

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

DISTRICT ADDRESS AND PHONE NUMBER 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax: (913) 495-5115	DATE(S) OF INSPECTION 6/26/2017-7/3/2017*
	FEI NUMBER 3008364285

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Joseph M. Huber , Pharmacy Manager

FIRM NAME Triad Isotopes Inc.	STREET ADDRESS 712 Westport Rd
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CITY, STATE, ZIP CODE, COUNTRY Kansas City, MO 64111-3130	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Durg 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:**

Your firm is producing sterile drugs under insanitary conditions.

- A. Your firm is not using a sporicidal agent in the ISO 5 areas used for sterile operations.
- B. Your firm is using non-sterile disinfectants in the ISO 5 areas used for sterile operations.
- C. Your firm does not perform any contact sampling on the permanent equipment in the ISO 5 LAF hood. Your firm has not tested the dose calibrator and periphery equipment to determine your sanitization is effective.
- D. Your firm does not measure the pressure differential between the ISO 5 hood used for sterile operations and the surrounding area.

**\*DATES OF INSPECTION**

6/26/2017(Mon),6/27/2017(Tue),6/28/2017(Wed),7/03/2017(Mon)

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Michele L Obert, Investigator	<input checked="" type="checkbox"/> Michele L Obert <small>Michele L Obert Investigator Signed by: Michele L Obert -5</small>	DATE ISSUED 7/3/2017