

<input type="checkbox"/> USP <795> 1.1 SCOPE: Designated individual(s) for performance/operations of facility and personnel for CNSP prep <ul style="list-style-type: none"> <input type="checkbox"/> Designated individual identified in SOP <input type="checkbox"/> Oversees training program to ensure personnel competency of compounding, handling, and preparing CNSPs <input type="checkbox"/> Responsible for selecting components <input type="checkbox"/> Monitoring/observing compounding activities and taking immediate corrective action for deficient practices <input type="checkbox"/> Ensure SOPs implemented and follow-up is carried out if problems, deviations, or errors are identified <input type="checkbox"/> Establishing, monitoring, & documenting procedures for handling and storage of CNSPs and/or components
<input type="checkbox"/> USP <795> 2. PERSONNEL TRAINING/EVALUATION: Documentation of initial competency and refresher every 12 mos <ul style="list-style-type: none"> <input type="checkbox"/> Hand hygiene <input type="checkbox"/> Garbing <input type="checkbox"/> Cleaning and sanitizing <input type="checkbox"/> Handling and transporting components and CNSPs <input type="checkbox"/> Measuring and mixing <input type="checkbox"/> Proper use of equipment and devices selected to compound CNSPs <input type="checkbox"/> Documentation of the compounding process (e.g., Master Formulation Records and Compounding Records) <input type="checkbox"/> Documented steps in the training procedure must include the following: <ul style="list-style-type: none"> <input type="checkbox"/> Read and understand this chapter, other applicable standards, and other relevant literature <input type="checkbox"/> Understand and interpret Safety Data Sheets (SDSs) and, if applicable, Certificates of Analysis (COA) <input type="checkbox"/> Read and understand procedures related to their compounding duties
<input type="checkbox"/> USP <795> 3. PERSONAL HYGIENE AND GARBING: Designated individual(s) responsible for evaluating personnel for exclusions from compounding because of risk of contamination from rashes, recent, tattoos, oozing sores, conjunctivitis, or active respiratory infection. Personnel must report condition. Exclusion must be documented. <input type="checkbox"/> USP <795> 3.1 Personnel Preparation: Personnel must remove before entering compounding area: <ul style="list-style-type: none"> <input type="checkbox"/> Remove personal outer garments (e.g., bandanas, coats, hats, jackets) <input type="checkbox"/> Remove all hand, wrist, piercings, and other exposed jewelry that could interfere with garbing/hand hygiene <input type="checkbox"/> Remove earbuds or headphones <input type="checkbox"/> USP <795> 3.2 Hand Hygiene: Documented in SOPs: <ul style="list-style-type: none"> <input type="checkbox"/> Wash hands and forearms up to the elbows with soap and water for at least 30 seconds. <input type="checkbox"/> Dry hands and forearms to the elbows completely with disposable towels or wipers. <input type="checkbox"/> Allow hands and forearms to dry thoroughly before donning gloves <input type="checkbox"/> Gloves should be wiped or replaced before beginning a CNSP with different components <input type="checkbox"/> All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if defective <input type="checkbox"/> USP <795> 3.3 Garb and Glove Requirements: Garbing and frequency is documented in SOPs <ul style="list-style-type: none"> <input type="checkbox"/> Gloves must be worn for all compounding activities <input type="checkbox"/> Garb should be worn for protection of personnel & must be appropriate for type of compounding performed <input type="checkbox"/> If gowns are worn, they may be re-used if not soiled <input type="checkbox"/> Gloves, shoe covers, hair covers, facial hair covers, face masks, or head coverings may not be re-used <input type="checkbox"/> Non-disposable garb, i.e goggles, should be cleaned and sanitized with 70% isopropyl alcohol before re-use
<input type="checkbox"/> USP <795> 4. BUILDINGS AND FACILITIES: All requirements are described in SOPs <ul style="list-style-type: none"> <input type="checkbox"/> 4.1 Compounding Space: Specifically designated for nonsterile compounding, sanitary, orderly, well-lit <ul style="list-style-type: none"> <input type="checkbox"/> Surfaces should be resistant to damage by cleaning and sanitizing agents; no carpeting allowed <input type="checkbox"/> Space designed, arranged, and used that minimizes cross-contamination from non-compounding areas

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<ul style="list-style-type: none"> <input type="checkbox"/> USP <795> 4.2 Storage Area: Temperature monitored and documented daily; immediately retrievable <ul style="list-style-type: none"> <input type="checkbox"/> Temperature monitoring equipment calibrated every 12 months if not specified by manufacturer <input type="checkbox"/> Adhere to SOPs to detect and prevent temperature excursions; CNSPs discarded if outside limits <input type="checkbox"/> CNSPs, components, equipment, & containers stored off floor & permits cleaning/inspection of area <input type="checkbox"/> USP <795> 4.3 Water Sources: Hot and cold water sink easily accessible <ul style="list-style-type: none"> <input type="checkbox"/> Sink must be emptied of all items unrelated to compounding and cleaned when visibly soiled before being used to clean any equipment used in nonsterile compounding <input type="checkbox"/> Purified, distilled, or reverse osmosis water used for rinsing equipment and utensils
<ul style="list-style-type: none"> <input type="checkbox"/> USP <795> 5. CLEANING AND SANITIZING: Documented in SOPs and cleaning logs <ul style="list-style-type: none"> <input type="checkbox"/> Work surfaces: beginning/end of each shift, after spills, surface contamination, between each CNSPs batch <input type="checkbox"/> Floors: Daily, after spills, and when surface contamination (e.g. splashes) is known or suspected <input type="checkbox"/> Walls: Every 3 months, after spills, and when surface contamination is known or suspected <input type="checkbox"/> Storage shelving: Every 3 months, after spills, and when surface contamination is known or suspected <input type="checkbox"/> Ceilings: When visibly soiled and when surface contamination is known or suspected
<ul style="list-style-type: none"> <input type="checkbox"/> USP <795> 6. EQUIPMENT AND COMPONENTS: Documented in SOPs and logs <ul style="list-style-type: none"> <input type="checkbox"/> USP <795> 6.1 Equipment: Must be suitable for the specific compounding process <ul style="list-style-type: none"> <input type="checkbox"/> Surfaces that contact components must not be reactive, additive, sorptive, or alter the quality of CNSPs <input type="checkbox"/> Stored in a manner to minimize the risk of contamination and facilitate use, maintenance and cleaning <input type="checkbox"/> Inspected/verified prior to use in accordance to manufacturer specifications <input type="checkbox"/> Calibrated/maintained every 12 months or manufacturer requirement, whichever is sooner <input type="checkbox"/> After compounding, equipment cleaned to prevent cross-contamination of the next preparation <input type="checkbox"/> Assessment performed to determine if CNSPs need closed-system equipment and processes to reduce exposure/contamination of employees, facility, and/or products <input type="checkbox"/> Minimum Frequency for Cleaning and Sanitizing Equipment in Nonsterile Compounding Area(s) <ul style="list-style-type: none"> <input type="checkbox"/> Containment ventilated enclosures: beginning/end of each shift, after spills, surface contamination, and between each CNSPs batch <input type="checkbox"/> Other equipment: Before first use, manuf recommendations and between each CNSPs batch <input type="checkbox"/> USP <795> 6.2 Components: SOPs for selection & inventory control of all components from receipt to use in CNSP <ul style="list-style-type: none"> <input type="checkbox"/> SDSs must be readily accessible to all personnel; Personnel must be instructed on how to retrieve & interpret <input type="checkbox"/> Component selection: A designated individual responsible for selecting components <input type="checkbox"/> Active Pharmaceutical Ingredient (API) and components other than APIs must: <ul style="list-style-type: none"> <input type="checkbox"/> Comply with the criteria in the USP–NF monograph <input type="checkbox"/> Have a Certificate of Analysis (COA) that includes the specifications and test results; API meets specs <input type="checkbox"/> Must be obtained from an FDA-registered facility in the U.S.; Non-U.S. complies with laws and regs <input type="checkbox"/> Component receipt: Documentation must be made for: <ul style="list-style-type: none"> <input type="checkbox"/> Components other than manuf products - information including the receipt date, quantity received, supplier name, lot number, expiration date, & results of any in-house or third-party testing performed <input type="checkbox"/> Date of receipt must be clearly and indelibly marked on each component package lacking an exp date <input type="checkbox"/> Components that lack a vendor’s exp date must not be used after 3 years from the date of receipt <input type="checkbox"/> Once removed from original container, excess components not used in compounding is discarded <input type="checkbox"/> Component evaluation before use: Inspect for correct identity, strength, purity, and quality of components <input type="checkbox"/> Component Spill and Disposal: Accessible SDSs reviewed and update every 12 months <ul style="list-style-type: none"> <input type="checkbox"/> SOPs in place for labeled contents of spill kits with refresher course for personnel every 12 months

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<p><input type="checkbox"/> USP <795> 7. MASTER FORMULATION & COMPOUNDING RECORDS: Must have SOPs & Documentation for new or altered</p> <p style="margin-left: 20px;"><input type="checkbox"/> USP <795> 7.1 Creating Master Formulation Records: Created for each unique formulation of a CNSP; contains:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Name, strength or activity, and dosage form <input type="checkbox"/> Identities and amounts of all components (e.g., particle size, salt form, purity grade, solubility) <input type="checkbox"/> Container–closure system(s) <input type="checkbox"/> Complete instructions for preparation, including equipment, supplies, & description of compounding steps <input type="checkbox"/> Physical description of the final CNSP <input type="checkbox"/> Assigned beyond-use date (BUD) and storage requirements <input type="checkbox"/> Reference source to support the assigned BUD and storage requirements <input type="checkbox"/> Calculations to determine/verify quantities and/or concentrations of components & strength/activity of API <input type="checkbox"/> Labeling and auxiliary labeling requirements <input type="checkbox"/> Quality control (QC) procedures (e.g., pH testing, visual inspection) and expected results <input type="checkbox"/> Other info needed to describe the compounding process & ensure repeatability (e.g., adjusting pH, temp) <p style="margin-left: 20px;"><input type="checkbox"/> 7.2 Creating Compounding Records: A Compounding Record documents the following of each CNSP:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Name, strength or activity, and dosage form of the CNSP <input type="checkbox"/> Date and time of preparation of the CNSP <input type="checkbox"/> Assigned internal identification number (e.g., prescription, order, or lot number) <input type="checkbox"/> A method to identify the individuals involved in the compounding process and verifying the final CNSP <input type="checkbox"/> Name, vendor or manufacturer, lot number, and expiration date of each component <input type="checkbox"/> Weight or measurement of each component <input type="checkbox"/> Total quantity compounded <input type="checkbox"/> Assigned BUD and storage requirements <input type="checkbox"/> Calculations to determine/verify quantities and/or concentrations of components & strength/activity of API <input type="checkbox"/> Physical description of the final CNSP <input type="checkbox"/> Results of quality control procedures (e.g., pH testing, visual inspection) <input type="checkbox"/> Master Formulation Record reference for the CNSP
<p><input type="checkbox"/> USP <795> 8. RELEASE INSPECTIONS: CNSPs must be visually inspected and documented:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Determine whether the physical appearance is as expected <input type="checkbox"/> Labeling matches the Compounding Record and the prescription or medication order <input type="checkbox"/> All checks, inspections, quality tests are detailed in Master Formulation Records and documented <input type="checkbox"/> Pre-release inspection must include visual inspection of container–closure integrity (e.g., checking for leakage, cracks in the container, or improper seals)
<p><input type="checkbox"/> USP <795> 9. LABELING: All labels, written, printed, or graphic matter on immediate CNSP container, package or wrapper</p> <p style="margin-left: 20px;"><input type="checkbox"/> Label on immediate container of the CNSP must, at a minimum, display the following information:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Assigned internal identification number (e.g., barcode, prescription, order, or lot number) <input type="checkbox"/> Active component(s), and amounts, activities, or concentrations <input type="checkbox"/> Dosage form <input type="checkbox"/> Amount or volume in each container <input type="checkbox"/> Storage conditions if other than controlled room temperature <input type="checkbox"/> BUD

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<input type="checkbox"/> USP <795> 9. LABELING: All labels, written, printed, or graphic matter on immediate CNSP container, package or wrapper <ul style="list-style-type: none"> <input type="checkbox"/> The labeling on the CNSP should display the following information: <ul style="list-style-type: none"> <input type="checkbox"/> Route of administration <input type="checkbox"/> Indication that the preparation is compounded <input type="checkbox"/> Any special handling instructions <input type="checkbox"/> Any warning statements that are applicable <input type="checkbox"/> Name, address, and contact information of the compounding facility if the CNSP is to be sent outside facility 															
<input type="checkbox"/> USP <795> 10. ESTABLISHING BEYOND-USE DATES: Each CNSP label must state date, or hour/date, beyond which the prep cannot be used and must be discarded <input type="checkbox"/> USP <795> 10.3 Establishing a BUD for a CNSP: The day that the preparation is compounded is considered Day 1 BUD by Type of Prep in absence of a USP-NF Compounded Preparation Monograph or CNSP-specific monograph: <table border="1" style="margin: 10px auto; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="padding: 2px;">Type of Preparation</th> <th style="padding: 2px;">BUDs (days)</th> <th style="padding: 2px;">Storage Temperature</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Non-preserved aqueous</td> <td style="padding: 2px;">14</td> <td style="padding: 2px;">Refrigerator</td> </tr> <tr> <td style="padding: 2px;">Preserved aqueous</td> <td style="padding: 2px;">35</td> <td style="padding: 2px;">Controlled room temp or refrigerator</td> </tr> <tr> <td style="padding: 2px;">Nonaqueous</td> <td style="padding: 2px;">90</td> <td style="padding: 2px;">Controlled room temp or refrigerator</td> </tr> <tr> <td style="padding: 2px;">Solid</td> <td style="padding: 2px;">180</td> <td style="padding: 2px;">Controlled room temp or refrigerator</td> </tr> </tbody> </table> <ul style="list-style-type: none"> <input type="checkbox"/> USP <795> 10.4 CNSPs Requiring Shorter BUDs: A shorter BUD must be established under the following circumstances: <ul style="list-style-type: none"> <input type="checkbox"/> API or any other components in the CNSP have an expiration date that is earlier than the BUD in USP <795> 10.3 <input type="checkbox"/> CNSP includes components from conventionally manufactured product(s) with shorter BUD in USP <795> 10.3 <input type="checkbox"/> CNSP includes components from other compounded preparations with shorter BUD in USP <795> 10.3 <input type="checkbox"/> Formulation is known to require a shorter BUD <input type="checkbox"/> USP <795> 10.5 Extending BUDs for CNSPs: If USP–NF compounded prep monograph has BUD for CNSP, then BUD stays <ul style="list-style-type: none"> <input type="checkbox"/> CNSPs WITH STABILITY INFORMATION: Exceptions: <ul style="list-style-type: none"> <input type="checkbox"/> Aqueous & nonaqueous CNSPs may be extended max 180 days if there is a stability study (published or unpublished) using a stability-indicating assay for the API(s), CNSP, and type of container-closure that will be used <input type="checkbox"/> If the BUD of the CNSP is extended beyond the BUDs in USP <795> 10.3, an aqueous CNSP should be submitted for antimicrobial effectiveness testing (AET). The compounder may rely on AET that is: <ul style="list-style-type: none"> <input type="checkbox"/> Conducted (or contracted for) once for each formulation in container–closure system packaged in. OR; <input type="checkbox"/> Provided by an FDA-registered facility or published in peer-reviewed literature sources if the CNSP formulation (including any preservative) and container–closure system are exactly the same as those tested unless a bracketing study is performed 	Type of Preparation	BUDs (days)	Storage Temperature	Non-preserved aqueous	14	Refrigerator	Preserved aqueous	35	Controlled room temp or refrigerator	Nonaqueous	90	Controlled room temp or refrigerator	Solid	180	Controlled room temp or refrigerator
Type of Preparation	BUDs (days)	Storage Temperature													
Non-preserved aqueous	14	Refrigerator													
Preserved aqueous	35	Controlled room temp or refrigerator													
Nonaqueous	90	Controlled room temp or refrigerator													
Solid	180	Controlled room temp or refrigerator													
<input type="checkbox"/> USP <795> 11. SOPS: Must be developed on all aspects of the compounding operation <ul style="list-style-type: none"> <input type="checkbox"/> All personnel who conduct or oversee compounding activities must be trained SOPs and follow them responsibly <input type="checkbox"/> One or more person(s) must be designated to ensure that SOPs are fully implemented <input type="checkbox"/> The designated individual(s) must ensure that follow-up occurs if problems, deviations, or errors are identified 															

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<input type="checkbox"/> USP <795> 12. QUALITY ASSURANCE AND QUALITY CONTROL: A facility's QA & QC programs must be formally established and documented in SOPs. A designated person must ensure facility has formal, written QA and QC programs that: <ul style="list-style-type: none"> <input type="checkbox"/> Adhere to procedures <input type="checkbox"/> Ensure prevention and detection of errors and other quality problems <input type="checkbox"/> Evaluate of complaints and adverse events <input type="checkbox"/> Ensure appropriate investigations and corrective actions <input type="checkbox"/> SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program <input type="checkbox"/> Designated person(s) for QA prgrm must have training, experience, responsibility, & authority to perform duties <input type="checkbox"/> QA/QC prgrm must be reviewed every 12 months by the designated person(s). Results and actions documented 								
<input type="checkbox"/> USP <795> 13. CNSP PACKAGING AND TRANSPORTING <ul style="list-style-type: none"> <input type="checkbox"/> USP <795> 13.1 Packaging of CNSPs: SOPs must describe packaging of CNSPs: <ul style="list-style-type: none"> <input type="checkbox"/> Personnel select and use packaging materials that maintain physical, chemical integrity and stability of CNSPs <input type="checkbox"/> Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation <input type="checkbox"/> Packaging materials must protect protecting personnel from exposure <input type="checkbox"/> USP <795> 13.2 Transporting CNSPs: SOPs describe mode of transportation, handling, & temp monitoring required 								
<input type="checkbox"/> USP <795> 14. COMPLAINT HANDLING AND ADVERSE EVENT REPORTING: SOPs for complaint & AE report receipt, acknowledgment, and handling. Complaints of quality, labeling, or possible adverse reactions to CNSPs <ul style="list-style-type: none"> <input type="checkbox"/> USP <795> 14.1 Complaint Handling: Designated person(s) reviews all complaints and determines if problem <ul style="list-style-type: none"> <input type="checkbox"/> If problem, thorough investigation into the cause of the problem must be initiated and completed <input type="checkbox"/> Investigation must consider whether the quality problem extends to other CNSPs <input type="checkbox"/> Corrective action, if necessary, must be implemented for all potentially affected CNSPs <input type="checkbox"/> Consider initiate recall of potentially affected CNSPs and/or cease and desist compounding until corrected <input type="checkbox"/> A readily retrievable written or electronic record of each complaint must be kept by the facility, regardless of the source of the complaint (e.g., e-mail, telephone, mail). Record must contain: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Name of the complainant or unique identifier</td> <td style="width: 50%;"><input type="checkbox"/> Name and strength of the CNSP</td> </tr> <tr> <td><input type="checkbox"/> Date the complaint was received</td> <td><input type="checkbox"/> Prescription or medication order number</td> </tr> <tr> <td><input type="checkbox"/> Nature of the complaint</td> <td><input type="checkbox"/> Lot number</td> </tr> <tr> <td><input type="checkbox"/> Response to the complaint</td> <td><input type="checkbox"/> Findings/Follow-up of any investigation</td> </tr> </table> <input type="checkbox"/> USP <795> 14.2 Adverse Event Reporting: Designated person(s) must ensure AE reports of a CNSP are reviewed <ul style="list-style-type: none"> <input type="checkbox"/> If AE investigation reveals quality problem likely to affect patients, patients and prescribers are notified <input type="checkbox"/> AE with a CNSP reported to FDA MedWatch program for human drugs; FDA Form 1932a for animal drugs 	<input type="checkbox"/> Name of the complainant or unique identifier	<input type="checkbox"/> Name and strength of the CNSP	<input type="checkbox"/> Date the complaint was received	<input type="checkbox"/> Prescription or medication order number	<input type="checkbox"/> Nature of the complaint	<input type="checkbox"/> Lot number	<input type="checkbox"/> Response to the complaint	<input type="checkbox"/> Findings/Follow-up of any investigation
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<input type="checkbox"/> Response to the complaint	<input type="checkbox"/> Findings/Follow-up of any investigation							
<input type="checkbox"/> USP <795> 15. DOCUMENTATION: Must have & maintain written or electronic documentation to demonstrate compliance <ul style="list-style-type: none"> <input type="checkbox"/> Personnel training, competency assessments, and corrective actions for any failures <input type="checkbox"/> Equipment records (e.g., calibration, verification, and maintenance reports) <input type="checkbox"/> Product(s) Certificate of Analysis (COA) <input type="checkbox"/> Receipt of components <input type="checkbox"/> SOPs, Master Formulation Records, and Compounding Records <input type="checkbox"/> Release inspection and testing records <input type="checkbox"/> Information related to complaints and adverse events including corrective actions taken <input type="checkbox"/> Results of investigation and corrective actions <input type="checkbox"/> Records must be legible and stored in a manner that prevents their deterioration and/or loss <input type="checkbox"/> All records readily retrievable for 3 years after prep or as required by the laws and regulations, whichever is longer 								

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