

STATE OF UTAH  
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## PHARMACY COMPOUNDING INSPECTION REPORT Sterile and Non-Sterile Preparations

Rev. 7/12/05

(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.*

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"/> | 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)  |                                      |   |   |   |  |   |  |   |
| 3.   | <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)  |                                      |   |   |   |  |   |  |   |
| 4.   | <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)   |                                      |   |   |   |  |   |  |   |
| 5.   | <input type="checkbox"/>  | <input type="checkbox"/> | <input type="checkbox"/> | The master worksheet sheet contains the following information:<br><table border="0" style="margin-left: 40px;"><tr><td><input type="checkbox"/> The formula</td><td><input type="checkbox"/> The components</td></tr><tr><td><input type="checkbox"/> The compounding directions</td><td><input type="checkbox"/> A sample label</td></tr><tr><td><input type="checkbox"/> Evaluation and testing requirements</td><td><input type="checkbox"/> Sterilization methods, if applicable</td></tr><tr><td><input type="checkbox"/> Specific equipment used during preparation<br/>such as specific compounding device</td><td><input type="checkbox"/> Storage requirements<br/>(UAC R156-17b-614)</td></tr></table> | <input type="checkbox"/> The formula | <input type="checkbox"/> The components | <input type="checkbox"/> The compounding directions | <input type="checkbox"/> A sample label | <input type="checkbox"/> Evaluation and testing requirements | <input type="checkbox"/> Sterilization methods, if applicable | <input type="checkbox"/> Specific equipment used during preparation<br>such as specific compounding device | <input type="checkbox"/> Storage requirements<br>(UAC R156-17b-614) |
| <input type="checkbox"/> The formula   | <input type="checkbox"/> The components                             |                          |                          |  |                                      |   |   |   |  |   |  |   |
| <input type="checkbox"/> The compounding directions  | <input type="checkbox"/> A sample label                             |                          |                          |  |                                      |   |   |   |  |   |  |   |
| <input type="checkbox"/> Evaluation and testing requirements   | <input type="checkbox"/> Sterilization methods, if applicable       |                          |                          |  |                                      |   |   |   |  |   |  |   |
| <input type="checkbox"/> Specific equipment used during preparation<br>such as specific compounding device | <input type="checkbox"/> Storage requirements<br>(UAC R156-17b-614) |                          |                          |  |                                      |   |   |   |  |   |  |   |

(Continued on next page.)

- |     | Yes                      | No                       | N/A                      |  |
|-----|--------------------------|--------------------------|--------------------------|--|
| 6.  | <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<br/>(UAC R156-17b-614)</li> </ul> |
| 7.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <p>The 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<br/>(UAC R156-17b-614)</li> </ul>  |
| 8.  | <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>  |
| 9.  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <p>The facility contains the following sources of drug stability information:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Trissell's "Handbook on Injectable Drugs," 13<sup>th</sup> Edition, 2004 (Recommended)</li> <li><input type="checkbox"/> Manufacturer recommendations</li> <li><input type="checkbox"/> Reliable published research<br/>(UAC R156-17b-614)</li> </ul>  |
| 10. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <p>Methods for establishing expiration dates shall be documented. (UAC R156-17b-614)</p>   |
| 11. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <p>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)</p>   |

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

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\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Printed Name of Pharmacist-in-Charge