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	1/23/2017-2/1/2017* FEI NUMBER 2245641

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Robert Parra , Director of Operations, Plant Manager	
FIRM NAME TEVA Pharmaceuticals USA, Inc.	STREET ADDRESS 8 Gloria Ln # 10
CITY, STATE, ZIP CODE, COUNTRY Fairfield, NJ 07004-3306	TYPE ESTABLISHMENT INSPECTED Drug 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

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

Specifically,

1. Your electronic Batch Record Review Checklist Forms used in the batch records, such as forms F-668, F-669, F-671, F-672, F-673, and F-675, Batch Record Review Checklist, revision 7, have multiple manual corrections as far back as October 2015. You firm failed to document changes on the forms through the procedure SOP-2165, revision 36, Preparation, Change Request, Routing and Approval of Electronic Procedures in Master Control, which requires change request of the forms through the electronic Document Control System. These forms have been corrected on multiple dates, and issued by your quality group from the saved (b) (4) version of the electronic master control record with hand-written corrections, which deviates from the approved forms in your Document Control System.

2. Your firm did not investigate the malfunction of the temperature chart located in the warehouse (b) (4) location M18 for a period 6/1-8/2016. Upon finding the issue on 06/08/2016, your quality group did not initiate a deviation, and did not conduct any investigation as outlined in 6.2.6 of the firm's internal procedure SOP-2290, revision 12, Recording Temperature in the Warehouse, Cold Storage Box(s) Trailer, Encapsulation Department Storage Area/Corridor, and Granulation Staging/Storage Areas. In addition, the quality group added a comment on the chart on 08/02/2016 that the temperature chart pen was stuck, and was fixed on 06/08/2016 with no further actions taken.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Helen Verdel, Investigator Niketa Patel, Investigator	2/1/2017 X Helen Verdel Helen Verdel Investigator Signed by: Helen Verdel -S	2/1/2017

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

OBSERVATION 2

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

Specifically,

1. On 01/23/2018, we observed forklift (b) (4) heavily covered in rust that is used for bringing final blend to encapsulation manufacturing room. In addition, your firm failed to follow your internal procedure SOP-2323, Cleaning of (b) (4) (b) (4) which requires in 6.1.4 to inform Supervisor if any problems with equipment observed.

2. In Mixing Rooms (b) (4) (b) (4), we observed (b) (4) PTFE (Polytetrafluoroethylene) spatulas with dents and approximately a 1 inch loose piece. In addition, your procedure SOP-8111, Granulation Room Clearance, does not include inspection of utensils before use.

OBSERVATION 3

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

Your firm performs (b) (4) on High Performance Liquid Chromatography (HPLC). These (b) (4) are not included in the instrument logbook or included with the final data package.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Robert Parra , Director of Operations, Plant 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 Drug Manufacturer

a) On 10/27/2016 and 11/01/2016, an analyst performed an assay test for Cephalexin Capsules USP, 500mg, Lot # 30308422, 30308423 and 30308424 on HPLC system (b) (4) and collected data using (b) (4) software. However,(b) (4) (b) (4) were made prior to analysis of system suitability and were not documented.

b) On 12/01/16 and 12/29/2016, an analyst performed an assay and impurity test for Cephalexin for Oral Suspension, USP 250mg/5mL, Lot # 30308647, 30308648 and 30308649 on HPLC system #(b) (4) and collected data using (b) (4) software. However, (b) (4) were made prior to analysis of system suitability and were not documented.

***DATES OF INSPECTION**
1/23/2017(Mon),1/24/2017(Tue),1/25/2017(Wed),1/26/2017(Thu),1/31/2017(Tue),2/01/2017(Wed)
2/1/2017

X Niketa Patel
Niketa Patel
Investigator
Signed by: Niketa Patel -S

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