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NON STERILE COMPOUNDING

INSPECTION

☐ New Opening ☐ Regular

INFORMATION

Pharmacy Name: _____ Date: ___/___/___

Pharmacy License Number: _____ Expiration Date: ___/___/___

Controlled Substance License Number: _____ Expiration Date: ___/___/___

DEA Registration Number: _____ Expiration Date: ___/___/___

Pharmacist-in-Charge (PIC): _____

Pharmacist-in-Charge License Number: _____ Expiration Date: ___/___/___ Case N

Compounding Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:(a)Shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations [UAC R156-17b-614a (3)]

GENERAL OPERATIONS AND INFORMATION

	Yes	No	
1.	☐	☐	Compounders shall acquire and maintain knowledge and skills in all areas (e.g., dosage form, patient population, and medical specialty) for which they compound. [USP-NF Chapter 795—*Categories of Compounding*]
2.			Which categories of compounding does the facility perform?
	☐	☐	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 date for that formulation with appropriate BUDs; or reconstitution or manipulation commercial products that may require the addition of one or more ingredients as directed by the manufacturer. Examples include *Captopril Oral Solution,* and *Indomethacin Topical Gel,* and *Potassium Bromide Oral Solution, Veterinary.* [USP-NF Chapter 795—*Categories of Compounding—Description of Categories*]
	☐	☐	Moderate- Making a preparation that requires special calculations or procedure (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. Examples include *Morphine Sulfate Suppositories,* diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known. [USP-NF Chapter 795—*Categories of Compounding—Description of Categories*]
	☐	☐	Complex- Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects. [USP-NF Chapter 795—*Categories of Compounding—Description of Categories*]
3.	☐	☐	The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device is in accordance with a licensed practitioner's prescription, medication order, or initiative based upon the practitioner/patient/pharmacist/compounder relationship in the normal course of professional practice[USP-NF Chapter 795—*Definitions—Compounding]*
4.	☐	☐	Does the facility compound nonsterile prescriptions which are then delivered to a practitioner for administration to the patient in the office, clinic or facility?

	Yes	No	
5.	☐	☐	A pharmacy licensed under this chapter may, subject to rules established by the Division, repackage or compound a prescription drug for sale to a practitioner if: the prescription drug: does not include a compounded drug; or includes a compounded drug; and is not a controlled substance; the pharmacy labels the prescription drug "for office use only"; the practitioner administers the drug to a patient in the practitioner's office or facility; and except in accordance with Title 58, Chapter 17b, Part 8, Dispensing Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, the practitioner does not dispense the drug to the patient. [UCA 58-17b-624(1)(a)(i)(ii)(A)(B)(b)(c)(d)] Pursuant to Section 58-17b-624, a pharmacy may repackage or compound a prescription drug for sale to a practitioner for office use provided that it is in compliance with all applicable federal and state laws and regulations regarding the practice of pharmacy, including, but not limited to the Food, Drug, and Cosmetic Act, 21 U.S.C A § 301 et seq. [R156-17b-624]
6.	☐	☐	Does the facility distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?
7.	☐	☐	Does the facility have a sales force that distributes samples containing active ingredients? List.
8.	☐	☐	Does the facility provide nonsterile compounded preparations to other pharmacies for dispensing?
9.	☐	☐	What does the facility compound? ☐ Tablets ☐ Liquids ☐ Troches ☐ Ointments ☐ Capsules ☐ Lozenges ☐ Creams ☐ Suppositories ☐ Patches ☐ Sprays ☐ Powders ☐ Oral Pastes ☐ Transdermals ☐ _____ ☐ _____ ☐ _____
10.	☐	☐	Does the facility compound vitamins or nutritional supplements? List.
11.	☐	☐	Does the facility compound investigational drugs? List.
12.	☐	☐	The facility does not prepare a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner. [UCA 58-17b-502 (13)]
13.	☐	☐	Does the facility perform compounding with hazardous drugs?
14.	☐	☐	Does the facility segregate hazardous drugs from normal compounding stock?
15.	☐	☐	MSDSs shall be readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facilities premises. Employees should be instructed on how to retrieve and interpret needed information. [USP-NF Chapter 795—*Compounding Documentation—Material Safety Data Sheets File*]
16.	☐	☐	Does the facility make nonsterile compounded preparations using bulk powder active pharmaceutical ingredients?
17.	☐	☐	All significant procedures preformed in the compounding area should be covered by written standard operating procedure (SOPs). Implementing SOPs establishes procedural consistency and also provides a reference for orientation and training of personnel. To ensure accountability, accuracy, quality, safety and uniformity in compounding procedures should be developed for the following: [USP-NF Chapter 795—*Compounding Documentation—Standard Operating Procedures*] ☐ Facility ☐ Equipment ☐ Personnel ☐ Packaging ☐ Storage ☐ Preparation
18.	☐	☐	A *United States Pharmacopeia (USP), National Formulary (NF), or Food Chemical Codex (FCC)* substance is the recommended source of all ingredients for compounding all preparations. [USP-NF Chapter 795—*Component Selection, Handling, and Storage(1)*]
19.	☐	☐	Bulk active ingredients must be procured from a facility registered with the federal Food and Drug Administration and must not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness. [R156-17b-614a (3)(c)(i)(ii)]

20. ☐ ☐ Bulk containers are labeled with appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels (see OSHA.gov), and Material Safety Data Sheets (MSDSs) are available to compounding personnel for all drugs and chemicals used in compounding. [USP-NF Chapter 795—*Responsibilities of the Compounder—General Principles of Compounding (3)*]

BEYOND USE DATING

21. ☐ ☐ All components used in the compounding of preparations must be store as directed by the manufacturer or according to *USP*, *NF*, or *FCC* monograph requirements, in a clean area, and under appropriation temperatures and humidity conditions (controlled room temperature, refrigerator, or freezer). [USP-NF Chapter 795—*Component Selection , Handling, and Storage (11)*]

22. ☐ ☐ For components that do not have expiration dates assigned by the manufacture or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date)* based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions. [USP-NF Chapter 795—*Component Selection, Handling, and Storage(6)*]

23. ☐ ☐ If the component has been transferred to a different container, that container shall be indentified with the component name, 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. [USP-NF Chapter 795—*Component Selection, Handling, and Storage(5)*]

24. ☐ ☐ The compounder shall ensure that the container and container closures used in packaging compounded preparations meet *USP* requirements (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Containers; Containers—Glass* <660>; *Containers—Plastics*<661>; *Containers—Performance Testing* <671>; Chapter <681>; Chapter <1136>; *Packaging Practice—Repackaging a Single Solid Oral Drug Product into a Unit-Dose Container*<1146>); and when available, compounding monographs. Compounders are not expected to perform the tests described in these chapters but should be knowledgeable about the stands described in them. [USP-NF Chapter 795—*Packaging and Drug Preparation Containers*]

25. ☐ ☐ The containers and closures shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the older stock is used first. The containers and container closures shall be stored in such a way as to permit inspection and cleaning of the storage area. [USP-NF Chapter 795—*Packaging and Drug Preparation Containers*]

26. ☐ ☐ The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. [USP-NF Chapter 795—*Stability Criteria and Beyond-Use Dating*]

27. ☐ ☐ The beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing. [R156-17b-614a (3)(g)]

28. ☐ ☐ Sources of drug stability information shall include the following: [R156-17b-614a (3)(g)(i)(A)(B)(C)]
☐References can be found in "Trissel's Handbook on Injectable Drugs", 17th Edition, October 31, 2012 ☐Manufacturer recommendations ☐Reliable, published research

29. ☐ ☐ These maximum BUDs (shown below) are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component. [USP-NF Chapter 795—*Stability Criteria and Beyond-Use Dating—General Guidelines for Assigning Beyond-Use Dates*]
BUDs for Nonaqueous Formulations—The BUD is not later that the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.

☐ ☐ BUDs for Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold

temperatures.

☐ ☐ BUDs for Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days.

30. ☐ ☐ These maximum BUDs recommended for nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated; and for sterile preparations for which a program of sterility testing is in place (see *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling).* [USP-NF Chapter 795—*Stability Criteria and Beyond-Use Dating—General Guidelines for Assigning Beyond-Use Dates*]

ENVIRONMENT

31. ☐ ☐ Compounding facilities shall have an adequate space that is specifically designated for compounding of prescriptions. This space shall provide the orderly placement of equipment and materials to prevent mixups among ingredients, containers, labels, in-process materials and finished preparations and is designed, arranged and used to prevent adventitious cross-contamination. [USP-NF Chapter 795—*Compounding Facilities*]

32. ☐ ☐ Areas used for sterile preparations shall be separated and distinct from the nonsterile compounding area (see Chapter <797>, *Environmental Quality and Control*). [USP-NF Chapter 795—*Compounding Facilities*]

33. ☐ ☐ Compounding is done in an appropriately clean and sanitized area dedicated to this activity (see section *Compounding Facilities*). [USP-NF Chapter 795—*Compounding Process—Criteria When Compounding Each Drug Preparation (4)*]

34. ☐ ☐ Only one preparation is compounded at one time in a specific workspace. [USP-NF Chapter 795—Compounding Process—*Criteria When Compounding Each Drug Preparation (5)*]

35. ☐ ☐ The entire compounding and storage area should be well lighted. [USP-NF Chapter 795—*Compounding Facilities*]

36. ☐ ☐ Heating, ventilation, and air conditioning systems shall be controlled to avoid decomposition and contamination of chemicals (see the *General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Storage Temperature and Humidity;* and the manufacturers' labeled storage conditions). [USP-NF Chapter 795—*Compounding Facilities*]

37. ☐ ☐ Potable water shall be supplied for hand washing and equipment washing. *Purified Water* (see *Purified Water* monograph) shall be used for compounding nonsterile preparations when formulations indicate the inclusion of water. *Purified Water* should be used for rinsing equipment and utensils. [USP-NF Chapter 795—*Compounding Facilities*]

38. ☐ ☐ Hazardous drugs shall be stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other personnel. [USP-NF Chapter 795—*Compounding Facilities*]

39. ☐ ☐ Disposal of all hazardous drugs wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedure to protect themselves and prevent contamination. [USP-NF Chapter 795—*Compounding Facilities*]

TRAINING

40. ☐ ☐ Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties. Such training should be documented. Compounding personnel should be evaluated annually. [USP-NF Chapter 795—*Responsibilities of the Compounder—General Principles of Compounding (1), Training*]

41. ☐ ☐ All employees involved in pharmaceutical compounding shall read and become familiar with the chapter (USP-NF Chapter 795). They should also become familiar with the contents of the *USP Pharmacists' Pharmacopoeia* and other relevant publications, including how to read and interpret MSDSs. [USP-NF Chapter 795—*Training*]

42. ☐ ☐ All employees shall read and become familiar with each of the procedures related to compounding, including

those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing. [USP-NF Chapter 795—*Training*]

COMPOUNDING EQUIPMENT

43. ☐ ☐ All equipment used in compounding is clean, properly maintained, and used appropriately. [USP-NF Chapter 795—*Responsibilities of the Compounder—General Principles of Compounding (4)*]

44. ☐ ☐ Equipment shall be stored to protect it from contamination and shall be located to facilitate its use, maintenance and cleaning. Automated, mechanical, electronic, and other types of equipment used in compounding or testing of compounded preparations shall be routinely inspected, calibrated as necessary, and checked to ensure proper performance. Immediately before compounding operations, the equipment shall be inspected by the compounder to determine its suitability for use. After use, the equipment shall be appropriately cleaned. [USP-NF Chapter 795—*Compounding Equipment*]

DOCUMENTATION

45. ☐ ☐ A master worksheet shall be developed and approved by a pharmacist for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master worksheet shall be used as the preparation worksheet from which each batch is prepared an on which all document for that batch occurs. The master worksheet may be stored electronically and shall contain at a minimum: [UAC R156-17b-614a (3)(d)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii)(A-D)(ix)(A-D)(x)(xi)(xii)(xiii)]

- ☐ Official or assigned name
- ☐ Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients
- ☐ Equipment needed to prepare the preparation
- ☐ Container used in dispensing
- ☐ Quality control procedures and expected results
- ☐ Description of final preparation
- ☐ Strength
- ☐ Description of all ingredients and their quantities
- ☐ Mixing instructions, which shall include: order of mixing, mixing temperature or other environmental controls, duration of mixing, and other factors pertinent to the replication of the preparation as compounded
- ☐ Packaging and storage requirements
- ☐ Dosage form of the preparation
- ☐ Compatibility and stability information, including references when available
- ☐ Sample labeling information, which shall contain, in addition to legally required information: generic name and quantity or concentration of each active ingredient, assigned beyond use date, storage conditions, and prescription or control number, whichever is applicable

46. ☐ ☐ A preparation worksheet for each batch of sterile or non-sterile pharmaceuticals shall document the following: [UAC R156-17b-614a (3)(e)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii)(ix)(x)(xi)(xii)(A-D)(xiii)(A,B,C,D)(I-III)(xiv)(xv)(xvi)]

- ☐ Official or assigned name
- ☐ Names and quantities of all components
- ☐ Name of the person who prepared the preparation
- ☐ Date of the preparation
- ☐ Proof of duplicate labeling information, which shall: be kept at the pharmacy, be immediately retrievable; include an audit trail for any altered form, and be reproduced in: the original format that was dispensed, and electronic version, or a scanned electronic version
- ☐ Strength and dosage of the preparation
- ☐ Sources, lot numbers, and expiration dates of components
- ☐ Name of the compounder who approved the preparation
- ☐ Assigned control number, if for anticipation of use or prescription number, if patient specific, whichever is applicable
- ☐ Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver
- ☐ Description of final preparation
- ☐ Master Formulation Record reference for the preparation
- ☐ Total quantity compounded
- ☐ Name of the person who performed the quality control procedures
- ☐ Duplicate label as described in the Master Formulation Record means the sample labeling information that is dispensed on the final product given to the patient and shall at minimum contain: active ingredients, beyond-use-date, storage conditions, and lot number
- ☐ Results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids)

47. ☐ ☐ Compounding records including the master worksheet, preparation worksheet, and prescription files, including refill information shall be maintained for a minimum of five years and be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

48. ☐ ☐ There shall a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follow USP-NF Chapters 795 and 797 standards. [R156-17b-614a (3)(h)]

COMPOUNDING PROCEDURES

49. ☐ ☐ Only authorized personnel are allowed in the immediate vicinity of the compounding operations. [USP-NF Chapter 795—*Responsibilities of the Compounder—General Principles of Compounding(6)*]

50. ☐ ☐ Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, face masks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for preventions of drug contamination. [USP-NF Chapter 795—*Compounding Process—Criteria When Compounding Each Drug Preparation (8)*]

51. ☐ ☐ 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. [USP-NF 795—*Compounding Process—Criteria When Compounding Each Drug Preparation*]

52. ☐ ☐ **LABELING OF FINISHED PREPARATIONS**

The label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum: [UAC R156-17b-614a (3)(g)(i)(ii)(iii)(iv)(v)(vi)]

☐ The unique lot number assigned to the batch
☐ Beyond use date and time, when applicable
☐ all solution and ingredient names, amounts, strengths and concentrations, when applicable
☐ Device-specific instructions, where appropriate
☐ Quantity
☐ Appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate

PRESCRIPTION LABELING

53. ☐ ☐ All prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or Agent shall bear at a minimum in addition what is required in Section 58-17b-602 the following: [UAC R156-17b-614a (3)(h)(i)(ii)(iii)]

☐ generic name and quantity or concentration of each active ingredient. In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation;
☐ assigned compounding record or lot number; and
☐ "This is a compounded preparation" or similar language.

PATIENT COUNSELING AND COMMUNICATION

54. ☐ ☐ At the time of dispensing the prescription, the patient or the patient's agent shall be counseled about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to report any adverse event and to observe and report to the compounder any changes in the physical characteristics of the compounded preparation (see Chapter <1191>, *Responsibility of the Pharmacist*). The compounder shall investigate and document any reported problem with a compounded preparation and shall take corrective action. [USP-NF Chapter 795—*Patient Counseling*]

VETERINARY COMPOUNDING

55. ☐ ☐ Does the facility compound for veterinary use?

56. ☐ ☐ If compounding for both humans and animals, are the API's or other components that are labeled for veterinary use only are segregated or marked in such way to prevent them from being used for human compounding?

57. ☐ ☐ The pharmacist shall be knowledgeable about the individual species' limitation in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, compounders making preparations for animals should use, when possible, formulations specifically developed for animal patients. If such formulations are not available, the compounder shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species. [USP-NF Chapter

795—*Compounding For Animal Patients]*

COMMENTS
(Use an additional sheet if necessary.)

☐By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: _____ **Date of Signature:** __ / __ / _____

Signature of Division Investigator: _____ **Date of Signature:** __ / __ / _____

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