British Pharmacopoeia 2000

Volume 1

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British Pharmacopoeia 2000

Volume I

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The monographs of the Third Edition of the European Pharmacopoeia (1997), as amended by the Supplement 2000 published by the Council of Europe in September 1999, are reproduced either in this edition of the British Pharmacopoeia or in the associated edition of the British Pharmacopoeia (Veterinary)
see General Notices, page 3

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British Pharmacopoeia Commission

Office:

Market Towers
1 Nine Elms Lane
London SW8 5NQ

Telephone: +44 (0)20 7273 0561
Fax: +44 (0)20 7273 0566
E-mail: bpcom@mca.gov.uk
Web site:

Laboratory:

Government Buildings
Block 2, Honeypot Lane
Stanmore
Middlesex HA7 1AY

Telephone: +44 (0)20 7972 1040
Fax: +44 (0)20 8951 3069
E-mail: queries@bpclab.co.uk
Web site: www.bpclab.co.uk

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Notices

Monographs of the European Pharmacopoeia are distinguished by a chaplet of stars against the title. The term European Pharmacopoeia, used without qualification, means the third edition of the European Pharmacopoeia comprising, unless otherwise stated, the main volume, published in 1996 as amended by any subsequent supplements and revisions.

Patents

In this Pharmacopoeia 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 Pharmacopoeia neither conveys, nor implies, licence to manufacture.

Effective dates

Much of the material in this edition enters into force on 1 December 2000 but certain material that has been published earlier by Gazette Notices became effective on the date stated in the relevant entry.

Preface

The British Pharmacopoeia 2000 is published 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 believes that the British Pharmacopoeia contributes significantly to the overall control of the quality of medicinal products by providing an authoritative statement of the quality that a product is expected to meet at any time during its period of use. The publicly available and legally enforceable Pharmacopoeial standards are designed to complement and assist the licensing and inspection processes and are part of the system for safeguarding purchasers and users of medicinal products.

The Medicines Commission wishes to record its appreciation for the services of all who have contributed to this important work.

British Pharmacopoeia Commission

The British Pharmacopoeia Commission is appointed by the Secretary of State concerned with health in Great Britain, the Minister of Agriculture, Fisheries and Food, the Department of Health, Social Services and Public Safety for Northern Ireland and the Department of Agriculture and Rural Development for Northern Ireland, acting jointly, in exercise of their powers under section 4 of the Medicines Act 1968.

The duties of the British Pharmacopoeia Commission are as follows:

(a) the preparation under section 99(1) of the Act of any new edition of the British Pharmacopoeia;

(b) the preparation under section 99(1) of the Act, as given effect by section 102(1) thereof, of any amendments of the edition of the British Pharmacopoeia published in 1968 or any new edition of it;

(c) the preparation under section 100 of the Act (which provides for the preparation and publication of lists of names to be used as headings to monographs in the British Pharmacopoeia) of any list of names and the preparation under that section as given effect by section 102(3) of the Act of any amendments of any published list;

(d) the preparation under section 99(3)(b) of the Act of any compendium or any new edition thereof;

(e) the preparation under section 99(3)(b) of the Act, as given effect by section 102(1) thereof, of any amendments to any such compendium.

Members of the British Pharmacopoeia Commission are appointed by Ministers, having regard to recommendations made by the Medicines Commission. Appointments are usually for a (renewable) term of 4 years.

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Vice-Chairman: J A Goldsmith[1] BSc PhD CChem FRSC FIQA
Formerly a Director of Technical Operations in the Pharmaceutical Industry; Visiting Professor, University of Strathclyde

A H Andrews[1] BVetMed PhD MRCVS
Veterinary Consultant

S Barton[2] BA DPhil BM BCh DCH DRCOG MRCGP MRCP
General practitioner; formerly Medical Director at the National Prescribing Centre

D I R Begg[1] FRPharmS FIQA MCPP
Consultant in Pharmaceutical Quality Assurance; Visiting Professor, University of Strathclyde

A F Fell[1] BPharm PhD FRPharmS CChem FRSC FIQA
Professor of Pharmaceutical Chemistry, University of Bradford

V Fenton-May[1] BPharm MI PharmM FRPharmS
Specialist Quality Controller to the Welsh Hospitals

A M T Lee[1] BVMS PhD MRCVS
A member of the Veterinary Medicines Directorate

J M Midgley[1] OBE BSc MSc PhD FRPharmS CChem FRSC
Professor of Pharmaceutical and Medicinal Chemistry, University of Strathclyde

A C Moffat[1] BPharm PhD DSc CChem FRSC FRPharmS MCPP
Chief Scientist, Royal Pharmaceutical Society of Great Britain

N Randall[1] PhD CChem FRSC FIQA
A Director of Quality Assurance in the Pharmaceutical Industry

G D Rees[1] BPharm PhD MRPharmS CChem MRSC FIQA
A Director of Quality Assurance in the Pharmaceutical Industry

A D Woolfson[1] BSc PhD CChem FRSC MPSNI
Professor of Pharmaceutics, Queens University of Belfast

Secretary and Scientific Director: R C Hutton BSc PhD CChem FRSC

[1]Term of office ends 31 December 2001
[2] Resigned March 1999

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Introduction

This edition of the British Pharmacopoeia supersedes the British Pharmacopoeia 1999 as amended by Amendments Sheets No. 1 and No. 2. It has been prepared by the British Pharmacopoeia Commission with the collaboration and support of its advisory Committees and experts, and contains 2,663 monographs for substances and articles used in the practice of medicine. Of these 1,302 monographs are of national origin and 1,361 have been reproduced from the 3rd edition of the European Pharmacopoeia. This new edition, together with its companion edition, the British Pharmacopoeia (Veterinary) 2000, thus contains all monographs of the 3rd edition of the European Pharmacopoeia as amended by the Supplement 2000. The user of the British Pharmacopoeia thereby benefits by finding within this one, comprehensively indexed, compendium all current United Kingdom pharmacopoeial standards for medicines for human use.

Effective Date The effective date for this edition is 1st December 2000 unless otherwise stated for an entry by an italicised statement showing the month and year of its implementation. Such italicised statements are given for certain monographs reproduced from the European Pharmacopoeia and are located below the chaplet of stars that appears alongside the monograph title, for example *'1/00'*.

Where a monograph which appeared previously in an earlier edition of the British Pharmacopoeia has not been included in this new edition it remains effective in accordance with Section 65(4) of the Medicines Act 1968.

Additions A list of monographs included within the Pharmacopoeia for the first time is given at the end of this introduction. It includes 54 new monographs of national origin and 85 new monographs reproduced from the 2000 supplement to the European Pharmacopoeia.

Additionally a number of new sections have been added, for example Supplementary Chapter I N on particulate contamination.

Revisions Monographs which have been amended technically by means of this edition are also listed at the end of this introduction. For the benefit of the reader this list indicates the section, or sections, of each monograph which has/have been revised.

European Pharmacopoeia In accordance with previous practice, all monographs and requirements of the European Pharmacopoeia are reproduced in this edition of the British Pharmacopoeia or where appropriate within its companion edition, the British Pharmacopoeia (Veterinary). Those texts of the European Pharmacopoeia not included in the 2000 Supplement but brought into effect on 1st January 2000 by rapid implementation are listed in Supplementary Chapter IV B.

Where a monograph has been reproduced from the European Pharmacopoeia this is signified by the presence of a European chaplet of stars alongside its title. Additionally, an explicit reference to the European Pharmacopoeia is contained within an italicised introductory statement. The entire European Pharmacopoeia text is then bounded by two horizontal lines bearing the symbol '*Ph Eur*'.

The European Pharmacopoeia texts have been reproduced in their entirety without editorial modification but where deemed appropriate additional statements of relevance to UK usage have been added (e.g. a list of BP preparations). It should be noted, however, that in the event of doubt of interpretation in any text of the European Pharmacopoeia, the text published in English under the direction of the Council of Europe should be consulted.

Correspondence between the general methods of the European Pharmacopoeia and the appendices of the British Pharmacopoeia 2000 is indicated in each appendix and by inclusion of a check list at the beginning of the appendices section.

Pharmacopoeial Requirements

It should be noted that any article intended for medicinal use which is described by a name at the head of a monograph in the current edition of the Pharmacopoeia must comply with that monograph '*whether or not it is referred to as BP*'.

It is also important to note that no requirement of the Pharmacopoeia can be taken in isolation. A valid interpretation of any particular requirement depends upon it being read in the context of (i) the monograph as a whole, (ii) the specified method of analysis, (iii) the relevant General Notices and (iv) where appropriate, the relevant general monograph. Familiarity with the General Notices of the Pharmacopoeia will facilitate the correct application of the requirements. Additional guidance and information on the basis of pharmacopoeial requirements is provided in Supplementary Chapter I. This non-mandatory text describes the general underlying philosophy and current approaches to particular aspects of pharmacopoeial control.

General Monographs

The General Monographs for dosage forms are grouped together at the beginning of Volume II. They are followed by the monographs for the individual formulated preparations arranged in alphabetical order. The General Monographs of the European Pharmacopoeia apply to all individual dosage forms of the type defined rather than to only those preparations for which a specific monograph is included (see the General Notices).

Infrared Reference Spectra

To enable the user to locate a particular reference spectrum without difficulty, all have been assigned specific serial numbers within this edition. These are then cited within the text wherever reference to that spectrum is made.

Sixteen new spectra have been added sequentially to the previous collection.

Acknowledgements

Close co-operation has continued with many organisations at home and overseas. These include the Medicines Control Agency (of which the Pharmacopoeia secretariat and laboratory staff are a part), the National Institute for Biological Standards and Control, the Veterinary Medicines Directorate, the Royal Pharmaceutical Society of Great Britain, the Association of the British Pharmaceutical Industry, the European Pharmacopoeia Commission and the European Department for the Quality of Medicines, the Therapeutic Goods Administration (Australia), the Health Protection Branch of the Canadian Department of Health and Welfare, the Committee of Revision of the United States Pharmacopeia, the Essential Drugs and Other Medicines Department of the World Health Organization (WHO) and the WHO Collaborating Centre for Chemical Reference Substances.

The British Pharmacopoeia Commission is greatly indebted to the members of its advisory Committees and Consultative Groups without whose dedicated enthusiasm and assistance this edition could not have been prepared.

Additions The following monographs of the British Pharmacopoeia 2000 were not included in the British Pharmacopoeia 1999.

Medicinal and Pharmaceutical Substances
Acetyltryptophan*
Acetyltyrosine*
Acitretin*
Air, Synthetic
Albendazole*
Alchemilla*
Ammonium Bromide*
Arnica Flower*
Atracurium Besilate
Benzbromarone*
Bezafibrate*
Bifonazole*
Boldo Leaf*
Bromperidol Decanoate*
Buflomedil Hydrochloride*
Calcium Glucoheptonate*
Camphor, Natural*
Cefamandole Nafate*
Cefatrizine Propylene Glycol*
Cefoperazone Sodium*
Ceftazidime*
Cellulose Acetate Butyrate*
Ciclopirox*
Cilastatin Sodium*
Clenbuterol Hydrochloride*
Cocoyl Caprylocaprate*
Diethylene Glycol Monopalmitostearate*
Dihydroergocristine Mesilate*
Dimetindene Maleate*
Dipivefrine Hydrochloride
Eleutherococcus*
Enalapril Maleate*
Ethylene Glycol Monopalmitostearate*
Flutamide*
Flutrimazole*
Fosfomycin Trometamol*
Fucus*
Glycerol Dibehenate*
Glycerol Distearate*
Glycerol Monolinoleate*
Glycerol Mono-oleates*
Haloperidol Decanoate*
Hawthorn Leaf and Flower*
Herbal Drugs*
Hexamidine Isetionate*
Hexylresorcinol*
Hypericum*
Iceland Moss*
Interferon Gamma-1B Concentrated Solution*
Javanese Turmeric*
Lemon Balm*
Leuprorelin*
Macrogol 6 Glycerol Caprylocaprate*
Macrogols*[1]
Magnesium Aspartate*
Magnesium Glycerophosphate*
Methanol
Metoprolol Succinate*
Mometasone Furoate*
Mupirocin*
Mupirocin Calcium*
Nicotine*
Nizatidine*
Nonoxinol 9*
Ofloxacin*
Olive Oil, Refined*
Olsalazine Sodium*
Passion Flower*
Pefloxacin Mesilate*
Penbutolol Sulphate*
Poloxamers*[2]
Prazepam*
Prednicarbate*
Products with Risk of Transmitting Animal Spongiform Encephalopathies*
Propylene Glycol Monopalmitostearate*
Simeticone*
Simeticone for Oral Use
Sodium Caprylate*
Sodium Hyaluronate*
Soya Oil, Refined*
Sulfaguanidine*
Tannic Acid*
Tioconazole
Tormentil*
Triethyl Citrate*
Wheat-germ Oil, Virgin*
Xylazine Hydrochloride*
Zinc Acetate*

Formulated Preparations: General Monographs
Herbal Drug Preparations*
Herbal Teas*

Formulated Preparations: Specific Monographs
Acebutolol Capsules
Acebutolol Tablets
Aciclovir Tablets, Dispersible
Amphotericin Oral Suspension
Cefadroxil Capsules
Cefadroxil Oral Suspension
Chlorhexidine Mouthwash
Dipivefrine Eye Drops
Dobutamine Intravenous Infusion
Domperidone Tablets
Doxycycline Tablets, Dispersible
Droperidol Injection

*Monograph of the European Pharmacopoeia

[1]This monograph replaces the monographs for Macrogol 300, Macrogol 400, Macrogol 1000, Macrogol 1500, Macrogol 3000, Macrogol 4000, Macrogol 6000, Macrogol 20,000 and Macrogol 35,000

[2]This monograph includes the requirements in the monograph for Poloxamer 188

Droperidol Tablets
Ergotamine Sublingual Tablets
Famotidine Tablets
Fenoterol Pressurised Inhalation
Fentanyl Injection
Flecainide Injection
Fluoxetine Capsules
Flurbiprofen Suppositories
Fosfestrol Injection
Fusidic Acid Cream
Fusidic Acid Eye Drops
Glyceryl Trinitrate Sublingual Spray
Glyceryl Trinitrate Transdermal Patches
Ketoprofen Gel
Methylphenobarbital Tablets
Miconazole Oromucosal Gel
Mitoxantrone Intravenous Infusion/
Mitozantrone Intravenous Infusion
Nimodipine Intravenous Infusion
Nimodipine Tablets
Norfloxacin Eye Drops
Norfloxacin Tablets
Nystatin Pastilles
Peppermint Oil Capsules, Gastro-resistant
Pimozide Tablets
Prochlorperazine Buccal Tablets
Promazine Oral Suspension
Silver Nitrate Solution, Sterile
Sodium Cromoglicate Eye Drops
Sulfasalazine Tablets
Sulpiride Tablets
Terfenadine Oral Suspension
Terfenadine Tablets
Tioconazole Cream
Tioconazole Nail Solution
Triamcinolone Hexacetonide Injection
Vindesine Injection

Radiopharmaceutical Preparations
Strontium[^{89}Sr] Chloride Injection*

Omissions

The following monographs of the British Pharmacopoeia 1999 are not included in the British Pharmacopoeia 2000.

Medicinal and Pharmaceutical Substances
Calcitonin (Pork)
Pyridostigmine Injection
Sulfacetamide Eye Drops
Sulfacetamide Eye Ointment
Tetracycline Intravenous Infusion

Formulated Preparations:
Specific Monographs
Ammonia and Ipecacuanha Mixture
Calcitonin (Pork) Injection
Carbenicillin Injection
Clioquinol Cream
Ipecacuanha Tincture
Nitrazepam Capsules

Immunological Products
Scorpion Venom Antiserum
Typhoid and Tetanus Vaccine
Typhus Vaccine

Radiopharmaceutical Preparations
Ferric[^{59}Fe] Citrate Injection

Technical Changes

The following monographs in the BP 2000 have been tehcnically amended since the publication of the BP 1999. This list does not include revised monographs of the European Pharmacopoeia. An indication of the nature of the change or the section of the monograph that has been changed is given in *italic type* in the right hand column.

Medicinal and Pharmaceutical Substances

Aloxiprin	*(Identification)*
Aluminium Glycinate	*(Identification)*
Aluminium Magnesium Silicate	*(Replaced by Ph Eur monograph)*
Aluminium Phosphate, Dried	*(Identification)*
Aluminium Powder	*(Identification)*
Ammonium Bicarbonate	*(Replaced by Ph Eur monograph)*
Attapulgite	*(Identification)*
Benethamine Penicillin	*(Identification)*
Benzatropine Mesilate	*(Melting point)*
Calamine	*(Residue on ignition)*
Clofazimine	*(Identification; Related substances; Assay)*
Coconut Oil	*(Replaced by Ph Eur monograph)*
Codeine Hydrochloride	*(Replaced by Ph Eur monograph)*
Dequalinium Choride	*(Replaced by Ph Eur monograph)*
Docusate Sodium	*(Replaced by Ph Eur monograph)*
Domiphen Bromide	*(Identification)*
Etodolac	*(Replaced by Ph Eur monograph)*
Fluvoxamine Maleate	*(Related substances)*
Hydrocortisone Sodium Phosphate	*(Identification)*

Hydrotalcite	*(Identification)*
Inositol Nicotinate	*(Identification)*
Kaolin, Light	*(Identification)*
Kaolin (Natural), Light	*(Identification)*
Octanoic Acid	*(Replaced by Ph Eur monograph)*
Pentazocine	*(Replaced by Ph Eur monograph)*
Pentazocine Hydrochloride	*(Replaced by Ph Eur monograph)*
Poloxamer 188	*(Subsumed by Ph Eur monograph for Poloxamers)*
Potassium Nitrate	*(Replaced by Ph Eur monograph)*
Stearic Acid	*(Replaced by Ph Eur monograph)*
Trazodone Hydrochloride	*(Related substances)*
Tribavirin	*(Specific optical rotation)*

Formulated Preparations: Specific Monographs

Acetylcysteine Injection	*(Specific optical rotation; Hydrogen sulphide)*
Aciclovir Oral Suspension	*(Acidity)*
Aloxiprin Tablets	*(Identification)*
Aluminium Hydroxide Oral Suspension	*(Identification)*
Aluminium Hydroxide Tablets	*(Identification)*
Amphotericin Lozenges	*(Identification)*
Amoxicillin Injection	*(Identification)*
Ampicillin Injection	*(Identification)*
Aprotinin Injection	*(Histamine)*
Aspirin Tablets	*(Dissolution)*
Benzylpenicillin Injection	*(Identification)*
Betamethasone Sodium Phosphate Tablets	*(Uniformity of content)*
Bumetanide Tablets	*(Related substances)*
Chlorhexidine Irrigation Solution	*(4-Chloroaniline; Related substances)*
Chlorpropamide Tablets	*(Related substances)*
Clofazimine Capsules	*(Content; Related substances; Assay)*
Clonidine Tablets	*(Assay)*
Clonidine Injection	*(Assay)*
Co-amilofruse Tablets	*(Identification; Assay)*
Co-codamol Tablets	*(Uniformity of content; Assay)*
Co-magaldrox Oral Suspension	*(Identification)*
Co-magaldrox Tablets	*(Identification)*
Diflunisal Tablets	*(Related substances)*
Doxorubicin Injection	*(Related substances)*
Econazole Cream	*(Identification; Assay)*
Etacrynic Acid Tablets	*(Related substances)*
Fluphenazine Decanoate Injection	*(Related substances)*
Fluvoxamine Tablets	*(Related substances)*
Furosemide Tablets/Frusemide Tablets	*(Related substances)*
Gliclazide Tablets	*(Dissolution)*
Glyceryl Trinitrate Tablets	*(Related substances; Uniformity of content; Assay)*
Heparin Injection	*(Identification)*
Hydrochlorothiazide Tablets	*(Related substances)*
Hydrotalcite Tablets	*(Identification)*
Hyoscine Tablets	*(Assay)*
Indoramin Tablets	*(Dissolution; Assay)*
Inositol Nicotinate Tablets	*(Identification)*
Ispaghula Husk Granules	*(Identification; Swelling index)*
Ispaghula Husk Effervescent Granules	*(Swelling index)*
Ispaghula Husk Oral Powder	*(Identification; Swelling index)*
Magnesium Sulphate Injection	*(Acidity or alkalinity)*
Methadone Oral Solution (1 mg per ml)	*(Content; Identification; Acidity)*
Metoprolol Injection	*(Identification)*
Miconazole Cream	*(Content; Related substances; Assay)*
Nalidixic Acid Tablets	*(Dissolution)*
Pentamidine Injection	*(Definition; Ammonium Isetionate; Related substances)*
Pentazocine Injection	*(Identification)*
Pentazocine Suppositories	*(Related substances)*

Phenoxymethylpenicillin Oral Solution	*(Identification)*
Pizotifen Tablets	*(Uniformity of content)*
Prednisone Tablets	*(Related substances)*
Procaine Benzylpenicillin Injection/ Procaine Penicillin Injection	*(Identification)*
Procaine Benzylpenicillin Injection, Fortified/ Procaine Penicillin Injection, Fortified	*(Identification)*
Prochlorperazine Tablets	*(Identification; Related substances)*
Sodium Fluoride Mouthwash	*(Assay)*
Sodium Fluoride Oral Drops	*(Assay)*
Sodium Fluoride Tablets	*(Uniformity of content)*
Tamoxifen Tablets	*(E-Isomer and other related substances)*
Triamcinolone Ointment	*(Related substances)*
Immunological products	
Bacillus Calmette-Guérin Vaccine, Percutaneous,	*(Production)*
Tetanus Vaccine	*(Production)*

Changes in Title

The following list gives the alterations in the titles of monographs of the British Pharmacopoeia 1999 that have been retained in the British Pharmacopoeia 2000.

BRITISH PHARMACOPOEIA 1999	BRITISH PHARMACOPOEIA 2000
Medicinal and Pharmaceutical substances	
Glycerol Monostearate 40—50	Glycerol Monostearate 40—55
Macrogol 7 Glycerol Cocoate	Macrogol Glycerol Cocoates
Oxytocin Concentrated Solution	Oxytocin Bulk Solution
Olive Oil	Virgin Olive Oil
Formulated Preparations: Specific Monographs	
Calcium Chloride Intravenous Infusion	Calcium Chloride Injection
Haemofiltration Solutions	Haemofiltration and Haemodiafiltration Solutions

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