British Pharmacopoeia 2002

VOLUME I

- Introduction
- General Notices
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Incorporating the requirements of the 4th Edition of the European Pharmacopoeia 2002 as amended by Supplements 4.1 and 4.2

British Pharmacopoeia 2002

Volume I

Published on the recommendation of the Medicines Commission pursuant to the Medicines Act 1968 and notified in draft to the European Commission in accordance with Directive 98/34/EEC.

The monographs of the Fourth Edition of the European Pharmacopoeia (2001), as amended by Supplement 4.1 published by the Council of Europe in October 2001 and Supplement 4.2 published by the Council of Europe in January 2002, are reproduced either in this edition of the British Pharmacopoeia or in the associated edition of the British Pharmacopoeia (Veterinary) .

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Effective date: 1 December 2002

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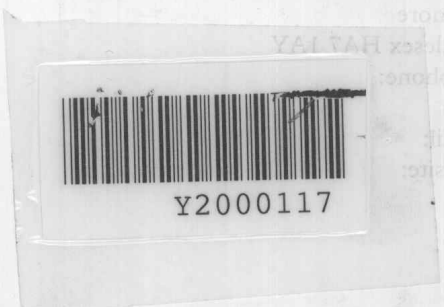

London: The Stationery Office

In respect of Great Britain:
THE DEPARTMENT OF HEALTH

In respect of Northern Ireland:
THE DEPARTMENT OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY

Published by The Stationery Office under licence from the Controller of Her Majesty's Stationery Office for the Department of Health on behalf of the Health Ministers

Printed in the United Kingdom by The Stationery Office Limited under the authority and superintendence of the Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament

First Published 2002

ISBN 0 11 322575 X

85180 C39 7/02

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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 fourth edition of the European Pharmacopoeia comprising, unless otherwise stated, the main volume, published in 2001 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 2002 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 2002 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 Health and Agriculture Ministers, that is to say in respect of England, Scotland and Wales the Secretary of State concerned with health in England and the Secretary of State concerned with the Environment, Food and Rural Affairs and in respect of Northern Ireland the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, 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.

Membership of the British Pharmacopoeia Commission

The list below includes those members who served during the period 2001 to 2002.

Chairman: D H Calam OBE MA DPhil CChem FRSC FRSA HonMRPharmS HonMBIRA
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Vice-Chairman: J A Goldsmith BSc PhD CChem FRSC FIQA
Visiting Professor, University of Strathclyde; formerly a Director of Technical Operations in the Pharmaceutical Industry

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Veterinary Consultant

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

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

A M T Lee BVMS PhD MRCVS
Member of the Veterinary Medicines Directorate

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

A C Moffat BPharm PhD DSc CChem FRSC FRPharmS FCPP
Chief Scientist, Royal Pharmaceutical Society of Great Britain

N Randall PhD CChem FRSC FIQA
Consultant in Quality Assurance; formerly a Director of Quality Assurance in the Pharmaceutical Industry

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A Director of Quality Assurance in the Pharmaceutical Industry

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

Secretary and Scientific Director: R C Hutton (until 31 December 2001) BSc PhD CChem FRSC

M G Lee (from 1 January 2002) BPharm PhD FRPharmS MRSC CChem

Membership of Committees and Consultative Groups

The Commission appointed the following Committees and Corresponding Consultative Groups to advise it in carrying out its duties. Membership has changed from time to time; the lists below include all who have served during the period 2001 to 2002.

COMMITTEES

A: Medicinal Chemicals: N Randall *(Chairman)*, G D Rees (*Vice-Chairman*), L Anderson, A L Barber, T G Beaumont, J C Berridge, A C Caws, A G Davidson, W J Lough, A J Woolfe

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(*Corresponding members* S Poole, L W Whitehouse)

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(*Corresponding members* E Griffiths, M L Kavanagh)

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P: Pharmacy: A D Woolfson (*Chairman*), R L Horder (*Vice-Chairman*), G Davison, G Eccleston, M C R Johnson, M G Lee, B R Matthews, S C Nichols, G Smith, M P Summers, J D Tovey, R Withington, P Wood

CONSULTATIVE GROUPS

L: Surgical Materials: J M Midgley *(Chairman)*, A Austin, G J Collyer, D J Harris, D Metcalfe, P Newlands, M Parkin, S Thomas

R: Radioactive Materials: A F Fell (*Chairman*), S R Hesslewood, D Lui, A M Millar, R D Pickett, A E Theobald, S Waters

Current members of staff of the Commission who have taken part in the production of this edition include:

Secretariat: M Vallender, F J Swanson, R Middleton, R A Pask-Hughes, P Holland

Laboratory: A Islam, D C Brougham, R L Turner, T Morarji, C M Shah, R Mannan, V Pathak, M Barrett, W Jeffries

Administrative: B F Delahunty, T Garrett, S Canciglia, A Chapman, S Benson

Introduction

This edition of the British Pharmacopoeia supersedes the British Pharmacopoeia 2001 as amended by Amendments No. 1. It has been prepared by the British Pharmacopoeia Commission with the collaboration and support of its advisory Committees and experts, and contains over 2800 monographs for substances and articles used in the practice of medicine. Some of these monographs are of national origin while others have been reproduced from the 4th edition of the European Pharmacopoeia. This new edition of the British Pharmacopoeia, together with its companion edition, the British Pharmacopoeia (Veterinary) 2002, contains all monographs of the 4th edition of the European Pharmacopoeia as amended by Supplements 4.1 and 4.2. 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 2002 unless otherwise stated for an entry by an italicised statement showing the month and year of its implementation. Such italicised statements, if included, are located below the chaplet of stars that appears alongside the monograph title.

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 14 new monographs of national origin and 46 new monographs reproduced from Supplements 4.1 and 4.2 of the European Pharmacopoeia.

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).

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. action and use statement, 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 2002 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.

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

Acknowledgements

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. The Commission also acknowledges the contribution of current and former members of staff of the BP.

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 Directorate 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 also acknowledges the advice of the publisher and the contribution made by Mr D Worsell, TSO Content Solutions, in the production of this edition which was in part published using the innovative ActiveText™.

Additions

The following monographs of the British Pharmacopoeia 2002 were not included in the British Pharmacopoeia 2001.

Medicinal and Pharmaceutical Substances

Black Horehound*
Butcher's Broom*
Horsetail*
Mastic*
Nadolol*
Pygeum Bark*
Red Poppy Petals*
Rifabutin*
Tramadol Hydrochloride*
Tribenoside*

Formulated Preparations: Specific Monographs

Carbomer Eye Drops
Cinnamon Tincture*
Effervescent Co-codamol Tablets
Dipotassium Hydrogen Phosphate Injection
Glycerol Eye Drops
Hydrocortisone Oromucosal Tablets
Indapamide Tablets
Standardised Ipecacuanha Liquid Extract*
Prolonged-release Isosorbide Mononitrate Tablets
Levomepromazine Injection/Methotrimeprazine Injection
Levomepromazine Tablets/Methotrimeprazine Tablets
Lidocaine Ointment/Lignocaine Ointment
Mefenamic Acid Tablets
Methylthioninium Injection/Methylene Blue Injection
Enteric-coated Naproxen Tablets
Paediatric Vitamins A, C and D Oral Drops

Blood Products

Dried Factor XI Fraction*

Immunological Products

Hepatitis A Vaccine (Inactivated, Virosome)*

Omissions

The following monographs of the British Pharmacopoeia 2001 are not included in the British Pharmacopoeia 2002.

Medicinal and Pharmaceutical Substances

Benethamine Penicillin
Etamiphylline Camsilate[1]
Ethyl Chloride
Sodium Propionate[1]

* denotes a monograph of the European Pharmacopoeia
[1]Monograph transferred to the British Pharmacopoeia (Veterinary)

Formulated Preparations: Specific Monographs

Etamiphylline Injection[1]
Etamiphylline Suppositories
Meglumine Iotalamate Injection
Procaine Benzylpenicillin Injection / Procaine Penicillin Injection[1]
Fortified Procaine Benzylpenicillin Injection / Fortified Procaine Penicillin Injection
Sodium Iotalamate Injection
Sorbitol Intravenous Infusion
Spectinomycin Injection

Technical Changes

The following monographs in the BP 2002 have been technically amended since the publication of the BP 2001. 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

Ammonium Glycyrrhizinate	*Replaced by Ph Eur monograph*
Carteolol Hydrochloride	*Replaced by Ph Eur monograph*
Flavoxate Hydrochloride	*Characteristics*
Flucloxacillin Magnesium	*Identification; Assay*
Fluocortolone Hexanoate	*Related foreign steroids* → *Related substances; Impurities*
Moxisylyte Hydrochloride	*Related substances*

Formulated Preparations: Specific Monographs

Allopurinol Tablets	*Related substances*
Aminoglutethimide Tablets	*Identification; Related substances; Azo-glutethimide*
Ampicillin Capsules	*Assay*
Ampicillin Injection	*Assay*
Ampicillin Oral Suspension	*Assay*
Enteric-coated Aspirin Tablets	*Dissolution*
Baclofen Oral Solution	*Lactam; Assay*
Baclofen Tablets	*Lactam*
Betamethasone Injection	*Assay*
Betamethasone Sodium Phosphate Tablets	*Assay*
Co-beneldopa Capsules	*Dissolution*
Co-fluampicil Capsules	*Identification; Assay*
Co-fluampicil Oral Suspension	*Identification; Assay*
Cortisone Tablets	*Related substances; Assay*
Compound Docusate Enema	*Definition; Identification*
Droperidol Injection	*Related substances*
Droperidol Tablets	*Related substances*
Flecainide Tablets	*Dissolution*
Hydrocortisone and Neomycin Cream	*Neomycin C*
Levodopa Tablets	*Dissolution*
Lisinopril Tablets	*Related substances*
Lorazepam Tablets	*Identification*
Mefenamic Acid Capsules	*Identification*
Metoclopramide Injection	*Assay*
Metoclopramide Tablets	*Assay*
Midazolam Injection	*Related substances; Assay*
Moxisylyte Tablets	*Related substances*

[1]Monograph transferred to the British Pharmacopoeia (Veterinary)

Nabumetone Oral Suspension	*Related substances; Assay*
Nabumetone Tablets	*Related substances; Assay*
Naproxen Tablets	*Dissolution*
Neomycin Eye Drops	*Neomycin C*
Nystatin Pastilles	*Labelling*
Paracetamol Suppositories	*4-Aminophenol*
Phytomenadione Tablets	*Menadione*
Sterile Potassium Chloride Concentrate	*Acidity or alkalinity*
Enteric-coated Prednisolone Tablets	*Related substances*
Prilocaine Injection	*Aromatic amines*
Salbutamol Injection	*Related substances*
Salbutamol Nebuliser Solution	*Salbutamol ketone*
Terbutaline Tablets	*Related substances; Assay*
Timolol Tablets	*Identification*
Radiopharmaceutical Preparations	
Iodinated [^{125}I] Albumin Injection	*Replaced by Ph Eur monograph*

Changes in Title

The following list gives the alterations in the titles of monographs of the British Pharmacopoeia 2001 that have been retained in the British Pharmacopoeia 2002.

BRITISH PHARMACOPOEIA 2001	BRITISH PHARMACOPOEIA 2002
Medicinal and Pharmaceutical Substances	
Cefadroxil	Cefadroxil Monohydrate

Contents

General Notices

Contents of the General Notices