

Third Edition

Extemporaneous Formulations

for

**Pediatric, Geriatric,
and Special Needs
Patients**

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Table of Contents

Preface.....	ix
--------------	----

Introduction.....	xi
-------------------	----

Part I: Elixir/Solution/Suspension/Syrup

Acetazolamide Suspension 25 mg/mL*	1
Acetylcysteine Solution 10 mg/mL.....	2
Acetylcysteine Solution 100 mg/mL.....	3
Allopurinol Suspension 20 mg/mL*.....	4
Amiodarone Suspension 5 mg/mL*.....	5
Amitriptyline Syrup 1 mg/mL*.....	6
Amlodipine Suspension 1 mg/mL*	7
Amphetamine and Dextroamphetamine (Adderall) Suspension 1 mg/mL*	8
Aprepitant Suspension 20 mg/mL*.....	9
Atenolol Syrup 2 mg/mL—Formulation 1*	10
Atenolol Syrup 2 mg/mL—Formulation 2*	11
Azathioprine Suspension 50 mg/mL*.....	12
Baclofen Suspension 10 mg/mL.....	13
Baclofen Syrup 5 mg/mL*.....	14
Benazepril Hydrochloride Suspension 2 mg/mL	15
Bethanechol Solution 1 mg/mL	16
Bethanechol Suspension 5 mg/mL*	17
Buspirone Hydrochloride Syrup 2.5 mg/mL*.....	18
Busulfan Syrup 2 mg/mL.....	19
Candesartan Suspension 1 mg/mL	20
Captopril Solution 1 mg/mL*.....	21
Captopril Suspension 0.75 mg/mL	22
Captopril Suspension 1 mg/mL*.....	23
Carvedilol Suspension 0.1 mg/mL.....	24
Carvedilol Suspension 1.67 mg/mL*	25
Chloroquine Phosphate Suspension 15 mg/mL	26
Chloroquine Phosphate Syrup 16.7 mg/mL*	27
Chlorpromazine Hydrochloride Syrup 100 mg/mL	28
Clonazepam Suspension 0.1 mg/mL*	29
Clonidine Suspension 0.01 mg/mL.....	30
Clonidine Syrup 0.1 mg/mL.....	31
Clopidogrel Suspension 5 mg/mL*.....	32
Codeine Phosphate Syrup 3 mg/mL.....	33

Cyclophosphamide Elixir 2 mg/mL	34
Cyclophosphamide Suspension 10 mg/mL*	35
Dantrolene Syrup 5 mg/mL*	36
Dapsone Suspension 2 mg/mL*	37
Dapsone Syrup 2 mg/mL*	38
Diltiazem Hydrochloride Suspension 12 mg/mL*	39
Dipyridamole Suspension 10 mg/mL*	40
Disopyramide Syrup 1 mg/mL	41
Disopyramide Syrup 10 mg/mL*	42
Dolasetron Suspension 10 mg/mL*	43
Ethacrynic Acid Solution 1 mg/mL*	44
Etoposide Solution 10 mg/mL.....	45
Flecainide Acetate Suspension 20 mg/mL*	46
Flecainide Acetate Syrup 5 mg/mL.....	47
Flucytosine Suspension 10 mg/mL*	48
Flucytosine Suspension 50 mg/mL#	49
Hydralazine Suspension 4 mg/mL*	50
Hydrocortisone Suspension 1 mg/mL	51
Hydrocortisone Suspension 2 mg/mL*	52
Hydroxyurea Syrup 100 mg/mL*.....	53
Hypromellose Suspension 10 mg/mL	54
Indinavir Liquid 10 mg/mL.....	55
Isradipine Syrup 1 mg/mL*	57
Ketoconazole Suspension 20 mg/mL*	58
Labetalol Hydrochloride Suspension 40 mg/mL.....	59
Labetalol Hydrochloride Syrup 10 mg/mL*	60
Lamotrigine Suspension 1 mg/mL*	61
Lansoprazole Solution 3 mg/mL.....	62
Lansoprazole Suspension 3 mg/mL.....	63
Levothyroxine Solution 25 mcg/mL*	64
Lisinopril Suspension 1 mg/mL.....	65
Lisinopril Syrup 1 mg/mL.....	66
Lisinopril Syrup 2 mg/mL*	67
Losartan Suspension 2.5 mg/mL*	68
Melatonin 1 mg/mL and Pyridoxine Hydrochloride 3.3 mg/mL Suspension	69
Melatonin Suspension 1 mg/mL	70
Methylcellulose Suspension 10 mg/mL (1%).....	71
Methyldopa Syrup 50 mg/mL	72
Metolazone Suspension 1 mg/mL*	73
Metoprolol Tartrate Suspension 10 mg/mL*	74
Metronidazole Suspension 10 mg/mL.....	75
Metronidazole Suspension 50 mg/mL*	76
Metronidazole Syrup 5 mg/mL.....	77

Mexiletine Solution 10 mg/mL*	78
Midazolam Gelatin 1 mg/mL	79
Midazolam Gelatin 2 mg/mL	80
Moxifloxacin Suspension 20 mg/mL	81
Naratriptan Suspension 0.5 mg/mL	82
Nifedipine Solution 10 mg/mL	83
Nifedipine Suspension 1 mg/mL	84
Olmesartan Suspension 2 mg/mL	85
Omeprazole Solution 2 mg/mL	86
Oxandrolone Suspension 1 mg/mL	87
Oxandrolone Suspension 2 mg/mL	88
Pantoprazole Solution 2 mg/mL—Formulation 1*	89
Pantoprazole Solution 2 mg/mL—Formulation 2*	90
Pentoxifylline Solution 20 mg/mL	91
Phenoxybenzamine Solution 2 mg/mL*	92
Potassium Perchlorate Solution 13.3 mg/mL	93
Propylthiouracil Suspension 5 mg/mL*	94
Pyrazinamide Suspension 10 mg/mL	95
Pyrazinamide Syrup 100 mg/mL*	96
Pyrimethamine Suspension 2 mg/mL*	97
Quinapril Syrup 1 mg/mL	98
Quinidine Sulfate Suspension 10 mg/mL*	99
Rifabutin Suspension 20 mg/mL*	100
Rifampin Suspension 25 mg/mL*	101
Rifampin Syrup 10 mg/mL	102
Rifaximin Suspension 20 mg/mL*	103
Sodium Phenylbutyrate Suspension 200 mg/mL	104
Spironolactone 5 mg/mL and Hydrochlorothiazide 5 mg/mL Suspension*	105
Spironolactone Suspension 25 mg/mL	106
Spironolactone Syrup 2.5 mg/mL	107
Spironolactone Syrup 5 mg/mL*	108
Spironolactone Syrup 10 mg/mL	109
Sulfasalazine Suspension 100 mg/mL*	110
Sumatriptan Suspension 5 mg/mL	111
Sunitinib Suspension 10 mg/mL	112
Tacrolimus Suspension 0.5 mg/mL*	113
Tacrolimus Suspension 1 mg/mL	114
Tadalafil Suspension 5 mg/mL	115
Temozolomide Suspension 10 mg/mL	116
Terbinafine Suspension 25 mg/mL	118
Terbutaline Syrup 1 mg/mL*	119
Tetracycline Suspension 25 mg/mL*	120
Thalidomide Suspension 20 mg/mL	121

Thioguanine Suspension 20 mg/mL*	122
Tiagabine Suspension 1 mg/mL*	123
Tinidazole Syrup 66.7 mg/mL	124
Topiramate Suspension 6 mg/mL*	125
Tramadol 7.5 mg/mL and Acetaminophen 65 mg/mL Suspension	126
Tramadol Suspension 5 mg/mL*	127
Ursodiol Suspension 25 mg/mL	128
Ursodiol Suspension 50 mg/mL	129
Ursodiol Syrup 60 mg/mL [#]	130
Valacyclovir Suspension 50 mg/mL*	131
Valsartan Suspension 4 mg/mL*	132
Vancomycin Syrup 25 mg/mL*	133
Verapamil Suspension 50 mg/mL*	134
Vorinostat Suspension 50 mg/mL	135
Ziprasidone Syrup 2.5 mg/mL	136
Zonisamide Syrup 10 mg/mL*	137

Part II: Topical/Ophthalmic Solution

Bacitracin Ophthalmic Solution 9,600 units/mL	141
Cefazolin Ophthalmic Solution 33 mg/mL	142
Cidofovir Intravitreal Solution 0.2 mg/mL	143
Cidofovir Intravitreal Solution 8.1 mg/mL	144
Fumagillin Ophthalmic Solution 70 mcg/mL	145
Ganciclovir Intravitreal Solution 20 mg/mL	146
Gentamicin Ophthalmic Solution 13.6 mg/mL (Fortified)	147
LET (Lidocaine 4%/Racepinephrine 0.225%/ Tetracaine 0.5%) Topical Solution	148
Tobramycin Ophthalmic Solution 13.6 mg/mL (Fortified)	149
Tobramycin Ophthalmic Solution 15 mg/mL	150
Vancomycin Ophthalmic Solution 31 mg/mL	151
Voriconazole Ophthalmic Solution 1 mg/mL	152
Voriconazole Ophthalmic Solution 10 mg/mL	153

Part III: Commercially Available Products

Alprazolam Suspension 1 mg/mL	157
Caffeine Citrate Solution 10 mg/mL	158
Caffeine Citrate Solution 20 mg/mL	159
Caffeine Citrate Syrup 20 mg/mL	160
Carbamazepine Syrup 40 mg/mL	161
Cimetidine Syrup 60 mg/mL	162

Ciprofloxacin Suspension 50 mg/mL	163
Enalapril Suspension 0.1 mg/mL.....	164
Enalapril Suspension 1 mg/mL—Formulation 1	165
Enalapril Suspension 1 mg/mL—Formulation 2	166
Famotidine Suspension 8 mg/mL.....	167
Famotidine Syrup 8 mg/mL.....	168
Fluconazole Solution 1 mg/mL.....	169
Fluoxetine Syrup 1 mg/mL.....	170
Fluoxetine Syrup 2 mg/mL.....	171
Furosemide Suspension 2 mg/mL.....	172
Gabapentin Suspension 100 mg/mL.....	173
Glycopyrrolate Suspension 0.5 mg/mL.....	174
Granisetron Hydrochloride Suspension 0.05 mg/mL.....	175
Granisetron Hydrochloride Syrup 0.2 mg/mL.....	176
Indomethacin Syrup 2 mg/mL.....	177
Itraconazole Suspension 20 mg/mL.....	178
Itraconazole Syrup 40 mg/mL.....	180
Levodopa 5 mg/mL and Carbidopa 1.25 mg/mL Suspension.....	182
Levofloxacin Suspension 50 mg/mL.....	183
Mercaptopurine Syrup 50 mg/mL.....	184
Midazolam Syrup 2.5 mg/mL.....	185
Morphine Hydrochloride Solution 1 mg/mL.....	186
Mycophenolate Mofetil Suspension 50 mg/mL.....	187
Mycophenolate Mofetil Syrup 100 mg/mL.....	188
Nizatidine Solution 2.5 mg/mL.....	190
Ondansetron Suspension 0.8 mg/mL.....	191
Oseltamivir Syrup 6 mg/mL*.....	192
Oseltamivir Syrup 15 mg/mL.....	193
Phenobarbital Suspension 10 mg/mL.....	194
Prednisolone Disodium Phosphate Solution 10 mg/mL.....	195
Prednisone Syrup 0.5 mg/mL.....	196
Propranolol Syrup 1 mg/mL.....	197
Ranitidine Syrup 15 mg/mL.....	198
Rufinamide Suspension 40 mg/mL.....	199
Sildenafil Suspension 2.5 mg/mL*.....	200
Sotalol Suspension 5 mg/mL*.....	201
Tacrolimus Cream 0.1%.....	202
Theophylline Suspension 5 mg/mL.....	203
Trimethoprim Syrup 10 mg/mL.....	204
Valganciclovir Suspension 30 mg/mL.....	205
Valganciclovir Suspension 60 mg/mL.....	206
Voriconazole Suspension 40 mg/mL.....	207
Zidovudine Syrup 10 mg/mL.....	208

Appendix A: An Overview of USP 795 Pharmaceutical Compounding— Nonsterile Preparations	211
Appendix B: ASHP Technical Assistance Bulletin on Compounding Nonsterile Products in Pharmacies	212
Appendix C: ASHP Guidelines on Pharmacy-Prepared Ophthalmic Products	225
Appendix D: Michigan Pediatric Safety Collaboration: Standardized Concentrations of Compounded Oral Liquids	229

Preface

Since the inaugural publication of *Extemporaneous Formulations* in 2003, legislation has been introduced to boost pediatric drug research. Following the Food and Drug Administration (FDA) Modernization Act in 1997 and the Best Pharmaceuticals for Children Act in 2002, the Pediatric Research Equity Act in 2003 ensured that new drugs intended for use in children would be studied in children. This Act was extended under the FDAAmendment Act (FDAAA) of 2007 to require sponsors to submit a pediatric assessment with every new drug application to the FDA. The results of the pediatric assessment may require that pediatric studies be submitted before the approval of the adult application or that pediatric studies be deferred until after adult approval as a post-marketing requirement. In addition, the Best Pharmaceuticals for Children Act was also extended for 5 years under the FDAAA. Nonetheless, a gap still exists for pharmaceuticals with appropriate pediatric formulations. There continues to be a need for pharmacists to prepare extemporaneous formulations. This is evident by the fact that 39 new formulations are added to this third edition, and only five existing formulations are reclassified to the “Commercially Available Products” section.

On the other hand, legislation regarding compounding continues to evolve. After the contamination events at the New England Compounding Center as well as other less publicized incidents, the Compounding Quality Act (part of the Drug Quality and Security Act) was passed in 2013 to clearly define the difference between pharmacy compounding and manufacturing through the reinstatement of section 503A and introduction of section 503B of the Federal Food, Drug, and Cosmetic Act. The FDA's Pharmaceutical Compounding Advisory Committee now makes recommendations regarding lists of drugs 503A and 503B compounders may not make. The Committee continues to add to the list of drugs withdrawn/removed from market for safety or efficacy reasons. Therefore, it is important that pharmacists who compound extemporaneous formulations be vigilant in consulting with the list on a regular basis.¹ In addition, various states (such as California) have enacted or are in the process of enacting regulations regarding sterile and nonsterile compounding. It is imperative that pharmacists who compound extemporaneous formulations stay up-to-date with their state regulations.

As with the previous two editions, we performed a comprehensive literature search to identify news drugs with extemporaneous formulations and new formulations of drugs that are in the previous editions. This effort resulted in 39 new formulations. Because two formulations (ganciclovir syrup 100 mg/mL and norfloxacin suspension 20 mg/mL) were deleted due to the active ingredient being discontinued, our grand total is 197 formulations in the third edition. In addition, we have also updated two of the existing formulations—lan-soprazole solution 3 mg/mL with new expiration of 7 days and propranolol syrup 1 mg/mL with an alternative diluent. As stated earlier, five existing formulations are reclassified to the “Commercially Available Products” section—enalapril suspension 1 mg/mL, levodopa 5 mg/mL and carbidopa 1.25 mg/mL suspension, mercaptopurine syrup 50 mg/mL, sildenafil suspension 2.5 mg/mL, and sotalol suspension 5 mg/mL. 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.

New to this edition, we have included the Michigan Pediatric Safety Collaboration's Standardized Concentrations of Compounded Oral Liquids in Appendix D. These standardized concentrations are also denoted by an asterisk (*) on the title of the monograph or (#) for alternative formulations. The Michigan Pediatric Safety Collaboration's standardization project marked the first attempt to standardize concentrations of compounded oral liquids in the United States. This initiative received the Cheers Award from the Institute for Safe Medication Practice (ISMP) in 2014 for the attempt to improve medication safety in pediatric patients in the state of Michigan. Note that not all of the formulations from this initiative are included in this book. Standardized concentrations are excluded mostly because they are supported only by tertiary references that are not substantiated by primary references. Nonetheless, we recognized that this is an extremely important first step to standardization of compounded oral liquids to improve the safety of the pediatric patients we care for, and, hence, we are committed to embrace and promote these standardized concentrations. Finally, we are excited to note that as part of its Safe Use Initiative to reduce preventable harm from medications, the FDA has awarded a 3-year contract to ASHP to develop and implement national standardized concentrations for intravenous and oral liquid medications. We will be sure to include these standardized concentrations in the next edition of this book!

As we embark on the Pharmacy Practice Model Initiative journey and expand the roles and responsibilities of our pharmacy technicians, we have recruited a certified technician as our co-author to help compile new formulations for this book. It is our hope that more pharmacy technicians will take on the advance activities and responsibilities of helping shape best practices in compounding extemporaneous formulations for our patients.

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Reference

1. http://www.ecfr.gov/cgi-bin/text-idx?SID=817cc7ee48b2145a155ade1144a24aec&mc=true&node=se21.4.216_124&rgn=div8

Introduction

Legal Considerations

Before a pharmacist engages in extemporaneous compounding activities, it is important to understand the legal implications. Extemporaneous formations compounded by a pharmacist, 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 met¹:

- The drug product is compounded upon the receipt of a valid prescription order for an individual patient or in limited quantities before the receipt of a valid prescription order based on a history of the licensed pharmacist receiving prescription orders for an individual patient.
- The drug product is compounded by a licensed pharmacist in a state licensed pharmacy or a federal facility.
- The drug product is compounded in compliance with the United States Pharmacopoeia (USP) 795 using USP/NF bulk drug substances, a component of an FDA-approved human drug product or bulk drug substances on a list developed by FDA through regulation.
- The bulk drug substances used is from a manufacturer registered under section 510 of the FD&C Act.
- The bulk drug substances used have valid certificates of analysis.
- The ingredients (other than bulk drug substances) used complies with the standards of an applicable USP or NF monograph and USP chapters on pharmacy compounding.
- 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.
- The drug products that are essentially copies of commercially available drug products are not compounded regularly or in inordinate amounts by a licensed pharmacist.
- The drug product is not identified by FDA regulation to present demonstrable difficulties for compounding that would result in an adverse effect on the safety or effectiveness of that drug product.
- The compounded drug products are not distributed out of state in more than 5% of the 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 FDA.

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, the recently published 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.”² 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, temperature, radiation, light, air, and humidity are environmental factors that 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.³ For this reason, alterations of the formulations listed in this handbook are strongly discouraged. The addition of flavoring agents may affect the pH and other chemical properties of the formulation, hence affecting 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 elixir, solution, or suspension unless testing has been performed to confirm the overall stability of the formulation.

The following is a brief description of the 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 less viscous than a syrup. The alcohol content of elixirs makes it a less desirable vehicle or base solution for preparing extemporaneous formulations in pediatric patients.

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

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

Solution—A solution is a liquid containing medication that is dissolved in water or other liquids.

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

Suspension—A suspension is a dispersion containing 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 or base solution to mask the taste of drugs. The high concentration of sugar in syrups provides preservative property as well.

Preparation Methods

The preparation methods of extemporaneous formulations are often determined by the source of the ingredients in the formulation (i.e., injectable, tablet or capsule, and oral liquid). In general, an injectable drug can be measured accurately by 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 or base solution, settle less quickly, and are less likely to cake once they settle. Therefore, particles to be suspended in the vehicle or base solution 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 and on its compatibility with the substance. The vehicle or base solution 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 or base solution should be used to rinse the mortar and the solution then 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 in the dispensing container.

Ideally, a light-resistant container should be used to protect the contents. It is also important to ensure that the storage condition of the extemporaneous formulations is appropriate. Refrigerator temperature should be maintained between 2 to 8°C (36 to 45°F) for formulations that require refrigeration. Formulations to be stored at room temperature should be maintained between 20 to 25°C (68 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 B) and the ASHP Guidelines on Pharmacy-Prepared Ophthalmic Products (Appendix C).

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Part I: Elixir/Solution/Suspension/Syrup
