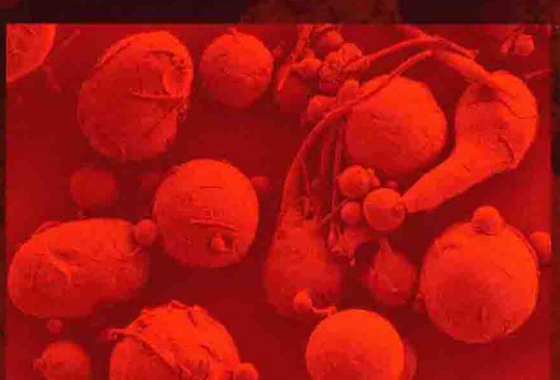
Handbook of Pharmaceutical Excipients

Seventh edition

Edited by
Raymond C Rowe, Paul J Sheskey, Walter G Cook, and Marian E Fenton



Pharmaceutical Press

APhA

Handbook of Pharmaceutical Excipients

SEVENTH EDITION

Edited by

Raymond C Rowe BPharm, PhD, DSC, FRPharmS, FRSC, CPhys, MInstP

Chief Scientist

Intelligensys Ltd, Stokesley, North Yorkshire, UK

Paul J Sheskey BSc, RPh

Principal Research Scientist

The Dow Chemical Company, Midland, MI, USA

Walter G Cook BSc, PhD

Research Fellow

Materials Science group of Pharmaceutical R&D, Pfizer, Sandwich, Kent, UK

Marian E Fenton BSc, MSc

Development Editor

Royal Pharmaceutical Society of Great Britain, London, UK

London • Philadelphia

Pharmaceutical Press

Published by Pharmaceutical Press

1 Lambeth High Street, London SE1 7JN, UK
University City Science Center, Suite 5E, 3624 Market Street, Philadelphia, PA 19104, USA

and the American Pharmacists Association
2215 Constitution Avenue, NW, Washington, DC 20037-2985, USA

Pharmaceutical Press is the publishing division of the Royal Pharmaceutical Society of Great Britain

First published 1986
Second edition published 1994
Third edition published 2000
Fourth edition published 2003
Fifth edition published 2006
Sixth edition published 2009
Seventh edition published 2012

Typeset by Data Standards Ltd, Frome, Somerset
Printed in Spain by Graphy Cems

ISBN 978 0 85711 027 5 (UK)
ISBN 978 1 58212 169 7 (USA)

A catalogue record for this book is available from the British Library

Preface

Pharmaceutical dosage forms contain both pharmacologically active compounds and excipients added to aid the formulation and manufacture of the subsequent dosage form for administration to patients. Indeed, the properties of the final dosage form (i.e. its bioavailability and stability) are, for the most part, highly dependent on the excipients chosen, their concentration and interaction with both the active compound and each other. No longer can excipients be regarded simply as inert or inactive ingredients, and a detailed knowledge not only of the physical and chemical properties but also of the safety, handling and regulatory status of these materials is essential for formulators throughout the world. In addition, the growth of novel forms of delivery has resulted in an increase in the number of the excipients being used and suppliers of excipients have developed novel coprocessed excipient mixtures and new physical forms to improve their properties. Some excipient monographs in the *Handbook* describe materials no longer in common use and a comment is included where this is the case. These monographs are retained in the *Handbook* as a resource for users who may need to understand or reproduce the performance and properties of an old product. This database has been conceived as a systematic, comprehensive resource of information on all of these topics.

The first edition of the *Handbook* was published in 1986 and contained 145 monographs. Subsequent editions have contained more monographs, as well as revised existing content. The data is available in print and online. This new edition contains 380 excipient monographs with enhanced online features, compiled by over 140 experts in pharmaceutical formulation or excipient manufacture from Australia, Europe, India, Japan, and the US. All the monographs have been reviewed and revised in the light of current knowledge. There has been a greater emphasis on including published data from primary sources although some data from laboratory projects included in previous editions have been retained where relevant. Variations in test methodology can have significant effects on the data generated (especially in the case of the compactability of an excipient), and thus cause confusion. As a consequence, the editors have been more selective in including data relating to the physical properties of an excipient. However, comparative data that show differences between either source or batch of a specific excipient have been retained as this was considered relevant to the behavior of a material in practice. Over the past few years, there has been an increased emphasis on the harmonization of excipients. For information on the current status for each excipient selected for harmonization, the reader is directed to the General Information Chapter <1196> in the USP35–NF30, the General Chapter 5.8 in PhEur 7.0, along with the 'State of Work' document on the PhEur EDQM website (www.edqm.eu), and also the General Information Chapter 8 in the JP XV. The Suppliers Directory (Appendix I) has also been completely updated with many more international suppliers included.

In a systematic and uniform manner, the *Handbook of Pharmaceutical Excipients* collects essential data on the physical properties of excipients such as: boiling point, bulk and tap density, compression characteristics, hygroscopicity, flowability, melting point, moisture content, moisture-absorption isotherms, particle size distribution, rheology, specific surface area, and solubility. Scanning electron microphotographs (SEMs) are also included for many of the excipients along with over 130 near-infrared (NIR) spectra specifically generated for this publication. In addition, the current edition includes over 150 infrared (IR) spectra. The *Handbook* contains information from various international sources and personal observation and comments from monograph authors, steering committee members, and the editors.

All of the monographs in the *Handbook* are thoroughly cross-referenced and indexed so that excipients may be identified by either a chemical, a nonproprietary, or a trade name. Most monographs list related substances to help the formulator to develop a list of possible materials for use in a new dosage form or product. Related substances are not directly substitutable for each other but, in general, they are excipients that have been used for similar purposes in various dosage forms.

The *Handbook of Pharmaceutical Excipients* is a comprehensive, uniform guide to the uses, properties, and safety of pharmaceutical excipients, and is an essential reference source for those involved in the development, production, control, or regulation of pharmaceutical preparations. Since many pharmaceutical excipients are also used in other applications, the *Handbook of Pharmaceutical Excipients* will also be of value to persons with an interest in the formulation or production of confectionery, cosmetics, and food products.

Arrangement

The information consists of monographs that are divided into 22 sections to enable the reader to find the information of interest easily. Although it was originally intended that each monograph contain only information about a single excipient, it rapidly became clear that some substances or groups of substances should be discussed together. This gave rise to such monographs as 'Coloring Agents' and 'Hydrocarbons'. In addition, some materials have more than one monograph depending on the physical characteristics of the material, e.g. Starch versus Pregelatinized Starch. Regardless of the complexity of the monograph they are all divided into 22 sections as follows:

1 Nonproprietary Names
2 Synonyms
3 Chemical Name and CAS Registry Number
4 Empirical Formula and Molecular Weight
5 Structural Formula
6 Functional Category
7 Applications in Pharmaceutical Formulation or Technology
8 Description
9 Pharmacopeial Specifications
10 Typical Properties
11 Stability and Storage Conditions
12 Incompatibilities
13 Method of Manufacture
14 Safety
15 Handling Precautions
16 Regulatory Status
17 Related Substances
18 Comments
19 Specific References
20 General References
21 Authors
22 Date of Revision

Descriptions of the sections appear below with information from an example monograph if needed.

Section 1, Nonproprietary Names

Lists the excipient names used in the current British Pharmacopoeia, European Pharmacopeia, Japanese Pharmacopeia, and the United States Pharmacopeia/National Formulary.

Section 2, Synonyms

Lists other names for the excipient, including trade names used by suppliers (shown in italics). The inclusion of one supplier's trade name and the absence of others should in no way be interpreted as an endorsement of one supplier's product over the other. The large number of suppliers internationally makes it impossible to include all the trade names.

Section 3, Chemical Name and CAS Registry Number

Indicates the unique Chemical Abstract Services number for an excipient along with the chemical name, e.g., Acacia [9000-01-5].

Sections 4 and 5, Empirical Formula and Molecular Weight and Structural Formula

Are self-explanatory. Many excipients are not pure chemical substances, in which case their composition is described either here or in Section 8.

Section 6, Functional Category

Lists the function(s) that an excipient is generally thought to perform, e.g., diluent, emulsifying agent, etc. For the purpose of consistency, the functional categories have been thoroughly revised and updated for the current edition of the *Handbook*; *see* Table I.

Note that the use of the general term 'stabilizing agent' or 'stabilizer' has been replaced with terms specific to the type of stability issue addressed:

Physical stability
Antiadherent
Anticaking agent
Dispersing agent
Emulsion stabilizing agent
Foam stabilizing agent
Gelling agent
Humectant
Suspending agent
Viscosity-increasing agent

Microbiological stability
Antimicrobial preservative

Chemical stability
Acidulant
Air displacement
Alkalizing agent
Antioxidant
Buffering agent
Complexing agent
Opacifier

Section 7, Applications in Pharmaceutical Formulation or Technology

Describes the various applications of the excipient. Therapeutic applications and experimental studies are included in Section 18, Comments.

Section 8, Description

Includes details of the physical appearance of the excipient, e.g., white or yellow flakes, etc.

Section 9, Pharmacopeial Specifications

Briefly presents the compendial standards for the excipient. Information included is obtained from the British Pharmacopoeia (BP), European Pharmacopeia (PhEur), Japanese Pharmacopeia (JP), and the United States Pharmacopeia/National Formulary (USP–NF). Information from the JP, PhEur, and USP–NF are included if the substance is in those compendia. If the excipient is not in the PhEur but is included in the BP, information is included from the BP. Pharmacopeias are continually updated with most now being produced as annual editions. However, although efforts were made to include up-to-date information at the time of publication of this edition, the reader is advised to consult the most current pharmacopeias or supplements.

Section 10, Typical Properties

Describes the physical properties of the excipient which are not shown in Section 9. All data are for measurements made at 20°C unless otherwise indicated. Where the solubility of the excipient is

Table I: Functional categories used in the *Handbook*.

Functional category	Alternative term	Definition
Acidulant	Acidifying agent	Agent added to make a system more acid, decreasing the value of pH
Adsorbent	Adsorbing agent; sorbent; sorbing agent	Agent used to bind another component from within a formulation, acting as a carrier, reservoir or sequestrant
Aerosol propellant	Propellant	Agent used to provide an energy source within a formulation for generation of an aerosol on actuation of a valve
Air displacement	Gas flushing agent; sparging agent	Agent used to replace air in a product or pack with a gas phase of known composition
Alcohol denaturant	Bittering agent; denaturant	Agent added to make alcohol unfit to drink
Alkalizing agent		Agent added to make a system more alkaline, increasing the value of pH
Anionic surfactant	Detergent; surface active agent; wetting agent	Agent carrying an overall negative charge, added to reduce surface and interfacial tension
Antiadherent	Antiadhesive agent	Agent added to reduce the tendency of materials to remain attached to other surfaces
Anticaking agent	Flow aid; glidant	Agent added to reduce the tendency of materials to form non-redispersible masses
Antifoaming agent	Foam preventing agent	Agent added to reduce the stability of foams formed during processing or use of formulated products
Antimicrobial preservative	Disinfectant; preservative	Agent used to prevent spoilage due to microbial growth within a formulation
Antioxidant		Agent used to stabilize a system against oxidative degradation
Bioadhesive material	Mucoadhesive membrane	Agent used to promote adhesion to biomembranes
Biocompatible material		An agent that can be used in a parenteral implant product without producing an immune or imflammatory response
Biodegradable material		Used in products that can be degraded to nontoxic components while implanted over time
Buffering agent	Buffer	Agent used to stabilize pH within a defined range
Cationic surfactant	Detergent; surface active agent; wetting agent	Agent carrying an overall positive charge, added to reduce surface and interfacial tension
Coating agent	Enteric coating agent; film-coating agent; modified-release coating agent; sugar-coating agent	Agent used to produce a cosmetic or functional layer on the outer surface of a dosage form
Colorant	Color; colored lake; dye	An agent that imparts colour to a formulation
Complexing agent	Chelating agent; sequestering agent	Agent added to combine with another component, commonly to maintain or improve solubility or chemical stability
Cryoprotectant		Agent added to prevent cell damage during freeze-drying
Desiccant	Water-absorbing agent	Agent used to adsorb or absorb water
Direct compression excipient		Agent used to produce powder blends with flow and compaction properties suitable for tablet making without intermediate granulation steps
Dispersing agent		Agent added to prevent aggregation in liquid formulations
Dry powder inhaler carrier		Agent used in dry powder inhalation blends as a diluent providing suitable uniformity, flow and dispersion properties
Emollient		Agent added to topical formulations to promote softening of the skin
Emulsifying agent	Emulsifier	Agent added to promote mixing of immiscible phases
Emulsion stabilizing agent	Emulsion stabilizer	Agent added to improve stability against phase separation
Film-forming agent	Film-former; polymer film-former	A material which forms a thin film with some mechanical strength when applied to dosage form or other surfaces
Flavor enhancer	Flavor-enhancing agent	Agent added to enhance flavor
Flavoring agent	Flavor	Agent added to impart flavor to a product
Foam stabilizing agent	Foam stabilizer	Agent added to improve physical stability of foam
Gelling agent	Gel thickening agent	Agent added to produce a gel texture in a product
Glidant	Flow aid	Agent added to improve powder flow
Humectant	Moisture retention agent	Agent added to retain water within a product
Lubricant	Friction-reducing agent; lubricating agent	Agent added to reduce friction effects during processing or use
Lyophilization aid	Freeze-drying agent	Agent added to produce suitable physical properties in a freeze-dried product
Membrane-forming agent	Membrane former	A material which forms a thin film with defined permeability properties when applied to a surface or dosage form
Microencapsulating agent	Encapsulating agent	Agent used to form microcapsules with desirable physical properties

Functional category	Alternative term	Definition
Modified-release agent	Controlled-release agent; extended-release agent; release-modifying agent; sustained-release agent	Agent used to control the release rate of active ingredient from a dosage form
Nonionic surfactant	Detergent; surface active agent; wetting agent	Agent containing no ionisable functional groups added to reduce surface and interfacial tension
Ointment base		A nonaqueous vehicle for topical products
Oleaginous vehicle		An oil-based vehicle for topical products
Opacifier	Opacifying agent	Agent added to reduce light transmission in a product
Penetration enhancer	Penetration agent; penetration promoter; skin penetrant	Agent used to increase permeability of active ingredient through skin tissues
Pigment	Colored lake	An insoluble coloring agent
Plasticizing agent	Plasticizer	Agent added to promote flexibilty of films or coatings
Solubilizing agent	Solubilizer	Agent added to promote solubility of an active ingredient
Solvent	Cosolvent	Component used as the vehicle for dissolved ingredients
Stiffening agent		Agent added to increase stiffness of creams and ointments
Suppository base		Agent used as the carrier for other ingredients in suppository formulations
Suspending agent		Agent added to improve dispersion stability of solids in liquids
Sweetening agent	Sweetener	Agent used to produce a sweet taste
Tablet and capsule diluent	Tablet and capsule filler; tablet diluent; tablet filler	Material used to produce appropriate dosage form size, performance and processing properties for tablets and/or capsules
Tablet and capsule disintegrant	Tablet disintegrant	Agent used to promote break-up of tablet and/or capsule formulations after ingestion
Tablet and capsule lubricant	Tablet lubricant	Agent added to reduce friction effects during tablet and/or capsule processing
Tablet and capsule binder	Tablet binder	Agent used to promote granule formulation during tablet and/or capsule processing
Taste-masking agent		Agent added to improve and/or disguise taste
Tonicity agent		Agent added to alter osmotic potential of liquid formulations
Transdermal delivery component		Component used specifically in transdermal devices
Vaccine adjuvant		Agent added to activate antibody response in vaccines
Viscosity-increasing agent	Rheology modifier; thickening agent; viscosity-controlling agent	Agent added to increase the viscosity of liquid semi-solid products
Water-repelling agent	Water repellent	Agent used to make formulations hydrophobic products

described in words, the following terms describe the solubility ranges:

Very soluble	1 part in less than 1
Freely soluble	1 part in 1–10
Soluble	1 part in 10–30
Sparingly soluble	1 part in 30–100
Slightly soluble	1 part in 100–1000
Very slightly soluble	1 part in 1000–10 000
Practically insoluble or insoluble	1 part in more than 10 000

Near-infrared (NIR) reflectance spectra of samples as received (i.e. the samples were not dried or reduced in particle size) were measured using a FOSS NIRSystems 6500 spectrophotometer (FOSS NIRSystems Inc., Laurel, MD, USA) fitted with a Rapid Content Analyser against a ceramic standard supplied with the instrument. The instrument was controlled by Vision (version 2.22) software. Spectra were recorded over the wavelength range 1100–2498 nm (700 data points) and each saved spectrum was the average of 32 scans. Solid powdered samples were measured in glass vials of approximately 20 mm diameter. Each sample was measured in triplicate and the mean spectrum taken. When more than one batch of a material was available, the mean of all the batches is presented. Liquid samples were measured by transflectance using a gold reflector (2 × 0.5 mm optical path-length, FOSS) placed in a 45 mm silica reflectance cell against air as the reference. Spectra are presented as plots of (a) $\log(1/R)$ *vs* wavelength (dashed line, scale on right-hand side) and (b) second-derivative $\log(1/R)$ *vs* wavelength (solid line, scale on left-hand side). R is the reflectance and $\log(1/R)$ represents the apparent absorbance. Second-derivative spectra were calculated from the $\log(1/R)$ values using an 11 point Savitzky-Golay filter with second-order polynomial smoothing. Note, peak positions and amplitudes in the second-derivative spectrum are very sensitive to the method used to calculate the second-derivative.

For this edition, infrared (IR) spectra have been adapted with permission from Informa Healthcare — *Pharmaceutical Excipients: Characterisation by IR, Raman, and NMR Spectroscopy* by David E Bugay and W Paul Findlay eds, Marcel Dekker, Vol 94, 1999. All samples conformed to the USP–NF for identity and purity, and were used as received. The IR spectra were acquired on a Nicolet model 740 Fourier transform (FT) IR spectrophotometer equipped with a water-cooled globar source, Ge/KBr beamsplitter, and a deuterated triglycine sulfate (DTGS) detector. Interferograms of 16K data points were collected at a spectral resolution of 2 cm^{-1}. The number of scans acquired for each sample varied so that a minimum signal-to-noise ratio of 5000:1 was achieved. For each data set, a phase angle was calculated and then a Happ-Genzel apodization function applied. The Fourier transform was performed and the phase was corrected on the real portion of the data using the calculated phase angle to produce the single-beam spectrum. Subsequent ratioing of the single beam spectrum to the reference spectrum produced a frequency domain IR spectrum. The intensity of the IR spectra have been normalized such that the most intense absorption band equals 1 intensity unit (absorbance or Kubelka-Munk (K-M) units) and all other band intensities are relative to that band. The Spectra-Tech Collector sampling accessory was used to acquire the DR IR spectra of the solid powdered excipients. Samples were diluted in KCl (~1–5% w/w sample to KCl), ratioed against a KCl background, and the resultant spectra displayed in K-M units. IR spectra of

liquid and waxy solid samples were acquired as neat smears (capillary film) between two 25– x 2–mm KBr transmission windows. A single beam data file was used as the background file for subsequent ratioing.

Where practical, data typical of the excipient or comparative data representative of different grades or sources of a material are included, the data being obtained from either the primary or the manufacturers' literature. In previous editions of the *Handbook* a laboratory project was undertaken to determine data for a variety of excipients and in some instances this data has been retained. For a description of the specific methods used to generate the data readers should consult the appropriate previous edition(s) of the *Handbook*.

Section 11, Stability and Storage Conditions

Describes the conditions under which the bulk material as received from the supplier should be stored. In addition some monographs report on storage and stability of the dosage forms that contain the excipient.

Section 12, Incompatibilities

Describes the reported incompatibilities for the excipient either with other excipients or with active ingredients. If an incompatibility is not listed it does not mean it does not occur but simply that it has not been reported or is not well known. Every formulation should be tested for incompatibilities prior to use in a commercial product.

Section 13, Method of Manufacture

Describes the common methods of manufacture and additional processes that are used to give the excipient its physical characteristics. In some cases the possibility of impurities will be indicated in the method of manufacture.

Section 14, Safety

Describes briefly the types of formulations in which the excipient has been used and presents relevant data concerning possible hazards and adverse reactions that have been reported. Relevant animal toxicity data are also shown.

Section 15, Handling Precautions

Indicates possible hazards associated with handling the excipient and makes recommendations for suitable containment and protection methods. A familiarity with current good laboratory practice (GLP) and current good manufacturing practice (GMP) and standard chemical handling procedures is assumed.

Section 16, Regulatory Status

Describes the accepted uses in foods and licensed pharmaceuticals where known. However, the status of excipients varies from one nation to another, and appropriate regulatory bodies should be consulted for guidance.

Section 17, Related Substances

Lists excipients similar to the excipient discussed in the monograph.

Section 18, Comments

Includes additional information and observations relevant to the excipient. Where appropriate, the different grades of the excipient available are discussed. Also includes therapeutic applications and experimental studies. Comments are the opinion of the listed author(s) unless referenced or indicated otherwise.

Section 19, Specific References

Is a list of references cited within the monograph.

Section 20, General References

Lists references which have general information about this type of excipient or the types of dosage forms made with these excipients.

Section 21, Authors

Lists the current authors of the monograph in alphabetical order. Authors of previous versions of the monograph are shown in previous printed editions of the text.

Section 22, Date of Revision

Indicates the date on which changes were last made to the text of the monograph.

Acknowledgments

A publication containing so much detail could not be produced without the help of a large number of pharmaceutical scientists based world-wide. The voluntary support of over 140 authors has been acknowledged as in previous editions, but the current editors would like to thank them all personally for their contribution. Grateful thanks also go to the members of the International Steering Committee who advised the editors and publishers on all aspects of the *Handbook* project. Many authors and Steering Committee members have been involved in previous editions of this text. For others, this was their first edition although not, we hope, their last. We extend our thanks to all for their support. Thanks are also extended to Roger Jee, Kelly Palmer, and Tony Moffat at The School of Pharmacy, University of London for supplying the NIR spectra, to Pfizer PGRD, Sandwich, UK for supplying SEMs, and to excipient manufacturers and suppliers who provided helpful information on their products. IR spectra have been adapted with permission from Informa Healthcare.

Thanks are also gratefully extended to the editorial and production staff of the Pharmaceutical Press and American Pharmacists Association, as well as to the team of dedicated copyeditors and proofreaders, who were involved in the production of this resource.

Two contributors, Stanley L Hem and Atul J Shukla, sadly passed away since the publication of the 6th print edition.

Raymond C Rowe, Paul J Sheskey, Walter Cook, Marian E Fenton
March 2012

Notice to Readers

The *Handbook of Pharmaceutical Excipients* is a reference work containing a compilation of information on the uses and properties of pharmaceutical excipients, and the reader is assumed to possess the necessary knowledge to interpret the information that this resource contains. The *Handbook of Pharmaceutical Excipients* has no official status and there is no intent, implied or otherwise, that any of the information presented should constitute standards for the substances. The inclusion of an excipient, or a description of its use in a particular application, is not intended as an endorsement of that excipient or application. Similarly, reports of incompatibilities or adverse reactions to an excipient, in a particular application, may not necessarily prevent its use in other applications. Formulators should perform suitable experimental studies to satisfy themselves and regulatory bodies that a formulation is efficacious and safe to use.

While considerable efforts were made to ensure the accuracy of the information presented in the *Handbook*, neither the publishers nor the compilers can accept liability for any errors or omissions. In particular, the inclusion of a supplier within the Suppliers Directory is not intended as an endorsement of that supplier or its products and, similarly, the unintentional omission of a supplier or product from the directory is not intended to reflect adversely on that supplier or its product.

Although diligent effort was made to use the most recent compendial information, compendia are frequently revised and the reader is urged to consult current compendia, or supplements, for up-to-date information, particularly as efforts are currently in progress to harmonize standards for excipients.

Data presented for a particular excipient may not be representative of other batches or samples.

Relevant data and constructive criticism are welcome and may be used to assist in the preparation of any future editions or digital versions of the *Handbook*. The reader is asked to send any comments to the Editor, Handbook of Pharmaceutical Excipients, Royal Pharmaceutical Society, 1 Lambeth High Street, London SE1 7JN, UK, or Editor, Handbook of Pharmaceutical Excipients, American Pharmacists Association, 2215 Constitution Avenue, NW, Washington, DC 20037-2985, USA.

Disclaimer and Liability

Further to the Notice to Readers above, all use of the *Handbook of Pharmaceutical Excipients* is entirely at the reader's own risk and the reader is responsible for ensuring that the information being used is consistent with normal, generally accepted pharmaceutical practice. The Publisher shall not, so far as is permissible by law, be liable for any claims or losses, including but not limited to direct or indirect, incidental, consequential loss, damage, costs, or expenses and any claims from third parties whether in contract, negligence or other tortuous action arising out of or in connection with the use of the *Handbook of Pharmaceutical Excipients*.

International Steering Committee

Editorial and Production Staff

Editorial Staff of the Pharmaceutical Press

Amy Cruse
Samuel Driver
Marian E Fenton
Elizabeth S Foan
Rebecca E Garner
Jennifer M Sharp
Nilufer Virani
Jo Watts

Production Staff of the Pharmaceutical Press

Tamsin Cousins
Simon Dunton
Karl Parsons
Linda Paulus
John Wilson

Editorial Staff of the American Pharmacists Association

Julian Graubart

Contributors

O AbuBaker
GlaxoSmithKline Inc
Collegeville, PA, USA

KS Alexander
University of Toledo
Toledo, OH, USA

LV Allen Jr
International Journal of Pharmaceutical Compounding
Edmond, OK, USA

FA Alvarez-Nunez
Amgen Inc
Thousand Oaks, CA, USA

GE Amidon
University of Michigan
Ann Arbor, MI, USA

GP Andrews
The Queen's University of Belfast
Belfast, UK

VD Antle
CyDex Pharmaceuticals Inc
Lenexa, KS, USA

NA Armstrong
Harpenden, Hertfordshire, UK

TI Armstrong
Pfizer Consumer Healthcare
Havant, Hampshire, UK

A Balasundaram
Pfizer Pharmatherapeutics
Sandwich, Kent, UK

BA Barner
The Dow Chemical Company
Midland, MI, USA

AC Bentham
Pfizer Global R&D
Sandwich, Kent, UK

C Bhugra
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

M Bond
Danisco (UK) Ltd
Redhill, Surrey, UK

K Boxell
Pfizer Global R&D
Sandwich, Kent, UK

S Brown
Pfizer Global R&D
Sandwich, Kent, UK

CG Cable
Royal Pharmaceutical Society
Edinburgh, UK

S Cantor
Pfizer Inc
Mount Airy, MD, USA

WG Chambliss
University of Mississippi
University, MS, USA

RK Chang
Supernus Pharmaceutical Inc
Rockville, MD, USA

R Chen
Pfizer Inc
Groton, CT, USA

D Chiappetta
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

WG Cook
Pfizer Global R&D
Sandwich, Kent, UK

JR Creekmore
AstraZeneca Pharmaceuticals LP
Wilmington, DE, USA

N Culver
Pfizer Inc
Groton, CT, USA

TC Dahl
Gilead Sciences
Foster City, CA, USA

PD Daugherity
Pfizer Inc
Groton, CT, USA

R Deanne
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

W Deng
University of Mississippi
University, MS, USA

E Draganoiu
Lubrizol Advanced Materials Inc
Cleveland, OH, USA

D Dubash
Pine Brook, NJ, USA

M Dudhedia
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

S Edge
Novartis Pharma AG
Basel, Switzerland

C Egger
Rockwood Pigments
Turin, Italy

H Ehlers
Åbo Akademi University
Turku, Finland

ME Fenton
Royal Pharmaceutical Society
London, UK

RT Forbes
University of Bradford
Bradford, UK

SO Freers
Grain Processing Corporation
Muscatine, IA, USA

B Fritzsching
BENEO-Palatinit GmbH
Mannheim, Germany

GP Frunzi
Time-Cap Labs Inc
Farmingdale, NY, USA

S Fulzele
Cephalon Inc
Brooklyn Park, MN, USA

LY Galichet
International Agency for Research on Cancer
Lyons, France

PL Goggin
Pfizer Global R&D
Sandwich, Kent, UK

S Gold
AstraZeneca
Macclesfield, Cheshire, UK

SR Goskonda
Sunnyvale, CA, USA

M Grachet
Pfizer Global R&D
Sandwich, Kent, UK

L Grove
General Chemical Corporation
Parsippany, NJ, USA

RT Guest
Lonza Biologics plc
Slough, Berkshire, UK

J Gunn
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

RT Gupta
SNDT Women's University
Mumbai, India

VK Gupta
CorePharma
Middlesex, NJ, USA

F Guth
BASF SE
Limburgerhof, Germany

E Hamed
Cephalon Inc
Brooklyn Park, MN, USA

BC Hancock
Pfizer Inc
Groton, CT, USA

BA Hanson
Schering-Plough Research Institute
Summit, NJ, USA

KP Hapgood
Monash University
Clayton, Victoria, Australia

O Häusler
Roquette Europe
Lestrem, France

X He
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

J Heinämäki
University of Tartu
Tartu, Estonia

P Heljo
University of Helsinki
Helsinki, Finland

SL Hem
Formerly, Purdue University
West Lafayette, IN, USA

L Hendricks
Innophos Inc
Cranbury, NJ, USA

S Hoag
University of Maryland at Baltimore
Baltimore, MD, USA

JC Hooton
AstraZeneca
Macclesfield, Cheshire, UK

WL Hulse
University of Bradford
Bradford, UK

M Isreb
University of Bradford
Bradford, UK

BR Jasti
University of the Pacific
Stockton, CA, USA

BA Johnson
Pfizer Inc
Groton, CT, USA

J Johnson
University of Tennessee
Memphis, TN, USA

DS Jones
The Queen's University Belfast
Belfast, UK

S Jones
Eastman Chemical Company
Kingsport, TN, USA

M Julien
Gattefossé SAS
Saint-Priest, France

B Kadri
PharmaForm, LLC
Austin, TX, USA

JS Kaerger
Aeropharm GmbH
Rudolstadt, Germany

AS Kearney
GlaxoSmithKline Inc
King of Prussia, PA, USA

VL Kett
The Queen's University of Belfast
Belfast, UK

AH Kibbe
Wilkes University School of Pharmacy
Wilkes-Barre, PA, USA

DD Ladipo
Pfizer Global R&D
Groton, CT, USA

N Ladyzhynsky
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

WJ Lambert
MedImmune
Gaithersburg, MD, USA

BA Langdon
Pfizer Global R&D
Groton, CT, USA

D Law
Abbott Laboratories
North Chicago, IL, USA

CM Lee
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

MG Lee
MHRA
London, UK

CS Leopold
University of Hamburg
Hamburg, Germany

J-X Li
Prinston Pharmaceutical Inc
Cranbury, NJ, USA

X Li
University of the Pacific
Stockton, CA, USA

H-P Lim
University of Maryland at Baltimore
Baltimore, MD, USA

EB Lindblad
Brenntag Biosector
Frederikssund, Denmark

O Luhn
BENEO-Palatinit GmbH
Mannheim, Germany

PE Luner
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

BR Matthews
Consultant
Surrey, UK

JS Maximilien
Pfizer Global R&D
Sandwich, Kent, UK

CP McCoy
The Queen's University of Belfast
Belfast, UK

C Medina
Amgen Inc
Thousand Oaks, CA, USA

RC Moreton
FinnBrit Consulting
Waltham, MA, USA

GL Mosher
Verrow Pharmaceuticals Inc
Lenexa, KS, USA

G Moss
Keele University
Keele, Staffordshire, UK

C Mroz
Colorcon Ltd
Dartford, Kent, UK

S Mujumdar
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

MP Mullarney
Pfizer Inc
Groton, CT, USA

S Murdande
Pfizer Inc
Groton, CT, USA

S Nema
Pfizer Global R&D
Chesterfield, MO, USA

S Obara
Shin-Etsu Chemical Co. Ltd
Niigata, Japan

A Palmieri
University of Florida
Gainesville, FL, USA

MA Pellett
PCS Ltd
Chichester, West Sussex, UK

L Peltonen
University of Helsinki
Helsinki, Finland

Y Peng
AstraZeneca Pharmaceuticals
Wilmington, DE, USA

M Penning
Mainz, Germany

JD Pipkin
CyDex Pharmaceuticals Inc
Lenexa, KS, USA

A Pirjanian
Amgen Inc
Thousand Oaks, CA, USA

F Podczeck
University College London
London, UK

P Pople
SNDT Women's University
Mumbai, India

W Qu
University of Tennessee
Memphis, TN, USA

A Rajabi-Siahboomi
Colorcon Inc
West Point, PA, USA

RD Reddy
Pfizer Inc
Groton, CT, USA

MA Repka
University of Mississippi
University, MS, USA

J Rexroad
Pacira Pharmaceuticals Inc
San Diego, CA, USA

B Richard
Pacira Pharmaceuticals Inc
San Diego, CA, USA

TL Rogers
The Dow Chemical Company
Bomlitz, Germany

RC Rowe
Intelligensys Ltd
Stokesley, UK

N Sandler
Åbo Akademi University
Turku, Finland

B Sarsfield
Bristol-Myers Squibb
New Brunswick, NJ, USA

P Satturwar
Apotex Inc
Toronto, ON, Canada

M Savolainen
University of Copenhagen
Copenhagen, Denmark

T Schmeller
BASF SE
Limburgerhof, Germany

A Schoch
BENEO-Palatinit GmbH
Mannheim, Germany

DR Schoneker
Colorcon Inc
West Point, PA, USA

J Schrier
Pacira Pharmaceuticals Inc
San Diego, CA, USA

CJ Sciarra
Sciarra Laboratories
Hickesville, NY, USA

JJ Sciarra
Sciarra Laboratories
Hickesville, NY, USA

HC Shah
Signet Chemical Corporation Pvt Ltd
Mumbai, India

SA Shah
ICON Development Solutions
Phoenix, AZ, USA

U Shah
Novartis Vaccines & Diagnostics
Holly Springs, NC, USA

RM Shanker
Pfizer Inc
Groton, CT, USA

PJ Sheskey
The Dow Chemical Company
Midland, MI, USA

J Shur
University of Bath
Bath, UK

S Sienkiewicz
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

D Simon
Roquette Frères
Lestrem, France

A Singh
University of Mississippi
University, MS, USA

KK Singh
SNDT Women's University
Mumbai, India

JLP Soh
Pfizer Global R&D
Sandwich, Kent, UK

RA Storey
AstraZeneca
Macclesfield, Cheshire, UK

C Subra
Gattefossé SAS
Saint-Priest, France

C Sun
University of Minnesota College of Pharmacy
Minneapolis, MN, USA

M Tanenbaum
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

M Tatipalli
University of Florida
Gainesville, FL, USA

AK Taylor
Baton Rouge
LA, USA

J Teckoe
Colorcon Ltd
Dartford, Kent, UK

C Telang
Boehringer-Ingelheim Pharmaceuticals Inc
Ridgefield, CT, USA

MS Tesconi
Pfizer Inc
Groton, CT, USA

S Tiwari
Colorcon Inc
West Point, PA, USA

D Traini
University of Sydney
Sydney, NSW, Australia

N Trivedi
Covidien
Webster Groves, MO, USA

BF Truitt
Xcelience, LLC
Tampa, FL, USA

CK Tye
Bristol-Myers Squibb
Princeton, NJ, USA

HM Unvala
Bayer Corp
Myerstown, PA, USA

S Wallace
Monash University
Hawthorn, VIC, Australia

D Wallick
The Dow Chemical Company
Midland, MI, USA

PJ Weller
BMJ Group
London, UK

W Yang
Astrazeneca
Waltham, MA, USA

P Ying
Pacira Pharmaceuticals Inc
San Diego, CA, USA

W Yu
Pfizer Inc
Groton, CT, USA

About the Editors

Raymond C Rowe

BPharm, PhD, DSc, FRPharmS, FRSC, MInstP

Raymond Rowe has been involved in the *Handbook of Pharmaceutical Excipients* since the first edition was published in 1986, initially as an author then as a Steering Committee member. He is currently Chief Scientist at Intelligensys, UK. He was formerly Senior Principal Scientist at AstraZeneca, UK, and Professor of Industrial Pharmaceutics at the School of Pharmacy, University of Bradford, UK. In 1998 he was awarded the Chiroscience Industrial Achievement Award, and in 1999 he was the British Pharmaceutical Conference Science Chairman. He has contributed to over 400 publications in the pharmaceutical sciences including a book and eight patents.

Paul J Sheskey

BSc, RPh

Paul Sheskey has been involved in the *Handbook of Pharmaceutical Excipients* as an author and member of the Steering Committee since the third edition. He is a Principal Research Scientist at The Dow Chemical Company in Midland, Michigan, USA. Paul received his BSc degree in pharmacy from Ferris State University. Previously, he has worked as a research pharmacist in the area of solid dosage form development at the Perrigo Company and the Upjohn (Pfizer) Company. Paul has authored numerous journal articles in the area of pharmaceutical technology. He is a member of the AAPS and the Controlled Release Society.

Walter G Cook

BSc, PhD

Walter Cook has been involved in the *Handbook of Pharmaceutical Excipients* as an author and member of the Steering Committee since the fourth edition. He is a Research Fellow in the Materials Science group of Pharmaceutical R&D at Pfizer, Sandwich, Kent, UK. Previously, Walter has held positions in formulation research and development at companies including AstraZeneca, UK and Abbott Laboratories, UK. He obtained a BSc in Pharmacy from the University of Strathclyde, UK and a PhD in Pharmaceutical Sciences from the University of Nottingham, UK.

Marian E Fenton

BSc, MSc

Marian Fenton (née Quinn) joined the publications department of the Royal Pharmaceutical Society of Great Britain in 2007 for the sixth edition of the *Handbook of Pharmaceutical Excipients*, having previously worked on the 34th and 35th editions of *Martindale: The Complete Drug Reference*. She has also previously worked at the National Institute for Medical Research, Blackwell Publishing, and Elsevier. Marian received her BSc (Hons) degree in microbiology from the University of Surrey, and her MSc in molecular genetics from the University of Leicester.