State of Connecticut
Department of Consumer Protection
Drug Control Division
DCP.DrugControl@ct.gov
www.ct.gov/dcp/dcd

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Pharmacy Inspection
Non-Sterile Compounding/USP <795>

Pharmacy Name

Inspection Date

Pharmacy Address

Phone Number

Fax Number

Pharmacy Manager/Director Name

Manager/Director E-mail

Licenses and Accreditations

CT Pharmacy License (PCY)/Expiration Date

CT Manufacturing License Number (CSM)/ Expiration Date

Date of last remodel/Construction

Date PEC/Compounding Equipment Moved

DEA License #/Expiration

FDA License/Expiration

PCAB Accreditation #/Expiration

Joint Commission Accreditation #/Expiration

Other

Personnel

Total # of Compounding Pharmacists

Total # of Compounding Technicians

Total # of Sales Personnel

List of Credential Personnel provided ○ Yes ○ No

Services/Products

Type of Compounding Performed

- ☐ Non-Sterile Compounding
- ☐ Sterile Compounding (See USP 797 Inspection)

Type of Non-Sterile Compounding Performed

- ☐ Simple
- ☐ Moderate
- ☐ Complex

A. General Operations

1. Does the pharmacy dispense non-sterile compounded preparations pursuant to a prescription? View record for legitimate prescription including a complete patient profile (allergies, disease states, other prescriptions and over the counter meds taken, etc.) and DUR performed. Watch for "list" of patients where the compounded preparation is delivered to the practitioner and no patient profile kept and no DUR performed.

○ Yes ○ No ○ N/A

Comments

2. Does the pharmacy distribute non-sterile compounded preparations to practitioners for office use?

○ Yes ○ No

Comments

3. Does the pharmacy distribute non-sterile compounded preparations to hospitals, clinics, or surgery centers?

○ Yes ○ No

Comments

4. Does the pharmacy provide non-sterile compounded preparations to other pharmacies for dispensing?

○ Yes ○ No

Comments

4a. If so, does the pharmacy have central fill contracts with these pharmacies for patient specific preparations or do they provide non-patient specific compounded preparations to other pharmacies?

○ Yes ○ No

Comments

5. Do non-sterile preparations for animals, does the compounding meet the same standards as compounding for human patients?

○ Yes ○ No ○ N/A

Comments

6. Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)?

○ Yes ○ No

Comments

7. Does the pharmacy compound topicals (creams, ointments, inserts, suppositories, patches, sprays, etc.)?

○ Yes ○ No

Comments

8. Does the pharmacy compound radiopharmaceuticals?

○ Yes ○ No

Comments

9. Does the pharmacy compound vitamin or nutritional supplements?

○ Yes ○ No

Comments

10. Does the pharmacy make a copy of an approved product?

○ Yes ○ No

Comments

10a. If yes, under what circumstances and how it is documented. Indicate volume or percent compounded currently in note.

11. Are products to be compounded appropriately identified as SIMPLE?

☐ Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s.

☐ Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.

Comments

12. Are products to be compounded appropriately identified as MODERATE?

☐ Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units.

☐ Making a preparation for which stability data for that specific formula is not available.

Comments

13. Are products to be compounded appropriately identified as COMPLEX?

○ Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.

○ N/A

Comments

14. Are products to be compounded appropriately identified as HAZARDOUS? National Institute for Occupational Safety and Health (NIOSH) list of drugs. Hazardous drugs exhibit: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low dose, or genotoxicity--includes hormone powders, chemotherapy, etc.

○ Yes ○ No

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15. Does the pharmacist perform an evaluation of the dose, safety and intended use if the preparation to be compounded?	○ Yes	○ No		Comments
16. For animal compounding, is the pharmacist knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used?	○ Yes	○ No	○ N/A	Comments
17. For animal compounding, is it determined and documented if the animal is used for food (meat, milk, eggs, etc.) versus a companion animal?	○ Yes	○ No	○ N/A	Comments
18. For animal compounding, is the pharmacist familiar with drug residues in the food chain and withdrawal times? How?	○ Yes	○ No	○ N/A	Comments
19. For animal compounding, is the pharmacist familiar with regulations regarding drug use in performance animals?	○ Yes	○ No	○ N/A	Comments

19a. How do the pharmacists get familiar with drugs in performance animals?

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B. Component Selection

1. Does the pharmacy make any compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)? ○ Yes ○ No Comments

2. Are certificates of analysis (COAs) obtained for all APIs? Select several products from the shelf and ask to see the COAs for those products. ○ Yes ○ No Comments

2a. Are COAs domestic or foreign in origin? ○ Domestic ○ Foreign Comments

3. If the source is a foreign FDA facility, does the pharmacy obtain information on the last FDA inspection of that facility and a copy of the report? ○ Yes ○ No Comments

4. Does the pharmacy perform any testing/analysis of APIs? . ○ Yes ○ No Comments

4a. If so, indicate how API is selected for testing, what tests are performed and if tested in-house or sent to an outside lab - indicate lab in notes

5. Are USP- or NF-grade substances used, if available? ○ Yes ○ No Comments

6. If compendial quality components are not available, are chemically pure, analytical reagent grade or American Chemical Society-certified components used? ○ Yes ○ No Comments

6a. How is it determined the products are free from impurities that raise human or animal safety concerns?

6b. Are other means used to establish purity and safety? Describe the means, such as lot analysis, manufacturer reputation, reliability of source. ○ Yes ○ No Comments

7. Do any of the API labels state "For Research Purposes Only" or "Not for Drug Use" or “Veterinary Use only” or similar? ○ Yes ○ No Comments

7a. If so, view invoices and record the source of these items and photos. Indicate how vet use only products are segregated to prevent them from being used for preparations compounded for humans.

8. Do any of the API have non-standard labels? ○ Yes ○ No Comments

9. Do all substances and components have a complete label including a batch control or lot number, and an expiration date? ○ Yes ○ No Comments

10. For substances without an expiration date assigned by the manufacturer or supplier, does the pharmacy have a procedure to assign a conservative expiration date and is it followed? ○ Yes ○ No Comments

10a. Containers labeled with date of receipt and the expiration date assigned is not greater than three (3) years, is supported with data and/or testing, and takes into consideration the nature of the component, its degradation mechanism, the container in which it's packaged, and the storage conditions. ○ Yes ○ No Comments

11. Are all APIs labeled with the date they were received? ○ Yes ○ No Comments

12. Does the pharmacy repackage APIs into smaller containers for ease of use? ○ Yes ○ No Comments

12a. If so, how is the expiration date determined for the repackaged product?

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13. Are bulk component containers labeled with appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels and are hazardous substances segregated? ○ Yes ○ No Comments

14. When manufactured products are used for compounding, do the labels contain a lot number and expiration date? ○ Yes ○ No Comments

15. When manufactured products are used for compounding, are all the other excipients in the product considered relative to the use, effectiveness, and stability of the compounded preparation to be made? ○ Yes ○ No Comments

16. Are any preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons? ○ Yes ○ No Comments

16a. How does the pharmacy determine this?

17. If compounding for food producing animals, does the compounder have a list of components prohibited for use? ○ Yes ○ No ○ N/A Comments

18. If components are used that are derived from ruminant animals (cow, sheep, goat) does the pharmacy obtain documentation that the component is in compliance with federal laws governing processing, use, and importation? (the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist) ○ Yes ○ No Comments

19. Do the ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards? ○ Yes ○ No Comments

19a. If not, how have the ingredients been determined to meet food-grade quality?

20. Where water is an ingredient, is purified or distilled water used? ○ Yes ○ No Comments

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C. Beyond Use Dating

1. Are BUDs assigned from the day of preparation?	○ Yes	○ No		Comments	
2. Are BUDs for non-aqueous formulations not later than the remaining time until the earliest expiration date of any API and not later than six (6) months?	○ Yes	○ No		Comments	
3. Are BUDs for water-containing oral formulations not later than 14 days when stored at controlled cold temperatures (refrigerated)?	○ Yes	○ No		Comments	
4. Are BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days?	○ Yes	○ No		Comments	
5. Are BUDs assigned based on dispensing in tight, light-resistant containers?	○ Yes	○ No		Comments	
6. Are any extended BUDs assigned? Provide a list of products with extended BUD and how justified.	○ Yes	○ No		Comments	
7. Is any testing done to support the extended BUDs? Provide a list of products tested and the results of such testing.	○ Yes	○ No		Comments	
8. Are any extended BUDs assigned greater than six (6) months from the date of compounding?	○ Yes	○ No	○ N/A	Comments	
9. When using a manufactured product as the active ingredient, is the expiration date of the manufactured product used as the BUD?	○ Yes	○ No	○ N/A	Comments	
10. Are appropriate microbiological preservatives (bacteria, yeast, and mold) used?	○ Yes	○ No		Comments	
10a. If not, why not and are products refrigerated?					
11. Are any other processes used to sterilize preservative free products? List types and ensure procedures include validation of the process.	○ Yes	○ No		Comments	

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D. Environment

1. Is the non-sterile compounding area a controlled environment and separate from the general pharmacy?	○ Yes	○ No	Comments	
2. Is there sufficient space available for the type and amount of compounding performed?	○ Yes	○ No	Comments	
3. Is entry into the non-sterile compounding area limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel)?	○ Yes	○ No	Comments	
4. Is only one preparation compounded at a time?	○ Yes	○ No	Comments	
5. Is the space orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations?	○ Yes	○ No	Comments	
6. Are procedures implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions?	○ Yes	○ No	Comments	
7. Is the compounding area well lit?	○ Yes	○ No	Comments	
8. Are heating, ventilation, and air conditioning systems controlled to maintain the integrity of components, chemicals and reduce risk of contamination?	○ Yes	○ No	Comments	
9. Does the pharmacy perform non-sterile compounding using a powder hood or isolator?	○ Yes	○ No	Comments	
9a. If so, indicate models and types of equipment used.				
10. Is appropriate protective attire (gowns, gloves, masks, etc.) available?	○ Yes	○ No	Comments	
11. Is there a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels?	○ Yes	○ No	Comments	
12. Is there adequate space to wash equipment and utensils including access to purified water for rinsing?	○ Yes	○ No	Comments	
13. Does the non sterile compounding area have a fan? View placement and indicate if the airflow affects disbursement of drug residue or contaminants	○ Yes	○ No	Comments	
14. Are both the temperature and humidity monitored 24/7 in the compounding areas? View documentation.	○ Yes	○ No	Comments	
15. Are there alarms or alerts when excursions are detected in the compounding area?	○ Yes	○ No	Comments	
15a. Is there an action plan when an excursion occurs?	○ Yes	○ No	Comments	
16. Is the bulk component storage area adequately arranged and maintained in a clean and sanitary condition?	○ Yes	○ No	Comments	
17. Are both the temperature and humidity monitored 24/7 in the bulk component storage areas (if separate from the compounding area)? View documentation.	○ Yes	○ No	Comments	
18. Are there alarms or alerts when excursions are detected in the bulk component storage area?	○ Yes	○ No	Comments	
18a. Is there an action plan when an excursion occurs?	○ Yes	○ No	Comments	

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19. Are hazardous drugs appropriately identified and marked, received, handled and stored by appropriately trained personnel? (OSHA regulations and NIOSH Alerts)	○ Yes	○ No	Comments	
20. Are all components, equipment, and containers stored off the floor and handled and stored to prevent contamination?	○ Yes	○ No	Comments	
21. Are all components and packaging containers and closures properly rotated to use oldest first?	○ Yes	○ No	Comments	
22. Is trash disposed of in a safe, sanitary, and timely manner including hazardous waste?	○ Yes	○ No	Comments	
22a. How is hazardous waste disposed of?				

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E. Training

1. Are pharmacists and technicians performing compounding appropriately trained and certified?	○ Yes	○ No	Comments	
2. Does the training include cleaning and disinfection, garb, manipulation of ingredients including quality testing, labeling, and hazardous material handling?	○ Yes	○ No	Comments	
3. Does the training process for the preparation of compounds include demonstration of the compounding procedure first followed by the trainee performing the procedure under supervision successfully before allowed to perform compounding?	○ Yes	○ No	Comments	
4. Does training include the operation of any equipment that may be used when preparing compounded products? Documentation needs to include training on operation, troubleshooting, and annual competency evaluation.	○ Yes	○ No	Comments	
5. Are employees performing non-sterile compounding evaluated at least annually (including hazardous drug handling) and is the evaluation documented?	○ Yes	○ No	Comments	
6. Does the pharmacy use relief personnel from outside agencies to perform non-sterile compounding?	○ Yes	○ No	Comments	

6a. How are training and certifications verified?

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F. Compounding Equipment

1. Is the appropriate equipment available and in good working order? View maintenance and calibration logs.	○ Yes	○ No		Comments
2. Is all equipment inspected for cleanliness and proper function prior to each use?	○ Yes	○ No		Comments
3. Is all equipment thoroughly cleaned promptly after each use to prevent cross contamination? Equipment and utensils washed using potable water with a soap or detergent, rinsing with purified water.	○ Yes	○ No		Comments
4. Does the pharmacy use separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products?	○ Yes	○ No		Comments
4a. If not, are there detailed procedures for meticulous cleaning of the equipment used for allergenic, cytotoxic, or hazardous ingredients immediately after use?	○ Yes	○ No		Comments
4b. Do the procedures include instructions that personnel performing cleaning are appropriately garbed?	○ Yes	○ No		Comments
5. If disposable equipment or supplies are used, are they disposed of appropriately?	○ Yes	○ No		Comments
6. Are scales, balances, or other equipment used for measurement validated and calibrated at least annually?	○ Yes	○ No		Comments
7. If a powder hood is used, has it been certified?	○ Yes	○ No	○ N/A	Comments
7a. How often is the powder hood certified?				
8. If biological safety cabinet (BSC), compounding aseptic isolator (CAI), or compounding aseptic containment isolator (CACI) hoods are used for hazardous substances, have they been certified? View copy of certification report. NOTE: If compounding with hazardous materials that are volatile, must use BSC or CACI only, and the cabinet must be vented to the outside.	○ Yes	○ No	○ N/A	Comments
8a. How often are the BCS or CACI units certified?				
9. If the hoods or isolators are located in a closed, controlled room environment, has the room been certified or tested? View copy of report or testing results	○ Yes	○ No	○ N/A	Comments
10. If the hoods or isolators are not located in a closed, controlled room environment, is there documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel?	○ Yes	○ No	○ N/A	Comments
11. Is there any environmental testing performed to detect contamination by drug residue in the pharmacy areas or areas served by the same ventilation system? Drug residue may cause cross contamination to other products and expose staff. Not required but is recommended if compounding with hazardous materials, not using a hood, or compounding room not segregated.	○ Yes	○ No		Comments

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G. Documentation

1. Does the pharmacy create a master formulation record the first time before compounding a new preparation? ○ Yes ○ No Comments

1a. Who reviews/approves?

2. Is every formulation evaluated for incompatibilities and the potential for an ineffective or toxic preparation? ○ Yes ○ No Comments

2a. If yes, how is the formulation evaluated?

3. Does the master formulation record contain: Comments

- ☐ Official or assigned name, strength, and dosage form
- ☐ All necessary calculations
- ☐ Description of all ingredients and their quantities
- ☐ Compatibility and stability information including references (when available)
- ☐ Equipment used for the preparation
- ☐ Mixing instructions to include order of mixing, temperatures, duration of mixing, and other pertinent factors
- ☐ Container used and packaging requirements
- ☐ Assigned BUD information
- ☐ Labeling information including the generic name of and quantity or concentration of each active ingredient
- ☐ Description of the finished preparation
- ☐ Storage requirements
- ☐ Quality control procedures and expected results

4. Does the pharmacy create a compounding record for each compound prepared? ○ Yes ○ No Comments

5. Does the compounding record include: Comments

- ☐ Official or assigned name, strength and dosage of the preparation
- ☐ Master Formulation Record reference
- ☐ Sources, lot numbers, and expiration dates of all components
- ☐ Total quantity or number of dosage units compounded
- ☐ Person compounding the preparation
- ☐ Person performing the quality control procedures
- ☐ Person who approved the preparation
- ☐ Date of compounding
- ☐ Assigned internal identification number or prescription number
- ☐ Description of the final preparation
- ☐ Assigned BUD
- ☐ Duplicate label
- ☐ Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)?
- ☐ Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate

6. Are all records kept for the length of time specified by the state? Indicate how long records are kept and where. ○ Yes ○ No Comments

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H. Compounding Procedure

1. Have the Master Formulation Record and the Compounding Record been reviewed by the compounder to ensure it is error free? ○ Yes ○ No Comments

2. Do compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality? How? ○ Yes ○ No Comments

2a. How is the check performed?

2b. Does this include a unit-by-unit physical inspection of the products? ○ Yes ○ No Comments

3. Do the containers and closures selected meet USP standards (from container supplier)? ○ Yes ○ No Comments

4. Is container selection determined by physical and chemical properties of the preparation? ○ Yes ○ No Comments

5. Do compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed? ○ Yes ○ No Comments

6. Do personnel don appropriate protective garb when performing compounding? Comments

- ☐ Gloves
- ☐ Gloves always
- ☐ Gloves sometimes
- ☐ Gowns
- ☐ Masks
- ☐ Other

7. Are routine compounding procedures for batch preparation completed and verified according to written procedures? Including: Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly ○ Yes ○ No Comments

8. Are procedures for in-process checks followed? These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product and documentation of the compounding accuracy is by someone other than the compounder to ensure proper measurement, reconstitution and component usage. ○ Yes ○ No Comments

9. If there are any deviations from the master formulation record, are these deviations recorded? ○ Yes ○ No Comments

9a. Is it determined if the deviation will affect the BUD? ○ Yes ○ No Comments

10. Is there a plan for cleaning? After each preparation, daily tasks, monthly tasks, etc. ○ Yes ○ No Comments

11. Are personnel appropriately garbed for protection when cleaning? ○ Yes ○ No Comments

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I. Finished Preparation Checks and Release

1. Is the finished preparation observed to appear as expected in the master formulation record and documented? ○ Yes ○ No Comments

2. As appropriate, is the final completed preparation assessed for weight, mixing, clarity, odor, color, consistency, pH, and strength? Is it documented? ○ Yes ○ No Comments

2a. Is the final completed preparation assessment documented? ○ Yes ○ No Comments

3. There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity? ○ Yes ○ No Comments

4. Is there a process in place to sample prepared products for potency and/or contamination? Required if using extended BUD. ○ Yes ○ No Comments

5. Does testing include physical, chemical, and microbiological characteristics? ○ Yes ○ No Comments

6. Are all products produced in batches tested? Required if using extended BUD. ○ Yes ○ No Comments

7. If any failed tests or discrepancies are observed, is there an investigation and are appropriate corrective actions taken before dispensing to patient? ○ Yes ○ No Comments

8. Are any products that are being tested dispensed or distributed before the test results are obtained? ○ Yes ○ No Comments

8a. Is the procedure for recalling a product that has been found to have an issue appropriate? ○ Yes ○ No Comments

9. Does the pharmacy have its own lab to perform testing? ○ Yes ○ No Comments

9a. If so, what testing is performed in house?

10. Does the pharmacy send samples to an outside lab to perform testing? ○ Yes ○ No Comments

10a. If so, provide the name of the lab performing testing for the pharmacy and what tests are performed.

11. Are there appropriate control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations? Validation of equipment and personnel performance documentation ○ Yes ○ No Comments

12. Do labels on batch preparations include:

- ☐ Name and Quantity of all contents
- ☐ Date and time
- ☐ Preparer
- ☐ Verifying Pharmacist Identifiers
- ☐ Stability (BUD)
- ☐ Auxiliary Labels
- ☐ Appropriate Packaging
- ☐ Hazardous Material labeling

Comments

13. Are batch preparations (in anticipation of prescriptions) of an appropriate volume? ○ Yes ○ No Comments

13a. Are batch products in stock all within their BUD (not outdated)? ○ Yes ○ No Comments

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14. Do labels on patient-specific containers, in addition to standard label requirements:

- ☐ Identifiers of the persons preparing the compound
- ☐ Identifiers for the persons performing the final verification
- ☐ BUD
- ☐ Indication that this is a compounded preparation
- ☐ Special storage requirements
- ☐ Appropriate Packaging
- ☐ Hazardous Material Labeling

Comments

15. Do labels on compounded preparations for food producing animals contain information regarding withdrawal times? ○ Yes ○ No ○ N/A Comments

16. Are preparations stored properly prior to dispensing based upon conditions upon which BUD was assigned? ○ Yes ○ No Comments

17. Are preparations examined immediately after preparation AND again immediately prior to dispensing for any signs of instability? ○ Yes ○ No Comments

18. If problems occur during compounding of an official USP monograph preparation, is it reported to USP? ○ Yes ○ No Comments

19. Are all issues that are reported to the pharmacy (adverse events, instability, etc.) documented, investigated, and corrective action taken? ○ Yes ○ No Comments

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