USP Chapter <795>

Pharmaceutical Compounding – Nonsterile Preparations

	USP <795> Provision	How FIRST® KITS help pharmacists comply
1	The dose, safety, and intended use of the preparation has been evaluated for suitability in terms of: • Chemical and physical properties of the components • Dosage form • Therapeutic appropriateness and route of administration, including local and systemic biological disposition	Each incoming component of a FIRST® Kit is accompanied by a certificate of analysis, and is also subject to compendial testing. With regard to both the bulk drug substance and the inactive ingredients, Azurity Pharmaceuticals conducts full USP monograph testing on the first three shipments from a supplier, abbreviated USP testing on samples from each subsequent shipment, and another full USP test each year.
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. In addition, a Compounding Record should be completed each time a preparation is compounded.	The ***Compounding Documentation*** section of USP Chapter <795> explains that, "[w]hen the compounder compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required." Consistent with that, each FIRST® Kit contains instructions for compounding the components.
3	Ingredients used in the formulation have their expected identity, quality, and purity. Certificates of Analysis, when applicable, and MSDSs have been consulted for all ingredients used.	Every shipment of bulk drug substances used in a FIRST® Kit is accompanied by a certificate of analysis, as is every shipment of inactive ingredients (e.g., the diluent or suspension with which the API is to be mixed when the pharmacist compounds the finished product). To further verify identity, quality, and purity, samples are tested from each incoming batch of ingredient, as well as from the beginning, middle, and end of each packaging run of the FIRST® Kits. A certificate of analysis is issued with the assembled kit, and no kit is released unless it has met applicable specifications. MSDSs are maintained for each ingredient, as well. Copies of certificates of analysis and MSDSs are made available to the pharmacist upon request.
4	Only one preparation is compounded at one time in a specific workspace.	Each kit is packaged to yield one preparation for one patient.
5	Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used.	Each kit contains the tools necessary to compound the product. They are packaged for one-time use only, in order to prevent contamination.
6	A reliable beyond-use date (BUD) is established to ensure that the finished preparation has its accepted potency, purity, quality, and characteristics, at least until the labeled BUD.	Documented interval (stability) testing supports the BUD for each bulk drug substance and for the compounded drug product. This ensures that the compounded product is acceptable in terms of potency/purity, quality, and characteristics with regard to the labeled BUD for the finished product.

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KIT-61

USP Chapter <795>

Pharmaceutical Compounding – Nonsterile Preparations *(continued)*

	USP <795> Provision	How FIRST® KITS help pharmacists comply
7	Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.	FIRST® Kits are pre-weighed and/or pre-measured for the convenience of the pharmacist, and it is done under cGMP, which yields a consistent product to the pharmacist and a consistent finished product if compounding is done in accordance with the instructions.
8	The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record.	Azurity Pharmaceuticals conducts testing on product compounded from its kits for all its products. The testing 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, acceptability, consistency of suspension/ solution component • Clarity, acceptability, consistency of finished suspension product Other testing, such as pH, acid neutralization, microbiological, is done as appropriate. All test results are kept on file at Azurity Pharmaceuticals.
9	The preparation is packaged as recommended in the Packaging and Drug Preparation Containers section of USP <795>.	The containers used for packaging each FIRST® Kit and components, and for providing the compounded product to a patient, meet USP requirements.
10	The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information. The labeling should indicate that "this is a compounded preparation."	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 dating. The kits also provide information necessary for the pharmacist to label the finished compounded drug product in compliance with applicable requirements.
11	The Master Formulation and the Compounding Record have been reviewed by the compounder to ensure that errors have not occurred in the compounding process and that the preparation is suitable for use.	Each FIRST® Kit is designed to allow the pharmacists to compound a finished product with a specific concentration, in accordance with a patient-specific prescription. To that end, Azurity Pharmaceuticals conducts careful research and analysis in developing its kits, which involves, among other things, analytical studies, including final compounded concentrations, homogeneity, total quantity, and stability to ensure accuracy and consistency of product. Further, as described above, once the kit is in production, there are extensive steps taken to provide the pharmacist with a consistent product.

FIRST® KITS

Faster, more convenient compounding

LESS than 3 Mins to prepare*

*excluding FIRST® Progesterone VGS

To learn more about FIRST® KITS, visit **www.azurity.com** or call **1-800-461-7449,** for assistance.