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, a 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.

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PP120F_0109

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 ($C_9H_{13}N_5O_4$). 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.

USP Monographs for Compounded Preparations

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

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

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 legial 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.

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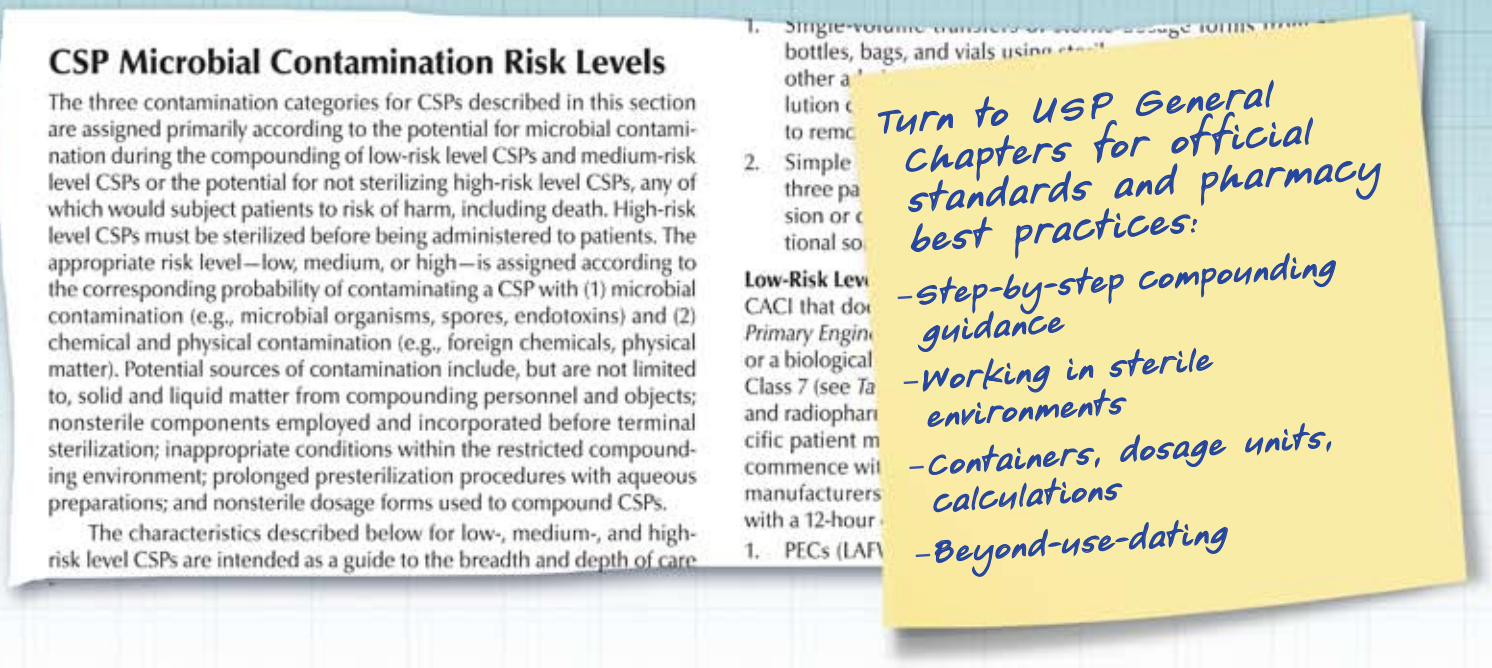
➥ ***See reverse for pharmacy-related General Chapters.***



USP Pharmacy-Related General Chapters

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

Chapters found in *2008–2009 USP Pharmacists' Pharmacopeia* and current *USP–NF.*