USP Chapter <795>

Pharmaceutical Compounding – Nonsterile Preparations

	USP <795> Provision	How FIRST® KITS help pharmacists comply
1	Materials selected for use in compounding: APIs and components: • Must comply with the criteria in the USP-NF monograph, if one exists, and any additional specifications for the component • In the United States, must be obtained from an FDA-registered facility. APIs and components: • Must have a Certificate of Analysis (COA) that includes specifications and test results, and show that the API meets the specifications	Every shipment of bulk drug substances from an FDA registered facility used in a FIRST® Kit is accompanied by a COA, as is every shipment of inactive components. To further verify identity, quality and purity, samples are tested from each incoming batch of ingredient, as well throughout each packaging run of the FIRST® Kits. A COA is issued with the assembled kit and no kit is released unless it has met applicable specifications. Material Safety Data Sheets (MSDSs) are maintained for each ingredient. Copies of COA's and MSDSs are made available to the pharmacist upon request.
2	A Master Formulation Record should be created before compounding a preparation for the first time. This record shall be followed each time that preparation is made.	CutisPharma creates the Master Formulation Record and provides a package insert for how to compound the components per section 7 of Chapter USP <795>.
3	Appropriate compounding equipment has been selected and inspected for cleanliness as well as correct functioning and is properly used. Packaging materials must maintain the physical and chemical integrity and stability of the compounded non-sterile preparation (CNSPs), as well as protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure.	Each kit contains the tools necessary to compound the product. They are packaged for one-time use only, in order to prevent contamination. The containers used for packaging each FIRST® Kit and components, as well as providing the compounded product to a patient, meet USP requirements.
4	When establishing a Beyond Use Date (BUD) for a CNSP, the following factors must be considered: • The chemical and physical stability properties of the API and any added substances in the preparation. • The compatibility of the container–closure system with the finished preparation. • If the BUD extends beyond those established in Section 10.3, Table 3, the microbial proliferation in the CNSP per USP <51> must be established	CutisPharma provides stability data to pharmacists upon request. CutisPharma is currently conducting AET testing on products with BUDs beyond those specified in Section 10, Table 3, per USP <51> requirements.

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Pharmaceutical Compounding – Nonsterile Preparations *(continued)*

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5	A facility's Quality Assurance and Quality Control (QA and QC) programs must be formally established and documented in SOPs to ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter and laws and regulations of the applicable regulatory jurisdiction.	FIRST® Kits are manufactured under cGMPs, which yield a consistent finished product if compounding is done in accordance with the instructions. Pre-release inspection includes: • USP API monograph testing • Stability of powder API • Stability of compounded product • Homogeneity of compounded product • Analytical testing of suspension components • Stability testing of compounded suspensions • Flavor, odor and color • Clarity and consistency of the suspension/solution components and finished products
6	Every dispensed CNSP must be labeled with adequate, legible identifying information to prevent errors during storage, dispensing and use. All labeling must be in compliance with laws and regulations of the applicable regulatory jurisdiction. The label on each immediate container of the CNSP must, at a minimum, display the following information: • Assigned internal identification number (e.g., barcode, prescription, order or lot number) • Active component(s) and amounts, activities, or concentrations • Dosage form • Amount or volume in each container • Storage conditions if other than controlled room temperature • BUD	The labeling on each kit as provided to a pharmacist meets applicable state and federal laws for bulk product provided for compounding, including instructions for use by the pharmacist, proper storage and expiration date and BUD guidelines, assigned internal identification number, active components, dosage forms and amount of volume in each container.