DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 4040 North Central Expressway, Suite 300<br>Dallas, TX 75204<br>(214) 253-5200 Fax:(214) 253-5314<br>Industry Information: www.fda.gov/oc/industry | 05/28/2015 - 06/05/2015*<br>FEI NUMBER<br>3011043554 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Luis Ricardo de Leon, Executive Officer and Pharmacist in Charge

| FIRM NAME | STREET ADDRESS |
|---|---|
| Pharm D Solutions, LLC | 1304 S Loop W |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Houston, TX 77054-4010 | Outsourcing Facility |

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 OBSERVED:**

## OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

A) Your media fill simulations are not performed under the most stressful and challenging conditions. For example,

1. The media fills dated 4/2/2015 and 4/6/2015 were conducted with a total of (b) (4) vials ((b) (4) control and (b) (4) test vials). The (b) (4) lots produced on 5/26/2015 consisted of syringes and eye droppers which were not evaluated in the media fills.

2. The media fills dated 4/2/2015 and 4/6/2015 failed to simulate the set-up process using (b) (4) . For example, the product "Columbus Quad Opthalmic Compound Opthalmic" (Ketorolac Tromethamine, USP 0.5%, Phenylephrine HCl, USP 2.5%, Tropicamide, USP 1%, Tetracaine HCl, USP 0.5%), lot # 05261503-JDL required the use of (b) (4) . The media fills utilized (b) (4) in the final preparation.

3. The media fills dated 4/2/2015 and 4/6/2015 were not performed under conditions which simulate actual production.

## OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm's procedures for monitoring the (b) (4) ISO 5 LAF hood are not suitable to ensure the quality of air. For example,

A) During periods of production, your firm does not conduct viable air monitoring or surface sampling (b) (4)

B) Testing for non-viable particulates is not conducted under dynamic conditions.

C) Your firm has not conducted surface monitoring of the pass through window between the (b) (4) ISO 7 rooms.

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**OBSERVATION 3**

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

Specifically, suitability testing for your (b) (4) test used to assess the sterility of finished drug products has not been performed. In addition, negative controls were not utilized.

**OBSERVATION 4**

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A) The pressure differentials are not alarmed. In addition, the pressure differentials are checked only at (b) (4) (b) (4) (b) (4).

B) In regard to smoke studies, on 6/1/2015, your firm placed a (b) (4) of the (b) (4) ISO 5 laminar flow hood and (b) (4) However, the study is incomplete in that:

1. Your firm failed to establish a protocol describing the acceptance criteria for the study.

2. The smoke study was not performed under dynamic conditions to verify that the operator or activities in the ISO 7 cleanroom do not affect the unidirectional airflow from the HEPA filters in the ISO 5 hood where drug products are produced.

**OBSERVATION 5**

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, your production records do not include a description of of the production process including (b) (4)

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## OBSERVATION 6

Batch production and control records do not include complete labeling control records, including specimens or copies of all labeling used for each batch of drug product produced.

Specifically, the specimens/copies of labels for the drug products which comprise the Quad Opthalmic Compound have not been retained.

## OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

A) SOP #5.002 entitled, "(b) (4) Cleaning of the Ante Room, Buffer Room, and Clean Room" (Undated) does not include requirements for the contact time for (b) (4) or (b) (4) disinfectants. The labeling for the products documents a (b) (4) minute contact time.

B) The (b) (4) and (b) (4) disinfectants are not (b) (4)

C) Your firm does not routinely use a sporicidal agent in the ISO 5 or 7 areas. In addition, SOP #5.002 has no requirements for the use of a sporicidal agent.

## OBSERVATION 8

The labels of your outsourcing facility's drug products are deficient.

Specifically the labels do not include information required by section 503B(a)(10)(A) and (B).

For example, your drug product labels do not contain the following:

1) The statements "This is a compounded drug" and "Office Use Only"
2) The date the drug was compounded.

In addition, the following information is not included on container labels for some drug products you produce:

1. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088

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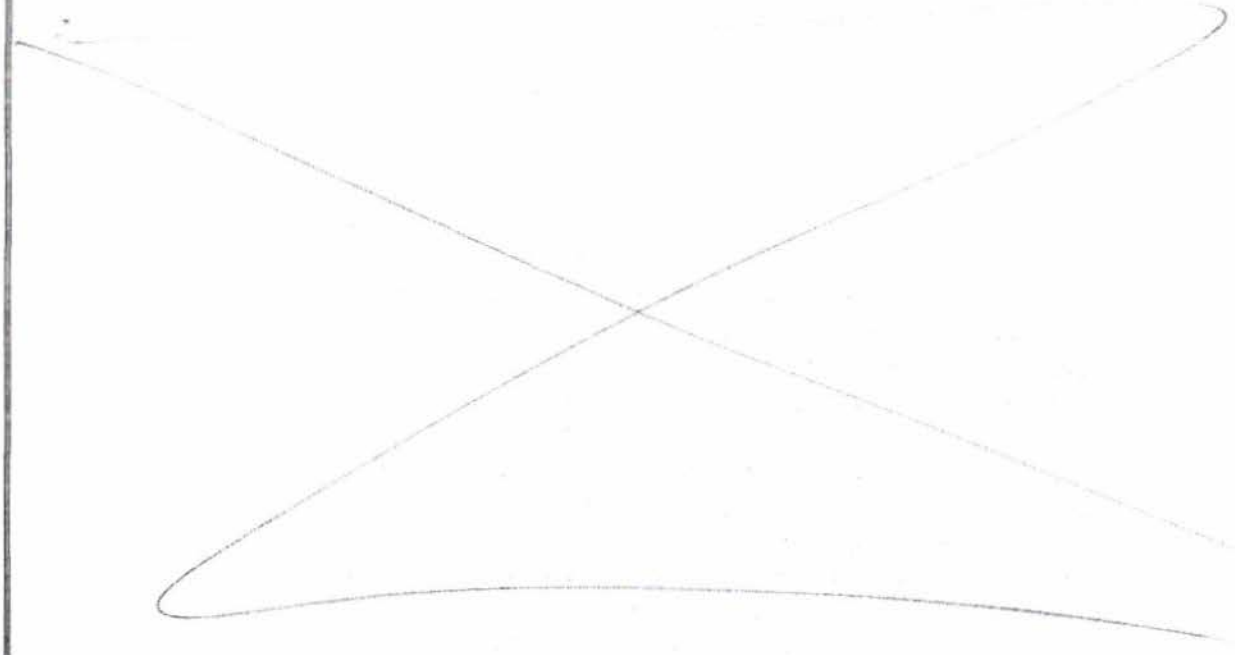
2. Directions for use including as appropriate, dosage and administration.

Examples of drug product labels which do not have this information include the following:

A) "Epinephrine 1:1000 0.2ml 0.2mg Injectable" (Epinephrine, USP 1mg/ml), lot #05261501-JDL (Production date: 5/27/2015, Expiration: 6/24/15)
B)"Columbus Quad Opthalmic Compound Opthalmic" (Ketorolac Tromethamine, USP 0.5%, Phenylephrine HCL, USP 2.5%, Tropicamide, USP 1.0%, Tetracaine HCl, USP 0.5%), lot #05261503-JDL (Production date: 5/27/2015, Expiration: 06/24/15)
C) "Vigamox Opthalmic Solution" (Moxifloxacin 0.5% (base), USP), lot #05261502-JDL (Production date: 5/27/2015, Expiration: 06/24/15)

*** DATES OF INSPECTION:**
05/28/2015(Thu), 05/29/2015(Fri), 06/01/2015(Mon), 06/02/2015(Tue), 06/05/2015(Fri)



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