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	8/26/2020-10/9/2020* FEI NUMBER 3011761882

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark K. Taylor, Owner and pharmacist-in-charge

FIRM NAME	STREET ADDRESS
EHT Pharmacy 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, On 8/26/2020, I observed the tableting room had a fine blue dust/residue coating the walls, ceiling, ceiling vent, blender lid, humidifier, air conditioner and a darker accumulation of the blue dust/residue on the wheels of your stationary blender. This blue colored dust/residue, which is generated during the production of tadalafil and sildenafil, was so pervasive that it had infiltrated into the other production areas of your facility.

On 09/01/2020, the room was reported to be clean, however the blue dust/residue was observed in the humidifier and as a coating on other surfaces.

The blue dust/residue was observed within your Non-Hazardous and Hazardous Rooms. For example, I observed a blue residue inside the unsealed transfer holes that lead to the Hazardous Room. The products compounded in these rooms do not contain blue coloring.

On 09/03/2020, production of Tadalafil 6mg lot P51 was observed in the tableting area. At the same time, in the Hazardous room a hazardous dermatological drug product ((b) (4)) was being produced.

Your firm uses all rooms to produce drug products. The production log shows that on a given day your firm produced approximately (b) (4) drug products. These include but are not limited to: tadalafil 6mg, tadalafil 9mg, dexamethasone phonophoresis 0.3% gel, tramadol 25mg/ ketorolac 10mg troches, and omeprazole (flavored) 2mg/ml suspension.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nancy M Espinal, Investigator William J Muszynski, Investigator	X Nancy M Espinal Investigator Signed By: 2001865749 Date Signed: 10-09-2020 12:28:09	10/9/2020

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OBSERVATION 2

Laboratory analysis of hormone sample determined the strength was below the declared label claim.

Specifically, On 09/01/2020, I observed (b) (4) had a failing potency result. The contract testing laboratory notified your firm on 07/14/2020 that the (b) (4) test result was 89.6% (Spec: (b) (4)). The failing result was confirmed by the contract testing laboratory. The stock drug (b) (4) was used in the production of approximately 9 other drug products.

On 09/03/2020, when asked if there was an investigation, the director of regulatory, quality and compliance provided a corrective action document with the date of 07/08/2020 for the failing product. I noted that the date of the corrective action was 6 days before the initial failure was notified (07/14/2020).

The pharmacist-in-charge verified and stated the corrective action had not been conducted for drug produced on 08/12/2020 using the failing (b) (4) stock.

(b) (4) has a beyond use date of 12/22/2020.

The record for (b) (4) does not have a weight for the ingredient, (b) (4) There was no deviation or investigation into this error. According to the "OUT OF SPECIFICATION INVESTIGATION" standard operating procedure section 8.4-8.5, all deviations must be documented and all validation failures must have a formal investigation and action plan.

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	Nancy M Espinal, Investigator William J Muszynski, Investigator X Nancy M Espinal Investigator Signed By 2001865749 Date Signed 10-09-2020 12 28 09	10/9/2020

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OBSERVATION 3

Buildings used in the processing of a drug product are not maintained in a good state of repair.

Specifically, I observed the wall in the Hazardous room and your compounding equipment cleaning area in disrepair.

For example,

A) I observed that the wall between the tablet compounding room and the Hazardous room has unsealed holes where blue residue/dust was observed. I observed the blue residue/dust on the perimeter of the wall (i.e. ceiling, floor and sides).
B) Equipment found drying near a yellow painted wall. The wall was torn, scratched, discolored and had dry wall exposed.

***DATES OF INSPECTION**

8/26/2020(Wed), 8/27/2020(Thu), 9/01/2020(Tue), 9/03/2020(Thu), 9/21/2020(Mon), 9/22/2020(Tue), 9/23/2020(Wed), 9/24/2020(Thu), 10/07/2020(Wed), 10/09/2020(Fri)

X William J Muszynski
Investigator
Signed By: William Muszynski -S
Date Signed: 10-09-2020 12:28:45

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nancy M Espinal, Investigator William J Muszynski, Investigator	X Nancy M Espinal Investigator Signed By: 2001865749 Date Signed: 10-09-2020 12:28:09	10/9/2020

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."