DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/17/2019-10/18/2019*
	FEI NUMBER 3012228279

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nayan (NMI) Patel, President

FIRM NAME	STREET ADDRESS
Auro Pharmacies Inc	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 I OBSERVED:

OBSERVATION 1

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

Specifically,

the ISO 5 classified hoods used for aseptic mixing/filling and (b) (4) are not adequately designed or maintained for the operations they are used for.

a) The firm has (b) (4) hoods ((b) (4)) used for mixing and a separate (b) (4) hoods ((b) (4)) used for filling operations. The hoods are not adequate for reasons including, but not limited to, the following:

I. All the filling hoods and four of the (b) (4) mixing hoods ((b) (4) (b) (4)) have cracks in the left- and right-side panels.

II. The ISO 5 hoods except (b) (4) are not designed in a way that allows cleaning of all surfaces. The light in the hoods reside in an open exposed crevice (b) (4) closest to the operator. The area is difficult to clean without inserting the cleaner's bodies into the hood. On 9/18/2019, I observed hood (b) (4) had dark material in the crevice. On 9/25/2018~~9~~, I observed the remaining hoods, with the exemption of (b) (4) also had dark material in the crevice.

III. One 10/01/2019, I observed the ISO 5 hoods (b) (4) and (b) (4) appeared to have scratching on the inner surface of the side walls.

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IV. The most recent smoke studies, which occurred during the May 2019 recertifications, were either not done under accurate dynamic conditions or did not display unidirectional flow for several ISO 5 hoods. For example:

a. Dynamic smoke studies for the filling hoods ((b) (4)) did not include equipment such as the non-viable particulate measuring device, active (b) (4) which are present during filling operations.

b. Hood (b) (4) dynamic smoke study did not simulate filling activities. The addition of rubber stoppers is the only manipulation occurring during the (b) (4) dynamic smoke study.

c. Hoods (b) (4) dynamic smoke studies did not have enough smoke to allow visualization of air flow. The specifications for the hoods does not specify maximum velocity variation between setpoints; variations as large as (b) (4) FPM were observed during the most recent certifications.

d. The dynamic smoke study for hood (b) (4) demonstrates that the hood generates turbulent air flow during mixing.

e. The static smoke study for hoods (b) (4) do not have adequate smoke to determine unidirectional airflow throughout the hood.

V. The recertification for the filling hoods ((b) (4)) occurring in May 2019 had average results below the manufacturers specifications. The recertification had an outflow velocity specification of (b) (4) feet-per minute (FPM). The

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manufacture's specifications for outflow velocity was (b) (4) FPM. Each hood has a recertification average below (b) (4) FPM. For example, the average outflow velocity for (b) (4) were 83, 84, 88, and 86 FPM respectively. Additionally, each hood had multiple individual area reading below (b) (4) FPM including. For example: Hood (b) (4) had three readings 77,78,79 FPM; Hood (b) (4) had two readings at 77 and 79 FPM; Hood (b) (4) had three readings at 72,76, and 79 FPM; Hood (b) (4) had one reading at 76 FPM. A total of (b) (4) readings is taken per hood.

VI. The recertification for the filling hoods ((b) (4)) occurring in May 2019 does not include viable particulate results.

Repeat Observation from inspection concluding on 6/29/2017.

OBSERVATION 2

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.

Specifically,
Your firm either failed to initiate or failed to adequately investigate out-of-specification (OOS) including environmental monitoring (EM) failures and sterility failures. The firm performs investigations under OOS and does not have a separate procedure for investigations. Examples include, but are not limited to the following:

a) Your firm did not investigate a viable EM failure occurring during the certification of the ISO 5 hood (b) (4) performed from May 29th to June 11th, 2018. During this certification the ISO 5 hood (b) (4) which is utilized for sterile filling operations, had fail results for viable airborne EM results and viable surface EM results. The specification has an action limit of (b) (4) CFU. The result was 1 CFU for each EM failure. The airborne microbial was identified as a gram-positive cocci and the surface microbial was not identified. No speciation was determined for either

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microbial. No OOS concerning the results, no internal investigation was documented, and the speciation was not performed for the results. The hood was used for sterile filling operations following this certification.

b) Your firm did not adequately investigate a settling plate EM failure occurring on 6/12/2018 during the production of lot 180612@1 of Calcium Gluconate in ISO 5 hood (b) (4) The investigation did not look at employee training records, did not include review of EM to the last known assurance of operation, review did not lead to OOS and EM failure would not show up in future reviews or trending.

c) Your firm did not adequately investigate multiple microbial EM failures occurring on 08/02/2018 in the filling suite, in the ISO 5 filling hoods, and on the filling operators. The investigation was described in OOS 18-0016. OOS 18-0016 did not involve a review of previous EM data for the failing room/equipment or the training records for the operators. The firm determined that the results did not affect their aseptic process based on a conclusion was not supported by the investigation.

d) OOS 19-004 investigation concerning sterility failures for (b) (4) lots 190423@1 of Glutathione and 190509@1 of Dexpanthenol was not conducted adequately. The (b) (4) ots were produced 26 days apart (04/23/2019 and 05/19/2019 respectively). The investigation documentation did not include an evaluation of production including batch record reviews, EM for hoods and rooms (non-viable or viable particulates, personnel monitoring, press plates), cleaning logs for the room, qualification of the hoods, retain samples, or previous OOS.

Repeat Observation from inspection concluding on 6/29/2017.

OBSERVATION 3

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

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Specifically,
the non-viable particulate data, viable particulate data and finished product visual inspection are not adequate to assure in-process materials or drug products conform to standards of quality. For Example:

a) Non-viable particulate (NVP) data is not collected, stored, or reviewed adequately to assure in-process materials or drug products conform to standards of quality. NVP data is collected (b) (4) (b) (4) of all sterile-drug products. The data is collected (b) (4) however, only an average read out is provided. No alarms occur for individual reading that are out-of-specification. The raw data is not backed-up or stored and can not be reviewed later. The review of the data is only the average throughout the entire filling process.

b) Your firm's 100% visual inspection is performed in (b) (4) with operators who have not been qualified to detect a standardized particulate size.

c) Your firm does not perform active-air monitoring of viable particulates during production. Viable particulates are monitored using a settling plate during production. However, evidence that the in-house generated settling plates maintain growth promotion attributes following up to four hours exposed in the ISO 5 hoods has not been performed.

Repeat Observation from inspection concluding on 6/29/2017.

OBSERVATION 4
The statistical quality control criteria fail to include appropriate acceptance levels and rejection levels.

Specifically,

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Your firm failed to establish acceptance criteria for the sampling and testing conducted by the quality control unit that are adequate to assure that batches of drug products meet each appropriate statistical quality control criteria as a condition for their approval and release.

a) Your firm does not review the rejection level of sterile finished-drug products. There is no statistical limit placed on the number of products that can be rejected during review of finished drug products. Two of the ten batches (Lot 190613@2 of Pyridoxal-5-Phosphate and 190708@2 of Calcium Gluconate) I reviewed had 10% or greater vials removed for particulate contamination occurring. These results were not flagged or investigated.

b) ~~Your firm does not perform active air monitoring of viable particulates during production. Viable particulates are monitored using a settling plate during production. However, evidence that the in house generated settling plates maintain growth promotion attributes following up to four hours exposed in the ISO 5 hoods has not been performed.~~

OBSERVATION 5

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

Specifically,

a) Your firm did not perform media fills under actual conditions or at intervals in all hoods. The firm has not conducted media fills for ISO 5 hood (b) (4) in 2019.

b) The cleaning wands used to clean the hoods has apparent degradation or filth contamination. The material at the end of the wand is discolored and has orange spots on it. These wands reside inside of the hood.

c) Currently, there is no program developed to evaluate (b) (4) and product compatibility. The firm's (b) (4) (b) (4) have not been evaluated for product compatibility. According to the (b) (4) log the current pharmaceutical grade (b) (4) usage occurred on 7/31/2018. Prior to this date your firm used non-pharmaceutical grade (b) (4).

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OBSERVATION 6

There was a failure to handle and store drug product containers and closures at all times in a manner to prevent contamination.

Specifically,
your firm stores vials utilized as container/closures in an ISO 8 classified room for up to 21 days without adequate hold time evidence to ensure they remain sterile. Following sterilization (b) (4), vials are held in non-air tight wrapping in an ISO 8 room for up to 21 days prior to use. The vials are used as container closures for all products. The hold time study supporting this hold-time does not include the number of vials tested or the testing method utilized for testing.

OBSERVATION 7

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,
Your firm used non-pharmaceutical grade API to produce at least two finished drug products.

a) Your firm produces sterile injectable drug product with dietary supplement grade Glutathione. Glutathione is used to produce drug products including Glutathione 200mg/ml MDV and Glutathione 200mg/ml SDV. Glutathione ingredient is received from one supplier and the certificate of analysis from that supplier indicates that the API meets the monograph for dietary supplements. Your firm has released at least (b) (4) lots of Glutathione since January 1st, 2019.
b) Your firm produces sterile drug product with dietary supplement grade Choline Chloride. Choline Chloride is used to produces drug products including MIC 25/50/50 mg/ml. Choline ~~Calcium~~ Chloride is received from one supplier and the certificate of analysis from that supplier indicates that the API meets the monograph for dietary supplements. Your firm has released at least (b) (4) ots of MIC 25/50/50 mg/ml since January 1st, 2019.

OBSERVATION 8

The quality control unit lacks authority to fully investigate errors that have occurred.

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Specifically,
Your quality unit has not acted adequately in its responsibilities. For example:

Microbial out-of-specifications occurring in production areas during hood recertifications occurring from May 29th to June 11th nor 6/12/2018 were not identified or investigated.

Investigations into microbial contamination documented in OOS 18-0016 and OOS 19-004 have not been conducted adequately.

Evaluation of equipment such as (b) (4) and container closures have not been evaluated adequately.

The quality unit released drug products made with non-pharmaceutical grade active pharmaceutical ingredients including Dietary Supplement grade Glutathione and Choline Chloride.

OBSERVATION 9

Routine calibration and checking of equipment is not performed according to a written program designed to assure proper performance.

Specifically,
Your firm's (b) (4) (b) (4) has not been revalidated or temperature mapped with adequate frequency. The (b) (4) (b) (4) last validation was approved in December 2016. During the December 2016 validation, there was significant variation in the temperature mapping profile. Biological indicators and endotoxin indicators are not placed in the (b) (4) areas during use.

OBSERVATION 10

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically,
your firm has not adequately established the reliability of API and preservative supplier's certificates of analyses. The qualification for three of three API or preservative suppliers reviewed do not include

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testing of any lots to ensure they meet the claims on the certificate of analyses provided by the supplier. The suppliers reviewed include suppliers of Methylcobalamin, Calcium Gluconate, Glutathione, and Benzol Alcohol. The Vendor Qualification procedure does not include testing to ensure API or preservative supplier certificate of analysis are accurate and representative of the product received.

OBSERVATION 11

Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

Specifically,
utensils used to weight and containers that hold components are not stored adequately to prevent contamination. On 9/17/2019, I observed the utensils and containers in the ISO 8 environment without protection. The utensils and containers are used to hold ingredients prior to mixing. The items did not have maximum hold times.

***DATES OF INSPECTION**

9/17/2019(Tue), 9/18/2019(Wed), 9/25/2019(Wed), 9/26/2019(Thu), 9/27/2019(Fri), 9/30/2019(Mon), 10/01/2019(Tue), 10/03/2019(Thu), 10/04/2019(Fri), 10/09/2019(Wed), 10/18/2019(Fri)

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