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GAP ANALYSIS SURVEY
COMPOUNDING NONSTERILE PREPARATIONS (2012)

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Note: The purpose of this form is to conduct a preliminary assessment of the pharmacy to determine compliance with USP *Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations.*

Outline

INTRODUCTION

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Is the pharmacy familiar with "Good Compounding Practices" as presented in *USP* General Chapter <795>?				

Is the pharmacy aware of the requirement to compound preparations of "acceptable strength, quality, and purity"?				
Is the pharmacy licensed and in good standing with the state board of pharmacy?				
Is the pharmacy licensed to handle controlled substances?				
Are all controlled substances records up to date and complete?				
Has the pharmacy been inspected by the State Board as a compounding pharmacy?				
Are any actions pending by the state board of pharmacy?				
Has the pharmacy been inspected by the FDA? If so, was a "483" issued?		____ ____	____ ____	
Does the pharmacist understand the difference between compounding, repackaging, and manufacturing?				
Are all compounded prescriptions dispensed pursuant to a prescription from a valid, licensed prescriber?				

DEFINITIONS

ITEM	**REQUIREMENTS**	**YES**	**NO**	**COMMENT/SOP**
Is the pharmacy aware of the *USP* definition of a "preparation"?				
Is the pharmacy aware of the *USP* definition of a "compounder"?				
Is the pharmacy aware of the *USP* definition of an "active pharmaceutical ingredient"?				
Is the pharmacy aware of the *USP* definition of "added substances"?				
Is the pharmacy aware of the synonyms of "added substances"?				
Does the pharmacy know the difference between compounding and manufacturing?				
Does the pharmacy know the criteria for designating a drug as a				

"hazardous drug"?				

CATEGORIES
Description of Categories

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Is the pharmacy familiar with the criteria used to determine the different categories of compounding?				
Is the pharmacy involved in "Simple Compounding?"				
Is the pharmacy involved in "Moderate Compounding?"				
Is the pharmacy involved in "Complex Compounding?"				

RESPONSIBILITIES OF THE COMPOUNDER
General Principles of Compounding

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Is documentation available that compounding is only done by individuals that are appropriately trained and validated?				
Is documentation available that designated compounding pharmacists are capable and qualified to compound?				
Is documentation available that designated compounding pharmacy technicians are capable and qualified to compound?				
Is documentation available that all ingredients used have their expected identity, quality, and purity?				
Are all bulk component containers appropriately labeled with OSHA hazard communication labels?				
Are MSDSs available for all drugs and chemicals?				
Is all equipment clean, properly maintained, and appropriately used?				
Is the compounding area suitable for its intended purpose?				
Are procedures in place to prevent				

cross-contamination and the handling of ingredients requiring special consideration?				
Are only authorized personnel allowed in the immediate area where compounding occurs?				
Is documentation available that all preparations are packaged and labeled appropriately?				
Is documentation available that all preparations are compounded in accordance with good compounding practices (*USP* Chapter <795>), official standards, and relevant scientific data and information?				
Is documentation available that all processes are consistent and under control?				
Are compounding conditions and procedures adequate for preventing errors?				
Do adequate procedures and records exist for investigating and correcting failures or problems in compounding, testing, or in the preparation itself?				

COMPOUNDING PROCESS

Criteria When Compounding Each Drug Preparation

ITEM	**REQUIREMENTS**	**YES**	**NO**	**COMMENT/SOP**
Are the 15 Compounding Process criteria followed to minimize errors and maximize the prescriber's intent?	1. Evaluation of the dose, safety and intended use of the preparation for the patient? 2. Creation of a Master Formulation Record the first time before compounding a new preparation? Also, the creation of a Compounding	____ ____	____ ____	

	Record for each compounded preparation? 3. Ingredients have been checked to confirm they have their expected identity, quality, and purity? 4. Compounding is done in clean and sanitized dedicated area? 5. Only one preparation at a time is compounded? 6. Equipment is appropriately selected and inspected for cleanliness, proper functioning and is properly used? 7. An appropriate beyond-use date is established for the finished preparation? 8. Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed and also is appropriate for their protection? 9. The preparation is compounded in accordance	____ ____ ____ ____ ____ ____ ____ ____ ____	____ ____ ____ ____ ____ ____ ____ ____ ____	

	with *USP* <795> standards? 10. Critical processes (weighing, measuring, and mixing) are verified so they will result in consistent preparations? 11. As appropriate, the final completed preparation is assessed for: •Weight? •Mixing? •Clarity? •Odor? •Color? •Consistency? •pH? •Strength? 12. The finished preparation is appropriately packaged? 13. The labeling on the finished preparation meets the applicable state and federal laws? 14. The Master Formulation Record and the compounding Record have been reviewed by the compounder to ensure it is error free? 15. The preparation is dispensed to	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____	

	the patient or caregiver with appropriate consultation?			

COMPOUNDING FACILITIES

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
For the type and amount of compounding done, is sufficient space available?				
Is the space orderly arranged with proper placement of equipment and materials to prevent mix-ups between: •Ingredients? •Containers? •Labels? •In-process materials? •Finished preparations?		 ____ ____ ____ ____ ____	 ____ ____ ____ ____ ____	
Is the space arranged to prevent cross-contamination?				
Is the compounding area well-lighted?				
Are heating, ventilation, and air condition systems controlled to avoid decomposition of chemicals?				
Is constant temperature maintained 24 hours per day, 7 days per week?				
Is the bulk storage area adequately arrange?				
Is the proper temperature and humidity maintained and suitably controlled in the bulk storage area?				
In the compounding area, are the following available: •Hot and cold potable water? •Soap or detergent? •Air driers or single-service towels?		 ____ ____ ____	 ____ ____ ____	
Are the compounding areas maintained in a clean and sanitary condition?				
Is the bulk storage area maintained in a clean and sanitary condition?				
Is trash disposed of in a safe,				

sanitary, and timely manner?				
Are hazardous drugs appropriately stored, prepared, and handled by appropriately trained personnel under conditions that protect them?				
Are hazardous drugs appropriately disposed of in accordance with applicable federal and state regulations?				

COMPOUNDING EQUIPMENT

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Is the equipment generally of appropriate design and size for the compounding that is performed?				
Is all equipment of appropriate design such that the surfaces that contact pharmaceutical components, in-process materials, or finished preparations is not reactive, additive, or adsorptive?				
Is all equipment inspected for cleanliness and proper functioning prior to each use?				
Is all equipment thoroughly cleaned promptly after use to avoid cross-contamination?				
Is equipment used for allergenic ingredients appropriately handled, cleaned, and stored immediately after use?				
Are all items of equipment inspected, maintained, and validated at appropriate intervals?				
If disposable equipment or supplies are used, are they disposed of appropriately?				

COMPONENT SELECTION, HANDLING, AND STORAGE

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Sources				
Are *USP*- or *NF*-grade substances used, if available?				
If *USP*- or *NF*-grade substances are				

not available, is another high-quality source used? If so, what determines the grade of substances purchased and used in compounding? Is the "purity" scale considered and appropriately used?		____ ____	____ ____	
Are drug substances purchased from an FDA-registered facility?				
Are Certificates of Analysis obtained for these substances?				
Are other means used of establishing purity and safety? If so, describe the means that are used: •Lot analysis •Manufacturer's reputation •Reliability of source				
Do all substances have a complete label, batch control numb, and future expiration date on the container?				
For substances without an expiration date assigned by the manufacturer or supplier, does the pharmacy have an SOP to assign a conservative expiration date on the substance and is it followed?				
When manufactured products are used for compounding, do the labels contain a batch control number and a future expiration date?				
When manufactured products are used for compounding, are all the other excipients in the product considered relative to the compounded preparation to be made?				
Are any preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons?				
Does the pharmacy compound				

dietary or nutritional supplements? If so, does the pharmacy adhere to *USP* <795> standards for their compounding?		____ ____	____ ____	
If components are used that are derived from ruminant animals, does the pharmacy receive written assurance that the component is in compliance with all federal laws governing processing, use, and importation?				
Are all components stored: •In a clean area? •Under appropriate temperature and humidity conditions? •Off the floor? •Handled as well as stored to prevent contamination?		____ ____ ____ ____	____ ____ ____ ____	
Are all components properly rotated?				

STABILITY CRITERIA AND BEYOND-USE DATING
General Guidelines for Assigning Beyond-use Dates

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Does the pharmacy understand the difference between an "expiration date" and a "beyond-use date"?				
Is every formulation evaluated for incompatibilities and the potential for an ineffective or even potentially toxic preparation?				
Are BUDs assigned based on *USP* <795>?				
Are BUDs assigned from the day of preparation?				
Are preparations stored properly prior to dispensing based upon conditions upon which the BUD was assigned?				
Are preparations labeled properly based upon conditions upon which the BUD was assigned?				
Is documentation maintained in the pharmacy upon which extended				

BUDs are assigned?				
Is every preparation examined immediately after preparation and immediately prior to dispensing for any signs of instability?				
Is a maximum 6-month BUD used for all compounded preparations? If not, why?		____	____	
Is the BUD assigned according to the source of the active ingredient?				
As appropriate, are microbiological preservatives used? If not, are instructions to refrigerate provided?		____ ____	____ ____	
Are BUDs placed on the label affixed to the prescription?				
If repackaging drug products, are the BUDs assigned according to the *USP* General Notices, *USP* General Chapters <681> and <1136>?				

PACKAGING AND DRUG PREPARATION CONTAINERS

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Is the pharmacy aware of the *USP* standards for glass and plastic containers?				
Is the pharmacy aware of the *USP* standards for unit-dose containers?				
Are suitable containers used for the compounded preparations in the pharmacy?				
Are the containers and closures stored off the floor? Are the containers and closures handled and stored to prevent contamination? Are the containers and closures properly rotated?		____ ____ ____	____ ____ ____	

COMPOUNDING DOCUMENTATION

•*Master Formulation Record*

•*Compounding Record*
•*Standard Operating Procedures*
•*Material Safety Data Sheets File*

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Are the record-keeping requirements of the state followed?				
Are compounding records and documents maintained for the time period required by the state?				
Are the required records maintained in the pharmacy? •Master Formulation Record? •Compounding Record? •SOPs? •MSDSs?		 ____ ____ ____ ____	 ____ ____ ____ ____	
Master Formulation Record				
Is a detailed Formulation Record maintained for each compounded preparation? •Name, strength, and dosage form? •All necessary calculations? •All ingredients and their quantities? •Compatibility and stability information? •Equipment used for the preparation? •Mixing instructions to include order of mixing, temperatures, duration of mixing and other pertinent factors? •Assigned BUD? •Container used? •Sample labeling information? •Description of the finished preparation? •Storage requirements? •Quality-control procedures?		 ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____	 ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____	
Compounding Record				
Is a detailed Compounding Record maintained for each compounded preparation? •Name and strength of the preparation?		 ____	 ____	

•Master Formulation record reference? •Sources and lot numbers of ingredients? •Total number of dosage units compounded? •Name of person compounding the preparation? •Date of compounding? •Assigned internal identification number or the prescription number? •Description of the final preparation? •Assigned BUD? •Results of quality-control procedures?		____ ____ ____ ____ ____ ____ ____ ____ ____	____ ____ ____ ____ ____ ____ ____ ____ ____	
If problems occur during compounding of an official *USP* monograph preparation, is this reported to the *USP?*				
Standard Operating Procedures				
Is every significant procedure in the compounding pharmacy addressed by a well-written and implemented SOP?				
Is each compounding personnel thoroughly familiar with the SOPs that govern their daily activities?				
Are the SOPs reviewed periodically and upgraded as needed?				
Material Safety Data Sheet File				
Are MSDSs readily accessible to all employees working with drug substances or bulk chemicals located on the compounding facility? •Print? •Electronic?		 ____ ____	 ____ ____	
Do employees know how to access the MSDSs?				

QUALITY CONTROL
Compounding Controls

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Does the compounder review each				

procedure in the compounding process?				
Does the compounder observe the finished preparation to ensure it appears as expected in the Master Formulation Record?				
If the finished preparation does not appear as it should, does the compounder investigate the discrepancy and take appropriate corrective action before the prescription is dispensed to the patient?				
Does the pharmacy regularly test preparations for physical, chemical, and microbiological characteristics?				
Is the pharmacy familiar with and utilize *USP* General Chapter <1163> Quality Control in Pharmaceutical Compounding?				
Are the routine compounding procedures for batch preparation completed and verified according to written procedures? •Calculations correct? •Weighing and measuring done correctly? •Order of mixing correct? •Compounding techniques performed correctly?		____ ____ ____ ____	____ ____ ____ ____	

PATIENT COUNSELING

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Is the patient properly counseled about the compounded preparation at the time of dispensing? •Proper use? •Storage? •Evidence of instability? •Disposal?		____ ____ ____ ____	____ ____ ____ ____	

TRAINING

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Is a training program in place for all				

personnel involved in compounding?				
Are all compounding personnel evaluated at least annually?				
Are all compounding personnel familiar with *USP* General Chapter <795>?				
Are personnel that handle hazardous drugs appropriately trained and evaluated?				
Are all training activities documented?				
Are compounding personnel prevented from compounding until they have been adequately trained and evaluated?				
Does the compounder realize they are solely responsible for the finished preparation?				

COMPOUNDING FOR ANIMAL PATIENTS

ITEM	REQUIREMENTS	YES	NO	COMMENT/SOP
Are all compounding personnel aware that preparations compounded for animal patients must meet the same standards as those for human patients?				
Do compounding personnel understand the issue of drug residues and the human food chain?				
Do compounding personnel understand drug withdrawal times?				
Are compounding personnel familiar with all appropriate laws and regulations governing compounding drugs for animal use?				
Are compounding personnel aware of the different physiological and biochemical aspects of animals as compared to humans and the effect on drug utilization and elimination?				

BUD = beyond-use date
FDA = U.S. Food and Drug Administration
MSDS = Material Safety Data Sheet

NF = National Formulary
OSHA = Occupational Safety & Health Administration
SOP = standard operating procedure
USP = United States Pharmacopeia