

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

300 River Place, Suite 5900
Detroit, MI 48207
(313) 393-8100 Fax: (313) 393-8139

Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

06/05-08/2017, 06/14/2017, 06/19/2017

FEI NUMBER

3011130315

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Bradley J. McCloskey, Pharmacist In Charge

FIRM NAME

Diversified Pharmacy Inc.

STREET ADDRESS

6054 Livernois Road

CITY, STATE AND ZIP CODE

Troy, MI 48098

TYPE OF 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 (I) (WE) OBSERVED:

Observation 1

The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically,

On 06/06/2017 during aseptic processing of methylcobalamin 1000 mg, a large patch of white residue was observed on the HEPA filter grate of an ISO5 hood being used. Your firm described this residue as a glare that was unable to be cleaned. On 06/07/2017, during the aseptic processing of Bimix (lot #06072017@28), we observed that this residue was no longer present,

Observation 2

ISO5 classified areas were not certified under representative dynamic conditions.

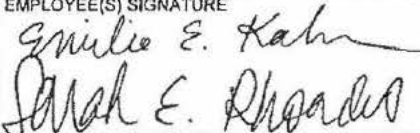
Specifically,

Smoke studies performed in the ISO5 laminar flow hoods were not performed under dynamic conditions that represent your aseptic processing practices. The dynamic smoke study videos that we viewed demonstrated an operator standing (b) (4). This was not representative of any of the aseptic operations that we observed between 06/06-07/2017. For example, we observed aseptic processing of Bimix (lot #06072017@28), on 06/07/2017, that included a (b) (4) all of which may affect laminar air flow.

Observation 3

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination

Specifically,

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (Print or Type) | DATE ISSUED |
|--------------------------|---|--|-------------|
| |  | Emilie E. Kahn, Investigator Sarah E. Rhoades, Investigator | 06/19/2017 |

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1. Glassware and stainless steel spatulas and spoons used, for non-sterile processing are only wiped with (b) (4) between use. These utensils are not product dedicated and your firm did not provide any assurance that residue from hazardous ingredients is removed after use.

For example, on 06/02/2017, Tretinoin 0.5 mg/gm moisturel with lot #06022017@96 and Estradiol 0.4 mg/gm emollient cr with lot #06022017@102 were processed without assurance that cross contamination via utensils was prevented. You provided a list of hazardous drugs processed with shared utensils, including Anastrozole, Letrozole, Cyclosporine, Azathioprine, Cloniphene, Colchicine, and Fluconazole.

2. Containers used to reduce drug substances from bulk stock may be used across products. Your firm could not provide any assurance that cross-contamination would be prevented or that these containers are product dedicated. You firm stated that hormones such as testosterone and progesterone are examples of "fast-mover" ingredients that may utilize this storage process.

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Emilie E. Kahn
Sarah E. Rhoades

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Emilie E, Kahn, Investigator
Sarah E. Rhoades, Investigator

DATE ISSUED

06/19/2017