Akron Pharmacy
Non-Sterile Compounding
Policy and Procedure Manual

Non-Sterile Compounding Area and Personnel

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**PLEASE NOTE: TO MINIMIZE CROSS CONTAMINATION, ALL COMPOUNDING OF NON-STERILE PRODUCTS TO BE DONE AFTER HOURS UNTIL FURTHER NOTICE. PLEASE INFORM PATIENTS THAT COMPOUNDED PRODUCTS WILL BE READY NEXT DAY. IF NECESSARY, PATIENT CAN CHOOSE TO COME DURING CLOSING TIME TO WAIT.

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. Only mixtures that require Level A requirements are to be compounded. If Level B and C requirements are needed, refer patient to Courtesy Pharmacy (905) 823-4664.

2. 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

3. The compounding area shall be arranged to prevent cross-contamination.

4. The compounding area shall have adequate lighting.

5. The compounding area shall have hot and cold potable water available nearby with soap, detergent and single service towels.

6. The compounding area shall be cleaned using antiseptic cleaning method before and after each compounding occurrence. A final cleaning with purified water is required

7. The equipment used in the compounding area shall be cleaned immediately after compounding to prevent cross contamination.

8. The compounding area is maintained with a constant temperature to avoid decomposition of chemicals.

9. 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. Long/fake nails are prohibited. No food/gum/drinks are to be used. Do not compound if suffering from upper respiratory tract infection. If required, PPE must be worn to minimize risk to compounding staff

10. A maintenance log must be kept to record the dates of cleaning and/or calibration of the Scientech Precision Balance. Calibration must be done yearly. Log is kept in the drawer below the balance.

Balance Functions and Features:

Autocalibration – To Calibrate the balance to an External Weight:

This procedure calibrates your balance to an external calibration weight. If your balance has a motorized internal calibration weight it will have a suffix of IW after the model number. Please use the procedure for Autocalibration to calibrate the balance to a Motorized Internal Calibration Weight.

Note: Dual range models must be placed in HI range before starting the calibration procedure.
Note: For correct calibration weight refer to specification charts in the back of the manual.
Note: The balance should be warmed up for at least one (1) hour prior to calibration and leveled according to the Unpacking and Setup section.
Note: Perform autocalibration every time you move your balance.

Calibrate the balance using a recently certified external calibration weight. Metrology handbooks state that the calibration weight utilized to calibrate a balance should have a tolerance no larger than the readability of the balance divided by 3. Therefore, SA/ZSA models need a ±0.033mg tolerance weight or better, SP/ZSP models need a ±0.33mg tolerance weight or better, SL/ZSL models need a ±3.3mg tolerance weight or better, and SG models need a ±33mg tolerance weight or better. In addition, these same handbooks recommend that all balances be calibrated using an external certified calibration weight even if the balance has an internal calibration weight.

	User Action	Balance Response
1	Remove any containers or weighing samples so that nothing is on the weighing pan, then press the ZERO button	Zeros are displayed
2	Press the RANGE/FUNCTION button (or MODE and RANGE buttons simultaneously for dual range balance models)	Balance display cycles repeatedly through PCS, HI OK LO, CAL 1, CAL 2,  and %.
3	Press the MODE button when CAL 1 appears	CAL 1 and a flashing 0 are displayed.
4	Wait 10 seconds for the balance to stabilize, then press the ZERO button.	The display stops flashing, CAL 1 and a solid 0 are displayed. In approximately 15 seconds, when this step is complete, a single weight or two alternating weights will begin flashing on the display.
5	Place one of the flashing weights on the balance's weighing pan.	The display stops flashing, CAL 1 and the selected weight are displayed.
6	**Do not remove the weight from the pan.**	The display will momentarily blink, then the selected weight will continue to be displayed. In approximately 15 seconds, when this step is complete, the display will blank, flash "OK", then display the calibration weight including decimal places. The balance is now calibrated and in the normal weighing mode. For balances with an internal weight press MODE to complete this step. This will not change the internal weight calibration factor.
7	Remove the calibration weight.	The display returns to zeros.

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

   Master Compounding formula can be found on the Akron SOP website

   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.

Akron Pharmacy
Section Non-Sterile

Training and Assessment

1. All personnel involved in compounding must possess expertise commensurate with their responsibilities. Therefore, before they undertake non-sterile compounding, they must have received the proper orientation, training and a skills assessment.
2. Use the Staff Skill Assessment, found on the Akron SOP site to assess the compounding skill of any staff involved in compounding prescriptions

Compound Recall Procedure

Purpose: To perform recall of compounds containing a API which the Pharmacy is notified by the manufacturer or Health Canada a recall is necessary.

Policy: The following procedures related to a recall procedure and must be adhered to.

Procedure:

1. When any staff member is notified of a recall of an API, they must alert the DM immediately.

2. The DM is responsible for initiating the recall procedure laid out in this manual

3. Compounds containing the recalled API must be identified. Run the Propel report "Mixture Movement" for the period indicated by the manufacturer or Heath Canada. If no time period is given, then the time period will be for 1 year. Identify all compounds containing the indicated API

4. Run the Propel report "Analysis of Drug" for all compounds containing the recalled API. The time period will the same as above.

5. For each prescription dispensed as indicated by the report, the formulation sheet will be reviewed to determine if the lot used in preparation for the compound is the recalled API.

6. For prescriptions determined to be affected by the recalled API, the patient will be contacted by the DM or a staff designated by the DM.

7. Information to be determined and documented in the patient's file should include:

a Is the affected compound being used by patient? If so, instruct patient to discontinue use and replacement prescription should be offered.

b If the compound is being used or used previously, was any side effects noticed.

c If the compound was used or being used, was it effective.