

EUROPEAN
PHARMACOPOEIA
3rd Edition

2000

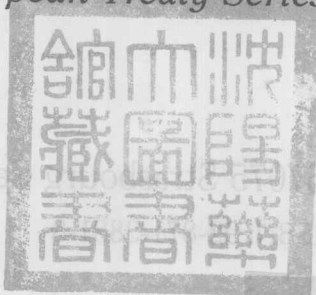
SUPPLEMENT

EUROPEAN PHARMACOPOEIA

Third Edition

Supplement 2000

*Published in accordance with the
Convention on the Elaboration of a European Pharmacopoeia
(European Treaty Series No. 50)*



Y155986

Council of Europe
Strasbourg

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© Council of Europe, 67075 Strasbourg Cedex, France - 1999

ISBN: 92-871-3881-8



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I. CONTENTS OF THE THIRD EDITION SUPPLEMENT 2000

For the information of the reader, lists are given below of: new monographs and general chapters added to the Pharmacopoeia with the publication of the first (1998), second (1999) and third (2000) supplements to the Third Edition (Volume 1999); monographs and general chapters that have been technically revised since the publication of the Third Edition; monographs and general chapters that have been corrected since the publication of the Third Edition; suppressed monographs.

International Harmonisation: monographs revised or elaborated in collaboration with the Pharmacopoeias of the United States and Japan are identified in the present list by «O». Residual differences between the harmonised texts of the three Pharmacopoeias are the subject of a commentary in Pharmeuropa.

SUPPLEMENT 1998

Monographs from Supplement 1998

The monographs below appeared in Supplement 1998 and were implemented on 1 January 1998, unless otherwise indicated in notes at the end of this section (Supplement 1998).

Aceclofenac
Acesulfame potassium
Acetazolamide
Alfentanil hydrochloride
Air, medical
Amoxicillin trihydrate
Arachis oil, hydrogenated
Aujeszky's disease vaccine (inactivated) for pigs
Aujeszky's disease vaccine (live) for pigs for parenteral administration, freeze-dried

Benperidol
Benzylpenicillin potassium
Benzylpenicillin procaine
Benzylpenicillin sodium
Betamethasone acetate
Betamethasone sodium phosphate
Birch leaf
Bitter-orange-flower oil
Bovine parainfluenza virus vaccine (live), freeze-dried
Bovine respiratory syncytial virus vaccine (live), freeze-dried
Bromperidol
Brompheniramine maleate
Bufexamac
Buprenorphine
Buprenorphine hydrochloride
Buserelin

Calcitriol⁽¹⁾
Calcium ascorbate
Calcium gluconate for injection
Calcium phosphate
Camphor, racemic
Carbasalate calcium

Carmellose sodium, low-substituted
Carmustine
Cascara
Cefalotin sodium
Cetirizine dihydrochloride
Chenodeoxycholic acid
Chlorcyclizine hydrochloride
Chlortalidone
Chlortetracycline hydrochloride
Cinnarizine
Clemastine fumarate
Cloxacillin sodium
Clozapine
Crotamiton
Cyanocobalamin

Dalteparin sodium
Dexamethasone
Dexamethasone sodium phosphate
Dicloxacillin sodium
Dicycloverine hydrochloride
Diethylene glycol monoethyl ether
Diprophylline
Dipyridamole
Dithranol
Dopamine hydrochloride
Doxapram hydrochloride

Egg drop syndrome '76 vaccine (inactivated)
Equine influenza vaccine (inactivated)
Etamsylate
Etofylline
Eucalyptus oil

Feline viral rhinotracheitis vaccine (inactivated)
Feline viral rhinotracheitis vaccine (live) freeze-dried
Fenbufen
Fentanyl
Fentanyl citrate
Fenticonazole nitrate
Flucloxacillin sodium

Fluocortolone pivalate
 Fluorescein sodium
 Formaldehyde solution (35 per cent)
 Framycetin sulphate
 Frangula bark
 Frangula bark dry extract, standardised

Galactose
 Gallium (^{67}Ga) citrate injection
 Guar

Haemodialysis solutions, concentrated, water for diluting
 Haemofiltration, solutions for
 Haloperidol
 Hawthorn berries
 Hepatitis A vaccine (inactivated, adsorbed)
 Hexetidine
 Histidine
 Hop strobile
 Human coagulation factor IX, freeze-dried
 Human coagulation factor VII, freeze-dried
 Human coagulation factor VIII, freeze-dried
 Human hepatitis B immunoglobulin for intravenous use
 Human prothrombin complex, freeze-dried
 Hydroxyethyl salicylate
 ◊Hypromellose phthalate

Indium (^{111}In) chloride solution
 Ipecacuanha root
 Ipratropium bromide
 Isosorbide mononitrate, diluted

Java tea

Ketoconazole

Labetalol hydrochloride
 Lactulose
 Lidocaine hydrochloride
 Liquorice root
 Lisinopril dihydrate
 Lomustine
 Lovage root

Maltitol
 Maltitol liquid
 Mefloquine hydrochloride
 Mepivacaine hydrochloride
 Metformin hydrochloride
 Mitoxantrone hydrochloride

Neomycin sulphate
 Neostigmine bromide
 Nitrendipine
 Nitrogen
 Nitrous oxide
 Nystatin

Omega-3-acid ethyl esters
 Oxybuprocaine hydrochloride
 Oxygen

Pancreas powder
 Paracetamol
 Penicillamine
 Phenytoin

Pimozide
 Pivampicillin
 Polymyxin B sulphate
 Polysorbate 80
 Potassium clavulanate
 ◊Potato starch
 Prazosin hydrochloride
 Prednisolone acetate
 Prednisolone sodium phosphate
 Protirelin
 Proxiphylline
 Pyridostigmine bromide
 Rabies vaccine (inactivated) for veterinary use
 Riboflavine sodium phosphate
 Rifamycin sodium

Salbutamol
 Salbutamol sulphate
 Salicylic acid (366)
 Selegiline hydrochloride
 Senna leaf
 Senna leaf dry extract, standardised
 Senna pods, Alexandrian
 Senna pods, Tinnevely
 Sodium chloride
 Sodium lactate solution
 Sodium laurilsulfate
 Sodium nitroprusside
 Soya-bean oil, hydrogenated
 Stannous chloride dihydrate
 ◊Sucrose
 Sulindac
 Sulphur for external use
 Sutures, sterile non-absorbable

Tenoxicam
 Terconazole
 Tinzaparin sodium
 DL- α -Tocopheryl hydrogen succinate
 RRR- α -Tocopheryl hydrogen succinate
 Triamcinolone acetonide
 Triamcinolone hexacetonide

Ursodeoxycholic acid

Vaccines for human use
 Valerian root

◊Wheat starch

Xylose

Zinc acexamate
 Zopiclone

General monographs on dosage forms

Eye preparations
 Chewing gums, medicated
 Intraruminal devices
 Tablets

General chapters from Supplement 1998

- 2.2.7. Optical rotation
- 2.2.41. Circular dichroism
- 2.4.23. Sterols in fatty oils
- 2.5.7. Unsaponifiable matter
- 2.5.29. Sulphur dioxide
- 2.5.30. Oxidising substances
- 2.5.31. Ribose in polysaccharide vaccines
- 2.6.7. Mycoplasmas
- 2.6.16. Test for extraneous agents in viral vaccines for human use
- 2.7.11. Assay of human coagulation factor IX
- 2.7.12. Assay of heparin in coagulation factor concentrates
- 2.9.4. Dissolution test for transdermal patches
- 2.9.14. Specific surface area by air permeability
- 5.1.3. Efficacy of antimicrobial preservation

(1) The revised version of this monograph entered into force on 1 October 1995.

SUPPLEMENT 1999**Monographs from Supplement 1999**

The monographs below appeared in Supplement 1999 and were implemented on 1 January 1999, unless otherwise indicated in notes at the end of this section (Supplement 1999).

Acetone
 Aciclovir
 Alcuronium chloride
 Alfalcidol
 Alfuzosin hydrochloride
 Alginic acid
 Allantoin
 ◊Alteplase for injection
 Amidotrizoic acid dihydrate
 Amikacin
 Amikacin sulphate
 Aminoglutethimide
 Amphotericin B
 Ampicillin sodium
 Ascorbic acid

Bacampicillin hydrochloride
 Bambuterol hydrochloride
 Beeswax, white
 Beeswax, yellow
 Belladonna leaf dry extract, standardised
 Benzalkonium chloride
 Benzalkonium chloride solution

Betadex
 Biotin
 Butyl parahydroxybenzoate
 Calcifediol
 Calcium dobesilate monohydrate
 Calcium levulinate dihydrate
 Calendula flower
 Canine adenovirus vaccine (inactivated)
 Canine distemper vaccine (live), freeze-dried
 Caprylocaproyl macroglycerides
 Carbenicillin sodium
 Carbomers
 Carbon dioxide
 Cefaclor
 Cefixime
 Cefotaxime sodium
 Cefuroxime axetil
 Centaury
 Cetostearyl alcohol (Type A) emulsifying
 Cetostearyl alcohol (Type B) emulsifying
 Cetylpyridinium chloride
 Chlorocresol
 Chlorpropamide
 Cholesterol
 Ciclopirox olamine
 Clebopride malate
 Cod-liver oil (type A)
 Cod-liver oil (type B)
 Copovidone
 Coriander
 Corticotropin
 Cottonseed oil, hydrogenated
 Couch grass rhizome
 Cyclizine hydrochloride
 Cyproterone acetate

Daunorubicin hydrochloride
 Decyl oleate
 Depropine citrate
 Dexchlorpheniramine maleate
 Digitoxin
 Dihydralazine sulphate (hydrated)
 Dimeticone
 Dinoprost trometamol
 Dinoprostone
 Dirithromycin
 Disodium phosphate dodecahydrate
 Dobutamine hydrochloride
 Doxycycline hyclate
 Duck viral hepatitis vaccine (live)

Elder flower
 Enoxaparin sodium
 Ergocalciferol
 Erythropoietin concentrated solution
 Estriol
 Ethanol (96 per cent)
 Ethanol, anhydrous
 Ethyl oleate
 Ethyl parahydroxybenzoate
 ◊Ethylcellulose
 Etilefrine hydrochloride
 Etoposide
 Eucalyptus leaf
 Eugenol

Feline infectious enteritis (feline panleucopenia) vaccine (inactivated)	Methacrylic acid - methyl methacrylate copolymer (1:1)
Feline infectious enteritis (feline panleucopenia) vaccine (live)	Methacrylic acid - methyl methacrylate copolymer (1:2)
Feline leukaemia vaccine (inactivated)	◊Methyl parahydroxybenzoate
Fenbendazole	Methylprednisolone
Fennel, bitter	Methylprednisolone hydrogen succinate
Fennel, sweet	Metixene hydrochloride
Fenugreek	Metoclopramide
Fludeoxyglucose (¹⁸ F) injection	Metrifonate
Flumazenil	Minocycline hydrochloride
Flumetasone pivalate	Mumps vaccine (live)
Fluoxetine hydrochloride	Myrrh
Fosfomycin calcium	Nadroparin calcium
Fosfomycin sodium	Netilmicin sulphate
Gallamine triethiodide	Nimodipine
Garlic powder	Norfloxacin
Glucose liquid	Nortryptiline hydrochloride
Glycerol trinitrate solution	Oleoyle macrogolglycerides
Guar galactomannan	Omega-3-acid triglycerides
Haemophilus type b conjugate vaccine	Oxolinic acid
Halothane	Oxybutynin hydrochloride
Homoeopathic preparations	Parnaparin sodium
Hydrocortisone	Pentaerythrityl tetranitrate, diluted
Imipenem	Pentamidine diisetonate
Insulin	Pertussis vaccine (acellular component, adsorbed)
Insulin human	Pheniramine maleate
Insulin injection, biphasic isophane	Phenoxymethylpenicillin
Insulin injection, isophane	Phenoxymethylpenicillin potassium
Insulin preparations, injectable	Phytomenadione
Insulin zinc injectable suspension	Picotamide monohydrate
Insulin zinc injectable suspension (amorphous)	Pilocarpine hydrochloride
Insulin zinc injectable suspension (crystalline)	Pilocarpine nitrate
Iobenguane (¹²³ I) injection	Piperacillin
Iobenguane (¹³¹ I) injection for diagnostic use	Piperacillin sodium
Iobenguane (¹³¹ I) injection for therapeutic use	Pivmecillinam hydrochloride
Iohexol	Porcine actinobacillosis vaccine (inactivated)
Iopamidol	Porcine progressive atrophic rhinitis vaccine (inactivated)
Iopanoic acid	Prilocaine
Isopropyl alcohol	Prilocaine hydrochloride
Itraconazole	Primrose root
Ivermectin	Promazine hydrochloride
Lactulose liquid	Promethazine hydrochloride
Lauroyl macrogolglycerides	Propacetamol hydrochloride
Lavender oil	Propranolol hydrochloride
Levocarnitine	Propyl gallate
Linoleoyl macrogolglycerides	Propyl parahydroxybenzoate
Lorazepam	Pseudoephedrine hydrochloride
Macrogol stearate	Quinidine sulphate
Macrogol stearyl ether	Quinine hydrochloride
Magnesium chloride 4.5-hydrate	Quinine sulphate
Magnesium chloride hexahydrate	Rabies vaccine for human use prepared in cell cultures
Maize oil, refined	Ramipril
Malathion	Rapeseed oil, refined
Maprotiline hydrochloride	Roxithromycin
Measles vaccine (live)	Rubella vaccine (live)
Measles, mumps and rubella vaccine (live)	Sage leaf
Medroxyprogesterone acetate	Sesame oil, refined
Mefenamic acid	Sodium alginate
Metamizole sodium	Sodium amidotrizoate
Methacrylic acid - ethyl acrylate copolymer (1:1)	Sodium cetostearyl sulphate
Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent	Sodium methyl parahydroxybenzoate
	Sodium propyl parahydroxybenzoate

Solution for organ preservation
Somatropin
Somatropin bulk solution
Somatropin for injection
Starch, pregelatinised⁽¹⁾
Stearoyl macrogolglycerides
Sufentanil citrate
Sunflower oil, refined

Talc
Technetium (^{99m}Tc) medronate injection
Technetium (^{99m}Tc) mertiatide injection
Terbutaline sulphate
Testosterone
Thyme
Thyme oil
Ticarcillin sodium
Tick-borne encephalitis vaccine (inactivated)
α-Tocopherol
α-Tocopheryl acetate
Triamcinolone
Triflusal
Tuberculin, old for human use
Tuberculin, purified protein derivative for human use

Valproic acid
Verapamil hydrochloride
Vindesine sulphate

Wheat-germ oil, refined
Wormwood

Xanthan gum
Xylitol

Yarrow
Yellow fever vaccine (live)

Zolpidem tartrate

General monographs on dosage forms

Preparations for inhalation
Rectal preparations

General chapters from Supplement 1999

- 2.2.27. Thin-layer chromatography
- 2.3.2. Identification of fatty oils by thin-layer chromatography
- 2.4.26. *N,N*-Dimethylaniline
- 2.5.32. Coulometric titration, micro-method
- 2.5.5. Peroxide value
- 2.6.2. Mycobacteria
- 2.6.14. Bacterial endotoxins
- 2.6.21. Nucleic acid amplification techniques
- 2.7.4. Assay of blood coagulation factor VIII
- 2.7.10. Assay of human coagulation factor VIII
- 2.9.20. Particulate contamination: visible particles
- 2.9.24. Resistance to rupture of suppositories and pessaries

(1) The revised version of this monograph entered into force on 1 January 1998.

SUPPLEMENT 2000

New monographs from Supplement 2000

The monographs below appear for the first time in Supplement 2000. They will be implemented on 1 January 2000 at the latest, unless otherwise indicated.

N-Acetyltryptophan
N-Acetyltyrosine
Acitretrin
Albendazole
Alchemilla
Aluminium magnesium silicate
Ammonium bromide
Ammonium hydrogen carbonate
Arnica flower
Avian paramyxovirus 3 vaccine (inactivated)

Benzbromarone
Bezafibrate
Bifonazole
Boldo leaf
Bromperidol decanoate
Buflomedil hydrochloride

Calcium glucoheptonate
D-Camphor
Caprylic acid
Cefamandole nafate
Cefatrizine propylene glycol
Cefoperazone sodium
Ceftazidime
Cellulose acetate butyrate
Ciclopirox
Cilastatin sodium
Clenbuterol hydrochloride
Coconut oil, refined
Cocoyl caprylocaprate
Codeine hydrochloride dihydrate

Dequalinium chloride
Detomidine hydrochloride for veterinary use
Diethylene glycol monopalmitostearate
Dihydroergocristine mesilate
Dimetindene maleate
Docusate sodium

Eleutherococcus
Enalapril maleate
Ethylene glycol monopalmitostearate
Etodolac

Flutamide
Flutrimazole
Fosfomycin trometamol
Fucus

Glycerol dibehenate
Glycerol distearate
Glycerol mono-oleates
Glycerol monolinoleate

Haloperidol decanoate
Hawthorn leaf and flower

Herbal drug preparations

Herbal drugs

Herbal teas

Hexamidine diisetonate

Hexylresorcinol

Hypericum

Iceland moss

Interferon gamma-1b concentrated solution

Leuporelin

Macrogol 6 glycerol caprylocaprate

Macrogols

Magnesium aspartate dihydrate

Magnesium glycerophosphate

Melissa leaf

Metoprolol succinate

Mometasone furoate

Mupirocin

Mupirocin calcium

Nicotine

Nizatidine

Nonoxinol 9

Ofloxacin

Olive oil, refined

Olsalazine sodium

Oxfendazole for veterinary use

Passion flower

Pefloxacin mesilate dihydrate

Penbutolol sulphate

Pentazocine

Pentazocine hydrochloride

Poloxamers

Potassium nitrate

Prazepam

Prednicarbate

Products of fermentation⁽¹⁾

Propylene glycol monopalmitostearate

Simeticone

Sodium caprylate

Sodium hyaluronate

Soya-bean oil, refined

Stearic acid

Strontium (⁸⁹Sr) chloride injection

Sulfaguanidine

Tannic acid

Tormentil

Triethyl citrate

Turmeric, Javanese

Wheat-germ oil, virgin

Xylazine hydrochloride

Zinc acetate dihydrate

Revised monographs from Supplement 2000

The monographs below have been technically revised since the publication of Supplement 1999. They will be implemented on 1 January 2000, unless otherwise indicated in notes at the end of this section (Supplement 2000).

Acetylsalicylic acid

Alanine⁽²⁾

Allopurinol

Amitriptyline hydrochloride⁽²⁾

Amoxicillin sodium

Aprotinin

Aprotinin concentrated solution

Arginine⁽²⁾

Arginine hydrochloride⁽²⁾

Aspartic acid⁽²⁾

Benserazide hydrochloride

Calcitonin (salmon)

Calcium folinate

Calcium hydroxide⁽²⁾

Calcium stearate

Carmellose calcium

Cellulose acetate

Cellulose acetate phthalate⁽²⁾

Charcoal, activated⁽²⁾

Chlorprothixene hydrochloride⁽²⁾

Chymotrypsin

Clostridium chauvoei vaccine for veterinary use⁽²⁾

Cortisone acetate

Croscarmellose sodium

Cysteine hydrochloride monohydrate⁽²⁾

Cystine⁽²⁾

Demeclocycline hydrochloride

Desipramine hydrochloride

Desmopressin

Dosulepin hydrochloride

Doxepin hydrochloride

Erythromycin stearate

Ethinylestradiol

Ferrous fumarate

Flecainide acetate

Glutamic acid⁽²⁾

Glycerol

Glycerol (85 per cent)

Glycerol monostearate 40-55

Gonadorelin acetate

Haemodialysis solutions for

Haemofiltration and for haemodiafiltration, solutions for

Hamamelis leaf

Histidine⁽²⁾

Histidine hydrochloride monohydrate⁽²⁾

Human plasma for fractionation⁽²⁾

◊Hydroxyethylcellulose

Hydroxyzine hydrochloride

Interferon alfa-2 concentrated solution

Iotalamic acid

Isoleucine⁽²⁾

(1) This monograph entered into force on 1 January 1999.

Isoprenaline hydrochloride
Isotretinoin
Ispaghula husk
Ispaghula seed

Lactitol monohydrate⁽²⁾
Leucine⁽²⁾
Lysine hydrochloride⁽²⁾

Macrogol cetostearyl ether
Macrogol glycerol cocoates
Magnesium stearate
Methionine⁽²⁾
Methotrexate
Morphine hydrochloride
Morphine sulphate

Nabumetone
Nalidixic acid
Naloxone hydrochloride dihydrate
Naphazoline hydrochloride
Naphazoline nitrate
Newcastle disease vaccine (inactivated)

Olive oil, virgin
Omeprazole
Oxytocin
Oxytocin bulk solution

Peritoneal dialysis, solutions for
Phenylalanine⁽²⁾
Piroxicam
Poliomyelitis vaccine (inactivated)
Polyacrylate dispersion 30 per cent
Prednisolone
Proline⁽²⁾
Propylthiouracil
Protamine hydrochloride
Protamine sulphate

Radiopharmaceutical preparations
Rhatany root

Serine⁽²⁾
Sodium cyclamate
Sodium valproate⁽²⁾
Sulfasalazine
Swine erysipelas vaccine (inactivated)

Threonine⁽²⁾
Tiaprofenic acid
RRR- α -Tocopherol
RRR- α -Tocopheryl acetate
Tragacanth
Tranexamic acid
Tretinoin
Trimethoprim⁽²⁾
Trypsin
Tryptophan⁽²⁾
Tylosin for veterinary use
Tylosin tartrate for veterinary use
Tyrosine⁽²⁾

Undecylenic acid⁽²⁾

Valine⁽²⁾

Water, for injections⁽³⁾
Water, purified⁽³⁾
Wool-fat, hydrogenated

Zinc undecylenate⁽²⁾

Corrected monographs from Supplement 2000

The monographs below have been corrected in Supplement 2000. They are implemented at the time of publication.

Aciclovir
Air, medical
Alcuronium chloride
Aluminium oxide, hydrated
Aluminium sulphate
Aminoglutethimide
Amphotericin B
Ampicillin sodium
Anise oil

Barium sulphate
Benperidol
Bromperidol

Calcifediol
Caprylocaproyl macrogolglycerides
Carbon dioxide
Cellulose acetate phthalate
Chewing gums, medicated
Chloral hydrate
Cinnarizine
Clozapine
Cod liver oil (type A)
Cod liver oil (type B)

Dimeticone
Dithranol

Elder flower
Erythropoietin concentrated solution
Ethanol, 96 per cent
Ethanol, anhydrous
Etilefrine hydrochloride
Eugenol

Fenbendazole
Fenofibrate
Fentanyl
Fentanyl citrate
Fenticonazole nitrate
Ferrous gluconate
Ferrous sulphate

Glucose, liquid

Haemodialysis solutions, concentrated, water for diluting
Haloperidol
Hop strobile
Hydrochlorothiazide

Isopropyl (alcohol)
Itraconazole

Java tea

Ketoconazole

Lactulose, liquid

Lisinopril dihydrate

Magnesium chloride 4.5 - hydrate

Magnesium chloride hexahydrate

Magnesium hydroxide

Magnesium trisilicate

Metoclopramide

Metrifonate

Nicotinamide

Nitrogen

Nitrous oxide

Norfloxacin

Omega-3-acid triglycerides

Oxytetracycline

Oxybuprocaine hydrochloride

Oxygen

Penicillamine

Pentobarbital sodium

Picotamide monohydrate

Pilocarpine hydrochloride

Pilocarpine nitrate

Pimozide

Prilocaine

Primula root

Pyridostigmine bromide

Rabies vaccine for human use prepared in cell cultures

Sage leaf (*salvia officinalis*)

Salicylic acid

Sodium chloride

Sodium lactate solution

Sodium salicylate

Somatropin

Somatropin bulk solution

Somatropin for injection

Sufentanil citrate

Sulpiride

Terconazole

Tetracycline

Thyme oil

New general chapters from Supplement 2000

2.2.42. Density of solids

2.2.43. Mass spectrometry

2.2.44. Total organic carbon in water for pharmaceutical use⁽¹⁾

2.4.27. Nickel in hydrogenated vegetable oils

2.4.28. 2-Ethylhexanoic acid

2.8.14. Assay of tannins in herbal drugs

2.9.25. Drug release from medicated chewing gum

2.9.26. Specific surface area by gas absorption

5.6. Assay of interferons

5.7. Table of physical characteristics of radionuclides mentioned in the European Pharmacopoeia

Revised general chapters from Supplement 2000

2.2.6 Refractive index⁽²⁾

2.2.24 Absorption spectrophotometry, infrared

2.2.25 Absorption spectrophotometry, ultraviolet and visible

2.2.31. Electrophoresis

2.4.22. Foreign oils in fatty oils by gas chromatography

2.5.6. Saponification value

2.6.1. Sterility⁽⁴⁾

2.6.12. Microbial examination of non-sterile products (total viable aerobic count)

2.6.13. Microbial examination of non-sterile products (test for specified micro-organisms)

2.9.7. Tablet friability of uncoated tablets

2.9.18. Preparations for inhalation

2.9.19. Particulate contamination - sub-visible particles⁽³⁾

2.9.22. Softening time determination of lipophilic suppositories

3.1. Materials used for the manufacture of containers

3.1.1. Materials for containers for human blood and blood components

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 (3.1.3)

3.1.4. Polyethylene without additives for containers for preparations for parenteral use and for ophthalmic preparations

3.1.5. Polyethylene with additives for containers for preparations for parenteral use and for ophthalmic preparations

3.1.6. Polypropylene for containers and closures for preparations for parenteral and ophthalmic use

3.1.7. Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations

3.1.8. Silicone oil used as a lubricant

3.1.9. Silicone elastomer for closures and tubing

3.1.12. Rubber for closures for containers for aqueous parenteral preparations and for powders for freeze-dried products

3.1.13. Plastic additives

3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion

3.2. Containers

3.2.2. Plastic containers and closures for pharmaceutical use

3.2.2.1. Plastic containers for aqueous solutions for parenteral infusion

5.1.4. Microbial quality of pharmaceutical preparations

5.3. Statistical analysis of results of biological assays and tests

Corrected general chapters from Supplement 2000

- 1.5. Abbreviations and symbols
- 2.1.6. Gas detector tubes
- 2.4.8. Heavy metals
- 2.4.24. Identification and control of residual solvents
- 2.4.25. Residual ethylene oxide and dioxan
- 2.5.26. Nitrogen monoxide and nitrogen dioxide in medicinal gases
- 2.6.14. Bacterial endotoxins
- 2.7.2. Microbiological assay of antibiotics
- 2.9.23. Pycnometric density of solids
- 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
- 5.4. Residual solvents
- 5.5. Alcoholimetric Tables

Suppression of monographs

The following monographs will be deleted on 1 January 1999.

- 2.4.20. Antioxydants in fatty oils
- Ethisterone
- Phenacetine
- Sterile reconstituted collagen strands

Texts whose title was changed in Supplement 2000

The following monographs have been merged into one single monograph «Macrogols».

- Macrogol 300
- Macrogol 400
- Macrogol 1000
- Macrogol 1500
- Macrogol 3000
- Macrogol 4000
- Macrogol 6000
- Macrogol 20000
- Macrogol 35000

The titles of the following monographs have been changed.

- Glycerol monostearate 40-50 becomes:
Glycerol monostearate 40-55
- Solutions for haemofiltration becomes:
Solutions for haemofiltration and haemodiafiltration
- Macrogol 7 glycerol cocoate becomes:
Macrogol glycerol cocoates
- Naloxone hydrochloride becomes:
Naloxone hydrochloride dihydrate
- Olive oil becomes:
Olive oil, virgin
- Oxytocin concentrated solution becomes:
Oxytocin bulk solution
- Primrose root becomes:
Primula root

The numbering of the following texts has been changed:

- 3.1.1. Materials based on plasticised poly(vinyl chloride) for (...) containers for aqueous solutions (...) is superseded, in part, by: 3.1.14.
- 3.1.2. Materials based on plasticised poly(vinyl chloride) for tubing (...) is superseded by: 3.1.1.2.
- 3.2.7. Plastic containers for aqueous solutions (...) is superseded by: 3.2.2.1.

- (1) This text entered into force on 1 July 1999.
- (2) The revised version of this text entered into force on 1 January 1999.
- (3) The revised version of this text entered into force on 1 July 1999.
- (4) The revised version of this text entered into force on 1 September 1998.

INTERNATIONAL HARMONISATION

The following texts have been revised or elaborated in collaboration with the Pharmacopoeias of Japan and of the United States in order to have harmonised texts in the three Pharmacopoeias. Residual differences are the subject of a commentary in Pharmeuropa.

- 2.2.31. Electrophoresis
- Alteplase for injection
- Ethylcellulose
- Hydroxyethylcellulose
- Hypromellose phthalate
- Methyl parahydroxybenzoate
- Potato starch
- Sucrose
- Wheat starch

II. CORRIGENDA

CONTENTS

The page number for the reagents in the table of contents should read '187' instead of '1875'.

INTRODUCTION

Page iv. General Principles. Read:

'General rules for interpretation of the texts of the Pharmacopoeia are given in the General Notices. The following information should also be noted.'

The general principles applied in the elaboration of the European Pharmacopoeia are laid down in the *Technical Guide for the Elaboration of Monographs* available as a special issue of *Pharmeuropa*.

The procedures for the tests and assays published in the individual monographs have been validated according to the current practice at the time of their elaboration for the purpose for which they are intended.

It is recognised that general chapters are used elsewhere than in the monographs of the Pharmacopoeia; in these circumstances users are recommended to consult the Technical Guide which gives extensive information on the application of many of the methods.'

GENERAL CHAPTERS

2.2.29. LIQUID CHROMATOGRAPHY

Page 33. Replace the following:

'The **number of theoretical plates** (n) may be calculated from data obtained under isothermal conditions from the formula:'

by:

'The **number of theoretical plates** (n) may be calculated from data obtained under isocratic conditions from the formula:'

2.2.33. NUCLEAR MAGNETIC RESONANCE SPECTROMETRY

Page 37. *Apparatus* - paragraphs 2) and 4). Replace:

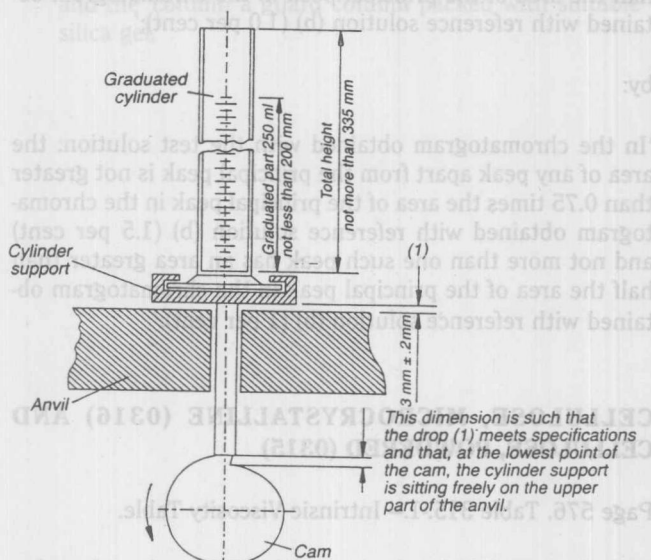
'carbon tetrachloride R'

by:

'deuterated chloroform R'

2.9.15. APPARENT VOLUME

Page 141. Replace the figure 2.9.15.1 by



4.1.1. REAGENTS

Delete Indophenol blue.

5.1.5. APPLICATION OF THE F_0 CONCEPT TO STEAM STERILISATION OF AQUEOUS PREPARATIONS

Page 288. Replace the following:

$$IF = N_0 - N = 10^{t/D}$$

by:

$$IF = \frac{N_0}{N} = 10^{t/D}$$

MONOGRAPHS

ALPRAZOLAM (1065)

Page 365. **TESTS - Related substances.** Replace the following:

— a stainless steel column 0.25 m long and 4.6 mm in internal diameter packed with *phenylsilyl silica gel for chromatography R* (5 μ m),

by:

— a stainless steel column 0.25 m long and 4.6 mm in internal diameter packed with *phenylsilyl silica gel for chromatography R1* (5 μ m),

BETAMETHASONE DIPROPIONATE (0809)

Page 475. TESTS - **Related substances**. Replace the following:

'In the chromatogram obtained with the test solution: the area of any peak apart from the principal peak is not greater than 0.75 times the area of the principal peak in the chromatogram obtained with reference solution (b) (2.0 per cent) and not more than one such peak has an area greater than half the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent);'

by:

'In the chromatogram obtained with the test solution: the area of any peak apart from the principal peak is not greater than 0.75 times the area of the principal peak in the chromatogram obtained with reference solution (b) (1.5 per cent) and not more than one such peak has an area greater than half the area of the principal peak in the chromatogram obtained with reference solution (b) (1 per cent);'

CELLULOSE, MICROCRYSTALLINE (0316) AND CELLULOSE, POWDERED (0315)

Page 576. Table 315.-1.- Intrinsic Viscosity Table.

In the bottom right-hand corner of the table, replace the value 3.417 by 2.417 which corresponds to the co-ordinate for 5.9 and η_{rel} 0.09.

Page 577. Insert new values for η_{rel} after the line commencing 9.9 as follows:

η_{rel}	0.0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
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CHLORHEXIDINE DIGLUCONATE SOLUTION (0658)

Page 601. IDENTIFICATION - Identification B. Replace the following:

'Reference solution. Dissolve 25 mg of calcium digluconate CRS in 1 ml of water R.'

by:

'Reference solution. Dissolve 25 mg of calcium gluconate CRS in 1 ml of water R.'

HYALURONIDASE (0912)

Page 972. ASSAY. Replace the following:

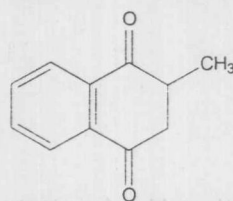
'Plot $(\ln h)^{-1}$ as a function of the reaction time ($t_1 + t_2/2$) in seconds. A linear relationship is obtained.'

by:

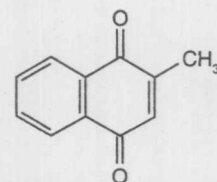
'Plot $(\ln \eta)^{-1}$ as a function of the reaction time ($t_1 + t_2/2$) in seconds. A linear relationship is obtained.'

MENADIONE (0507)

Page 1154. Replace the chemical formula:



by:

**PROPYLENE GLYCOL MONOSTEARATE (1143)**

Page 1400. IDENTIFICATION - Identification B. Replace the following:

'The retention time and size of the two principal peaks in the chromatogram obtained..'

by:

'The retention times of the two principal peaks in the chromatogram obtained..'

TETRACOSACTIDE (0644)

Page 1621. TESTS - **Amino acids**. Glycine had been omitted from the table of amino acids which should now read as follows:

Lysine	Threonine	Glycine	Isoleucine
Histidine	Serine	Alanine	Leucine
Arginine	Glutamic acid	Valine	Tyrosine
Aspartic acid	Proline	Methionine	Phenylalanine

VACCINES FOR VETERINARY USE (0062)

Page 1702. TESTS - **Mycoplasmas**. Following the republication of the test for mycoplasmas in Supplement 1998 the test may be amended by deleting the sentence:

'Depending on the origin of any cells used for production of the vaccine, the composition of the culture media and the target species, carry out either the test for avian mycoplasmas, or the test for non-avian mycoplasmas and ureaplasmas, or both.'

VINBLASTINE SULPHATE (0748)

Page 1711. ASSAY. Replace the following:

'— a stainless steel column 0.25 m long and 4.6 mm in internal diameter packed with *octylsilyl silica gel for chromatography R* (5 μ m). Place between the pump and the injector a guard column packed with suitable silica gel,'

- by:
- ‘— a stainless steel column 0.25 m long and 4.6 mm in internal diameter packed with *octylsilyl silica gel for chromatography R* (5 µm). Place between the injector and the column a guard column packed with suitable silica gel,’

VINCRISTINE SULPHATE (0749)

Page 1712. ASSAY. Replace the following:

- ‘— a stainless steel column 0.25 m long and 4.6 mm in internal diameter packed with *octylsilyl silica gel for chromatography R* (5 µm). Place between the pump and the injector a guard column packed with suitable silica gel,’
- by:
- ‘— a stainless steel column 0.25 m long and 4.6 mm in internal diameter packed with *octylsilyl silica gel for chromatography R* (5 µm). Place between the injector and the column a guard column packed with suitable silica gel,’

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