

Compounding Material Labelling Procedure

This document is prepared by www.pharmasist.ca

IMPORTANT: All compounding stock expires 3 years after opening or at the manufacturer's expiry date, whichever occurs first. All containers must be labelled with the opening date upon first use.

1. Purpose

To ensure all compounding ingredients and raw materials are appropriately labelled, tracked, and used within acceptable expiry periods to maintain product quality, patient safety, and pharmacy compliance.

Expiry Rule <ul style="list-style-type: none">• Use the shorter of:<ul style="list-style-type: none">• 3 years from opening date, OR• Manufacturer's expiry date.• The earliest date becomes the assigned expiry date.	Opening Date Requirement <ul style="list-style-type: none">• Every container must be labelled immediately upon first opening.• Opening date must be clearly visible.• Labels must remain legible throughout use.• Replace damaged labels immediately.
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2. Existing Open Stock

- Review all currently opened compounding ingredients and chemicals.
- Assign an expiry date of two (2) years from today's implementation date unless the manufacturer's expiry occurs sooner.
- Apply a label showing:
 - Date Opened (if known)
 - Assigned Expiry Date
 - Staff Initials
- Remove and dispose of materials already beyond the assigned expiry date.

3. Newly Opened Stock

- Immediately label every newly opened bottle, container, jar, or package.
- Record opening date at first use.
- Calculate expiry as 3 years after opening unless manufacturer expiry occurs first.
- Write expiry date directly on the label.
- Initial the label when required by pharmacy policy.

Required Label Information <ul style="list-style-type: none">• Material name.• Lot number (if applicable).• Date opened.• Assigned expiry date.• Staff initials.	Inspection Checklist <ul style="list-style-type: none">• Opening date present.• Expiry date present.• Label legible.• Container properly sealed.• No expired material in active stock.
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4. Example

Material: Hydrocortisone USP Powder Manufacturer Expiry: 2029-08-31 Date Opened: 2026-06-01 Calculated Expiry (3 years): 2029-06-01 Assigned Expiry: 2029-06-01 (earlier date)	
Material: Zinc Oxide USP Powder Manufacturer Expiry: 2027-03-31 Date Opened: 2026-06-01 Calculated Expiry (3 years): 2029-06-01 Assigned Expiry: 2027-03-31 (manufacturer expiry is earlier)	

5. Responsibilities

- All pharmacy staff involved in compounding are responsible for applying opening-date labels.
- The designated pharmacist shall verify compliance during routine inspections.
- Expired compounding materials must be removed from active stock immediately.
- Periodic audits should be conducted to ensure compliance.