Any correspondence regarding this publication should be sent to the publisher, American Society of Health-System Pharmacists, 4500 East-West Highway, suite 900, Bethesda, MD 20814, attention: Special Publishing.

The information presented herein reflects the opinions of the contributors and advisors. It should not be interpreted as an official policy of ASHP or as an endorsement of any product.

Because of ongoing research and improvements in technology, the information and its applications contained in this text are constantly evolving and are subject to the professional judgment and interpretation of the practitioner due to the uniqueness of a clinical situation. The editors and ASHP have made reasonable efforts to ensure the accuracy and appropriateness of the information presented in this document. However, any user of this information is advised that the editors and ASHP are not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information in the document in any and all practice settings. Any reader of this document is cautioned that ASHP makes no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the information contained in this document and specifically disclaims any liability to any party for the accuracy and/or completeness of the material or for any damages arising out of the use or non-use of any of the information contained in this document.

Vice President, Publishing Office: Daniel J. Cobaugh, PharmD, DABAT, FAACT
Editorial Director, Special Publishing: Lori N. Justice, PharmD
Editorial Coordinator, Special Publishing: Elaine Jimenez
Director, Production and Platform Services, Publishing Operations: Johnna M. Hershey, BA
Printing: KGL/Sheridan
Cover and Page Design: David Wade

Library of Congress Cataloging - in - Publication Data
Title: Extemporaneous formulations for pediatric, geriatric and special needs patients / Rita K. Jew, Winson Soo-Hoo, Elham Amiri, Jamie M. Gomes.
Description: Fourth edition. | Bethesda, MD : The American Society of Health-System Pharmacists, [2022] | Includes bibliographical references. | Summary: "The 4th edition of this book continues to serve as a trusted resource for the preparation of extemporaneous formulations to meet patient needs. It contains a total of 312 formulations, including 129 new formulations, 47 of which are new drugs and 36 new concentrations of drugs that were in the previous edition, with the remaining 46 being different formulations of drugs that are in the previous editions"-- Provided by publisher.
Subjects: MESH: Drug Compounding | Aged | Child | Formularies as Topic | Pharmaceutical Solutions | Suspensions | Laboratory Manual
Classification: LCC RM301.25 (print) | LCC RM301.25 (ebook) | NLM QV 25 | DDC 615.1/9--dc23
LC record available at https://lccn.loc.gov/2021007373
LC ebook record available at https://lccn.loc.gov/2021007374

© 2022, American Society of Health-System Pharmacists, Inc. All rights reserved.

No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, microfilming, and recording, or by any information storage and retrieval system, without written permission from the American Society of Health-System Pharmacists.

ASHP is a service mark of the American Society of Health-System Pharmacists, Inc.; registered in the U.S. Patent and Trademark Office.

DOI: 10.37573/9781585286522
## TABLE OF CONTENTS

Preface ........................................................................................................................... xi
Introduction .............................................................................................................. xiv
Acknowledgments ................................................................................................... xviii

### PART I: SOLUTION/SUSPENSION/SYRUP

- Acetazolamide Suspension 25 mg/mL - Formulation 1 .............................................. 3
- Acetazolamide Suspension 25 mg/mL - Formulation 2 .............................................. 4
- Acetylcysteine Solution 10 mg/mL ........................................................................... 5
- Acetylcysteine Solution 100 mg/mL ........................................................................ 6
- Allopurinol Suspension 20 mg/mL - Formulation 1 .................................................. 7
- Allopurinol Suspension 20 mg/mL - Formulation 2 .................................................. 8
- Amiodarone Hydrochloride Suspension 5 mg/mL - Formulation 1* ...................... 9
- Amiodarone Hydrochloride Suspension 5 mg/mL - Formulation 2 ...................... 11
- Amitriptyline Hydrochloride Suspension 10 mg/mL ............................................... 12
- Amitriptyline Hydrochloride Suspension 20 mg/mL ............................................... 13
- Amitriptyline Hydrochloride Syrup 1 mg/mL .......................................................... 14
- Amphetamine and Dextroamphetamine (Adderall) Suspension 1 mg/mL ............. 15
- Atenolol Suspension 1 mg/mL ................................................................................ 16
- Atenolol Suspension 5 mg/mL ................................................................................ 17
- Atenolol Syrup 2 mg/mL - Formulation 1* .............................................................. 18
- Atenolol Syrup 2 mg/mL - Formulation 2* .............................................................. 19
- Atropine Sulfate Suspension 0.1 mg/mL ................................................................ 20
- Azathioprine Suspension 50 mg/mL ....................................................................... 21
- Benazepril Hydrochloride Suspension 2 mg/mL ..................................................... 23
- Bethanechol Chloride Solution 1 mg/mL .................................................................. 24
- Bethanechol Chloride Suspension 5 mg/mL* .......................................................... 25
- Buspirone Hydrochloride Syrup 2.5 mg/mL ............................................................ 26
- Busulfan Syrup 2 mg/mL ........................................................................................ 27
- Candesartan Cilexetil Suspension 1 mg/mL ............................................................. 28
- Captopril Solution 1 mg/mL* .................................................................................. 29
- Captopril Suspension 0.75 mg/mL ......................................................................... 30
- Captopril Suspension 0.8 mg/mL .......................................................................... 31
- Captopril Suspension 1 mg/mL .............................................................................. 32
- Carvedilol Suspension 0.1 mg/mL .......................................................................... 33
- Carvedilol Suspension 1.67 mg/mL ....................................................................... 34
- Carvedilol Suspension 5 mg/mL ............................................................................ 35
- Celecoxib Suspension 10 mg/mL - Formulation 1 ...................................................... 36
- Celecoxib Suspension 10 mg/mL - Formulation 2 ................................................... 37
- Chloroquine Phosphate Suspension 15 mg/mL - Formulation 1 ........................... 38
- Chloroquine Phosphate Suspension 15 mg/mL - Formulation 2 ........................... 40
- Chloroquine Phosphate Syrup 16.7 mg/mL* .......................................................... 41
- Chlorpromazine Hydrochloride Syrup 100 mg/mL ................................................ 42
- Cinacalcet Suspension 5 mg/mL ............................................................................. 43
- Clonazepam Suspension 0.1 mg/mL ..................................................................... 44
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clonazepam Suspension</td>
<td>0.2 mg/mL</td>
</tr>
<tr>
<td>Clonidine Hydrochloride Suspension</td>
<td>0.01 mg/mL</td>
</tr>
<tr>
<td>Clonidine Hydrochloride Syrup</td>
<td>0.02 mg/mL</td>
</tr>
<tr>
<td>Clonidine Hydrochloride Syrup</td>
<td>0.1 mg/mL</td>
</tr>
<tr>
<td>Clopidogrel Bisulfate Suspension</td>
<td>5 mg/mL</td>
</tr>
<tr>
<td>Codeine Phosphate Syrup</td>
<td>3 mg/mL</td>
</tr>
<tr>
<td>Cyclophosphamide Suspension</td>
<td>10 mg/mL</td>
</tr>
<tr>
<td>Dantrolene Sodium Syrup</td>
<td>5 mg/mL</td>
</tr>
<tr>
<td>Dapsone Suspension</td>
<td>2 mg/mL - Formulation 1</td>
</tr>
<tr>
<td>Dapsone Suspension</td>
<td>2 mg/mL - Formulation 2</td>
</tr>
<tr>
<td>Dapsone Syrup</td>
<td>2 mg/mL</td>
</tr>
<tr>
<td>Diclofenac Sodium Suspension</td>
<td>5 mg/mL</td>
</tr>
<tr>
<td>Diltiazem Hydrochloride Suspension</td>
<td>12 mg/mL</td>
</tr>
<tr>
<td>Diltiazem Suspension</td>
<td>12 mg/mL</td>
</tr>
<tr>
<td>Dipyridamole Suspension</td>
<td>10 mg/mL - Formulation 1</td>
</tr>
<tr>
<td>Dipyridamole Suspension</td>
<td>10 mg/mL - Formulation 2</td>
</tr>
<tr>
<td>Disopyramide Syrup</td>
<td>1 mg/mL</td>
</tr>
<tr>
<td>Disopyramide Syrup</td>
<td>10 mg/mL</td>
</tr>
<tr>
<td>Dolasetron Mesylate Suspension</td>
<td>10 mg/mL</td>
</tr>
<tr>
<td>Erlotinib Suspension</td>
<td>10 mg/mL</td>
</tr>
<tr>
<td>Eslicarbazepine Acetate Suspension</td>
<td>40 mg/mL</td>
</tr>
<tr>
<td>Ethacrynic Acid Solution</td>
<td>1 mg/mL</td>
</tr>
<tr>
<td>Etoposide Solution</td>
<td>10 mg/mL</td>
</tr>
<tr>
<td>Flecainide Acetate Suspension</td>
<td>20 mg/mL - Formulation 1*</td>
</tr>
<tr>
<td>Flecainide Acetate Suspension</td>
<td>20 mg/mL - Formulation 2</td>
</tr>
<tr>
<td>Flucytosine Suspension</td>
<td>10 mg/mL</td>
</tr>
<tr>
<td>Flucytosine Suspension</td>
<td>50 mg/mL*</td>
</tr>
<tr>
<td>Glutamine Suspension</td>
<td>250 mg/mL</td>
</tr>
<tr>
<td>Granisetron Hydrochloride Suspension</td>
<td>0.05 mg/mL</td>
</tr>
<tr>
<td>Granisetron Hydrochloride Syrup</td>
<td>0.2 mg/mL</td>
</tr>
<tr>
<td>Hydralazine Hydrochloride Suspension</td>
<td>4 mg/mL*</td>
</tr>
<tr>
<td>Hydrochlorothiazide Suspension</td>
<td>2 mg/mL</td>
</tr>
<tr>
<td>Hydrocortisone Hemisuccinate Suspension</td>
<td>2 mg/mL</td>
</tr>
<tr>
<td>Hydrocortisone Sodium Phosphate Suspension</td>
<td>2 mg/mL</td>
</tr>
<tr>
<td>Hydrocortisone Suspension</td>
<td>1 mg/mL - Formulation 1</td>
</tr>
<tr>
<td>Hydrocortisone Suspension</td>
<td>1 mg/mL - Formulation 2</td>
</tr>
<tr>
<td>Hydrocortisone Suspension</td>
<td>2 mg/mL*</td>
</tr>
<tr>
<td>Hydroxychloroquine Sulfate Suspension</td>
<td>25 mg/mL</td>
</tr>
<tr>
<td>Hydroxyurea Syrup</td>
<td>100 mg/mL*</td>
</tr>
<tr>
<td>Hypromellose Suspension</td>
<td>10 mg/mL</td>
</tr>
<tr>
<td>Imatinib Syrup</td>
<td>40 mg/mL</td>
</tr>
<tr>
<td>Imipramine Hydrochloride Suspension</td>
<td>5 mg/mL</td>
</tr>
<tr>
<td>Indinavir Liquid</td>
<td>10 mg/mL</td>
</tr>
<tr>
<td>Isradipine Syrup</td>
<td>1 mg/mL</td>
</tr>
<tr>
<td>Ketoconazole Suspension</td>
<td>20 mg/mL - Formulation 1</td>
</tr>
<tr>
<td>Ketoconazole Suspension</td>
<td>20 mg/mL - Formulation 2</td>
</tr>
<tr>
<td>Ketoprofen Suspension</td>
<td>20 mg/mL</td>
</tr>
</tbody>
</table>
Labetalol Hydrochloride Suspension 40 mg/mL - Formulation 1* ..................94
Labetalol Hydrochloride Suspension 40 mg/mL - Formulation 2 ..................95
Labetalol Hydrochloride Syrup 10 mg/mL .............................................96
Lamotrigine Suspension 1 mg/mL - Formulation 1 .................................97
Lamotrigine Suspension 1 mg/mL - Formulation 2 .................................98
Lansoprazole Solution 3 mg/mL* .........................................................99
Lansoprazole Suspension 3 mg/mL .......................................................100
Lapatinib Suspension 50 mg/mL .........................................................101
Lenalidomide Suspension 1.25 mg/mL ................................................102
Losartan Suspension 2.5 mg/mL .........................................................103
Melatonin Suspension 1 mg/mL .........................................................104
Melatonin Suspension 3 mg/mL .........................................................105
Melatonin 1 mg/mL and Pyridoxine Hydrochloride 3.3 mg/mL Suspension...106
Methylcellulose Suspension 10 mg/mL (1%) .........................................107
Methyldopa Syrup 50 mg/mL ...............................................................108
Metolazone Suspension 1 mg/mL .......................................................109
Metoprolol Tartrate Suspension 10 mg/mL - Formulation 1* .................110
Metoprolol Tartrate Suspension 10 mg/mL - Formulation 2 ......................111
Metronidazole Suspension 10 mg/mL ................................................112
Metronidazole Suspension 50 mg/mL* ................................................113
Metronidazole Syrup 5 mg/mL - Formulation 1 ......................................114
Metronidazole Syrup 5 mg/mL - Formulation 2 ......................................115
Mexiletine Solution 10 mg/mL .............................................................116
Minocycline Hydrochloride Suspension 10 mg/mL .............................117
Minoxidil Suspension 1 mg/mL ...........................................................118
Moxifloxacin Suspension 20 mg/mL ....................................................119
Naratriptan Hydrochloride Suspension 0.5 mg/mL .............................120
Nifedipine Solution 10 mg/mL .........................................................121
Nifedipine Suspension 1 mg/mL .......................................................122
Nifedipine Suspension 4 mg/mL - Formulation 1* ..............................123
Nifedipine Suspension 4 mg/mL - Formulation 2 ..............................124
Olmesartan Medoxomil Suspension 2 mg/mL ....................................125
Omeprazole Solution 2 mg/mL ...........................................................126
Omeprazole Suspension 2 mg/mL .....................................................127
Oxandrolone Suspension 1 mg/mL ....................................................128
Oxandrolone Suspension 2 mg/mL ....................................................129
Oxandrolone Suspension 3 mg/mL ....................................................130
Pantoprazole Solution 2 mg/mL - Formulation 1 ..................................131
Pantoprazole Solution 2 mg/mL - Formulation 2 ..................................132
Penicillamine-D Suspension 50 mg/mL .............................................133
Pentoxifylline Solution 20 mg/mL .....................................................134
Phenoxybenzamine Hydrochloride Solution 2 mg/mL .......................135
Procainamide Hydrochloride Suspension 50 mg/mL ........................136
Propylthiouracil Suspension 5 mg/mL - Formulation 1 .....................137
Propylthiouracil Suspension 5 mg/mL - Formulation 2 .....................138
Pyrazinamide Suspension 10 mg/mL ..............................................139
Pyrazinamide Suspension 100 mg/mL .............................................140
Pyrazinamide Syrup 100 mg/mL* ................................................................. 141
Pyridoxine Hydrochloride Suspension 50 mg/mL .................................... 142
Pyrimethamine Suspension 2 mg/mL - Formulation 1 ......................... 143
Pyrimethamine Suspension 2 mg/mL - Formulation 2 ......................... 144
Quinapril Syrup 1 mg/mL .................................................................... 145
Quinidine Sulfate Suspension 10 mg/mL - Formulation 1 ..................... 146
Quinidine Sulfate Suspension 10 mg/mL - Formulation 2 ..................... 147
Riboflavin Suspension 10 mg/mL ....................................................... 148
Rifabutin Suspension 20 mg/mL ......................................................... 149
Rifampin Suspension 25 mg/mL - Formulation 1* ................................. 150
Rifampin Suspension 25 mg/mL - Formulation 2 ................................. 152
Rifampin Syrup 10 mg/mL .................................................................. 153
Rifaximin Suspension 20 mg/mL ........................................................ 154
Rosuvastatin Suspension 4 mg/mL .................................................... 155
Sodium Benzoate Syrup 250 mg/mL ................................................ 157
Sodium Phenylbutyrate Suspension 200 mg/mL ................................. 158
Spironolactone 5 mg/mL and Hydrochlorothiazide 5 mg/mL Suspension - Formulation 1 ................................................................. 159
Spironolactone 5 mg/mL and Hydrochlorothiazide 5 mg/mL Suspension - Formulation 2 ................................................................. 161
Sulfadiazine Suspension 100 mg/mL ................................................... 162
Sulfasalazine Suspension 100 mg/mL - Formulation 1 ......................... 163
Sulfasalazine Suspension 100 mg/mL - Formulation 2 ......................... 164
Sumatriptan Succinate Suspension 5 mg/mL ..................................... 165
Sunitinib Malate Suspension 10 mg/mL ............................................... 166
Tacrolimus Monohydrate Suspension 0.5 mg/mL ............................... 167
Tacrolimus Monohydrate Suspension 1 mg/mL ................................... 168
Tacrolimus Suspension 0.5 mg/mL ..................................................... 169
Tacrolimus Suspension 1 mg/mL* ...................................................... 170
Tadalafil Suspension 5 mg/mL .......................................................... 171
Temozolomide Suspension 10 mg/mL ................................................ 172
Terbinafine Hydrochloride Suspension 25 mg/mL .............................. 174
Terbinafine Suspension 25 mg/mL ..................................................... 175
Terbutaline Sulfate Suspension 1 mg/mL .......................................... 176
Tetracycline Hydrochloride Suspension 25 mg/mL - Formulation 1 ....... 177
Tetracycline Hydrochloride Suspension 25 mg/mL - Formulation 2 ........ 179
Thalidomide Suspension 20 mg/mL .................................................... 180
Thiamine Suspension 100 mg/mL ...................................................... 181
Thioguanine Suspension 20 mg/mL* ................................................ 182
Tiagabine Hydrochloride Suspension 1 mg/mL - Formulation 1 .......... 183
Tiagabine Hydrochloride Suspension 1 mg/mL - Formulation 2 ........ 184
Tinidazole Suspension 66.7 mg/mL .................................................... 185
Topiramate Suspension 5 mg/mL ....................................................... 186
Tramadol Hydrochloride Suspension 5 mg/mL .................................. 187
Tramadol Hydrochloride Suspension 10 mg/mL ................................ 188
Tramadol Hydrochloride Suspension 7.5 mg/mL and Acetaminophen 65 mg/mL Suspension ...................................................... 189
<table>
<thead>
<tr>
<th>Name</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ursodiol Suspension 20 mg/mL</td>
<td>191</td>
</tr>
<tr>
<td>Ursodiol Suspension 25 mg/mL</td>
<td>192</td>
</tr>
<tr>
<td>Ursodiol Suspension 30 mg/mL</td>
<td>193</td>
</tr>
<tr>
<td>Ursodiol Suspension 50 mg/mL</td>
<td>194</td>
</tr>
<tr>
<td>Ursodiol Syrup 60 mg/mL - Formulation 1*</td>
<td>195</td>
</tr>
<tr>
<td>Ursodiol Syrup 60 mg/mL - Formulation 2*</td>
<td>196</td>
</tr>
<tr>
<td>Valacyclovir Hydrochloride Suspension 50 mg/mL*</td>
<td>197</td>
</tr>
<tr>
<td>Valsartan Suspension 4 mg/mL - Formulation 1</td>
<td>198</td>
</tr>
<tr>
<td>Valsartan Suspension 4 mg/mL - Formulation 2</td>
<td>199</td>
</tr>
<tr>
<td>Verapamil Hydrochloride Suspension 50 mg/mL</td>
<td>200</td>
</tr>
<tr>
<td>Ziprasidone Mesylate Syrup 2.5 mg/mL</td>
<td>201</td>
</tr>
<tr>
<td>Zonisamide Suspension 10 mg/mL - Formulation 1</td>
<td>202</td>
</tr>
<tr>
<td>Zonisamide Suspension 10 mg/mL - Formulation 2</td>
<td>203</td>
</tr>
<tr>
<td>Zonisamide Syrup 10 mg/mL*</td>
<td>204</td>
</tr>
</tbody>
</table>

**PART II: TOPICAL/OPHTHALMIC SOLUTION**

- Cefazolin Sodium Ophthalmic Solution 33 mg/mL...207
- Cidofovir Intravitreous Solution 0.2 mg/mL.....208
- Cidofovir Intravitreous Solution 8.1 mg/mL....209
- Ganciclovir Intravitreous Solution 20 mg/mL...210
- Gentamicin Sulfate Ophthalmic Solution 13.6 mg/mL (Fortified).......211
- LET (Lidocaine 4%/Racepinephrine 0.225%/Tetracaine 0.5%)
  Topical Solution.................................212
- Tobramycin Sulfate Ophthalmic Solution 13.6 mg/mL (Fortified)....213
- Tobramycin Sulfate Ophthalmic Solution 15 mg/mL.....214
- Vancomycin Hydrochloride Ophthalmic Solution 31 mg/mL......215
- Voriconazole Ophthalmic Solution 1 mg/mL.........216
- Voriconazole Ophthalmic Solution 10 mg/mL......217

**PART III: COMMERCIALY AVAILABLE PRODUCTS**

- Acetaminophen Suspension 50 mg/mL.................221
- Alprazolam Suspension 1 mg/mL - Formulation 1...222
- Alprazolam Suspension 1 mg/mL - Formulation 2...223
- Amlodipine Besylate Suspension 1 mg/mL - Formulation 1....224
- Amlodipine Besylate Suspension 1 mg/mL - Formulation 2.....225
- Aprepitant Suspension 20 mg/mL..................226
- Aripiprazole Suspension 1 mg/mL..................227
- Baclofen Suspension 2 mg/mL.......................228
- Baclofen Suspension 10 mg/mL - Formulation 1........229
- Baclofen Suspension 10 mg/mL - Formulation 2........230
- Baclofen Syrup 5 mg/mL*.........................231
- Caffeine Citrate Solution 20 mg/mL...............232
- Carbamazepine Suspension 25 mg/mL................233
- Carbamazepine Syrup 40 mg/mL........................234
- Cholecalciferol Suspension 50,000 units/mL.......235
- Ciprofloxacin Hydrochloride Suspension 50 mg/mL - Formulation 1....236
Ciprofloxacin Hydrochloride Suspension 50 mg/mL - Formulation 2 .......................... 237
Cyclosporine Suspension 100 mg/mL ........................................................................ 238
Dexamethasone Suspension 1 mg/mL ..................................................................... 239
Diazoxide Suspension 10 mg/mL - Formulation 1 ..................................................... 240
Diazoxide Suspension 10 mg/mL - Formulation 2 ..................................................... 241
Enalapril Maleate Suspension 0.1 mg/mL ................................................................. 242
Enalapril Maleate Suspension 1 mg/mL - Formulation 1 ........................................... 244
Enalapril Maleate Suspension 1 mg/mL - Formulation 2 ........................................... 246
Enalapril Maleate Suspension 1 mg/mL - Formulation 3 ........................................... 248
Famotidine Suspension 8 mg/mL ............................................................................. 249
Famotidine Syrup 8 mg/mL ..................................................................................... 250
Fluconazole Solution 1 mg/mL ................................................................................ 251
Fluoxetine Hydrochloride Syrup 1 mg/mL ............................................................... 252
Fluoxetine Hydrochloride Syrup 2 mg/mL ............................................................... 253
Furosemide Suspension 2 mg/mL ............................................................................ 254
Furosemide Suspension 9.6 mg/mL .......................................................................... 255
Gabapentin Suspension 50 mg/mL .......................................................................... 256
Gabapentin Suspension 100 mg/mL - Formulation 1 ................................................. 257
Gabapentin Suspension 100 mg/mL - Formulation 2 ................................................. 259
Glycopyrrolate Suspension 0.2 mg/mL ..................................................................... 260
Glycopyrrolate Suspension 0.5 mg/mL - Formulation 1 ............................................. 261
Glycopyrrolate Suspension 0.5 mg/mL - Formulation 2 ............................................. 262
Haloperidol Suspension 0.5 mg/mL ......................................................................... 263
Indomethacin Syrup 2 mg/mL ................................................................................ 264
Isoniazid Suspension 10 mg/mL .............................................................................. 265
Itraconazole Suspension 20 mg/mL - Formulation 1 ............................................... 266
Itraconazole Suspension 20 mg/mL - Formulation 2 ............................................... 268
Itraconazole Syrup 40 mg/mL ................................................................................ 269
Levodopa 5 mg/mL and Carbidopa 1.25 mg/mL Suspension - Formulation 1 ........ 271
Levodopa 5 mg/mL and Carbidopa 1.25 mg/mL Suspension - Formulation 2 ........ 272
Levofoxcin Suspension 50 mg/mL - Formulation 1 .................................................... 273
Levofoxcin Suspension 50 mg/mL - Formulation 2 .................................................... 274
Levothyroxine Sodium Solution 25 mcg/mL ............................................................ 275
Lisinopril Suspension 1 mg/mL - Formulation 1 ....................................................... 276
Lisinopril Suspension 1 mg/mL - Formulation 2 ....................................................... 277
Lisinopril Syrup 1 mg/mL ....................................................................................... 278
Lisinopril Syrup 2 mg/mL ....................................................................................... 279
Lorazepam Suspension 1 mg/mL ............................................................................ 280
Mercaptopurine Suspension 10 mg/mL ................................................................... 281
Mercaptopurine Syrup 50 mg/mL ............................................................................ 282
Methadone Hydrochloride Suspension 10 mg/mL .................................................. 284
Methotrexate Syrup 2 mg/mL ................................................................................ 285
Midazolam Hydrochloride Gelatin 1 mg/mL ............................................................ 287
Midazolam Hydrochloride Gelatin 2 mg/mL ............................................................ 288
Midazolam Hydrochloride Suspension 1 mg/mL ..................................................... 289
Midazolam Hydrochloride Syrup 2.5 mg/mL ........................................................... 290
Morphine Hydrochloride Solution 1 mg/mL ............................................................ 291
Morphine Sulfate Solution 0.4 mg/mL* .................................................................292
Mycophenolate Mofetil Suspension 50 mg/mL....................................................293
Mycophenolate Mofetil Suspension 100 mg/mL ..................................................294
Naproxen Suspension 25 mg/mL........................................................................296
Nitrofurantoin Suspension 2 mg/mL...................................................................297
Nizatidine Solution 2.5 mg/mL...........................................................................298
Ondansetron Hydrochloride Suspension 0.8 mg/mL - Formulation 1..............300
Ondansetron Hydrochloride Suspension 0.8 mg/mL - Formulation 2 .......301
Oseltamivir Phosphate Suspension 6 mg/mL......................................................302
Oseltamivir Phosphate Syrup 6 mg/mL..............................................................303
Oseltamivir Phosphate Syrup 15 mg/mL............................................................304
Phenobarbital Suspension 9 mg/mL..................................................................306
Phenobarbital Suspension 9.3 mg/mL................................................................308
Phenobarbital Suspension 10 mg/mL................................................................309
Phenobarbital Suspension 15 mg/mL................................................................310
Phenytoin Suspension 15 mg/mL.......................................................................311
Potassium Chloride Syrup 1 mEq/mL.................................................................312
Prednisolone Disodium Phosphate Solution 10 mg/mL.................................313
Prednisolone Sodium Phosphate Suspension 1.4 mg/mL...................................315
Prednisone Syrup 0.5 mg/mL.............................................................................316
Pregabalin Suspension 20 mg/mL......................................................................317
Propranolol Hydrochloride Suspension 0.5 mg/mL.........................................318
Propranolol Hydrochloride Suspension 1 mg/mL...............................................319
Propranolol Hydrochloride Suspension 5 mg/mL...............................................320
Rufinamide Suspension 40 mg/mL....................................................................321
Sertraline Hydrochloride Suspension 10 mg/mL................................................322
Sildenafil Citrate Suspension 2.5 mg/mL.........................................................292
Sertraline Hydrochloride Suspension 1 mg/mL..................................................294
Sertraline Hydrochloride Suspension 0.5 mg/mL...............................................296
Sildenafil Citrate Suspension 10 mg/mL............................................................297
Sildenafil Citrate Suspension 5 mg/mL...............................................................298
Sildenafil Citrate Suspension 0.8 mg/mL............................................................299
Sildenafil Citrate Suspension 0.5 mg/mL............................................................300
Sildenafil Citrate Suspension 0.3 mg/mL.............................................................301
Sildenafil Citrate Suspension 0.1 mg/mL.............................................................302
Sildenafil Citrate Suspension 0.05 mg/mL..........................................................303
Sildenafil Citrate Suspension 0.02 mg/mL..........................................................304
Sildenafil Citrate Suspension 0.01 mg/mL...........................................................305
Sildenafil Citrate Suspension 0.005 mg/mL........................................................306
Sildenafil Citrate Suspension 0.002 mg/mL........................................................307
Sildenafil Citrate Suspension 0.001 mg/mL........................................................308
Sildenafil Citrate Suspension 0.0005 mg/mL.....................................................309
Sildenafil Citrate Suspension 0.0002 mg/mL.....................................................310
Sildenafil Citrate Suspension 0.0001 mg/mL......................................................311
Sildenafil Citrate Suspension 0.00005 mg/mL....................................................312
Sildenafil Citrate Suspension 0.00002 mg/mL....................................................313
Sildenafil Citrate Suspension 0.00001 mg/mL....................................................314
Sildenafil Citrate Suspension 0.000005 mg/mL..................................................315
Sildenafil Citrate Suspension 0.000001 mg/mL..................................................316
Sildenafil Citrate Suspension 0.0000005 mg/mL..............................................317
Sildenafil Citrate Suspension 0.0000001 mg/mL...............................................318
Sildenafil Citrate Suspension 0.00000005 mg/mL...........................................319
Sildenafil Citrate Suspension 0.00000001 mg/mL............................................320
Sildenafil Citrate Suspension 0.000000005 mg/mL.........................................321
Sildenafil Citrate Suspension 0.000000001 mg/mL.........................................322
Sildenafil Citrate Suspension 0.0000000005 mg/mL......................................323
Sildenafil Citrate Suspension 0.0000000001 mg/mL........................................324
Sildenafil Citrate Suspension 0.00000000005 mg/mL......................................325
Sildenafil Citrate Suspension 0.00000000001 mg/mL.......................................326
Sildenafil Citrate Suspension 0.000000000005 mg/mL....................................327
Sildenafil Citrate Suspension 0.000000000001 mg/mL....................................328
Sildenafil Citrate Suspension 0.0000000000005 mg/mL................................329
Sildenafil Citrate Suspension 0.0000000000001 mg/mL..................................330
Sildenafil Citrate Suspension 0.00000000000005 mg/mL................................331
Sildenafil Citrate Suspension 0.0000000000001 mg/mL................................332
Sildenafil Citrate Suspension 0.00000000000005 mg/mL................................333
Sildenafil Citrate Suspension 0.00000000000001 mg/mL................................334
Sildenafil Citrate Suspension 0.000000000000005 mg/mL..............................335
Sildenafil Citrate Suspension 0.000000000000001 mg/mL.............................336
Sildenafil Citrate Suspension 0.0000000000000005 mg/mL.............................337
Sildenafil Citrate Suspension 0.0000000000000001 mg/mL............................338
Sildenafil Citrate Suspension 0.00000000000000005 mg/mL..........................339
Sildenafil Citrate Suspension 0.00000000000000001 mg/mL..........................340
Sildenafil Citrate Suspension 0.000000000000000005 mg/mL........................341
Sildenafil Citrate Suspension 0.000000000000000001 mg/mL........................342
Sildenafil Citrate Suspension 0.0000000000000000005 mg/mL....................343
Sildenafil Citrate Suspension 0.0000000000000000001 mg/mL.....................344
Sildenafil Citrate Suspension 0.00000000000000000005 mg/mL...................345
Sildenafil Citrate Suspension 0.00000000000000000001 mg/mL..................346
Appendix A. An Overview: USP <795> Pharmaceutical Compounding – Nonsterile Preparations.......................... 349
Appendix B. Looking Ahead: USP <795> Pharmaceutical Compounding – Nonsterile Preparations Revisions .................. 351
Appendix C. ASHP Technical Assistance Bulletin on Compounding Nonsterile Products in Pharmacies ......................................................... 355
Appendix D. ASHP Guidelines on Pharmacy-Prepared Ophthalmic Products ............................................................................. 369
Appendix E. ASHP Standardize 4 Safety List of Compounded Oral Liquid Standardized Concentrations ............................................. 373
When we kicked off preparations for this fourth edition of *Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients* in April 2019, we were anticipating publication of the major revision of United States Pharmacopoeia (USP) General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations. The revised chapter was published on June 1, 2019, with an expected official date of December 1, 2019. After reviewing the revisions in the chapter, we decided to introduce additional fields in each monograph to address the requirements of the revised USP <795>. The new fields include “Equipment and Supplies,” “Quality-Control Procedures,” “Labeling Requirements,” “Study Container Type,” “Referenced Manufacturers” (of the various ingredients and vehicles), and “Stability-Indicating Study” (to indicate whether the study falls into that category). Instead of the “Expiration Date” field, we differentiated stability dating from beyond-use date (BUD). Inclusion of these fields necessitated that we perform a comprehensive review of the references in our existing monographs as well as review them for the new formulations.

After two levels of appeals on the BUD provisions, on March 12, 2020, the USP Appeals Panel granted the appeals to USP <795> and recommended that the Compounding Expert Committee further deliberate on the issues raised concerning the BUD provisions. Hence, the current official USP <795> (last revised in 2014) remains official until further notice. Despite the USP decision, we decided to add all but one of the new fields mentioned previously to each monograph in this fourth edition because most of the new requirements in the chapter were not the focus of the appeal. We have excluded the BUD field from this current edition until we receive a final verdict from USP. We included a “Storage Conditions/Stability” field instead of “Expiration Date.” Note that although the physical description of the final compounded nonsterile preparation (CNSP) is required in the Master Formulation Record, this information is not included in each monograph in this book because the physical description often was not documented in the reference, and the color of the CNSP may change depending on the manufacturer of the tablets or capsules used for the formulation.

We have taken a conservative approach and recommend that a powder containment hood be used when preparing all formulations that require active pharmaceutical ingredient (API) powder and when opening capsules or triturating tablets, as per the revised USP <795>. Similarly, we recommend that a containment-primary engineering control (C-PEC), such as a containment ventilated enclosure (CVE) or biological safety cabinet (BSC), be used when compounding antineoplastic drugs and other hazardous drugs on the National Institute for Occupational Safety and Health (NIOSH) list. The exact device used during compounding depends on the risk assessment performed by an individual institution for each hazardous drug. A summary of the new requirements in the remanded USP <795> is included in Appendix B (BUD revisions not included).

The fourth edition of this book thus represents countless hours of recreating the book from scratch, and it now contains a total of 312 formulations—triple the number in the
first edition, which contained 103 formulations. As with the previous three editions, we performed a comprehensive literature search to identify new drugs with extemporaneous formulations and new formulations of drugs that are in the previous editions. This effort resulted in 129 new formulations, 47 of which are new drugs and 36 of which are new concentrations of drugs that were in the previous edition. The remaining 46 formulations are different formulations of drugs that appeared in the previous editions. Introduced in this edition are formulations that use a new vehicle, SyrSpend SF, and API instead of tablets or capsules. Because API is pure drug with no other excipients, as in tablets and capsules, stability of the formulation is not affected if the API is acquired from a different vendor, whereas stability of the formulation could theoretically be affected by different excipients if a different manufacturer is used for tablets or capsules.

We also deleted 14 formulations in this edition: 3 because of active ingredient no longer commercially available (bacitracin ophthalmic solution 9,600 units/mL, fumagillin ophthalmic solution 70 mcg/mL, and ranitidine hydrochloride syrup 15 mg/mL); 3 because of diluent used no longer commercially available (Roxane diluent for atenolol syrup 2 mg/mL, flecainide acetate syrup 5 mg/mL, and propranolol hydrochloride syrup 1 mg/mL); 7 because of inadequate stability data when the reference articles were reviewed with more stringent criteria (caffeine citrate solution 10 mg/mL, caffeine citrate syrup 20 mg/mL, cimetidine syrup 60 mg/mL, potassium perchlorate solution 13.3 mg/mL, tacrolimus cream 0.1%, topiramate suspension 6 mg/mL, and vorinostat suspension 50 mg/mL); and 1 because the vehicle (aromatic elixir) is too difficult to compound (cyclophosphamide elixir 2 mg/mL). In most cases, alternatives are available for these deleted formulations, either as commercially available liquid formulation and/or availabilities of other formulations in this book. We are happy to note that regulatory requirements to include pediatric assessment for new drug applications have slowly narrowed the gap for appropriate pediatric pharmaceutical formulations. This change is evident in the fact that 7 drugs representing 13 formulations have been reclassified to the “Commercially Available Products” section of this book since its last publication 4 years ago compared with 4 medications (consisting of 9 formulations) over a 6-year period with the third edition. On the other hand, one drug, granisetron, has been reclassified from the “Commercially Available Products” section because the commercially available oral solution was discontinued from the market.

Again, only formulations that have published and documented stability data are included. We continue to provide multiple published formulations of medications with the same concentration as well as formulations with various concentrations so that readers can choose the most appropriate formulation for their patients or institutions.

In the third edition of this book, we included the Michigan Pediatric Safety Collaboration’s Standardized Concentrations of Compounded Oral Liquids in the appendix and denoted those concentrations with an asterisk (*) on the title of specific monographs. With the introduction of standardized concentrations of compounded oral liquids via the ASHP Standardize 4 Safety Initiative, we decided to include that national standard in the fourth edition instead. We have included the list of ASHP Standardize 4 Safety List of Compounded Oral Liquid Standardized Concentrations in Appendix E and denote the concentration and its corresponding formulation with an asterisk (*) on the title of the monograph.
We hope that this fourth edition of *Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients*, with its many major changes, will continue to serve as a trusted resource in addition to the USP monographs when you prepare extemporaneous formulations to meet your patients' needs!

Rita K. Jew
Winson Soo-Hoo
Elham Amiri
Jamie M. Gomes
LEGAL CONSIDERATIONS

Before a pharmacist engages in extemporaneous compounding activities, it is important to understand the legal implications. Extemporaneous formulations compounded by a pharmacist and intended for use in humans are exempt from three provisions (section 501 (a)(2)(B): good manufacturing practice; section 502 (f)(1): labeling of drugs with adequate directions for use; and section 505: approval of drugs under new drug applications or abbreviated new drug applications) of the Food, Drug, and Cosmetic (FD&C) Act provided that the following conditions of section 503A are met:

1. The drug product is compounded upon receipt of a valid prescription order for an individual patient or in limited quantities before receipt of a valid prescription order based on a history of the licensed pharmacist receiving prescription orders for an individual patient.

2. The drug product is compounded by a licensed pharmacist in a state-licensed pharmacy or a federal facility.

3. The drug product is compounded in compliance with USP <795> using USP/National Formulary (NF) bulk drug substances, a component of a US Food and Drug Administration (FDA)-approved human drug product, or bulk drug substances on a list developed by the FDA through regulation.

4. The bulk drug substances used are from a manufacturer registered under section 510 of the FD&C Act and have valid certificates of analysis (COA).

5. The ingredients used (other than bulk drug substances) comply with the standards of an applicable USP or NF monograph and USP chapters on pharmacy compounding.

6. The drug product is not on the list of drug products withdrawn or removed from the market because it has been found to be unsafe or not effective.

7. The drug products that are essentially copies of commercially available drug products are not compounded regularly or in inordinate amounts by a licensed pharmacist.

8. The drug product is not identified by FDA regulation as presenting demonstrable difficulties for compounding that would result in an adverse effect on the safety or effectiveness of that drug product.

9. The compounded drug products are not distributed out of state in more than the FDA-allowed maximum percentage of total prescription orders by the licensed pharmacist or licensed pharmacy unless the drug product is compounded in a state that has entered into a memorandum of understanding with the FDA.

EXTEMPORANEOUS COMPOUNDING

Appendix A outlines the general principles of compounding nonsterile preparations as described in USP <795> to ensure that preparations compounded are of appropriate strength, quality, and purity. In addition, USP <800> should be consulted for up-to-date standards for handling and compounding of hazardous drugs.
USP defines stability of an oral liquid formulation as “the extent to which the preparation retains, within specified limits, and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.”

When evaluating the stability of a formulation, its chemical, physical, and microbiological stability must be considered. In addition to the properties of the ingredients used to compound the formulation, environmental factors such as temperature, radiation, light, air, and humidity can affect the stability of an extemporaneous formulation. The overall stability of an extemporaneously prepared formulation can also be affected by particle size, pH, the water and solvents used, the container used, and the presence of other chemicals. For this reason, alterations of the formulations listed in this book are strongly discouraged. The addition of flavoring agents may affect the pH and other chemical properties of the formulation and thus affect the shelf life of the formulation. Therefore, if a flavoring agent is needed, it should be added to the dose of the medication immediately before its administration. Flavoring agents should not be added to the entire bottle of the solution, suspension, or syrup unless testing has been performed to confirm the overall stability of the formulation.

What follows are brief definitions of preparation methods and techniques as well as packaging and storage requirements of extemporaneously prepared formulations.

**DEFINITIONS**

**Elixir**

An elixir is a clear, sweetened, alcohol-containing solution that is used mainly for drugs that are insoluble in water alone. It is usually not as sweet and is less viscous than a syrup. The alcohol content of an elixir makes it a less desirable vehicle for preparing extemporaneous formulations in pediatric patients.

**Levigating Agent**

A levigating agent is used to moisten and soften a tablet to facilitate preparation of a liquid, especially when a large number of tablets is required or the tablets are extremely difficult to crush. Preferably, the vehicle used for the product is used as the levigating agent.

**Simple Syrup**

Simple syrup is a sucrose solution that is made with purified water.

**Solution**

A solution is a liquid that contains medication that is dissolved in water or other liquids.

**Suspending Agent**

A suspending agent is used to prevent agglomeration of the dispersed particles and increase viscosity of the liquid. Use of the agent allows for slow settling of the drug particles to ensure uniform distribution and accurate measurement of the dose.

**Suspension**

A suspension is a dispersion that contains fine, insoluble particles suspended in a liquid medium.
**Syrup**

A syrup is a concentrated solution of sugar, such as sucrose, in water or other aqueous liquid used as a vehicle to mask the taste of drugs. The high concentration of sugar in syrups also provides preservative properties.

**PREPARATION METHODS**

The preparation methods of extemporaneous formulations are often determined by the source of the ingredients in the formulation (ie, injectable, tablet or capsule, oral liquid). In general, an injectable drug can be measured accurately using a syringe. Oral liquid should be measured using a graduated cylinder. Graduations on dispensing bottles are not accurate and should not be used as a measuring device unless they are calibrated.

When using tablets or capsules to prepare a formulation, the tablets or capsules must be thoroughly and uniformly pulverized by trituration. Trituration is a process in which substances are reduced to fine particles in a mortar with a pestle. Small particles are more easily dispersed throughout the vehicle, settle less quickly, and are less likely to cake once they settle. Therefore, particles to be suspended in the vehicle must be small and uniform to ensure consistency and accuracy of dosing. Once triturated, the powder should be levigated with a levigating agent. The levigating agent is selected on the basis of its ability to form a smooth paste with the powder to be levigated as well as its compatibility with the substance. The vehicle should be added to the paste in increasing amounts and mixed thoroughly. The mixture should be transferred to a graduated cylinder. A small amount of vehicle should be used to rinse the mortar and pestle, and the solution then should be poured into the graduated cylinder. The volume should be adjusted in the graduated cylinder to the quantity required for the formulation. The final product should be placed into the dispensing container.

Ideally, a light-resistant container should be used to protect the contents. It is also important to ensure that the storage conditions of extemporaneous formulations are appropriate. Refrigerator temperature should be maintained between 2°C and 8°C (36°F to 45°F) for formulations that require refrigeration. Formulations to be stored at room temperature should be maintained between 20°C and 25°C (68°F to 77°F).

For a comprehensive overview of necessary considerations when preparing extemporaneous formulations, please refer to the ASHP Technical Assistance Bulletin on Compounding Nonsterile Products in Pharmacies (Appendix C) and the ASHP Guidelines on Pharmacy-Prepared Ophthalmic Products (Appendix D).

**REFERENCES**


ACKNOWLEDGMENTS

We would like to recognize the following individuals for proofreading of the final content before publication:

**Bethany Baker, PharmD, MHA**
Director of Pharmacy Clinical Services
Children’s Mercy Kansas City
Kansas City, MO

**Michael Bunn, PharmD, MS**
Product Strategy Senior Advisor
Express Scripts
Pittsburgh, PA

**Michael C. Dejos, PharmD, BCPS, CHOP, LSSBB, DPLA**
System Medication Safety Officer
Methodist Le Bonheur Healthcare
Memphis, TN

**Allison R. King, PharmD, FASHP**
Investigational Drug Pharmacist
PGY1 Residency Coordinator
Children’s Mercy Kansas City
Kansas City, MO

**Colleen D. Lauster, PharmD, BCPS, CDCES**
Ambulatory Care Clinical Pharmacist
Beaumont Health
Royal Oak, MI

**Janet Misko, RPh**
Senior Software Quality Assurance Analyst
McKesson Pharmacy Systems
Pittsburgh, PA