

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	<small>DATE(S) OF INSPECTION</small> 2/12/2018-2/16/2018 <small>FEI NUMBER</small> 3009988995	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Raymond R. Carlson, Pharmacist/Owner		
<small>FIRM NAME</small> RC Compounding Services, LLC	<small>STREET ADDRESS</small> 3030 Center Rd	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Poland, OH 44514-2158	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Sterile Drug Products	
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>		
<p><b>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</b></p> <p><b>OBSERVATION 1</b></p> <p>Personnel placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.</p> <p>Specifically,</p> <p>On 02/12/2018, during the observation of production of Serum Tears in the ISO 5 Laminar Air Flow Hood, we observed an employee remove the caps from sterile droptainers and place the caps and containers in a pile, blocking the first pass ISO 5 air flow.</p>		
<p><b>OBSERVATION 2</b></p> <p>Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.</p> <p>Specifically,</p> <p>A. On 02/13/2018, we observed an employee use non-sterile (b) (4) to clean the ISO 5 Laminar Air Flow Hood. The employee was observed spraying a sterile wipe with non-sterile (b) (4) and then cleaning the work surface and sides inside of the ISO 5 Laminar Air Flow Hood.</p>		
<p><b>SEE REVERSE OF THIS PAGE</b></p>	<small>EMPLOYEE(S) SIGNATURE</small> Matthew B Casale, Investigator Jazmine N Still, Investigator	<small>DATE ISSUED</small> 2/16/2018  <div style="text-align: center;"> <small>Matthew B Casale Investigator Signed by Matthew B. Casale-S Date Signed 02-16-2018 17:43:16</small>  <span style="font-size: 2em;">X</span> </div>

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<p>B. Additionally, the employee noted above was observed spraying the outside of the ISO 5 Laminar Air Flow Hood and a chair in front of the opening of the ISO 5 Laminar Air Flow Hood, causing non-sterile (b) (4) to enter the ISO 5 Laminar Air Flow Hood.</p>		
<p><b>OBSERVATION 3</b>                      Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.</p> <p>Specifically,</p> <p>On 02/12/2018, we observed an employee don non-sterile gloves; then put on sterile sleeves, touching them with the non-sterile gloves; then remove the non-sterile gloves, exposing bare hands; don sterile gloves; and then begin producing sterile drug products.</p>		
<p><b>OBSERVATION 4</b>                      Non-sterilized and Non-depyrogenated equipment was used in sterile drug production.</p> <p>Specifically,</p> <p>A) While filling syringes of sterile Testosterone Cypionate 200 mg for injection, an employee was observed making a makeshift heat shield to hold vials in the ISO 5 hood. The employee made the shield out of a sterile wipe that they rolled up on a non-sterile table in the ISO 7 anteroom and stapled it closed with non-sterile staples before putting it in the ISO 5 hood without any decontamination step.</p> <p>B) On 02/13/2018, we observed an employee spray the pH electrode with (b) (4) water and then measure the pH of epinephrine solution in the ISO 7 cleanroom before using it in production of</p>		
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syringes of sterile Epinephrine/Lidocaine Intraocular Solution 0.01 mg:20 mg/ml. The (b) (4) water is poured into a non-sterile spray bottle in the ISO 7 anteroom before it is used to spray the pH electrode.		
<p><b>OBSERVATION 5</b>                      Your facility design allowed the influx of poor quality air into a higher classified area.</p> <p>Specifically,</p> <ul style="list-style-type: none"> <li>A. There are no air returns in the ISO 7 cleanroom or ISO 7 anteroom. Strong palpable air flow can be felt at the top, bottom, and sides of the doors exiting the cleanroom to the anteroom and the anteroom to the unclassified area.</li> <li>B. There is no evidence that the ISO 7 anteroom was qualified while the wall mounted air conditioner was in operation to demonstrate that the air conditioner does not affect the air quality in the ISO 7 anteroom.</li> </ul>		
<p><b>OBSERVATION 6</b>                      You produced highly potent drugs without providing adequate containment, cleaning of work surfaces and cleaning of personnel to prevent cross-contamination.</p> <p>Specifically,</p> <ul style="list-style-type: none"> <li>A. Sterile hazardous drugs such as tacrolimus, testosterone, and progesterone are produced in the same ISO 5 Laminar Air Flow Hood as all other sterile drug products with only a (b) (4) (b) (4) decontamination step in between hazardous and non-hazardous drug production.</li> </ul>		
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<p>B. Non-sterile hazardous drugs such as testosterone, estradiol, progesterone, and azathioprine are produced in the same safety hoods as all other non-sterile drug products with only a soapy water wash and (b) (4) decontamination step in between hazardous and non-hazardous drug production.</p>			
<div style="border-bottom: 1px solid black; margin-bottom: 10px;"> <p style="font-size: small;">X Jazmine N Still Investigator Signed By: 2001954135 Date Signed: 02-16-2018 17:44:46</p> </div>			
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