

NONSTERILE COMPOUNDING DOCUMENTATION

When compounding nonsterile preparations (CNSP), documentation is necessary in order to be able to systematically trace, evaluate and replicate the steps throughout the compounding process. When the CNSP is compounded according to manufacturer's labeling instructions, no further documentation is required. For example, when reconstituting an oral antibiotic according to manufacturer's instructions, the amount of purified water added does not have to be recorded. All other CNSP do require additional documentation in the form of a Master Formulation Record and a Compounding Record. The Master Formulation Record is the general information that will be used each time a particular CNSP is compounded, a recipe to follow. The Compounding Record is the specific information for a specific CNSP.

The Master Formulation Record must include:

1. Official or assigned name, strength, and dosage form of the CNSP
2. Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients
3. Description of all ingredients and their quantities
4. Compatibility and stability information, including references when available
5. Equipment needed to prepare the preparation, when appropriate
6. Mixing instructions that should include:
 - a. Order of mixing
 - b. Mixing temperatures or other environmental controls
 - c. Duration of mixing
 - d. Other factors pertinent to the replication of the preparation as compounded
7. Sample labeling information, which shall contain, in addition to legally required information:
 - a. Generic name and quantity or concentration of each active ingredient
 - b. Assigned Beyond Use Date (BUD)
 - c. Storage conditions
 - d. Prescription or control number, whichever is applicable
8. Container used in dispensing
9. Packaging and storage requirements
10. Description of final preparation
11. Quality control procedures and expected results

The Compounding Record must include:

1. Official or assigned name, strength, and dosage of the preparation
2. Master Formulation Record reference for the CNSP
3. Names and quantities of all components
4. Sources, lot numbers, and expiration dates of components

5. Total quantity compounded
6. Name of the person who prepared the CNSP, name of the person who performed the quality control procedures, and name of the pharmacist who approved the CNSP
7. Date of preparation
8. Assigned control or prescription number
9. Assigned BUD
10. Duplicate label as described in the Master Formulation Record
11. Description of final preparation
12. Results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)
13. Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver