County of Los Angeles **Department of Health Services**

ValleyCare

OLIVE VIEW-UCLA MEDICAL CENTER/HEALTH CENTERS
PHARMACY
POLICY & PROCEDURE

NUMBER: 1144
VERSION: 1

SUBJECT/TITLE: **206 - PHARMACEUTICAL COMPOUNDING:NON-STERILE PREPARATIONS**

POLICY: The Pharmacy shall follow quality control procedures for the compounding of non-sterile preparations

PURPOSE: To comply with all regulatory standards to insure the integrity of compounded medications

DEPARTMENTS: **PHARMACY**

DEFINITIONS: Compounding, Quality Control, Expiration Date

PROCEDURE:

A pharmacist responsibilities in compounding drug preparations are to dispense a finished preparation that is in compliance with established standards set forth by the Board of Pharmacy, ASHP, and USP/NF. Such compounded preparations shall be of acceptable strength, quantity, and purity with appropriate packaging and labeling in accordance with good compounding practices, official standards, and relevant scientific data and information.

A Pharmacist shall supervise all compounding activities and ensure that supportive personnel are adequately trained to perform assigned function.

1. USP-NF components (chemicals) manufactured by FDA-inspected manufactures are to be used as the FIRST CHOICE for compounding.

   If not obtainable from an FDA-registered facility, then the Pharmacy shall attempt to obtain components that are American Chemical Society – certified, or of a Food Chemical Codex grade.

   If not obtainable from any of the above sources, the component may be obtained form a source deemed acceptable and reliable in the professional judgment of the pharmacist.

"OPENED" COMPONENT CONTAINERS
In the absence of other data, **all "raw" materials (chemicals) over (1) year old are to be discarded once opened.**
Indicate date opened on the container and initial.

2. Chemicals and medications used to prepare medications are accurately labeled with contents, expiration dates, and warnings (when applicable).

3. Compounded preparations are of acceptable strength, quality and purity, with appropriate packaging and labeling, and prepared in accordance with good compounding practices, official standards, and relevant scientific data and information.

4. To avoid chemical contamination, the compounding work area, weight balance, and equipment (spatula, stirring rod, graduate cylinder, pill tile, glassware, etc.) shall be cleaned **IMMEDIATELY** after use. Compounding areas are to be in a clean and sanitary condition.

5. The work area shall be will lighted

6. The compounder shall use appropriate technique, resources and precautions prior to compounding.
   a. Wear surgical masks, gloves, & gowns, if needed.
   b. Clean compounding area and equipment
   c. c) To avoid contamination, use appropriate clean/aseptic technique
   d. d) The Biological Safety Cabinet may be used when the compounding involves acids and/or other caustic type ingredients (i.e. acetic acid)

7. Foot traffic in area is to be kept to a minimum

8. Appropriate stability information and beyond use dating shall be determined using manufacture's information , or other published articles/references. .

   Refer to Policy 205 referencing expiration dating of Pharmacy preparations.

9. After compounding, all used ingredient containers use shall be returned back to its designated area.

10. A pharmacist is responsible for the checking of the final compounded preparations accuracy, purity, and labeling.

11. WEIGHT BALANCES

Torsion "Class A" and "C" balances are annually certified by a qualified vendor technician. Documentation is on a sticker attached to the weight balance.

A. **Formulations Book and References**

1. Inpatient Pharmacy's oral and topical extemporaneous preparations shall be compounded per protocols on file in the Pharmacy formulations book (located in the Inpatient compounding area) and/or using other published references on file or obtained from a reliable source via the internet.

2. Material Safety Data Sheets

B. **Documentation of Compounding**

1. Each compounded, extemporaneous preparation shall be logged on the "**Extemporaneous Compounding Log**" form which includes the following information. (Refer to log form)
   a) Date Code (Identifies batch number & date prepared)
   b) Drug Name & Strength: (Name of preparation & strength)
   c) Dosage form
   d) Manufacture(s) name, Lot #, Expiration date (Identifies names of ingredients & their manufacture and expiration dates)
   e) OV's Expiration Date: (Identifies beyond-use-date of final product)
   f) Quantity and Size/Volume of final product:
   g) Packed By: (Identifies the name of compounder)
   h) Checked By: (Identifies name of checking pharmacist)
   i) Floor: (Identifies location of requesting Ward/Clinic)

2. Documentation of Pediatric/ Neonatal ICU is kept in "Extemporaneous Compounding Log for Peds/NICU" binder located in that service area.
   (Refer to Policy 521, Pediatrics & NICU)

C. **Labeling (MM 5.01.09)**

1. Inpatient Ward Use Labeling
   a. Name of the product and active ingredients
   b. Strength of the product or its contents
   c. Quantity/Volume
   d. Expiration Date
   e. Auxiliary information (i.e. "for external use, poison, etc.")
   f. Any storage requirements (refrigerate, protect from light, etc.)

g. Pharmacist initials
h. Pharmacy lot # (History of the preparation may be traced)

For **OUTPATIENT Pharmacy** , refer to patient labeling requirements section in Pharmacy Policy 404, Discharge Prescriptions.

D. **Expiration Dates**
(Refer to Policy 205, EXPIRATION DATING OF PHARMACY PREPARATIONS)

E. **Consultation (Title 22)**
The pharmacist shall be consulted on proper methods for repackaging and labeling of bulk cleaning agents, solvents, chemicals and poisons used throughout the hospital

References: Remington, Pharmacy Law 1716.2 (2009), Title 22, Practice Standards of ASHP , 2004-USP (795) & (1075), Medication Management 2009	
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