## PURPOSE:

To allow orders for compounded drugs or drug mixtures not commercially available as appropriate to meet the needs of the patient population, following applicable rules and regulations and standards set forth in USP <797> and USP <800>.

## LEVEL:

All Physicians, Nurse, Pharmacists and other Healthcare Professionals of Riverside Medical Center Inc. (RMCI).

## DEFINITION OF TERMS:

**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.

## POLICY:

1. Compounded drugs shall be prescribed when the physician determines, in his/her professional judgment, that the compounded drugs' benefits over any approved alternative, justify the risk for a particular patient.

2. All compounded formulas shall be preceded as an addition to the RMCI Formulary and shall be approved by the Pharmacy and Therapeutic Committee (PTC).

3. Standard formulas shall be available in the Pharmacy Division.

4. The goal is preparation of safe and effective products using the best available resources and techniques.

**DOCUMENTATION:**

New Policy

**DISSEMINATION:**

1. RMCI Hospital Communicator
2. Conducting hospital wide continuing education to all healthcare professionals.

**REFERENCES:**


1. USP-NF
2. Remington Pharmaceutical Services
3. American Society of Health-System Pharmacist Guidelines on Compounding Sterile Preparation.
4. Canadian Society of Hospital Pharmacist Standards.
5. Manufacturer's Package Insert.
6. ASHP
7. ISMP
8. World Health Organization (2007). Control of Concentrated Electrolyte Solutions.
9. Standard Operating Procedures relating to chemotherapy at Abbey House Veterinary Hospital

**APPROVAL:**

| | Name/Title | Signature | Date |
|---|---|---|---|
| Prepared by: | **MA. MADELYN N. LACSON, RPh., RN**<br>Inpatient Pharmacy Supervisor | | 6/24/22 |
| Verified: | **STEPHANIE CAMILLE O. SAMONTE, RPh.**<br>Inpatient Clinical Pharmacist | | 6/24/22 |
| | **MIRIAM HOPE D. BRAVO, RPh.**<br>Inpatient Pharmacy Manager | | 6/27/22 |
| Reviewed by: | **DENNIS C. ESCALONA, MN, FPCHA, FPSQua**<br>Quality Assurance Supervisor | | 6/28/2022 |
| Recommending Approval: | **PRINCESS M. ABELLON, MBA**<br>Pharmacy Division Officer | | 6/29/2022 |
| | **FREDERIC IVAN L. TING, MD**<br>OIC-Total Quality Division | | 6/30/2022 |
| Approved: | **GENESIS GOLDI D. GOLINGAN**<br>President and CEO | | 9/1/22 |

## PURPOSE:

To discuss the processes involved in drug compounding.

## SCOPE:

Applies to all Pharmacy Division staff of Dr. Pablo O. Torre Memorial Hospital

## PERSON RESPONSIBLE:

Pharmacists, Pharmacy and Therapeutics Committee (PTC)

## PROCEDURE:

1. Prepare compounded drugs in situations where drugs not commercially available are widely used on literature reports and where there exists a formula for the preparation of these products. The following includes, but may not be limited, to reasons for ordering and preparing compounded drugs:
   1.1. The drug required is not manufactured in the needed strength.
   1.2. The physician requests a different form of the drug to improve patient compliance with prescribed drug therapy (for swallowing or taste purposes, etc).
   1.3. The prescribed drug needs to be combined in forms not available from the manufacturer to improve patient response to prescribed drug therapy.
   1.4. The patient is allergic to inactive ingredients (dye, lactose, etc.) in the manufactured form of the drug.
   1.5. The prescribed therapy requires tailoring to the individual patient (intravenous feeding solutions, chemotherapy, etc).
2. Review the medical record of the patient. The risks of the patient receiving compounded drugs, along with the benefits, will be weighed in the context of a specific patient's medical condition. If the pharmacist, in his/her clinical expertise feels the risks weigh the benefits, the physician shall be contacted for revision of the order.

3. If the Prescribing Physician has ordered a compounded drug that is either found to be unsafe or ineffective and removed from the market, or is listed in the FDA's regulations as difficult to compound, the physician will be contacted for revision of the order.
4. If the physician does not revise the order and insists on the preparation of the compounded drug, the pharmacist will contact the Chairman of the PTC to resolve the situation with the physician. Drug to be compounded must be individually prescribed for an identified patient.
5. If the formula is not available or if the product is to be made from non-sterile drugs or impure chemicals, the PTC will review the possibility of pharmacy mixing these products on an individual basis.
6. Previously marketed drugs found to be unsafe or ineffective and removed from the market may not be compounded.
7. All sterile preparation requirements for preparing compounded sterile drugs/products will be followed. As outlined in USP General Chapter <797> (USP 27-NF22).
8. Preparation of Chemotherapy drugs must only be undertaken by trained personnel in the safety cabinet in the chemo room. A list of persons trained in the use of the safety cabinet will be maintained and kept in the chemo room.
9. Persons preparing drugs must wear full PPE e.g. Disposable gown, sleeves, gloves and goggles.
10. Double gloving while preparing the drugs will reduce the contamination of ancillary objects following preparation. Outer gloves should be removed in the safety cabinet and placed in a zip lock cytotoxic disposal bag before removal from the cabinet.
11. Work should be organized, and the area used for preparation should be kept clutter free.
12. THINK AHEAD and get all the equipment ready for preparation ready before starting. This will significantly reduce the chance of accidents.
13. Disposable absorbent mats should be used in the safety cabinet.
14. ALWAYS use luer lock syringes.

15. ALWAYS use luer lock syringes.
16. All prepared drugs should be labeled properly which includes the following data:
    a. Patient Name
    b. Generic Name
    c. Brand Name
    d. Concentration (in mg.)
    e. diluent
    f. final volume
    g. Date Prepared
    h. Expiry Date
    i. Infusion Rate
    j. Prepared by
    k. Checked by
    l. Auxiliary label
17. Prepared drugs should be kept in the safety cabinet, in a kidney bowl, until ready for use.
18. Drugs should be prepared as close to the time of administration as possible.

**REFERENCES:**


1. USP-NF
2. Remington Pharmaceutical Services
3. American Society of Health-System Pharmacist Guidelines on Compounding Sterile Preparation.
4. Canadian Society of Hospital Pharmacist Standards.
5. Manufacturer's Package Insert.
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| | **FREDERIC IVAN L. TING, MD**<br>OIC-Total Quality Division | | 6/30/22 |
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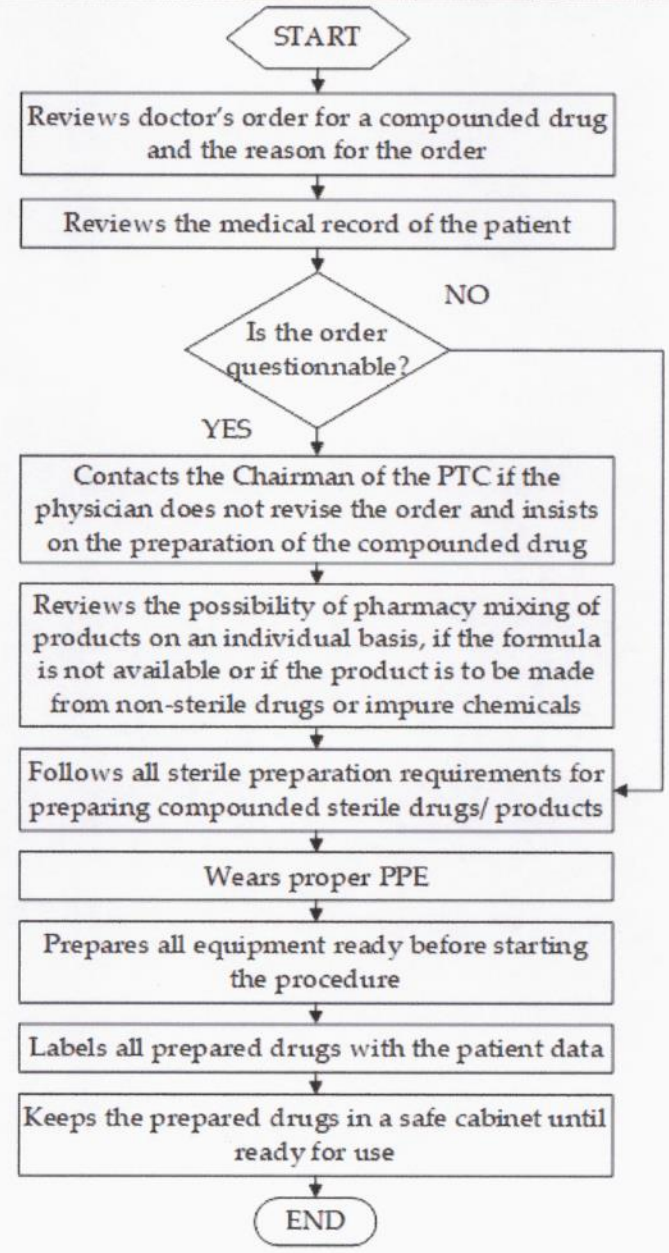
## FLOWCHART



| DR. PABLO O. TORRE MEMORIAL HOSPITAL<br>B.S. Aquino Drive, Bacolod City, Negros Occidental, 6100 | Document Code: | DPOTMH-J-P20-FC01 |
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| | Name/Title | Signature | Date |
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| Prepared by: | **MA. MADELYN N. LACSON, RPh., RN**<br>Inpatient Pharmacy Supervisor | | 6/24/22 |
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| KEY TASKS | PERSON RESPONSIBLE |
|---|---|
| 1. Reviews doctor's order for a compounded drug and the reason for the order | Pharmacist |
| 2. Reviews the medical record of the patient | Pharmacist |
| 3. Contacts the physician:<br>3.1. if the order is deemed risky for the patient<br>3.2. has ordered a compounded drug that is found unsafe or ineffective<br>3.3. has been removed from the market or is listed in the FDA's regulation as difficult to compound | Pharmacist |
| 4. Contacts the Chairman of the PTC if the physician does not revise the order and insists on the preparation of the compounded drug | Pharmacist |
| 5. Reviews the possibility of pharmacy mixing of products on an individual basis, if the formula is not available or if the product is to be made from non-sterile drugs or impure chemicals | Pharmacy and Therapeutics Committee |
| 6. Follows all sterile preparation requirements for preparing compounded sterile drugs/ products | Pharmacist |
| 7. Wears proper PPE | Pharmacist |
| 8. Prepares all equipment ready before starting the procedure | Pharmacist |
| 9. Labels all prepared drugs with the patient data | Pharmacist |
| 10. Keeps the prepared drugs in a safe cabinet until ready for use | Pharmacist |

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