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TITLE/DESCRIPTION: **MEDICATION COMPOUNDING**			
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PURPOSE:

To allow orders for hazardous medication compounding, sterile medication compounding and non-sterile medication compounding for drug preparations not commercially available as appropriate to meet the needs of the patient population, following applicable rules and regulations and standards set forth in USP <795>, <797> and USP <800>.

DEFINITIONS:

Aseptic technique - protocols and procedures that are observed to prevent contamination of drugs, packaging, equipment, or supplies by microorganisms during preparation.

Compounding - also known as pharmaceutical compounding and/or compounding pharmacy is the mixing of drugs by a compounding pharmacist to fit the unique needs of a patient. This may be done for medically necessary reasons, such as to change the form of the medication from solid pill to liquid, to avoid a non-essential ingredient that the patient is allergic to, or to obtain the exact dose needed. It may also be done for voluntary reasons, such as adding favorite flavors to a medication.

Compounded Sterile Preparations (CSP) - biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that, under USP 797, must be compounded using aseptic techniques.

Extemporaneous Compounding - is the preparation of a medication or drug product designed to meet the needs of individual patients most especially when the needed product is not commercially available.

Hazardous Drugs - are substances that may cause harm to individuals due to their toxic properties.

The characteristics of hazardous drugs include:

a) Carcinogenicity - they may cause cancer.
b) Teratogenicity - they may cause birth defects or developmental abnormalities in fetuses.
c) Reproductive toxicity - they may impair fertility or cause reproductive harm.
d) Organ toxicity - they can cause damage to organs like the liver, kidneys, or heart.
e) Genotoxicity - they may alter genetic material, leading to mutations or other DNA damage.
f) Toxicity by absorption - these drugs can be harmful even when absorbed through the skin or mucous membranes.

Magic mouthwash - is a term commonly used to describe a variety of compounded oral solutions that are used to treat mouth ulcers, sores, and other oral mucositis (inflammation of the mucous membranes in the mouth). It's a combination of ingredients that can be customized depending

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on the patient's needs, and it's typically used to relieve pain, reduce inflammation, and prevent infections in the mouth.

The composition of magic mouthwash can vary, but common ingredients include:

a) **Anesthetic (e.g., Lidocaine or Benzocaine)** - Provides numbing relief to reduce pain and discomfort.
b) **Antihistamine (e.g., Diphenhydramine)** - reduces inflammation and can help with allergic reactions or irritation.
c) **Antacid (e.g., Maalox)** - helps to coat the mouth and relieve discomfort from irritation or heartburn.
d) **Antibiotics (e.g., Metronidazole or Tetracycline)** - used to prevent or treat bacterial infections.
e) **Corticosteroids (e.g., Hydrocortisone)** - used to reduce inflammation and swelling.

Non-sterile compounding - preparation of medications that do not require a sterile environment.
Oral Potassium Chloride - solution of 10% Potassium Chloride (10g/100ml) equivalent to 134 meq/100ml.
Papertabs - drugs compounded in powdered form and divided into needed doses and packaged into individual paper containers.
Sterile compounding - defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication (USP 797).
USP 795 - provides standards for compounding quality non-sterile medication preparations.
USP 797 - provides standards for compounding quality sterile medication preparations.
USP 800 - provides standards for the safe handling of hazardous drugs in the healthcare setting.

RESPONSIBILITY:

Staff Pharmacists, Compounding Pharmacists, Clinical Pharmacists, Pharmacy Technicians, Nurses, Nursing Clerks, Physicians

POLICY:

1. A compounding prescription order from a physician shall be provided for compounded medications either through a written prescription or via the Computerized Provider Order Entry (CPOE).

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2. The compounding prescription order shall be verified by a pharmacist before dispensing and compounding.

3. Sterile preparations of hazardous substances shall be compounded based on USP 800 guidelines in a sterile environment and only by trained compounding pharmacists.
   3.1 Before compounding hazardous drugs, a risk assessment should be performed to evaluate the potential exposure to hazardous drugs and to decide what safety controls and procedures are necessary.
   3.2 **Facility Design and Engineering Controls**:
   Primary Engineering Controls (PEC) - for compounding hazardous drugs, negative pressure rooms, biological safety cabinets (BSCs), or compounding aseptic containment isolators (CACIs) are required to minimize exposure.
   Secondary Engineering Controls (SEC) - these include areas like the room where the PEC is located, which should maintain negative pressure and be equipped with appropriate ventilation systems.
   3.3 **Personal Protective Equipment (PPE):**
   - PPE includes sterile gloves, gowns, eye protection, and respiratory protection. Appropriate PPE should be worn by personnel when handling hazardous drugs, especially during compounding and clean-up.

   3.4 **Environmental Monitoring:**
   - Regular environmental monitoring should be performed to ensure the integrity of the compounding area. This includes air sampling and surface wipe testing to detect the presence of hazardous drugs.

   3.5 The USP 800 guidelines refer to the list of hazardous drugs maintained by the National Institute for Occupational Safety and Health (NIOSH). This list is used to identify drugs that should be handled following the USP 800 guidelines.

4. Sterile preparations of non-hazardous substances shall be compounded based on USP 797 guidelines in a sterile environment and only by trained compounding pharmacists.
   4.1 USP 797 classifies compounded sterile preparations into three risk levels, based on the complexity of the preparation and the potential for contamination:
   4.1.1 Low-Risk Compounding:
   a. Involves simple procedures like reconstituting or mixing drugs.
   b. Prepared in a ISO Class 5 environment (i.e., a cleanroom or laminar airflow workbench).

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c. Minimal chance of contamination.
d. Examples: Preparing a single-dose solution for injection.

4.1.2 Medium-Risk Compounding:
a. Involves more complex procedures, such as compounding multiple ingredients or large quantities.
b. Can include situations where the preparation is intended for multiple patients.
c. Examples: Parenteral nutrition solutions or preparing a batch of sterile drugs.

4.1.3 High-Risk Compounding:
a. Involves the use of non-sterile ingredients, improperly stored sterile ingredients, or preparations made in environments with a high potential for contamination.
b. Examples: Compounding from bulk powders or using non-sterile equipment.

4.2 Environment Requirements
- USP 797 specifies that compounding sterile preparations shall be done in environments that minimize the risk of contamination. These include:

a) Clean Rooms and Controlled Environments:
- ISO Class 7 or better for the room, and ISO Class 5 (a sterile environment, such as a laminar flow hood or biological safety cabinet) for direct compounding.

b) Air Quality Control:
- Regular monitoring of air quality and particle counts.
- Air filtration systems (HEPA filters) are required to maintain appropriate cleanliness levels.

c) Temperature and Humidity Control:
- Controlled environmental conditions are essential to prevent microbial growth or contamination.

5. Non-sterile preparations shall be compounded based on USP 795 guidelines in the non-sterile compounding area of the pharmacy.

5.1 **Compounding Conditions:**
Environment - the environment in which compounding is done shall be clean and sanitary. Compounding areas shall be appropriately designed, equipped, and maintained.
Equipment - appropriate tools and equipment shall be used, and they should be kept in good condition.

5.2 **Personnel:**
- Compounding shall be performed by qualified personnel trained in the compounding process and familiar with USP <795> standards.

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- Personnel shall follow proper hand hygiene and use personal protective equipment (PPE) to prevent contamination.

5.3 **Ingredients:**
- The ingredients used in compounding shall be of appropriate quality and shall be sourced from reputable suppliers.
- It is important to check the quality of excipients and active pharmaceutical ingredients (APIs) before use.

5.4 **Compounding Process:**
- Compounding shall follow a written formula or recipe that details the precise ingredients, quantities, and steps involved.
- Procedures shall be standardized to ensure consistency and accuracy in the preparation of compounded medications.

5.5 **Stability and Beyond-Use Dating:**
A beyond-use date (BUD) shall be assigned to the compounded preparation, which is based on the stability of the medication.
- The BUD is determined by factors such as the chemical stability of the ingredients, the type of formulation, and storage conditions.

5.6 **Quality Assurance and Recordkeeping:**
- A log of all extemporaneously compounded products is recorded in a logbook which includes the patient name the product is served to, the station/room number of the patient, the medication compounded, the name and signature of the compounding pharmacist, and the checker.

5.7 **Patient Education:**
- Patients shall be provided with clear instructions regarding how to use the compounded medication.
- Counseling shall include guidance on storage, administration, and potential side effects or complications.

6. Training of compounding pharmacists for hazardous compounding shall be done under the supervision of certified compounding pharmacists for an appropriate time-frame. Skill and knowledge evaluation shall be done for granting of certification.

7. Compounding area shall comply to standards set by USP 795, 797 and 800.

8. Safety protocols shall be observed throughout the duration of the compounding process.

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9. There shall be a documentation of pre-treatment checks, treatment procedure, compounding process, adverse drug reactions during treatment and potential reasons for not proceeding with treatment.

10. Proper labeling shall be observed for all compounded products. Labels are printed and attached to the finished product upon final checking.

    10.1 All prepared drugs should be labeled properly which includes the following data:

a. Patient Name	g. Date and time prepared
b. Generic Name	h. Expiry Date and time
c. Brand Name	i. Infusion Rate (when applicable)
d. Concentration	j. Prepared by
e. Diluent (when applicable)	k. Checked by
f. Final volume (when applicable)	l. Auxiliary label

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PROCEDURE (SOP):

I. **Compounding of Sterile Medication Preparations**

1. The dispensing pharmacist receives the order for the sterile compounding preparation either through written prescription or via the Computerized Provider Order Entry (CPOE).
2. The dispensing pharmacist transcribes the order and endorses to the compounding pharmacist.
3. The compounding pharmacist reviews the compounding order and completes the compounding worksheet.
4. The compounding pharmacist observes donning protocols and wear full PPE which includes disposable gowns, sleeves, gloves and goggles, prior to entering the sterile compounding room.
5. The compounding pharmacist follows all sterile preparation requirements for preparing compounded sterile drugs/products as outlined in USP General Chapter <797> (USP 27-NF22).
6. Once the compounding process is complete, the compounding pharmacist endorses the completed preparation to the assigned checker for double-checking and labeling of the finished product.
7. The compounding pharmacist documents the compounding works via the hospital information system preparation work-list.
8. The finished product is then dispensed after final checks.

II. **Compounding of Hazardous Medication Preparations**

1. The dispensing pharmacist receives the order for compounding of the hazardous medication through written prescription or CPOE.
2. The dispensing pharmacist transcribes the order and endorses to the compounding pharmacist
3. The compounding pharmacist receives the compounding order and completes the compounding worksheet.
4. The compounding pharmacist observes donning protocols and wear full PPE which includes disposable gowns, sleeves, gloves, and goggles, before entering the sterile compounding room for hazardous substances.
5. The compounding pharmacist follows all sterile preparation requirements for preparing compounded sterile drugs/products as outlined in accordance to USP 800 guidelines.
6. Endorses the completed product to the assigned checker to double check and ensures that safety protocols and the sterile condition of the product is maintained.
7. The assigned pharmacist checker double-checks the completed product for any discrepancies and

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once approved, attaches the complete label to the product.

8. Dispenses and endorses the finished product to the nurse-in-charge for proper administration.
9. The compounding pharmacist documents the compounding works via the hospital information system preparation work-list.
10. The compounding pharmacist properly disposes PPE, containers, tools and supplies used for hazardous compounding using a cytotoxic disposal bag and placed in the hazardous substances waste bin.

III. **Compounding of Non-sterile Preparations**

1. The dispensing pharmacist receives the order for the non-sterile drug preparation via CPOE.
2. The dispensing pharmacist transcribes the medication order and endorses it for compounding.
3. The compounding pharmacist double checks the order and prepares the necessary tools, equipment and compounding ingredients.
4. The compounding pharmacist sterilizes the compounding area using an alcohol wipe and dons a disposable glove prior to compounding.
5. The compounding pharmacist follows procedure observed for commonly ordered non-sterile preparations:
   5.1 Paper tablets

A) **Materials Needed**

- Specially manufactured paper for divided powders:
  - Vegetable parchment – a thin semi-opaque moisture-resistant paper
  - White bond – an opaque paper with no moisture-resistant properties
  - Glassine – a glazed, transparent moisture-resistant paper
  - Waxed – a transparent, waterproof paper

Note: Hygroscopic and volatile drugs can be protected best by using waxed paper, double-wrapped with bond paper to improve the appearance of the completed powder.

- The powder papers may be of any size convenient to the order but usual sizes are 2.75x3.75 and 3x4.5
- Gridded glass pill tile
- Spatula/razor as divider
- Mortar and pestle

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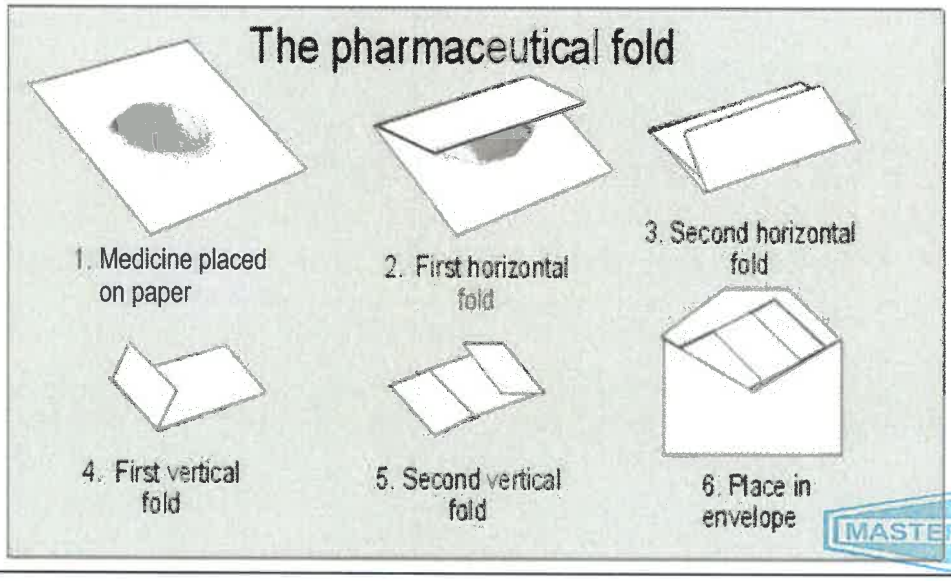
- Medication label
- Non-sterile gloves

B) **Procedure**

1. Double-check physician's order prior to compounding. Calculate and double-check dose and number of paper tabs needed.
2. Prepare materials needed. These should be cleaned prior to use. Use nonsterile gloves.
3. Clean compounding area
4. Pulverize tablet orders prior to dividing
5. Use block-and-divide method
6. Appropriately fold papertabs (Figure 1)
7. Label each papertab with the generic name and dose of the medication
8. Place completed papertabs in a ziplock and place completed medication label containing the patient's name, room number, date, generic name, brand name, dose, signa and signature of compounding pharmacist
9. Also place the evidence of the medication (e.g. empty capsule shells, foil wrap) inside the ziplock.

FIGURE 1

Folding of paper



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5.2 **Oral Potassium Chloride**

A) **Materials Needed**
- 100 ml amber bottle
- 10 g Potassium chloride powder
- Graduated cylinder
- Medication label

B) **Procedure**
1. Double check physician's order prior to compounding
2. Sterilize amber bottle
3. Place 10 g potassium chloride powder in the amber bottle
4. Add distilled water to make 100 ml (approx. 90 ml)
5. Add complete label indicating medication name, dose, frequency, compounding date and time, expiration date and time.

C) **Storage**
- Oral KCL stability is 48 hrs. and must be stored at 2-8 degrees celsius
- Always double check for any instability (e.g. precipitation, discoloration) prior to administration

5.3 **Oral Vancomycin**

Usual Dose per Solution: 5g/100ml solution
Final Concentration: 50 mg/ml
Usual Dosage and Frequency: 125 mg/2.5 ml, 2.5 ml PO Q6H for 10 days

A) **Materials Needed**
- Vancomycin Vial – Five 1 g vials or Ten 500 mg vials (Total grams is 5 grams)
- Three 50 ml sterile/distilled water polyamp for reconstitution
- 1 sterilized amber bottle
- Syringes (if 1 g vial is used, use 10 cc syringe for reconstitution, if 500 mg vial is used, use 5 cc syringe)
- Stevia powder
- Label

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B) **Procedure**

1. Double check the doctor's order for the final dose and concentration of the solution
2. Reconstitute 5 g of Vancomycin powder with 50ml sterile water (allow the powder to dissolve without vigorously shaking the vial). For the 1 g vial, 10 ml is used to reconstitute each vial while for the 500 mg vial, 5 ml is used.
3. Transfer the reconstituted vancomycin into the amber bottle using the appropriate syringe
4. Add the remaining sterile water to make 100 ml and add 1 sachet of stevia powder
5. Properly label the final product

C) **Storage**

- Oral Vancomycin Solutions can remain stable for 14 days when refrigerated (2-8 degrees celsius). The final solution should be clear and be free from any cloudiness, precipitation or discoloration.

5.4 **Magic Mouthwash**

Usual order is a 1:1:1 ratio with a total volume of 180 ml
Usual use: to treat mouth sores especially chemotherapy induced sores.

A) **Materials Needed**

- (please refer to doctor's order for exact ingredients needed as these may vary)
- Maalox plus suspension 60 ml
- Benadryl 12.5 mg/5 ml syrup 60 ml
- Lidocaine 2% amp

B) **Procedure**

1. Double check doctor's order and prepare ingredients prior to compounding
2. Use appropriately sized bottle based on the volume desired
3. Mix ingredients based on the ratio given
4. Properly label the finished product containing the patient's name and room number, generic names of medication used, dose, frequency, compounding date and expiry date

C) **Storage**

- Stability of the finished product is 21 days stored at 2-8 degrees celsius

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6. The assigned pharmacist as checker labels the patient's name and room number, generic names and brand names (when applicable) of medication used, dose, frequency, compounding date and time and expiry date and time of the product by the pharmacist assigned as checker.
7. A log of all extemporaneously compounded products in a logbook which includes the patient name the product is served to, the station/room number of the patient, the medication compounded, the name and signature of the compounding pharmacist and the checker.
8. The compounding pharmacist disposes waste materials for the compounding process.

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WORK INSTRUCTION:

KEY TASKS	PERSON RESPONSIBLE
STERILE COMPOUNDING	
1. Receives the order for the sterile compounding preparation either through written prescription or via the Computerized Provider Order Entry (CPOE).	Dispensing Pharmacist
2. Transcribes the compounding order, dispenses the needed medications and endorses this to the compounding pharmacists.	
3. Reviews the compounding order and completes the compounding worksheet.	Compounding Pharmacist
4. Observes donning protocols and wear full PPE which includes disposable gowns, sleeves, gloves and goggles, prior to entering the sterile compounding room.	
5. Follows all sterile preparation requirements for preparing compounded sterile drugs/products as outlined in USP General Chapter <797> (USP 27-NF22).	
6. Endorses the completed preparation to the assigned checker for double-checking and labeling of the finished product, once the compounding process is complete.	
7. Double-checks the finished preparation, prints and add the complete label to the finished preparations and dispenses this to the administering nurse.	Staff Pharmacist - Checker
HAZARDOUS PREPARATION COMPOUNDING	
8. Receives the order for hazardous drug compounding via CPOE.	Staff Dispensing Pharmacist
9. Transcribes the compounding order, dispenses the needed medications and endorses this to the compounding pharmacists	

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10. Receives the compounding order and completes the compounding worksheet.	Compounding Pharmacist
11. Observes donning protocols and wear full PPE which includes disposable gowns, sleeves, gloves, and goggles, before entering the sterile compounding room for hazardous substances.	
12. Completes the preparation worksheet prior to compounding. Compounds the hazardous preparation order according to USP 800 guidelines and follows proper PPE use. Endorses the completed product to the checker.	
13. Documents the compounding works via the hospital information system preparation work-list.	
14. Properly disposes PPE, containers, tools and supplies used for hazardous compounding using a cytotoxic disposal bag and placed in the hazardous substances waste bin.	
15. Double-checks the finished preparation, prints and add the complete label to the finished preparations, and dispenses this to the administering nurse. Instruct the administering nurse about proper hazardous administration.	Staff Pharmacist - Checker
COMPOUNDING NON-STERILE PREPARATIONS	
16. Receives the order for hazardous drug compounding via CPOE.	Dispensing Pharmacist
17. Transcribes the medication order and endorses it for compounding.	
18. Double checks the order and prepares the necessary tools, equipment and compounding ingredients. Sterilizes the compounding area using an alcohol wipe	Compounding Pharmacist

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and dons a disposable glove prior to compounding. Compounds the ordered non-sterile preparation following the designed procedure and USP 795 guidelines.	
19. Checks and labels the finished product prior to dispensing and records the compounded product in the extemporaneous compounding logbook.	Staff Pharmacist - Checker

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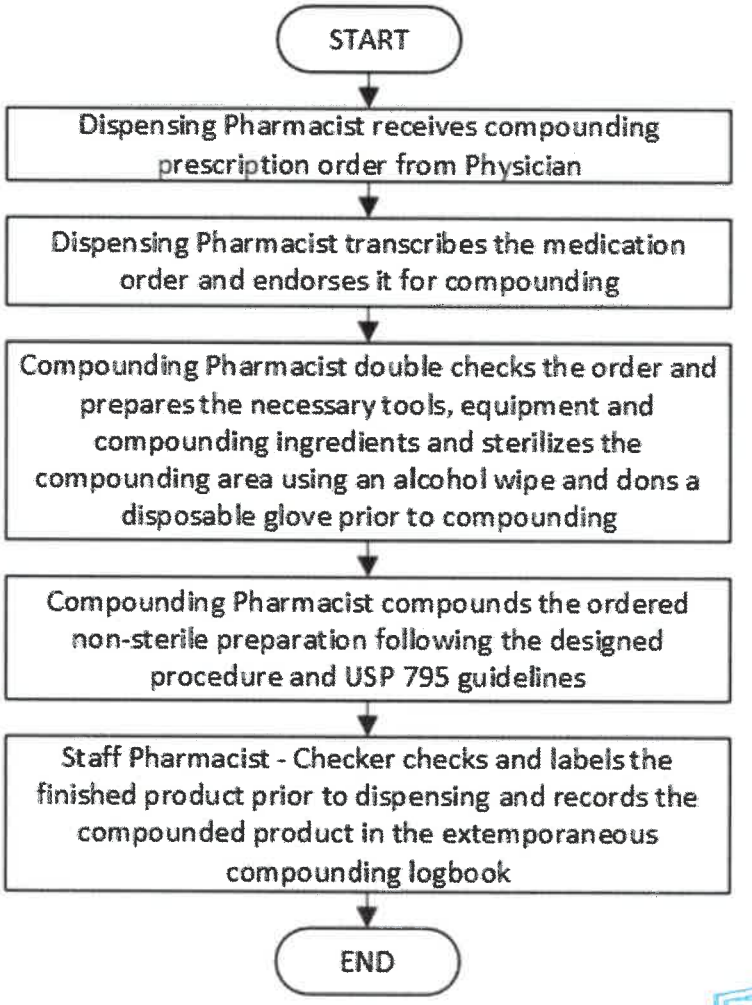
WORK FLOW:

COMPOUNDING NON-STERILE PREPARATIONS



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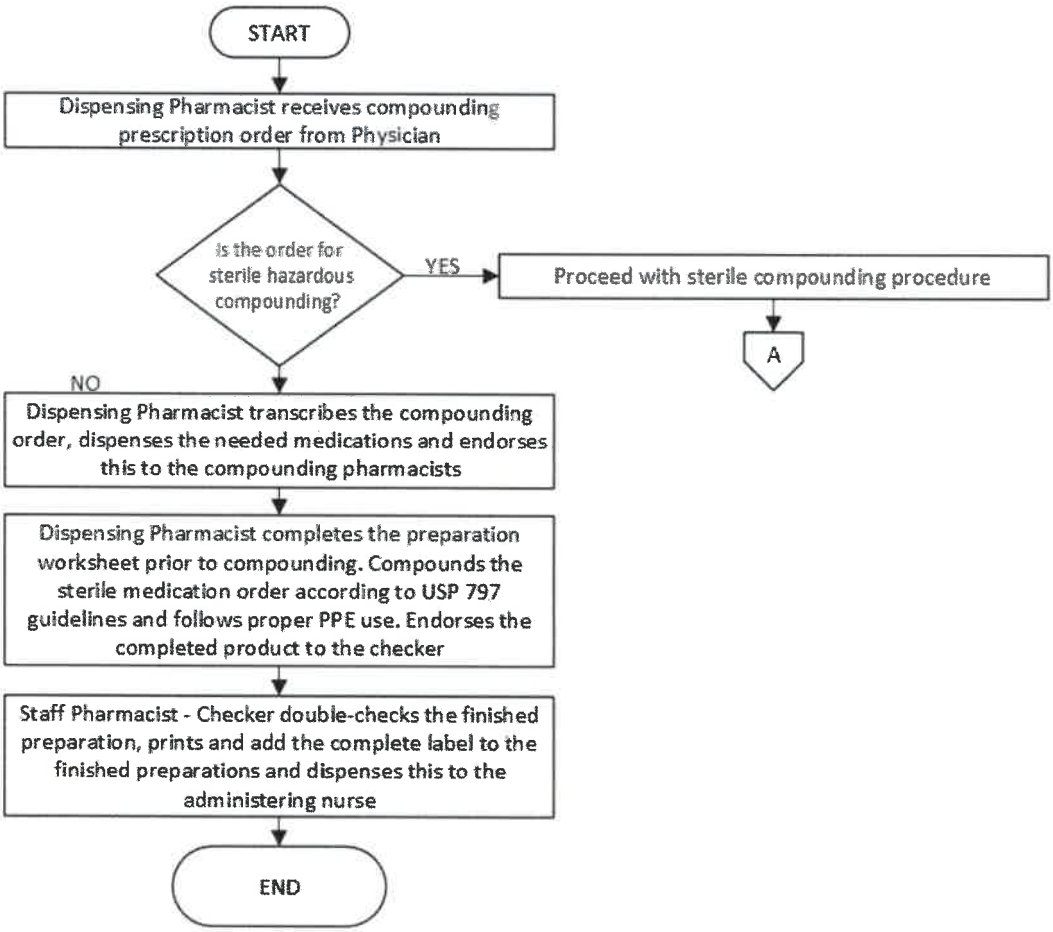
HAZARDOUS PREPARATION COMPOUNDING



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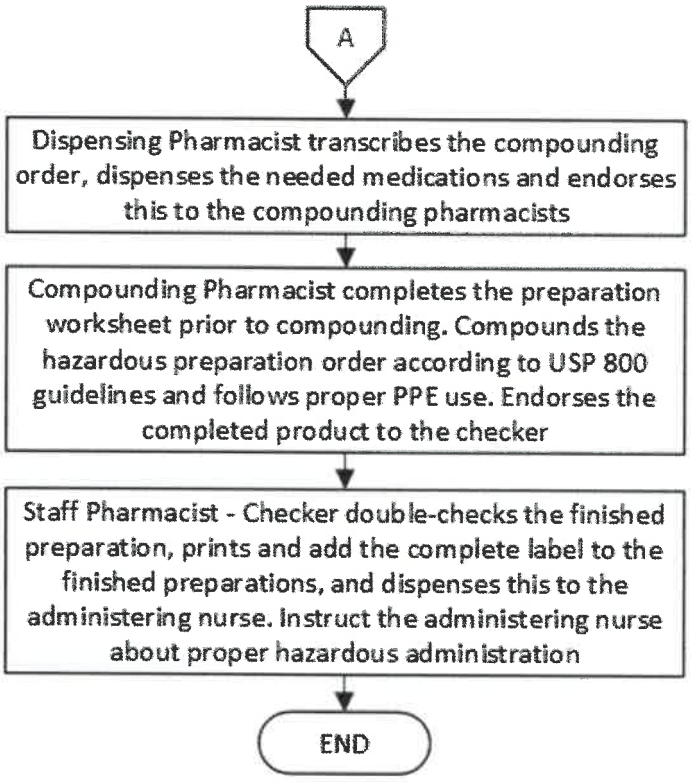

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DR. PABLO O. TORRE MEMORIAL HOSPITAL

METRO PACIFIC HEALTH
THE HEART OF FILIPINO HEALTHCARE

DEPARTMENT: Pharmacy Division		**POLICY NUMBER:** DPOTMH-MPP-PHAR-P020-(01)	
TITLE/DESCRIPTION: **MEDICATION COMPOUNDING**			
EFFECTIVE DATE: April 30, 2025	**REVISION DUE:** April 29, 2028	**REPLACES NUMBER:** DPOTMH-J-P20	**NO. OF PAGES:** 19 of 20
APPLIES TO: Pharmacy Division, Nursing Service Division		**POLICY TYPE:** Multi Disciplinary	

FORMS: N/A

EQUIPMENT:

1. Class II Biosafety Cabinet
2. Laminar flowhood

REFERENCES:

1. United States Pharmacopeia 795, 797 and 800
2. American Society of Health-System Pharmacist Guidelines on Compounding Sterile Preparation
3. 2018, McAuley, D. Vancomycin "The Global RPh" derived from Lexicomp and https://globalrph.com/dilution/vancomycin/
4. 2020, Stacy, B. and Lewis, P. "Comparative Stability Study of Unit-dose Vancomycin Hydrochloride Oral Solutions in Plastic Capped Oral Syringes and Plastic Sealed Dosage Cups" The International Journal of Pharmaceutical Compounding Vol. 24, Number 3 derived from https://ijpc.com/Abstracts/Abstract.cfm?ABS=4803
5. American Society of Health System Pharmacists
6. https://www.mayoclinic.org/tests-procedures/chemotherapy/expert-answers/magic-mouthwash/faq-2005807

RIVERSIDE MEDICAL CENTER, INC.

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