British Pharmacopœia 1988

Volume I

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Notice

Patents

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

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Preface

The British Pharmacopœia 1988 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 preparation of this edition has made very heavy demands on the members of the British Pharmacopœia Commission, its committees and, in particular, its staff. The Medicines Commission wishes to record appreciation for the services of all who have contributed to this important work. In particular it takes this opportunity to acknowledge the outstanding contribution made by Dr C A Johnson, who retired after exactly twenty-five years of service, of which eight were as Scientific Director and twelve as Secretary and Scientific Director.

British Pharmacopœia Commission

The British Pharmacopœia Commission is appointed by the Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of their powers under section 4 of the Medicines Act 1968.

The duties of the British Pharmacopœia Commission are as follows:

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

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

Membership of the British Pharmacopœia Commission

Chairman

J B Stenlake† CBE DSc PhD FPS CChem FRSC FRSE
Honorary Professor of Pharmacy in the University of Strathclyde

Vice-Chairman

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Professor of Clinical Pharmacology in the University of London

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A Veterinary Surgeon

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Principal and Dean of The Royal Veterinary College, University of London

D H Calam† MA DPhil CChem FRSC
Head of Antibiotics and Chemistry Division, National Institute for Biological Standards and Control

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A Scientific Adviser in the Pharmaceutical Industry

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D I Magrath‡ BA PhD
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Director, Department of Pharmaceutical Sciences, Pharmaceutical Society of Great Britain

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Chief Pharmacist, Department of Health and Social Security

Secretary and Scientific Director

C A Johnson CBE DSc(Hon) BPharm BSc FPS CChem FRSC MPhA

*Term of office ends 31 December 1991.
†Term of office ends 31 December 1989.
‡Term of office ended 31 December 1987.
§Term of office ended 31 December 1985.

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 1984 to 1986.

COMMITTEES

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B: Medicinal Chemicals	A Holbrook (*Chairman*), A F Fell (*Vice-Chairman*), F Bailey, J K Bailey, P H Cobb, G Drewery, E J Kempster, M Martin-Smith, R N Thornhill, A A Wagland, D Watt (*Corresponding member* B Warren)
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E: Antibiotics	J A Holgate (*Chairman*), J F Chissell (*Vice-Chairman*), E Addison, A E Bird, A K Coulter, P J Duff, J W Lightbown, H C Macfarlane, D Moriau, G F Snook (*Corresponding members* C R Broom, R K Howard, M E Duncan, J Purves, A H Thomas)
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J: Immunological Products	J W G Smith (Chairman to December 1985), I Davidson (Chairman from January 1986), F W Sheffield (*Vice-Chairman*), I G S Furminger, J R Hepple, P A Knight, A M T Lee, D I Magrath, J Melling, J Prydie, D H Thornton, P W Wells (*Corresponding members* T W F Pay, G C Schild)
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M: Nomenclature	G F Phillips (*Chairman*), P Turner (*Vice-Chairman*), G R Brown*, G Bryan, D H Calam, E W Godly, P W Golightly, W Hancock, Sir Frank Hartley, G R Kitteringham, A F Machin, H McNulty, H J Rogers†, A Wade (*Corresponding members* G R Tudhope, A Wehrli)
N: Veterinary Medicine and Doses	A O Betts (*Chairman*), W G Allen (*Vice-Chairman*), R J Bywater, A P Davidson, I Davidson, D E Jones, A R M Kidd, A Knifton, P Lees, D G McBeath, D A Rutty

CONSULTATIVE GROUPS

S: Human Medicine and Doses	P Turner (*Chairman*), M W Greaves, M H Lader, L E Ramsay, A Richens, G R Tudhope, G N Volans, J D Williams
T: General Analytical Methods	D H Calam (*Chairman*), F Bailey, G P R Carr, A K Coulter, A G Davidson, D W Mathieson, G F Phillips, W I Stephen, J S Wragg
U: Reagents	A Holbrook (*Chairman*), J A Clark, E J Newman, L F Oughton, W I Stephen
V: Radioactive Materials	A F Fell (*Chairman*), I C Downing, D E Lovett, D Lui, N Veall, T L Whateley
W: Surgical Sutures	J A Holgate (*Chairman*), J O Dawson, G G Pafford
X: Plastics and Plastic Containers	B A Wills (*Chairman*), C A M Chard, K J Child, M N Duncan, J E Pentelow, J L Sharp

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

Secretariat A R Rogers, M L Rabouhans, R B Trigg, L M Billett, H J Judd, M Vallender, L F Bosher, T L Overman, R A Pask-Hughes

Laboratory P Creed, A Islam, D C Brougham, R Middleton, R L Turner, B J Fish, E A Meff, C J Woollam, P K Dhanjal, T Morarji, J W Hayes, R Mannan, V Pathak, C M Shah

Administrative J T Stewart, F Madon, C Clark, K Miller, S Mitchell, W Allwright, J Hoban, J Luby, U K Magecha, Y M White, D Whyte

*Deceased July 1984.
†Deceased March 1987.

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Membership of the European Pharmacopœia Commission

The membership of the Commission on 30 June 1987 was as follows:

Chairman:	P Arends
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Belgium (B):	C L Lapière, P Janssens, H Vanderhaeghe, J Bosly*, P Jacqmain*, R Kinget*
Cyprus (CY):	E Kkolos
Denmark (DK):	P Frandsen, H G Kristensen, P Helboe*, A Sørensen*, M Thomsen*
Finland (SF):	J Halmekoski, L Turakka, A Kaukinen*
France (F):	A Artiges, Y Cohen, M Pesez, J P Billon*, P Delomenie*, F J Pellerin*
Federal Republic of Germany (D):	E Boll, W Hennessen, G Schorn, H D Brede*, K Thoma*
Greece (GR):	S Philianos, G Salem, A Tsoka
Iceland (ISL):	I J Petersen, V G Skulason
Ireland (IRL):	T McGuinn, R F Timoney
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Netherlands (NL):	A W M Indemans, C A Teijgeler, H L Vos, J van Noordwijk*, H M Smits*
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Sweden (S):	P Lindgren, M B Ohrner, I Sjöholm, L Sjödin*
Switzerland (CH):	G Rotzler, U Salzmann, D Sonanini, P Buri*, I Kapetanidis*
United Kingdom (UK):	J A Holgate, C A Johnson, J B Stenlake, D H Calam*, I Davidson*, B A Wills*
Observers:	
(EEC)	F Sauer
(Portugal)	A Correia Alves, L Nogueira Prista

*Alternates.

Membership of Groups of Experts of the European Pharmacopœia Commission

The membership of the Groups of Experts on 30 June 1987 was as follows:

Group No 1: Biological Methods and Statistical Analysis	J van Noordwijk *(Chairman)*, J Dony *(B)*, M Gay *(CH)*, G Hofrichter *(D)*, A German *(F)*, R Aureli *(I)*, D Fystro *(N)*, L Sjödin *(S)*, M L Rabouhans *(UK)*
Group No 1CM: Microbiological Contamination	H G Kristensen *(Chairman)*, J Dony *(B)*, M Gay *(CH)*, H Seyfarth *(D)*, E A Christensen *(DK)*, P Petitjean *(F)*, J Lavdiotis *(GR)*, R Aureli *(I)*, D Fystro *(N)*, O Ringertz *(S)*, A L Davison *(UK)*
Group No 1L: Limulus Amoebocyte Lysate Test (LAL)	J van Noordwijk *(Chairman)*, J Dony *(B)*, A Gardi *(CH)*, A Krüger *(D)*, J Storck *(F)*, L Bellentani *(I)*, D Fystro *(N)*, P Lindgren *(S)*, G A Sabey *(UK)*
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Group No 2: Chemical Methods	M Pesez *(Chairman)*, P Dumont (B), E Keller *(CH)*, E Boll *(D)*, P Helboe *(DK)*, J P Billon *(F)*, G Minola *(I)*, X Perlia *(CH)*, A Bult *(NL)*, G P R Carr *(UK)*
Group No 3: Nomenclature and Drafting	P Jacqmain *(Chairman)*, P Braeckman *(B)*, L Anker *(CH)*, A Erb *(D)*, P Delomenie *(F)*, E Cingolani *(I)*, H L Vos *(NL)*, C A Johnson *(UK)*
Group No 4: Physical and Physico-chemical Methods	X Perlia *(Chairman)*, L Molle *(B)*, E Keller *(CH)*, E Boll *(D)*, F J Pellerin *(F)*, G G Gallo *(I)*, A Bult *(NL)*, J Vessman *(S)*, G P R Carr *(UK)*
Group No 5: Reagents	H L Vos *(Chairman)*, A Haemers *(B)*, J C Beyer *(CH)*, D Giegling *(D)*, J L Millet *(F)*, A Rossetti *(I)*, P W F Brunsmann *(NL)*, E J Newman *(UK)*
Group No 6: Biological Substances	J van Noordwijk *(Chairman)*, A Lauwers *(B)*, E Stürmer *(CH)*, A Häussler *(D)*, P Frandsen *(DK)*, M Percheron *(F)*, L Tentori *(I)*, F C Arntzen *(N)*, F C Hillen *(NL)*, L Sjödin *(S)*, E Palva *(SF)*, A F Bristow *(UK)*
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Group No 11A: Vitamin A	B Borsje *(Chairman)*, R Schwob *(CH)*, U Thiele *(D)*, J Ampilhac *(F)*, G Cavina *(I)*, G F Phillips *(UK)*
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Group No 15: Sera and Vaccines	W Hennessen *(Chairman)*, V Dostal *(A)*, P Lemoine *(B)*, F Reigel *(CH)*, W Schneider *(D)*, J Leerhøy *(DK)*, A A German *(F)*, C Collotti Ferretti *(I)*, R Winsnes *(N)*, J W Dorpema *(NL)*, M Tiru *(S)*, T Kuronen *(SF)*, D I Magrath *(UK)*
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Group No 16: Plastic Containers for Pharmaceutical Use	R F Timoney *(Chairman)*, W Lhoest *(B)*, S Thorens *(CH)*, R Rößler *(D)*, V Handlos *(DK)*, J P Billon *(F)*, L Gramiccioni Valsecchi *(I)*, J W A Averink *(NL)*, A Arbin *(S)*, J E Pentelow *(UK)*

Introduction

This edition of the British Pharmacopœia, the fourteenth since the merging of the London, Edinburgh and Dublin Pharmacopœias in 1864, has been prepared by the British Pharmacopœia Commission with the collaboration and support of its advisory committees and other experts. The committees in particular are vital to the healthy growth and maintenance of the Pharmacopœia. For this reason members are selected to provide a wide range of expertise, advice and opinion. In this connection it is of interest to note, and a source of satisfaction to the Commission, that scientists from the National Biological Standards Laboratory in Australia and an officer from the World Health Organization in Geneva have been appointed as corresponding members to three of the committees. The international nature of much pharmaceutical production now demands a more international approach from pharmacopœial authorities. The British Pharmacopœia Commission is very conscious of this and endeavours to foster it by dedicated adherence to the aims of the European Pharmacopœia Commission, by continuing and regular contact with the United States Pharmacopeia Convention and by occasional exchange of views with other pharmacopœial authorities and with the World Health Organization. A further international dimension is brought to the work because of the extensive use made of the British Pharmacopœia in many countries of the world. This is evident from the considerable correspondence received containing comment, question or criticism. In this connection the British Pharmacopœia Commission would like to stress that it relies heavily on dialogue with users of the Pharmacopœia. Constructive comment is welcome from whatever quarter and is vital to the continuing relevance of the Commission's work.

The New Edition

This new edition of the Pharmacopœia contains 2100 monographs for substances and articles used in the practice of medicine. Of these, some 495 are edited versions of monographs now included in the growing European Pharmacopœia (see below). The effective date for this edition is 1 December 1988. From this date this edition supersedes the British Pharmacopœia 1980 as amended by its various addenda. If a monograph that appeared in the earlier edition has not been included in this edition then that monograph remains effective, in accordance with Section 65(4) of the Medicines Act 1968.

There have been some major changes to the Formulated Preparations section which are discussed in greater detail below. These changes have allowed the Pharmacopœia Commission to concentrate its efforts on producing standards that will apply to a range of products of similar type rather than only to a product manufactured to a fixed formulation. They allow greater flexibility in the formulation of many official preparations so that manufacturers may avoid the use of auxiliary ingredients that might from time to time become regarded as undesirable, at least in certain circumstances or conditions. The greater freedom in formulation also allows the development of more stable and

possibly more palatable versions of certain products. It has to be borne in mind that many of the fixed formulae included in earlier compendia were designed for extemporaneous dispensing. Over the past two decades or so the practice of manufacturing such preparations in bulk to obviate extemporaneous dispensing has grown and many of the traditional formulae have been shown to be inappropriate for large-scale production and for long-term storage. The greater freedom that is conferred by the new policy allows a manufacturer to modify certain aspects of the formulation to achieve a more commercially acceptable product. This freedom is, however, accompanied by an increased responsibility to ensure the stability and acceptability of the modified preparation.

These changes in the formulary, together with certain other changes of emphasis throughout the Pharmacopœia, have given rise to the need for a substantially revised collection of General Notices. It is stressed that the General Notices are an essential and mandatory part of the Pharmacopœia. Requirements in the monographs must be interpreted in the light of these notices; it follows that the user of the Pharmacopœia must have a ready acquaintance with them. To facilitate this, and to stress their importance, the General Notices have been presented in full on tinted paper at the beginning of both Volumes I and II of this edition.

As in the 1980 edition Volume I contains the monographs for medicinal and auxiliary substances whilst Volume II comprises the formulary (now contained in a section entitled Formulated Preparations), sections dealing with blood products, immunological products, radiopharmaceutical preparations and surgical materials and the extensive appendices. In this edition the necessary infra-red spectra have been incorporated at the end of Volume I.

Some Additions

Monographs included in the Pharmacopœia for the first time are listed at the end of this Introduction. These include aprotinin, a proteolytic enzyme inhibitor, and aprotinin injection; the beta-adrenoceptor antagonist atenolol and atenolol tablets; the oral hypoglycaemic agent glipizide and glipizide tablets; the tranquilliser temazepam; the antispasmodic agent mebeverine hydrochloride and mebeverine tablets and, together with monographs for tablets, the hypotensive agent prazosin hydrochloride and the antacid hydrotalcite.

Also included for the first time is a general monograph for pressurised inhalations which includes a test for deposition of the emitted dose. This general monograph incorporates the requirements of the European Pharmacopœia for Pressurised Pharmaceutical Preparations. With the exception of these European Pharmacopœia requirements, which apply to all pressurised inhalations, the requirements of the general monograph will apply to those pressurised inhalations that are the subject of an individual monograph in the Pharmacopœia. It is hoped to add a monograph for a pressurised inhalation of salbutamol in an addendum to this edition. The test for deposition of the emitted dose uses a simplified cascade impactor. It is an *in vitro* test that is designed to contribute to an assurance of satisfactory aerosol formulation; its role is thus akin to that of the dissolution test for solid oral dosage forms.

The new monographs for atenolol and atenolol tablets referred to above include a high-performance liquid chromatographic test for Related substances that is recognised to provide only partial control of the likely impurities. Other methods are available but none has so far shown itself to be sufficiently robust to serve as a pharmacopœial procedure. The Commission is continuing the development of a more

satisfactory test or tests and it is hoped that early improvements to the present requirements will be possible.

Of particular interest is the newly introduced monograph for human insulin. This has been modelled closely on the monograph for insulin and is included as an interim measure whilst work aimed at providing more comprehensive requirements for insulins having the structure of natural human insulin continues in connection with the European Pharmacopœia. The newly introduced monograph defines human insulin as a protein having the normal structure of the natural antidiabetic hormone produced by the human pancreas. Production either by enzymatic modification of insulin obtained from the pancreas of the pig or by a procedure based on recombinant deoxyribonucleic acid (DNA) technology in micro-organisms is recognised. In either case the production must be followed by appropriate purification and, where recombinant DNA technology is used, the production must be based on an approved host-vector system. This interim monograph has been introduced in order that the various monographs for insulin preparations may be modified, where appropriate, to recognise the rapidly growing importance of such preparations made from human insulin.

The Basis of Pharmacopœial Requirements

The basis on which the requirements of the Pharmacopœia are established was discussed in detail in the Introduction to the British Pharmacopœia 1980. Since a proper understanding of the basis is essential to the correct use of the requirements the section is reproduced below in a slightly expanded form.

The Pharmacopœia provides a publicly available statement concerning the quality of a product that is expected to be demonstrable at any time during its accepted shelf-life; it does not provide a collection of minimum standards with which a manufacturer must comply before release of a product. Change may occur during storage and distribution and the pharmacopœial requirements are set to acknowledge acceptable levels of change and to reject materials showing unacceptable levels. It follows that the prudent manufacturer will, where considerations of product stability demand, apply specifications that are more exacting than those laid down in the Pharmacopœia. It also follows that a manufacturer may use any methods of analysis and any general control procedures that are deemed to be appropriate to confirm that the product is acceptable. In so doing the manufacturer must recognise that, at any time during its claimed shelf-life, the product may be challenged independently by the methods of the Pharmacopœia and that compliance with the limits imposed will be required. In the event of any doubt or dispute as to whether or not a material is of pharmacopœial quality, as a General Notice makes clear, the methods of the Pharmacopœia alone are authoritative.

This view of pharmacopœial requirements is also significant when considering the amount of sample to be taken for test. In an overall programme designed to give assurance of quality of a manufactured product the statistical validity of any sampling programme must be beyond doubt. The standards of the Pharmacopœia, on the other hand, are intended to apply to the sample available, perhaps the container of dispensed tablets provided to a patient in accordance with a prescription. The Pharmacopœia requires that twenty of those tablets should meet the test for Uniformity of weight; a manufacturer establishing a sampling and testing protocol designed to ensure ultimate compliance with the pharmacopœial requirements will need to operate at a level designed to show with an acceptable degree of confidence that any twenty tablets, taken at random from a given batch, will meet the requirements.

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