

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

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802		07/17/2017-07/21/2017	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER	
Matthew L. McDonald, Owner		3013497126	
FIRM NAME	STREET ADDRESS		
Triad Rx, Inc.	26258 Pollard Road		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED		
Daphne, AL 36526	Producer of Sterile and Non-sterile Drugs		

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) (WE) OBSERVED:

OBSERVATION 1

Cleaning pads or wipes used in the ISO 5 area are not sterile.

Specifically, the (b) (4) wipers used to clean the ISO 5 area are not sterile.

OBSERVATION 2

The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically, a lyophilizer and a portable dehumidifier are located in the clean room (ISO 7) adjacent to the ISO 5 area.

OBSERVATION 3

Inadequately or un-protected product intended to be sterile was observed to be exposed to lower than ISO 5 quality air.


Specifically, drug products intended to be lyophilized are (b) (4) in the ISO 5 area, partially stoppered, and then transferred to the lyophilizer (ISO 7 area) via unprotected/uncovered trays.

OBSERVATION 4

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically, on 07/17/2017, I observed clean room operator, with initials (b) (6) perform aseptic processing in the ISO 5 area. The operator did not always disinfect or change gloves before reentering the ISO 5 area after retrieving materials or discarding waste in the ISO 7 area. The following lots were produced without adequate glove disinfection/changes:

-Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, lot 07172017@25

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Brandon C. Heltmaler, Investigator	DATE ISSUED 07/21/2017
-----------------------------------	--------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------	---------------------------

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

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802		07/17/2017-07/21/2017
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER
Matthew L. McDonald, Owner		3013497126
FIRM NAME	STREET ADDRESS	
Triad Rx, Inc.	26258 Pollard Road	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Daphne, AL 36526	Producer of Sterile and Non-sterile Drugs	

-Sermorelin Acetate 3mg/GHRP-6 3mg, Lyophilized, lot 07172017@24

OBSERVATION 5

Personnel engaged in aseptic processing were observed with exposed hands, wrists, legs, hair, or mouth.

Specifically, on 07/17/2017, I observed clean room operator, with initials (b) (6) enter the ISO 5 area with bare hands then put on sterile gloves and proceed with aseptic processing. The following lots were produced:

- Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, lot 07172017@25
- Sermorelin Acetate 3mg/GHRP-6 3mg, Lyophilized, lot 07172017@24

OBSERVATION 6

Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically, on 07/17/2017, I observed clean room operator, with initials (b) (6) move a (b) (4) from the ISO 7 area to the ISO 5 area without first disinfecting the equipment.

OBSERVATION 7


Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.

Specifically, on 07/17/2017, I observed clean room operator, with initials (b) (6) place hands and arms over open glass vials during aseptic filling of the following products:

- Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, lot 07172017@25
- Sermorelin Acetate 3mg/GHRP-6 3mg, Lyophilized, lot 07172017@24

OBSERVATION 8

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Brandon C. Holmeyer, Investigator	DATE ISSUED 07/21/2017
--------------------------	--------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------	---------------------------

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

DISTRICT ADDRESS AND PHONE NUMBER

404 BNA Dr., Bldg. 200, Ste. 500
Nashville, TN 37217-2597
(615) 366-7801 Fax: (615) 366-7802

DATE(S) OF INSPECTION

07/17/2017-07/21/2017

FEI NUMBER

3013497126

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Matthew L. McDonald, Owner

FIRM NAME

Triad Rx, Inc.

STREET ADDRESS

26258 Pollard Road

CITY, STATE, ZIP CODE, COUNTRY

Daphne, AL 36526

TYPE ESTABLISHMENT INSPECTED

Producer of Sterile and Non-sterile Drugs

Specifically, your firm's batch sizes for injectable drug products range in volume from (b) (4) to (b) (4) (b) (4) and from (b) (4) to (b) (4). However, the last media fill performed only consisted of (b) (4). Additionally, media fills previously performed do not simulate all steps for lyophilized products including but not limited (b) (4) manipulations, transfer, and lyophilization.

OBSERVATION 9

The use of sporicidal agents in the cleanrooms and/or ISO 5 area is inadequate or infrequent.

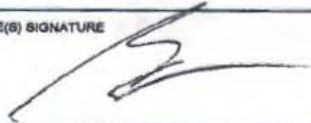
Specifically, your firm uses a prepared bleach water solution that consists of (b) (4) of (b) (4) (b) (4) mixed with (b) (4). However, your firm has not established an effective contact time for this concentration/strength and the contact time is not currently monitored by your firm.

***DATES OF INSPECTION**

07/17/2017, 07/18/2017, 07/19/2017, 07/21/2017

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Print or Type)

Brandon C. Helmeier, Investigator

DATE ISSUED

07/21/2017