Division of Professional Licensing
UTAH DEPARTMENT OF COMMERCE

160 E 300 S
P.O. Box 146741
Salt Lake City, Utah 84114-6741

Phone: (801) 530-6628
Toll Free : (866) 275-3675
Online: DOPL.utah.gov
Email: DOPLInvestigations@utah.gov

NON-STERILE COMPOUNDING

INSPECTION

☐ Opening ☐ Random

INFORMATION

Pharmacy Name: _____ Date: _____

Pharmacy License Number: _____ Expiration Date: _____

Designated Person(s): _____

_____

_____

_____

A person engaging in sterile or non-sterile compounding shall practice in accordance with all applicable federal and state laws and rules, and in accordance with the USP-NF, including USP General Chapter <795> Pharmaceutical Compounding- Non-Sterile Preparations. These operating standards shall apply to any person licensed under Title 58, Chapter 17b, Pharmacy Practice Act, that engages in compounding. R156-17b-614e(1)(b)(2)(a)

General Operations and Information

	Yes	No	
1.	☐	☐	Does the facility compound non-sterile prescriptions which are then delivered to a practitioner for administration to the patient in the office, clinic or facility?
2.	☐	☐	Does the facility distribute non-sterile compounded preparations to hospitals, clinics, or surgery centers?
3.	☐	☐	Does the facility dispense non-sterile compounded preparations pursuant to a prescription?
4.	☐	☐	Does the facility have a sales force that distributes samples containing active ingredients? List on separate sheet.
5.	☐	☐	A pharmacy licensed under this chapter may, subject to rules established by the Division, repackage or compound a prescription drug for sale to a practitioner if: the prescription drug: does not include a compounded drug; or includes a compounded drug; and is not a controlled substance; the pharmacy labels the prescription drug "for office use only"; the practitioner administers the drug to a patient in the practitioner's office or facility; and except in accordance with Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, the practitioner does not dispense the drug to the patient. [UCA 58-17b-624(1)(a)(i)(ii)(A)(B)(b)(c)(d)] Pursuant to Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use provided that it is in compliance with all applicable federal and state laws and regulations regarding the practice of pharmacy, including, but not limited to the Food, Drug, and Cosmetic Act, 21 U.S.C A § 301 et seq. [R156-17b-624]
6.	☐	☐	Does the facility compound investigational drugs? If so, list on separate sheet.
7.	☐	☐	Does the facility compound vitamins or nutritional supplements? If so, list on separate sheet.
8.			What does the facility compound?

☐ Tablets ☐ Transdermals ☐ Ointments ☐ Suppositories ☐ Oral Pastes

☐ Capsules ☐ Liquids ☐ Sprays ☐ Powders ☐ Creams

☐ Patches ☐ Lozenges ☐ Troches ☐ Other:

9.	☐	☐	The facility does not prepare a prescription drug for sale to another pharmacist or pharmaceutical facility. [UAC 58-17b-102(18)(b)(i)]

10. ☐ ☐ Does the facility perform compounding with hazardous drugs?

11. ☐ ☐ The facility does not prepare a prescription drug in a dosage from which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner. [UCA 58-17b502(13)]

12. ☐ ☐ Does the facility make non-sterile compounded preparations using bulk powder active pharmaceutical ingredients?

13. ☐ ☐ The facility does not prepare a prescription drugs, sterile products, or devices which have been withdrawn from the market for safety reasons. [UAC 58-17b-102(18)(b)(iii)]

14. ☐ ☐ Does the facility compound for veterinary use?

15. ☐ ☐ If compounding for both humans and animals, are the API's or other components that are labeled for veterinary use only are segregated or marked in such way to prevent them from being used for human compounding?
N/A ☐

Designated Person(s)

16. ☐ ☐ The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSPs. [USP-NF Chapter 795-*Oversight by Designated Person(s)*]

17. ☐ ☐ The Designated Person(s) must have the training, experience, responsibility, and authority to perform all duties related to the compounding process. [USP-NF Chapter 795-*Oversight by Designated Person(s) & Quality Assurance and Quality Control*]

18. ☐ ☐ The responsibilities of the Designated Person(s) include but not limited to: [USP-NF Chapter 795-*Oversight by Designated Person(s) & Quality Assurance and Quality Control*]

- ☐ Overseeing a training program to ensure competency of personnel involved in compounding, handling and preparing CNSPs
- ☐ Selecting components
- ☐ Monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed
- ☐ Ensuring that standard operating procedures (SOPs) are fully implemented and follow-up is carried out if problems, deviations, or errors are identified.
- ☐ Establishing, monitoring and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs
- ☐ Reviewing the QA & QC program at least once every 12 months. Results of the review must be documented and appropriate action taken.

19. ☐ ☐ The Designated Person(s) must be identified in the facility's SOPs. [USP-NF Chapter 795- *Oversight by Designated Person(s)*]

Personnel Training and Evaluation

20. ☐ ☐ Personnel who compound or have direct oversight of compounding personnel must complete training initially and at least every 12 months in appropriate compounding principles and practices as described in this section. [USP-NF Chapter 795-*Personnel Training and Evaluation*]

21. ☐ ☐ Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs, must undergo training as required by the facility's SOPs. [USP-NF Chapter 795-*Personnel Training and Evaluation*]

22. ☐ ☐ Training and competency of personnel must be documented. Knowledge and competency must be demonstrated initially and at least every 12 months in at least the following core competencies: [USP-NF Chapter 795-*Personnel Training and Evaluation*]

- ☐ Hand hygiene
- ☐ Garbing
- ☐ Cleaning and sanitizing
- ☐ Measuring and Mixing
- ☐ Proper use of equipment and devices selected to compound CNSPs
- ☐ Documentation of the compounding process
- ☐ Handling and Transporting components and CNSPs

23. ☐ ☐ Training procedures must include the following: [USP-NF Chapter 795-*Personnel Training and Evaluation*]

- ☐ Understand of the requirements in USP-NF-Chapter 795
- ☐ Understand and interpret safety data sheets (SDSs) and, if applicable certificates of analysis (COA)
- ☐ Read and understand procedures related to compounding duties.

24. ☐ ☐ Upon completion of the training program, the Designated Person(s) and/or assigned trainer must document that personnel have been trained and successfully completed competency assessments. [USP-NF Chapter 795-*Personnel Training and Evaluation*]

25. ☐ ☐ Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel. [USP-NF Chapter 795-*Personnel Training and Evaluation*]

Personal Hygiene and Garbing

26. ☐ ☐ Individuals entering the compounding area must maintain appropriate personal hygiene. Individuals must evaluate whether they have a personal risk of potentially contaminating the compounding environment and CNSP . Individuals must report these conditions to the designated person(s). Because of the risk of contaminating the CNSP and the environment, the designated person(s) is responsible for evaluating whether these individuals should be excluded from working in compounding areas until their conditions have resolved. [USP-NF Chapter 795-*Personal Hygiene and Garbing*]

27. ☐ ☐ Personnel engaged in compounding must maintain appropriate hand hygiene and maintain appropriate cleanliness required for the type of compounding performed. Before entering the compounding area, compounding personnel must remove any items that are not easily cleanable and that might interfere with garbing. At a minimum, personnel must: [USP-NF Chapter 795-*Personal Hygiene and Garbing*]

- Remove personal outer garments
- Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing or hand hygiene
- Remove earbuds or headphones

*The designated person(s) may permit accommodations provided that the quality of the environment and CNSP will not be affected. All accommodations should be documented

28. ☐ ☐ Personnel must preform procedures necessary for appropriate hand hygiene when entering the compounding area to compound. [USP-NF Chapter 795-*Personal Hygiene and Garbing*]

- ☐ Wash hands with soap and water for at least 30 seconds- the use of alcohol based hand rub alone is not sufficient.
- ☐ Dry hands completely with disposable towels or wipes.
- ☐ After inspecting gloves for holes, punctures or tears; don gloves.

29. ☐ ☐ Gloves must be worn for all compounding activities. [USP-NF Chapter 795- *Personal Hygiene and Garbing*]

30. ☐ ☐ Compounding personnel must be appropriately garbed for the type of compounding performed and should be worn as needed for the protection of personnel from chemical exposures and for prevention of CNSP contamination. [USP-NF Chapter 795-*Personal Hygiene and Garbing*]

31. ☐ ☐ Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. [USP-NF Chapter 795-*Personal Hygiene and Garbing*]

32. ☐ ☐ Garb must be stored in a manner that minimizes contamination. [USP-NF Chapter 795- Personal Hygiene and Garbing]

33. ☐ ☐ Disposable garb must not be laundered. If gowns are worn, they may be reused if not damaged or soiled. [USP-NF Chapter 795-*Personal Hygiene and Garbing*] ☐ N/A

34. ☐ ☐ If gowns are to be reused, they must remain in the compounding area, and should only be reused during the same shift. [USP-NF Chapter 795-*Personal Hygiene and Garbing*] ☐ N/A

35. ☐ ☐ If compounding an HD, appropriate personal protective equipment (PPE) must be worn and disposed of in accordance with USP-NF Chapter 800. [USP-NF Chapter 795-*Personal Hygiene and Garbing*]

36. ☐ ☐ The facility's SOPs must describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment. [USP-NF Chapter 795-*Personal Hygiene and Garbing*]

37. ☐ ☐ Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility' SOPs. [USP-NF Chapter 795-*Personal Hygiene and Garbing*]

Buildings and Facilities

38. ☐ ☐ An area must be designated for non-sterile compounding. The method of designation must be described in the facility's SOPs. Other activities must not be occurring in the compounding area at the same time as compounding. [USP-NF Chapter 795-*Buildings and Facilities*]

39. ☐ ☐ The compounding area must be well lit and must be maintained in a clean, orderly, sanitary condition and in a good state of repair. [USP-NF Chapter 795-*Building and Facilities*]

40. ☐ ☐ The compounding area must provide for the orderly placement of equipment and materials to prevent mix-ups among components, containers, labels, in-process materials and finished CNSPs. [USP-NF Chapter 795-*Buildings and Facilities*]

41. ☐ ☐ All CNSPs, components, equipment, and containers must be stored off the floor in a manner that prevents contamination and permits inspection and cleaning of the storage area(s). [USP-NF Chapter 795-*Buildings and Facilities*]

42. ☐ ☐ Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains with the appropriate range for the CNSPs and components. [USP-NF Chapter 795 - *Buildings and Facilities*]

43. ☐ ☐ The results of temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable. [USP-NF Chapter 795-*Buildings and Facilities*]

44. ☐ ☐ All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by manufacturer or every 12 months if not specified by the manufacturer. [USP-NF Chapter 795-*Buildings and Facilities*]

45. ☐ ☐ The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s). When it is known that a CNSP or component has been exposed to temperatures either below or above the store temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised, and if so, the CNSP or component must be discarded. [USP-NF Chapter 795-*Buildings and Facilities*]

46. ☐ ☐ A source of hot and cold water and an easily accessible sink must be available. The sink must be emptied of all items unrelated to compounding and must be cleaned if visibly soiled before being used to clean any equipment used in non-sterile compounding. [USP-NF Chapter 795-*Buildings and Facilities*]

Cleaning and Sanitizing

47. ☐ ☐ Cleaning and sanitizing the surfaces in the non-sterile compounding area(s) must occur on a regular basis at a minimum frequencies listed below. If compounding is not performed daily, cleaning and sanitizing must be completed before initiating compounding. Cleaning and sanitizing must be repeated when spills occur and when surfaces are visibly soiled. [USP-NF Chapter 795-Cleaning and Sanitizing]

Work Surfaces :

- At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination is known or suspected
- Between compounding CNSPs with different components

Floors:

- Daily on days when compounding occurs, after spills, and when surface contamination is known or suspected

Walls:

- When visibly soiled, after spills, and when surface contamination is known or suspected

Ceilings:

- When visibly soiled and when surface contamination is known or suspected

Storage Shelving:

- Every 3 months, after spills, and when surface contamination is known or suspected

48. ☐ ☐ All applicable cleaning and sanitizing must be documented daily when compounding occurs. [USP-NF Chapter 795-*Cleaning and Sanitizing*]

49. ☐ ☐ Cleaning and sanitizing agents must be selected and used with the consideration of compatibility, effectiveness, and minimal potential to leave residues. [USP-NF Chapter 795-*Cleaning and Sanitizing*]

50. ☐ ☐ If cleaning and sanitizing are performed as separate steps, cleaning must be performed first. [USP-NF Chapter 795-*Cleaning and Sanitizing*]

Equipment and Components

51. ☐ ☐ The equipment and components used for compounding a CNSP must be suitable for the specific compounding process. Equipment surfaces that contact components must not be reactive, additive, or sorptive and must not alter the quality of the CNSP. [USP-NF Chapter 795-*Equipment and Components*]

52. ☐ ☐ Equipment must be stored in a manner that minimizes the risk of contamination and must be located to facilitate equipment use, maintenance, and cleaning. [USP-NF Chapter 795-*Equipment and Components*]

53. ☐ ☐ Equipment and devices used in the compounding or testing of compounded preparations must be inspected prior to use and, if appropriate verified for accuracy as recommended by the manufacturer at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent. [USP-NF Chapter 795-*Equipment and Components*]

54. ☐ ☐ Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. [USP-NF Chapter 795-*Equipment and Components*]

55. ☐ ☐ If a BSC,CVE, or other non-disposable device is used, it must be cleaned as described below: [USP-NF Chapter 795- *Equipment and Components*]

CVE

- At the beginning, and end of each shift on days when compounding occurs, after spills, and when surface contamination is know or suspected. Clean and sanitize the horizontal work surface of the CVE between compounding CNSPs with different components.

BSC

- At the beginning, and end of each shift on days when compounding occurs, after spills, and when surface contamination is known or suspected. Clean and sanitize the horizontal work surface of the BSC between compounding CNSPs with different components. Clean and sanitize under the work surface at least monthly.

Other devices and equipment used in compounding operations

- Before first use and thereafter in accordance with the manufacturer's recommendation. If no recommendation is available, between compounding CNSPs with different components.

56. ☐ ☐ After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation. [USP-NF Chapter 795- *Equipment and Components*]

57. ☐ ☐ If a CVE or BSC is used, it must be certified at least every 12 months according to manufacturer specifications or other laws and regulations of the applicable regulatory jurisdiction. [USP-NF Chapter 795-*Equipment and Components*]
N/A ☐

58. ☐ ☐ The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented. [USP-NF Chapter 795- *Equipment and Components*]

59. ☐ ☐ Designated person(s) must be responsible for selecting components to be used in compounding. [USP-NF Chapter 795- Equipment and Components]

APIs

- Must comply with the criteria in the *USP-NF* monograph, if one exists
- Must have a COA that includes specifications and test results for the component that show the API meets expected quality. In the United States, must be manufactured by an FDA-registered facility.

Water

- Purified water or better quality must be used for compounding non-sterile drug preparations when formulations indicate the inclusion of water.

60. ☐ ☐ Upon receipt of components other than conventionally manufactured products, the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists. [USP-NF Chapter 795- *Equipment and Components*]

61. ☐ ☐ The following information must be documented according to the facility's SOPs. [USP-NF Chapter 795- *Equipment and Components*]

- ☐ Receipt date
- ☐ Quantity received
- ☐ Lot number
- ☐ Expiration date
- ☐ Supplier name
- ☐ Results of any in-house or third-party testing performed

62. ☐ ☐ For all components that lack a vendor expiration date, the date of receipt by the compounding facility must be clearly and indelibly marked on each packaging system. Packaging systems of components that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations {797}, 9.3.2 *Component receipt* if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation. [USP-NF Chapter 795- *Equipment and Components*]

63. ☐ ☐ Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Any other lots of that component from the same vendor must be examined to determine whether the other lots have the same defect. [USP-NF Chapter 795- *Equipment and Components*]

64. ☐ ☐ Before use, compounding personnel must visually re-inspect all components. Each packaging system must be inspected to detect any container breakage, looseness of the cap or closure, or deviation from the expected appearance or texture of the contents that might have occurred during storage. [USP-NF Chapter 795- *Equipment and Components*]

65. ☐ ☐ Compounding personnel must ascertain before use that components are of the correct identity based on the labeling and have been stored under required conditions in the facility. [USP-NF Chapter 795- *Equipment and Components*]

66. ☐ ☐ If the identity, strength, purity, and quality of components intended for preparation of CNSPs cannot be verified , the components must be immediately rejected. Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. [USP-NF Chapter 795- *Equipment and Components*].

67. ☐ ☐ All components must be handled in accordance with the manufacturer's instructions or per laws and regulations of the applicable regulatory jurisdiction. The handling must minimize the risk of contamination, mix-ups, and deterioration. For each use, the lot must be examined for evidence of deterioration and other aspects of unacceptable quality. [USP-NF Chapter 795- *Equipment and Components*]

68. ☐ ☐ The facility must maintain current chemical hazard and disposal information. Such information must be made accessible to compounding personnel. [USP-NF Chapter 795- *Equipment and Components*]

69. ☐ ☐ The facility must have a readily accessible spill kit in the compounding area. [USP-NF Chapter 795- *Equipment and Components*]

70. ☐ ☐ All personnel who may be required to remediate a spill must receive training in spill management of chemicals used and stored at the compounding facility. Training must be conducted at least every 12 months and documented for all personnel who may be required to clean up a spill. [USP-NF Chapter 795- *Equipment and Components*]

71. ☐ ☐ Waste of any component must be disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction. [USP-NF Chapter 795- *Equipment and Components*].

72. ☐ ☐ The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs. [USP-NF Chapter 795- *Equipment and Components*]

Master Formulation and Compounding Records

73. ☐ ☐ An MFR must be created for each unique formulation of a CNSP. CNSPs are to be prepared according to the MFR. An MFR must include at least the following information: [USP-NF Chapter 795- *Master Formulation and Compounding Records*]

- ☐ Name, Strength/Activity and Dosage Form ☐ Identities and amounts of all components ☐ Container closure system(s)
- ☐ Complete instructions for preparing CNSP- including equipment, supplies, & description of compounding steps
- ☐ Physical description of the final CNSP ☐ BUD & Storage requirements ☐ Reference source for BUD
- ☐ Labeling Requirements ☐ QC Procedures and Expected results ☐ Other information needed to ensure reapeatability
- ☐ If applicable, calculations to determine & verify quantities and/or concentrations of components and strength or activity of the API(s)

74. ☐ ☐ Any changes or alterations to the MFR must be approved and documented according to the facility's SOPs [USP-NF Chapter 795- *Master Formulation and Compounding Records*]

75. ☐ ☐ A compounding record must be created for all CNSPs. Each compounding record must be reviewed for completeness before the CNSP is released. A CR must include at least the following information: [USP-NF Chapter 795- *Master Formulation and Compounding Records*]

- ☐ Name, Strength/Activity and Dosage Form ☐ Date of preparation ☐ Assigned identification number
- ☐ Identity of compounder and individual verifying the final CNSP ☐ Weight/measurement of each component
- ☐ Name, vendor/manufacturer, lot number & expiration date of each component ☐ Total quantity compounded
- ☐ BUD & Storage requirements ☐ Physical description of the final CNSP ☐ Results of QC procedures
- ☐ MFR reference for CNSP
- ☐ If applicable, calculations to determine & verify quantities and/or concentrations of components and strength or activity of the API(s)

Release Inspections and Testing

76. ☐ ☐ All release inspections must be included in the facility's documentation. All checks, inspections, and any other required tests to ensure the quality of the CNSP must be detailed in the facility's MFR. [USP-NF Chapter 795- *Release Inspections and Testing*]

77. ☐ ☐ At the completion of compounding, before releasing and dispensing, the CNSP must be visually inspected to determine whether the physical appearance and characteristics of the CNSP is as expected. The CNSP must be visually inspected to confirm that the CNSP and its labeling match the CR and the prescription or medication order. The inspection must include a visual inspection of container closure integrity. [USP-NF Chapter 795- *Release Inspections and Testing*]

78. ☐ ☐ When a CNSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted immediately before it is released or dispensed to make sure that the CNSP does not exhibit any defects that could develop during storage. Any CNSP found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected and segregated from active stock to prevent use before disposal. [USP-NF USP Chapter 795- *Release Inspections and Testing*]

Labeling

79. ☐ ☐ The label on each container of the prepared CNSP must, at a minimum, display prominently and legibly the following information [USP-NF Chapter 795- *Labeling* & R156-17b-614a(2)(a)(i-iii)]:

- ☐ Assigned internal identification number
- ☐ Generic name of Active ingredient(s), and their amounts(s), activity(ies), or concentration(s)
- ☐ Storage condition if other than controlled room temperature
- ☐ Dosage Form
- ☐ BUD
- ☐ Total amount or volume if it is not obvious from the container

80. ☐ ☐ The requirements described in Subsection (2)(a)(i) shall not apply to a label on the container of a drug that a health care provider administers to a patient at a pharmaceutical administration facility; or a hospital licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act. [R156-17b-614a(2)(b)(i-ii)]

N/A ☐

81. ☐ ☐ The label of the CNSP must be verified to ensure that it conforms with the following [USP-NF Chapter 795- *Labeling*]

- ☐ Prescription or Medication Order
- ☐ MFR
- ☐ CR

82. ☐ ☐ Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups[USP-NF Chapter 795- *Labeling*]

Establishing Beyond-Use-Dates

83. ☐ ☐ BUD limit by type of preparation in the absence of a USP-NF compounded preparation monograph or CNSP-specific stability information [USP-NF Chapter 795- *Establishing Beyond-Use-Dates*]

- ☐ Non-preserved aqueous dosage forms- BUD 14 days when stored in the refrigerator
- ☐ Preserved aqueous dosage forms- BUD 35 days when stored at controlled room temperature or refrigerator
- ☐ Oral liquids (non-aqueous)- BUD 90 days when stored at controlled room temperature or refrigerator
- ☐ Other non-aqueous dosage forms- BUD 180 days when stored at controlled room temperature or refrigerator

84. ☐ ☐ The BUD's listed above are the BUD limits for CNSPs in the absence of specific stability information. This does not absolve the designated person(s) from performing due diligence if there is existing stability data that would require a shorter BUD. [USP-NF Chapter 795- *Establishing Beyond-Use-Dates*]

85. ☐ ☐ The BUD of the CNSP must not exceed the shortest remaining expiration date of any of the commercially available starting components. [USP-NF Chapter 795- *Establishing Beyond-Use-Dates*]

86. ☐ ☐ When compounding from a USP-NF compounded preparation monograph for the CNSP, the BUD must not exceed the BUD specified in the monograph. [USP-NF Chapter 795- *Establishing Beyond-Use-Dates*]

87. ☐ ☐ CNSPs with stability information: if there is a stability study using a stability-indicating analytical method for the API(s), CNSP formulation, and material of composition of the container closure that will be used, then the BUD indicated by the study may be used in lieu of the BUD's specified for aqueous and non-aqueous dosage forms, up to a maximum of 180 days. [USP-NF Chapter 795- *Establishing Beyond-Use-Dates*]

88. ☐ ☐ If the BUD of the CNSP is extended beyond the BUD listed above, an aqueous CNSP must be tested for antimicrobial effectiveness. [USP-NF Chapter 795- *Establishing Beyond-Use-Dates*]

SOPs

89. ☐ ☐ Facilities preparing CNSPs must develop SOPs on all aspects of the compounding operation. [USP-NF Chapter 795- *SOPs*]

90. ☐ ☐ All personnel who conduct or oversee compounding activities must be trained in the facility's SOPs and be responsible for ensuring that they are followed. [USP-NF Chapter 795 *SOPs*].

Quality Assurance and Quality Control

91. ☐ ☐ A facility's QA and QC program must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in USP-NF Chapter 795 and the laws and regulations of the applicable regulatory jurisdiction. [USP-NF Chapter 795 *Quality and Assurance and Quality Control*].

92. ☐ ☐ Designated Person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of ;[USP-NF Chapter 795 *Quality and Assurance and Quality Control*]

- ☐ Adherence to procedures
- ☐ Prevention and detection of errors and other quality problems
- ☐ Evaluation of complaints and adverse events
- ☐ Appropriate investigations and corrective actions

93. ☐ ☐ The facility's SOP must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program. [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

The facility must have procedures in place to; [USP-NF Chapter 795- *Quality and Assurance and Quality Control]*

- ☐ Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of failure of specifications with the potential to cause patient harm
- ☐ Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy
- ☐ Investigate if other lots are affected and recall if necessary

94. ☐ ☐ Any SOP for recall of dispensed CNSPs must contain the following procedures: [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

- ☐ Determine the severity of the problem and the urgency for implementation and completion of the recall
- ☐ Determine the distribution of any affected CNSP, including the data and quantity of distribution
- ☐ Identify patients who have received the CNSP
- ☐ Disposal and documentation of the recalled CNSP
- ☐ Investigate and document the reason for recall

95. ☐ ☐ The facility must document the implementation of the recall procedures. The recall must be reported to appropriate regulatory bodies as required by the laws and regulations of the applicable regulatory jurisdiction. [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

96. ☐ ☐ The facility must develop and implement SOPs for handling complaints. [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

97. ☐ ☐ Designated Person(s) must review all complaints to determine whether the complaint indicates a potential quality problem with CNSP. If it does, a thorough investigation into the cause of the problem must be initiated and completed. The investigation must consider whether the quality problem extends to other CNSPs. Corrective action, if necessary, must be implemented for all potentially affected CNSPs. [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

98. ☐ ☐ A readily retrievable written or electronic record of each complaint must be kept by the facility. The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

99. ☐ ☐ The complaint record must also include the findings of any investigation and any follow-up. [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

100. ☐ ☐ Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained in accordance with the record keeping requirements. [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

101. ☐ ☐ A CNSP that is returned in connection with a complaint must be quarantined until it is destroyed after completion of the investigation and in accordance with laws and regulations of the applicable regulatory jurisdiction. [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

102. ☐ ☐ Adverse events potentially associated with the quality of CNSPs must be reported in accordance with facility's SOPs and all laws and regulations of the applicable regulatory jurisdiction. If the investigation into an adverse event reveals a quality problem with a CNSP that is likely to affect other patients, those patients and prescriber's potentially affected must be informed. [USP-NF Chapter 795- *Quality and Assurance and Quality Control*]

CNSP Packaging and Transporting

103. ☐ ☐ Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure.[USP-NF Chapter 795- *CNSP Packaging and Transporting*]

104. ☐ ☐ If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any specific handling instructions, and whether temperature monitoring devises are needed. [USP-NF Chapter 795- *CNSP Packaging and Transporting*]
N/A ☐

105. ☐ ☐ The facility's SOPs must describe packaging of CNSPs. [USP-NF Chapter 795- *CNSP Packaging and Transporting*]

Documentation

106. ☐ ☐ All facilities where CNSPs are prepared must have and maintain written or electronic documentation to demonstrate compliance with the requirements in USP-NF 795. This documentation must include, but is not limited to, the following; [USP-NF Chapter 795-*Documentation*]

- ☐ Personnel training, competency assessments, and qualification records including corrective actions for any failures
- ☐ Equipment records
- ☐ COAs and all documentation required for components not conventionally manufactured
- ☐ Receipt of components
- ☐ SOPs, MFRs, and CRs
- ☐ Release inspection and testing records
- ☐ Information related to complaints and adverse events including corrective actions taken Results of investigations and corrective actions
- ☐ Records of cleaning and sanitizing the designated compounding area
- ☐ Temperature logs
- ☐ Accommodations to personnel compounding CNSPs
- ☐ Required routine reviews

107. ☐ ☐ Records must be legible and stored in a manner that prevents their deterioration and/or loss. [USP-NF Chapter 795- *Documentation*]

108. ☐ ☐ All required CRs for a particular CNSP must be readily retrievable for at least 2 years after preparation or as required by the laws and regulations of the applicable regulatory jurisdiction, whichever is longer. [USP-NF Chapter 795- *Documentation*]

Inspection Comments

☐ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: Date:

Name of Responsible Party (Print):

Signature of Division Investigator: Date:

Name of Division Investigator (Print):

Revised 9/2025