DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	8/29/2022-9/9/2022* FEI NUMBER 3011761882

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Mark K. Taylor, Chief Executive Officer and Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
Curexa - East, LLC dba Curexa	3007 Ocean Heights Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Egg Harbor Township, NJ 08234-7749	Producer of non-sterile drug products

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

Non-microbial contamination was observed in your production area.

Specifically,

A. We observed blue powder-like residue in several areas of your facility such as:

i. On 09/02/2022, we observed blue powder-like residue outside of the dedicated rooms used for production of sildenafil, tadalafil, or vardenafil containing (b) (4) products. The blue powder-like residue was observed on wall surfaces and along crevices of the wall-mounted air conditioning unit in the "Nonhazardous Compounding (b) (4) " room, which is located adjacent to the (b) (4) dedicated rooms. The wall-mounted air conditioning unit is located above and between the table worksurfaces and (b) (4) hood (b) (4), and remains on to maintain approximately room temperature.

No blue colored (b) (4) products are produced in the "Nonhazardous Compounding (b) (4) " room. The last time products containing blue coloring were tableted was 08/11/2022. (b) (4), such as "(b) (4): #2 NO CLINDA-TRET0.03%/HA0.5%/NIACINAMIDE3%/AA 1% NOURISIL" are produced in the "Nonhazardous Compounding (b) (4) ", within (b) (4) t hood (b) (4) and atop table worksurfaces, prior to adding the hazardous material (e.g., tretinoin) in the hazardous suite. On 09/02/2022, Technician (b) (6) produced lot 090120222 of " (b) (4) : HYDROQUINONE 6%/NIACINAMIDE 2%/GLYCERIN 10% NO VIT C ANHYDR/SILIC" in the "Nonhazardous Compounding (b) (4) " room where the aforementioned blue powder-like residue was observed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sena G Dissmeyer, Investigator Jessica S Estriplet, Investigator	X Sena G Dissmeyer Investigator Signed By: Sena G. Dissmeyer -S Date Signed: 09-09-2022 18:39:16	9/9/2022

ii. On 09/01/2022, we observed blue powder-like residue in a gap in the corner of the wall between the "Non-Hazardous Compounding (b) (4) " and the "Nonhazardous Compounding (b) (4) " room. Additionally, the corner of a (b) (4) separating the spaces had the residue on the side facing the "Non-Hazardous Compounding (b) (4) ".

iii. On 09/01/2022, we observed blue powder-like residue in the dedicated "Non-Hazardous Compounding (b) (4) " room, inside the (b) (4) , within the crevices of the left-side agitator shaft, and on the left and right side flat interior walls of the (b) (4) .

iv. On 09/01/2022, we observed blue powder-like residue in the dedicated "Non-Hazardous Compounding (b) (4) " room on the interior top-front corner crevices, and interior top edges of (b) (4) hood (b) (4) . On 08/29/2022, we observed Technician (b) (6) producing "NALTREXONE HCL (SUCROSE GRANULAR) (b) (4) 4.5MG CAPSULES", lot 0825202226, in hood (b) (4) in the dedicated "Non-Hazardous Compounding (b) (4) " room.

B. On 08/29/2022, we observed build-up of tan colored and grey colored residue clumps in the interior top-front corner crevices where the metal frame pieces meet the (b) (4) , work surface edges, and behind the slotted back work zone panels of non-product-dedicated (b) (4) hoods (b) (4) , and (b) (4) .

Non-hazardous drugs, such as "(b) (4) MOUTH WASH TETRACYCLINE 2GMS/LIDOCAINE 2%/DIPHAN 20ML/NYSTATIN 20ML/ML" and "CEPHALEXIN (2.4ML MOLD) 375MG SUPPOSITORY", are produced in hoods (b) (4) , and (b) (4) in "Lab (b) "/ "Lab (b) ". On 08/29/2022, we observed Technician (b) (6) producing Rx (b) (6) , as "SUCRALFATE 2GM/60ML ENEMA" in hood (b) (4) in Lab (b) (4)

Hazardous drugs, such as "METHIMAZOLE (ANIMAL) 5MG/ML FIXED OIL", are produced in hood (b) (4) in the hazardous suite. On 08/29/2022, Technician (b) (6) produced " (b) (4) NO CLINDA-TRET0.06%/HA0.5%/NIACINAMIDE3%/AA 1%(FROM STOCK) NOURISIL", lot 0829202218, in

part in hood (b) (4).

C. On 09/02/2022, we observed reddish-brown discoloration on the HEPA filter of (b) (4) airflow (b) (4) hood (b) (4) ((b) (4)) located in the "Nonhazardous Compounding (b) (4) " room. (b) (4), such as " (b) (4) : CLINDA PH 1%/TRET 0.02%/NIAC 4%/AZELAIC 5% (b) (4) 0.02% (b) (4) ", are produced, in part, in hood (b) (4) in the "Nonhazardous Compounding ((b) (4))" room.

D. On 08/30/2022, we observed (b) (4) (with the product name, (b) (4) topical finasteride & minoxidil"), container closures (empty glass bottles) being transported from outside the building into the front entrance by Lab Assistant (b) (6). According to Pharmacist-In-Charge (b) (6), the interior surfaces of the bottles are not cleaned prior to filling them with the topical solution product. Inventory Coordinator (b) (6) explained that when space is limited inside the firm, the unpackaging of the individually wrapped glass bottles, and placing them into (b) (4) bins, occurs behind the facility. The bins containing glass bottles are then transported into the facility for use in production.

E. On 08/29/2022, we observed materials that are not easily cleanable, such as tape and a tan colored thin paper-like covering, being used as coverings of (b) (4) on multiple (b) (4) (hoods (b) (4) , and (b) (4)).

OBSERVATION 2

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

Specifically,

A. On 09/07/2022, Technician (b) (6) did not use a deactivating or decontaminating agent to clean a (b) (4) spatula after it was used in the production of Rx (b) (6), " (b) (4) : HYDROQUINONE 4%/ TRETINOIN 0.025%/HYDROCORTISONE 1% NOURISIL", in the hazardous product area. The same (b) (4) spatula was subsequently used in the production of Rx (b) (6) , "C-TESTOSTERONE 178MG/ML". Similarly, a (b) (4) stirring rod was used in the production of "METHIMAZOLE (ANIMAL)(STOCK)", lot 09072022@ (b) (4), and then it was wiped with a paper towel dampened with (b) (4)

(b) (4) and placed back into a container holding other utensils for use in further production operations. The (b) (4) stirring rod is one of (b) (4) (b) (4) stirring rods utilized in production of drug products within biological safety cabinet (b) (4). Quality Department personnel explained that the cleaning process between different hazardous drug products includes wiping work surfaces and utensils with (b) (4) as a deactivating and decontaminating agent. (b) (4) was not used to clean these two utensils.

B. On 09/07/2022, we observed Technician (b) (6) using a (b) (4) mixing blade, stored outside the hazardous suite, inside the hazardous suite to produce "(b) (4) TRANEX ACID 6%/AZEL ACID 10%/ KOJI ACID 6%/ASO ACID1%/NIAC 2% ANHYDR/SILIC", lot 090420228. Quality Control Manager (b) (6) explained the blades are used in the production of both hazardous and non-hazardous drug products. The technician did not wipe the (b) (4) mixing blade with any cleaning agents prior to assembling it onto the mixer.

C. There is no assurance that your cleaning process removes product and cleaning agent residue from your (b) (4) glassware and utensils used in non-sterile hazardous and non-hazardous production areas. (b) (4) dish detergent and a (b) (4) sponge are used to (b) (4) clean (b) (4) spatulas, glassware, (b) (4) sieves, capsule machine parts, (b) (4) mortar and pestle jars and spindles, and (b) (4) mortar and pestle sets. Some undefined utensils are also washed in a (b) (4) using a (b) (4) detergent (b) (4). On 08/30/2022 and 09/07/2022, we observed technicians cleaning equipment and utensils with the aforementioned dish detergent.

OBSERVATION 3

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, on 08/29/2022, we observed naltrexone HCl capsules, lot 0825202226, being produced in the dedicated "Non-Hazardous Compounding ((b) (4))" room. We observed inconsistent fill heights of the drug (b) (4) mixture loaded into the individual capsules in the (b) (4) capsule machine. Approximately 50 out of (b) (4) capsules were filled at a noticeably lower (b) (4) fill height than the others.

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*DATES OF INSPECTION

8/29/2022(Mon), 8/30/2022(Tue), 8/31/2022(Wed), 9/01/2022(Thu), 9/02/2022(Fri), 9/06/2022(Tue), 9/07/2022(Wed), 9/09/2022(Fri)

X Jessica S Estriplet
Investigator
Signed By: Jessica S. Estriplet -S
Date Signed: 09-09-2022 18:39:45

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EMPLOYEE(S) SIGNATURE

Sena G Dissmeyer, Investigator
Jessica S Estriplet, Investigator

X Sena G Dissmeyer
Investigator
Signed By: Sena G. Dissmeyer -S
Date Signed: 09-09-2022 18:39:16

DATE ISSUED
9/9/2022

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."