

British Pharmacopœia 1980
Addendum 1981

British Pharmacopœia 1980 Addendum 1981

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Notices

The General Notices and Appendices included in the British Pharmacopœia 1980 apply to all matter contained in this Addendum unless the contrary is specifically stated.

The Addendum has the same authority as the British Pharmacopœia 1980. Monographs and Appendices of the British Pharmacopœia 1980 that are amended by this Addendum supersede, in their amended forms, the original monographs and appendices.

Monographs of the European Pharmacopœia are distinguished by a five-pointed star against the title.

Patents

In this Addendum certain drugs and preparations have been included notwithstanding the existence of actual or potential patent rights. In so far as such substances are protected by Letters Patent their inclusion in this Addendum neither conveys, nor implies, licence to manufacture.

Preface

This Addendum amends the British Pharmacopœia 1980 and is published by Her Majesty's Stationery Office for the Health Ministers on the recommendation of the Medicines Commission in accordance with Section 99(6) of the Medicines Act 1968.

The Medicines Commission takes this opportunity to express its deep regret at the death of Sir Derrick Dunlop who served the British Pharmacopœia Commission so notably for many years, ten of them as its Chairman.

The Medicines Commission records its appreciation of all who have contributed to the preparation of the Addendum.

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* Term of office ends 31 December 1981.

** Term of office ends 31 December 1983.

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Introduction

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- | | |
|---|--|
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| V: Radioactive Materials | W. G. Overend (Chairman), I. C. Downing, D. E. Lovett, N. Veall, T. L. Whateley, D. Lui. |
| W: Surgical Sutures | S. C. Jolly (Chairman), J. O. Dawson, M. R. Gaston, J. A. Holgate. |
| X: Plastics and Plastic Containers | B. A. Wills (Chairman), C. A. M. Chard, K. J. Child, M. N. Duncan, S. C. Jolly, J. E. Pentelow, D. C. M. Squirrell. |

Introduction

It was stated in the Introduction to the British Pharmacopœia 1980 that the British Pharmacopœia Commission intended to issue Addenda to the main work at about twelve-monthly intervals. It was added that successive addenda would be cumulative in nature so that at any given time the user would simply need to have the British Pharmacopœia 1980 and the current Addendum available. The present volume is the first in this proposed series of cumulative addenda and, as well as introducing new and amended material into the Pharmacopœia, also includes matter that has been added or amended by means of notices given in the London, Edinburgh and Belfast Gazettes in the interim period between publication of the Pharmacopœia itself and of this first Addendum. It follows, therefore, that the same Effective Date does not apply to all items included in the Addendum and each entry therefore carries an indication of the month and the year in which it entered into force. The relevance of this indication will become more apparent once the second cumulative Addendum has been published.

Committees of the Pharmacopœia

The British Pharmacopœia Commission is deeply indebted to the expertise and the considerable voluntary work that has been made available to it over the years by members of its advisory Committees and Panels. Because of the increasing complexity and the highly specialised nature of some of the work the number of such committees and panels has tended to increase, as can be seen by examining the introductory sections of successive pharmacopœias published during the past three decades. The present need for economy however, has dictated a critical re-appraisal of the committee structure and this has resulted in a considerable reduction in the number of standing committees and in the total membership. Thus, work on the present Addendum was begun with the Committee structure (and largely the membership) detailed in the preliminary section of the British Pharmacopœia 1980 (pages xi and xii of Volume I) but was completed with the new Committee structure that is given in this publication. To augment the standing committees a number of Corresponding Consultative Groups has been established to provide expert knowledge, opinion and advice on a corresponding basis.

The Commission has noted with deep regret the deaths, during 1980, of Sir Derrick Dunlop, who was Chairman of the Commission responsible for the editions of 1953 and 1958, of Mr W. T. Wing, a member of the Sterile Materials Committee from 1963 until 1978, of Dr S. E. Piercy, a member of the Immunological Products (Veterinary) Panel from its inception in 1973 until 1978 and of Mr W. C. Johnson, a member of various Committees between 1946 and 1968.

New materials included in this Addendum

35 Monographs in this Addendum are devoted to substances not previously described in the Pharmacopœia; in addition many preparations have been included for the first time. The new substances include the analgesic and

anti-inflammatory agents aloxiprin, fenoprofen calcium and ketoprofen, the cytotoxic substances cytarabine, mitobronitol and thioguanine, the dopa-decarboxylase inhibitor carbidopa, the appetite suppressant diethylpropion hydrochloride and the tranquilliser thiopropazate hydrochloride. Monographs are also included for the vasodilator isosorbide dinitrate (in a suitable inert diluent), for the sympathomimetic amines terbutaline sulphate and xylometazoline hydrochloride, for the anticonvulsant sodium valproate, for the respiratory stimulant ethamivan and for the cardiac depressant verapamil hydrochloride. Also included for the first time are monographs for three esters of testosterone, the decanoate, the enanthate and the isocaproate, all androgens and anabolic steroids, and for dros-tanolone propionate which blocks the action of oestrogens. The beta adrenoceptor blocking agent pindolol, flucytosine (used in the treatment of fungal infections) and the antibiotic fusidic acid are all the subject of new monographs as are a number of materials used for topical application, for example the counter-irritant diethylamine salicylate, the antibacterial phenoxyethanol and the sun-screening agent aminobenzoic acid. Among the monographs for pharmaceutical aids included for the first time are povidone, the dimethicones and dispersible cellulose as well as the tablet disintegrant sodium starch glycolate and the antimicrobial preservatives potassium sorbate and sorbic acid. In addition to the substances referred to above three new monographs for blood products are included in this Addendum. Those for plasma-reduced blood and for concentrated red blood cells supersede the single monograph in the British Pharmacopœia 1980 entitled Concentrate of Red Blood Cells. The other addition to this section is a monograph for fresh frozen plasma. Finally, three new surgical dressings using a synthetic adhesive mass have been included.

Pharmaceutical preparations

Commonly encountered preparations including many of the substances referred to above have been included in this Addendum, for example fenoprofen calcium tablets, ketoprofen capsules, verapamil hydrochloride tablets and injection, aminobenzoic acid lotion, diethylamine salicylate cream, sodium valproate elixir and xylometazoline hydrochloride nasal drops. Certain preparations for well-recognised combinations of medicinal substances are also included, for example co-trimoxazole mixture, levodopa and carbidopa tablets and fluocortolone pivalate and fluocortolone hexanoate cream and ointment. In these latter preparations it is interesting to note the use of high-pressure liquid chromatography for assay purposes, a technique that has also been applied to other steroid preparations in this Addendum such as triamcinolone acetonide cream, dental paste and ointment and that is likely to find increasing use in this type of application in the future. Reformulations of, for example, Aqueous Cream and Hydrous Ointment have been included to provide products that will better withstand challenge by the test for Efficacy of Antimicrobial Preservatives in Pharmaceutical Products.

General Revision

Opportunity has been taken to revise and strengthen existing monographs where necessary. For example infra-red spectroscopy (for identification purposes) has been added to a number of monographs; where this is the case the relevant infra-red absorption spectra, together with those necessary to support monographs for some of the new materials referred to above (56 in all), are being made available as a supplement to the collection of spectra contained in British Pharmacopœia 1980 Infra-red Reference Spectra, published by Her Majesty's Stationery Office. Other improvements include

the addition of tests for related substances or for specific potential impurities in certain monographs, for example a test based on gas chromatography for evaluation of related impurities in methypyrone, one based on thin-layer chromatography for related substances in prilocaine hydrochloride and one based on a colorimetric reaction for dimethylaniline in bupivacaine hydrochloride. Certain products may be contaminated with residues of hydrazine and the Commission is currently considering suitable methods for their examination. It is also seeking advice on appropriate limits of contamination, bearing in mind the toxicity of hydrazine and the dosage of the product. Substances in the BP 1980 itself or in the present Addendum for which a limit test for hydrazine is under review include carbidopa and phenelzine sulphate.

In cases where changes and additions to a monograph under revision have been substantial the entire revised monographs have been provided since these will be of greater convenience to the user. Typical examples are provided by the replacement monographs for self-emulsifying glyceryl monostearate and for calcium gluconate tablets.

Additions

ADDITIONS TO THE BRITISH PHARMACOPŒIA 1980

Aloxiprin
 Aminobenzoic Acid
 Carbidopa
 Cytarabine
 Diethylamine Salicylate
 Diethylpropion Hydrochloride
 Diluted Isosorbide Dinitrate
 Dimethicones
 Dispersible Cellulose
 Drostanolone Propionate
 Ethamivan
 Fenoprofen Calcium
 Flucytosine
 Fusidic Acid
 Guaiphenesin
 Ketoprofen
 Mitobronitol
 Phenoxyethanol
 Pindolol
 Potassium Sorbate
 Povidone
 Sodium Starch Glycollate
 Sodium Valproate
 Sorbic Acid
 Terbutaline Sulphate
 Testosterone Decanoate
 Testosterone Enanthate
 Testosterone Isocaproate
 Thioguanine
 Thiopropazate Hydrochloride
 Verapamil Hydrochloride
 Xylometazoline Hydrochloride

Formulary

CAPSULES
Ketoprofen Capsules

CREAMS
Diethylamine Salicylate Cream
Fluocortolone Pivalate and Fluocortolone Hexanoate Cream
Triamcinolone Acetonide Cream

ELIXIR
Sodium Valproate Elixir

EYE DROPS
Sulphacetamide Sodium Eye Drops

INJECTABLE PREPARATIONS
Cytarabine Injection
Drostanolone Propionate Injection
Morphine and Atropine Injection
Verapamil Hydrochloride Injection

LOTION
Aminobenzoic Acid Lotion

MIXTURES
Co-trimoxazole Mixture
Pædiatric Co-trimoxazole Mixture

NASAL DROPS
Xylometazoline Hydrochloride Nasal Drops

OINTMENTS
Compound Benzoic Acid Ointment
Fluocinolone Acetonide Ointment
Fluocortolone Pivalate and Fluocortolone Hexanoate Ointment
Triamcinolone Acetonide Ointment

PASTES
Triamcinolone Acetonide Dental Paste

TABLETS
Aloxiprin Tablets
Amodiaquine Tablets
Effervescent Calcium Gluconate Tablets
Fenoprofen Calcium Tablets
Flucytosine Tablets
Isosorbide Dinitrate Tablets
Levodopa and Carbidopa Tablets
Mitobronitol Tablets
Nicotinamide Tablets
Pindolol Tablets
Pyridoxine Hydrochloride Tablets
Sodium Valproate Tablets
Thioguanine Tablets
Thiopropazate Hydrochloride Tablets
Verapamil Hydrochloride Tablets

BLOOD PRODUCTS

Concentrated Red Blood Cells
Fresh Frozen Plasma
Plasma-reduced Blood

SURGICAL DRESSINGS

Impermeable Plastic Surgical Synthetic
Adhesive Tape
Permeable Non-Woven Surgical Synthetic
Adhesive Tape
Permeable Woven Surgical Synthetic
Adhesive Tape

Amendments

The following monographs of the British Pharmacopœia 1980 are amended (this list includes those amendments in Amendments issued with the British Pharmacopœia 1980 and those in Amendments No 2).

Adrenaline
Adrenaline Acid Tartrate
Allopurinol
Almond Oil
Aluminium Glycinate
Amodiaquine Hydrochloride
Amphotericin
Anhydrous Dextrose
Aspirin
Atropine Sulphate
Barium Sulphate for Suspension
Bendrofluazide
Benzoic Acid
Benztropine Mesylate
Biperiden
Borax
Bupivacaine Hydrochloride
Busulphan
Caffeine
Calcium Chloride
Calcium Hydrogen Phosphate
Calcium Hydroxide
Calcium Sodium Lactate
Candididin
Carbenoxolone Sodium
Carbimazole
Carbromal
Cascara
Castor Oil
Cephalexin
Cephaloridine
Cephradine
Chlorambucil
Chlorhexidine Acetate
Chlorhexidine Gluconate Solution
Chloroform
Chloroquine Phosphate
Chloroquine Sulphate
Chlorthalidone
Choline Theophyllinate
Cinchocaine Hydrochloride
Cinnamon Oil
Citric Acid Monohydrate
Clioquinol
Coconut Oil
Crotamiton
Cyclomethycaine Sulphate
Cyclophosphamide
Cyproheptadine Hydrochloride
Dextropropoxyphene Hydrochloride
Dextropropoxyphene Napsylate
Diamorphine Hydrochloride
Diazoxide
Dibromopropamidine Isethionate
Dichloralphenazone
Digitoxin
Digoxin

Dihydrocodeine Tartrate
Diphenoxylate Hydrochloride
Dipipanone Hydrochloride
Diprophylline
Disopyramide Phosphate
Dried Aluminium Hydroxide
Dried Ferrous Sulphate
Edrophonium Chloride
Ergometrine Maleate
Ergotamine Tartrate
Erythromycin Estolate
Erythromycin Stearate
Ethambutol Hydrochloride
Ethionamide
Ferrous Fumarate
Ferrous Gluconate
Ferrous Sulphate
Fluoxymesterone
Fractionated Palm Kernel Oil
Framycetin Sulphate
Gentamicin Sulphate
Glibenclamide
Glycerol
Glyceryl Monostearate
Guaiphenesin
Halothane
Hard Fat
Heavy Magnesium Carbonate
Heavy Magnesium Oxide
Heparin Calcium
Hydroxocobalamin
Hydroxychloroquine Sulphate
Hyoscine Butylbromide
Hyoscine Hydrobromide
Indian Squill
Indomethacin
Industrial Methylated Spirit
Insulin
Iopanoic Acid
Kanamycin Acid Sulphate
Lavender Oil
Levodopa
Light Kaolin
Light Magnesium Carbonate
Light Magnesium Oxide
Liquid Paraffin
Lyncestrenol
Magnesium Trisilicate
Menotrophin
Mestranol
Methandienone
Methylcellulose 20
Methylcellulose 2500
Methylcellulose 4500
Methyldopa
Methyprylone
Nandrolone Decanoate

Nandrolone Phenylpropionate
 Neomycin Sulphate
 Nicotinamide
 Nystatin
 Nystatin (Dermatological)
 Estradiol Benzoate
 Oxprenolol Hydrochloride
 Oxygen
 Oxymetholone
 Oxyphenbutazone
 Paracetamol
 Peppermint Oil
 Phenindione
 Phenol
 Phenoxybenzamine Hydrochloride
 Phenoxymethylpenicillin Potassium
 Phthalylsulphathiazole
 Polysorbate 60
 Polysorbate 80
 Potassium Chloride
 Powdered Digitalis Leaf
 Powdered Tragacanth
 Prilocaine Hydrochloride
 Primaquine Phosphate
 Prochlorperazine Maleate
 Promethazine Theoclate
 Propylthiouracil
 Pseudoephedrine Hydrochloride
 Purified Talc
 Purified Water
 Pyroxylin
 Quinine Dihydrochloride
 Riboflavine Sodium Phosphate
 Rifampicin
 Self-Emulsifying Glyceryl Monostearate
 Silver Nitrate
 Sodium Acid Citrate
 Sodium Acid Phosphate
 Sodium Aurothiomalate
 Sodium Calciumedetate
 Sodium Diatrizoate
 Sodium Fusidate
 Sodium Phosphate
 Sodium Stibogluconate
 Solvent Ether
 Sorbitan Monolaurate
 Sorbitan Mono-oleate
 Sorbitan Monostearate
 Squill
 Sterilisable Maize Starch
 Stilboestrol
 Sulphamethoxypyridazine
 Sulphamethoxazole
 Sulphuric Acid
 Theophylline
 Thioridazine Hydrochloride
 Titanium Dioxide
 Triethanolamine
 Trimethoprim
 Water for Injections
 White Beeswax
 Wool Alcohols
 Wool Fat

Annex

Calcium Hydrogen Phosphate
 Water for Injections

Formulary

CAPSULES

Cephradine Capsules
 Cycloserine Capsules
 Disopyramide Phosphate Capsules
 Indomethacin Capsules
 Levodopa Capsules
 Metyrapone Capsules
 Sodium Fusidate Capsules

CREAM

Aqueous Cream

ELIXIRS

Dichloralphenazone Elixir
 Dicyclomine Elixir
 Ephedrine Hydrochloride Elixir
 Pædiatric Digoxin Elixir
 Pædiatric Paracetamol Elixir
 Triclofos Elixir

EYE DROPS

Eye Drops
 Zinc Sulphate and Adrenaline Eye Drops

EYE OINTMENTS

Eye Ointments
 Oxyphenbutazone Eye Ointment
 Sulphacetamide Eye Ointment

GRANULES

Pancreatin Granules

INJECTABLE PREPARATIONS

Injectable Preparations
 Bupivacaine and Adrenaline Injection
 Bupivacaine Hydrochloride Injection
 Chloroquine Phosphate Injection
 Chloroquine Sulphate Injection
 Compound Sodium Lactate Intravenous Infusion
 Co-trimoxazole Injection
 Diamorphine Injection
 Dimercaprol Injection
 Dipipanone Injection
 Edrophonium Injection
 Heparin Injection
 Hyoscine Butylbromide Injection
 Iodised Oil Fluid Injection
 Iron Dextran Injection
 Lævulose Intravenous Infusion
 Lignocaine Hydrochloride Injection
 Lypressin Injection
 Menotrophin Injection
 Methohexitone Injection
 Morphine Sulphate Injection
 Oxytocin Injection
 Phentolamine Injection
 Phenytoin Injection
 Phytomenadione Injection
 Sodium Aurothiomalate Injection
 Sodium Stibogluconate Injection
 Tetracycline Injection
 Trisodium Edetate Injection

LINCTUS

Strong Pholcodine Linctus

MIXTURES

Alkaline Gentian Mixture

Ammonia and Ipecacuanha Mixture
 Ammoniated Rhubarb and Soda Mixture
 Ammonium Chloride Mixture
 Ammonium Chloride and Morphine Mixture
 Aromatic Chalk with Opium Mixture
 Aromatic Magnesium Carbonate Mixture
 Chloral Mixture
 Ipecacuanha and Morphine Mixture
 Kaolin Mixture
 Kaolin and Morphine Mixture
 Magnesium Hydroxide Mixture
 Magnesium Sulphate Mixture
 Magnesium Trisilicate Mixture
 Sodium Salicylate Mixture
 Strong Sodium Salicylate Mixture
 Pædiatric Chalk Mixture
 Pædiatric Ferrous Sulphate Mixture
 Pædiatric Kaolin Mixture
 Potassium Citrate Mixture

OINTMENTS

Ointments
 Hydrous Ointment

SOLUTIONS

Green S and Tartrazine Solution
 Strong Sodium Hypochlorite Solution

SPRAYS

Compound Adrenaline and Atropine Spray

SUPPOSITORIES

Suppositories
 Indomethacin Suppositories

SUSPENSIONS

Barium Sulphate Suspension

SYRUPS

Lemon Syrup

TABLETS

Tablets
 Allopurinol Tablets
 Aluminium Hydroxide Tablets
 Aspirin Tablets
 Aspirin and Codeine Tablets
 Azathioprine Tablets
 Bisacodyl Tablets
 Busulphan Tablets
 Calcium Gluconate Tablets
 Carbenoxolone Tablets
 Carbimazole Tablets
 Cephalixin Tablets
 Chloroquine Phosphate Tablets
 Chloroquine Sulphate Tablets
 Chlorthalidone Tablets
 Choline Theophyllinate Tablets
 Compound Magnesium Trisilicate Tablets
 Dichloralphenazone Tablets
 Dispersible Aspirin Tablets
 Ethambutol Tablets
 Ferrous Gluconate Tablets
 Fluoxymesterone Tablets
 Folic Acid Tablets
 Glibenclamide Tablets

Hydroxychloroquine Tablets
 Hyoscine Butylbromide Tablets
 Iopanoic Acid Tablets
 Levodopa Tablets
 Methandienone Tablets
 Methypyrone Tablets
 Nicoumalone Tablets
 Nitrazepam Tablets
 Oxytetracycline Tablets
 Oxytocin Tablets
 Pædiatric Dispersible Aspirin Tablets
 Pancreatin Tablets
 Phenindione Tablets
 Phenolphthalein Tablets
 Primaquine Tablets
 Propylthiouracil Tablets
 Pyrimethamine Tablets
 Sulphadimidine Tablets
 Sulphamethizole Tablets
 Sulphamethoxypyridazine Tablets
 Sulphapyridine Tablets
 Tetracycline Tablets

Blood Products

Anticoagulant and Preservative Solutions for Blood
 Anti-D (Rh₀) Immunoglobulin Injection
 Dried Factor VIII Fraction

Immunological Products

Vaccines
 Inactivated Influenza Vaccine (Surface Antigen)
 Influenza Vaccine, Live (Intranasal)

Radiopharmaceutical Preparations

L-Selenomethionine (⁷⁵Se) Injection

Surgical Dressings

Absorbent Cotton
 Absorbent Cotton and Viscose Ribbon Gauze
 Absorbent Viscose Wadding
 Belladonna Adhesive Plaster
 Elastic Adhesive Bandage
 Elastic Surgical Adhesive Tape
 Elastic Web Bandage
 Extension Plaster
 Half-spread Elastic Adhesive Bandage
 Impermeable Plastic Surgical Adhesive Tape
 Permeable Plastic Surgical Adhesive Tape
 Salicylic Acid Adhesive Plaster
 Semipermeable Waterproof Plastic Surgical Adhesive Tape
 Ventilated Elastic Adhesive Bandage
 X-Ray-Detectable Absorbent Cotton Ribbon Gauze
 Zinc Oxide Surgical Adhesive Plaster

INTRODUCTION TO THE BRITISH PHARMACOPŒIA 1980

Page xxiii

Additions, right hand column

Delete the following:

Sublimed Sulphur

Zinc Stearate

12/80

Page xxxi

To the list of monographs in the European Pharmacopœia which have not been included in the British Pharmacopœia 1980 add:

Sodium Bromide

12/80

GENERAL NOTICES

Atomic Weights Line 3. For 'Appendix XXIV' read 'Appendix XXII'.

12/80

Preservatives Add the following statement:

'In this connection it should be noted that formulations for which a full recipe is given in the British Pharmacopœia are intended for extemporaneous dispensing. If such preparations are manufactured with the intention that they be stored, suitable antimicrobial preservatives may be included or, if one is mentioned in the recipe, suitable alternatives may be substituted provided that their identity and concentration are stated on the label.'

12/80

Doses Add the following statement:

'In writing prescriptions and expressing doses it is recommended that 'microgram' should be written in full; when an abbreviation is essential, the contraction 'mcg' should be used.'

12/81

Contents

	PAGE
NOTICES	vi
PREFACE	vii
MEMBERSHIP OF THE BRITISH PHARMACOPŒIA COMMISSION	viii
MEMBERSHIP OF COMMITTEES AND GROUPS	x
INTRODUCTION	xii
GENERAL NOTICES	xviii
MONOGRAPHS	
Medicinal and Pharmaceutical Substances	1
Formulary	42
Blood Products	76
Immunological Products	81
Radiopharmaceutical Preparations	84
Surgical Materials	88
CONTENTS OF THE APPENDICES	A1
INDEX	A13