Akron Pharmacy
Non-Sterile Compounding
Policy and Procedure Manual

Non-Sterile Compounding Area and Personnel

Date: Mar 3,2022
Date Revised:

Purpose: To assure a clean compounding environment that meets current 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. In 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. Attire and dress must be appropriate. Use designated compounding lab coat. Remove all jewellery. Long hair must be tied back and out of the way

9. **Self-Check Protocol (When Only One Pharmacist is On Duty)**

When compounding must be completed by a single pharmacist, the following structured self-verification steps will be used;

- **Calculation Verification**

All calculations will be documented and rechecked after a time delay (minimum 5 minutes) or after stepping away from the workspace.

- **Ingredient Verification**

Each ingredient will be verified against the formula using:

  - Original container label
  - DIN or ingredient name
  - Expiry date and lot number

- **Physical Product Verification**

Visual and physical inspection of the final product for:

  - Correct appearance, volume, and consistency
  - Container type and closure
  - Absence of contamination

- **Label Verification**

Final label checked against the original prescription for:

  - Patient name
  - Drug, strength, dosage form
  - Directions, beyond-use date, storage

Ingredients, Handling & Storage

Purpose: To assure that the ingredients (chemicals), handling and storage meets official compendial standards.

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

Procedure:

1. Only USP or NF chemicals registered manufacturers should be used for compounding.
    a. All ingredient (chemicals) shall have a complete label, batch control number and expiration date on the container.

2. All ingredients (chemicals) shall be stored according to manufacturer specifications.

3. Compounded preparations will be assigned Beyond Use Dating (BUD) from the day of preparation based upon referenced sources.
4. In case of accidental exposure, accidents or spills, consult the ingredients' Safety Data Sheet available on the SOP website. Administer first aid if applicable and call 911 if necessary.

Compounding Records

Purpose: To assure that Compounding Records meet provincial requirements

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. Equipment used for the preparation vi. Mixing instructions to include order of mixing, temperatures, duration of mixing and other pertinent factors.
      vii. Assignment of a BUD
      viii. Type of container required ix. Label requirements
      x. 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. Equipment maintenance records shall be maintained, including documentation of checks of balances, refrigerators, and freezers.

3. Material Safety Data Sheets (MSDS's) shall be available to all compounding personnel for all drugs and chemicals used in compounding. Presently MSDs can be found on the Akron SOP website.

4. Pharmacists or trained staff will be the only staff that compound. Compounding staff will complete the Compounding Knowledge Assessment Form yearly to ensure they are adequately trained.

Packaging Containers & Labeling

Purpose: To assure that all compounded preparation containers and associated labels adheres OCP requirements.

Policy: The following procedure related to compounded preparation containers and associated labels shall be adhered to:

Procedure:

Containers :

1. All compounded preparation containers used in packaging shall meet USP requirements

    a. Container suppliers shall be expected to supply, upon request, verification of USP container compliance.

2. Container-drug interactions will be considered by the Pharmacist that have sorptive or leaching properties.

3. All compounding preparation containers shall be stored off the floor, handled and stored to prevent contamination. They shall be rotated so that the oldest stock is used first.

Labeling:

1. All compounded preparations shall meet all requirements for prescriptions dispensed.

2. In addition, the following shall be placed on the prescription label or at a minimum on an auxiliary label.
    a. The prescription number assigned to the compounded product.

b. The beyond use date (BUD) which is calculated from the day of the preparation.

For Nonaqueous Formulations—The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
For Water-Containing Oral Formulations—The BUD is not later than 14 da s when stored at controlled cold temperatures,
For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 da s.

c. The concentration of each active ingredient in the final preparation as appropriate.

d. Name of the final product or the name of each active ingredient.

e. Storage conditions

3. If a compounded preparation is intended for a licensed prescribers office use, then a statement to that effect must be on the label or an auxiliary label.

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