

**British Pharmacopœia 1980**  
**Addendum 1981**

# **British Pharmacopœia 1980 Addendum 1981**

Published on the recommendation of the  
Medicines Commission  
pursuant to the Medicines Act 1968

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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

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 drosanolone 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 glycollate 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 methypylone, 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  
Ethinyllovan  
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  
Paediatric 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  
 Candicidin  
 Carbenoxolone Sodium  
 Carbimazole  
 Carbromal  
 Cascara  
 Castor Oil  
 Cephalixin  
 Cephaloridine  
 Cephadrine  
 Chlorambucil  
 Chlorhexidine Acetate  
 Chlorhexidine Gluconate Solution  
 Chloroform  
 Chloroquine Phosphate  
 Chloroquine Sulphate  
 Chlorthalidone  
 Choline Theophyllinate  
 Cinchocaine Hydrochloride  
 Cinnamon Oil  
 Citric Acid Monohydrate  
 Chioquinol  
 Coconut Oil  
 Crodamiton  
 Cyclomethycaine Sulphate  
 Cyclophosphamide  
 Cyproheptadine Hydrochloride  
 Dextropropoxyphene Hydrochloride  
 Dextropropoxyphene Napsylate  
 Diamorphine Hydrochloride  
 Diazoxide  
 Dibromopropamide 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  
 Lyncæstrenol  
 Magnesium Trisilicate  
 Menotrophin  
 Mestranol  
 Methandienone  
 Methylcellulose 20  
 Methylcellulose 2500  
 Methylcellulose 4500  
 Methyldopa  
 Methypylone  
 Nandrolone Decanoate

Nandrolone Phenylpropionate  
 Neomycin Sulphate  
 Nicotinamide  
 Nystatin  
 Nystatin (Dermatological)  
 Œstradiol 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

Cephadrine 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  
 Ipanoic 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 (Rh<sub>0</sub>) Immunoglobulin Injection  
 Dried Factor VIII Fraction

**Immunological Products**

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

**Radiopharmaceutical Preparations**

L-Selenomethionine (<sup>75</sup>Se) 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

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