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	11/1/2022-11/10/2022* FEI NUMBER 2245641

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. David R. Blair, Site General Manager

FIRM NAME	STREET ADDRESS
TEVA Pharmaceuticals USA, Inc.	8 Gloria Ln # 10
CITY, STATE, ZIP CODE, COUNTRY Fairfield, NJ 07004-3306	TYPE ESTABLISHMENT INSPECTED Finished 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

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

During the inspectional walkthrough of your facility on 11/01/2022, we observed build-up of unknown residue in multiple locations within two production rooms that were documented as Major Cleaned. For example,

- Unknown pink/red residue was found on the (b) (4) of the (b) (4) Blender (A-1) in Mixing Room (b) (4). The last drug product manufactured on this equipment was Cefadroxil 500mg capsules (Batch/Lot #2000058803). The blend of Cefadroxil 500mg capsule formulation does not include any dye/flavor, however, the previous batch/lot manufactured on this equipment was a campaign of three (3) batches/lots of Cephalexin FOS 250mg/5ml (Batch/Lot #s 2000056923, 2000056924, and 2000056925). The blend of Cephalexin FOS 250mg/5ml include cherry flavor and FD&C Red #40 in the formulation.
- Unknown residue was found on the outside surface of the (b) (4) Blender in Mixing Room (b) (4).
- Unknown residue was found on the (b) (4) workstation located in Mixing Room (b) (4)
- Unknown residue was found on the (b) (4) of the (b) (4) Blender in Mixing Room (b) (4). The last U.S. marketed drug product manufactured on this equipment was Cephalexin 500mg capsules (Batch/Lot #30312170)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica S Estriplet, Investigator Brandy N Lepage, Investigator Jogy George, Investigator * * Supervisory Investigator (JG)	X Jessica S Estriplet Investigator Signed By: Jessica S Estriplet -S Date Signed: 11-10-2022 14:35:18	11/10/2022

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The equipment logbooks for both rooms were documented to have undergone major cleaning. This major cleaning activity was performed and verified by production personnel.

OBSERVATION 2

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

- You currently have (b) (4) equipment with IDs: (b) (4) (b) (4) and (b) (4) on-site. The current equipment qualification report, dated 1994, is documented as qualified for Cephalexin 250mg capsules. However tablet products have been inspected on the (b) (4) equipment. For example, (b) (4) was used to screen approximately (b) (4) batches/lots of several commercial tablet and capsule products from (b) (4) to (b) (4). Additionally, (b) (4) was used to screen approximately (b) (4) batches/lots of several commercial tablet and capsule products from (b) (4) to (b) (4) The Site Quality Management stated that this equipment is no longer in-use, however, there are no procedural controls that prevent the future use of this equipment.
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OBSERVATION 3

Deviations from written production and process control procedures are not recorded and justified.

Specifically,

- Cephalexin Tablets 500mg (Batch/Lot #30309389) had two (2) reported complaints. This lot/batch was part of a trend investigation for defective coating covered under (b) (4) PR ID #1392935. As part of the complaint investigation, the batch was subjected to additional

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Level II AQL tests. Subsequently, the same batch/lot was run through a screening equipment (b) (4) that was not documented as qualified with tablet products. The (b) (4) report (PR ID #1392935) and your applicable SOP(s) on AQL tests are silent on the circumstances that dictate the use of (b) (4) for the screening of tablets. After screening with (b) (4) investigation states that 21.3kg (34,466 tablets) were rejected. The remaining tablets were packaged and released for U.S. distribution in February 2018.

☐Cephalexin Tablets 500mg (Batch/Lot #30310836), with similar defective coating (as described above for batch/lot #30309389) was investigated under (b) (4) PR ID #1662029. This batch was rejected after Level II AQL test yielded failing results.

☐From November 2018 to March 2021, the firm recorded approximately 30 complaints related to defective coating for Cephalexin Tablets 500mg. Coating process enhancements were recommended based on CAPA PR ID #1473451 (created November 2019). An additional CAPA PR ID #1687925 (created July 2020) to implement the process enhancements are still pending.

***DATES OF INSPECTION**

11/01/2022(Tue), 11/02/2022(Wed), 11/03/2022(Thu), 11/04/2022(Fri), 11/07/2022(Mon), 11/09/2022(Wed), 11/10/2022(Thu)

X Jogy George
Investigator
Signed By: 2001622444
Date Signed: 11-10-2022 14:36:58

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica S Estriplet, Investigator Brandy N Lepage, Investigator Jogy George, Investigator* * Supervisory Investigator (JG)	X Jessica S Estriplet Investigator Signed By: Jessica S Estriplet -S Date Signed: 11-10-2022 14:38:18	11/10/2022