# British Pharmacopoeia (Veterinary) 2010

## BP (Vet)

A companion volume to the British Pharmacopoeia 2010 providing standards for substances, preparations and immunological products used in veterinary medicine

Incorporating the requirements of the 6th edition of the European Pharmacopoeia as amended by Supplements 6.1 to 6.5

# British Pharmacopoeia (Veterinary) 2010

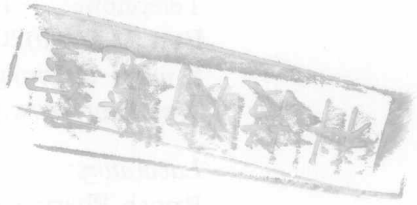
Prepared by the British Pharmacopoeia Commission, published in accordance with Section 99(6) of The Medicines Act 1968 and notified in draft to the European Commission in accordance with Directive 98/34/EEC.

The monographs of the Sixth Edition of the European Pharmacopoeia (2007), as amended by Supplements 6.1 to 6.5 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*

Effective date: 1 January 2010

*see Notices*





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# British Pharmacopoeia (Veterinary) 2010

# Contents

# 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 Sixth Edition of the European Pharmacopoeia comprising, unless otherwise stated, the main volume, published in 2007 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 2010. 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) 2010, a companion volume to the British Pharmacopoeia 2010, is prepared by the British Pharmacopoeia Commission and is published for Ministers 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, on behalf of the Secretary of State for Health, by the 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.

# Expert Advisory Groups, Panels of Experts and Working Parties

Members of Expert Advisory Groups, Panels of Experts and Working Parties are appointed by the British Pharmacopoeia Commission.

The duties of the members are as follows:

(a) To collaborate in the preparation and revision of Monographs, Appendices and Supplementary Chapters for inclusion in the British Pharmacopoeia and British Pharmacopoeia (Veterinary).

(b) To collaborate in the preparation and revision of Monographs, Methods and General Chapters of the European Pharmacopoeia.

(c) To collaborate in the preparation and revision of the list of names to be used as titles for monographs of the British Pharmacopoeia and British Pharmacopoeia (Veterinary).

Members of Expert Advisory Groups, Panels of Experts and Working Parties are usually appointed for a (renewable) term of 4 years.

# Membership of the British Pharmacopoeia Commission

The list below includes those members who served during the period 2008 to 2009.

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

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

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 FRSC
*Associate Head, School of Pharmacy and Life Sciences, Robert Gordon University, Aberdeen*

Mr Barry Capon CBE MA DL (*Lay representative*)
*Non-executive Director, Norfolk and Waveney Mental Health NHS Foundation Trust*

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

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

Dr Thomas D Duffy BSc PhD FRPharmS CChem MRSC FCQI CQP MRQA
*Director, Lowden International (providing consultancy and training to pharmaceutical organisations)*

Mr Christopher Goddard BSc DIS CSci EurChem CChem FRSC
*Quality Control Manager, Recipharm Limited*

Dr Keith Helliwell BPharm PhD MRPharmS
*Senior Technical Adviser, William Ransom & Son PLC*

Dr Rodney L Horder BPharm PhD MRPharmS
*Divisional Vice President, Global European Quality and Regulatory Strategy, Abbott*

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

Dr Lincoln Tsang BPharm LLB PhD FRSC FIBiol FRSA FRPharmS Solicitor
*Life Sciences Lawyer; Partner, Arnold & Porter LLP*

| | |
|---|---|
| | Mrs Josephine Turnbull LLB (*Lay representative*)<br>*Chairman of Tees, Esk and Wear Valley NHS Trust* |
| | Professor Elizabeth Williamson BPharm PhD MRPharmS<br>*Professor of Pharmacy, University of Reading* |
| | Professor Peter York BSc PhD DSc FRPharmS CChem FRSC<br>*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 2008 to 2009.

## EXPERT ADVISORY GROUPS

**ABS: Antibiotics**

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

**HCM: Herbal and Complementary Medicines**

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

**MC1: Medicinal Chemicals**

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

**MC2: Medicinal Chemicals**

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

**MC3: Medicinal Chemicals**

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

**NOM: Nomenclature**

J K Aronson (*Chairman*), L Tsang (*Vice-Chairman*), M Ahmed, G Gallagher, P W Golightly, A D McNaught, G P Moss, C Preston, R Thorpe, B Warner
(*Corresponding members* R G Balocco Mattavelli, E M Cortés Montejano, J Robertson)

**PCY: Pharmacy**

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

**ULM: Unlicensed Medicines**

V Fenton-May (*Chairman*), T D Duffy (*Vice-Chairman*), I Beaumont, A Charvill, P Forsey, W Goddard, S Jones, M A Oldcorne, A Pandya, N J Precious, J Rothwell, J Smith

## PANELS OF EXPERTS

| | |
|---|---|
| **BIO: Biological and Biotechnological Products** | M A Dow (*Chairman*), L Tsang (*Vice-Chairman*), A F Bristow, D H Calam, J Cook, J Lawrence, B Mason, A Onadipe, A M Pickett, S Poole, D Sesardic, P Sheppard, W J Tarbit, J N A Tettey, A H Thomas, R Thorpe |
| **BLP: Blood Products** | B Cuthbertson, A R Hubbard, S Jenkins, J Lawrence, P Varley |
| **IGC: Inorganic and General Chemicals** | C T Goddard (*Chairman*), A C Cartwright, B M Everett, P Henrys, D Malpas, C Mroz, I D Newton |
| **MIC: Microbiology** | V Fenton-May (*Chairman*), S Denyer, D P Hargreaves, B R Matthews, P Newby |
| **RAD: Radioactive Materials** | S R Hesslewood, A M Millar, R D Pickett, S Waters |
| **VIP: Veterinary Immunological Products** | A M T Lee (*Chairman*), A H Andrews, A M Brady, 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 |

# Current British Pharmacopoeia Staff

**Secretariat** M Vallender (*Editor-in-Chief*)

S Young (*Head of Science*)

M Barrett, L Caller, A Evans, J Francomb, P Holland, R A Pask-Hughes, J Pound, F J Swanson, R L Turner, M Whaley

**Administrative** M Cumberbatch, B F Delahunty, W Jeffries, D Myburgh, J Paine


*ISO 9001*
*FS 27268*

# Current British Pharmacopoeia Laboratory Staff

J Gan, P Hansal, K Harper, M Kram, R Mannan, A Panchal, H Patel, K Patel, M Patel, N Patel, C Provis-Evans, P Webb


*ISO 9001*
*FS 27613*

# Introduction

The British Pharmacopoeia (Veterinary) 2010 supersedes the British Pharmacopoeia (Veterinary) 2009. The British Pharmacopoeia (Veterinary) 2010 has been prepared by the British Pharmacopoeia Commission in accordance with the Medicines (British Pharmacopoeia Commission) Order 1970 (SI 1970 No. 1256) as amended (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. Under the terms of the Medicines Act 1968 it is an offence to sell or supply a medicinal product in the United Kingdom 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 2010 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 2010.

This edition, together with the British Pharmacopoeia 2010, contains all the monographs of the 6th edition of the European Pharmacopoeia as amended by Supplements 6.1 to 6.5. 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.

**Book Format**

The formats of the British Pharmacopoeia are regularly reviewed. For this new edition, the weight of the book format for the British Pharmacopoeia (Veterinary) has been reduced with the use of a lighter weight paper.

**Effective Date**

The effective date for this edition is 1 January 2010.

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.

**General Notices**

The British Pharmacopoeia (Veterinary) General Notices (Parts II and III) have been amended as follows.

**Crude Drugs: Traditional Herbal and Complementary Medicines; Homoeopathic Medicines**

These General Notices in Part II have been amended to clarify the use of the acronyms 'THM' and 'THMP' and to provide a definition of the term 'Potentisation' when used in homoeopathic medicines.

## Part III

The British Pharmacopoeia General Notices (Part III) have been amended to harmonise with the changes published in Supplement 6.5 of the 6th edition of the European Pharmacopoeia.

**Additions**

A list of monographs included for the first time in the British Pharmacopoeia (Veterinary) 2010 is given at the end of this introduction. It includes 2 new monographs reproduced from the 6th edition of the European Pharmacopoeia as amended by Supplements 6.1 to 6.5.

**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).

**Revisions**

### Bacterial Endotoxins

In line with the BP policy on refinement of methods, the monograph for Oxytetracycline Injection has been revised to replace the test for Pyrogens with a test for Bacterial endotoxins.

### Reference Substances

5 monographs for formulated preparations have been amended to refer to new British Pharmacopoeia Chemical Reference Substances established by the British Pharmacopoeia Laboratory.

**Infrared Reference Spectra**

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

**Editorial Changes**

### Chromatographic tests

The new format for chromatographic tests, introduced in the BP (Vet) 2008 to delineate sample preparation, chromatographic conditions, system suitability and acceptance criteria has been refined and applied to a further 7 monographs. The format will continue to be harmonised in future editions for all BP (Vet) monographs.

### Dissolution tests

A new format, similar to the one for chromatographic tests, has been applied to tests for Dissolution in BP monographs. The new format will continue to be harmonised in future editions for all BP monographs.

**European Pharmacopoeia**

All monographs of the 6th 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 xxxx*'. Where the