Alabama State Board of Pharmacy
111 Village Street
Hoover, Alabama 35242
(205) 981-2280

USP 795 Compounding

Name of Pharmacy	**Corporate Name if different**		**Al. license number**
Street Address	**Street Address additional**		**DEA Number**
City	**State AL**	**Zip**	**County Jefferson**
Phone number	**FAX number**	**Owner**	
Pharmacist-in-charge	**Email**		**License**
Case Number	**Inspection type**	**Status**	**Date**
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GENERAL STANDARDS	YES	Comment
Compounded drugs are only dispensed pursuant to a prescription or chart order. Products prepared for specific patient and delivered to patient, patient's representative or to physician to administer to specific patient.		
Pharmacy prepares and sells some/all products on invoice to a practitioner without product being intended for specific patient—defined as <u>manufactures</u>		
Policy manual to outline and explain all components of operation of the compounding pharmacy. <u>Documentation</u>		
All pharmacists and technicians are registered with the Alabama Board of Pharmacy and have a current license <u>Documentation</u>		
CATEGORIES OF COMPOUNDING	**YES**	**COMMENT**
For the three categories of nonsterile compounding described in this section, different levels of experience, training, and physical facilities are associated with each category.		
SIMPLE—Making a preparation that has a *United States Pharmacopeia* (*USP*) compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate BUDs; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer		
MODERATE—Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine		

quantities of components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available.		
COMPLEX—Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes		
GENERAL PRINCIPLES OF COMPOUNDING	**YES**	**COMMENT**
Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties. Such training should be documented.		
All personnel who handle hazardous products are fully trained in safety, handling, storage and disposal of such products		
All personnel who handle hazardous products have signed a statement of understanding regarding associated training and risks.		
Employees have demonstrated competency in compounding and supervisor has signed off on employee's proficiency.		
Only one product should be compounded at a time.		
All equipment used in compounding is clean, properly maintained, and used appropriately.		
Policy in place to manage employee safety events and issues.		
Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) for protection of personnel from chemical exposures and for prevention of drug contamination.		
Only authorized personnel are allowed in the immediate vicinity of the drug compounding operations.		
Compounding conditions and procedures are adequate for preventing errors.		
All aspects of compounding are appropriately documented.		
Adequate procedures and records exist for investigating and correcting failures or problems in compounding, testing, or the preparation itself.		
SOURCE OF INGREDIENTS/QUALITY STANDARDS	**YES**	**COMMENT**
First attempt to use components manufactured in an FDA-registered facility. Container should have a batch control number and expiration date.		
When ingredients cannot be obtained from an FDA registered facility, compounding ingredients of the appropriate identity, purity, and quality are purchased from reliable sources and are properly stored according to manufacturer specifications or *USP* standards.		
<u>Quality standards for chemicals, drugs and food</u> Analytical Reagent (ARA): Certified American Chemical Society (ACS): Food Chemicals Codex grade (FCC):		
If ingredients are not obtained from sources with such recognized standards, they have been certified through independent analysis.		
If a manufactured drug product is used as the source of the active ingredient, it should be from an FDA-registered facility. Consider the effect of all ingredients in the product.		

Components in containers with an expiration date from the manufacturer may be used up to the expiration date, if handled as directed..		
Packages of ingredients that lack a supplier expiration date are assigned a conservative expiration date not to exceed 3 years based on the nature of the component and it's degradation mechanism, the container in which it is packaged and the storage conditions.		
If a product is transferred from the original manufacturer's container, the container is identified with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that is equivalent to or better than that of the original container		
Non sterile ingredients, substances and excipients are official USP or NF grade.(All Certificates of analysis are on file.) Ingredients used in the formulation have their expected identity, quality, and purity.		
If the formulation is for humans, ingredients are not on a list of federally recognized drugs or specific drug products that have been withdrawn or removed from the market for safety or efficacy reasons (see www.FDA.gov).		
If the formulation is for food-producing animals, ingredients are not on a list of components prohibited for use in food-producing animals.		
Certificates of Analysis are available when applicable, and MSDSs have been consulted for all ingredients used.		
All ingredients are stored as directed, in a clean area, at proper temperature and humidity, off the floor and handled to prevent contamination. Products are rotated for dating and properly labeled.		
FACILITIES	**YES**	**COMMENT**
The compounding environment is suitable for its intended purpose; and procedures are implemented to prevent cross-contamination, especially when compounding with drugs (e.g., hazardous drugs and known allergens like penicillin) that require special precautions.		
There shall be adequate space for all processes		
Areas for sterile compounding shall be separate and distinct from non-sterile compounding areas		
Potable water, which meets standards for drinking water, shall be available for hand and equipment washing.		
Hand and equipment washing shall be easily accessible and should include hot and cold water, soap or detergent and an air-drier or single-use towels.		
Purified water shall be used for all non-sterile compounding		
Plumbing system shall be free of defects which could cause contamination		
Compounding area should be well lighted.		
Heating, ventilation and air-conditioning shall be controlled to protect products and for suitable working conditions.		
Compounding areas shall be clean, orderly, in sanitary conditions and in good state of repair.		
Waste shall be disposed of in a timely and sanitary manner.		
Hazardous products shall be properly stored, used and discarded.		

EQUIPMENT	YES	COMMENT
Records are available for review for all equipment used in compounding. Including but are not limited to, equipment setup, calibration, filter changes, any periodic testing required and cleaning of the equipment.		
Daily calibration of equipment and weight certification as required.		
Autoclave and dry heat ovens are certified		
Annual outside certification of equipment.		
PREPARING PRODUCT	**YES**	**COMMENT**
A Master Formulation Record should be created before compounding a preparation for the first time. This record shall be followed each time that preparation is made.		
1. Official or assigned name, strength, and dosage form of the preparation		
3. Description of all ingredients and 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:		
• Order of mixing		
• Mixing temperatures or other environmental controls • Duration of mixing • Other factors pertinent to the replication of the preparation as compounded		
7. Sample labeling information		
8. Container to use in dispensing		
9. Packaging and storage requirements		
10. Description of final preparation		
11. Quality control procedures and expected results		
Appropriate compounding equipment has been selected and inspected for cleanliness and correct functioning and is properly used		
Personnel have good hand hygiene and are appropriately clothed.		
Correct, in-date ingredients are selected		
A compounding record is prepared each time a product is prepared		
Compounding record shall contain at a minimum:		
1. Official or assigned name, strength, and dosage of the preparation		
2. Master Formulation record reference for the preparation		
3. The name and strength and quantity used of each component		
4. The order of each step in the compounding of each sterile product		
5. Sources, lot numbers and expiration dates of each component		
6. Name and initials of the person who prepared the preparation 7. Name of the person and initials who performed the quality control procedures, and the name and initials of the compounder who approved the preparation		
8. The date the preparation was made		
9. The assigned lot number		
10. The assigned Beyond Use Date		
11. A duplicate label as described in the Master Formulation record		
12. Description of the final preparation		

13. Reconciliation and yield of the product compounded 14. Results of quality control procedures (e.g., weight range of the filled capsules, PH of aqueous liquids, etc.) 15. Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver		
Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.		
The preparation is suitably packaged for patient use, and the container that is selected will protect the preparation from undue environmental exposure until at least the discard-after or beyond-use date.		
The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and this information is recorded on the Compounding Record		
The Master Formulation Record and the Compounding Record have been reviewed by the compounder to ensure that errors have not occurred in the compounding process and that the preparation is suitable for use.		
The preparation container is labeled according to all applicable state and federal laws. The labeling shall include the BUD and storage and handling information. The labeling should indicate that "this is a compounded preparation."		
Equipment used to compound non-sterile drug products is cleaned immediately after compounding to prevent cross contamination		
The preparation is delivered to the patient or caregiver with the appropriate consultation. The patient or caregiver has been adequately informed about ways to identify obvious evidence of instability in the compounded preparation. **The preparation is labeled with explicit storage and administration instructions.**		
BEYOND USE DATE	**YES**	**COMMENT**
Compounder must use manufacturer and literature for information on stability, compatibility and degradation.		
In the absence of stability information that is applicable to a specific drug and preparation, the following maximum Beyond-Use-Dates (BUDs) are recommended when packaged in tight, light-resistant containers and stored at controlled room temperature unless otherwise indicated:		
<u>Nonaqueous Formulations</u> ***Where the Manufactured Drug Product is the Source of Active Ingredient*-The BUD is not later than 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier.** ***Where a USP or NF Substance is the Source of Active Ingredient*-The BUD is not later than 6 months.**		
<u>Water-Containing Oral and Sterile Liquid Formulations</u> **BUD is not later than 14 days when stored at cold temperatures between 2° and 8° C (36° and 46° F).**		
<u>Water-Containing External-Use Liquid and Semi-Solid Formulations</u> **BUD is not later than 30 days**		
<u>For All Other Formulations</u>		

The Bud is not later than the intended duration of therapy or 30 days, whichever is earlier. These limits may be exceeded when there is valid scientific stability information that is directly applicable to the specific preparation (i.e., the same drug concentration range, pH, excipients, vehicle, water contents, etc.		
QUALITY CONTROL	**YES**	**COMMENT**
Control procedures for monitoring each final non-sterile product and for validating the compounding process are in place. The control procedures must include, without limitation:		
Any variation of more than plus or minus 10% in the weight of capsules, tablets or any other solid form of a dosage unit		
The adequacy of mixing to ensure uniformity and homogeneity of each compounded product		
If applicable, the clarity, completeness and pH of the compounded product		
If applicable, the even distribution of coloring agents		
Any variation of more than plus or minus 10% in the actual yield of a compounded product as compared to the theoretical yield of the compounded product		

COMMENTS: