USP <795> Guideline Update Quick Comparison Sheet

Cleaning

Unlike USP <797>, the 2014 (current until November 2023) version of USP <795> does not have a specific recommended cleaning schedule, and only offers vague guidance such as "The areas used for compounding shall be maintained in clean, orderly, and sanitary conditions and shall be maintained in a good state of repair." Upcoming USP 795 guidelines do detail a specific cleaning schedule in Tables 1 and 2:

Site	Minimum Frequency
Work Surfaces	At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected Between compounding CNSPs with different components
Floors	Daily on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected
Walls	When visibly soiled, after spills, and when surface contamination (e.g., from splashes) is known or suspected
Ceilings	When visibly soiled and when surface contamination (e.g., from splashes) is known or suspected
Storage Shelving	Every 3 months, after spills, and when surface contamination (e.g., from splashes) is known or suspected
CVE (Containment ventilated enclosures) and BSCs (biological safety cabinets)	At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected Clean and sanitize the horizontal work surface of the CVE between compounding CNSPs with different components Additionally, BSCs should also be cleaned and sanitized at least monthly
Other devices and equipment	Before first use and thereafter in accordance with the manufacturer's recommendations, if no recommendation is available, between compounding CNSPs with different components

Garbing

(for non-hazardous non-sterile compounding)

USP <795> guidelines to be official in November of 2023 offer much greater clarity on recommended garb and garb related protocol

Garb	USP <795> Official Until November 2023	USP <795> To Be Official November 2023
Gloves	Not specifically required. The guideline states that personnel must "wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination"	Required for all compounding activities
Gown	Not specifically required. The guideline states that personnel must "wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination"	Must be worn if deemed appropriate for the type of compounding performed to protect both compounder and compounded preparation
Shoe Cover	Not specifically required. The guideline states that personnel must "wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination"	Must be worn if deemed appropriate for the type of compounding performed to protect both compounder and compounded preparation
Head or Hair Cover	Not specifically required. The guideline states that personnel must "wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination"	Must be worn if deemed appropriate for the type of compounding performed to protect both compounder and compounded preparation

Facial Hair Cover	Not specifically required. The guideline states that personnel must "wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination"	Must be worn if deemed appropriate for the type of compounding performed to protect both compounder and compounded preparation
Face Mask	Not specifically required. The guideline states that personnel must "wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination"	Must be worn if deemed appropriate for the type of compounding performed to protect both compounder and compounded preparation
Garb Change Frequency	Not addressed	Replace garb immediately if it is visibly soiled or if integrity is compromised. All gloves must be inspected for holes/tears etc. and replaced immediately if defects are noted
May Garb be Reused?	Not addressed	Garb should be removed when leaving the compounding area, all garb other than gowns should be discarded. Gowns may be reused, but if they are, they must remain in the compounding area and should only be reused during the same shift

Beyond Use Dating

Current USP <795> (since 2014)

BUD by Type of Formulation	
For Water-Containing Oral Formulations	The BUD is not later than 14 days when stored at controlled cold temperatures
For Water Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations	The BUD is not later than 30 days.
For Nonaqueous Formulations	The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier

Updated USP <795> (To be official Nov 1st, 2023)

BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or CNSP-Specific Stability Information (Table 4)	
Non-preserved aqueous dosage forms ($a_w \geq 0.60$)	14 days refrigerated
Preserved aqueous dosage forms ($a_w \geq 0.60$)	35 days controlled room temperature or refrigerated
Oral liquids (nonaqueous) ($a_w < 0.60$)	90 days controlled room temperature or refrigerated
Other nonaqueous dosage forms ($a_w < 0.60$)	180 days controlled room temperature or refrigerated

A Quick Note on Water Activity (a_w):

Water activity is a measurement of the ratio of vapor pressure of the substance in question when at equilibrium with the surrounding air to the vapor pressure of distilled water under identical conditions. So, for example, an a_w of 0.6 means that the vapor pressure of the substance in question is 60% that of pure water. Water activity should not be mistaken for water content. Water content is a measure of how much water is in a particular substance by weight or volume, whereas a_w is a measure of water that is available for reaction or accessible to microbes. Even items with relatively low water content can still have relatively high a_w. Notably, USP clarifies that these new guidelines do not require compounders to measure a_w for particular compounds, but can use table 3, Water Activity (a_w) of Common Compounded Nonsterile Dosage Forms, presented in USP <795> to infer whether their preparation is aqueous or non-aqueous. If a_w is not tested for a preparation known to contain water, such as a cream or aqueous suspension, the a_w should be assumed to be equal to or greater than 0.6 and, in the absence of an appropriate study, the beyond-use date should be consistent with the maximum beyond-use date listed in table 4 of new USP <795> guidelines.

Stability Testing For BUD Extension

	USP <795> (Since 2014)	Updated USP <795> To be Official Nov 2023
Strength or formulation extrapolation permitted?	Unclear: the guidelines do not specifically state that a formula must be exact to allow for BUD extension instead using statements like "the compounder shall refer to the manufacturer for stability information and to the literature for applicable information on stability, compatibility, and degradation of ingredients; shall consider stability factors in ⟨1191⟩; and shall use his or her compounding education and experience. All stability data shall be carefully interpreted in relation to the actual compounded formulation."	If you extend your BUD, the formula in the study cited must be identical in strength, composition, and container closure or your formula must fall within a high and low bracket of varying strengths across the same formulation. The removal or addition of extra ingredients, including any flavors not in the original study, will result in the study being invalidated for a given product.
Stability-Indicating Analytical Method	Not specified	Required
Antimicrobial Effectiveness Testing (AET) per USP <51>	No, though, the guideline does state that BUDs should be assigned conservatively and that "the potential for microbial proliferation in the preparation" should be considered when assigning a BUD.	Yes, AET must be performed for an aqueous CNSPs assigned an extended BUD. The AET may be conducted once for each formulation in a container closure of a specific composition in which it will be packaged, or you may rely on AET results provided by an FDA-registered facility or peer-reviewed literature
Container Closure Requirements	Not specified, though, the guideline does state that BUDs should be assigned conservatively and that "the container in which it is packaged" should be considered when assigning a BUD.	You are required to use a container closure of the same composition to that used in any study cited to extend the BUD of a preparation

Competency/Training

	USP <795> (Since 2014)	Updated USP <795> To be Official Nov 2023
Required Core Competencies	Not specifically listed, per the guideline "Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties."	Hand hygiene Garbing Cleaning and sanitizing Handling and transporting components and CNSPs Measuring and mixing Proper use of equipment and devices selected to compound CNSPs Documentation of the compounding process
Required Frequency of Evaluation in Core Competencies	Compounding personnel "should" be evaluated at least annually	Initially and every 12 months
Training Procedure Requirements	Understand the requirements in USP <795> Understand and interpret safety data sheets (SDSs) and, if applicable, certificates of analysis (COA) Read and understand procedures related to their compounding duties All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs.	Understand the requirements in USP <795> Understand and interpret safety data sheets (SDSs) and, if applicable, certificates of analysis (COA) Read and understand procedures related to their compounding duties Hazardous drug specific requirements are addressed in USP <800>
Documentation of Training	All training activities shall be documented. The compounder shall meet with employees to review their work and answer any questions the employees may have concerning compounding procedures The compounder will sign the documentation records to show the employee was appropriately trained	All facilities where CNSPs are prepared must have and maintain written or electronic documentation to demonstrate compliance with the requirements in this chapter. This includes personnel training, competency assessments, and qualification records including corrective actions for any failures
Oversight of Training	Procedures are demonstrated for the employee and then must be repeated by the employee without assistance, under the direct supervision of the compounder	Training and observation may be performed by the designated person or assigned trainer, personnel must be guided through the training process, and then must perform the procedure under direct supervision of the designated person or trainer

	Employee must demonstrate verbal and functional knowledge of the procedure before they can work unobserved	Personnel must demonstrate verbal and functional knowledge and understanding of the procedure before they can work without direct supervision If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements of this chapter.

Primary and Secondary Engineering Controls (The Compounding Space)

	USP <795> (Since 2014)	Updated USP <795> To be Official Nov 2023
Compounding Area	Compounding facilities shall have an adequate space specifically designed for compounding of prescriptions (separate area not specified) Well lit, clean, sanitary, orderly, and in a state of good repair	A specific area must be designated for nonsterile compounding, other activities must not occur in the compounding area while compounding is occurring Well lit, clean, sanitary, orderly, and in a state of good repair There should not be carpet in the compounding area Room must be designed in a way to minimize cross contamination
Storage Area	Temperature and humidity monitoring should be maintained as required for certain components and dosage forms (monitoring frequency not specified) All CNSPs, components, equipment, and containers must be stored off the floor to prevent cleaning and inspection and prevents contamination	Temperature monitoring at least once daily while open or with a continuously monitoring device, results must be documented and stored All temperature monitoring equipment is calibrated every 12 months or as specified by the manufacturer All CNSPs, components, equipment, and containers must be stored off the floor to prevent cleaning and inspection and prevents contamination
Water Sources	Potable water must be available for hand washing, purified water shall be used for CNSP formulation and should be used for rinsing equipment and utensils	Hot and cold water and an easily accessible sink must be available Purified Water, distilled water, or reverse osmosis water should be used for rinsing equipment and utensils
Particulate Control	Not specifically discussed	Weighing, measuring, or manipulating components that could generate airborne particles must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce contamination and exposure risk If containment ventilated enclosure (CVE) or biological safety cabinet (BSC) is used, it must be inspected every 12 months or according to manufacturer or other applicable laws