

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/1/2016-12/2/2016* FEI NUMBER 3012228279
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Nayan Patel, Pharm.D. , President

FIRM NAME Auro Pharmacies Inc	STREET ADDRESS 511 S Harbor Blvd Ste F
CITY, STATE, ZIP CODE, COUNTRY La Habra, CA 90631-9375	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:**

**OBSERVATION 1**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

A. The process simulations conducted by your firm on (b) (4) are inadequate and do not represent the actually manufacturing operations of Ascorbic Acid 500mg/ml. For example:

- 1) The process simulations were conducted using (b) (4)
- 2) The inspection process of the process simulations vials are not described in the SOP-SC-01.1365.01, "Aseptic Media Filling Procedure" and process simulation protocol. Your firm indicated that (b) (4) (b) (4) before they are (b) (4)
- 3) Growth promotion conducted for incubated vials are inadequate in that unknown amounts of organisms were used for the growth promotion. Your firm conducted the growth promotion of the incubated vials by using (b) (4) to inoculate the vials.

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- 4) The process simulations do not represent actual production filling batch size. Operators filled (b) (4) batches for the process simulations. The manufactured Ascorbic Acid 500mg/ml batches are (b) (4) .
- 5) The process simulations conducted had operational times that were shorter than the manufactured Ascorbic Acid 500mg/ml.

**(b) (4)**

Ascorbic Acid Lot #	Start time	End time	Operation time
161026@1	(b) (4)		
161028@1	(b) (4)		
161102@1	(b) (4)		

- B. Your firm failed to performed smoke studies under dynamic conditions for ISO 5 laminar flow hoods involved with manufacturing of Ascorbic Acid 500 mg/ml Lot # 161026@1, 161028@1, and 161102@1.

There are (b) (4) laminar flow hoods inside the ISO 7 Room (b) (4). Laminar flow hood (b) (4) (b) (4) were involved in the manufacturing of Ascorbic Acid 500 mg/ml lot # 161026@1, 161028@1, and 161102@1. Only laminar flow hood # (b) (4) had smoke study conducted under (b) (4) . All (b) (4) laminar flow hoods can be used for aseptic filling operations.

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**OBSERVATION 2**

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

Specifically,

- A. Your firm has not performed qualification of the Room (b) (4) to demonstrate that ISO 5 and ISO 7 environmental conditions can be met. For example, your firm does not conduct viable and non-viable monitoring in dynamic conditions.
- B. Your firm does not have a justification or rational to support the sampling sites used for monitoring the environment during aseptic filling operation.
- C. Your firm's current environmental monitoring program does not include any non-viable particulate monitoring during filling of sterile drug product.
- D. Your firm's monitoring of the pressure differentials throughout the classified areas where aseptic filling occurs is inadequate. Room pressure is monitored (b) (4) the (b) (4). Pressure differentials are not monitored during aseptic filling of the product manufactured which does not assure notification of a disruption in established pressure cascade for a prolonged duration which could impact the classified areas.
- E. Your firm has no justification for the alert and action limits set for environmental monitoring.

**OBSERVATION 3**

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Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically,

Your firm does not have a hold time study to support the (b) (4)

This lot was compounded and (b) (4) Bioburden was not performed prior to (b) (4)

**OBSERVATION 4**

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

Specifically,

- A. On 11/02/2016, aseptic fill process support staffs with exposed eye area were observed to have placed their face directly in front of the ISO 5 laminar flow hood during the filling process of Ascorbic Acid 500mg/ml lot # 161102@1.
- B. On 11/02/2016, one aseptic fill process support staff with exposed eye area was observed reaching inside and place (b) (6), (b) (7) face in front of the ISO 5 laminar flow hood during the filling process of Ascorbic Acid 500mg/ml lot # 161102@1.
- C. On 11/01/2016, (b) (4) operators with exposed eye area were observed placing their faces in front of the ISO 5 laminar flow hood during the cleaning process.
- D. On 11/01/2016, one operator with exposed eye area was observed placing (b) (6), (b) (7) head inside the ISO 5 laminar flow hood during the cleaning process.

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- E. On 11/02/16, (b) (4) unqualified operators were observed to be gowned inside the ISO 7 area and assisting with manufacturing and filling process including environmental monitoring of Ascorbic Acid 500mg/mL lot # 161102@1.
- F. On 11/01/16 and 11/02/16, (b) (4) personnel were observed to be moving repeatedly between the ISO 7 and ISO 8 rooms without following the gowning procedure and process to transfer components and perform environmental monitoring.
- G. On 11/02/16, operators were observed to be sitting down on the bench while putting on the sterile boots after donning on the sterile gown inside the room (b) (4), Gowning In Room. These operators were involved with compounding and filling of Ascorbic Acid 500mg/ml lot # 161102@1.

**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 adequate control over equipment and closures to maintain their sterility. For example,

- A. Your firm does not have a study to show the adequacy and sterility of the (b) (4) (b) (4).

For example, the (b) (4) (b) (4), and (b) (4) at the (b) (4). The (b) (4) are then (b) (4) (b) (4) for used in Ascorbic Acid 500mg/ml Lot # 161026@1, 161028@1, and 161102@1.

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Additionally, the (b) (4) procedure, SOP-SC-01.1390.01, (b) (4) , stated that (b) (4) to be recorded on the (b) (4) log. Your firm did not fill the log until 11/01/16. These stoppers were used in Ascorbic Acid 500mg/ml Lot # 161102@1.

B. On 11/02/16, operators were observed using previously (b) (4) rubber stoppers that are stored in ISO 7 and moved to ISO 5 laminar flow hood to be used in aseptically filled vials of Ascorbic Acid 500 mg/ml lot # 161102@1. Rubber stoppers are stored in (b) (4) and (b) (4). Operators placed (b) (4) within the ISO 5 laminar flow hood. The (b) (4) (b) (4) are placed back on a (b) (4) within ISO 7 area.

C. On 11/02/16, an operator was observed moving (b) (4) containing (b) (4) (b) (4) from ISO 8 Room (b) (4) through ISO 8 Room (b) (4) into ISO 7 Room (b) (4) before placing into the ISO 5 laminar flow hood.

### OBSERVATION 6

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

Specifically,

A. No sporicidal agent used in the ISO 5 Laminar Flow Hood where aseptic filling occurs.

B. Your firm re-uses old sterile (b) (4) bottles to refill with new (b) (4) (b) (4) from a bulk container with no assurance of sterility and documenting new lot number of the (b) (4) on the bottle. On 11/1/16, a technician was observed to refill an old bottle of

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(b) (4) (b) (4) with (b) (4) from a bulk one gallon bottle from (b) (4) that was used to clean the ISO 5, ISO 7 and ISO 8 areas.

**OBSERVATION 7**

Written records are not always made of investigations into unexplained discrepancies.

Specifically,

- A. Your firm failed to investigate action level excursion involving personnel monitoring of the (b) (4) for operator (b) (6), (b) (7)(C) during an aseptic filling of the product on 11/28/16. The documented action level is (b) (4) 7 CFUs was reported for operator (b) (7)(C), (b) (6).
- B. Your firm failed to investigate several action level excursions involving viable particulate monitoring during operation of ISO 7 and ISO 8 rooms.
  - 1) On (b) (4), an action level excursion of TMTC (Too many to count) was found in Room (b) (4) Room), however an investigation or follow up was not conducted.
  - 2) On (b) (4), an action level excursion of 41 CFU was found in Room (b) (4) (b) (4) Room); however an investigation or follow up was not conducted.
  - 3) On (b) (4), an action level excursion of 100 CFU was found in Room (b) (4) Room); however an investigation or follow up was not conducted.
  - 4) On (b) (4), action level excursions of 31 and 79 CFU were found in Room (b) (4) (b) (4) Room); however an investigation or follow up was not conducted. Additionally action level excursions of 100 CFU was found in Room (b) (4)

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Room) and 100 CFU was found in Room (b) (4) Room); however an investigation or follow up was not conducted.

- 5) On (b) (4) , an action level excursion of 24 CFU was found in Room (b) (4) (b) (4) Room); however an investigation or follow up was not conducted.
- 6) On (b) (4) , an action level excursion of 24 CFU was found in Room (b) (4) (b) (4) Room); however an investigation or follow up was not conducted.

C. Your firm failed to investigate pressure differential excursion between Cleanroom (b) (4) on the day of production for Ascorbic Acid 500 mg/ml Lot # 161102@1.

Additionally, your firm does not have a written procedure or process for investigating excursions occurred within your facility.

**OBSERVATION 8**

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 does not perform growth promotion testing of new batches of media (b) (4) ) that were (b) (4) for use in media fill and environmental monitoring to ensure that the media used can support microbiological growth.

**OBSERVATION 9**

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

Specifically,

Suitability testing for the sterility test method necessary to demonstrate that the product does not interfere with the test, has not been performed by the contract testing laboratory which conducts the release testing of the product made.

**OBSERVATION 10**

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

Specifically,

Your firm could not provide the supporting data including batch worksheet and drug substance supplier for the Ascorbic Acid (b) (4) lot # (b) (4) that is used to support the 180 days expiration date. The stability study was started on (b) (4) with Ascorbic Acid (b) (4) lot # (b) (4). No comparison can be made for the Ascorbic Acid (b) (4) lot # (b) (4) to the formulation, drug substance, and container closure (b) (4) to ensure that they are the same.

**OBSERVATION 11**

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

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Specifically, your firm's 100% visual inspection of the finished product vials is inadequate. For example,

- A. There is no written procedure describing the process for 100% visual inspection of filled vials.
- B. No formal training process for the visual inspectors to ensure that inspectors are provided with adequate training to perform the inspection process.
- C. No qualification process for the visual inspectors to ensure that they are properly qualified to perform the inspection process. The finished sterile drug product vials are amber.

**OBSERVATION 12**

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically,

Your firm does not have container closure study for the container and closure used for Ascorbic Acid 500 mg/ml. Your firm's management indicated that study was performed but unable to locate the study supporting documents and data.

**OBSERVATION 13**

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

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Your firm has not performed a verification to show the (b) (4) step for the rubber stoppers and product vials are adequate in reducing microbial load, endotoxin, and particulates.

**OBSERVATION 14**

The quality control unit lacks authority to review production records to assure that no errors have occurred.

Specifically,

Your firm failed to thoroughly complete and review the qualification documents for the (b) (4) and (b) (4). Your firm provided the following documents and indicated that they were the final reports for the qualification of the listed equipment. However, these documents have not been completed and reviewed prior to use for processing components, vials, rubber stoppers, and utensils in the Ascorbic Acid 500 mg/ml Lot # 161026@1, 161028@1, and 161102@1.

- Document VAL-SC-05.5002.01, (b) (4) Equipment Installation, Operational & Performance Qualification AN 0530. Qualification was started on 04/06/16 and the last run was completed on 04/11/16.
- Document VAL-SC-05.5004.01, (b) (4) Equipment Installation, Operational and Performance Qualification AN 0042. Qualification was started on 04/15/16 and the last run was completed on 05/11/16.
- Document VAL-SC-05.5003.01, (b) (4) Equipment Installation, Operational & Performance Qualification AN 0550. Qualification was started on 04/25/16 and the last run was completed on 05/05/16.

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**OBSERVATION 15**

There is a lack of written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination and testing of labeling and packaging materials.

Specifically,

Your firm does not have a written procedure describing the receipt, identification, storage, handling, sampling, and examination of labeling and packaging materials.

**OBSERVATION 16**

Procedures designed to assure that correct labels, labeling and packaging materials are used for drug products are not written.

Specifically,

Your firm does not have a written procedure describing the labeling operations of finished drug products.

**\*DATES OF INSPECTION**

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