

Non-Sterile Pharmacy Policies and Procedures

Non-Sterile Compounding Area

Policy # NSC-101
Date Effective: 02/01/2017
Date Revised:
Approved by: Michael Burns

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. 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.

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Ingredients, Handling & Storage

Policy # NSC-102
Date Effective: 02/01/2017
Date Revised:
Approved by: Michael Burns

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 manufactured by FDA inspected / 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. 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 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.

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Compounding Records

Policy # NSC-103
Date Effective: 02/01/2017
Date Revised:
Approved by: Michael Burns

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. 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

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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 of 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. Pharmacists will be the only staff that compound and training is validated via their licensing.

Packaging Containers & Labeling

Policy # NSC-104
Date Effective: 02/01/2017
Date Revised: 10/14/2019
Approved by: Michael Burns

Purpose: *To assure that all compounded preparation containers and associated labels adheres to state, federal and compendial 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 of <795>.
 - 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 federal and state 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 internal control number assigned to the compounded product.
 - b. The beyond use date (BUD) which is calculated from the day of the preparation.

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BUD by Type of Formulation*
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 days when stored at controlled cold temperatures.
For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations —The BUD is not later than 30 days.

- 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. All compounded preparations should include a statement on the label or auxiliary label that this prescription has been compounded based upon a prescription from your prescriber.
4. 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.