USP <795> Guidelines
For Standard Operating Procedures

As defined in USP <795>, any pharmacy that engages in the practice of compounding is required to have Standard Operating Procedures (SOP) in place to state how different areas of practice are handled.

As stated in USP <795>, all significant procedures in the compounding area should be covered by written standard operating procedures (SOPs). Procedures should be developed for the **facility, equipment, personnel, preparation, packaging, and storage of compounded preparations** to ensure accountability, accuracy, quality, safety, and uniformity in compounding. Implementing SOPs establishes procedural consistency and also provides a reference for orientation and training of personnel

The following document is designed to be a guideline to aid pharmacies in producing their own SOP's to be compliant with state law. The items on this checklist should be included in the SOP. This is a guideline, not all inclusive. Pharmacies should write their SOP with their own practice in mind.

Patient Counseling of Compounded Medications:
□ Procedure to educate patient and/or caregiver on how to use the compounded preparation.
    □Includes storage, handling, and disposal of preparations; potential adverse effects and any other information deemed necessary
□Procedure in effect to report any changes in preparations, adverse side effects, etc. reported by patient. Includes investigation and reporting to proper authorities.
□Procedure for recall of compounded preparations

Quality Control
Compounding pharmacies must have a documented quality control plan that contains the following:
□Observation of the finished product, documenting any discrepancies and the corrective action taken
□The Master Formulation Record, the Compounding Record and associated written procedures shall be followed in execution of the compounding process. Any deviation shall be documented.

□Check and recheck each procedure at each stage of the process will be documented
□Have written procedures that describe the tests or examinations conducted on the compounded preparations,
□Control procedures shall be established to monitor the ouput and verify performance of compounding equipment

Compounding Documentation

There are specific documentation requirements for compounding. These are the Master Formulation Record and the Compounding Record. Both of these are required to be retained for the same length of time that a prescription hard copy would be required to be retained.

Master Formulation Record:
□The Master Formulation Record (MFR) shall contain the following information:

1. The name, strength and dosage form of the preparation
2. Calculations required 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 if appropriate.
5. Equipment required to prepare preparation
6. Detailed mixing instructions
7. Sample labeling information, including, generic name and quantity or concentration of each active ingredient, assigned BUD, storage conditions, and prescription or control number
8. Container used in dispensing
9. Packaging and storage requirements
10. Description of final preparation
11. Quality control measures and expected results

Compounding Record
□The Compounding Record (CR) shall contain the following information:

1. The name, strength and dosage form of the preparation
2. MFR reference for the preparation
3. Names and quantities of all components
4. Source, lot numbers, and expiration dates of components
5. Total quantity compounded

6. Name of person(s) who prepared the preparation, who performed the quality control procedures, and who approved the preparation
7. Date of preparation
8. Assigned control or RX number
9. Assigned BUD
10. Duplicate label as described in the MFR
11. Description of final preparation
12. Results of quality control procedures
13. Documentation of any quality control issues and any adverse reactions or preparation problems reported by patient or caregiver.

Packaging and Drug Preparation Containers

Procedure that ensures the compounder understands the importance of containers used to package compounded medications:

□Utilize packaging that meets USP requirements and be familiar with the USP standards for containers used to package compounded preparations.

□The container used depends on the physical and chemical properties of the compounded preparation. Compounders should consider container drug interactions for substances that have absorptive or leaching properties.

□Containers and closures are stored off the floor

□Containers are rotated so that the oldest stock is used first.

Animal Patients

Animal patient must be identified as either companion animal or food animal.

□Documentation of Withdrawal Time (WDT) if patient is a food animal. The WDT must be on the label of the preparation.

□Be knowledgeable about physiology, metabolic toxicity of medications for each species

□Document compliance with all state and federal laws regarding drug use in animals.

Component Selection, handling and Storage

□Documentation of sourcing for components that are USP, NF, FCC

□Component expiration dates may be honored if the following are met:

Stored in original container under recommended conditions
Minimal exposure from opening/closing container
Withdrawals performed by trained individuals

□Document expiration of components, using the following as guidelines

□Components moved to new containers have the following documentation:
component name
Original supplier
Lot or control number
Transfer date
Expiration date
□Components without expiration dates are given conservative dates no more than three years from the date received
□Manufactured drugs must be from an FDA registered facility and have expiration/lot on the label

□Guidelines for component selection
□When using manufactured drugs, consider all components of that product and not just the active ingredient to determine therapeutic appropriateness and stability
□When preparing dietary or nutritional supplements, use USP, NF, or FCC products when available. If unavailable, products with a food grade standard and a proven record of safety in humans should be used
□Components from ruminant animal require the supplier to provide written assurance the product is compliant with all regulations
□Be aware of components that have be removed from the market by the FDA for efficacy reasons

□Store everything according to storage suggestions from the manufacturer
Clean area
Appropriate temperature and humidity
Off the floor
Rotated (old to new)
Labeled

Compounding Process

Pharmacy should have a designated compounding area
□Pharmacy personnel authorized to be in compounding area
□Technique for working in the designated compounding area and behaviors to avoid.
□Personal hygiene

Beyond Use Date

Each preparation dispensed must have a Beyond Use Date (BUD) on the label

□The following are the BUD guidelines from USP <795>

Non-aqueous formulation- 6 months

Water containing non-oral – 30 days

Water containing oral – 14 days, refrigerated

□All formulas need a source for BUD. If using one from above, site USP 795. Otherwise, the source must by cited

□BUD cannot by later than the earliest expiration date of the Active Pharmaceutical Ingredient (API)

□If a pharmacist feels that BUD for a particular product are inadequate, they may use professional judgment to assign a different BUD. However, they must be prepared to defend that judgment.