



March 17, 2022

[Submitted electronically via www.USP.org]
 United States Pharmacopeia
 12601 Twinbrook Pkwy
 Rockville, MD 20852

RE: Proposed Revision to General Chapter <795>

ASHP is pleased to submit comments regarding the proposed revisions to USP General Chapter <795>. ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization’s 60,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. ASHP has a long history of supporting the safe practice of nonsterile and sterile compounded preparations.

Section	Comments or recommendations
5 Cleaning and Sanitizing; Glossary	<p>Section 5 references cleaning and sanitizing. Our understanding is that isopropyl alcohol is sufficient for sanitizing in this context; however, the glossary defines a sanitizing agent as “an agent for reducing, on inanimate surfaces, the number of all forms of microbial life including fungi, viruses, and bacteria.”</p> <p>This definition would require an agent capable of killing spore-forming microbes in all applications of cleaning and sanitizing, including work surfaces in between compounding CNSPs with different components.</p> <p>ASHP recommends modifying the glossary definition of sanitizing agent so that isopropyl alcohol may be used for cleaning and sanitizing purposes.</p>
6.1 Equipment	<p>The chapter states that “Weighing, measuring or otherwise manipulating components that could generate airborne chemical particles ... must be assessed to determine if these activities must be performed in a closed-system processing device.”</p> <p>This language is ambiguous and only requires responsible person(s) to make a determination as to whether a closed-system processing device is necessary; it does not require the use of a closed-system processing device. If this is the intent, ASHP suggests a section in an FAQ document to help responsible person(s) to make the determination when the use of such a device is warranted.</p> <p>If the intent is to require a closed-system processing device, ASHP asks the Expert Committee to weigh the benefits of a closed-system processing device for compounding powder forms of non-hazardous bulk drug substances and excipients</p>

	<p>against the possible impact this requirement may have on accessibility to compounded nonsterile preparations. Not all facilities will have the physical space or resources for a closed-system processing device which could make it difficult for patients to access specific CNSPs. We ask that the committee consider the possibility of an assessment of risk based on frequency and volume of compounding using powder forms, and the types of non-hazardous bulk drug substances or excipients used when determining whether a closed-system processing device is required.</p>
<p>6.1 Equipment, Table 2</p>	<p>The table on minimum frequency for cleaning a CVE and BSC states “at the beginning and end of each shift.”</p> <p>It’s possible several shifts or days may lapse without compounding activity that requires the use of a CVE or BSC. ASHP recommends that the committee consider “at the beginning and end of each shift when compounding activity occurs,” or similar interval that accounts for low usage (i.e., daily or weekly when not in regular use).</p>
<p>6.2.2 Component receipt</p>	<p>This paragraph requires examination of “any other lots” of an ingredient found to be of unacceptable quality, but does not address other containers of the same lot as the ingredient found to be of unacceptable quality. “Any other lots” can be changed to “all lots” in order to add clarity.</p>
<p>6.2.3 Component evaluation before use</p>	<p>Section 6.2.3 states that “If the correct identity, strength, purity, and quality of components intended for preparation of CNSPs cannot be confirmed (e.g., containers with damaged or incomplete labeling), the components must be immediately rejected.”</p> <p>Intact containers and complete labeling are not confirmation of component quality. The quality of a component must be assumed based on the manufacturer COA, proper storage and handling after receipt, and the container integrity. ASHP is concerned that the word “confirmed” may be construed as a requirement to perform laboratory analysis before using a component. We suggest the expert committee consider changing the word “confirmed” to “predicted” or “expected.”</p>
<p>10.3 Establishing a BUD for a CNSP, Table 4</p>	<p>Table 4 describes the BUDs for preserved and non-preserved aqueous dosage forms; however, it does not contain a footnote or other explanation for how the responsible person(s) determines what is effectively preserved. The table does not reference USP Chapter <51> testing and the revised Chapter <795> only requires antimicrobial effectiveness testing if extending the BUD of a preserved aqueous solution beyond the default 35-day limit in Table 4.</p> <p>ASHP asks the expert committee to address this either in the chapter or in an FAQ document to help guide compounders in understanding how to determine what meets the intent of a preserved aqueous solution in Table 4 and whether USP Chapter <51> testing is required to apply a 35-day BUD.</p>

ASHP appreciates this opportunity to provide USP with feedback on the proposed revisions to General Chapter <795>. I have also appreciated the opportunity to provide direct feedback during public meetings of the Compounding Expert Committee while the chapter revisions and comments have been discussed.

We look forward to continuing to work with USP and the Compounding Expert Committee to protect patient and healthcare worker health and safety. Please contact me if you have any questions about ASHP's comments. I can be reached by telephone at 301-664-8617 or by email at mganio@ashp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Ganio". The signature is fluid and cursive, with a large initial "M" and "G".

Michael Ganio, Pharm.D., M.S., BCPS, BCSCP, FASHP
Senior Director, Pharmacy Practice and Quality
Center on Medication Safety and Quality
ASHP
4500 East-West Highway, Suite 900
Bethesda, Maryland 20814
Phone: 301-664-8617