

BRITISH PHARMACEUTICAL CODEX

1959



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The Council of the Pharmaceutical Society acknowledges the assistance received from the British Pharmacopœia Commission, and the permission granted by the General Medical Council to include in the British Pharmaceutical Codex information relating to substances and preparations contained in the British Pharmacopœia.

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*Resigned, October 1957

PREFACE

This new edition of the British Pharmaceutical Codex has been prepared by the Codex Revision Committee at the direction of the Council of the Pharmaceutical Society of Great Britain. The Committee was reconstituted for this purpose in March 1955 and with the assistance of its subcommittees has thoroughly revised the information and specifications in existing monographs and has added many new monographs. The first edition of the British Pharmaceutical Codex, published in 1907, was intended to provide information on drugs in common use throughout the British Commonwealth and this has been the aim in preparing the five editions which followed. The Codex Revision Committee has endeavoured to maintain in this, the seventh edition, the high reputation of the Codex as a reference book. The British Pharmaceutical Codex has also become of increasing importance as a source of standards for drugs, surgical dressings and pharmaceutical preparations not included in the British Pharmacopœia. The provision of adequately detailed standards has, therefore, received full attention from the Committee and its subcommittees.

The many new and valuable drugs and ancillary substances introduced each year into medical and pharmaceutical practice have made it necessary to exclude a number of monographs in order to keep the size of the book within reasonable bounds but the problem of selection has become increasingly difficult. A number of drugs and preparations fall into disuse or disrepute during the five years between each edition and these are omitted. There is, however, a relatively large group of medicines which, while no longer accepted as being necessary by medical and pharmacological authorities, remains in considerable use. Because the Codex is used in many countries and in many circumstances, selection within this category is difficult and may sometimes be arbitrary. Nevertheless, before deciding to exclude substances or preparations, the Committee examined all available relevant information including the extent to which these medicines are used and prescribed.

Apart from changes in the contents listed in the Introduction, there have been several minor changes in style although essentially the format and the scope of this edition are similar to those of the British Pharmaceutical Codex 1954.

The Council of the Pharmaceutical Society greatly appreciates the expert knowledge of and the considerable time spent preparing the British Pharmaceutical Codex 1959 by the members of the Codex Revision Committee (page viii) and its ten subcommittees. The composition of the Subcommittees is given on pages x-xiii.

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Members of the editorial and laboratory staff of the Scientific Publications Department who have assisted in the preparation of the British Pharmaceutical Codex 1959 include G. R. Brown, B. Pharm., B.Sc., F.P.S.; F. G. Farrell, B.Pharm., M.P.S., A.R.I.C.; L. Priest, M.Sc., B. Pharm., F.P.S.; Barbara S. A. Smith, B. Pharm., F.P.S.; G. Smith, B.Sc., F.P.S.; S. L. Ward.

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Various experts contributed information on special points and gave valuable advice, and a number of pharmacists assisted by preparing and commenting on products made according to proposed new and amended formulæ. In particular the Codex Revision Committee is indebted to:

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INTRODUCTION

In preparing the seventh edition of the British Pharmaceutical Codex, the Codex Revision Committee has been guided by principles identical with those it adopted in preparing the previous edition. The number of new general monographs is approximately the same as of those added to the previous edition, whereas very many fewer have been deleted in this revision. The new monographs are for substances which pharmaceutical and clinical evidence and experience have shown to be of value. It is worth noting that of the sixty-one new monographs for non-pharmacopœial substances in the British Pharmaceutical Codex 1954 over half have now been added to the British Pharmacopœia, as have half of the thirty-four substances in this category added by the 1957 Supplement. Most of the older drugs retained in the Codex have been included for their proven value. There are, however, a number of long-established drugs for which little published evidence of therapeutic efficacy exists but which are still frequently prescribed and obviously retain the confidence of many medical practitioners. Monographs for these drugs are included unless there is some overriding reason for their exclusion. Just as the method of selection is the same as for the British Pharmaceutical Codex 1954 so there has been no major alteration in the style of the monographs. Certain titles in Part I have been rearranged, e.g. Insulin Injection instead of Injection of Insulin, following similar changes in the British Pharmacopœia 1958. The main titles of preparations in Part VI have not, however, been similarly amended because the grouping of preparations in that part makes the style of title used in the British Pharmaceutical Codex 1954 more convenient. As in the British Pharmacopœia, abbreviations of English titles are given but the abbreviations of Latin titles are also included as synonyms.

The British Pharmaceutical Codex has two important functions, namely to give information on drugs and other pharmaceutical materials and to provide specifications for those substances which are not included in the British Pharmacopœia. The information on the actions and uses of drugs differs from that in most other reference books in that it has been prepared, after discussion of the published evidence and private experience, by members of a subcommittee of medical and pharmaceutical experts. This fact applies not only to the 70 new monographs in Part I; the 667 monographs which were also in the British Pharmaceutical Codex 1954 or the 1957 Supplement have been re-examined and in many cases amended to take into account new evidence or altered practice. The specifications and methods in the standards have been amended where experience or modification in materials has shown such amendments to be desirable. The specifications in new monographs are similar in style to those in the British Pharmaceutical Codex 1954 and are intended to characterise each drug, to limit significant impurities, and to control the content of pure substance by an assay designed to give an accurate and reproducible result. Many of

these specifications and amendments are based on the recommendations of pharmaceutical manufacturers who, as in the past, have greatly assisted the subcommittees. Members of subcommittees have themselves undertaken much experimental work in developing methods and standards and, as far as practicable, all new and amended tests and assays have been tried out in the Society's laboratories. Several new monographs for substances used solely for pharmaceutical formulation have been added, e.g. Isopropyl Myristate, Hard Macrogol, Liquid Macrogol and Methylcellulose 20.

Antisera, Vaccines and Related Products are, as hitherto, described in Part II and Preparations of Human Blood in Part III. Specifications and statements on actions and uses in these monographs have been drafted or thoroughly revised by a subcommittee composed of specialists on these two groups of products. A monograph has been introduced on Rabies Antiserum which is used in conjunction with Rabies Vaccine in rabies prophylaxis. A proposal to include a monograph for Poliomyelitis Vaccine presented a difficult problem. In Great Britain, as in most other countries, detailed specifications are applied by the government licensing authorities and current standards are likely to be amended with further experience. The great importance of this vaccine, however, made the inclusion of a monograph most desirable and, therefore, one has been included with a standard referring in part to the official regulations.

Part IV, which deals with Surgical Ligatures and Sutures, has been considerably expanded. The additions are a general monograph for non-absorbable sutures and ten monographs describing five different suture materials in non-sterile and sterile form. A major difficulty has been that these materials are graded for other purposes by a variety of methods. For simplicity, all these sutures have been related to the gauges used for surgical catgut although one catgut gauge may cover several finer gauges in other materials.

There are no additions to Surgical Dressings in Part V and only two of the three dressings added to the British Pharmaceutical Codex 1954 by the Supplement 1957 have been retained. Penicillin Gauze has been omitted because of increasing evidence that it may cause sensitisation, and five other materials, now little used, have also been excluded. Amendments have been made to the specifications for various dressings, and of particular importance is the inclusion in a number of monographs of tests to exclude the use of fluorescent whitening agents. These agents have in the recent past been added to materials used to prepare some dressings but they effect little improvement in the appearance of dressings prepared from properly bleached yarn although they may mask inadequate bleaching. The Committee also took into account that there was no satisfactory evidence that the whitening agents were free from toxicity in the circumstances in which dressings are used.

The policy governing inclusion of monographs in Part VI is the same as that in the previous revision; new formulæ are only included if the substances named in them are freely available to pharmacists. Most new drugs are not so available and can be obtained only in the form of one or more

products of a single manufacturer. There is usually little point in including formulæ in these circumstances and there is the possibility in the first few years of a drug's existence that the manufacturer may be impelled by experience to make changes in the character and content of preparations of the drug. An alteration of general interest in the formulary section is in the directions for making eye-drops. The procedure described in the 1954 and earlier editions of the British Pharmaceutical Codex did not ensure that bacteria and moulds were not present in freshly prepared eye-drops. Sterilisation of the eye-drops in the final container by autoclaving is the ideal procedure but this is not generally applicable because of the instability of many of the medicaments and because most eye-drop bottles are not suitable for sterilisation under these conditions. The Committee has, therefore, decided to specify that, with a few exceptions, eye-drops should be heated at 98° to 100° in the final container to kill any pathogenic bacteria which may be present. The inclusion of an antibacterial substance which might serve as a bactericide for bacterial spores at 98° to 100° and for vegetative bacteria in the cold was considered. Such a substance should be compatible with the majority of medicaments and should not cause pain. None of the substances suggested has proved acceptable but the problem is still being investigated. An amendment to the general standard for tablets permits the addition of colouring where specified in the individual monographs but colour is permitted only in one instance in this edition. The standards for preparations have been re-examined and the limits adjusted where the tolerances have been inconsistent with those usually permitted. Standards for some preparations usually made extemporaneously have been adjusted to take into account information on the degree of accuracy practicable in dispensing liquids. Certain dyes, formerly provided with standards in Part I, have been omitted and, where they are specified in Part VI, the term "food grade of commerce" is appended. This has been done as these dyes are permitted by The Colouring Matter in Food Regulations, 1957. Detailed standards for dyes used for colouring food have been or are being prepared by the British Standards Institution at the request of the Ministry of Agriculture, Fisheries and Food and it seems unnecessary to issue separate standards for such dyes which are used in relatively small amounts in pharmaceutical preparations.

Appendixes I to XIII are similar to those of the sixth edition. Those relating to the standards in Parts I to VI have been amended in accordance with the changes in those standards and Appendix XIII, on isotonic solutions, has been revised and expanded. The appendixes of the Supplement 1957 on assays for hyaluronidase, erythromycin, phenoxymethylpenicillin, polymyxin B, and tetracycline are not included in this edition as appropriate assays for these substances are now described in the British Pharmacopœia. The appendix of the Supplement 1957 on the determination of protamine sulphate has, however, been retained with minor modifications.

Three new appendixes XIV, XV, and XVI, have been added, dealing respectively with milliequivalents, biological assays for Eye Ointment of Chloramphenicol and for Neoarsphenamine, and uniformity of diameter

of tablets. As solutions of some electrolytes given by intravenous infusion are being increasingly prescribed in terms of milliequivalents, Appendix XIV has been designed to assist pharmacists in formulating infusion solutions in such terms. The appendix on the uniformity of diameter of tablets is similar to the corresponding appendix of the British Pharmacopœia and deals with most of the uncoated tablets of the British Pharmaceutical Codex. The diameters specified are those recommended by the Association of British Pharmaceutical Industry whose co-operation in preparing this appendix is gratefully acknowledged.

ADDITIONS

The following monographs have been added:

Part I, General Monographs

Acetrizic Acid	Hard Macrogol
Aminometradine	Liquid Macrogol
Amiphenazole Hydrochloride	†Mannitol
Antazoline Methanesulphonate	Mecamylamine Hydrochloride
†Bacitracin	†Menaphthone Sodium Bisulphite
Bemegride	Meprobamate
Benactyzine Hydrochloride	Meralluride
Benethamine Penicillin	Mercaptopurine
Benzalkonium Bromide Solution	Methylcellulose 20
Bismuth Glycollylarsanilate	†Methylergometrine Maleate
Busulphan	†Neomycin Sulphate
Chloramphenicol Cinnamate	Nitrofurazone
Chloramphenicol Palmitate	Papaverine Sulphate
Chlorhexidine Gluconate Solution	†Paramethadione
Chlorhexidine Hydrochloride	Diluted Pentaerythritol Tetranitrate
Chlormerodrin	Phenmetrazine Hydrochloride
Chlorothiazide	Pholcodine Tartrate
Chlorotrianisene	Phytomenadione
Choline Theophyllinate	†Piperazine Phosphate
Crotamiton	Pipradrol Hydrochloride
Dequalinium Chloride	†Prednisone Acetate
†Dextran Injection	†Procyclidine Hydrochloride
Dextromethorphan Hydrobromide	†Propantheline Bromide
Dicyclomine Hydrochloride	Propylhexedrine
Dimethicone 20	Pyridostigmine Bromide
Dipipanone Hydrochloride	†Sodium Antimonylgluconate
†Absorbable Dusting Powder	Sodium Diatrizoate
†Ethylenediamine Hydrate	†Sodium Radio-iodide (¹³¹ I) Injection
Fludrocortisone Acetate	†Sodium Radio-iodide (¹³¹ I) Solution
Glutethimide	†Sodium Radiophosphate (³² P) Injection
Halothane	†Sodium Radiophosphate (³² P) Solution
Hamamelis Water	†Suxamethonium Bromide
Hexachlorophane	Tolbutamide
†Strong Hydrogen Peroxide Solution	Triprolidine Hydrochloride
Isopropyl Myristate	
Levallorphan Tartrate	

†Also included in the British Pharmacopœia 1958.

ADDITIONS—*continued***Part II, Antisera, Vaccines and Related Products**

Poliomyelitis Vaccine
 Rabies Antiserum

†Typhoid-paratyphoid A and B and
 Tetanus Vaccine

Part III, Preparations of Human Blood

†Human Gamma Globulin

†Human Gamma Globulin Injection

†Also included in the British Pharmacopœia 1958.

Part IV, Surgical Ligatures and Sutures

Non-absorbable Surgical Sutures
 Linen Suture
 Sterilised Linen Suture
 Monofilament Nylon Suture
 Sterilised Monofilament Nylon
 Suture

Plaited Nylon Suture
 Sterilised Plaited Nylon Suture
 Twisted Silk Suture
 Sterilised Twisted Silk Suture
 Plaited Silk Suture
 Sterilised Plaited Silk Suture

Part VI, Formulary

Cachets of Sodium Aminosalicylate
 †Capsules of Carbon Tetrachloride
 Cetrimide Emulsifying Wax
 Creams
 Cream of Dimethicone
 Cream of Hydrocortisone
 Ear-drops of Chloramphenicol
 Elixir of Nux Vomica
 †Emulsion of Chloroform
 †Emulsion of Cod-liver Oil
 Emulsion of Liquid Paraffin with
 Cascara
 †Emulsion of Peppermint
 †Liquid Extract of Belladonna
 †Dry Extract of Hamamelis
 †Dry Extract of Nux Vomica
 †Liquid Extract of Quillaia
 †Liquid Extract of Senna
 †Eye Ointment of Atropine with
 Mercuric Oxide
 Eye Ointment of Hydrocortisone
 †Eye Ointment of Penicillin
 †Concentrated Infusion of Quassia
 †Injection of Bismuth
 †Injection of Mepacrine Methane-
 sulphonate
 †Injection of Morphine and Atropine
 †Injection of Neoarsphenamine

Injection of Noradrenaline
 Oily Injection of Phenol
 †Injection of Quinine and Urethane
 Injection of Sodium Acetizoate
 †Compound Injection of Sodium
 Chloride
 Linctus of Ipecacuanha and Squill for
 Infants
 Linctus of Methadone
 †Ammoniated Liniment of Camphor
 Lozenges of Benzalkonium
 †Lozenges of Penicillin
 Mixture of Chloral
 Mixture of Ferrous Sulphate
 Mixture of Ferrous Sulphate for
 Infants
 Alkaline Mixture of Gentian with
 Phenobarbitone
 Mixture of Gentian with Rhubarb
 Mixture of Ipecacuanha and
 Ammonia for Infants
 Mixture of Magnesium Trisilicate and
 Belladonna
 Compound Camphorated Mixture of
 Opium
 Mixture of Strychnine and Iron
 †Ointment of Boric Acid
 Cetomacrogol Emulsifying Ointment

†A monograph for a preparation of similar or identical composition was included in the British Pharmacopœia 1953 and was omitted from the British Pharmacopœia 1958.

ADDITIONS—*continued*

- Cetrimide Emulsifying Ointment
 Ointment of Macrogol
 †Strong Ointment of Mercuric Nitrate
 †Dilute Ointment of Mercury
 †(Strong) Ointment of Mercury
 †Ointment of Penicillin
 †Oleated Mercury
 Compound Paint of Podophyllin
 †Aromatic Powder of Chalk
 †Aromatic Powder of Chalk with Opium
 †Compound Effervescent Powder
 †Compound Powder of Liquorice
 †Compound Powder of Rhubarb
 †Strong Solution of Ammonium Acetate
 †Arsenical Solution
 Solution of Sodium Chloride
 Buffered Solution-tablets of Penicillin
 †Aromatic Spirit of Ammonia
 †A monograph for a preparation of similar or identical composition was included in the British Pharmacopœia 1953 and was omitted from the British Pharmacopœia 1958.
- †Suppositories of Hamamelis
 †Syrup of Senna
 †Tablets of Acetylsalicylic Acid and Phenacetin
 †Tablets of Acetylsalicylic Acid with Ipecacuanha and Opium
 Tablets of Amylobarbitone Sodium
 Compound Tablets of Aneurine
 Strong Compound Tablets of Aneurine
 †Tablets of Barbitone
 Tablets of Belladonna and Phenobarbitone
 Compound Tablets of Magnesium Trisilicate
 †Tablets of Mercurous Chloride
 †Tablets of Phenacetin
 †Tablets of Sulphathiazole
 Trisulphonamide Tablets
 †Tincture of Digitalis

DELETIONS

The following monographs of the British Pharmaceutical Codex 1954, as amended by the Supplement 1957, are not included in the British Pharmaceutical Codex 1959.

Part I, General Monographs

- | | |
|------------------------------|-------------------------------|
| Agar | Dicoumarol |
| Amaranth | Digitalin |
| Amidopyrine | Dill |
| †Amylene Hydrate | Viscous Injection of Diodone |
| Anise | †Diphenan |
| Benzamine Hydrochloride | Ephedra |
| Benzene | Ephedrine Sulphate |
| Bismuth Oxyiodogallate | Euonymus |
| †Bismuth Salicylate | Euphorbia |
| †Butyl Aminobenzoate | Green Ferric Ammonium Citrate |
| Caffeine and Sodium Benzoate | Ferric Quinine Citrate |
| Calcium Alginate | †Serum Gonadotrophin |
| †Calcium Chloride | Halazone |
| Calcium Mandelate | Green Hellebore |
| Calumba | Hexamethonium Chloride |
| Soluble Casein | Hexamethonium Iodide |
| Sulphated Castor Oil | Homatropine |
| Chamomile | Dilute Hydrocyanic Acid |
| Chaulmoogra Oil | Iodoform |
| Cinchona | †Iodophthalein |
| †Cinchophen | Prepared Jalap |
| Codeine | Jalapin |
| Cubeb | Krameria |
- †Also omitted from the British Pharmacopœia 1958.