

CE
room

HANDBOOK OF PHARMACEUTICAL EXCIPIENTS

THIRD EDITION



APhA
American
Pharmaceutical
Association

(PP)
Pharmaceutical Press

EDITED BY
ARTHUR H. KIBBE

Handbook of PHARMACEUTICAL EXCIPIENTS

Third Edition

Edited by
Arthur H. Kibbe, Ph.D.

Professor and Chair
Department of Pharmaceutical Sciences
Wilkes University School of Pharmacy
Wilkes-Barre, Pennsylvania



American Pharmaceutical Association
Washington, D.C.



London, United Kingdom

Published by the American Pharmaceutical Association
2215 Constitution Avenue NW, Washington, DC 20037-2985, USA
www.aphanet.org
and the Pharmaceutical Press
1 Lambeth High Street, London SE1 7JN, UK
www.pharmpress.com

© 1986, 1994, 2000 American Pharmaceutical Association and Pharmaceutical Press

First edition 1986
Second edition 1994
Third edition 2000

Printed in the United States of America

ISBN: 0-85369-381-1 (UK)
ISBN: 0-917330-96-X (USA)

Library of Congress Cataloging-in-Publication Data

Handbook of pharmaceutical excipients / edited by Arthur H. Kibbe.--3rd ed.
p. ; cm.

Includes bibliographical references and index.

ISBN 0-917330-96-X

1. Excipients--Handbooks, manuals, etc. I. Kibbe, Arthur H. II. American Pharmaceutical Association.

[DNLM: 1. Excipients--Handbooks. QV 735 H236 2000]

RS201.E87 H36 2000

615'.19--dc21

99-044554

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

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.

Managing Editor: Melanie Segala
Copyeditor: Paul Gottehrer
Indexer: Lillian Rodberg
Compositor: Roy Barnhill
Cover Designer: Tim Kaage

- HFC (difluoroethane), 184
hydrocarbons (HC), 236
nitrogen, 352
nitrous oxide, 353, 354
tetrafluoroethane (HFC), 560
- Air displacement agents**
carbon dioxide, 83
nitrogen, 352
- Airvol*, 424
Akucell, 87
Alba red (D&C red #39), 147
Alboline, 345
Albuconn, 5
Albumin, 5
bovine serum, 6
human solution, 5
Albuminar, 5
Albumini humani solutio, 5
Albuminisol, 5
Albumin solution, 5
Albuspan, 5
Albutein, 5
Alcohol(s), 7
absolute, 8
 β -aminoethyl, 350
benzyl, 41
cetearyl, 112
cetostearyl, 112, 120, 538, 586
cetyl, 113, 117, 538
dehydrated, 8
denatured, 8
dilute, 8
furfuryl, 230
 β -hydroxyethyl phenyl, 370
isopropyl, 8, 263
lanolin, 139, 287, 288-290, 346, 348, 349, 363, 365
mineral oil, 346, 348, 349
octadecyl, 537
paraffin, 365
petrolatum, 289, 363, 365
 β -phenylethyl, 372
2-phenylethyl, 372
phenylethyl, 127, 372
phenylic, 367
polyvinyl, 424
sec-propyl, 263
propyl, 264
propylic, 264
stearyl, 113, 120, 537, 635
 β,β,β -trichloro-*tert*-butyl, 126
wool, 288, 365
- Alcohol benzylicus, 41
Alcohol cetylicus, 117
Alcohol cetylicus et stearylicus, 112
Alcohol isopropylicus, 263
Alcohol stearylicus, 537
Alcoholis adipis lanae, 288
Alcoramnosan, 240
Aldehyde
ethylprotocatechuic, 208
methylprotocatechuic, 576
vanillin, 576
- Aldo MS*, 225
Aldo MO, 223
Aleuritic acid, 463
- Alfadex, 165
Algin, 465
Alginate, 6
Alginic acid, 10, 445, 446, 465, 466
Aliphatic polyesters, 13, 272, 273
Alixural purple SS (D&C violet #2 lake), 148
Alizarin cyanine (D&C green #5), 147
Alizarin cyanine (D&C green #5 lake), 148
Alizurrol purple SS (D&C violet #2), 147
- Alkalizing agents**
diethanolamine (DEA), 180
monoethanolamine, 350
potassium citrate, 429
sodium bicarbonate, 474
sodium citrate, 482
triethanolamine, 572
- Alkamuls SMS*, 511
Alkamuls STS, 511
Alkylbenzyltrimethylammonium chloride, 33
Alkyl benzyl dimethyl ammonium chloride, 33
Alkyldimethyl(phenylmethyl)ammonium chloride, 33
- Allomalenic acid, 213
Allura red AC (D&C red #40), 147
Alpha-carotene, 146
Alpha-cyclodextrin, 165
Alpha-cyclosamylose, 165
Alpha-dextrin, 165
Alpha tocopherol, 18
d-Alpha tocopherol, 19
dl-Alpha tocopheryl acetate, 19
d-Alpha tocopheryl acid succinate, 19
dl-Alpha tocopheryl acid succinate, 19
Alphazurine FG (D&C blue #4), 147
Alphazurine FG (D&C blue #4 lake), 148
Alumina, 149
Aluminum magnesium silicate, 295
Aluminum powder, 149
Aluminum silicate, hydrated, 269
Alvanol, 424
Amalty, 313
Amberlite IRP-88, 383
Amberlite resins, physico-chemical properties
summary, 384
Amerchol CAB, 365
Americhol L-101, 349
Amido, 522
Amidon, 522
Amilo, 522
2-Aminoethanol, 350
 β -Aminoethyl alcohol, 350
3-Amino-*N*-(α -carboxyphenethyl)succinamic acid *N*-methyl ester, 27
3-Amino-*N*-(α -methoxycarbonylphenethyl)-succinamic acid, 27
Ammonio methacrylate copolymer, 401
Ammonium, saccharin, 455
Ammonium citrate, ferric, 149
Ammonium ferrocyanide, ferric, 149
Amorphous wax, 591
Amylopectin, 527
 α -Amylose, 527
Amylum, 522
Anatase titanium dioxide, 565
Anhydride, titan, 565
- 1,4-Anhydro-D-glucitol, 511
Anhydrosorbital monoisostearate, 511
Anhydrosorbitol monostearate, 511
Anhydrous citric acid, 141
Anhydrous dextrose, 177
Anhydrous dibasic calcium phosphate, 60
Anhydrous dibasic sodium phosphate, 493
Anhydrous Emcompress, 60
Anhydrous 4-*O*- α -D-glucopyranosyl- β -D-glucopyranose, 322
Anhydrous lanolin, 286
Anhydrous magnesium carbonate, 301
Anhydrous monobasic sodium phosphate, 496
Anhydrous potassium citrate, 430
Anhydrous silicic acid, light, 143
Anhydrous sodium citrate, 483
Anhydrous sodium propionate, 499
Anhydrous sodium salt, 499
Anhydrous sodium sulfite, 491
Anion-exchange *Amberlite* resins, 384
Anionic emulsifying wax, 585
Annatto extract, 149
Anthocyanins, 146
Anthracine 12, 49
- Anticaking agents**
calcium phosphate, tribasic, 68
magnesium trisilicate, 309
talc, 555
- Anticoagulants**
editic acid (EDTA), 191
- Antimicrobial preservatives. See also Antiseptics; Disinfectants**
- acids
benzoic, 38
editic (EDTA), 191
phenolic, 367
sorbic, 508
- alcohols, 7
benzyl, 41
isopropyl, 263
benzethonium chloride, 33
bronopol, 46
butylparaben, 53
cetrimide, 114
chlorhexidine, 121
chlorobutanol, 126
chlorocresol, 129
cresol, 158
ethylparaben, 205
glycerol, 220
imidurea, 261
methylparaben, 340
phenol, 367
phenoxyethanol, 370
phenylethyls, alcohol, 372
phenylmercuric acetate, 374, 378, 381
phenylmercuric borate, 377, 381
phenylmercuric nitrate, 379
potassium sorbate, 431
propylene glycol, 442
propylparaben, 450
sodium benzoate, 471
sodium propionate, 498
sorbic acid, 508
thimerosol, 562

Antioxidant synergists

edetic acid (EDTA), 191

Antioxidants

acids

ascorbic, 21

fumaric, 213

malic, 311

alpha tocopherol, 18

ascorbic acid palmitate, 25

butylated hydroxyanisole, 49

propyl gallate, 447

sodium ascorbate, 468

sodium metabisulfite, 490

Antiseptics, 46. See also Antimicrobial preservatives; Disinfectants

benzalkonium chloride, 33

cetrimide, 114

chlorhexidine, 121

phenylmercuric acetate, 374, 378

phenylmercuric borate, 377

phenylmercuric nitrate, 379

thimerosal, 562

APM, 27

Apple acid, 311

Aquacoat, 195

Aqua purificata, 580

Aquasorb, 87

Aquateric, 99

Aracel 161, 225

Aracel 169, 225

Arachis oil, 360

Arachis oleum, 360

Arcton, 134

Argilla, 269

Arlacel C, 511

Arlacel 20, 511

Arlacel 40, 511

Arlacel 60, 511

Arlacel 80, 511

Arlacel 83, 511

Arlacel 85, 511

Arlacel 180, 223

Arlacel 987, 511

Arlatone, 412

Armostat 801, 225

Armotan M5, 511

Armotan ML, 511

Armotan MO, 511

Armotan MP, 511

Ascorbic acid, 21, 26

Ascorbic acid 6-hexadecanoate, 25

L-Ascorbic acid monosodium salt, 468

Ascorbilis palmitas, 25

Ascorbyl palmitate, 23, 25, 469

Aspartame, 4, 27

N- α -L-Aspartyl-L-phenylalanine 1-methyl ester, 27

Aspartyl phenylamine methyl ester, 27

Assugrin, 485

A-TAB, 60

Atlas G-595, 223

Atlas G-3712, 407

Atlas 110K, 511

Atmos 150, 225

Atmul 67, 84, 124, 225

Avedex, 172

Avicel, 102

Aytex P, 522

Azote, 352

B-1459, 599

Bacteriostatic water, for injection, 583

Bases

for medicated confectionery

polydextrose, 389

sucrose, 539

ointment

alcohols, 288, 365

lanolin, 286, 290

paraffin, 358

petrolatum, 362

polyethylene glycol, 392

organic, meglumine, 332

suppository, 398, 579

hard fat, 550

polyethylene glycol, 392

Basic phenylmercury nitrate, 379

Beeswax, white, 595

Beetroot red (betanin), 146

Beet sugar, 539

1,2-Benisothiazolin-3-one 1,1-dioxide, 454

Benne oil, 460

Bentonite, 30, 269

Bentonite magma, 32

Bentonitum, 30

Benzalkonii chloridum, 33

Benzalkonium chloride, 33

Benzene, β -hydroxyethyl, 372

1,2-Benzenedicarboxylic acid, 182

1,2-Benzenedicarboxylic acid dibutyl ester, 183

Benzeneethanol, 372

Benzeneformic acid, 38

Benzenemethanol, 41

Benzenocarboxylic acid, 38

Benzenylcarboxylate, 44

Benzethonium chloride, 35

1,2-Benzisothiazol-3(2H)-one 1,1 dioxide, 454

Benzoic acid, 38, 472

Benzoic acid benzyl ester, 44

Benzoic acid phenylmethyl ester, 44

Benzoic sulfimide, 454

Benzosulfimide, 454

1,2-Benzothiazolin-3-one 1,1-dioxide sodium salt, 457

Benzyl alcohol, 41

Benzyl benzoate, 44

Benzyl carbinol, 372

Benzylis benzoas, 44

Benzylmethanol, 372

Benzyl phenylformate, 44

Beta-apo-8'-carotenal, 146

Beta-apo-8'-carotenoic acid, ethyl ester of (C30), 146

Beta-carotene, 146, 149, 150

Beta-cycloamylose, 165

Beta cyclodextrin, 165

Betacyclodextrinun, 165

Betadex, 165

Beta-dextrin, 165

Betanin (beetroot red), 146

Beta tocopherol, 20

Betonite, 298

BFI (Brittle Fracture Index), 637

BHA, 49

Bicarbonate

potassium, 476

sodium, 474

Binders

acacia, 1

alginic acid, 10

carboxymethylcellulose, 87

cellulose

hydroxyethyl, 240

hydroxypropyl, 244, 249

dextrin, 172

flavoring fixative, ethylcellulose, 195

gelatin, 215

glucose, liquid, 218

guar gum, 232

hydrogenated vegetable oil, type I, 578

hydroxyethyl cellulose, 240

hydroxypropyl methylcellulose, 252

liquid glucose, 218

magnesium aluminum silicate, 295

maltodextrin, 317

methylcellulose, 252, 336

polyethylene oxide, 399

polymethacrylates, 401

povidone, 433

sodium alginate, 465

starch, 522, 528

vegetable oil, hydrogenated, type I, 578

zein, 606

Biopure 100, 261

Biphosphate, sodium, 496

N,N'-Bis(4-chlorophenyl)-3,1,2-diimino-2,4,11,13-tetraazetradecane-diimidamine, 121

1,4-Bis(2-ethylhexyl) ester, 188

Bis(2-ethylhexyl) sodium sulfosuccinate, 188

1,2-Bis(2-ethylhexyl) sulfosuccinate, 189

Bis(hydroxyethyl)amine, 180

Bismuth oxychloride, 149

1,6-Bis[N'-(p-chlorophenyl)]-N⁵-biguanido hexane, 121

Bisomel, 265

Bis-sorb, 531

Bisulfite, 491

BKC, 33

Black PN, 150

Blanose, 87

Bleached shellac, 462

Bleached wax, 595

Blue coloring agents, 147

BNPDBronosol, 46

Boletic acid, 213

Bolus alba, 269

Bonding Index (BI), 637

Borate

phenylmercuric, 375, 377, 562

phenylmercury, 377

Borculo whey products, lactoses, 279, 282

Bourbonal, 208

Bovine serum albumin, 6

Brazil wax, 587

Breox PEG, 392

Brij, 407