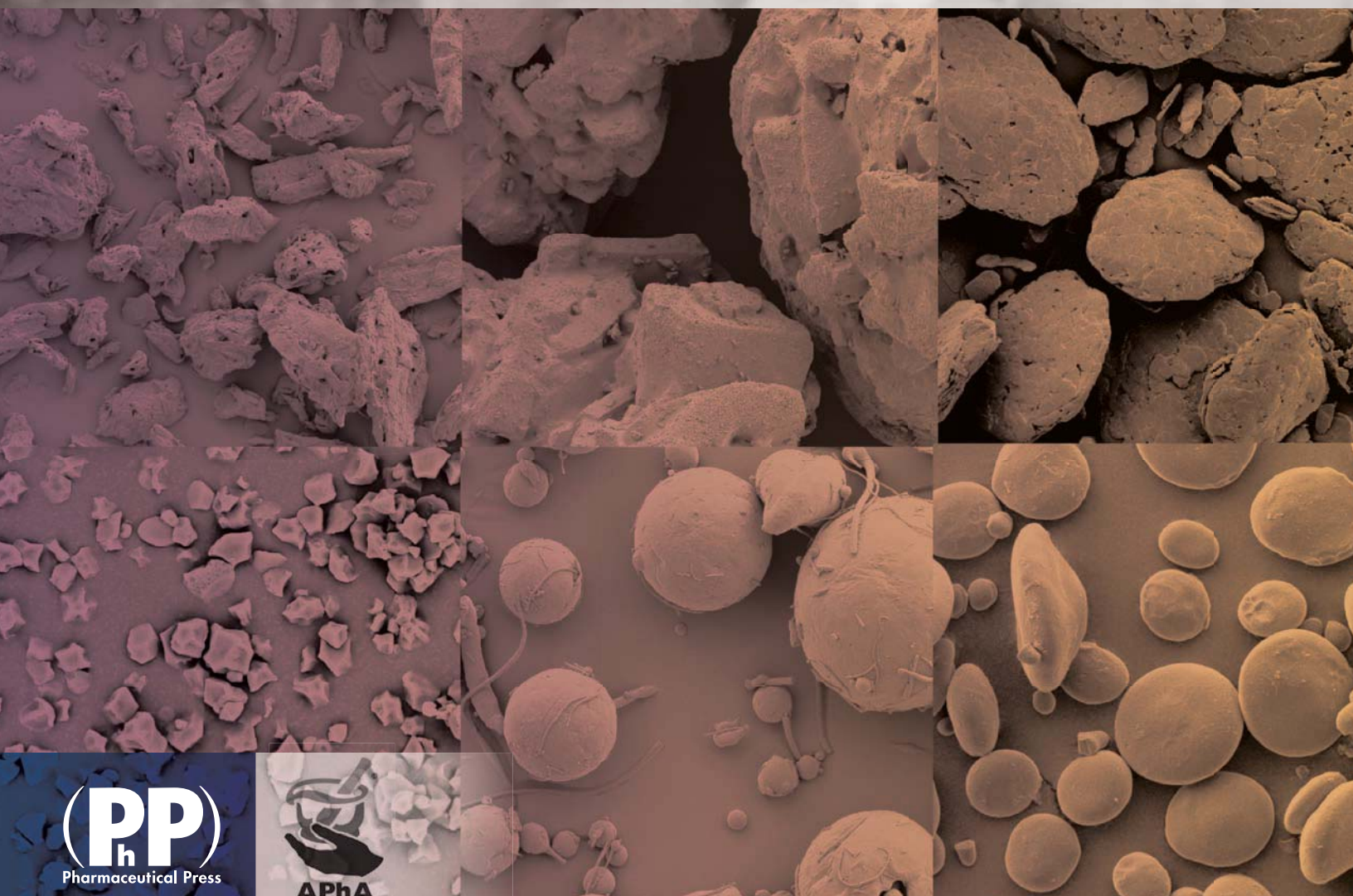


# Handbook of Pharmaceutical Excipients

Sixth edition

Edited by  
Raymond C Rowe, Paul J Sheskey and Marian E Quinn



**PP**  
Pharmaceutical Press



**DOCKET  
ALARM**

Find authenticated court documents without watermarks at [docketalarm.com](https://docketalarm.com).

# Handbook of Pharmaceutical Excipients

---

---

# Handbook of Pharmaceutical Excipients

---

SIXTH 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

**Application Development Leader**

*The Dow Chemical Company, Midland, MI, USA*

**Marian E Quinn** BSc, MSc

**Development Editor**

*Royal Pharmaceutical Society of Great Britain, London, UK*



**Published by the Pharmaceutical Press**

An imprint of RPS Publishing

1 Lambeth High Street, London SE1 7JN, UK  
100 South Atkinson Road, Suite 200, Grayslake, IL 60030-7820, USA

**and the American Pharmacists Association**

2215 Constitution Avenue, NW, Washington, DC 20037-2985, USA

© Pharmaceutical Press and American Pharmacists Association 2009

**(PP)** is a trade mark of RPS Publishing

RPS Publishing is the publishing organisation 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

Typeset by Data Standards Ltd, Frome, Somerset  
Printed in Italy by L.E.G.O. S.p.A.

ISBN 978 0 85369 792 3 (UK)  
ISBN 978 1 58212 135 2 (USA)

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, without the prior written permission of the copyright holder.

The publisher makes no representation, express or implied, with regard to the accuracy of the information contained in this book and cannot accept any legal responsibility or liability for any errors or omissions that may be made.

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

# Contents

---

<i>Preface</i>	x
<i>Arrangement</i>	xi
<i>Acknowledgments</i>	xiii
<i>Notice to Readers</i>	xiii
<i>International Steering Committee</i>	xiv
<i>Editorial Staff</i>	xv
<i>Contributors</i>	xvi
<i>About the Editors</i>	xx
<i>New Monographs</i>	xxi
<i>Related Substances</i>	xxii
<i>Bibliography</i>	xxiv
<i>Abbreviations</i>	xxv
<i>Units of Measurement</i>	xxvii

## Monographs

### A

Acacia	1
Acesulfame Potassium	3
Acetic Acid, Glacial	5
Acetone	7
Acetyltributyl Citrate	8
Acetyltriethyl Citrate	10
Adipic Acid	11
Agar	13
Albumin	14
Alcohol	17
Alginic Acid	20
Aliphatic Polyesters	23
Alitame	28
Almond Oil	29
Alpha Tocopherol	31
Aluminum Hydroxide Adjuvant	34
Aluminum Monostearate	35
Aluminum Oxide	37
Aluminum Phosphate Adjuvant	38
Ammonia Solution	39
Ammonium Alginate	41
Ammonium Chloride	42
Ascorbic Acid	43
Ascorbyl Palmitate	46
Aspartame	48
Attapulgate	51

### B

Benzalkonium Chloride	56
Benzethonium Chloride	59
Benzoic Acid	61
Benzyl Alcohol	64
Benzyl Benzoate	66
Boric Acid	68
Bronopol	70
Butylated Hydroxyanisole	73
Butylated Hydroxytoluene	75
Butylene Glycol	77
Butylparaben	78

### C

Calcium Acetate	82
Calcium Alginate	83
Calcium Carbonate	86
Calcium Chloride	89
Calcium Hydroxide	91
Calcium Lactate	92
Calcium Phosphate, Dibasic Anhydrous	94
Calcium Phosphate, Dibasic Dihydrate	96
Calcium Phosphate, Tribasic	99
Calcium Silicate	101
Calcium Stearate	103
Calcium Sulfate	105
Canola Oil	108
Carbomer	110
Carbon Dioxide	115
Carboxymethylcellulose Calcium	117
Carboxymethylcellulose Sodium	118
Carrageenan	122
Castor Oil	126
Castor Oil, Hydrogenated	128
Cellulose, Microcrystalline	129
Cellulose, Microcrystalline and Carboxymethylcellulose Sodium	134
Cellulose, Powdered	136
Cellulose, Silicified Microcrystalline	139
Cellulose Acetate	141
Cellulose Acetate Phthalate	143
Ceratonia	146



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.