DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	09/22/2015 - 11/05/2015* FEI NUMBER 3011893599

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Nayan (nmi) Patel, Pharm.D., President

FIRM NAME	STREET ADDRESS
Auro Pharmacies, Inc.	520 W La Habra Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
La Habra, CA 90631-5308	Producer of 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 OBSERVED:

OBSERVATION 1

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

Specifically,

A. Your firm did not perform endotoxin testing before the product was released. For example,

Products	Lot #	Date Endotoxin tested	Date Released
Ascorbic Acid 500 mg/ml with preservative	150821@1	Not tested	09/04/15
	150821@3	Not tested	09/04/15
Glutathione 200 mg/ml with preservative	150819@34	10/15/15	09/02/15
	150901@58	Not tested	09/15/15
	150902@16	10/02/15	09/15/15
Ascorbic Acid 500 mg/ml preservative free	150827@4	09/28/15	09/10/15
	150803@28	09/24/15	08/17/15
	150804@45	Not tested	08/18/15

For Ascorbic Acid 500 mg/ml with preservative, sublot 150821@1 and 150821@3 were not tested. Sublot (b) (4) (b) (4) sublot (b) (4) and (b) (4) was selected for endotoxin testing.

For Glutathione 200mg/ml with preservative, sublot 150901@58 was not tested. Sublot (b) (4), (b) (4); sublot (b) (4), was selected for endotoxin testing.

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For Ascorbic Acid 500mg/ml preservative free, sublot 150804@45 was not tested. Sublot (b) (4), (b) (4) (b) (4), was selected for endotoxin testing.

B. Your firm does not performed endotoxin testing on every sublot manufactured of the finished sterile drug product. Your firm manufactures (b) (4) of the sterile drug product and (b) (4) is selected for endotoxin testing.

C. Your endotoxin (b) (4) method has not been validated to ensure the reliability of the results generated by the test method.

D. Your firm's sterility test method is inadequate in that suitability was not determined for the following products:

1) Ascorbic Acid 500mg/ml preservative free. The suitability test conducted by an outside laboratory was a (b) (4) method. Your firm is using (b) (4) method.

2) Glutathione 200 mg/ml with preservative. This sterile drug product has (b) (4) as preservative.

E. The number of container taken for the sterility testing is inadequate in that (b) (4) taken for sterility testing regardless of how many vials filled during processing of sterile drug products. For example,

1) Ascorbic Acid 500 mg/ml Injection with Preservative Lot# 150821@1 (b) (4) vials)

2) Ascorbic Acid 500 mg/ml Injection Preservative Free Lot# 150803@28 (b) (4) vials)

3) Ascorbic Acid 500 mg/ml Injection Preservative Free Lot# 150819@4 (b) (4) vials)

4) Ascorbic Acid 500 mg/ml Injection Preservative Free Lot# 150902@10 (b) (4) vials)
5) Glutathione 200 mg/ml Injection with Preservative Lot# 150812@48 ((b) (4) vials)
6) Glutathione 200 mg/ml Injection with Preservative Lot# 150819@34 (b) (4) and (b) (4) vials)
7) Glutathione 200 mg/ml Injection with Preservative Lot# 150902@16 (b) (4) vials)

OBSERVATION 2

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

Specifically,

A. Your firm does not perform the (b) (4) (b) (4) after processing and filling of bulk sterile drug solutions into the finished vial (b) (4) the solutions.

B. Process simulations conducted by your firm is inadequate in that growth promotion was not conducted on the media used to perform the process simulation to ensure that it can support microbiological growth.

C. Your firm has not conducted process simulation of the lyophilization process including the (b) (4) (b) (4)

D. You firm has not conducted process simulation for the (b) (4) and (b) (4) of the vial and rubber stoppers for use in aseptc procesing.

E. Your firm has not validated the lyophilization (b) (4) for use in manufacturing of the following sterile drug products:

1) HCG Injection

2) Glutathione Lyophilize 600 mg/vial Injection

F. On 09/24/2015, an operator was observed placing hands on the surface of the laminar flow hood and continue to perform aseptic processing without sanitizing the gloves. The operator was processing Ascorbic Acid 500mg/ml with preservative Lot # 150924@4.

G. On 09/24/2015, an operator was observed sitting down on a chair with elbow on the surface of the laminar flow hood and leaning forward inside the laminar flow hood during the aseptic processing operation. The operator was processing Germanium Sesquioxide Injection 100 mg/ml Lot # 150923@3.

OBSERVATION 3

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

Specifically,

Your environmental monitoring program of the aseptic processing is inadequate in that

A. Viable air environmental monitoring stopped on 08/12/15 because of a (b) (4) . No viable air monitoring has been performed until the (b) (4) on 10/5/15.

B. Personnel is not monitor after each operational shift. The personnel is monitored (b) (4) regardless of how many times operators perforemd aseptic processing.

C. On 09/22/15, an operator was observed spraying and sanitizing gloves immediately before taking the fingertips monitoring. The operator was processing Magnesium Chloride Injection 200 mg/ml Lot # 150922@9.

D. No action and alert limits were established for the personnel monitoring of (b) (4) .

E. Environmental monitoring procedure SOP-SC-01.1320.01, "Central Drugs Environmental Monitoring Procedure Sterile Compounding Pharmacy" revision 01, effective date 25-SEP-15,

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was drafted after the initiation of the current inspection.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Your firm did not perform growth promotion of the media ((b) (4) and (b) (4)) (b) (4) for use in sterility testing and environmental monitoring to ensure that the media used will support microbiological growth.

OBSERVATION 5

Approved components, drug product containers, and closures are not retested or reexamined as appropriate for identity, strength, quality and purity after exposure to conditions that might have an adverse effect with subsequent approval or rejection by the quality control unit.

Specifically,

Your firm does not have a study or data to support that processed depyrogenated vials and (b) (4) stoppers, and (b) (4) can be stored for indeterminate amount of time in the ISO 8 and ISO 7 area before being used in processing of sterile drug products in ISO 5 area. Vial and stoppers are stored in (b) (4) and covered with (b) (4). (b) (4)

OBSERVATION 6

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

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A. There were no documented investigations conducted for out of specification endotoxin test results. For example

1) Ascorbic Acid 500 mg/ml preservative free lot # 150804/39
2) Ascorbic Acid 500 mg/ml preservative free lot # 150803/28
3) Ascorbic Acid 500 mg/ml preservative free lot # 150812/1,2,28
4) Ascorbic Acid 500 mg/ml preservative free lot # 150818/3
5) Ascorbic Acid 500 mg/ml preservative free lot # 150813/48
6) Ascorbic Acid 500 mg/ml preservative free lot # 150819/1,2,3,4

These lots were retested and results met the specification. Lots were subsequently released. No explanations why the original failed to meet the specification.

The investigation was not conducted as required by Procedure SOP-SC-01.1102.01, "Central Drugs Quality Non Conformance Policy Sterile Compounding Pharmacy", revision 01, effective date 12-JAN-15. The procedure stated that nonconformance would be documented when non-conforming event occurred.

B. Investigations into the following Quality Related Events were not documented:

1) Quality Related Event Meeting dated December 29, 2014, stated, "Clinic suspected medications have high endotoxin level."

2) Quality Related Event Meeting dated April 2015, stated "Medical office report patient reaction to injection site using Vit D3 Oil injection."

3) Incident report dated 09/09/15 stated, "Patient complained about respiratory distress, swelling, aches, and pain."

C. Investigations were not conducted for the following personnel monitoring recoveries:

Date	Location	CFU recovered
(b) (4) (b) (4), (b) (6)	(b) (4)	8
(b) (4) (b) (4), (b) (6)	(b) (4)	TNTC

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(b) (4)	(b) (4), ((b) (6))	(b) (4)	32
			10
			9
			28
			53
			6
			6

Your firm did not have alert and action limits for (b) (4) monitoring recoveries.

OBSERVATION 7

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

A. Your firm has not conducted stability testing program for Ascorbic Acid 500mg/ml Injection with preservative to ensure that the product can support the assigned shelf life of 6-month expiration date.

B. Your firm does not have the ongoing stability programs to ensure that sterile drug products maintain the potency and sterility throughout the assigned 6-month shelf life.

C. Your firm has not conducted preservative effectiveness determination for all sterile drug products that contain a preservative to ensure that the preservative system is effective to inhibit microbial growth through the product shelf life. The preservative is not assayed to determine the concentration in the sterile drug solutions.

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OBSERVATION 8

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

Specifically,

Your firm does not use sporicidal agents for the disinfecting of the laminar flow hoods which are used for aseptic processing of sterile drug products. Only (b) (4) solution is used on the floor (b) (4)

OBSERVATION 9

Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically,

A. The sterile disposable gown is used in the morning shift and then reused in the afternoon shift after taking a lunch break. The gown is removed and placed in a plastic in the gowning area.

B. Gowning certification program does not include personnel monitoring as part of the evaluation. Procedure SOP-SC-01.1135.01, titled "Central Drug Gowning and Gowning Certification Procedure" was not established until September 22, 2015. This procedure includes provision for personnel monitoring during the certification.

*** DATES OF INSPECTION:**
09/22/2015(Tue), 09/23/2015(Wed), 09/24/2015(Thu), 09/28/2015(Mon), 09/30/2015(Wed), 10/02/2015(Fri), 10/26/2015(Mon), 10/30/2015(Fri), 11/05/2015(Thu)

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