Lee Davis Pharmacy/O&B Pharmacy
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Non-Sterile & Hazardous Pharmacy Policies & Procedures

Written by: Edward Hairfield, CPhT **Written Date:** 12/21/2023

Approved by: Gregory Taylor, PharmD **Approved Date**: 01/01/2024

Purpose:

*The purpose of this is to ensure compliance with **Virginia BOP** & **USP 800 & 795** guidelines regarding non-sterile and hazardous compounding at Lee Davis Pharmacy.*

Application:

This document applies to all individuals who are licensed pharmacists and technicians who have completed their yearly training for non-sterile and hazardous compounding. Upon completion of training, each individual should know the correct rules and law as well as hand washing techniques and sanitization of the compounding work station.

Table of Contents:

Non-Sterile Compounding Area

Policy # LDP-101
Date Effective: 01/01/2024
Date Revised:
Approved By: Greg Taylor, PharmD

Purpose:

To assure a clean compounding environment that meets current USP <795> standards.

Policy:

There shall be a designated area for compounding non-sterile products.

Procedure:

1. There shall be adequate space arranged with proper placement of equipment and materials to prevent mix-ups between:
    a. Ingredients
    b. Containers
    c. Labels
    d. Process materials
    e. Finished preparations
2. The compounding area shall be arranged to prevent cross-contamination.
3. The compounding area shall have adequate lighting.
4. The compounding area shall have hot and cold potable water available nearby with soap, detergent and single service towels
5. The compounding area shall be cleaned using antiseptic cleaning method before and after each compounding occurrence.
6. The equipment used in the compounding area shall be cleaned immediately after compounding to prevent cross contamination.
7. The compounding area is maintained with a constant temperature to avoid decomposition of chemicals.
8. The compounding specialist/pharmacist will document each time their hands are washed.
9. The compounding area will be documented each time by the compounding specialist/pharmacist each time the designated compounding area is cleaned before and after each use.

Non-Sterile Ingredients, Handling & Storage

Policy # LDP-102
Date Effective: 01/01/2024
Date Revised:
Approved By: Greg Taylor, Pharm D

Purpose:

To assure that the ingredients (chemicals), handling and storage meets official completion standards

Policy:

The following procedures related to ingredients (chemicals) shall be adhered to

Procedure:

1. Only USP or NF chemicals manufactured by FDA inspected/registered manufacturers should be used for compounding.
    a. All ingredients (chemicals) shall have a complete label, batch control number and expiration date on the container
2. A certificate of analysis shall be obtained for all ingredients (chemicals) purchased.
3. All ingredients (chemicals) shall be stored according to USP-NF and manufacturer specifications.
4. Compounded preparations will be assigned a Beyond Use Dating (BUD) from the day of preparation based upon USP <795>. A maximum 6 month BUD shall be used for all compounded preparations.

Non-Sterile & Hazardous Compounding Records

Policy # LDP-103
Date Effective: 01/01/2024
Date Revised:
Approved By: Greg Taylor, PharmD

Purpose:

To assure that compounding records meet all federal and state regulations.

Policy:

All compounding documentation and records will adhere to the following procedure

Procedure:

1. Compounding records shall be maintained for the following:
    a. A master compounding formulation and process including:
        i. Name, strength, and dosage form
        ii. All necessary calculations
        iii. All ingredients and their calculations
        iv. Compatibility and stability information
        v. Mixing instructions to include order of mixing, temperatures, duration of mixing and other pertinent factors
        vi. Assignment of a BUD
        vii. Type of container required
        viii. Label requirements
        ix. Storage requirements
    b. A detailed compounding record is maintained for each compounded preparation as follows:
        i. Name and strength of the preparation
        ii. Master formulation record reference
        iii. Sources and lot numbers of ingredients
        iv. Total number of dosage units compounded
        v. Name of person compounding the preparation

vi. Date of compounding
vii. Assigned prescription number
viii. Description of the final preparation
ix. Assigned BUD

2. There shall be a log of all compounded items, including batch records and sample batch labels.
3. Equipment maintenance records shall be maintained, including documentation of checks and balances, refrigerators, and freezers.
4. There shall be a record of ingredients (chemicals) purchased, including certificates of analysis.
5. Material Safety Data Sheets (MSDS's) shall be available to all compounding personnel for all drugs and chemicals used in compounding.
6. Pharmacist(s) and Compounding Specialist(s) will be the only staff that compound and training is validated via their licensing.

Hazardous Compounding Area

Policy # LDP-104
Date Effective: 01/01/2024
Date Revised:
Approved By: Greg Taylor, PharmD

Purpose:

To ensure the safety of employees and patients when compounding hazardous materials in the hazardous room per USP <800>

Policy:

There shall be a designated area for compounding of hazardous materials

Procedure:

1. When compounding hazardous materials, the compounding specialist/pharmacist shall ensure the safety of those around them when compounding a hazardous material.
2. The contents of such hazardous compound shall be weighed, mixed and all of its materials in the containment of said hazardous room.
    a. No compounding equipment shall leave the hazardous room until finished and wiped down to be washed or thrown in its respective hazardous black bin.
3. Before entering the hazardous room, the compounding specialist/pharmacist shall wash their hands with warm soapy water and document each washing.
4. Upon entering the room, the compounding specialist/pharmacist shall have all materials needed to compound said hazardous material.
5. Hazardous compounds shall be labeled correctly and wiped down with alcohol before leaving the hazardous room.
6. Each compounding specialist/pharmacist shall have the proper PPE to ensure safety from hazardous materials.
    a. Proper gown and gloves shall be worn at all times of hazardous compounding
    b. Mask and hair net shall be properly adorned when compounding with gown and gloves.
        i. The proper way is hairnet and mask
        ii. Then followed by gloves and gown

Hazardous Ingredients, Handling & Storage

Policy # LDP-105
Date Effective: 01/01/2024
Date Revised:
Approved By: Greg Taylor, PharmD

Purpose:

To ensure that hazardous materials and equipment are handled and stored appropriately.

Policy:

The hazardous room shall store and contain all hazardous ingredients (chemicals) and equipment used for compounding hazardous materials.

Procedure:

1. Only USP or NF chemicals manufactured by FDA inspected/registered manufacturers should be used for compounding.
    a. All ingredients (chemicals) shall have a complete label, batch control number and expiration date on the container
2. Ingredients (chemicals) and items that have come into contact with materials considered hazardous shall be stored properly in the hazardous room per USP <800>
3. Items that have come into contact with hazardous ingredients (chemicals) shall include but not be limited to:
    a. Mortar and Pestle
    b. Beakers
    c. Spatulas
    d. Spoons
    e. Hot Plate/Scale
4. A certificate of analysis shall be obtained for all hazardous ingredients (chemicals) purchased.
5. All ingredients (chemicals) shall be stored according to USP-NF and manufacturer specifications.

6. Compounded preparations will be assigned a Beyond Use Dating (BUD) from the day of preparation based upon USP <800>. A maximum of 6 month BUD shall be for all compounded medications.

Hand Washing Technique

Policy # LDP-106
Date Effective: 01/01/2024
Date Revised:
Approved By: Greg Taylor, PharmD

Purpose: *The compounding specialist/pharmacist shall keep a record of all hand washing documentation when compounding for USP <800> & <795>.*

Policy: *Per the Virginia Board of Pharmacy, each individual who compounds must document when they wash their hands before and after compounding.*

Procedure:

1. Before compounding anything at Lee Davis Pharmacy, each employee, whether it be the compounding specialist or pharmacist, must document each time they wash their hands.
2. There shall be adequate documentation of each hand washing for before and after compounding at the compounding station in a book labeled correctly.
3. There shall be no more than 2 minutes of hand washing between each compound.
    a. In order to maintain the 2 minutes of washing correctly, each person should have a specific song in their head or sing *Happy Birthday* song in their head no more than 3 times.
        i. This shall maintain the cleanliness of the compounding specialist/pharmacist hands.
4. Each time handwashing occurs, the person shall document it in the correct book with the date and time of handwashing and the pharmacist on duty's initials.

Training for USP <800> & <795>

Policy # LDP-107
Date Effective: 01/01/2024
Date Revised:
Approved By: Greg Taylor, PharmD

Purpose: *To ensure training is up to date and maintained for Virginia Board of Pharmacy records.*

Policy: *Each technician (compounding specialist) and pharmacist shall undergo yearly training for compounding per Virginia Board of Pharmacy. Each compounding specialist/pharmacist shall not go more than 30 days without proper training.*

Procedure:

1. Each technician (compounding specialist) and pharmacist who compounds shall go through yearly training and sign off appropriately/documented for Lee Davis Pharmacy records.
    a. The head compounding specialist/pharmacist, whomever that shall be, shall ensure each person working under O&B Pharmacy/Lee Davis Pharmacy shall complete their training no later than January 5th of each year, unless that day falls on a day where the store is off.
    b. Each person who does not complete their training in a timely manner shall be prohibited from compounding under O&B Pharmacy/Lee Davis Pharmacy.
2. The appropriate paperwork for each training for all compounding specialist & pharmacist shall be properly stored in the training binder near the pharmacist bench and labeled accordingly.
3. Every 6 months, each compounding specialist and pharmacist shall be refreshed on their compounding skills with an evaluation to ensure the highest quality of compounding.