DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	10/31/2017-11/17/2017* FEI NUMBER 3010299526

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Gary K. Rice, Executive VP of Operations

FIRM NAME	STREET ADDRESS
Diplomat Pharmacy Inc. dba Diplomat Specialty Pharmacy	4100 S Saginaw Street
CITY, STATE, ZIP CODE, COUNTRY Flint, MI 48507-2687	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and 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

The ISO 5 classified aseptic processing areas had difficult to clean equipment or surface.

Specifically, rust-colored residues and discolorations were observed on your facility's ISO 5 (b) (4) laminar flow hoods and HEPA filter screens.

ISO 5 Hoods	Residue/Discoloration Locations	
(b) (4) Laminar Flow Hood	HEPA Filter Screens	Hoods
(b) (4)		

On 10/31/17 during the processing of Enoxaparin Lot 10312017@1 for prescriptions (b) (6) and (b) (6), and Neupogen Lot 10312017@2 for prescriptions (b) (6), and (b) (6) in hood (b) (4), we observed rust-colored residues on the HEPA filter screen. We also observed difficult to clean, rust-colored residues embedded in the crevasses on the bottom left panel of hood (b) (4) specifically between the critical ISO 5 working surface and the side panel. The following drug products are routinely processed aseptically inside these ISO 5 hoods: Enoxaparin, Neupogen, and Procrit.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Emily J Orban, Investigator Bei Y He, Investigator	X Emily J Orban Investigator Signed By 2000532336 Date Signed 11-17-2017 10 36 43	11/17/2017

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OBSERVATION 2

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 10/25/17, your firm received out-of-specification (OOS) potency test results for Dexamethasone 40 MG CAP. lot 10052017@7 and 10 MG CAP. lot 10052017@5. The "formula worksheets" showed these two lots were produced at your facility on 10/5/17. The potency test performed on 10/19/17 by your contract laboratory for these two lots had OOS results of 153% and 143%, respectively for Dexamethasone 40 MG and 10 MG capsules (specification (b) (4) %). Additional samples were sent for retesting to the same contract laboratory and to a second contract laboratory on 10/25/17; both re-test sample results were within specification.

After receiving the OOS results, all remaining inventory of Dexamethasone 40 MG CAP. lot 10052017@7 and 10 MG CAP. lot 10052017@5 were removed from the dispensing center. However, prior to obtaining the OOS potency results, the following prescriptions had already been dispensed to patients for Dexamethasone lot 10052017@5 and 10052017@7:

Prescriptions dispensed to patients from 10/5/17 to 10/12/17:	
40 MG Dexamethasone Lot 10052017@7, Capsules (b) (6)	**10 MG Dexamethasone** Lot 10052017@5, Capsules (b) (6)

OBSERVATION 3

Inadequately protected product intended to be sterile was exposed to lower than ISO 5 classified aseptic processing area quality air.

Specifically,

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On 10/31/17, we observed the HEPA filter patch in hood (b) (4) to be greater than (b) (4) in size. The HEPA filter patch was measured by your firm to be 4.5" X 1.5"; however, your vendor's procedure states that (b) (4) should exceed or be greater than (b) (4) in size. Since this HEPA filter repair dated 11/18/16, your firm has continued to aseptically process drug products such as Enoxaparin, Neupogen, and Procrit for patients in hood (b) (4)

OBSERVATION 4

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, the cleaning wipes used in the ISO 5 classified aseptic processing areas are not sterile.

Non-sterile low-linting wipes were observed to be used during aseptic processing on 10/31/17. Prior to and after each prescription filled in the hoods, non-sterile wipes were observed to be sprayed with sterile (b) (4) and used to sanitize the critical ISO 5 working surfaces in hood (b) (4) and in the (b) (4). In addition, prior to transferring materials into the hoods, the technician was observed wiping the materials with the non-sterile wipes sprayed with sterile (b) (4). For example, we observed the following drug products processed on 10/31/17:

- Enoxaparin Lot 10312017@1 for prescriptions (b) (6) in hood (b) (4)
- Neupogen Lot 10312017@2 for prescriptions (b) (6) and (b) (6) in hood (b) (4)
- Synribo Lot 10312017@3 for prescription (b) (6) in the (b) (4)

***DATES OF INSPECTION**

10/31/2017(Tue), 11/01/2017(Wed), 11/02/2017(Thu), 11/03/2017(Fri), 11/08/2017(Wed), 11/17/2017(Fri)

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X Bei Y He
Investigator
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EMPLOYEE(S) SIGNATURE

Emily J Orban, Investigator
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Investigator
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DATE ISSUED
11/17/2017