

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	DATE(S) OF INSPECTION 5/29/2019-6/4/2019*
	FEI NUMBER 3002401385

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Mr. Mark Shinabery, Owner

FIRM NAME Custom Compounding Center	STREET ADDRESS 11700 Kanis Rd
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CITY, STATE, ZIP CODE, COUNTRY Little Rock, AR 72211-3729	TYPE ESTABLISHMENT INSPECTED Producer of Drug Products
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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.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:  
OBSERVATION 1**

You produced hazardous drugs without providing adequate cleaning of work surfaces to prevent cross-contamination.

Specifically,

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.

**\*DATES OF INSPECTION**

5/29/2019(Wed), 5/30/2019(Thu), 5/31/2019(Fri), 6/03/2019(Mon), 6/04/2019(Tue)

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Jason R Caballero, Investigator	Jason R Caballero Investigator Signed By Jason R. Caballero-S Date Signed 06-04-2019 14:29:02 X _____	DATE ISSUED 6/4/2019