

TIPS FOR PREPARING A MASTER FORMULA DOCUMENT

The California State Board of Pharmacy has adopted [compounding regulations](#) that took effect Jan. 1, 2017. A key provision of the regulations describes requirements for creating a master formula document, which is the specific recipe prepared in writing by a pharmacy before compounding any preparation.

The elements required for a master formula document are listed in California Code of Regulations, Title 16, section 1735.2, subsection (e). Note that section 1735.2(e) requires that the document be prepared before compounding a drug preparation. In preparing the master formula document, a pharmacist will exercise his or her professional judgment in determining and memorializing how the drug preparation will be compounded.

In addition, section 1735.2(e) lists eight specific elements that must be included in a master formula document. The required elements are:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond-use date for the preparation, and the rationale or reference source justifying its determination. (Note: This must refer to a specific document that explains the rationale behind the beyond-use date.)

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug. (Note: This should include detailed and specific steps that were used to prepare the drug so that anyone with training could compound the formula.)

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

The following pages contain a sample of master formula documents that include the elements required by section 1735.2(e) – including detailed and specific compounding steps used to prepare the drug and quality reviews required at each step in preparation of the drug.

NOTE: THIS SAMPLE IS FOR EDUCATIONAL PURPOSES ONLY AND IS NOT INTENDED FOR USE AS A SUBSTITUTE FOR A PHARMACIST USING HIS OR HER PROFESSIONAL JUDGMENT TO PREPARE A MASTER FORMULA FOR COMPOUNDING.

SAMPLE DRUG A PCA

Number of Unit to Compound: One (100ml) Cassette

<u>Ingredients:</u>	1MG/ML	2MG/ML	4MG/ML	10MG/ML
Sample drug A 10mg/ml inj	10ml	20ml	40ml	100ml
0.9% Sodium Chloride inj	90ml	80ml	60ml	-

Equipment:

Isolator Company A

Metal Tray

Supplies:

1-100ml CADD Cassette 1-0.9% Sod Chl Inj 100ml 2-60ml syringes 2-18G needles
2-Alcohol Prep Pads

Clean Room Gear:

Bouffant Cap Mask Gown Gloves Shoe Covers

Procedures:

1. Complete IV Compounding Record sheet and place all ingredients inside a basket to be checked by the pharmacist.
- 2. The pharmacist must perform initial quality review by verifying all calculations are correct and ingredients and supplies are free of particle and discoloration before the following procedures may be performed.**
3. If the isolator was turned OFF, allow isolator to operate for at least 10 minutes.
4. Wipe down all materials and supplies with sterile alcohol and place the materials and supplies inside metal tray.
5. Place metal tray in the antechamber and close the antechamber door.
6. Wait at least one minute to purge the antechamber before retrieving the materials.
7. Insert hands into the glove ports and retrieve the materials through the internal sliding door, closing the sliding door promptly.

8. Remove materials from metal tray and stage them inside main chamber.
9. Wait at least one minute for the main chamber to return to ISO 5 conditions before compounding.
- 10. Inspect vials for particles and discoloration before removing vial caps; wipe rubber tops with alcohol.**
11. Draw up sample drug A with 60ml syringe and 18G needle.
12. Remove needle from syringe and white cap from un-clamped CADD cassette extension.
13. Connect CADD cassette extension to syringe and transfer sample drug A solution into CADD cassette.
14. Withdraw air bubble from cassette, clamp cassette extension, and disconnect syringe.
15. Transfer 0.9% Sodium Chloride into CADD cassette by repeating steps 7-11.
16. Clamp CADD cassette extension and secure with sterile RED cap.
- 17. Inspect final CADD cassette for precipitation and air bubbles.**
18. Place final product and waste materials back on metal tray.
19. Open glass sliding door and transfer metal tray to antechamber.
20. Remove hands from glove ports and open antechamber door to retrieve metal tray.
21. Dispose waste and sharps appropriately.
- 22. The pharmacist must perform final quality review to ensure final product is properly labeled and free of precipitations.**

Beyond Use Date:

14 Days (Under Refrigeration)

Reference:

Trissel, Lawrence A., Handbook on Injectable Drugs 16th Edition, sample drug A, p. xxx.

Company A Universal Compounding Aseptic Isolator Quick-Start Operating Guide, January 20XX

USP Chapter 797, 2014