monohydrate for homoeopathic preparations (2146)
 Copper for homoeopathic preparations (1610)
 Hedera helix for homoeopathic preparations (2092)
 Hyoscyamus for homoeopathic preparations (2091)
 Hypericum for homoeopathic preparations (2028)
 Iron for homoeopathic preparations (2026)
 Oriental cashew for homoeopathic preparations (2094)
 Saffron for homoeopathic preparations (1624)

Monographs

Acacia (0307)
Acacia, spray-dried (0308)
Acamprosate calcium (1585)
Acebutolol hydrochloride (0871)
Aceclofenac (1281)
Acesulfame potassium (1282)
Acetazolamide (0454)
Acetylcholine chloride (1485)
Acetylcysteine (0967)
 β -Acetyldigoxin (2168)
Acetylsalicylic acid (0309)
N-Acetyltryptophan (1383)
N-Acetyltyrosine (1384)
Acitretin (1385)
Adenine (0800)
Adipic acid (1586)
Agar (0310)
Agnus castus fruit (2147)
Agrimony (1587)
Alanine (0752)
Albendazole (1386)
Alchemilla (1387)
Alginic acid (0591)
Allantoin (1288)
Almagate (2010)
Aloes, Barbados (0257)
Aloes, Cape (0258)
Alprazolam (1065)
Alprenolol hydrochloride (0876)
Aluminium magnesium silicate (1388)
Aluminium oxide, hydrated (0311)
Aluminium phosphate gel (2166)
Aluminium phosphate, hydrated (1598)
Ambroxol hydrochloride (1489)
Amfetamine sulphate (0368)
Amidotrizoic acid dihydrate (0873)
Amikacin (1289)
Amikacin sulphate (1290)
Aminocaproic acid (0874)
Aminoglutethimide (1291)
Amisulpride (1490)
Ammonium bromide (1389)
Ammonium chloride (0007)
Ammonium hydrogen carbonate (1390)
Amobarbital (0594)
Amobarbital sodium (0166)
Amoxicillin sodium (0577)
Amoxicillin trihydrate (0260)
Ampicillin, anhydrous (0167)
Ampicillin sodium (0578)
Ampicillin trihydrate (0168)
Angelica root (1857)
Antazoline hydrochloride (0972)
Apomorphine hydrochloride (0136)
Arachis oil, hydrogenated (1171)
Arginine (0806)
Arginine aspartate (2096)
Arginine hydrochloride (0805)
Arnica flower (1391)
Articaine hydrochloride (1688)
Artichoke leaf (1866)
Ash leaf (1600)
Asparagine monohydrate (2086)
Aspartame (0973)
Aspartic acid (0797)
Astemizole (1067)
Atenolol (0703)
Atropine (2056)
Atropine sulphate (0068)
Azathioprine (0369)
Azelastine hydrochloride (1633)
Bacampicillin hydrochloride (0808)
Barbital (0170)
Basic butylated methacrylate copolymer (1975)
Bearberry leaf (1054)
Beclometasone dipropionate, anhydrous (0654)
Beclometasone dipropionate monohydrate (1709)
Belladonna leaf (0221)
Belladonna, prepared (0222)
Bendroflumethiazide (0370)
Benfluorex hydrochloride (1601)
Benperidol (1172)
Bentonite (0467)
Benzethonium chloride (0974)
Benzocaine (0011)
Benzoic acid (0066)
Benzoyl peroxide, hydrous (0704)
Benzylpenicillin, benzathine (0373)
Benzylpenicillin potassium (0113)
Benzylpenicillin, procaine (0115)
Benzylpenicillin sodium (0114)
Betahistine dihydrochloride (1665)
Betahistine mesilate (1071)
Betamethasone (0312)
Betamethasone dipropionate (0809)
Betamethasone valerate (0811)
Betaxolol hydrochloride (1072)
Bezafibrate (1394)
Bifonazole (1395)
Bilberry fruit, dried (1588)
Bilberry fruit, fresh (1602)
Biotin (1073)
Biperiden hydrochloride (1074)
Birch leaf (1174)
Bisacodyl (0595)
Bismuth subcarbonate (0012)
Bismuth subgallate (1493)
Bismuth subnitrate, heavy (1494)
Bismuth subsalicylate (1495)
Bitter-orange flower (1810)

Black horehound (1858)
Bleomycin sulphate (0976)
Bogbean leaf (1605)
Borax (0013)
Boric acid (0001)
Bromhexine hydrochloride (0706)
Bromperidol (1178)
Brompheniramine maleate (0977)
Brotizolam (2197)
Buckwheat herb (2184)
Budesonide (1075)
Buflomedil hydrochloride (1398)
Bumetanide (1076)
Bupivacaine hydrochloride (0541)
Buprenorphine (1180)
Buspirone hydrochloride (1711)
Butcher's broom (1847)
Caffeine (0267)
Caffeine monohydrate (0268)
Calcifediol (1295)
Calcitriol (0883)
Calcium acetate (2128)
Calcium ascorbate (1182)
Calcium carbonate (0014)
Calcium chloride dihydrate (0015)
Calcium chloride hexahydrate (0707)
Calcium folinate (0978)
Calcium glucoheptonate (1399)
Calcium gluconate (0172)
Calcium gluconate for injection (0979)
Calcium glycerophosphate (0980)
Calcium hydrogen phosphate, anhydrous (0981)
Calcium hydrogen phosphate dihydrate (0116)
Calcium lactate, anhydrous (2118)
Calcium lactate monohydrate (2117)
Calcium lactate pentahydrate (0468)
Calcium lactate trihydrate (0469)
Calcium levulinate dihydrate (1296)
Calcium pantothenate (0470)
Calcium phosphate (1052)
Calcium stearate (0882)
Calcium sulphate dihydrate (0982)
D-Camphor (1400)
Camphor, racemic (0655)
Caprylocaproyl macrogolglycerides (1184)
Capsicum (1859)
Carbachol (1971)
Carbamazepine (0543)
Carbasalate calcium (1185)
Carbidopa (0755)
Carbocisteine (0885)
Carbomers (1299)
Carboplatin (1081)
Carmellose calcium (0886)
Carmellose sodium (0472)
Carmellose sodium, low-substituted (1186)
Carteolol hydrochloride (1972)
Carvedilol (1745)
Cascara (0105)
Cefaclor (0986)
Cefadroxil monohydrate (0813)
Cefalexin monohydrate (0708)
Cefapirin sodium (1650)
Cefazolin sodium (0988)
Cefixime (1188)
Cefoperazone sodium (1404)
Cefoxitin sodium (0990)
Cefuroxime axetil (1300)
Cefuroxime sodium (0992)
Celiprolol hydrochloride (1632)
Cellulose acetate (0887)
Cellulose acetate butyrate (1406)
Cellulose acetate phthalate (0314)
Cellulose, microcrystalline (0316)
Cellulose, powdered (0315)
Centauray (1301)
Centella (1498)
Cetirizine dihydrochloride (1084)
Cetostearyl alcohol (type A), emulsifying (0801)
Cetrimide (0378)
Cetylpyridinium chloride (0379)
Chamomile flower, Roman (0380)
Charcoal, activated (0313)
Chenodeoxycholic acid (1189)
Chitosan hydrochloride (1774)
Chlorambucil (0137)
Chloramphenicol (0071)
Chloramphenicol palmitate (0473)
Chloramphenicol sodium succinate (0709)
Chlorcyclizine hydrochloride (1086)
Chlordiazepoxide (0656)
Chlorhexidine diacetate (0657)
Chlorhexidine dihydrochloride (0659)
Chlorobutanol, anhydrous (0382)
Chlorobutanol hemihydrate (0383)
Chloroquine phosphate (0544)
Chlorothiazide (0385)
Chlorphenamine maleate (0386)
Chlorpromazine hydrochloride (0475)
Chlorpropamide (1087)
Cholecalciferol concentrate (oily form) (0575)
Cholecalciferol concentrate (powder form) (0574)
Cholecalciferol concentrate (water-dispersible form) (0598)
Cimetidine (0756)
Cimetidine hydrochloride (1500)
Cinchona bark (0174)
Cinnarizine (0816)
Cisapride tartrate (1503)
Cisplatin (0599)
Citric acid, anhydrous (0455)
Citric acid monohydrate (0456)

Clarithromycin (1651)
Clazuril for veterinary use (1714)
Clebopride malate (1303)
Clemastine fumarate (1190)
Clindamycin hydrochloride (0582)
Clindamycin phosphate (0996)
Clobazam (1974)
Clobetasol propionate (2127)
Clobetasone butyrate (1090)
Clomipramine hydrochloride (0889)
Clonazepam (0890)
Clotrimazole (0757)
Cocaine hydrochloride (0073)
Codeine (0076)
Codeine phosphate hemihydrate (0074)
Codeine phosphate sesquihydrate (0075)
Cola (1504)
Colistimethate sodium (0319)
Copovidone (0891)
Coriander (1304)
Cortisone acetate (0321)
Cotton, absorbent (0036)
Cottonseed oil, hydrogenated (1305)
Couch grass rhizome (1306)
Croscarmellose sodium (0985)
Crosopovidone (0892)
Cyanocobalamin (0547)
Cyclizine hydrochloride (1092)
Cyclopentolate hydrochloride (1093)
Cysteine hydrochloride monohydrate (0895)
Cystine (0998)
Dapsone (0077)
Deptropine citrate (1308)
Dequalinium chloride (1413)
Desipramine hydrochloride (0481)
Deslanoside (0482)
Desoxycortone acetate (0322)
Detomidine hydrochloride for veterinary use (1414)
Devil's claw root (1095)
Dexamethasone (0388)
Dexamethasone acetate (0548)
Dexchlorpheniramine maleate (1196)
Dextran 1 for injection (1506)
Dextromoramide tartrate (0021)
Dextropropoxyphene hydrochloride (0713)
Diazoxide (0550)
Dibrompropamide diisetonate (2300)
Diclazuril for veterinary use (1718)
Dicloxacillin sodium (0663)
Dicycloverine hydrochloride (1197)
Dienestrol (0483)
Diethylene glycol palmitostearate (1415)
Diethylstilbestrol (0484)
Digitalis leaf (0117)
Digitoxin (0078)
Dihydroergotamine mesilate (0551)
Dihydroergotamine tartrate (0600)
Diltiazem hydrochloride (1004)
Dimenhydrinate (0601)
Dimetindene maleate (1417)
Diphenhydramine hydrochloride (0023)
Diphenoxylate hydrochloride (0819)
Dipotassium phosphate (1003)
Diprophylline (0486)
Dirithromycin (1313)
Disodium phosphate, anhydrous (1509)
Disopyramide phosphate (1005)
Dithranol (1007)
Dobutamine hydrochloride (1200)
Dog rose (1510)
Domperidone (1009)
Domperidone maleate (1008)
Dosulepin hydrochloride (1314)
Doxapram hydrochloride (1201)
Doxepin hydrochloride (1096)
Doxycycline hyclate (0272)
Doxycycline monohydrate (0820)
Droperidol (1010)
Econazole nitrate (0665)
Elder flower (1217)
Eleutherococcus (1419)
Emetine hydrochloride heptahydrate (0080)
Emetine hydrochloride pentahydrate (0081)
Enalapril maleate (1420)
Enoxolone (1511)
Ephedrine, anhydrous (0488)
Ephedrine hemihydrate (0489)
Ephedrine hydrochloride (0487)
Ephedrine hydrochloride, racemic (0715)
Equisetum stem (1825)
Ergometrine maleate (0223)
Erythromycin (0179)
Erythromycin ethylsuccinate (0274)
Erythromycin stearate (0490)
Esketamine hydrochloride (1742)
Estradiol benzoate (0139)
Estradiol valerate (1614)
Estriol (1203)
Ethacridine lactate monohydrate (1591)
Ethambutol hydrochloride (0553)
Ethinylestradiol (0140)
Ethionamide (0141)
Ethylcellulose (0822)
Etilefrine hydrochloride (1205)
Etofylline (0492)
Febantel for veterinary use (2176)
Felodipine (1013)
Fenbendazole for veterinary use (1208)
Fenbufen (1209)
Fentanyl (1210)
Fentanyl citrate (1103)

Fenticonazole nitrate (1211)
Fenugreek (1323)
Ferrous fumarate (0902)
Ferrous gluconate (0493)
Ferrous sulphate, dried (2340)
Feverfew (1516)
Finasteride (1615)
Flubendazole (1721)
Flucloxacillin sodium (0668)
Fluconazole (2287)
Flucytosine (0766)
Fludrocortisone acetate (0767)
Flumazenil (1326)
Flumequine (1517)
Flumetasone pivalate (1327)
Flunarizine dihydrochloride (1722)
Flunitrazepam (0717)
Flunixin meglumine for veterinary use (1696)
Fluocinolone acetonide (0494)
Fluocortolone pivalate (1212)
Fluorescein sodium (1213)
Flupentixol dihydrochloride (1693)
Flurazepam monohydrochloride (0905)
Fluspirilene (1723)
Flutrimazole (1424)
Fosfomycin calcium (1328)
Fosfomycin sodium (1329)
Frangula bark (0025)
Fructose (0188)
Fumitory (1869)
Furosemide (0391)
Galactose (1215)
Gallamine triethiodide (0181)
Garlic powder (1216)
Gelatin (0330)
Gentamicin sulphate (0331)
Ginkgo leaf (1828)
Ginseng (1523)
Glibenclamide (0718)
Gliclazide (1524)
Glipizide (0906)
Glucose, anhydrous (0177)
Glucose, liquid, spray-dried (1525)
Glucose monohydrate (0178)
Glutamic acid (0750)
Glutathione (1670)
Glycerol monolinoleate (1429)
Glycerol mono-oleate (1430)
Glycine (0614)
Goldenrod (1892)
Goldenrod, European (1893)
Goldenseal rhizome (1831)
Granisetron hydrochloride (1695)
Greater celandine (1861)
Griseofulvin (0182)
Guanethidine monosulphate (0027)
Guar (1218)
Guar galactomannan (0908)
Haemodialysis solutions, concentrated, water for diluting (1167)
Halofantrine hydrochloride (1979)
Haloperidol (0616)
Hamamelis leaf (0909)
Hawthorn berries (1220)
Hawthorn leaf and flower (1432)
Hawthorn leaf and flower dry extract (1865)
Heptaminol hydrochloride (1980)
Hexamidine diisetonate (1436)
Hexobarbital (0183)
Histamine dihydrochloride (0143)
Histidine (0911)
Histidine hydrochloride monohydrate (0910)
Homatropine hydrobromide (0500)
Homatropine methylbromide (0720)
Hop strobile (1222)
Human antithrombin III concentrate (0878)
Human coagulation factor VII (1224)
Human coagulation factor XI (1644)
Human haematopoietic stem cells (2323)
Hydrocortisone (0335)
Hydrocortisone acetate (0334)
Hydrocortisone hydrogen succinate (0768)
Hydromorphone hydrochloride (2099)
Hydroxocobalamin acetate (0913)
Hydroxocobalamin chloride (0914)
Hydroxocobalamin sulphate (0915)
Hydroxyethylcellulose (0336)
Hydroxypropylcellulose (0337)
Hydroxyzine hydrochloride (0916)
Hymecromone (1786)
Hyoscine butylbromide (0737)
Hypromellose (0348)
Hypromellose phthalate (0347)
Ibuprofen (0721)
Iceland moss (1439)
Ichthammol (0917)
Imipenem (1226)
Imipramine hydrochloride (0029)
Indapamide (1108)
Indian frankincense (2310)
Indometacin (0092)
Insulin aspart (2084)
Insulin, human (0838)
Insulin injection, biphasic (0831)
Insulin injection, biphasic isophane (0832)
Insulin injection, isophane (0833)
Insulin lispro (2085)
Insulin zinc injectable suspension (0837)
Insulin zinc injectable suspension (amorphous) (0835)
Insulin zinc injectable suspension (crystalline) (0836)

Iopamidol (1115)
Iopanoic acid (0700)
Iotalamic acid (0751)
Ioxaglic acid (2009)
Ipecacuanha, prepared (0093)
Ipecacuanha root (0094)
Isoconazole (1018)
Isoconazole nitrate (1017)
Isoleucine (0770)
Isoniazid (0146)
Isosorbide dinitrate, diluted (1117)
Isosorbide mononitrate, diluted (1118)
Isoxsuprine hydrochloride (1119)
Ispaghula husk (1334)
Ispaghula seed (1333)
Isradipine (2110)
Itraconazole (1335)
Ivermectin (1336)
Ivy leaf (2148)
Java tea (1229)
Josamycin propionate (1982)
Kanamycin acid sulphate (0033)
Kelp (1426)
Ketoconazole (0921)
Ketotifen hydrogen fumarate (1592)
Knotgrass (1885)
Labetalol hydrochloride (0923)
Lactitol monohydrate (1337)
Lactose, anhydrous (1061)
Lactose monohydrate (0187)
Lemon verbena leaf (1834)
Leucine (0771)
Levamisole hydrochloride (0726)
Levocabastine hydrochloride (1484)
Levocarnitine (1339)
Levodopa (0038)
Levomepromazine hydrochloride (0505)
Levomepromazine maleate (0925)
Levomethadone hydrochloride (1787)
Levonorgestrel (0926)
Levothyroxine sodium (0401)
Lime flower (0957)
Linseed (0095)
Liothyronine sodium (0728)
Liquorice root (0277)
Lisinopril dihydrate (1120)
Lithium carbonate (0228)
Loosestrife (1537)
Loperamide hydrochloride (0929)
Lorazepam (1121)
Lovage root (1233)
Lynestrenol (0558)
Lysine hydrochloride (0930)
Macrogol lauryl ether (1124)
Macrogol 6 glycerol caprylocaprate (1443)
Macrogolglycerol cocoates (1122)
Magnesium acetate tetrahydrate (2035)
Magnesium aspartate dihydrate (1445)
Magnesium carbonate, heavy (0043)
Magnesium carbonate, light (0042)
Magnesium chloride 4.5-hydrate (1341)
Magnesium chloride hexahydrate (0402)
Magnesium glycerophosphate (1446)
Magnesium hydroxide (0039)
Magnesium oxide, heavy (0041)
Magnesium oxide, light (0040)
Magnesium peroxide (1540)
Magnesium stearate (0229)
Magnesium sulphate heptahydrate (0044)
Magnesium trisilicate (0403)
Maleic acid (0365)
Malic acid (2080)
Mallow flower (1541)
Maltitol (1235)
Maltodextrin (1542)
Manganese sulphate monohydrate (1543)
Marshmallow leaf (1856)
Marshmallow root (1126)
Meadowsweet (1868)
Mebendazole (0845)
Mefenamic acid (1240)
Megestrol acetate (1593)
Meglumine (2055)
Melilot (2120)
Melissa leaf (1447)
Mepivacaine hydrochloride (1242)
Mepyramine maleate (0278)
Mercuric chloride (0120)
Mesalazine (1699)
Mesterolone (1730)
Mestranol (0509)
Metformin hydrochloride (0931)
Methacrylic acid - ethyl acrylate copolymer (1:1) (1128)
Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent (1129)
Methacrylic acid - methyl methacrylate copolymer (1:1) (1127)
Methacrylic acid - methyl methacrylate copolymer (1:2) (1130)
Methadone hydrochloride (0408)
Methaqualone (0510)
Methionine (1027)
DL-Methionine (0624)
Methyl parahydroxybenzoate (0409)
Methylatropine bromide (0511)
Methylatropine nitrate (0512)
Methylcellulose (0345)
Methylhydroxyethylcellulose (0346)
Methylphenobarbital (0189)
Methylprednisolone (0561)
Methylprednisolone acetate (0933)

Methylprednisolone hydrogen succinate (1131)
Methyltestosterone (0410)
Methylthionium chloride (1132)
Metoclopramide (1348)
Metolazone (1757)
Metoprolol succinate (1448)
Metoprolol tartrate (1028)
Metrifonate (1133)
Metronidazole (0675)
Miconazole nitrate (0513)
Midazolam (0936)
Milk-thistle fruit (1860)
Minocycline hydrochloride dihydrate (1030)
Minoxidil (0937)
Modafinil (2307)
Mometasone furoate (1449)
Morantel hydrogen tartrate for veterinary use (1546)
Motherwort (1833)
Moxonidine (1758)
Mullein flower (1858)
Mupirocin (1450)
Mupirocin calcium (1451)
Myrrh (1349)
Naftidrofuryl hydrogen oxalate (1594)
Nalidixic acid (0701)
Naphazoline hydrochloride (0730)
Naphazoline nitrate (0147)
Naproxen (0731)
Narrow-leaved coneflower root (1821)
Neostigmine bromide (0046)
Neostigmine metilsulfate (0626)
Netilmicin sulphate (1351)
Nettle leaf (1897)
Nevirapine, anhydrous (2255)
Niclosamide, anhydrous (0679)
Niclosamide monohydrate (0680)
Nicotinamide (0047)
Nicotinic acid (0459)
Nifedipine (0627)
Nifuroxazide (1999)
Nimesulide (1548)
Nimodipine (1245)
Nitrazepam (0415)
Nitrendipine (1246)
Nitrofurantoin (1135)
Nitrofurantoin (0101)
Nizatidine (1453)
Nomegestrol acetate (1551)
Norethisterone (0234)
Norethisterone acetate (0850)
Norfloxacin (1248)
Norgestrel (0940)
Nortriptyline hydrochloride (0941)
Noscapine (0516)
Noscapine hydrochloride (0515)
Oak bark (1887)
Ofloxacin (1455)
Olive leaf (1878)
Olsalazine sodium (1457)
Opium dry extract, standardised (1839)
Opium, prepared (1840)
Opium, raw (0777)
Opium tincture, standardised (1841)
Orphenadrine citrate (1759)
Orphenadrine hydrochloride (1760)
Ouabain (0048)
Oxaliplatin (2017)
Oxazepam (0778)
Oxfendazole for veterinary use (1458)
Oxitropium bromide (2170)
Oxolinic acid (1353)
Oxprenolol hydrochloride (0628)
Oxybuprocaine hydrochloride (1251)
Oxybutynin hydrochloride (1354)
Oxymetazoline hydrochloride (0943)
Oxytocin (0780)
Paclitaxel (1794)
Pale coneflower root (1822)
Papaverine hydrochloride (0102)
Paracetamol (0049)
Passion flower (1459)
Pelargonium root (2264)
Penbutolol sulphate (1461)
Penicillamine (0566)
Pentamidine diisetonate (1137)
Pentazocine lactate (2000)
Pentobarbital (0200)
Pentobarbital sodium (0419)
Pergolide mesilate (1555)
Pethidine hydrochloride (0420)
Pheniramine maleate (1357)
Phenobarbital (0201)
Phenobarbital sodium (0630)
Phenolphthalein (1584)
Phenolsulfonphthalein (0242)
Phenoxyethylpenicillin (0148)
Phentolamine mesilate (1138)
Phenylalanine (0782)
Phenylephrine (1035)
Phenylephrine hydrochloride (0632)
Phenylpropanolamine hydrochloride (0683)
Phenytoin (1253)
Phenytoin sodium (0521)
Phthalylsulfathiazole (0352)
Physostigmine salicylate (0286)
Physostigmine sulphate (0684)
Phytosterol (1911)
Pilocarpine hydrochloride (0633)
Pilocarpine nitrate (0104)
Pimozide (1254)
Pindolol (0634)

Pipemidic acid trihydrate (1743)
Piperacillin (1169)
Piperacillin sodium (1168)
Piperazine adipate (0423)
Piperazine citrate (0424)
Piracetam (1733)
Piretanide (1556)
Piroxicam (0944)
Pivampicillin (0852)
Pivmecillinam hydrochloride (1359)
Polyacrylate dispersion 30 per cent (0733)
Poly(vinyl acetate) (1962)
Poly(vinyl acetate) dispersion 30 per cent (2152)
Poly(vinyl alcohol) (1961)
Potassium acetate (1139)
Potassium bromide (0184)
Potassium carbonate (1557)
Potassium chloride (0185)
Potassium citrate (0400)
Potassium dihydrogen phosphate (0920)
Potassium hydrogen aspartate hemihydrate (2076)
Potassium hydrogen carbonate (1141)
Potassium hydrogen tartrate (1984)
Potassium hydroxide (0840)
Potassium iodide (0186)
Potassium metabisulphite (2075)
Potassium nitrate (1465)
Potassium perchlorate (1987)
Potassium sodium tartrate tetrahydrate (1986)
Potassium sorbate (0618)
Potassium sulphate (1622)
Potato starch (0355)
Povidone, iodinated (1142)
Pravastatin sodium (2059)
Prazepam (1466)
Prazosin hydrochloride (0856)
Prednicarbate (1467)
Prednisolone (0353)
Prednisolone acetate (0734)
Prednisolone pivalate (0736)
Prednisone (0354)
Prilocaine hydrochloride (1363)
Primaquine diphosphate (0635)
Primidone (0584)
Primula root (1364)
Probenecid (0243)
Procainamide hydrochloride (0567)
Procaine hydrochloride (0050)
Prochlorperazine maleate (0244)
Progesterone (0429)
Proguanil hydrochloride (2002)
Proline (0785)
Promazine hydrochloride (1365)
Propacetamol hydrochloride (1366)
Propafenone hydrochloride (2103)
Propantheline bromide (0857)
Propranolol hydrochloride (0568)
Propyl gallate (1039)
Propyl parahydroxybenzoate (0431)
Propylthiouracil (0525)
Protamine hydrochloride (0686)
Protamine sulphate (0569)
Proxiphylline (0526)
Pseudoephedrine hydrochloride (1367)
Psyllium seed (0858)
Purple coneflower herb (1823)
Purple coneflower root (1824)
Pygeum africanum bark (1886)
Pyrantel embonate (1680)
Pyrazinamide (0859)
Pyridostigmine bromide (1255)
Pyridoxine hydrochloride (0245)
Pyrimethamine (0288)
Quinine hydrochloride (0018)
Quinine sulphate (0019)
Ramipril (1368)
Red poppy petals (1881)
Repaglinide (2135)
Restharrow root (1879)
Rhatany root (0289)
Rhubarb (0291)
Ribavirin (2109)
Riboflavin sodium phosphate (0786)
Rifabutin (1657)
Risperidone (1559)
Roselle (1623)
Roxithromycin (1146)
Salbutamol (0529)
Salbutamol sulphate (0687)
Salicylic acid (0366)
Saw palmetto fruit (1848)
Senna leaf (0206)
Senna pods, Alexandrian (0207)
Senna pods, Tinnevely (0208)
Serine (0788)
Silica, colloidal anhydrous (0434)
Silica, colloidal hydrated (0738)
Silica, dental type (1562)
Silica, hydrophobic colloidal (2208)
Silver, colloidal, for external use (2281)
Silver nitrate (0009)
Sodium alginate (0625)
Sodium aminosalicylate dihydrate (1993)
Sodium ascorbate (1791)
Sodium aurothiomalate (1994)
Sodium benzoate (0123)
Sodium bromide (0190)
Sodium caprylate (1471)
Sodium chloride (0193)
Sodium citrate (0412)
Sodium cromoglicate (0562)

Sodium cyclamate (0774)
Sodium dihydrogen phosphate dihydrate (0194)
Sodium glycerophosphate, hydrated (1995)
Sodium hydrogen carbonate (0195)
Sodium hydroxide (0677)
Sodium iodide (0196)
Sodium methyl parahydroxybenzoate (1262)
Sodium molybdate dihydrate (1565)
Sodium perborate, hydrated (1997)
Sodium polystyrene sulphonate (1909)
Sodium propionate (2041)
Sodium propyl parahydroxybenzoate (1263)
Sodium salicylate (0413)
Sodium starch glycolate (type C) (1566)
Sodium stearate (2058)
Sodium sulphate, anhydrous (0099)
Sodium sulphate decahydrate (0100)
Sodium valproate (0678)
Sotalol hydrochloride (2004)
Soya-bean oil, hydrogenated (1265)
Spironolactone (0688)
St. John's wort (1438)
Stannous chloride dihydrate (1266)
Stearic acid (1474)
Stearoyl macroglycerides (1268)
Stramonium leaf (0246)
Stramonium, prepared (0247)
Succinylsulfathiazole (0357)
Sucrose (0204)
Sugar spheres (1570)
Sulfadiazine (0294)
Sulfadimidine (0295)
Sulfadoxine (0740)
Sulfafurazole (0741)
Sulfaguanidine (1476)
Sulfamerazine (0358)
Sulfamethizole (0637)
Sulfamethoxazole (0108)
Sulfamethoxypyridazine for veterinary use (0638)
Sulfanilamide (1571)
Sulfasalazine (0863)
Sulfathiazole (0742)
Sulfinpyrazone (0790)
Sulfisomidine (0639)
Sulindac (0864)
Sulpiride (1045)
Suxibuzone (1574)
Talc (0438)
Tannic acid (1477)
Tartaric acid (0460)
Temazepam (0954)
Terbinafine hydrochloride (1734)
Terbutaline sulphate (0690)
Terconazole (1270)
Terfenadine (0955)
Testosterone (1373)
Testosterone propionate (0297)
Tetracaine hydrochloride (0057)
Tetracycline (0211)
Tetracycline hydrochloride (0210)
Tetrazepam (1738)
Tetryzoline hydrochloride (2101)
Theobromine (0298)
Theophylline (0299)
Theophylline monohydrate (0302)
Thiamazole (1706)
Thiamine nitrate (0531)
Thiamphenicol (0109)
Thioridazine hydrochloride (0586)
Threonine (1049)
Tiamulin for veterinary use (1660)
Tiamulin hydrogen fumarate for veterinary use (1659)
Tiapride hydrochloride (1575)
Tibolone (1739)
Ticarcillin sodium (0956)
Timolol maleate (0572)
Tinidazole (1051)
Tolbutamide (0304)
Tolfenamic acid (2039)
Torasemide, anhydrous (2132)
Tormentil (1478)
Tosylchloramide sodium (0381)
Tramadol hydrochloride (1681)
Tranexamic acid (0875)
Tretinoin (0693)
Triacetin (1106)
Triamterene (0058)
Trichloroacetic acid (1967)
Trifluoperazine hydrochloride (0059)
Trihexyphenidyl hydrochloride (1626)
Trimetazidine dihydrochloride (1741)
Trimethoprim (0060)
Trometamol (1053)
Tropisetron hydrochloride (2102)
Tropium chloride (1798)
Troloxerutin (2133)
Tryptophan (1272)
Tyrosine (1161)
Ubidecarenone (1578)
Urea (0743)
Ursodeoxycholic acid (1275)
Valerian root (0453)
Valine (0796)
Vancomycin hydrochloride (1058)
Verapamil hydrochloride (0573)
Verbena herb (1854)
Vinorelbine tartrate (2107)
Viscose wadding, absorbent (0034)
Wheat starch (0359)
White horehound (1835)

Wild pansy (flowering aerial parts) (1855)
Wild thyme (1891)
Willow bark (1583)
Wool alcohols (0593)
Wool fat (0134)
Wool fat, hydrogenated (0969)
Wormwood (1380)
Xanthan gum (1277)
Xylazine hydrochloride for veterinary use (1481)
Xylometazoline hydrochloride (1162)
Xylose (1278)

Yarrow (1382)
Zidovudine (1059)
Zinc acetate dihydrate (1482)
Zinc acexamate (1279)
Zinc chloride (0110)
Zinc oxide (0252)
Zinc stearate (0306)
Zinc sulphate heptahydrate (0111)
Zinc sulphate hexahydrate (1683)
Zinc undecylenate (0539)

TEXTS WHOSE TITLE HAS CHANGED FOR THE 6th EDITION

The titles of the following texts have been changed in the 6th Edition.

GENERAL CHAPTERS

2.8.12. Determination of essential oils in herbal drugs (*previously Determination of essential oils in vegetable drugs*)

3.2.2.1. Plastic containers for aqueous solutions for infusion (*previously Plastic containers for aqueous solutions for parenteral infusion*)

5.2.1. Terminology used in monographs on biological products (*previously Terminology used in monographs on vaccines*)

MONOGRAPHS

Vaccines for veterinary use

Aujeszky's disease vaccine (live) for pigs for parenteral administration (0745) (*previously Aujeszky's disease vaccine (live) for pigs for parenteral administration, freeze-dried*)

Bovine parainfluenza virus vaccine (live) (1176) (*previously Bovine parainfluenza virus vaccine (live), freeze-dried*)

Bovine respiratory syncytial virus vaccine (live) (1177) (*previously Bovine respiratory syncytial virus vaccine (live), freeze-dried*)

Brucellosis vaccine (live) (*Brucella melitensis* Rev. 1 strain) for veterinary use (0793) (*previously Brucellosis vaccine (live) (Brucella melitensis Rev. 1 strain), freeze-dried, for veterinary use*)

Canine distemper vaccine (live) (0448) (*previously Canine distemper vaccine (live), freeze-dried*)

Distemper vaccine (live) for mustelids (0449) (*previously Distemper vaccine (live) for mustelids, freeze-dried*)

Feline calicivirus vaccine (live) (1102) (*previously Feline calicivirus vaccine (live), freeze-dried*)
Infectious bovine rhinotracheitis vaccine (live) (0696) (*previously Infectious bovine rhinotracheitis vaccine (live), freeze-dried*)

Monographs

Pine sylvestris oil (1842) (*previously pine sylvestris oil*)

Silica, hydrophobic colloidal (2208) (*previously Silica, hydrophobic colloidal anhydrous*)

TEXTS DELETED

The following texts are deleted as of 1 January 2008.

GENERAL CHAPTERS

2.9.24. Resistance to rupture of suppositories and pessaries

2.9.28. Test for deliverable mass or volume of liquid and semi-solid preparations

MONOGRAPHS

Monographs

Acriflavinium monochloride (2043)

ERRATA

In the following monographs, after the heading „Other detectable impurities“ in the Impurities section, read: „(the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph *Substances for pharmaceutical use (2034)*. It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. *Control of impurities in substances for pharmaceutical use*)“

Articaine hydrochloride (1688)
Biperiden hydrochloride (1074)
Caffeine (0267)
Caffeine monohydrate (0268)
Ibuprofen (0721)
Ifosfamide (1529)
Metformin hydrochloride (0931)
Naphazoline hydrochloride (0730)

Norethisterone acetate (0850)
Oxaliplatin (2017)
Potassium clavulanate (1140)
Potassium clavulanate, diluted (1653)
Testosterone propionate (0297)
Thiamine hydrochloride (0303)
Thiamine nitrate (0531)
Tranexamic acid (0875)