MASTER FORMULATION RECORD

Nomenclature and definitions in each box.

References:

1. USP <7> Labeling
2. USP General Notice and Requirement
3. USP <797> 2008 version
4. ISMP Guidelines for Safe Electronic Communication of Medication Information
5. ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations

NAME OF PREPARATION (name, strength, dosage form, route of administration)

1. Format of preparation name:
   [Generic Name][Brand Name] [Strength as metric unit] [Name of base solution] [Route of administration] [dosage form]
   e.g., oxytocin (PITOCIN) 30 units in 500 mL sodium chloride 0.9% IV injection
2. When expressing a generic drug name, use all lower-case letters as the primary expression of drug nomenclature unless using FDA/ISMP list of Tall Man Letters:
   e.g., niCARdipine (CARDENE) 50mg in 25 0mL sodium chloride 0.9% IV injection
3. When expressing a brand drug name, use uppercase letters WITHOUT Trademark symbols (e.g., TM, ®):
   e.g., HYDROmorphone (DILAUDID) 20 mg in 100 mL sodium chloride 0.9% IV injection
4. For drug names ending with the letter "l," capitalize the "L" (e.g., propranolol 20 mg) to avoid confusion with the numeral 1 in the dose that follows the drug name.
5. Do not abbreviate drug names or refer to them by shortened names.
6. Strength should be shown as total strength/total volume for all compounded drugs and concentration (Strength/ mL) should be indicated for all titratable drips:
   e.g., Total strength/total volume: 500 mg/10 mL
   Concentration(Strength/mL) : 50 mg/mL
   or
   Total strength/total volume: 25,000 Units/5 mL
   Concentration(Strength/mL) : 5,000 Units/mL
7. Strength as decimal point should be shown with a zero preceding the decimal point and without trailing zero following decimal point.
   e.g., express as 0.2 mg, not .2 mg or express as 4 mg, not 4.0 mg)
8. Spell out the word "units." Never use the abbreviation U, which easily can be mistaken as a zero, causing a 10-fold overdose. Never abbreviate international units as IU; this measure, which has been misread as IV (intravenous), can be expressed as "units" alone.
9. For acceptable route abbreviations, use all uppercase letters—IV, IM, SUBQ, PO, and NAS, without spaces or periods between the letters.
10. Add "CSP: Compounded Sterile Preparation" at the end of CNR name search.
11. A standard process is needed for expressing combination and compounded products, including products that are often referred to by coined names (e.g., magic mouthwash). Comment: USP is currently developing such a standard: Currently ingredients not on product name
    Clack's Solution: no ingredient description (Diphenhydramine, Nystatin, Tetracycline, Hydrocortisone)
    Magic Mouthwash: no ingredient description (Diphenhydramine, Maalox, Nystatin, Lidocaine)

INGREDIENTS and Calculation (name, strength if applicable, quantity/amount)

1. List of each active ingredient and base solution.

2. Express measures in a standard fashion using USP standard abbreviations for dosage units as follows:
   g = gram(s)
   mg = milligram(s) (do not use mgs)
   mcg = microgram(s) (do not use the Greek letter mu [μ], which has been misread as mg)
   L (uppercase) = liter(s)
   mL (lowercase/uppercase) = milliliter(s) (do not use cc, ml, mLs, or mls)
   mEq = milliequivalent(s)
   mmol = millimole(s)
3. Express doses that cross a threshold from one dosing unit of measure to the next possible dosing unit of measure (e.g., mcg to mg, mg to g) the same way the dose or concentration/strength is expressed on the product label, without using unnecessary zeros (e.g., 1 g preferred over 1,000 mg, unless this differs from the product label). For specific drugs, once a threshold is crossed (e.g., mcg to mg, mg to g), continue using that dosing unit of measure for each subsequent dose (e.g., vancomycin 750 mg, 1 g, 1.25 g, 1.5 g; not 750 mg, 1 g, 1,250 mg, 1,500 mg).
4. Indicate strength/ml or the strength/total volume format for each ingredient if applicable.
5. Dry solids, which need to be reconstituted, should follow the same format, with the exception that only the total strength of the drug should be listed, not the strength/total volume or strength/mL.
6. Indicate the quantity/amount of each ingredient to be used as metric unit.
7. Amount of base solution should follow RHS Overfill Policy to decide the need of removing drug volume and/or manufacturers overfill volume from base solution container.
8. Describe container closure system of each ingredient: e.g., 5ml Vial or 250ml bag.

EQUIPMENT and SUPPLIES

1. Compounding environment should meet USP 797 medium risk sterile compound preparation requirement for batch compounding. Current USP797 2008 version only allows medium batch compound when you meet strict clean room requirements (e.g., >30 ACPE in anteroom and buffer room). No batch compound with SCA.
2. List all equipment and supplies needed for sterile compounding:

e.g., ISO Class 5 hood in Cleanroom Suite, Syringes, Needles, Sterile alcohol swabs, Sterile 70% Isopropyl Alcohol (IPA).

COMPOUNDING INSTRUCTIONS

1. Describe step by step procedure for compounding.
2. General garbing and aseptic technique requirement should be included.
   e.g., Follow facility's sterile compounding procedure for hand washing, PPE garbing, and cleaning/ disinfecting of ISO Class 5 hood. Use aseptic techniques at all times. Wipe the vial and bag with sterile IPA before placing in the hood. Visually inspect the ingredient for particles or discoloration. Wipe the vial stopper and bag port with alcohol swabs.
3. Compounding instruction should follow package insert, Lexi-comp, or other peer reviewed literature if applicable.
4. After sterile compounding, the contents of the container are thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other defects.

CONTAINER-CLOSURE SYSTEM

Describe the dispensing container as a final preparation.

e.g., 500ml IV Infusion bag, 5ml vials with sterile seal, 10ml syringe with sterile cap.

PHYSICAL DESCRIPTION OF FINAL PREPARATION

e.g., Sterile, clear, colorless aqueous solution.

QUALITY CONTROL PROCEDURES AND EXPECTED RESULTS:

1. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.
2. Visual inspection of Compounded Sterile Preparations to ensure the absence of particulate matter or discoloration in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

ASSIGNED BEYOND USE DATE and STORAGE REQUIREMENTS

1. Review Chemical Stability of compound.
   2-1: Follow stability information from Manufacturer's Package Insert, LEXI, or Trissel's.
   2-2: If stability information is not available as same strength, storage temperature, or container of compounded product, stability should be carefully extrapolated from reliable literature sources based on group review.
2. Decide sterility based on compounding risk level and intended storage condition. Refer to USP 797 risk level BUD.
   2-1. Medium Risk Level (Batch compound) at controlled room temperature: 30h.
   2-2: Medium Risk Level (Batch compound) in a refrigerator: 9 days.
3. Determine final Beyond Use Date and storage based on review of chemical stability (#1) and compounding risk sterility (#2).
4. BUD Policy for extrapolation from literature.

REFERENCES (supporting stability, BUD, storage, etc.)

e.g., USP 797, Trissel's, Lexicomp.

Trissel's LA. Zhang Y, Douglass K, et al, "Extended stability of oxytocin in common infusion solutions", Int. J

Pharmaceutics Compound, 2006; Volume 10: pp. 156-8.

Kaushal G, "Stability-indicating HPLC method for the determination of the stability of oxytocin Parenteral solutions prepared in polyolefin bags", Drug Discov Ther, 2012;Feb;6(1):49-54.

OTHER INFORMATION

If applicable.

Credit: Soyon Lee, PharmD, BCPS