# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Non-Sterile Compounding Inspection: Instruction Sheet and Form

(Revised 12/16/24)

The NVBOP's established self-assessment inspection process provides management the opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services.

**Please have the self-assessment form completed and available for review by the first day of the month listed on your inspection notice. An inspector will review the form with you and inspect your facility during the month listed on your inspection notice.**

**To minimize any disruption to your facility during the inspection process please have the following available:**

1. Completed Non-Sterile Compounding Inspection form along with prior year inspection form
2. Most recent certification report for any powder hoods located at the pharmacy and documentation of corrective action taken by facility for any failures documented on the certification report
3. Prior 12 months of competency documentation for compounding personnel
4. Examples of compounding worksheets
5. Examples of master formulations
6. SOP's relevant to the non-sterile compounding process
7. Potency testing results (if utilizing BUD in excess of USP 795 guidelines)

**The revised USP-795 guidelines were published on 11/1/2022 and the implementation date is 11/1/2023.**

**Compounded Non-Sterile products that must comply with USP-795 include but are not limited to the following dosage forms:**

Solid oral preparations

Liquid oral preparations

Rectal preparations

Vaginal preparations

Topical preparations

Nasal and Sinus preparations intended for local application

Otic preparations

**Practices not subject to the requirements in USP Chapter 795:**

Non-sterile Radiopharmaceuticals: Covered in USP-825

Administration: Preparation of a single dose for a single patient when administration will begin within 4 hours of beginning the preparation. This includes crushing a tablet or opening a capsule to mix with food or liquid to facilitate patient dosing.

Reconstitution: Reconstitution of a conventionally manufactured non-sterile product in accordance with the directions contained in the manufacturer approved labeling.

Repackaging: Repackaging of conventionally manufactured drug products.

Splitting Tablets: Breaking or cutting a tablet into smaller portions.

**Personnel and settings affected:**

USP-795 applies to all persons who prepare compounded non-sterile products and all places where compounded non-sterile products are prepared.

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 compounded non-sterile products.

The designated person(s) must be identified in an SOP.

Please see USP 795 for more details on the responsibilities of the designated person(s).

| Pharmacy Information | |
|---|---|
| Date Completed: | |
| Pharmacy Name: | |
| Pharmacy License #: | |
| Pharmacy Address: | |
| Pharmacy Telephone #: | |
| Pharmacy Fax #: | |
| Pharmacy Email: | |
| Managing Pharmacist Name: | |
| Managing Pharmacist start date: | |
| Name of Designated Person(s): | |

| **List of compounding personnel approved to compound non-sterile products (Make copies of this page if additional space is needed)** | | | |
|---|---|---|---|
| # | Name (First, Last) | License Number | Position |
| 1 | | | |
| 2 | | | |
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| Personnel Training and Evaluation | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 2 | Have all personnel who compound or have direct oversight of compounding CNSP's been initially trained and qualified by demonstrating knowledge and competency according to the requirements listed in USP-795 before being allowed to perform their job functions independently? | | | |
| | Do all personnel who compound or have direct oversight of compounding CNSP's have documentation of training every 12 months by demonstrating knowledge and competency according to the requirements listed in USP-795? | | | |
| | Has the designated person(s) created and implemented a training program that describes the required training, the frequency of training, and the process for evaluating the competency of the personnel? | | | |
| USP 795 Section 2 | Is the training and observation performed by the designated person(s) or an assigned trainer? | | | |
| USP 795 Section 2 | Is all initial and ongoing training documentation available for NVBOP inspector's review? | | | |

| Personal Hygiene and Garbing | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 3 – 3.3 | The designated person(s) evaluates compounding personnel to confirm if they meet the requirements to enter the compounding environment? | | | |
| USP 795 Section 3 – 3.3 | Compounding personnel at a minimum remove the following items prior to entering the compounding area: personal outer garments, exposed jewelry, earbuds or headphones? | | | |
| USP 795 Section 3 – 3.3 | Proper handwashing techniques are utilized when entering the compounding area? | | | |
| USP 795 Section 3 – 3.3 | Gloves are worn for all compounding activities? | | | |
| USP 795 Section 3 – 3.3 | Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised? | | | |
| USP 795 Section 3 – 3.3 | Garbing requirements and frequency of changing is documented in the pharmacy's SOP's? | | | |
| USP 795 Section 3 – 3.3 | Gowns are the only garb that is potentially re-used? | | | |
| USP 795 Section 3 – 3.3 | If compounding an HD, appropriate PPE is worn and disposed of in accordance with USP 800? | | | |

| Compounding Area | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 4.1 | There is a designated area for nonsterile compounding? | | | |
| USP 795 Section 4.1 | Compounding area is well lit and maintained in a clean, orderly, sanitary condition and in a good state of repair? | | | |
| USP 795 Section 4.1 | The compounding area provides for the orderly placement of equipment and materials to prevent mix-ups among components, containers, labels, in-process materials, and finished CNSP's? | | | |
| USP 795 Section 4.1 | The compounding area is designed in a way that minimizes cross contamination from non-compounding areas? | | | |

| Storage Area | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 4.2 | Temperature monitoring for the storage area is performed either manually once daily on days that the facility is open or continuously with a temperature recording device? | | | |
| USP 795 Section 4.2 | When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits the designated person(s) determines whether the CNSP or component integrity has been compromised, and if so, the CNSP must be discarded? | | | |
| USP 795 Section 4.2 | All CNSP's, components, equipment, and containers are stored off the floor? | | | |

| Water Sources | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 4.3 | A source of hot and cold water and an easily accessible sink is available? | | | |
| USP 795 Section 4.3 | The sink is emptied of all items unrelated to compounding and is cleaned if visibly soiled? | | | |

| Cleaning and Sanitizing | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 5 | If compounding is not performed daily then cleaning and sanitizing takes place prior to initiating compounding? | | | |
| USP 795 Section 5 | Cleaning and sanitizing is repeated when spills occur or when surfaces are visibly soiled? | | | |
| USP 795 Section 5 | If cleaning and sanitizing are performed as separate steps then cleaning is performed first? | | | |
| USP 795 Section 5 | Work surfaces are cleaned at the beginning and end of each shift, after spills, and when surface contamination is known or suspected? | | | |
| USP 795 Section 5 | Work surfaces are cleaned between compounding CNSP's with different components? | | | |
| USP 795 Section 5 | Floors are cleaned daily, after spills, and when surface contamination is known or suspected? | | | |
| USP 795 Section 5 | Walls are cleaned when visibly soiled, after spills, and when surface contamination is known or suspected? | | | |
| USP 795 Section 5 | Ceilings are cleaned when visibly soiled and when surface contamination is known or suspected? | | | |
| USP 795 Section 5 | Storage shelving is cleaned every 3 months, after spills, and when surface contamination is known or suspected? | | | |

| Equipment | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 6.1 | Equipment is stored in a manner that minimizes the risk of contamination and is located to facilitate equipment use, maintenance, and cleaning? | | | |
| USP 795 Section 6.1 | Equipment and devices used in the compounding process are 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 795 Section 6.1 | Equipment is cleaned after compounding to prevent cross contamination? | | | |
| USP 795 Section 6.1 | If a CVE or BSC is utilized it is certified at least every 12 months? | | | |
| USP 795 Section 6.1 | CVE or BSC is cleaned and sanitized per USP 795 guidelines? | | | |

| Components | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 6.2 | The compounding facility has written SOP's for the selection and inventory control of all components from receipt to use in a CNSP? | | | |
| USP 795 Section 6.2 | The designated person is responsible for selecting components to be used in compounding? | | | |
| USP 795 Section 6.2 | APIs: Must comply with the criteria in the USP-NF monograph, if one exists<br>Must have a COA that includes specifications and test results for the component<br>In the US, must be manufactured by an FDA-registered facility<br>Outside the US, must comply with the laws and regulations of the applicable jurisdiction | | | |
| USP 795 Section 6.2 | Purified water or better quality is used for compounding nonsterile drug preparations when formulations indicate the inclusion of water? | | | |
| USP 795 Section 6.2 | The COA is reviewed to ensure that the component has met the acceptance criteria in an USP-NF monograph? | | | |
| USP 795 Section 6.2 | The date of receipt by the compounding facility is clearly marked on each component package that lacks a vendor expiration date? | | | |
| USP 795 Section 6.2 | Packages that lack a vendor expiration date are not used by the compounding facility after 3 years from the date of receipt? | | | |
| USP 795 Section 6.2 | Any component that is found to be of unacceptable quality is promptly rejected, clearly labeled as rejected, and segregated from active stock? | | | |
| USP 795 Section 6.2 | Before use, all components are visually re-inspected? | | | |
| USP 795 Section 6.2 | Compounding personnel 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 795 Section 6.2 | Once removed from the original container, any component not used in compounding is discarded and not returned to the original container to minimize the risk of contaminating the original container? | | | |
| USP 795 Section 6.2 | There is a spill kit readily available in the compounding area? | | | |
| USP 795 Section 6.2 | The facility has SDS sheets available for all products used in the compounding area? | | | |
| USP 795 Section 6.2 | There is documented training at least every 12 months for all personnel who may be required to clean up a spill? | | | |

| Master Formulations | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 7.1 | A master formulation record has been created for each unique formulation of a CNSP? | | | |
| USP 795 Section 7.1 | Any changes or alterations to a master formulation record are approved and documented according to the facility's SOP? | | | |
| USP 795 Section 7.1 | CNSP's are prepared according to the master formulation record and the details of each preparation are documented on a compounding record? | | | |
| USP 795 Section 7.1 | Each master formulation record contains the following information?<br>Name, strength or activity, and dosage form of the CNSP<br>Identities and amounts of all components; if applicable, relevant characteristics of components<br>Container closure system(s)<br>Complete instructions for preparing the CNSP including equipment, supplies, and description of compounding steps<br>Physical description of the final CNSP<br>beyond-use-date and storage requirements<br>Reference source to support the assigned BUD | | | |

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|---|---|---|---|---|
| | If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API'(s)<br>Labeling requirements<br>Quality control procedures<br>Other information needed to describe the compounding process and ensure repeatability | | | |

| **Compounding Records** | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 7.2 | A compounding record is created for all CNSP's? | | | |
| USP 795 Section 7.2 | Each compounding record is reviewed for completeness before the CNSP is released? | | | |
| USP 795 Section 7.2 | The name or other unique identifier of the person completing the review and the date of the review is documented on the compounding record? | | | |
| USP 795 Section 7.2 | The compounding records permits traceability of all components in the case of a recall or known quality issue? | | | |
| USP 795 Section 7.2 | The compounding record contains the following information?<br>Name, strength or activity, and dosage form of the CNSP<br>Date, or date and time, or preparation of the CNSP<br>Assigned internal identification number<br>A method to identify the individuals involved in the compounding process and individuals verifying the final CNSP<br>Name, vendor or manufacturer, lot number, and expiration date of each component<br>Weight or measurement of each component<br>Total quantity of the CNSP compounded<br>Assigned beyond-use-date and storage requirements<br>If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s)<br>Physical description of the final CNSP<br>Results of quality control procedures<br>Master formulation record reference for the CNSP | | | |

| **Visual Inspection** | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 8.1 | The CNSP is visually inspected at the completion of compounding, before releasing, and dispensing, to determine whether the physical appearance of the CNSP is as expected? | | | |

| **Labeling** | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 9 | The label of each container of the prepared CNSP contains the following information?<br>Assigned internal identification number<br>Active ingredient(s) and their amount(s), activity(ies), or concentration(s)<br>Storage conditions if other than controlled room temperature<br>BUD<br>Dosage form<br>Total amount or volume if it is not obvious from the container | | | |
| USP 795 Section 9 | The label of the CNSP is verified to ensure that it conforms with the prescription order, master formulation record, and compounding record? | | | |

| Beyond Use Dates | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 10 | All CNSP labels state the date, or the hour and date, beyond which the preparation cannot be used and must be discarded? | | | |
| USP 795 Section 10 | The pharmacy is following the parameters set forth in USP 795 based on water activity to determine BUD for specific products?<br><br>Refrigerated non-preserved aqueous dosage forms (aw >= 0.60) – 14 day BUD<br>Preserved aqueous dosage forms (aw >=0.60) – 35 days room temperature or refrigerator BUD<br>Oral liquids (nonaqueous) with aw <0.60 – 90 days room temperature or refrigerator BUD<br>Other nonaqueous dosage forms with aw < 0.60 – 180 days room temperature or refrigerator BUD | | | |
| USP 795 Section 10 | The assigned BUD of the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components? | | | |
| USP 795 Section 10 | Does the pharmacy assign beyond use dates in excess of USP 795 guidelines?<br>If yes, is antimicrobial effectiveness testing completed for all aqueous CNSP's? | | | |

| Quality Assurance and Quality Control | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 12 | Has the designated person(s) completed a formal, written QA and QC program and are the programs reviewed at a minimum every 12 months? | | | |

| Notification about and Recall of Dispensed CNSP's | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 12.1 | Does the pharmacy have a documented procedure in place to meet all of the recall requirements listed in USP 795? | | | |

| Complaint Handling | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 12.2 | Does the pharmacy have documented SOP's in place to handle complaints? | | | |
| USP 795 Section 12.2 | Does the designated person(s) review all complaints to determine whether a potential quality problem exists with the CNSP? | | | |
| USP 795 Section 12.2 | Do the records of complaints include the findings of the investigation and any follow-up that was required? | | | |

| Transporting of CNSP's | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 13.2 | Does the pharmacy utilize temperature monitoring devices for any products that are shipped and require refrigeration? | | | |

| Documentation | | | | |
|---|---|---|---|---|
| **Citation** | **Question** | **Yes** | **No** | **NA** |
| USP 795 Section 14 | Does the pharmacy maintain written or electronic documentation for the following items?<br>Personnel training, competency assessments, and qualification records including corrective actions for any failures<br>Equipment records (e.g. calibration, verification, and maintenance reports)<br>COA's and all documentation required for components not conventionally manufactured<br>Receipt of components<br>SOP's, MFR's, and CR's<br>Release inspection and testing records<br>Information related to complaints and adverse events including corrective actions taken<br>Results of investigations and corrective actions<br>Records of cleaning and sanitizing the designated compounding area<br>Temperature logs<br>Accommodations to personnel compounding CNSP's | | | |

| Notes |
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Your location will be inspected by an agent of the Nevada Board of Pharmacy. **All unsatisfactory conditions must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business. Please attach a copy of any documentation and corrective action you have taken to this inspection form for future review on inspection.**

| | |
|---|---|
| Date: | |
| Pharmacist Printed Name: | |
| Pharmacist Signature: | |