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.
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 could 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 needed for each category.

### 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> Elastic 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**
- **<1256> Written Prescription Drug Information—Guidelines**

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