

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Rm 900 U.S. Customhouse 200 Chestnut Street Philadelphia, PA 19106 215-597-4390 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 7/18-21/2017
	FEI NUMBER 3013075945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Matthew S. Valasek, R.Ph, MBA, Director of Pharmacy Operations

FIRM NAME Diamond Drugs, Inc.	STREET ADDRESS 645 Kolter Drive
CITY, STATE AND ZIP CODE Indiana, PA 15701	TYPE OF ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drugs

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 (I) (WE) OBSERVED:

OBSERVATION 1

The ISO 5 laminar air flow hood was not certified under dynamic conditions.

Specifically, there is no evidence to demonstrate that dynamic smoke studies of the ISO 5 laminar air flow hood have been conducted in order to assess uni-directional air flow under actual conditions. Sterile products produced in the ISO 5 laminar air flow hood include Vancomycin 1.4gm/D5W, Penicillin G Potassium 20000000 Unit Solution, and Daptomycin in Normal Saline 170mg/10ml.

OBSERVATION 2

Disinfecting agents used in the ISO 5 laminar air flow hood are not sterile.

Specifically, the non-sterile disinfecting solution (b) (4) was used on a (b) (4) as a cleaning agent in the ISO 5 laminar air flow hood.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nancy Scheraga -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Nancy F. Scheraga, CSO	DATE ISSUED 07/21/2017
	<small> This label prepared by Nancy Scheraga, S DR on US Govt's Governmental org-495 org-FDA on-Profile on-Nancy Scheraga, S 0 9 2342 19200300 100 1 1-2001915534 date 2017 07 21 14 59 28 04 00 </small>		