British Pharmacopœia 1973

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Notice concerning 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.

Preface

In 1970 the General Medical Council assigned to the Crown the copyright of the British Pharmacopœia in so far as that right was vested in the Council. In accordance with Section 98 of the Medicines Act 1968, from the date of the assignment Section 47 of the Medical Act 1956, which made it the Council's responsibility to publish the British Pharmacopœia, ceased to have effect.

Section 99 of the Medicines Act 1968 provides for the preparation of future editions of the British Pharmacopœia to become the responsibility of the Medicines Commission and for their publication by the Health Ministers on its recommendation. Under Section 4 of the Act the Health Ministers, on the recommendation of the Medicines Commission, established a committee to be called the British Pharmacopœia Commission for the purpose of continuing the work of the previous Commission appointed by the General Medical Council. To avoid the interruption of work on the present edition which was already well under way the members appointed to the new British Pharmacopœia Commission were the same as those of its predecessor except for Professor E. F. Scowen, M.D., D.SC., F.R.C.P., F.R.C.S., F.R.C.P.EDIN., F.R.C.PATH., who indicated that in view of his many commitments he did not wish to be appointed. F. Hartley, C.B.E., B.SC., PH.D., F.P.S., F.R.I.C., Dean of the School of Pharmacy, University of London, accepted the Chairmanship of the new Commission and J. B. Harman, M.A., M.D., F.R.C.P., F.R.C.S., accepted an invitation to become a member.

The assets and liabilities of the General Medical Council in connection with the former British Pharmacopœia were transferred to the Secretary of State for Social Services and the lease of the British Pharmacopœia Commission's offices and laboratory to the Ministry of Public Buildings and Works (now the Department of the Environment). The members of the Commission's staff were offered appointments in the Department of Health and Social Security.

This is the twelfth edition of the British Pharmacopœia and under the new arrangements it 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 work of the European Pharmacopœia Commission which was referred to in the Addendum 1971 to the British Pharmacopœia 1968 continues and has resulted in the publication of a number of new monographs. The standards in these monographs have been adopted for inclusion in this edition.

The preparation of a new edition of the British Pharmacopœia makes heavy demands on the members of the British Pharmacopœia Commission, its committees and its staff. The Medicines Commission wishes to record its appreciation of the services of all those who have contributed to this important work and have by their co-operation enabled it to be brought to a successful conclusion.

British Pharmacopœia Commission

Chairman	F. Hartley, C.B.E., B.SC., PH.D., F.P.S., F.R.I.C., Dean of the School of Pharmacy, University of London.
	D. C. M. Adamson, F.R.I.C., M.CHEM.A., formerly a Chief Analyst in the Pharmaceutical Industry.
	D. R. Bangham, M.B., B.S., Director of the Division of Biological Standards, National Institute for Medical Research, London.
	A. G. Fishburn, F.P.S., F.R.I.C., Chief Medicines Inspector, Department of Health and Social Security.
	D. C. Garratt, PH.D., D.SC., HON. M.P.S., F.R.I.C., M.CHEM.A., Scientific Adviser to the Pharmaceutical Society of Great Britain.
	J. C. Hanbury, C.B.E., M.A., B.PHARM., F.P.S., F.R.I.C., Executive in the Pharmaceutical Industry.
	J. B. Harman, M.D., F.R.C.P., F.R.C.S., Consultant Physician, St. Thomas's Hospital, London.
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	W. G. Overend, PH.D., D.SC., F.R.I.C., Professor of Chemistry in the University of London.
	F. T. Perkins, M.SC., PH.D., Head of the Division of Immunological Products Control, National Institute for Medical Research, London.
	J. B. Stenlake, D.SC., PH.D., F.P.S., F.R.I.C., F.R.S.E., Professor of Pharmacy in the University of Strathclyde.
	G. M. Wilson, M.D., D.SC., F.R.C.P., Regius Professor of Practice of Medicine in the University of Glasgow.
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Scientific Director	C. A. Johnson, B.PHARM., B.SC., F.P.S., F.R.I.C., M.PH.A.

Office of the Commission: 8 Bulstrode Street, London W1M 5FT

Introduction

The twelfth edition of the British Pharmacopœia was begun by the last British Pharmacopœia Commission to be appointed by the General Medical Council under the administrative arrangements recommended in 1928 by a Sub-committee of the Committee on Civil Research. The edition has been completed by the British Pharmacopœia Commission appointed by the Health Ministers on the recommendation of the Medicines Commission in accordance with the Medicines Act 1968. The new Commission acknowledges the considerable contribution made by its predecessor under the Chairmanship of Professor E. F. Scowen, M.D., D.SC., F.R.C.P., F.R.C.S., F.R.C.P.EDIN., F.R.C.PATH.

The duties of the British Pharmacopœia Commission are set out in the Medicines (British Pharmacopœia Commission) Order 1970, in the following manner:

(a) the preparation under section 99(1) of the Medicines Act 1968 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; and
(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(2) of the Act of any amendments of any published list.

The Commission appointed the following Committees and Panels to advise it in carrying out its duties and is greatly indebted to the members for undertaking the often arduous tasks allotted to them and for the zealous manner in which they performed their duties.

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The Commission is also indebted to many other experts who have been consulted on special topics, including Charlotte Anderson, R. A. Bassett, Ethel Bidwell, Rosemary Biggs, W. P. Cleland, J. Crofton, P. J. Gaffney, L. P. Garrod, I. Goodier, J. F. Goodwin, M. J. Groves, W. A. Jones, B. Öhrner, J. Rudinger, J. G. Scadding, Sir Ronald Bodley Scott, I. B. Sneddon, B. Swindells and F. W. Webb.

Close co-operation was maintained with the following bodies at home and overseas: the Department of Pharmaceutical Sciences of the Pharmaceutical Society of Great Britain, Codex Revision Committee, Medical Research Council, Hospital Pharmacists Consultative Committee, Board of Customs and Excise, Association of Anæsthetists of Great Britain and Ireland, Faculty of Dental Surgery of the Royal College of Surgeons of England, Association of the British Pharmaceutical Industry, Association of Clinical Pathologists, Laboratory of the Government Chemist of the Department of Trade and Industry, Central Public Health Laboratory, National Physical Laboratory of the Department of Trade and Industry, Patent Office Trade Marks Registry, Society for Analytical Chemistry, National Biological Standards Laboratory (Australia), Food and Drug Directorate of the Department of National Health and Welfare (Canada), Committee of Revision of the United States Pharmacopeia, American Pharmaceutical Association, Indian Pharmacopœia Committee, Department of Health (New Zealand), Department of Health (South Africa), Nordic Pharmacopœia Council, and Pharmaceutical Unit of the World Health Organisation.

The Commission is grateful for the help it continues to receive from these bodies and from M. G. Allmark, A. J. M. Bailey, J. V. Bergen, G. R. Brown, D. Cook, L. F. Dodson, M. Fors, G. L. Kalbfleisch, L. Levi, T. J. Macek, Sir William Refshauge, A. G. Shaw, and O. Wallén.

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The following members of the staff of the Commission were engaged in the production of this edition: Irene Ladden, B.PHARM., Sylvia Richens, F.P.S., Cherry M. King, B.SC., F. Breslin, L.R.I.C., Christine M. Allen, Patricia O. Creed, L.R.I.C., R. B. Trigg, A.R.I.C., and M. K. Partridge.

Lists are given below of the monographs added to or deleted from the Pharmacopœia by means of this edition, which contains 1277 monographs, an increase of 128 over the eleventh edition.

Among the articles described in the Pharmacopœia for the first time are the antibiotics Bacitracin Zinc, which replaces Bacitracin, Capreomycin Sulphate, Cephalexin, Kanamycin Sulphate, Lymecycline, and Propicillin Potassium; Framycetin Sulphate consists principally of neomycin B sulphate and is accordingly susceptible to a more precise definition of biological activity than the antibiotic still retained under the title Neomycin Sulphate. New synthetic substances include Carbenoxolone Sodium used in the treatment of gastric ulcer, Clomiphene Citrate, used in the treatment of infertility, Ethambutol Hydrochloride, an anti-tubercular substance, Fenfluramine Hydrochloride, an appetite suppressant, and Practolol, a beta adrenergic receptor blocking agent. New anæsthetics comprise a short-acting general anæsthetic, Propanidid, and a local analgesic, Prilocaine Hydrochloride. Monographs are also provided on the cardiac glycosides, Lanatoside C and Deslanoside, and on Vincristine Sulphate, a cytotoxic agent used in the treatment of neoplastic disease. Sodium Cromoglycate was added to the last edition of the Pharmacopœia by means of an Addendum. It is supplemented in this edition by a monograph on the encapsulated form in which it is presented for the prophylaxis of asthma by administration from an inhaler. To distinguish it from presentations of similar appearance which are taken by mouth, the title 'Cartridges' has been adopted. The name Co-trimoxazole was selected for the anti-infective mixture of Trimethoprim and Sulphamethoxazole in the proportion of one to five and is incorporated in the title of the new monograph on tablets of this combined form of therapy.

Several new radioactive preparations are described, including an injection containing technetium-99m, which is the first example in the Pharmacopœia of a radioactive preparation normally dispensed from a generator, and an injection of the gaseous isotope xenon-133. Macrisalb (I^{131}) Injection is a suspension of radio-iodinated human albumin degraded to form insoluble aggregates and intended for the examination of the lungs. A specification is also provided for the highly purified form of fibrinogen required for isotopic labelling. Work is continuing with the preparation of monographs on synthetic polypeptides. The specification for Pentagastrin added to the previous edition was completed without recourse to biological testing, but with increases in the number of amino-acid residues present in molecules there is a greater risk of errors in peptide structure and it has therefore been found necessary in preparing the monograph on Tetracosactrin Acetate to employ a wide range of chemical, physical, and biological analytical procedures. New pharmaceutical aids include certain polyethylene glycols (macrogols) and Fractionated Palm Kernel Oil, which is used as a basis in the preparation of suppositories. The monograph on Light Kaolin describes the special form of the material used for oral administration and containing a substance designed to assist its dispersion in aqueous vehicles. Light kaolin to which a dispersing agent has not been added is available and is equally suitable for the same medicinal uses when formulated appropriately; it is introduced in this edition under the title Light Kaolin (Natural). The monograph on Strong Potassium Chloride Solution was formerly part of the monograph on Potassium Chloride Injection and was intended for the extemporaneous preparation of the Injection, for example, by addition to an intravenous infusion of dextrose or saline solution. The addition of other medicaments to intravenous infusions is now viewed unfavourably and specific formulations for infusion solutions of potassium chloride are therefore provided in the new monographs on Potassium Chloride and Dextrose Injection and Potassium Chloride and Sodium Chloride Injection, but the standards for the Strong Solu-

tion have been retained because the preparation is still in demand. Two vaccines that are described for the first time are Typhoid and Tetanus Vaccine and Intracutaneous Typhoid-paratyphoid A and B Vaccine, the latter being a more potent form of the vaccine. The omission of the paratyphoid components from the official enteric fever vaccines was considered during the revision in light of reports that they contributed little to the efficacy of but greatly to the untoward reactions obtained with the vaccines. The decision to retain these was based on evidence that there is a need for protection against paratyphoid B and because there is a continuing high demand for the mixed vaccines. The standards for the various forms of diphtheria and tetanus prophylactics adsorbed on mineral carriers have been separated from those of the unadsorbed formol toxoids and are given in new monographs with distinctive titles; alum precipitated toxoids and toxoid-antitoxin floccules are no longer described.

Numerous important changes have been made to the monographs retained from the previous edition. Under the provisions of the Medicines Act 1968, the standards in the monographs of the European Pharmacopœia take precedence over those in the British Pharmacopœia or other compendia when medicinal articles are offered for sale, prescribed, or demanded by titles at the head of a monograph without reference to a particular compendium. Two volumes of the European Pharmacopœia have now been published. The first was issued in November 1969 and the Public Health Committee (Partial Agreement) of the Council of Europe resolved that it should be brought into effect by January 1, 1972. Volume II was published in November 1971 and is to be made effective by July 1, 1973. The standards in the monographs in this British Pharmacopœia for articles also the subject of monographs in both volumes of the European Pharmacopœia are therefore, in conformity with the provisions of the Medicines Act, referred to the European Pharmacopœia but the monographs are retained in the British Pharmacopœia because by this means additional titles may be attached to the articles and information added on storage, labelling, dose, and action and use. No modifications are made to the standards set out in the European Pharmacopœia and care has also been taken to ensure that no requirements are included in the monographs in the British Pharmacopœia on preparations of the substances described in the European Pharmacopœia that would involve the application to such substances of additional or more stringent tests than those laid down by the European Pharmacopœia. Moreover a number of monographs intended for future volumes of the European Pharmacopœia have reached an advanced stage of preparation and their requirements have been taken into account in revising the corresponding monographs of the British Pharmacopœia.

Progress has been made with the elimination of subsidiary titles from the monographs of the British Pharmacopœia, especially those abbreviated forms which effect little shortening, but there has been a reversal in the practice instituted in the 1953 edition of abandoning Latin titles. The change is the result of the use of Latin titles as the main titles in the European Pharmacopœia, a practice which has enabled the monographs in the English and French editions to be arranged in the same order. These titles, which are official names, have been incorporated in the monographs in the British Pharmacopœia to facilitate identification of the corresponding specification in the European Pharmacopœia. A number of important changes have been made to the English titles of certain individual monographs in this edition. Attention is drawn in particular to alterations in the titles of the monographs on dextrose. The generally accepted scientific name is glucose, a term which is commonly applied to the monohydrate but has not been used in pharmacy because of possible confusion with liquid glucose. After full consideration and consultation it has been decided to move towards the adoption of glucose as the main name and in this edition, as a first step towards the accom-

plishment of this objective, Glucose and Anhydrous Glucose have been adopted as subsidiary titles for the monographs on dextrose monohydrate and anhydrous dextrose respectively. At the same time and in conformity with these new names the unqualified term Dextrose now applies to the monohydrate. It should be noted that the terms 'Medicinal Glucose' and 'Purified Glucose' are no longer official and that none of the changes affect the titles of the official injectable solutions; Dextrose Injection, for example, continues to be known under this name. Hitherto it has been the practice in the Pharmacopœia to allow only Anhydrous Dextrose to be used for the preparation of injectable solutions but the European Pharmacopœia includes a monograph, entitled Dextrose Monohydrate for Parenteral Use, which describes a quality that would be equally suitable for the purpose. Authority is accordingly given for the substitution of an equivalent amount of material complying with the requirements of the European Pharmacopœia whenever Anhydrous Dextrose is prescribed. A change has also been made in the official name of the preparation of starch intended for use as a dusting powder for surgeons' gloves. Reports in the literature of granulomata occurring as a result of the use of this preparation promoted investigation into the desirability of including a test to ensure that the powder, which was formerly described under the name 'Absorbable Dusting Powder', was in fact absorbed by the tissues. This work is continuing but in the meantime it has been considered desirable to discourage the assumption that the substance is completely absorbed under all conditions by altering the title to 'Sterilisable Maize Starch'. A footnote to the monograph directs that this substance is to be supplied when Absorbable Dusting Powder is demanded.

Descriptions of taste continue to be included where appropriate because they frequently supply useful information but indiscriminate examination may be hazardous and the General Notice now excludes taste as an official standard. The tests for identification in the monographs are not intended to establish proof of identity although when taken in conjunction with responses to other tests in the specification there is often little doubt that the active ingredient is the substance which it is purported to be. The identification tests have however been strengthened in this edition by considerably extending the application of infra-red analysis and chromatography. Notably, a comprehensive scheme for the identification and differentiation of the official steroids based on thin-layer chromatography has been developed in conjunction with the appropriate Group of Experts of the European Pharmacopœia and is adopted in this edition.

Special attention has been paid in the revision to the detection and limitation of impurities that may occur in substances as a result of the method of manufacture or from deterioration on storage. Wherever possible the tests have also been applied to the formulated products, often with less stringent limits so as to allow for possible increases in the levels of the impurities resulting from the method of preparing the product or possible deterioration during storage even though the article is kept under proper conditions. It is necessary in fixing the standards of the Pharmacopœia to make these allowances since the official requirements may be enforced at any time after issue. Licensing authorities will expect, and a prudent manufacturer will be aware of the need to keep to, standards more exacting than the minimum limits laid down in the Pharmacopœia to ensure as far as possible that the patient will receive satisfactory medication. They will also be aware that the requirements of the Pharmacopœia by themselves may not necessarily be sufficient assurance that the medicinal product will always be suitable for its intended purpose. A satisfactory formulation and the rigorous application of sound manufacturing practice are the essential requisites but careful regard should also be had to the provisions the product would be called upon to meet by the Pharmacopœia, which by constantly modifying existing tests

or adding new ones, is able to stimulate the general adoption of beneficial advances in pharmaceutical practice. It was the introduction into the Pharmacopœia of the test for the disintegration of tablets that brought much needed improvements in tablet manufacture generally and in this edition assays for individual tablets are introduced in a number of monographs where undue variation in the content of active ingredient from tablet to tablet is especialiy undesirable. Similar requirements will be added to further monographs on tablets and capsules as the methods of analysis are worked out. Progress has also been made towards devising a general method for ascertaining the rate at which less soluble medicaments are dissolved out of tablets and capsules. It was evident from the enquiries made in the course of the investigation into a suitable method of test that insufficient attention had been paid to this aspect, the object of which is to achieve greater uniformity in the rate of release of the medicament, and the eventual inclusion of such tests in the Pharmacopœia should promote increased awareness of the need to avoid batch to batch variation.

The labelling requirements in the Pharmacopœia have been reviewed in accordance with the principle that all the necessary information should appear on the label on the immediate container and preferably also on the package. Exceptions are made for small containers where the labels are not sufficiently large for all the information to be given in a legible manner on the label on the container and the procedure is explained in the General Notice on Labelling, which also requires that an official article shall carry a reference by which its history may be traced. In addition to the General Notice there are labelling requirements in the general monographs on dosage forms and in certain individual monographs. The practice of requiring less stable products to be labelled with the date of manufacture is discontinued and the emphasis is now placed on the date after which the preparation is not intended to be used. This date must be assessed by those preparing the articles, since they are in possession of the information on which the assessments may be made, but occasionally the monograph does give an indication of the probable period over which a preparation may retain its potency provided it is stored under suitable conditions.

The statements on dosage and action and use which occur in many monographs have been thoroughly reviewed in consultation with specialists. The statements on dose are valuable in providing authoritative, although by no means binding, advice to the prescriber and pharmacist on the usual range that is employed. They are also necessary for the compilation of the statements appended to many monographs on dosage forms, on the strength of a preparation to be dispensed in the absence of instructions. In addition, the information on the quantities to be administered and the frequency and route of administration is of value in drawing up analytical specifications. In the previous edition the view was expressed that the amount of active principle in a preparation should preferably be stated in terms of the therapeutically active entity irrespective of the derivative that was employed. The purpose of this suggestion was to aid the prescriber in assessing the doses of different forms of presentation. The present Commission endorses this suggestion but reiterates that the practice is one which should be instituted when a preparation is first formulated in view of the difficulties of changing the situation subsequently.

The general monographs on capsules, tablets, and injections have been modified in a number of respects. For Capsules, methylcellulose is no longer recognised as a shell material, but general permission is given for the inclusion of diluents provided they meet the stipulations in the General Notice on Added Substances. In the monograph on Tablets reference is no longer made to moulded tablets, or tablet triturates, a type of formulation that has declined in use. For Injections, in addition to the modified requirements concerning large-volume

infusion liquids referred to elsewhere, a statement has been added on intrathecal injections, the methods of sterilisation have been qualified to permit variations in the conditions for the various methods of heat sterilisation, and a new criterion for the efficacy of added bactericides is described. The tolerances for the test for uniformity of weight of sterile powders have been made more stringent and glass containers for injectable products are now required to comply with the standards laid down in the European Pharmacopœia; this change makes it unnecessary to retain the test for limit of alkalinity of glass. A new monograph on Suppositories lays down general requirements for uniformity of weight, appearance, and disintegration. In accordance with the normal practice of the Pharmacopœia these requirements are provided only for use in establishing the quality of suppositories that are the subject of monographs in the Pharmacopœia; they are not necessarily suitable for application to other suppositories.

Modifications to the requirements in individual monographs include the introduction, in the monograph on Pancreatin, of improved methods of assay and the raising of the minimum standards for the activity of each enzyme. The new assay is based on that devised by the International Commission for the Standardisation of Pharmaceutical Enzymes. It utilises a Standard Preparation of Pancreatin which has been set up by the British Pharmacopœia Commission. The minimum levels of activity of the three enzymes, amylase, protease, and lipase, have been increased to about two and a half times those formerly official. The monographs on Sodium Chloride Injection, Lignocaine and Adrenaline Injection, and Dithranol Ointment, which formerly admitted only one particular strength, are now revised to cover all strengths whereas the monograph on Cascara Tablets is restricted to one strength, following the introduction of a chemical method of assay based on the procedure described in the European Pharmacopœia for cascara. Changes have been made to other galenical preparations, including the reformulation of tinctures of stramonium and hyoscyamus, which are now prepared by a process of direct extraction from the leaf.

The investigations begun by an earlier Commission into the occurrence of microbial contamination in medicinal substances and preparations that are not required to be sterile have been continued and tests for the absence of certain specified organisms have been added to a number of animal and vegetable products, including thyroid and pancreatin. Suggested methods of examination for the presence of the organisms are described in a new appendix; if other methods are used their validity must be established by adequate controls. In a number of monographs, instead of adding specific tests, modifications designed to reduce the incidence of microbial contamination have been made; Peppermint Water may now only be prepared by dilution of the concentrated water and chloroform is included in the formula for Magnesium Hydroxide Mixture.

The Commission accepted a recommendation early in the preparation of the new Pharmacopœia that the general methods of analysis should be brought into line with those of the European Pharmacopœia, with the object of reducing the number of methods and processes which analysts are called upon to use. This policy involves the re-examination and re-evaluation of many of the standards in the monographs and it has not been possible to complete the necessary work within the span of one edition. In this Pharmacopœia the changes have been accomplished for the determination of boiling range (formerly called distillation range) and boiling point, the Karl Fischer method of estimating water, the procedures for ascending and descending paper chromatography, and the tests for sterility and pyrogens, all of which are now to be conducted in accordance with the instructions in the European Pharmacopœia. In addition a new appendix on the determination of colour of solutions and Method I for the determination of melting point specify the European Pharmacopœia procedures. The work

of adapting existing requirements will continue and new monographs will in future be compiled using as far as possible the methods of the European Pharmacopœia.

The new test for sterility differs in several respects from the procedure hitherto described in the British Pharmacopœia. Emphasis is placed on the use of the membrane filtration method, tests for both bacterial and fungal contamination have to be applied, and provision is made for the examination of larger volumes of liquid preparations. Fuller instructions are also given on the number of containers to be tested when a batch of a preparation is being examined. The sterility test is provided to establish compliance with the requirements of the Pharmacopœia. It is unsuitable, and is not intended, for use by a producer as the sole means of judging that a batch of a preparation is sterile. In the production of sterile materials frequent and more extensive testing is essential in order to keep the chosen method of sterilisation under surveillance and to ensure the absence of contamination from all sources.

Among the modifications made to other appendices are the substitution of a gas-liquid chromatographic procedure for estimating the amount of alcohol in galenicals and the addition of statements to the sections on specific optical rotation and ultra-violet light absorption that the official standards refer to the dried, anhydrous, or solvent-free substance whenever requirements for loss on drying, water, or other solvents are included in the monograph. The appendix on flame photometry has been adjusted to incorporate atomic absorption spectrophotometry and the additional methods of non-aqueous titration and electrophoresis now included in the appendices have been transferred there from monographs in view of their wider application. The system for denoting the size of sieves has been changed to accord with the scheme adopted in British Standard 410: 1969, in which the number of the sieve is denoted by the length of the side of the aperture; the new system is similar to that under discussion by the International Standards Organisation and used in the European Pharmacopœia. Changes have been made to the apparatus for the disintegration test for capsules and tablets and a new test for the disintegration of suppositories is described. The appendix on weights and measures no longer recommends the use of the abbreviation 'G' for gram (the spelling 'gramme' has been abandoned) in stating the doses and strengths of medicinal articles. The use of the apothecaries' system of weights and measures has declined to such an extent that the risk of confusion with the abbreviation 'gr.' for grain is no longer considered sufficient to justify prolonging the departure from international practice. The appendix does however continue to advise that the word 'microgram' should be given in full; if an abbreviated form is unavoidable 'mcg' should be used because it is less likely to cause confusion than other recommended contractions and symbols. When writing quantities on prescriptions or orders milligrams should be used for quantities of less than a gram and micrograms for quantities less than a milligram.

Topics which form the subjects of new appendices include radioactive preparations, plastic containers, and testing for microbial contamination and particulate matter. The appendix on radioactive preparations defines a number of terms and processes used in the preparation, standardisation, and dispensing of radioactive therapeutic and diagnostic materials, while that on plastic containers sets out those factors that should be taken into account in choosing a plastic container for a particular preparation and describes tests that may be useful as part of the process of selection. The tests serve an additional purpose in that they are the methods to be used in the examination of official injections supplied in plastic containers of 500 ml or more. Another new requirement introduced for large-volume infusion solutions is the test for particulate matter, which limits the presence of particles invisible to the naked eye. In this edition it is applied to

a limited number of intravenous infusions, whether supplied in glass or plastic containers, but its field of application is likely to be widened as further experience is gained. The test does not replace the equally important stipulation that injectable solutions should not contain particles of foreign matter that can readily be observed on visual inspection; if contamination with cellulosic material is suspected examination in plane polarised light is an added safeguard.

The account of the design and precision of biological assays which was introduced in the British Pharmacopœia 1953 and proved a feature of successive editions no longer appears. Instead the reader is referred to the European Pharmacopœia for an up-to-date and extended version which is based largely on the appendix originally published in the British Pharmacopœia. The Commission wishes to record a special acknowledgement of the considerable contribution made to the compilation of the new version by the members of its Biological Assays Committee and their colleagues, including F. W. Harpley.

The use of reference materials in chemical and physical assays and tests continues to expand. The names of Authentic Specimens and British Chemical Reference Substances are no longer stated in the appendices but a complete list may be obtained on request. Reference Substances are also in course of establishment by the European Pharmacopœia Commission and it is the intention when these become available to require their use, wherever they are appropriate, for the British Pharmacopœia. The tests and assays of the Pharmacopœia in which reference substances are employed have been devised on the basis of the particular specimens that are issued and it is important that these materials be used, especially in carrying out the tests for impurities and the assays. It is also important to realise that Authentic Specimens are issued solely for use in connection with the tests and assays of the Pharmacopœia and may not be suitable for other purposes.

Additions

The following monographs of the British Pharmacopœia 1973 were not included in the British Pharmacopœia 1968 as amended by the Addendum 1969 and the Addendum 1971.

Adsorbed Diphtheria and Tetanus Vaccine
Adsorbed Diphtheria, Tetanus, and Pertussis Vaccine
Adsorbed Diphtheria Vaccine
Adsorbed Tetanus Vaccine
Aluminium Phosphate Gel
Aluminium Phosphate Tablets
Aminophylline Suppositories
Bacitracin Zinc
Capreomycin Injection
Capreomycin Sulphate
Carbenoxolone Sodium
Carbenoxolone Tablets
Cephalexin
Cephalexin Capsules
Cephalexin Tablets
Cetomacrogol 1000
Cetomacrogol Emulsifying Ointment
Cetomacrogol Emulsifying Wax
Cetrimide Emulsifying Ointment
Clomiphene Citrate
Clomiphene Tablets
Co-trimoxazole Tablets
Danthron
Deslanoside
Dextran 70 Injection
Dextrose Monohydrate for Parenteral Use
Dried Aluminium Phosphate Gel
Dried Human Fibrinogen for Isotopic Labelling
Dried Smallpox Vaccine
Ethambutol Hydrochloride
Ethambutol Tablets
Fenfluramine Hydrochloride
Fenfluramine Tablets
Fractionated Coconut Oil
Fractionated Palm Kernel Oil
Framycetin Sulphate
Intracutaneous Typhoid-paratyphoid A and B Vaccine
Kanamycin Injection
Kanamycin Sulphate
Lanatoside C
Light Kaolin (Natural)
Lymecycline
Lymecycline and Procaine Injection
Lymecycline Capsules
Macrisalb (^{131}I) Injection
Macrogol 300
Macrogol 1540
Macrogol 4000
Meglumine Diatrizoate Injection
Phenol and Glycerol Injection
Phenylbutazone Suppositories
Phenylpropanolamine Hydrochloride
Potassium Chloride and Dextrose Injection
Potassium Chloride and Sodium Chloride Injection
Practolol
Practolol Injection

Practolol Tablets
Prilocaine Hydrochloride
Propanidid
Propicillin Potassium
Propicillin Tablets
Pseudoephedrine Hydrochloride
Salbutamol Sulphate
Salbutamol Tablets
Secbutobarbitone
L-Selenomethionine (^{75}Se) Injection
Sodium Cromoglycate Cartridges
Sodium Methyl Hydroxybenzoate
Sodium Pertechnetate (^{99m}Tc) Injection
Sodium Propyl Hydroxybenzoate
Strong Potassium Chloride Solution
Suppositories
Tetracosactrin Acetate
Tetracosactrin Zinc Injection
Tropicamide
Typhoid and Tetanus Vaccine
Vincristine Injection
Vincristine Sulphate
Xenon (^{133}Xe) Injection
Xylose

Monographs of the Addendum 1969

The following monographs were added to the British Pharmacopœia 1968 by means of the Addendum 1969.

Allopurinol
Allopurinol Tablets
Amphotericin
Azathioprine
Azathioprine Tablets
Beclomethasone Dipropionate
Bethanidine Sulphate
Bethanidine Tablets
Bupivacaine Hydrochloride
Carbenicillin Injection
Carbenicillin Sodium
Chlormadinone Acetate
Clofibrate
Clofibrate Capsules
Diazepam
Diazepam Capsules
Diazepam Tablets
Dihydrocodeine Injection
Dihydrocodeine Tablets
Dihydrocodeine Tartrate
Dried Human Albumin
Ecothiopate Iodide
Eltor Vaccine
Ethacrynic Acid
Ethacrynic Acid Tablets
Ethynodiol Diacetate
Fluocortolone Hexanoate
Fluocortolone Pivalate
Fluphenazine Hydrochloride
Fluphenazine Tablets
Haloperidol
Haloperidol Tablets
Human Albumin
Idoxuridine
Inulin
Inulin Injection
Lithium Carbonate
Lithium Carbonate Tablets
Mefenamic Acid
Mefenamic Acid Capsules
Megestrol Acetate
Metformin Hydrochloride
Metformin Tablets
Methaqualone
Methotrexate
Methotrexate Tablets
Mixed Cholera Vaccine
Penicillamine Tablets
Phenazocine Hydrobromide
Phenazocine Injection
Phenazocine Tablets
Sodium Iodide (^{125}I) Solution
Thiotepa
Thiotepa Injection
Tolnaftate
Typhoid Vaccine

Monographs of the Addendum 1971

The following monographs were added to the British Pharmacopœia 1968 by means of the Addendum 1971.

Alprenolol Hydrochloride
Alprenolol Injection
Alprenolol Tablets
Aminocaproic Acid
Aminocaproic Acid Injection
Carbamazepine
Carbamazepine Tablets
Cephalothin Injection
Cephalothin Sodium
Chlormerodrin (^{197}Hg) Injection
Desferrioxamine Injection
Desferrioxamine Mesylate
Diphenoxylate Hydrochloride
Doxycycline Capsules
Doxycycline Hydrochloride
Dydrogesterone
Dydrogesterone Tablets
Gentamicin Injection
Gentamicin Sulphate
Human Antihæmophilic Fraction
Hydroxyprogesterone Hexanoate
Hydroxyprogesterone Injection
Indomethacin
Indomethacin Capsules
Indomethacin Suppositories
Iodinated (^{125}I) Human Serum Albumin Injection
Lincomycin Capsules
Lincomycin Hydrochloride
Lincomycin Injection
Melphalan
Melphalan Injection
Melphalan Tablets
Methacycline Capsules
Methacycline Hydrochloride
Methotrexate Injection
Metyrapone
Metyrapone Capsules
Nitrazepam
Nitrazepam Tablets
Pentagastrin
Pentagastrin Injection

Phenformin Hydrochloride
Phenformin Tablets
Protriptyline Hydrochloride
Protriptyline Tablets
Rubella Vaccine (Live Attenuated)
Salbutamol
Senna Tablets
Slow Lithium Carbonate Tablets
Sodium Cromoglycate
Sorbitol
Sorbitol Injection
Sulphamethoxazole
Trimethoprim
Trimipramine Maleate
Trimipramine Tablets
Vinblastine Injection
Vinblastine Sulphate

The following monographs were added to the British Pharmacopœia 1968 by means of special amendments.

Levodopa
Levodopa Capsules
Levodopa Tablets

Deletions

The following monographs of the British Pharmacopœia 1968 as amended by the Addendum 1969 and the Addendum 1971 are not included in the British Pharmacopœia 1973.

Aminacrine Hydrochloride
Antitoxins
Atropine
Bacitracin
Bemegride
Bemegride Injection
Calcium Cyclamate
Calcium Hydroxide Solution
Caramiphen Hydrochloride
Caramiphen Tablets
Carbromal Tablets
Cascara Elixir
Chlorinated Lime
Chlormadinone Acetate
Compound Gentian Tincture
Cottonseed Oil
Cresol and Soap Solution
Cyclamic Acid
Diphtheria and Pertussis Vaccine
Heavy Kaolin
Human Fibrin Foam
Hyoscyamus Dry Extract
Hyoscyamus Liquid Extract
Ichthammol
Kaolin Poultice
Lucanthone Hydrochloride
Lucanthone Tablets
Measles Vaccine (Inactivated)
Mecamylamine Hydrochloride
Mecamylamine Tablets
Melarsoprol
Mixed Cholera Vaccine
Morphine Hydrochloride Solution
Naphazoline Hydrochloride
Nealbarbitone
Nealbarbitone Tablets
Paraffin Ointment
Paromomycin Capsules
Paromomycin Sulphate
Pempidine Tablets
Pempidine Tartrate
Phenolsulphonphthalein
Phytomenadione Capsules
Potassium Chloride Injection
Prednisone Acetate
Proflavine Hemisulphate
Sesame Oil
Sodium Antimonylgluconate
Sodium Antimonylgluconate Injection
Sodium Cyclamate
Solapsone
Solapsone Tablets
Staphylococcus Antitoxin
Staphylococcus Toxoid
Stibophen
Stibophen Injection
Stramonium Liquid Extract
Strong Dithranol Ointment
Strong Hydrogen Peroxide Solution
Sulphadiazine Sodium
Suramin
Suramin Injection
Tolu Balsam
Tolu Syrup
Tricyclamol Chloride
Tricyclamol Tablets
Trimetaphan Camsylate
Trimetaphan Injection
Tryparsamide
Tryparsamide Injection
Typhoid-paratyphoid A, B, and C Vaccine

European Pharmacopœia

In the following monographs of the British Pharmacopœia 1973, the standards to be applied are those of the European Pharmacopœia.

Acacia
Adrenaline Acid Tartrate
Alum
Amethocaine Hydrochloride
Aminophylline
Ammonium Chloride
Amylobarbitone Sodium
Anhydrous Dextrose
Ascorbic Acid
Aspirin
Atropine Sulphate
Bacillus Calmette-Guérin Vaccine
Barium Sulphate
Belladonna Herb
Benzocaine
Benzylpenicillin
Betamethasone
Borax