EXTEMPORANEOUS FORMULATIONS
for Pediatric, Geriatric, and Special Needs Patients

4th EDITION

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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!

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INTRODUCTION

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 met1:

• 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.

• 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 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.2

• 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).

• 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.

• 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.3

• 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 as presenting 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 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


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