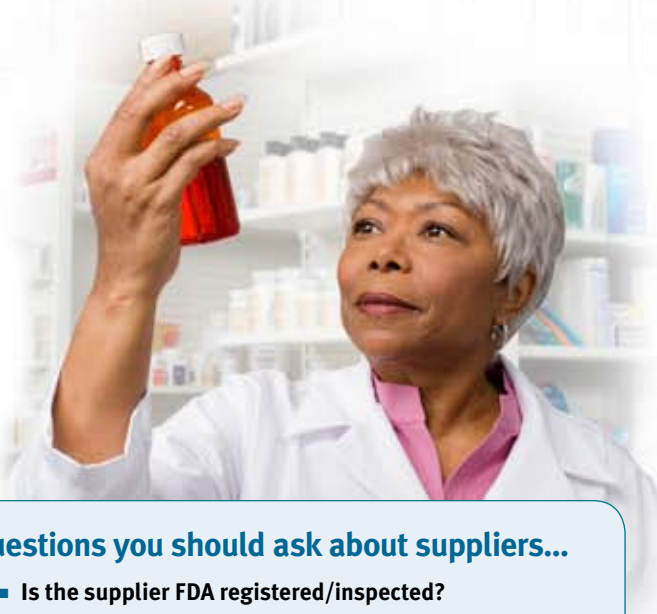


Compounding Pharmacy Resources

USP has always supported the critical role of pharmacy and continues that support today by establishing standards for the medicines that pharmacists use to manage their patients' diseases. USP sets the standards for compounded medicines under the guidance of volunteer pharmacy compounding experts from around the world. These volunteers direct the development and revision of monographs and General Chapters for both sterile and nonsterile compounded preparations. To support effective and accurate use of its standards, USP also offers pharmacy-dedicated publications, education opportunities, and additional resources that promote patient safety and quality care.



Your responsibility under the law...

Practitioners who compound should understand their responsibility to comply with USP standards. Pharmacy compounding is regulated by state boards of pharmacy, many of which require that pharmacists comply with general *USP–NF* standards relating to compounding practices. In addition, federal law requires that compounded preparations meet *USP–NF* standards, including ingredient standards and the “recipe” for the preparation. Despite the fact that the FDA does not directly regulate compounding, the requirements of the Federal Food Drug and Cosmetic Act apply equally to drugs that are compounded and to those that are manufactured. For compounding practitioners that means drugs sold in the United States that are recognized in official compendia (including *USP–NF*) must adhere to compendial standards for quality, purity, and strength, as well as packaging and labeling.

Questions you should ask about suppliers...

- Is the supplier FDA registered/inspected?
- Is the supplier reputable?
- Is the supplier licensed with applicable state and/or federal authorities?
- Do the supplier's substances meet *USP–NF* standards?
- If *USP–NF* grade substances are not available, is there a Certificate of Analysis?

USP Compounding Standards—Current and Future Initiatives

Current: *USP 31–NF 26*, official through April 30, 2009, features 129 monographs for compounded preparations. On June 1, 2008, revisions to **General Chapter <797> Pharmaceutical Compounding—Sterile Preparations** became official. In addition, the Compounding Pharmacy Expert Committee is working on merging **Chapter <1075> Good Compounding Practices** into **<795> Pharmaceutical Compounding—Nonsterile Preparations**. Other relevant chapters for pharmacists to be aware of include <1> Injections, <1121> Nomenclature, <1160> Pharmaceutical Calculations in Prescription Compounding, <1163> Quality Assurance in Pharmaceutical Compounding, and <1176> Prescription Balances and Volumetric Apparatus.

Future: USP looks forward to pharmacy’s active involvement in keeping these standards current by providing comments and data when revisions are needed. **By 2015, USP anticipates adding 100–200 nonsterile and sterile compounded preparation monographs.** USP is reaching out to the compounding community for assistance with these endeavors. Projects include stability studies by universities and laboratories, collaborating with pharmacies for formula validation, student projects for determining validity of formulations, collaborating with manufacturers for preparations no longer for sale in the US, and using published formulations with current references for monograph submission.

USP endorses accreditation of pharmacies by the Pharmacy Compounding Accreditation Board (PCAB) and is a member of its governing board. For information on PCAB, visit www.pcab.info.

Personnel Cleansing and Gowning

Personnel are critical keys to the maintenance of asepsis when carrying out their assigned responsibilities. They must be thoroughly trained in aseptic techniques and be highly motivated to maintain these standards each time they prepare a sterile product.

Prior to entering the buffer or clean area, operators should remove outer lab jackets or the like, makeup, and jewelry and should thoroughly scrub hands and arms to the elbow. After drying hands and arms they should properly don clean, nonshedding uniform components, including hair covers, shoe covers, knee-length coats or coveralls, and appropriate protective gloves, in that order. The coats should fit snugly at the wrists and be zipped or snapped closed in the front. Shoe covers should be donned so that feet then touch the floor only on the clean side of the bench or other demarcation. Face masks should be donned just before beginning activities in the DCCA to minimize airborne contaminants from coughing, sneezing, and talking.

When preparing CSPs in a vertical flow LAFW with a transparent shield between the face of the operator and sterile components, or when using an isolator, wearing a face mask is optional, but head and facial hair must be covered.

Ganciclovir Oral Suspension

SOURCE: USP

Ganciclovir Oral Suspension contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ganciclovir (C₈H₁₁N₅O₄). Prepare Ganciclovir Oral Suspension 100 mg per mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* (795)):

Ganciclovir	10 g
Vehicle for Oral Solution (regular or sugar-free), NF, a sufficient quantity to make	100 mL

If using Ganciclovir Capsules, empty the contents of the Capsules providing the appropriate amount of drug into a suitable mortar, or add Ganciclovir powder to the mortar. Add sufficient Vehicle to wet the powder, and work to a smooth paste. Add additional Vehicle to about half the final volume, and transfer the contents of the mortar to a calibrated bottle. Using additional Vehicle, rinse out the mortar, and transfer the contents, stepwise and quantitatively, to bring to final volume, and mix well.
Caution—Avoid skin contact or inhalation of ganciclovir by using protective gloves and a fume hood or surgical mask.

Packaging and storage—Preserve in tight, light-resistant containers. Store at controlled room temperature.

Labeling—Label it to state that it is to be well shaken before use, and to state the beyond-use date.

USP Reference standards (11)—USP Ganciclovir RS.

pH (791): between 4.0 and 5.0.

Beyond-use date: 90 days after the day on which it was compounded.

Assay—
25 mM Monobasic sodium phosphate buffer—Prepare a 25 mM monobasic sodium phosphate solution, and adjust with phosphoric acid to a pH of 2.5.

USP Official monographs and chapters provide essential information for

- Compounding sterile and nonsterile preparations-- including veterinary medications
- Beyond-use-dating, packaging and labeling preparations
- Preparing for internal, state, and the Joint Commission inspections

USP Compounding monographs are FDA-enforceable.

Education and Publications for the Compounding Professional

<797> Education Courses

USP supports the use of its standards with practical, timely training courses that are developed and delivered by USP experts.

- **Processing and Compliance Tools for USP <797>**: This 2-day course provides practical experience and insight in implementing the new <797> requirements.
- **<797> Webinar Series**: Six on-demand webinars providing an overview of General Chapter <797> and its key components (e.g., contamination risk levels, immediate use, cleansing and garbing, sterilization methods, facility design).



USP-NF

The official compendia of U.S. drug standards, the *USP-NF* features more than 4,200 monographs—along with tests, methods, and industry best practices—for drug substances, dosage forms, compounded preparations, dietary supplements, parenterals, biologics, and more. *USP-NF* standards are FDA-enforceable for drugs manufactured or compounded in the United States. The current edition, *USP 31-NF 26*, is official through April 30, 2009.

USP Pharmacists' Pharmacopeia

Created especially for pharmacists, this comprehensive reference features official FDA-enforceable *USP-NF* monographs for sterile and nonsterile compounded preparations, abridged *USP-NF* monographs for drug substances and excipients, dietary supplements, flavorings, regulatory and legal information, pharmacy-related General Chapters, veterinary compounding monographs and information, and other helpful pharmacy resources. Published every two years with five *Supplements*, the latest edition was released in April 2008.



<797> Guidebook



To help pharmacists accurately interpret and apply new <797> requirements (official June 1, 2008), USP experts created the *USP <797> Guidebook to Pharmaceutical Compounding—Sterile Preparations*. It provides easy-to-read versions of the revisions, along with documents on enforceability, General Notices, and the current official text of *USP 31* General Chapter <797>.

TO LEARN MORE about USP's role in compounding pharmacy, visit—
www.usp.org/goto/compounding.

USP U.S. PHARMACOPEIA
*The Standard of Quality*SM

ISO 9001:2000 Certified

➔ See reverse for pharmacy-related General Chapters.

USP Monographs for Compounded Preparations

Acacia Syrup	Milk of Bismuth	Collodion	Metoprolol Tartrate Oral Suspension	Ringer's Injection
Acetazolamide Oral Suspension	Calamine Lotion	Flexible Collodion	Mineral Oil Emulsion	Rose Water Ointment
Diluted Acetic Acid	Phenolated Calamine Lotion	Coriander Oil	Morphine Sulfate Suppositories	Salicylic Acid Collodion
Diluted Alcohol	Calcium Hydroxide Topical Solution	Diltiazem Hydrochloride Oral Solution	Myrrh Topical Solution	Senna Oral Solution
Allopurinol Oral Suspension	Camphor Spirit	Diltiazem Hydrochloride Oral Suspension	Nitromersol Topical Solution	Sodium Hypochlorite Topical Solution
Alprazolam Oral Suspension	Captopril Oral Solution	Dipyridamole Oral Suspension	Hydrophilic Ointment	Sumatriptan Succinate Oral Suspension
Aluminum Acetate Topical Solution	Captopril Oral Suspension	Dolasetron Mesylate Oral Solution	White Ointment	Sunflower Oil
Aluminum Subacetate Topical Solution	Caraway	Dolasetron Mesylate Oral Suspension	Yellow Ointment	Suspension Structured Vehicle
Anise Oil	Caraway Oil	Fennel Oil	Ondansetron Hydrochloride Oral Suspension	Sugar-Free Suspension Structured Vehicle
Anticoagulant Citrate Dextrose Solution	Carbol-Fuchsin Topical Solution	Ferrous Sulfate Syrup	Vehicle for Oral Solution	Syrup
Anticoagulant Citrate Phosphate Dextrose Adenine Solution	Cardamom Oil	Flucytosine Oral Suspension	Vehicle for Oral Solution, SF	Tetracycline Hydrochloride Oral Suspension
Anticoagulant Citrate Phosphate Dextrose Solution	Cardamom Seed	Ganciclovir Oral Suspension	Vehicle for Oral Suspension	Tolu Balsam Syrup
Anticoagulant Heparin Solution	Compound Cardamom Tincture	Green Soap	Orange Oil	Tolu Balsam Tincture
Anticoagulant Sodium Citrate Solution	Aromatic Cascara Fluidextract	Green Soap Tincture	Sweet Orange Peel Tincture	Vanilla
Aromatic Elixir	Cefazolin Ophthalmic Solution	Hydralazine Hydrochloride Oral Solution	Compound Orange Spirit	Vanilla Tincture
Atenolol Oral Solution	Cherry Juice	Diluted Hydrochloric Acid	Orange Syrup	Verapamil Hydrochloride Oral Solution
Azathioprine Oral Suspension	Cherry Syrup	Ichthammol Ointment	Paregoric	Verapamil Hydrochloride Oral Suspension
Baclofen Oral Suspension	Chocolate	Indomethacin Topical Gel	Peppermint Spirit	Xanthan Gum Solution
Belladonna Tincture	Chocolate Syrup	Ipecac Oral Solution	Hydrophilic Petrolatum	Zinc Oxide and Salicylic Acid Paste
Bentonite Magma	Compound Clioquinol Topical Powder	Ketoconazole Oral Suspension	Piroxicam Cream	Zinc Oxide Ointment
Compound Benzaldehyde Elixir	Clonazepam Oral Suspension	Labetalol Hydrochloride Oral Suspension	Polyethylene Glycol Ointment	Zinc Oxide Paste
Benzyl Benzoate Lotion	Clove Oil	Lemon Oil	Progesterone Vaginal Suppositories	Zinc Sulfide Topical Suspension
Bethanechol Chloride Oral Solution	Coal Tar Ointment	Lemon Tincture	Quinidine Sulfate Oral Suspension	
Bethanechol Chloride Oral Suspension	Coal Tar Topical Solution	Magnesium Citrate Oral Solution	Compound Resorcinol Ointment	
	Cocaine and Tetracaine Hydrochlorides and Epinephrine Topical Solution	Metolazone Oral Suspension	Rifampin Oral Suspension	
		Metoprolol Tartrate Oral Suspension		

*Official compounded preparation monographs featured in 2008-2009 *USP Pharmacists' Pharmacopeia* through the second supplement.

CSP Microbial Contamination Risk Levels

The three contamination categories for CSPs described in this section are assigned primarily according to the potential for microbial contamination during the compounding of low-risk level CSPs and medium-risk level CSPs or the potential for not sterilizing high-risk level CSPs, any of which would subject patients to risk of harm, including death. High-risk level CSPs must be sterilized before being administered to patients. The appropriate risk level—low, medium, or high—is assigned according to the corresponding probability of contaminating a CSP with (1) microbial contamination (e.g., microbial organisms, spores, endotoxins) and (2) chemical and physical contamination (e.g., foreign chemicals, physical matter). Potential sources of contamination include, but are not limited to, solid and liquid matter from compounding personnel and objects; nonsterile components employed and incorporated before terminal sterilization; inappropriate conditions within the restricted compounding environment; prolonged presterilization procedures with aqueous preparations; and nonsterile dosage forms used to compound CSPs.

The characteristics described below for low-, medium-, and high-risk level CSPs are intended as a guide to the breadth and depth of care

1. Single-volume transfers of sterile dosage forms from bottles, bags, and vials using aseptic technique.
2. Simple three-part compounding or additional so...

Low-Risk Level CSPs
 CACI that do not require a Primary Engineering Control or a biological safety cabinet (see Table 1) and radiopharmaceutical patient medications commence with manufacturers with a 12-hour shelf life.
 1. PECs (LAF)

Turn to USP General Chapters for official standards and pharmacy best practices:

- step-by-step compounding guidance
- Working in sterile environments
- Containers, dosage units, calculations
- Beyond-use-dating

USP Pharmacy-Related General Chapters

<1> Injections	<797> Pharmaceutical Compounding—Sterile Preparations	<1121> Nomenclature
<21> Thermometers	<821> Radioactivity	<1136> Packaging—Unit-of-Use
<31> Volumetric Apparatus	<823> Radiopharmaceuticals for Positron Emission Tomography—Compounding	<1146> Packaging Practice—Repackaging a Single Solid Oral Drug Product into a Unit-Dose Container
<41> Weights and Balances	<831> Refractive Index	<1150> Pharmaceutical Stability
<51> Antimicrobial Effectiveness Testing	<841> Specific Gravity	<1151> Pharmaceutical Dosage Forms
<61> Microbial Limit Tests	<905> Uniformity of Dosage Units	<1160> Pharmaceutical Calculations in Prescription Compounding
<71> Sterility Tests	<911> Viscosity	<1163> Quality Assurance in Pharmaceutical Compounding
<85> Bacterial Endotoxins Test	<1035> Biological Indicators for Sterilization	<1176> Prescription Balances and Volumetric Apparatus
<151> Pyrogen Test	<1041> Biologics	<1177> Good Packaging Practices
<201> Thin-Layer Chromatographic Identification Test	<1045> Biotechnology-Derived Articles	<1178> Good Repackaging Practices
<345> Assay for Citric Acid/Citrate and Phosphate	<1070> Emergency Medical Services Vehicles and Ambulances—Storage of Preparations	<1184> Sensitization Testing
<381> Elastomeric Closures for Injections	<1072> Disinfectants and Antiseptics	<1191> Stability Considerations in Dispensing Practice
<601> Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers	<1075> Good Compounding Practices	<1207> Sterile Product Packaging—Integrity Evaluation
<621> Chromatography	<1078> Good Manufacturing Practices for Bulk Pharmaceutical Excipients	<1208> Sterility Testing—Validation of Isolator Systems
<660> Containers—Glass	<1079> Good Storage and Shipping Practices	<1211> Sterilization and Sterility Parametric Release
<661> Containers—Plastics	<1080> Bulk Pharmaceutical Excipients—Certificate of Analysis	<1221> Teaspoon
<671> Containers—Performance Testing	<1086> Impurities in Official Articles	<1222> Terminally Sterilized Pharmaceutical Products—Parametric Release
<681> Repackaging into Single-Unit Containers and Unit-Dose Containers for Nonsterile Solid and Liquid Dosage Forms	<1091> Labeling of Inactive Ingredients	<1223> Validation of Alternative Microbiological Methods
<729> Globule Size Distribution in Lipid Injectable Emulsions	<1092> The Dissolution Procedure: Development and Validation	<1231> Water for Pharmaceutical Purposes
<731> Loss on Drying	<1101> Medicine Dropper	<1241> Water-Solid Interactions in Pharmaceutical Systems
<741> Melting Range or Temperature	<1111> Microbiological Attributes of Nonsterile Pharmaceutical Products	<1251> Weighing on an Analytical Balance
<771> Ophthalmic Ointments	<1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products	<1265> Written Prescription Drug Information—Guidelines
<776> Optical Microscopy	<1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments	
<785> Osmolality and Osmolarity	<1117> Microbiological Best Laboratory Practices	
<788> Particulate Matter in Injections	<1118> Monitoring Devices—Time, Temperature, and Humidity	
<791> pH		
<795> Pharmaceutical Compounding—Nonsterile Preparations		