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## PHARMACY COMPOUNDING INSPECTION REPORT

### Sterile and Non-Sterile Preparations

Rev. 10/22/2012

(Please print clearly or type information.)

Pharmacy Name: \_\_\_\_\_ Date: \_\_\_\_\_

Address: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Pharmacy License Number: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Controlled Substance License Number: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

DEA Registration Number: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Pharmacist-in-Charge: \_\_\_\_\_

Pharmacist-in-Charge License Number: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

*Facilities engaged in extensive 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.*

### SECTION I – General Compounding

Please answer the following questions. For every “no” answer, provide an explanation on an attached sheet.

- |    | Yes                      | No                       | N/A                      |  |
|----|--------------------------|--------------------------|--------------------------|--|
| 1. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The facility follows USP-NF Chapter 795, compounding of non-sterile preparations. (UAC R156-17b-614)   |
| 2. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The facility follows USP-NF Chapter 797, compounding of sterile preparations, if applicable.<br>If checked yes fill out <i>Section II – Sterile Compounding</i> . (UAC R156-17b-614)   |
| 3. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Bulk active ingredients must be component of FDA approved drugs listed in the approved drug products prepared by the center for Drug Evaluation and Research of the FDA. (UAC R156-17b-614)  |
| 4. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Compounding using drugs that are not part of a FDA approved drug listed in the approved drug products prepared by the Center for Drug Evaluation and Research of the FDA requires an investigational new drug application (IND). The IND approval shall be kept in the pharmacy for five years for inspection. (UAC R156-17b-614)                                      |
| 5. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | A master worksheet sheet 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 sheet shall be used as the preparation worksheet sheet from which each batch is prepared and on which all documentation for that batch occurs. (UAC R156-17b-614) |

(Continued on next page.)

- |  | Yes   | No                       | N/A                      |  |  |   |
|--|---|--------------------------|--------------------------|--|--|---|
| 6.   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <p>The master worksheet sheet contains the following information:</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> The formula name and strength<br/> <input type="checkbox"/> The compounding directions<br/> <input type="checkbox"/> Evaluation and testing requirements<br/> <input type="checkbox"/> Specific equipment used during preparation such as specific compounding device<br/> <input type="checkbox"/> Beyond use date information </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> The components (ingredients and quantities)<br/> <input type="checkbox"/> A sample label<br/> <input type="checkbox"/> Sterilization methods, if applicable<br/> <input type="checkbox"/> Storage requirements </td> </tr> </table> <p style="text-align: right; margin-right: 100px;">(UAC R156-17b-614)</p>   | <input type="checkbox"/> The formula name and strength<br><input type="checkbox"/> The compounding directions<br><input type="checkbox"/> Evaluation and testing requirements<br><input type="checkbox"/> Specific equipment used during preparation such as specific compounding device<br><input type="checkbox"/> Beyond use date information | <input type="checkbox"/> The components (ingredients and quantities)<br><input type="checkbox"/> A sample label<br><input type="checkbox"/> Sterilization methods, if applicable<br><input type="checkbox"/> Storage requirements |
| <input type="checkbox"/> The formula name and strength<br><input type="checkbox"/> The compounding directions<br><input type="checkbox"/> Evaluation and testing requirements<br><input type="checkbox"/> Specific equipment used during preparation such as specific compounding device<br><input type="checkbox"/> Beyond use date information | <input type="checkbox"/> The components (ingredients and quantities)<br><input type="checkbox"/> A sample label<br><input type="checkbox"/> Sterilization methods, if applicable<br><input type="checkbox"/> Storage requirements |                          |                          |  |  |   |
| 7.   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <p>A preparation worksheet sheet for each batch of sterile or non-sterile pharmaceuticals shall document the following:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes</li> <li><input type="checkbox"/> Manufacturer lot number for each component</li> <li><input type="checkbox"/> Component manufacturer or suitable identifying number</li> <li><input type="checkbox"/> Container specifications (e.g. syringe, pump cassette)</li> <li><input type="checkbox"/> Unique lot or control number assigned to batch</li> <li><input type="checkbox"/> Expiration date of batch prepared products</li> <li><input type="checkbox"/> Date of preparation</li> <li><input type="checkbox"/> Name, initials or electronic signature of the person or persons involved in the preparation</li> <li><input type="checkbox"/> Names, initials or electronic signature of the responsible pharmacist</li> <li><input type="checkbox"/> End-product evaluation and testing specifications, if applicable</li> <li><input type="checkbox"/> Comparison of actual yield to anticipated yield, when appropriate</li> <li><input type="checkbox"/> Dosage units compounded</li> <li><input type="checkbox"/> Prescription numbers</li> </ul> <p style="text-align: center;">(UAC R156-17b-614)</p> |  |   |
| 8.   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <p>The sample label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The unique lot number assigned to the batch</li> <li><input type="checkbox"/> All solution and ingredient names, amounts, strengths and concentrations, when applicable</li> <li><input type="checkbox"/> Quantity</li> <li><input type="checkbox"/> Expiration date and time, when applicable</li> <li><input type="checkbox"/> Appropriate ancillary instructions, such as storage instructions or cautionary statements, including warning labels where appropriate</li> <li><input type="checkbox"/> Device-specific instructions, where appropriate</li> </ul> <p style="text-align: center;">(UAC R156-17b-614)</p>  |  |   |
| 9.   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <p>The compounding records including the master worksheet, preparation worksheet, and MSDS files shall be kept for a minimum of 5 years.(UAC R156-17b-612)</p>   |  |   |
| 10.  | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <p>The expiration date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing. (UAC R156-17b-614)</p>  |  |   |
| 11.  | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | <p>All prescription labels shall bear at minimum the following in addition to what is required in UAC 58-17b-602:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The unique lot number assigned to the batch</li> <li><input type="checkbox"/> Beyond use date</li> <li><input type="checkbox"/> Appropriate ancillary instructions, such as storage instructions or cautionary statements, including warning labels where appropriate</li> <li><input type="checkbox"/> All solution and ingredient names, amounts, strengths and concentrations, when applicable</li> <li><input type="checkbox"/> Quantity</li> </ul> <p style="text-align: center;">(UAC R156-17b-614)</p>  |  |   |

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- |     | Yes                      | No                       | N/A                      |   |
|-----|--------------------------|--------------------------|--------------------------|---|
| 12. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The facility contains the following sources of drug stability information:<br><br><input type="checkbox"/> Trissell's "Handbook on Injectable Drugs," 13 <sup>th</sup> Edition, 2004 (Recommended)<br><input type="checkbox"/> Manufacturer recommendations<br><input type="checkbox"/> Reliable published research<br>(UAC R156-17b-614) |
| 13. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Methods for establishing expiration dates shall be documented. (UAC R156-17b-614)   |
| 14. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The facility maintains documentation regarding an ongoing quality control program that monitors and evaluates personnel performance, equipment and facility's compliance with following the USP-NF Chapters 795 and 797 standards. (UAC R156-17b-614)   |
| 15. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The facility supplies potable water (purified water) for hand and equipment washing. Purified water must also be used for rinsing equipment and utensils. (USP-NF 795 Compounding Environment – Facilities)   |
| 16. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 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. (UAC R156-17b-402)   |

**SECTION II – Sterile Compounding – Fill out this section if checked “yes” to question 2**

*Facilities engaging in sterile compounding shall be required to follow and maintain all appropriate standards of USP-NF Chapter 795 – non-sterile compounding as well as USP-NF Chapter 797 – sterile compounding. Written documents shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility.*

- |    | Yes                      | No                       | N/A                      |  |
|----|--------------------------|--------------------------|--------------------------|--|
| 1. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Standard Operating Procedures shall be created and maintained in written format addressing the following:<br><br><input type="checkbox"/> Proper cleaning and maintenance of sterile compounding areas and equipment<br><small>(USP-NF 797 Cleaning and Disinfecting the Compounding Area)</small><br><input type="checkbox"/> Personnel cleansing and garbing<br><small>(USP-NF 797 Personnel Cleansing and Garbing)</small><br><input type="checkbox"/> Sterilization methods, if applicable<br><small>(USP-NF 797 Sterilization Methods)</small><br><input type="checkbox"/> Training of personnel involved in compounding<br><small>(USP-NF 797 Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures)</small><br><input type="checkbox"/> Methods used to determine expiration dates<br><small>(USP-NF 797 Determining Beyond-Use Dates)</small><br><input type="checkbox"/> Storage requirements<br><small>(USP-NF 797 Monitoring Controlled Storage Areas and Use and Storage)</small><br><input type="checkbox"/> Proper use of equipment<br><small>(USP-NF 797 Equipment)</small><br><input type="checkbox"/> Evaluation and testing requirements<br><small>(USP-NF 797 Verification of Compounding Accuracy and Sterility and Compounding Accuracy Checks)</small><br><input type="checkbox"/> Formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes.<br><small>(USP-NF 797 Verification of Compounding Accuracy and Sterility and Compounding Accuracy Checks)</small><br>*For more on written policies and procedures see <i>USP-NF 797 Suggested Standard Operating Procedures.</i><br><small>(USP-NF 797)</small> |
| 2. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | In absence of proper testing the following beyond use dates are maintained and followed:<br><br><input type="checkbox"/> For a low-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the sterile preparations are properly stored and are exposed for not more than 48 hours at controlled room temperatures, for not more than 14 days at a cold temperature, and for 45 days in solid frozen state between -25° and -10°<br><br><input type="checkbox"/> For a medium-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the sterile preparations are properly stored and are exposed for not more than 30 hours at controlled room temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state between -25° and -10°  |

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Yes No N/A

For a high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the sterile preparations are properly stored and are exposed for not more than 24 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for 45 days in solid frozen state between -25° and -10°  
(USP-NF 797 CSP Microbial Contamination Risk Levels)

3.    Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. (USP-NF 797 Facility Design and Environmental Controls)

4.    Primary engineering controls (a device or room that provides an environment suitable for sterile compounding such as a laminar airflow workbench, biological safety cabinet, compounding aseptic isolator, and/or compounding aseptic containment isolators) shall maintain ISO Class 5 or better conditions for 0.5-µm particles (dynamic operating conditions) while compounding sterile preparations.  
(USP-NF 797 Facility Design and Environmental Controls)

5.    Primary engineering controls shall be located within a restricted access ISO Class 7 buffer/ante-area.  
(USP-NF 797 Placement of Primary Engineering Controls)

6.    Primary engineering controls and secondary (buffer and ante-areas) shall be certified following procedures such as those outlined in *Certification Guide for Sterile Compounding Facilities* (CAG-003-2006) and shall be performed by a qualified individual no less than every 6 months and whenever a device or room is relocated or altered or major service to the facility is performed.  
(USP-NF 797 Viable and Nonviable Environmental Sampling and Testing)

7.    Assurance of sterility in a compounded sterile preparation is mandatory (USP-NF Chapter 795 Sterility)

8.    Compounding personnel who prepare compounded sterile preparations shall perform didactic review and pass written and media-fill testing of aseptic manipulative skill initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding.  
(USP-NF 797 Personnel Training and Evaluation in Aseptic Manipulation Skills)

9.    The compounding procedures and sterilization methods for compounded sterile preparations correspond to correctly designed and verified written documentation in the compounding facility. Verification requires planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining sterility, accuracy, and purity of finished compounded sterile products. (USP-NF 797 Verification of Compounding Accuracy and Sterility)

10.    A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the an-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device.  
(USP-NF 797 Viable and Nonviable Environmental Sampling Testing)

***\*The foregoing list of factors is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.***

REMARKS: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

(Additional information may be noted on back)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Pharmacist-in-Charge

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Division Investigator