British Pharmacopoeia (Veterinary) 2008

BP (Vet)

A companion volume to the British Pharmacopoeia 2008 providing standards for substances, preparations and immunological products used in veterinary medicine

Incorporating the requirements of the 5th edition of the European Pharmacopoeia 2004 as amended by Supplements 5.1 to 5.8

British Pharmacopoeia (Veterinary) 2008

Published on the recommendation of the British Pharmacopoeia Commission pursuant to The Medicines Act 1968 and notified in draft to the European Commission in accordance with Directive 98/34/EEC.

The monographs of the Fifth Edition of the European Pharmacopoeia (2004), as amended by Supplements 5.1 to 5.8 published by the Council of Europe are reproduced either in this edition of the British Pharmacopoeia (Veterinary) or in the associated edition of the British Pharmacopoeia.

see General Notices

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British Pharmacopoeia (Veterinary) 2008

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 Fifth Edition of the European Pharmacopoeia comprising, unless otherwise stated, the main volume, published in 2004 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 New and revised monographs of national origin enter into force on 1 January 2008. Monographs of the European Pharmacopoeia have previously been published by the Council of Europe and have been brought into effect by means of Notices published in the Belfast, Edinburgh and London Gazettes.

Preface

The British Pharmacopoeia (Veterinary) 2008, a companion volume to the British Pharmacopoeia 2008, is published for Ministers on the recommendation of the British Pharmacopoeia Commission in accordance with Section 99(6) of The Medicines Act 1968.

The British Pharmacopoeia Commission believes that the British Pharmacopoeia (Veterinary) contributes significantly to the overall control of the quality of materials used in the practice of veterinary medicine, by providing an authoritative statement of the quality that a product, material or article is expected to meet at any time during its period of use. The Pharmacopoeial standards, which are publicly available and legally enforceable, are designed to complement and assist the licensing and inspection processes and are part of the system for safeguarding animal and human health.

The British Pharmacopoeia Commission wishes to record its appreciation of the services of all those who have contributed to the preparation of this work.

British Pharmacopoeia Commission

The British Pharmacopoeia Commission is appointed by the NHS Appointments Commission, the body responsible for appointments to all of the Medicines Act 1968 Advisory Bodies.

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(6) of the Act, of any compendium, or any new edition thereof, containing information relating to substances and articles which are or may be used in the practice of veterinary medicine or veterinary surgery;

(e) to frame clear and unequivocal technical advice in order to discharge the Commission's responsibilities both for the British Pharmacopoeia, the British Pharmacopoeia (Veterinary) and British Approved Names and as the national pharmacopoeial authority with respect to the European Pharmacopoeia.

Members of the British Pharmacopoeia Commission are appointed for a (renewable) term of 4 years and, under the requirements laid down by the Office of the Commissioner for Public Appointments, can serve for a maximum of 10 years.

Membership of the British Pharmacopoeia Commission

The list below includes those members who served during the period 2006 to 2007.

Chairman Professor David Woolfson BSc PhD CChem FRSC MPSNI
Professor of Pharmaceutics, Queens University of Belfast

Vice-Chairman Mr V'Iain Fenton-May BPharm MI PharmM FRPharmS
Specialist Quality Controller to the Welsh Hospitals

Dr Anthony H Andrews BVetMed PhD MBIAC DipECBHM FRSM MRCVS
Veterinary Consultant

Professor Graham Buckton BPharm PhD DSc AKC FRPharmS CChem FRSC
Professor of Pharmaceutics; School of Pharmacy, University of London

Professor Donald Cairns BSc PhD MRPharmS CSci CChem MRSC
Associate Head, School of Pharmacy, Robert Gordon University, Aberdeen

Mr Barry Capon CBE (*Lay representative*)
Non-executive Director, Norfolk and Waveney Mental Health Partnership

Professor Alastair Davidson BSc PhD FRPharmS CChem FRSC
Visiting Professor of Pharmaceutical Sciences, University of Strathclyde

Mrs Margaret A Dow MSc PhC
Consultant in the regulation of biological and biotechnological products

Dr Thomas D Duffy BSc PhD FRPharmS CChem MRSC FIQA MRQA
Consultant in quality management systems, quality assurance and training in production, development and QC Laboratories

Mr Christopher Goddard BSc DIS CSci EurChem CChem FRSC
Quality Control Manager, Ashton Pharmaceuticals Limited

Dr Rodney L Horder BPharm PhD MRPharmS
Vice President, Global Pharmaceutical R & D Quality Assurance, Abbott Laboratories

Dr Aileen M T Lee BVMS PhD MRCVS
Member of the Veterinary Medicines Directorate
Specialism: Regulation of Veterinary Immunological Products

Professor Anthony C Moffat BPharm PhD DSc CChem FRSC FRPharmS FFIP
Head, Centre for Pharmaceutical Analysis, The School of Pharmacy, University of London

	Dr Lincoln Tsang BPharm LLB PhD FRSC FIBiol FRSA MRPharmS Solicitor *Life Sciences Lawyer; Partner, Arnold & Porter LLP*
	Mrs Josephine Turnbull LLB (*Lay representative*) *Chairman of County Durham and Darlington Priority Services Trust; member of the Parole Board of England and Wales*
	Professor Elizabeth Williamson BPharm PhD MRPharmS *Professor of Pharmacy, University of Reading*
	Professor Peter York BSc PhD DSc FRPharmS CChem FRSC *Professor of Physical Pharmaceutics, University of Bradford*
Secretary and Scientific Director	Dr Gerard Lee BPharm PhD FRPharmS MRSC CChem

Membership of Expert Advisory Groups, Panels of Experts and Working Parties

The Commission appointed the following Expert Advisory Groups, Panels of Experts and Working Parties 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 2006 to 2007.

EXPERT ADVISORY GROUPS

ABS: Antibiotics (formerly Committee E)

R L Horder (*Chairman*), P York (*Vice-Chairman*), A Ambrose, A H Andrews, J F Chissell, J Dolman, P Ellis, S Green, R Harryman, A Livingstone, W Mann, W F H McLean, S Patel, C G Taylor, I R Williams

CX: Excipients (disbanded, 30 June 2006)

G Buckton (*Chairman*), C Mroz (*Vice-Chairman*), E Anno, A C Cartwright, R Cawthorne, M Kearsley, B R Matthews, M I Robertson

HCM: Herbal and Complementary Medicines (formerly Committee G)

A C Moffat (*Chairman*), L A Anderson (*Vice-Chairman*), M Berry, K Chan, T Chapman, A Charvill, K Helliwell, P J Houghton, C Leon, W F H McLean, J D Phillipson, M Pires, J Sumal, E Williamson (*Corresponding member* B P Jackson)

MC1: Medicinal Chemicals (formerly Committee A)

A G Davidson (*Chairman*), D Cairns (*Vice-Chairman*), M Ahmed, L Anderson, J C Berridge, M Broughton, A J Caws, P Fleming, A Hardy, W J Lough, D Malpas

MC2: Medicinal Chemicals (formerly Committee B)

T D Duffy (*Chairman*), C T Goddard (*Vice-Chairman*), D Billington, F Breslin, M Cole, B M Everett, K Goode, A J Hutt, S Jones, M A Lee, J Lim, K McKiernan, B Midcalf, P Murray, M Turgoose

MC3: Medicinal Chemicals (formerly Committee D)

V Fenton-May (*Chairman*), E Williamson (*Vice-Chairman*), S Arkle, J F Chissell, C T Goddard, W J Poling, W K L Pugh, G G Skellern, W H Smith, R Tomlinson, R Torano, I R Williams

NOM: Nomenclature (formerly Panel N)

J K Aronson (*Chairman*), L Tsang (*Vice-Chairman*), M Ahmed, D Cousins, G Gallagher, P W Golightly, D Masieh, A McNaught, H McNulty, G P Moss, R J Taylor, R Thorpe
(*Corresponding members* R G Balocco Mattavelli, E M Cortés Montejano, J Robertson)

PCY: Pharmacy (formerly Committee P)

R L Horder (*Chairman*), A D Woolfson (*Vice-Chairman*), M Aulton, E Baker, S Branch, G Buckton, G Davison, G Eccleston, D Elder, R Lowe, B R Matthews, J F McGuire, S C Nichols, R Shaw, M P Summers, K Truman, P Wood

PANELS OF EXPERTS

BIO: Biological and Biotechnological Products (formerly Panel H)	M A Dow (*Chairman*), L Tsang (*Vice-Chairman*), C Booth, A F Bristow, D H Calam, J Cook, T Forsey, R Johnson, J Lawrence, B Mason, A Onadipe, A M Pickett, S Poole, N Randall, D Sesardic, P Sheppard, W J Tarbit, J N A Tettey, A H Thomas, R Thorpe, S Vass
BLP: Blood Products (formerly Panel HB)	B Cuthbertson, A R Hubbard, J Lawrence, T J Snape, R Thorpe, P Varley
IGC: Inorganic and General Chemicals (formerly Panel CI)	C T Goddard (*Chairman*), A C Cartwright, B M Everett, P Henrys, D Malpas, C Mroz, I D Newton
J: Immunological Products (disbanded, 30 June 2006)	M J Corbel, M A Dow, A M Pickett, D Sesardic, A H Thomas
MIC: Microbiology (formerly Panel M)	V Fenton-May (*Chairman*), A H Andrews, R Baird, C Booth, S Denyer, S Gorman, D P Hargreaves, R Johnson, B R Matthews, W F H McLean, P Newby, P Taylor
RAD: Radioactive Materials (formerly Panel R)	S R Hesslewood, D Lui, A M Millar, R D Pickett, S Waters
VIP: Veterinary Immunological Products (formerly Panel JV)	A M T Lee (*Chairman*), A H Andrews, K Redhead, J Salt, P W Wells

WORKING PARTIES

CX: Excipients	G Buckton (*Chairman*), C Mroz (*Vice-Chairman*), E Anno, R Cawthorne, B R Matthews, M I Robertson
UM: Unlicensed Medicines	V Fenton-May (*Chairman*), T D Duffy (*Vice-Chairman*), I Beaumont, C Cable, P Forsey, S Jones, A Lowey, A Nunn, A Pandya, J Smith, D Wallace

Current members of staff of the British Pharmacopoeia Laboratory who have taken part in the production of this edition include:

R Gaur (*Laboratory Manager*), M Azizi, L Fletcher, A Jordan, R Mannan, A Panchal, D Parmar, K Patel, M Patel, N Patel, J Rana, S Rihal

British Pharmacopoeia Staff

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

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S Young (*Head of Science*)

A Bentley, M Barrett, A Evans, P Holland, M O'Kane, R A Pask-Hughes, F J Swanson, N Thomas, R L Turner

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Introduction

The British Pharmacopoeia (Veterinary) 2008 supersedes the British Pharmacopoeia (Veterinary) 2007. It is published for Ministers on the recommendation of the British Pharmacopoeia Commission in accordance with section 99(6) of the Medicines Act 1968.

This edition is published as a companion volume to the British Pharmacopoeia 2008 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 2008.

This edition, together with the British Pharmacopoeia 2008, contains all the monographs of the 5th edition of the European Pharmacopoeia as amended by Supplements 5.1 to 5.8. Users of the British Pharmacopoeia and British Pharmacopoeia (Veterinary) therefore benefit by finding within these two compendia all current pharmacopoeial standards for veterinary medicines used within the United Kingdom.

Effective Date

The effective date for this edition is 1 January 2008.

Where a monograph which appeared previously in an earlier edition of the British Pharmacopoeia has not been included in this edition, it remains effective in accordance with the Medicines Act 1968.

Expert Advisory Groups and Panels of Experts

A comprehensive review of the membership of the Committees and Panels of Experts was undertaken. The Committees were renamed Expert Advisory Groups (EAGs) and the letter designations for the EAGs and Panels of Experts were changed to reflect more closely the name of the EAG and Panel. The Committee on Excipients was disbanded and its work will now be undertaken by Working Parties of the Pharmacy EAG. The Panel of Experts on Immunological Products was disbanded and the remit of the panel incorporated into that of the Panel of Experts on Biological and Biotechnological Products. The Panel of Experts on Nomenclature was replaced by a new Expert Advisory Group on Nomenclature.

General Notices

Three areas of change have been introduced to the British Pharmacopoeia (Veterinary) General Notices (Part II) as follows.

Definition of terms

A new General Notice has been added to clarify terms such as 'about', 'corresponds' and 'similar' used throughout the publication.
The clarification is intended to facilitate the interpretation of monographs of the British Pharmacopoeia.

Crude Drugs; Traditional Herbal and Complementary; Homoeopathic Medicines

The General Notice on Crude Drugs has been broadened to encompass traditional herbal and complementary medicines. A separate General Notice has also been added to cover Homoeopathic Medicines.

Storage

This General Notice has been amended to clarify the use of the terms 'tamper-evident containers' and 'tamper-proof containers' throughout the Pharmacopoeia.

Additions

A list of monographs included for the first time in the British Pharmacopoeia (Veterinary) 2008 is given at the end of this introduction. It includes a new general monograph of national origin for Veterinary Oral Pastes and 6 new monographs reproduced from Supplements 5.6, 5.7 and 5.8 of the European Pharmacopoeia.

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 only to those preparations for which a specific monograph is described (see the General Notices).

Infrared Reference Spectra

As with the previous edition, the reference spectra are placed in alphabetical order within this edition.

Editorial Changes

Action and use

An extensive review of the Action and use statements has been undertaken. Changes have been made to the monographs included in Volumes I and II of the British Pharmacopoeia 2008. A combined statement is included indicating, where known, the pharmacological action and the therapeutic use of the substance or preparation. For the first time, Action and use statements have been included in relevant monographs for Formulated Preparations.

Stationary phases

A comprehensive review of the terms 'stationary phase A', 'stationary phase B' and 'stationary phase C' has been made and 13 monographs have been amended to refer to the appropriate silica gel for chromatography in this edition.

Dissolution

British Pharmacopoeia monographs have been harmonised with the Ph Eur test method to refer to Apparatus 1 and 2. The 2 veterinary monographs affected have been harmonised.

Chromatographic tests

A new format for chromatographic tests is introduced in this edition to delineate sample preparation, chromatographic conditions, system suitability and acceptance criteria. The format will be harmonised in future editions for all BP monographs.

European Pharmacopoeia

All monographs of the 5th edition of the European Pharmacopoeia, which are used in veterinary practice but not normally in human medicine in the United Kingdom, are reproduced in this edition of the British Pharmacopoeia (Veterinary). Each of these monographs is signified by a European chaplet of stars alongside its title. Additionally, reference to the European Pharmacopoeia monograph number is included immediately below the title in italics in the form '*Ph Eur monograph xxx*'. Where the title in the British Pharmacopoeia is different from that in the European Pharmacopoeia, an approved synonym has been created (see Appendix XXI B (Vet)) and the Ph Eur title is included before the monograph number. 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 but, where deemed appropriate, additional statements of relevance to UK usage have been added (e.g. 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) 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(s).

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.

Innovations As a new initiative, the British Pharmacopoeia (Veterinary) 2008 will be available as an e-book.

Acknowledgements The British Pharmacopoeia Commission is greatly indebted to the members of its Expert Advisory Groups and Panels of Experts without whose dedicated enthusiasm and assistance this edition could not have been prepared.

Close co-operation has continued with many organisations at home and overseas. These include the Veterinary Medicines Directorate, the Medicines and Healthcare products Regulatory Agency, 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 & HealthCare, 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 publishing team at The Stationery Office, in particular Mr Phil Halls, Dr Clare Collett and Dr Gill Hodgson, in the production of this edition.

Additions The following monographs of the British Pharmacopoeia (Veterinary) 2008 were not included in the British Pharmacopoeia (Veterinary) 2007.

Medicinal and Pharmaceutical Substances
Dembrexine Hydrochloride Monohydrate*
Spectinomycin Sulphate Tetrahydrate*

Formulated Preparations: General Monographs
Veterinary Oral Pastes

Immunological Products
Feline Chlamydiosis Vaccine (Inactivated)*
Mycoplasma Gallisepticum Vaccine (Inactivated)*
Salmonella Enteritidis Vaccine (Inactivated) for Chickens*
Salmonella Typhimurium Vaccine (Inactivated) for Chickens*

Omissions The following monographs of the British Pharmacopoeia (Veterinary) 2007 are not included in the British Pharmacopoeia (Veterinary) 2008.

Formulated Preparations: Specific Monographs
Chloramphenicol Injection

* denotes a monograph of the European Pharmacopoeia.

Technical Changes

The following monographs in the British Pharmacopoeia (Veterinary) 2008 have been technically amended since the publication of the British Pharmacopoeia (Veterinary) 2007. 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.

Medicinal and Pharmaceutical Substances	
Cefalonium	*Assay*

Changes in Title

The following list gives the alterations in the titles of monographs of the British Pharmacopoeia (Veterinary) 2007 that have been retained in the British Pharmacopoeia (Veterinary) 2008.

BRITISH PHARMACOPOEIA (VETERINARY) 2007	**BRITISH PHARMACOPOEIA (VETERINARY) 2008**
Formulated Preparations: Specific Monographs	
Fenbendazole Veterinary Paste	Fenbendazole Veterinary Oral Paste
Ivermectin Veterinary Paste	Ivermectin Veterinary Oral Paste
Immunological Products	
Veterinary Antisera	Veterinary Immunosera