

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	<small>DATE(S) OF INSPECTION</small> 5/29/2019-6/4/2019*  <small>FEI NUMBER</small> 3002401385	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Mr. Mark Shinabery, Owner		
<small>FIRM NAME</small> Custom Compounding Center	<small>STREET ADDRESS</small> 11700 Kanis Rd	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Little Rock, AR 72211-3729	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of 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 I OBSERVED:</b>  <b>OBSERVATION 1</b></p> <p>You produced hazardous drugs without providing adequate cleaning of work surfaces to prevent cross-contamination.</p> <p>Specifically,</p> <p>Your firm failed to utilize an oxidizing agent to clean immediately following the handling of testosterone, estrogen, and morphine containing drug products in your (b) (4) hoods, "(b) (4) " serial number # (b) (4) and "(b) (4) " serial number # (b) (4) Your firm only utilizes (b) (4) (b) (4) to clean between compounding drug products, per your standard operating procedure, "Room Cleaning Procedures and Spill Handling" , SOP #3.007.</p>		
<p><b>*DATES OF INSPECTION</b>                      5/29/2019(Wed), 5/30/2019(Thu), 5/31/2019(Fri), 6/03/2019(Mon), 6/04/2019(Tue)</p>		
<b>SEE REVERSE OF THIS PAGE</b>	<small>EMPLOYEE(S) SIGNATURE</small> Jason R Caballero, Investigator  <div style="text-align: right; font-size: small;">                         Jason R Caballero                          Investigator                          Signed By Jason R. Caballero -S                          Date Signed 06-04-2019 14:29:02                          X _____                     </div>	<small>DATE ISSUED</small> 6/4/2019