British Pharmacopoeia (Veterinary) 2002

BP (VET)

A companion volume to the British Pharmacopoeia 2002 providing standards for substances, preparations and immunological products used in veterinary medicine

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

British Pharmacopoeia (Veterinary) 2002

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The monographs of the Fourth Edition of the European Pharmacopoeia (2001), as amended by Supplement 4.1 published by the Council of Europe in October 2001 and Supplement 4.2 published by the Council of Europe in January 2002, are reproduced either in this edition of the British Pharmacopoeia (Veterinary) or in the associated edition of the British Pharmacopoeia.
see General Notices, page 3

Effective date: 1 December 2002
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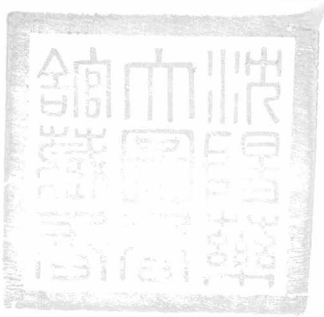

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Notices

Monographs of the European Pharmacopoeia are distinguished by a chaplet of stars against the title. The term European Pharmacopoeia, used without qualification, means the fourth edition of the European Pharmacopoeia comprising, unless otherwise stated, the main volume, published in 2001 as amended by any subsequent supplements and revisions.

Patents

In this Pharmacopoeia certain drugs and preparations have been included notwithstanding the existence of actual or potential patent rights. In so far as such substances are protected by Letters Patent their inclusion in this Pharmacopoeia neither conveys, nor implies, licence to manufacture.

Effective dates

Much of the material in this edition enters into force on 1 December 2002 but certain material that has been published earlier by Gazette Notices became effective on the date stated in the relevant entry.

Preface

The British Pharmacopoeia (Veterinary) 2002 is published for the Agriculture Ministers on the recommendation of the Medicines Commission in accordance with section 99(6) of the Medicines Act 1968.

Together with the British Pharmacopoeia 2002, to which it is a companion volume, the British Pharmacopoeia (Veterinary) 2002 should be of great value to all those concerned with the quality of materials used in the practice of veterinary medicine.

The Medicines Commission wishes to record its appreciation for the services of all who have contributed to the preparation of this work.

British Pharmacopoeia Commission

The British Pharmacopoeia Commission is appointed by the Health and Agriculture Ministers, that is to say in respect of England, Scotland and Wales the Secretary of State concerned with health in England and the Secretary of State concerned with the Environment, Food and Rural Affairs and in respect of Northern Ireland the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, acting jointly, in exercise of their powers under section 4 of the Medicines Act 1968.

The duties of the British Pharmacopoeia Commission are as follows:

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

(b) the preparation under section 99(1) of the Act, as given effect by section 102(1) thereof, of any amendments of the edition of the British Pharmacopoeia published in 1968 or any new edition of it;

(c) the preparation under section 100 of the Act (which provides for the preparation and publication of lists of names to be used as headings to monographs in the British Pharmacopoeia) of any list of names and the preparation under that section as given effect by section 102(3) of the Act of any amendments of any published list;

(d) the preparation under section 99(3)(b) of the Act of any compendium or any new edition thereof;

(e) the preparation under section 99(3)(b) of the Act, as given effect by section 102(1) thereof, of any amendments to any such compendium.

Members of the British Pharmacopoeia Commission are appointed by Ministers, having regard to recommendations made by the Medicines Commission. Appointments are usually for a (renewable) term of 4 years.

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

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Member of the Veterinary Medicines Directorate

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Professor of Pharmaceutics, Queens University of Belfast

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

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

Membership of Committees and Consultative Groups

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

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

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

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

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

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

Introduction

This edition of the British Pharmacopoeia (Veterinary) has been prepared by the British Pharmacopoeia Commission in accordance with the Medicines (British Pharmacopoeia Commission) Amendment Order 1982 (SI 1982 No. 1335). This empowers the British Pharmacopoeia Commission to prepare a compendium under section 99(3)(b) of the Medicines Act 1968 containing information relating to substances and articles which are or may be used in the practice of veterinary medicine or veterinary surgery. In the United Kingdom, under the terms of section 65 of the Medicines Act 1968, it is an offence to sell or supply a medicinal product that is the subject of a monograph in the Pharmacopoeia if that product does not comply with the standards specified in the monograph.

This edition is published as a companion volume to the British Pharmacopoeia 2002 and thus contains only those monographs for substances and preparations used exclusively or predominantly in veterinary medicine within the United Kingdom, together with such additional texts as are necessary to support them. It therefore follows that any reference to a monograph, appendix or reagent not contained within this edition is to be construed as a reference to the said monograph, appendix or reagent contained within the British Pharmacopoeia 2002.

This new edition together with the British Pharmacopoeia 2002 contains all the monographs of the 4th edition of the European Pharmacopoeia as amended by Supplements 4.1 and 4.2. Users of the British Pharmacopoeia and British Pharmacopoeia (Veterinary) therefore benefit by finding within these two comprehensively indexed editions all current pharmacopoeial standards for veterinary medicines used within the United Kingdom.

Effective date

The effective date for this edition, which supersedes the British Pharmacopoeia (Veterinary) 2001, as amended by Amendments No. 1, is 1st December 2002 unless otherwise stated for an entry by an italicised statement showing the month and year of its implementation. Such italic statements, if included, are located below the chaplet of stars that appears alongside the monograph title.

Where a monograph which appeared previously in an earlier edition of the British Pharmacopoeia (Veterinary) has not been included in this new edition it remains effective in accordance with section 65(4) of the Medicines Act 1968.

Additions and Revisions

A list of monographs included within this pharmacopoeia for the first time is given at the end of this introduction. It includes 2 new monographs reproduced from the supplements of the European Pharmacopoeia.

Monographs which have been amended technically by means of this edition are also listed at the end of this introduction. For the benefit of the reader this list indicates the section, or sections, of each monograph which has/have been revised.

European Pharmacopoeia

All monographs of the 4th edition of the European Pharmacopoeia as amended by Supplements 4.1 and 4.2 which are used in veterinary practice but not normally in human medicine in the United Kingdom, are reproduced in this edition. Each of these monographs is signified by a European chaplet of stars alongside its title. Additionally, explicit reference is made to the European Pharmacopoeia within an italicised introductory statement. The entire European Pharmacopoeia text is then bounded by two horizontal lines bearing the symbol '*Ph Eur*'.

The European Pharmacopoeia texts have been reproduced in their entirety without editorial modification but, where deemed appropriate, additional statements of relevance to UK usage have been added (*eg* action and use statement, a list of BP (Vet) preparations). It should be noted, however, that in the event of doubt of interpretation in any text of the European Pharmacopoeia, the text published in English under the direction of the Council of Europe should be consulted.

Correspondence between the general methods of the European Pharmacopoeia and the appendices of the British Pharmacopoeia (Veterinary) 2002 is indicated in each appendix. A check list is also provided at the beginning of the appendices section. This provides a full listing of the European Pharmacopoeia method texts with their British Pharmacopoeia and British Pharmacopoeia (Veterinary) equivalents.

Pharmacopoeial Requirements

Pharmacopoeial requirements for articles used in veterinary medicine are established on the same basis as those used in human medicine. A proper understanding of the basis upon which these requirements are established is essential for their application and advice is provided within the General Notices of the British Pharmacopoeia (Veterinary) and the Supplementary Chapters to the British Pharmacopoeia. It should be noted that no requirement of the Pharmacopoeia can be taken in isolation. A valid interpretation of any particular requirement depends upon it being read in the context of (i) the monograph as a whole, (ii) the specified method of analysis, (iii) the relevant General Notices and (iv) where appropriate, the relevant General Monograph.

Where a preparation that is the subject of a monograph in the British Pharmacopoeia is supplied for use in veterinary medicine, the standards of the British Pharmacopoeia apply, unless otherwise justified and authorised. Attention is drawn to the Notice permitting the designation British Pharmacopoeia (Veterinary) [BP (Vet)] to be used in place of the designation British Pharmacopoeia [BP] where a preparation complying with the British Pharmacopoeia is supplied for use in veterinary medicine with the approval of the competent authority.

General Monographs

The General Monographs which are applicable only to veterinary dosage forms are grouped together within this volume at the beginning of the Formulated Preparations section. They are followed by the individual dosage form monographs arranged in alphabetical order. The General Monographs of the European Pharmacopoeia apply to all individual dosage forms of the type defined rather than to only those preparations for which a specific monograph is described (see the General Notices).

Acknowledgements The British Pharmacopoeia Commission is greatly indebted to the members of its advisory Committees and Consultative Groups without whose dedicated enthusiasm and assistance this edition could not have been prepared. The Commission also acknowledges the contribution of current and former members of staff of the BP.

Close co-operation has continued with many organisations at home and overseas. These include the Veterinary Medicines Directorate, the Medicines Control Agency (of which the Pharmacopoeia secretariat and laboratory staff are a part), the National Institute for Biological Standards and Control, the Royal Pharmaceutical Society of Great Britain, the National Office of Animal Health, the Association of the British Pharmaceutical Industry, the European Pharmacopoeia Commission and the European Directorate for the Quality of Medicines, the Therapeutic Goods Administration (Australia), the Health Protection Branch of the Canadian Department of Health and Welfare, the Committee of Revision of the United States Pharmacopeia, the Essential Drugs and Other Medicines Department of the World Health Organization (WHO) and the WHO Collaborating Centre for Chemical Reference Substances.

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

Additions The following monographs of the British Pharmacopoeia (Veterinary) 2002 were not included in the British Pharmacopoeia (Veterinary) 2001.

Medicinal and Pharmaceutical Substances
Enilconazole*
Etamiphylline Camsilate[1]
Sodium Propionate[1]

Formulated Preparations: Specific Monographs
Etamiphylline Injection[1]
Procaine Benzylpenicillin Injection[1]

Omissions The following monographs of the British Pharmacopoeia (Veterinary) 2001 are not included in the British Pharmacopoeia (Veterinary) 2002.

Immunological Products
Canine Contagious Hepatitis Vaccine, Living[2]

Technical Changes The following monographs in the BP (Vet) 2002 have been technically amended since the publication of the BP (Vet) 2001. This list does not include revised monographs of the European Pharmacopoeia. An indication of the nature of the change or the section of the monograph that has been changed is given in *italic type* in the right hand column.

Formulated Preparations: Specific Monographs

Ampicillin Sodium and Cloxacillin Sodium Intramammary Infusion (Lactating Cow)	*Identification; Assay*
Ampicillin Trihydrate and Cloxacillin Benzathine Intramammary Infusion (Dry Cow)	*Assay*
Ampicillin Tablets	*Assay*
Procaine Benzylpenicillin Intramammary Infusions	*Related substances*

* denotes a monograph of the European Pharmacopoeia
[1]Monograph transferred from the British Pharmacopoeia
[2]Monograph suppressed by the European Pharmacopoeia on 1 April 2002

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Contents of the General Notices

General Notices

Part I

The British Pharmacopoeia (Veterinary) comprises the entire text within this publication. The word 'official' is used in the Pharmacopoeia to signify 'of the Pharmacopoeia'. It applies to any title, substance, preparation, method or statement included in the general notices, monographs and appendices of the Pharmacopoeia. The abbreviation for British Pharmacopoeia (Veterinary) is BP (Vet).

European Pharmacopoeia

Monographs of the European Pharmacopoeia are reproduced in this edition of the British Pharmacopoeia (Veterinary) by incorporation of the text published under the direction of the Council of Europe (Partial Agreement) in accordance with the Convention on the Elaboration of a European Pharmacopoeia (Treaty Series No. 32 (1974) CMND 5763) as amended by the Protocol to the Convention (Treaty Series No MISC16 (1990) CMND 1133). They are included for the convenience of users of the British Pharmacopoeia (Veterinary). In cases of doubt or dispute reference should be made to the Council of Europe text.

Monographs of the European Pharmacopoeia are distinguished by a chaplet of stars against the title and by an italicised statement preceding the Definition. The beginnning and end of text from the European Pharmacopoeia are denoted by means of horizontal lines with the symbol '*Ph Eur*' ranged left and right, respectively.

The general provisions of the European Pharmacopoeia relating to different types of dosage form are included in the appropriate general monograph in that section of either the British Pharmacopoeia or the British Pharmacopoeia (Veterinary) entitled Monographs: Formulated Preparations. These general provisions apply to all veterinary dosage forms of the type defined, whether an individual monograph is included in the British Pharmacopoeia (Veterinary) or not.

Texts of the European Pharmacopoeia are governed by the General Notices of the European Pharmacopoeia. These are reproduced as Part III of these notices (page 16).

Part II

The following general notices apply to the statements made in the monographs of the British Pharmacopoeia (Veterinary) other than those reproduced from the European Pharmacopoeia and to the statements made in the appendices of the British Pharmacopoeia (Veterinary) other than when a method, test or other matter described in an appendix is invoked in a monograph reproduced from the European Pharmacopoeia.

Official Standards

The requirements stated in the monographs of the Pharmacopoeia apply to articles that are intended for veterinary medicinal use but not necessarily to articles that may be sold under the same name for other purposes. An article intended for veterinary medicinal use that is

described by means of an official title must comply with the requirements of the relevant monograph. A formulated preparation must comply throughout its assigned shelf-life (period of validity). The subject of any other monograph must comply throughout its period of use.

A monograph is to be construed in accordance with any general monograph or notice or any appendix, note or other explanatory material that is contained in this edition and that is applicable to that monograph. All statements contained in the monographs, except where a specific general notice indicates otherwise and with the exceptions given below, constitute standards for the official articles. An article is not of Pharmacopoeial quality unless it complies with all of the requirements stated. This does not imply that a manufacturer is obliged to perform all the tests in a monograph in order to assess compliance with the Pharmacopoeia before release of a product. The manufacturer may assure himself that a product is of Pharmacopoeial quality by other means, for example, from data derived from validation studies of the manufacturing process, from in-process controls or from a combination of the two. Parametric release in appropriate circumstances is thus not precluded by the need to comply with the Pharmacopoeia. The general notice on Assays and Tests indicates that analytical methods other than those described in the Pharmacopoeia may be employed for routine purposes.

Requirements in monographs have been framed to provide appropriate limitation of potential impurities rather than to provide against all possible impurities. Material found to contain an impurity not detectable by means of the prescribed tests is not of Pharmacopoeial quality if the nature or amount of the impurity found is incompatible with good pharmaceutical practice.

The status of any statement given under the side-headings Definition, Production, Characteristics, Storage, Labelling or Action and use is defined within the general notice relating to the relevant side-heading. In addition to any exceptions indicated by one of the general notices referred to above, the following parts of a monograph do not constitute standards: (a) a graphic or molecular formula given at the beginning of a monograph; (b) a molecular weight; (c) a Chemical Abstracts Service Registry Number; (d) any information given at the end of a monograph concerning impurities known to be limited by that monograph; (e) information in any annex to a monograph. Any statement containing the word 'should' constitutes non-mandatory advice or recommendation.

The expression 'unless otherwise justified and authorised' means that the requirement in question has to be met, unless a competent authority authorises a modification or exemption where justified in a particular case. The term 'competent authority' means the national, supranational or international body or organisation vested with the authority for making decisions concerning the issue in question. It may, for example, be a licensing authority or an official control laboratory. For a formulated preparation that is the subject of monograph in the British Pharmacopoeia (Veterinary) any justified and authorised modification to, or exemption from, the requirements of the relevant general monograph of the European Pharmacopoeia is stated in the individual monograph. For example, the general monograph for Tablets requires that Uncoated Tablets, except for chewable tablets,