DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	3/22/2022-4/1/2022* FEI NUMBER 3003197096

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert Terry, Vice President, HSV Site Director

FIRM NAME	STREET ADDRESS
TriRx Huntsville Pharmaceutical Services, LLC	120 Vintage Dr Ne
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Huntsville, AL 35811-8216	Drug Product Manufacturer

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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not followed.

Specifically,

Your current process controls are not sufficient to prevent the presence of objectionable microorganisms in the operational areas of this site. The following cases were reported, among others:

1. *On 05/19/2021, your microbiology laboratory reported the presence of Burkholderia cepacia complex* (b) (4) *in water-samples collected from the manufacturing area port* (b) (4) *Your water test report indicated that the following drug products were manufactured prior the water-sampling of port* (b) (4) *(05/14/2021), and identified as potentially affected:*
   - *Lactulose (Bulk lot 20002930) lot # 20002931*
   - *Nystatin (Bulk lot 20002927) lot # 20002929*
   - (b) (4)

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EMPLOYEE(S) SIGNATURE
Libia M Lugo, Investigator
Clinton J Lott, Investigator
Brittny C Cargo, Investigator

X Libia M Lugo Investigator Signed By: Libia M. Lugo Leon -S Date Signed: 0 -01-2022 18:35:52

DATE ISSUED
4/1/2022

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Your investigations concluded that the contamination was caused by a water leak in the (b) (4) (b) (4) *was quarantined,* (b) (4) *water system was sanitized* (b) (4) *on 05-21-2021); then re-sampled with no recurrence. The port was released for use in production on 29/05/2021.*

The lactulose batch #20002931 and the nystatin batch #20002929 due were released from this site based on microbiology test results and relying on product preservatives to (b) (4) (b) (4) *was released based on a current challenge study to demonstrate the drug product resistance to B. cepacia.*

2. *Your microbiology laboratory reported the presence Burkholderia cepacia complex and Ralstonia pickettii in sample and control plates of microbiology testing conducted on 10/24/2020, the microbiology reported the following results:*
   - (b) (4) *Burkholderia cepacia complex; Fusarium oxysporum; Brevibacillus choshinensis*
   - *Lactulose lot # 20001722* (b) (4) *Ralstonia pickettii; Burkholderia cepacia complex*
   - (b) (4) *Negative Control* (b) (4) *Burkholderia cepacia complex*
   - (b) (4) *Negative Control* (b) (4) *Burkholderia cepacia complex*

   Your microbiology laboratory investigation determined that drug product samples and microbiology controls may have been contaminated with the water retained in the (b) (4) *for laboratory testing. Also indicating that this* (b) (4) *was not properly cleaned prior use in microbiology testing.*

3. *Environmental monitoring air and surface samples collected from 06/26/2020 to 12/01/2020 from*

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different manufacturing areas and warehouse (e.g., sample room [redacted] Line (b) (4) and line-(b) (4) presented an orange spreading mold later identified as Neurospora sitofilia / tetrasperma and Purpureocillium lilacinum (MNOE-0720.002)

Your investigation in this regard indicated that the contamination with this fungus came from wooden pallets left unattended in a box truck with conditions of high humidity and high temperatures that led to the growth and spread of this fungus in the areas of manufacturing and packaging.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

Your Quality Unit and Quality Control Unit do not initiate investigations to identify the root cause and to determine if other batches manufactured and stored under similar conditions have been also impacted.

1. *Your Quality Unit does not identify the source of contamination on batches of drug products and raw materials further used in the production area. For example,*

   - *On 07/2022, the microbiology laboratory isolated species Metabacillus halosaccharovorans in Nystatin active ingredient lot # 20014623 based on no hazard associated to this species on the raw material.*

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- *On 01/14/2022,* (b) (4) *was released to the market after microbiology laboratory isolated Pseudomonas putida spp.*

2. *Your Quality Unit does not initiate investigations to identify the potential root cause for rejected drug products and raw materials, and to identify the source of contamination with potentially objectionable microorganisms. For example,*

   - *On 01/29/2022, your microbiology laboratory isolated Enterococcus faecalis in an incoming sample of Niacinamide lot #*(b) (4) *(raw material). After sampled, the material was stored in the warehouse. Even though a supplier corrective action request was sent to the supplier; no investigation has been initiated at your site to identify the source of the contamination and any potential contamination to other materials.*

3. *Your Quality Control Laboratory allows the averaging of retest results with acceptable and out-of-specification values. Your SOP 299667 for laboratory investigations does not require* (b) (4)

(b) (4)

***DATES OF INSPECTION**

3/22/2022(Tue), 3/23/2022(Wed), 3/24/2022(Thu), 3/25/2022(Fri), 3/29/2022(Tue), 3/30/2022(Wed), 3/31/2022(Thu), 4/01/2022(Fri)

X Clinton J Lott
Investigator
Signed By: Clinton J. Lott -S
Date Signed: 04-01-2022 18:38:03

X Brittny C Cargo
Investigator
Signed By: Brittny C. Cargo -S
Date Signed: 04-01-2022 18:38:35

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."