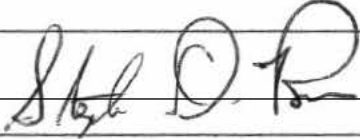



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 05/28/2015 - 06/05/2015*
		FEI NUMBER 3011043554
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED <b>TO: Luis Ricardo de Leon, Executive Officer and Pharmacist in Charge</b>		
FIRM NAME Pharm D Solutions, LLC	STREET ADDRESS 1304 S Loop W	
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77054-4010	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
<p>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.</p>		
<b>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</b>		
<b>OBSERVATION 1</b>		
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 Ophthalmic Compound Ophthalmic" (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) (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.		
<b>OBSERVATION 2</b>		
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.		
<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Stephen D. Brown, Investigator	DATE ISSUED 06/05/2015
		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
		PAGE 1 OF 4 PAGES





DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		DATE(S) OF INSPECTION 05/28/2015 - 06/05/2015*
		FEI NUMBER 3011043554
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED <b>TO:</b> Luis Ricardo de Leon, Executive Officer and Pharmacist in Charge		
FIRM NAME Pharm D Solutions, LLC	STREET ADDRESS 1304 S Loop W	
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77054-4010	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
<b>OBSERVATION 6</b>		
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 Ophthalmic Compound have not been retained.		
<b>OBSERVATION 7</b>		
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.		
<b>OBSERVATION 8</b>		
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: <a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a> and 1-800-FDA-1088		
<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Stephen D. Brown, Investigator 	DATE ISSUED 06/05/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>		<small>DATE(S) OF INSPECTION</small> 05/28/2015 - 06/05/2015*	
		<small>FEI NUMBER</small> 3011043554	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> <b>TO:</b> Luis Ricardo de Leon, Executive Officer and Pharmacist in Charge			
<small>FIRM NAME</small> Pharm D Solutions, LLC		<small>STREET ADDRESS</small> 1304 S Loop W	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Houston, TX 77054-4010		<small>TYPE ESTABLISHMENT INSPECTED</small> Outsourcing Facility	
<p>2. Directions for use including as appropriate, dosage and administration.</p> <p>Examples of drug product labels which do not have this information include the following:</p> <p>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)</p> <p>B) "Columbus Quad Ophthalmic Compound Ophthalmic" (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)</p> <p>C) "Vigamox Ophthalmic Solution" (Moxifloxacin 0.5% (base), USP), lot #05261502-JDL (Production date: 5/27/2015, Expiration: 06/24/15)</p>			
<p><b>* DATES OF INSPECTION:</b>                      05/28/2015(Thu), 05/29/2015(Fri), 06/01/2015(Mon), 06/02/2015(Tue), 06/05/2015(Fri)</p> <div style="text-align: center; font-size: 4em; opacity: 0.5;">X</div>			
<b>SEE REVERSE OF THIS PAGE</b>	<small>EMPLOYEE(S) SIGNATURE</small> Stephen D. Brown, Investigator		<small>DATE ISSUED</small> 06/05/2015