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British Pharmacopoeia 1998

Volume I

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British Pharmacopoeia Commission

Office:

Market Towers
1 Nine Elms Lane
London SW8 5NQ
Telephone: +44 (0)171 273 0561
Facsimile: +44 (0)171 273 0566

Laboratory:

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

Telephone: +44 (0)1
Fac

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Preface

The British Pharmacopoeia 1998 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 authorititative 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 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 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

Chairman D Ganderton[2] OBE BPharm PhD FRPharmS
Visiting Professor of Pharmaceutics, the University of London

Vice-Chairman P Turner[4] CBE MD BSc FRCP FFPM HonMRPharmS CBiol FIBiol
Professor of Clinical Pharmacology, the University of London

D H Calam[2,5] OBE MA DPhil HonMRPharmS CChem FRSC
European Co-ordinator, National Institute for Biological Standards and Control

W G Allen[2] MRCVS
A Veterinary Surgeon

J J Ayres[2] Bsc PhD
A Director of Quality Assurance in the Pharmaceutical Industry

A C Caws[1] BSc CChem MRSC
Formerly a Senior Analyst in the Pharmaceutical Industry

A F Fell[3] BPharm PhD FRPharmS CChem FRSC FIQA *Professor of Pharmaceutical Chemistry, the University of Bradford*

J A Goldsmith[2] BSc PhD CChem FRSC FIQA
Formerly a Director of Technical Operations in the Pharmaceutical Industry; Visiting Professor to the University of Strathclyde

A M T Lee[2] BVMS PhD MRCVS
Formerly a member of the Veterinary Medicines Directorate

J M Midgley[2] BSc MSc PhD FRPharmS CChem FRSC
Professor of Pharmaceutical and Medicinal Chemistry, Department of Pharmaceutical Sciences, the University of Strathclyde

A C Moffat[3] BPharm PhD DSc CChem FRSC FRPharmS MCPP
Director, Department of Pharmaceutical Sciences, Royal Pharmaceutical Society of Great Britain

G F Phillips[1] OBE MSc HonMRPharmS CChem FRSC
Formerly Superintendent, Environmental and Forensic Services, Laboratory of the Government Chemist; Visiting Professor in Analytical Chemistry to Glasgow Caledonian University

L E Ramsay[6] MB ChB FRCP
Consultant Physician, Royal Hallamshire Hospital; Professor of Clinical Pharmacology and Therapeutics, University of Sheffield

N Randall[3] PhD CChem FRSC FIQA
A Director of Quality Assurance in the Pharmaceutical Industry

G D Rees[2] BPharm PhD MRPharmS CChem MRSC FIQA
A Director of Quality Assurance in the Pharmaceutical Industry

H E C Worthington[1] BPharm PhD FRPharmS
Formerly a Head of Pharmacy, Research and Development in the Pharmaceutical Industry

Secretary and Scientific Director R C Hutton BSc PhD CChem FRSC

[1]Term of office ended 31 December 1995.
[2]Term of office ends 31 December 1997.
[3]Term of office ends 31 December 1999.
[4]Deceased December 1994
[5]Vice-Chairman from March 1995
[6] resigned December 1997

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 1995 to 1997.

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(*Corresponding member* G L Mattok)

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CONSULTATIVE GROUPS

L: Surgical Materials: J M Midgley *(Chairman)*, T D Turner *(Vice-Chairman)*, D T Britton, J Chaston, G J Collyer, D A Conyers, D J Harris, D Metcalfe, P Newlands, S A Norton, P J Perry, K Rawlings, S Thomas

S: Human and Veterinary Medicines: L E Ramsay *(Chairman)*, W G Allen, D H Calam, D Ganderton, D Hepburn, A M T Lee, R M Lee

V: Radioactive Materials: A F Fell *(Chairman)*, S R Hesslewood, D Lui, A M Millar, R D Pickett, S Waters, T L Whateley

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

Secretariat: M L Rabouhans, R B Trigg, H J Judd, M Vallender, R A Pask-Hughes, E A Castles, P Holland, F J Swanson, S K Branch

Laboratory: A Islam, P Creed, D C Brougham, R Middleton, R L Turner, E A Meff, C J Woollam, P K Dhanjal, T Blackford-Swaries, T Morarji, C M Shah, R Mannan, V Pathak, M Barrett, A Ferrão, Y Mulukutla

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Introduction

This, the sixteenth, edition of the British Pharmacopoeia has been prepared by the British Pharmacopoeia Commission with the collaboration and support of its advisory committees and other experts. In addition to these individuals directly involved in preparation of the Pharmacopoeia, the British Pharmacopoeia Commission would like to thank all those users of the Pharmacopoeia from the United Kingdom and overseas who have provided comment on pharmacopoeial issues. Dialogue with users is an essential element of pharmacopoeial development and the British Pharmacopoeia Commission welcomes constructive comment from whatever quarter.

The New Edition This new edition of the Pharmacopoeia contains 2470 monographs for substances and articles used in the practice of medicine. The effective date for this edition is 1 December 1998. From this date this edition supersedes the British Pharmacopoeia 1993 as amended by its various addenda and amendments sheets. 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.

Volume I contains the monographs for medicinal and pharmaceutical substances, whilst Volume II comprises the sections dealing with formulated preparations, blood products, immunological products, radiopharmaceutical preparations and surgical materials together with the infrared spectra, the appendices, the supplementary chapters and a comprehensive index. The General Notices are printed on tinted paper in each volume.

The opportunity provided by publication of the new edition has been used to consolidate the main volumes of the previous edition with its four addenda and to introduce a number of changes throughout the Pharmacopoeia. New features in this edition include improved text layout to distinguish European Pharmacopoeia monographs more clearly and a shorter Introduction that is more focussed on the changes made in this edition. This latter improvement has been achieved by providing an explanation of the basis of pharmacopoeial requirements and other fundamental aspects of pharmacopoeial philosophy in the Supplementary Chapters. Attention is drawn to these and other significant changes elsewhere within the relevant sections of the Introduction.

Some Additions Monographs for substances and preparations included in the Pharmacopoeia for the first time are listed at the end of this Introduction. Substances that are new to the Pharmacopoeia include the anti-inflammatory and analgesic benzydamine hydrochloride, the hypolipidaemic colestipol hydrochloride, disodium pamindronate used in the treatment of malignant hypercalcaemia, the corticosteroid

fluticasone propionate and the cation exchange resin sodium polystyrene sulphonate used in the treatment of hyperkalaemia. Monographs for a range of formulated preparations of these substances are included in Volume II together with a number of new monographs for formulated preparations of substances that are already in the Pharmacopoeia. These latter include preparations of the antibiotic ciprofloxacin, the analgesic anti-inflammatory diclofenac sodium and the anticholinergic bronchodilator ipratropium bromide.

The monographs for Colestipol Hydrochloride and Colestipol Granules are unusual in their use of pyrograms for identification purposes.

New European Pharmacopoeia monographs reproduced in this edition include those for the fibrinolytic alteplase, the cytotoxic carmustine, the bronchodilator etamsylate and the antibacterial imipenem.

Revision In addition to many improvements to the requirements of individual monographs such as the addition of dissolution requirements to a number of tablet and capsule monographs, technical revision of specifications in this new edition includes a review and rationalisation of identification tests to reduce the burden of testing, wherever possible. The policy of the British Pharmacopoeia Commission with respect to monographs developed in recent years has been to include the minimum number of tests for identification commensurate with providing adequate asurance of identity of the substance or preparation being examined (see General Notices). In many monographs reliance is now placed on infrared spectroscopy together, where relevant, with a test for the counter ion. This policy has now been extended by reviewing earlier monographs especially those for which four or more identification tests were specified and removing any tests considered superfluous.

To assist users of the Pharmacopoeia a list has been included at the end of the Introduction indicating those monographs which have been technically amended by means of this edition.

In preparing this edition the practice of cross-referencing from a monograph for a formulated preparation to the corresponding monograph for the parent substance has been significantly reduced. In particular cross references to monographs from the European Pharmacopoeia have been removed. The relevant tests are now included in full in the monograph for the formulated preparation. Where there are several monographs for formulated preparations, a cross reference from one preparation to another may be given, where appropriate.

European Pharmacopoeia Approximately 1280 monographs now comprise the monograph section of the third edition of the European Pharmacopoeia. In accordance with established practice, all these monographs are reproduced either in this edition of the British Pharmacopoeia or, where appropriate, in the associated edition of the British Pharmacopoeia (Veterinary). The user of the British Pharmacopoeia thus benefits by finding within this one, comprehensively indexed, compendium all current pharmacopoeial standards for medicines for human use in the United Kingdom.

Changes have been made in this edition to the way in which the monographs of the European Pharmacopoeia are presented in order to

distinguish them more clearly from monographs that are specific to the British Pharmacopoeia. In addition to the European 'chaplet of stars' symbol alongside the title, European Pharmacopoeia monographs are distinguished by an explicit reference to the European Pharmacopoeia within an italicised introductory statement. The beginning and end of the full text of the European Pharmacopoeia monograph is indicated clearly by means of horizontal lines bearing the symbol '*Ph Eur*' ranged left and right; the text is included without any editorial modification.

Where appropriate, the monographs provide additional statements of relevance to UK usage (such as the list of BP preparations). All such statements are placed together at the head of the monograph for ease of reference.

Correspondence between the general methods of the European Pharmacopoeia and the appendices of the BP 1998 is indicated in each appendix and by means of a complete check list at the beginning of the appendices. Attention is drawn to this check list by means of a note at the foot of all pages in the relevant sections of the Pharmacopoeia devoted to monographs.

The General Notices of the European Pharmacopoeia have been reproduced in full at the end of the relevant section of this edition. They are provided for application to the monographs and other texts from the European Pharmacopoeia.

While the above changes are designed to assist users of the British Pharmacopoeia, it is emphasised that, in the event of doubt of interpretation of any text from the European Pharmacopoeia, the text published in English under the direction of the Council of Europe must be consulted. A General Notice stresses the mandatory nature of this injunction.

General Notices The British Pharmacopoeia comprises the entire text within the publication. The interpretation of the Pharmacopoeia is governed by the General Notices. In this edition, the General Notices are presented in three parts each of which is introduced by an italicised statement.The first part includes a notice concerning incorporation of monographs from the European Pharmacopoeia. The second part applies to all text other than that reproduced from the European Pharmacopoeia. The third part consists of the entire General Notices of the European Pharmacopoeia that apply to all texts from the European Pharmacopoeia. While this approach results in a certain amount of repetition within the General Notices as a whole, providing separate notices for the interpretation of text specific to the British Pharmacopoeia and of text from the European Pharmacopoeia is intended to be more convenient to the user of the Pharmacopoeia. Such a separation is consistent with the clearer distinction that is being made between these texts of different provenance.

A statement has been added within the second part of the General Notices to the notice on Assays and Tests to indicate that a temperature in a test for Loss on drying, where no range is given, implies a range of ± 2° around the stated temperature.

Changes in title A list of the monographs of the BP 1993 for which the title has been changed in the BP 1998 is provided at the end of this Introduction. With the exceptions of Fractionated Coconut Oil, Pregelatinised Maize

Starch, Propyliodone Suspension and Propyliodone Oily Suspension, these changes are necessary to bring the titles in the British Pharmacopoeia in line with the names that manufacturers are now required to use on product labels and leaflets in accordance with EC Directive 92/27/EEC.

Normal practice within the British Pharmacopoeia when changing the title of a monograph is to retain the former title as a subsidiary title for at least one edition. This is not possible for these changes since use of the former name is not permitted on product labels, *etc.* In order to provide continuity a statement has therefore been added to all affected monographs and a cross-referenced entry has been included in the Index. These statements are in the form 'When [BP 93 title] is prescribed or demanded, [BP 98 title] shall be dispensed or supplied.' For example the monograph for Levothyroxine Tablets includes the following statement 'When thyroxine tablets are prescribed or demanded, Levothyroxine Tablets shall be dispensed or supplied.'. Statements of this type are an established feature of certain monographs where it is considered advisable to provide a link between the name at the head of a monograph and some other 'unofficial' descriptor that may still be used by prescribers or purchasers of medicines for the same substance or preparation. Inclusion of such an 'equivalence statement' within the British Pharmacopoeia provides an official, primary source of authoritative information. It is hoped that this will assist those responsible for managing the changes in the names of medicines arising from implementation of the Directive to provide relevant advice to, for example, prescribers and dispensing pharmacists.

For substances for which there is a Recommended International Nonproprietary Name (rINN), it has been necessary to omit any subsidiary titles from the BP 1998. For example, the 'Vitamin C' subsidiary titles have been omitted from the monographs for Ascorbic Acid, Ascorbic Acid Injection and Ascorbic Acid Tablets. Statements of the type described above have been included, where appropriate, to provide continuity.

The title of some monographs listed now consists of two names presented on separate lines, for example, 'Alimemazine Tablets' followed by 'Trimeprazine Tablets', or 'Trihexyphenidyl Tablets' followed by 'Benzhexol Tablets'. This form of title reflects United Kingdom legislation that will require by means of a Statutory Instrument that the label of medicinal products containing certain specified substances state both the rINN and the British Approved Name (BAN) for the substance. This 'dual labelling' approach has been adopted by the United Kingdom authorities for a small number of substances for at least five years. In these monographs (identified in the list by the symbol 'DL') a statement indicates that in the United Kingdom both names within the title must be used for the purposes of product labelling. No equivalence statement has been added in these cases, since continuity of name is provided within the dual title.

At the time of going to press with this edition of the British Pharmacopoeia, the draft Statutory Instrument was still under consideration. If changes either to the list of substances to be included in the Instrument or to other aspects of the requirements are made which impinge on the titles of monographs in this edition, the necessary

pharmacopoeial amendments will be published in an Amendments sheet.

Adrenaline and noradrenaline are the terms used in the titles of monographs in the European Pharmacopoeia and are thus the official names in use in the 25 member states party to the Convention on the Elaboration of a European Pharmacopoeia. These terms are therefore used in the first part of the dual titles for all relevant monographs in the British Pharmacopoeia with the rINN in the second part, for example, 'Adrenaline Injection' followed by 'Epinephrine Injection'.

The title changes discussed above are reflected in consequential changes throughout the texts of the affected monographs, other than in monographs of European Pharmacopoeia origin; they are also reflected in the list of Approved Synonyms (see below). In those monographs where the title now consists of two names, the first of these names only is generally used throughout the text. For example, in the monograph the title for which is 'Tetracaine Eye Drops' followed by 'Amethocaine Eye Drops' the definition states 'Tetracaine Eye Drops are a sterile solution of Tetracaine Hydrochloride in Purified Water.' The reference to Tetracaine Hydrochloride in this definition is to be interpreted as invoking the standards of the monograph now entitled 'Tetracaine Hydrochloride' followed by 'Amethocaine Hydrochloride'. In addition, as noted above a statement in each monograph makes it clear that, for the purposes of product labelling, both names have to be used together.

Approved Synonyms

A consolidated list is published as Appendix XXI B. In consolidating the lists from the Addenda to the BP 1993 changes have been made on the following basis.

The Ph Eur title is the English main title given in the European Pharmacopoeia. Omission of the Latin sub-titles and consequent re-arrangement in alphabetical order of English title provides a simpler, more easily used list. To assist the user further, vaccines, antisera and diagnostics have been grouped together in a separate section for Immunological Products.

Changes have also been made to the consolidated list to reflect the changes in monograph titles described above. Those Approved Synonyms that were previously required in order to allow use of a BAN in a British Pharmacopoeia monograph title in place of the rINN used in the corresponding European Pharmacopoeia title have been omitted together with any Approved Synonyms that were established to allow for British Pharmacopoeia subsidiary titles that are no longer included.

The Basis of Pharmacopoeial Requirements

A proper understanding of the basis on which the requirements of the Pharmacopoeia are established is essential to the correct interpretation of the requirements. Extensive explanatory text and guidance is provided in Supplementary Chapter I. An introduction to this chapter describes the general underlying philosophy and this is followed by separate sections explaining the current approach to a particular aspect of pharmacopoeial control and, where appropriate, giving an indication as to future developments.

In addition to any advice or guidance provided either in the Supplementary Chapters or in this Introduction to the Pharmacopoeia, it is important to note that the status, scope and interpretation of Pharmacopoeial statements is governed by the General Notices. No

requirement of the Pharmacopoeia can be taken in isolation; a valid interpretation of any particular requirement depends on it being read in the context of (i) the specified method of analysis (which may include reference to an Appendix), (ii) the monograph as a whole, (iii) where appropriate, the relevant general monograph and (iv) the relevant General Notices.

It is emphasised that any article described by a name at the head of a monograph in the current edition of the Pharmacopoeia, *whether or not it is referred to as 'BP'*, must comply with that monograph. The name at the head of a monograph is to be interpreted in accordance with the General Notice on Titles. In particular, a formulated preparation that is labelled with a title that includes the full nonproprietary name of the active ingredient, where this is not included in the title of the monograph, must also comply with the monograph. Thus, for example, a preparation labelled Labetalol Hydrochloride Tablets must comply with the monograph for Labetalol Tablets.

International Units

The term 'Unit' has been replaced, wherever appropriate in this edition, by 'IU' the abbreviation for International Unit. In previous editions of the Pharmacopoeia, the General Notice on Biological Assays and Tests stated that, wherever possible, the primary standard was the respective International Standard or Reference Preparation and that the Unit was the International Unit. Using 'IU' within all relevant texts is, however, more transparent than relying on this General Notice alone.

Monographs will continue to refer to units other than International Units, where appropriate, for example, for certain enzymes for which the primary standard is a reference preparation established by the International Pharmaceutical Federation (FIP) and adopted by the European Pharmacopoeia Commission (see also Supplementary Chapter I H). Labelling statements in monographs, other than those from the European Pharmacopoeia, which require the use of IU will retain the term 'Unit' in parentheses after 'IU' for an interim period to avoid confusion and to allow those manufacturers that currently label their products in Units to continue to use existing labels.

Formulated Preparations

The arrangement of the section of the Pharmacopoeia for Formulated Preparations of the British Pharmacopoeia 1993 has been maintained in this edition. All the general monographs are grouped at the beginning of the section, followed by the individual monographs arranged in alphabetical order.

The sub-section for General Monographs includes all the general monographs of the European Pharmacopoeia, distinguished by a chaplet of stars, together with, where appropriate, additional statements that apply only to the individual formulation monographs of the British Pharmacopoeia. Such additional text is clearly identified by a sub-heading such as 'Tablets of the British Pharmacopoeia' and by an italicised statement clarifying its sphere of application. For each general monograph, this additional text includes a list indicating all preparations of that type that are the subject of a monograph in the British Pharmacopoeia 1998.

The cross-references in the individual preparation monographs have been modified, where necessary, to refer to the title of the revised European Pharmacopoeia general monograph. For example, Eye

Drops, Eye Lotions and Eye Ointments include the statement *'The (eye drops* etc*) comply with the requirements stated under Eye Preparations and with the following requirements.'*. All such statements are in italics for emphasis.

Users of the British Pharmacopoeia are reminded that the general monographs of the European Pharmacopoeia apply to all individual dosage forms of the type defined rather than only to those for which there is a specific monograph within the British Pharmacopoeia (see the General Notices).

Attention is drawn to the Production sections that are now to be found in most of the general monographs of the European Pharmacopoeia for formulated preparations. These sections draw attention to particular aspects of the manufacture, including development, of the type of preparation in question. Unless the form of wording used within a particular Production statement makes it clear that it constitutes a recommendation or guidance, all statements within Production sections of monographs are to be interpreted as mandatory instructions to manufacturers. Examples of non-mandatory statements include those which make reference to certain general texts published in section 5 of the European Pharmacopoeia. Such texts include non-mandatory methods of test that may be used by a manufacturer to demonstrate the suitability of a product with respect to certain characteristics, for example, the efficacy of antimicrobial preservation. These texts are reproduced within the appendices of the British Pharmacopoeia.

Attention is also drawn to changes to the Definition and Labelling sections of certain individual monographs for formulated preparations that have been made to take account of the publication of Standard Terms by the Council of Europe [Pharmeuropa, Special Issue, 1998, in press]. It is understood that the Standard Terms are to be used in providing relevant information for the Summary of Product Characteristics (SPC), leaflet and labelling of medicinal products receiving a European Community authorisation and that Member States are also expected to require them to be used for the same purposes for national authorisations.

Many of the Standard Terms for the pharmaceutical form are used in the titles of British Pharmacopoeia monographs for formulated preparations and therefore appear already on the label as part of the nonproprietary name of the product. Certain terms in established use in the UK, however, have not been designated as Standard Terms. As a consequence the titles of a small proportion of the formulated preparations in this edition contain terms other than Standard Terms. These preparations include well-established and widely used preparations such as Codeine Linctus, Simple Linctus, Calamine Lotion and Talc Dusting Powder. In all such cases, in the interests of transparency, reference to the relevant Standard Term has been incorporated into the Definition and Labelling sections of the monograph in this edition. It is emphasised, however, that the established title of the monograph is unchanged. For Codeine Linctus, for example, the title of the monograph and therefore the nonproprietary name of the preparation remains as Codeine Linctus, but the Definition states that ' Codeine Linctus is an *oral solution*

containing ...'. and a Labelling statement has been added 'The label indicates the pharmaceutical form as 'oral solution.'. Thus all manufacturers will be expected to continue to use Codeine Linctus as the nonproprietary name of their product (with or without an additional tradename), but they will need to use the Standard Term 'oral solution' when providing information concerning the pharmaceutical form.

This approach has been chosen to avoid the potential for medication errors due to confusion and to minimise the impact of labelling changes both on compliance with quality specifications and on the prescribing and supply of generic medicines

Surgical Materials The Surgical Materials section of the Pharmacopoeia has been further revised in the light of the developments within Europe associated with the promulgation of a European Community directive on medical devices. All the remaining monographs for dressings have been omitted from this edition. The only monographs remaining in this section are those of the European Pharmacopoeia. It is understood that those for absorbent cottons and absorbent viscose gauzes have been retained in the European Pharmacopoeia on the basis that they describe 'base materials' rather than surgical dressings as such. The monographs of the European Pharmacopoeia for surgical sutures have been revised and restructured in recognition that sutures are medical devices as defined in Directive 93/42/EEC.

Appendices During the production of the British Pharmacopoeia 1998 the opportunity has been taken to remove certain of the Appendices or parts of Appendices that are no longer required in any monograph (such as certain of the methods for the determination of nitrogen, Appendix VIII H, and the methods of test for surgical dressings, formerly Appendix XX). At the same time, methods that are mentioned infrequently in monographs have been transferred to the monographs rather than maintained in an Appendix. The Appendices have been extensively restructured to reflect these and other changes.

New Appendices have been created to accommodate certain general texts and methods of the European Pharmacopoeia. Appendix XII H, for example, is the test for uniformity of content that was previously included in the relevant general monographs such as that for Tablets. Appendix XV now contains a collection of general texts on the production and testing of vaccines that were previously appended to the general monograph for vaccines. Appendix XX now contains the texts on plastic material previously not included in the British Pharmacopoeia. The only general text of the European Pharmacopoeia that is not included in this edition is that on statistical analysis (section 5.3). This text is currently under review by the European Pharmacopoeia Commission and consideration will be given to its inclusion in the British Pharmacopoeia once this review and any consequent revision is complete.

A list of the contents of the Appendices of the British Pharmacopoeia 1998 is provided at the beginning of the Appendices together with a list of European Pharmacopoeia general methods each with its BP Appendix equivalent.

Supplementary Chapters Supplementary Chapters are an innovation that was introduced during the lifetime of the previous edition. This non-mandatory section