STANDARD OPERATING PROCEDURE

Non-Sterile Compounding SOP

Document no.	SOP-PHA-007
Revision	1.0
Owner	Pharmacist in Charge
Effective date	September 15, 2026
Review cycle	Every 12 months

1. Purpose

To prepare non-sterile compounded medications accurately and consistently, with documented calculations, ingredient verification and pharmacist checks at each critical step.

2. Scope

Applies to non-sterile compounds such as creams, ointments, oral suspensions and capsules prepared in the pharmacy. Sterile compounding requires a separate cleanroom procedure not covered here.

Definitions

Master formulation record	The standardized recipe for a compound, listing ingredients, quantities, equipment and preparation steps.
Compounding record	The batch-specific document capturing the ingredients, lot numbers, calculations and checks used for one preparation.
Beyond-use date (BUD)	The date after which a compounded preparation should not be used, based on stability and ingredients.

3. Responsibilities

Compounding Pharmacist	Calculates and verifies quantities, compounds or supervises compounding, and performs final verification.
Pharmacy Technician	Prepares the work area, weighs and measures ingredients, and compounds under pharmacist supervision.
Pharmacist in Charge	Approves master formulation records and reviews compounding logs periodically.

RACI matrix

Activity	Compounding Pharmacist	Pharmacy Technician	Pharmacist in Charge
Verify or create master formulation record	R	I	A
Calculate and double-check quantities	R/A	C	I
Weigh, measure and compound	A	R	-
Perform final verification against the record	R/A	I	-

R = Responsible, A = Accountable, C = Consulted, I = Informed

4. Materials and PPE

Materials, tools and systems

- Master formulation records
- Calibrated balance and measuring devices
- Compounding slab, mortar and pestle or mixing equipment
- Certificates of analysis for active ingredients
- Compounding batch record forms
- Labels with beyond-use date fields

Personal protective equipment

- Disposable nitrile gloves
- Compounding gown or coat
- Hair and shoe covers
- Eye protection when handling irritant powders or liquids

5. Procedure

Step	Task	Owner	Done
5.1	**Verify the compounding order** Confirm the prescriber's order is complete and clinically appropriate, and check that a master formulation record exists or needs to be created.	Compounding Pharmacist	☐
5.2	**Confirm or create the master formulation record** Use the existing master formulation record, or draft a new one listing ingredients, quantities, equipment, method and beyond-use date criteria for pharmacist approval.	Compounding Pharmacist	☐
5.3	**Verify ingredients before use** Check each ingredient's identity, potency, expiration date and certificate of analysis against the formulation record before weighing.	Pharmacy Technician	☐
5.4	**Calculate quantities with a double-check** Calculate the amount of each ingredient needed for the batch size, and have a second qualified person independently verify the calculation before weighing begins. **Checkpoint:** Quantity calculations are independently double-checked before any ingredient is weighed.	Compounding Pharmacist	☐
5.5	**Prepare the compounding area** Clean and clear the compounding area of unrelated materials, and gather all equipment and ingredients needed for the batch before starting.	Pharmacy Technician	☐
5.6	**Don compounding garb** Put on gown, gloves, hair and shoe covers, and eye protection as required for the ingredients being handled.	Pharmacy Technician	☐
5.7	**Weigh and measure ingredients** Weigh or measure each ingredient on calibrated equipment, recording the actual weight or volume used on the compounding record. **Warning:** Never estimate a quantity; use a calibrated balance or graduate for every ingredient.	Pharmacy Technician	☐
5.8	**Compound per the formulation record** Follow the mixing, trituration or dilution steps in the master formulation record in the order specified, without substituting technique.	Pharmacy Technician	☐

Step	Task	Owner	Done
5.9	**Perform in-process checks** Check in-process attributes specified by the record, such as weight, uniformity of appearance or pH, and document results on the compounding record.	Compounding Pharmacist	☐
5.10	**Package and label the preparation** Package the finished compound and label it with the ingredients, strength, beyond-use date, storage conditions and any required auxiliary warnings.	Pharmacy Technician	☐
5.11	**Perform final pharmacist verification** Compare the finished preparation, label and compounding record against the master formulation record before release to the patient. **Checkpoint:** Final verification confirms ingredients, calculations, appearance and label all match the formulation record.	Compounding Pharmacist	☐
5.12	**Clean up and file the batch record** Clean equipment and the compounding area per the equipment's cleaning instructions, and file the completed batch record with the master formulation record.	Pharmacy Technician	☐

6. Quality checks

- Every batch has an independently double-checked calculation on file.
- Ingredient certificates of analysis are verified before use.
- Final verification against the master formulation record is documented for every batch.
- Labels show a beyond-use date consistent with the formulation record.

7. Records

- Master formulation records
- Compounding batch records
- Certificates of analysis
- Final verification sign-offs

8. KPIs

- Percentage of batches with a completed double-check before weighing
- Number of compounding errors caught at final verification
- Average batch preparation time by preparation type
- Number of master formulation records reviewed per year

9. Common mistakes

- Weighing ingredients before the calculation double-check is complete.
- Skipping the certificate of analysis check on a familiar ingredient.
- Compounding from memory instead of following the master formulation record step by step.
- Labeling with an estimated beyond-use date instead of one supported by the formulation record.

10. Revision history

Revision	Date	Description	Reviewed by
1.0	September 15, 2026	Initial release	Ilia Pirozhenko

Approval

Prepared by	Approved by	Date

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