DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	7/9/2018-8/2/2018* FEI NUMBER 3011893599

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ashwin K. Patel, Chief Operations Officer

FIRM NAME	STREET ADDRESS
Auro Pharmacies, Inc.	520 W La Habra Blvd
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
La Habra, CA 90631-5308	Producer of sterile and non sterile drug products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

The ISO 5 classified aseptic processing areas had visibly dirty equipment or surface.

Specifically, we observed apparent brown and white residue in the ISO 5 classified hoods that are used in the production of sterile drugs. You stated the hoods are cleaned (b) (4) production day. However, your firm was unaware of these observations until they were discussed on 07/09/2018 and subsequently on 07/18/2018. For example:

A. On 07/09/2018, we observed apparent brown residue on the HEPA filter of an ISO 5 classified (b) (4) laminar flow hood, identified as Hood #2. This hood is used in dispensing of sterile drug products. In addition, we also observed apparent white residue on the(b) (4) surface, along with apparent brown residue in one perforation of the(b) (4) . Both the residue on the filter, and the(b) (4) , are located on the ceiling directly above where sterile drug products are dispensed into final containers. This hood was last used to produce "NAD TRIHYDRATE 250 MG/VIAL LYOPHILIZED INJECTABLE", lot 180531@12 on 05/31/2018, RX (b) (6) .

B. On 07/18/2018, we observed apparent brown residue in two perforations of an ISO 5 classified (b) (4) laminar flow hood, identified as Hood #4. The (b) (4) of this hood is located on the ceiling directly above where sterile drug products are dispensed into final containers. On 07/09/2018, we observed this hood used to produce "TESTOSTERONE CYPIONATE/ENANTHATE OIL INJECTION 126/54 MG/ML INJECTABLE", lot 180709@21.

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		Kenneth O. Gee, Investigator Andrew K. Haack, Investigator	08/02/2018

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C. On 07/18/2018, we observed apparent brown residue in five perforations of an ISO 5 classified (b) (4) laminar flow hood, identified as Hood #5. The (b) (4) of this hood is located on the ceiling directly above where drug sterile drug products are dispensed into final containers. On 07/09/2018, we observed this hood used to produce "TESTOSTERONE CYPIONATE/ENANTHATE OIL INJECTION 160/40 MG/ML INJECTABLE", lot 180709@23. In addition, your firm identified a sterility test failure for the production of "ASCORBIC ACID INJECTION NO PRESERVATIVE 500 MG/ML INJECTABLE", lot 160829@5, on 08/29/2016.

D. On 07/09/2018, we observed apparent white residue on the (b) (4) surface of the (b) (4) and apparent brown residue in one circular metal perforation forming the ceiling of an ISO 5 classified (b) (4) laminar flow hood, identified as Hood #1. The (b) (4) is located on the ceiling directly above where drug products purporting to be sterile are mixed. This hood was used to produce "ATROPINE SULFATE 0.01%, OPHTHALMIC", lot 180702@33 on 07/02/2018, RX (b) (6) .

E. On 07/18/2018, we observed apparent brown residue on the HEPA filter of an ISO 5 classified (b) (4) laminar flow hood, identified as Hood #3. In addition, we also observed apparent brown residue in one perforation of the (b) (4) . The airflow of this hood directs air from the HEPA filter through the (b) (4) , both of which are located on the (b) (4) , to where sterile drug products are mixed. On 07/09/2018, we observed this hood was used to produce "TESTOSTERONE CYPIONATE/ENANTHATE OIL INJECTION 126/54 MG/ML INJECTABLE", lot 180709@21.

F. On 07/18/2018, we observed apparent brown and black residue on the surface of the air supply vent covers supplying ISO 7 classified air to the aseptic compounding room. The air supply vent covers are located on the ceiling, and above Hood #3 and Hood #5, which are used to mix and dispense purported sterile drug products, respectively. In addition, Hood #3 and Hood #5 are used in the production of several sterile drug products including "TESTOSTERONE CYPIONATE/ENANTHATE OIL INJECTION 126/54 MG/ML INJECTABLE", lot 180709@21, and "TESTOSTERONE CYPIONATE/ENANTHATE OIL INJECTION 160/40 MG/ML INJECTABLE", lot 180709@23 both on 07/09/2018.

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OBSERVATION 2

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically, you had viable air monitoring samples above action levels (b) (4) (b) (4)) consecutively in January, February and March of 2018 in ISO 5 hoods that are used in the production of sterile drugs. Your firm continued to produce sterile drugs without implementing a corrective and preventive action.

A. On 01/08/2018, your firm recovered 1 CFU/cubic meter from viable air samples collected from ISO 5 Hood #3 during production of "TESTOSTERONE CYPIONATE/ENANTHATE OIL INJECTION 126/54 MG/ML INJECTABLE", lot 180108@25, RX (b) (6) .

B. On 02/28/2018, your third-party contractor recovered 1 CFU/cubic meter from viable air particle monitoring during routine preventive maintenance of the (b) (4) laminar air flow ISO 5 classified Hood #2. This hood was used to produce "NAD TRIHYDRATE 250 MG/VIAL LYOPHILIZED INJECTABLE", lot 180430@16 on 04/30/2018, RX (b) (6) .

C. Subsequently, on 03/08/2018, your firm recovered 1 CFU/cubic meter from viable air sample from ISO 5 classified Hood #4. This hood was used to produce "TESTOSTERONE ENANTHATE CYPIONATE OIL INJECTION 126/54MG/ML INJECTABLE", lot 180314@17 on 03/14/2018, RX (b) (6)

OBSERVATION 3

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

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Specifically,

A. Your firm had two media fill failures on 10/06/2016 and subsequently on 03/08/2018. Your firm continued processing sterile products despite these two media fill failures. For example:

1. On 10/06/2016, a media fill batch was performed using (b) (4) mL vials in ISO 5 classified Hood #4. Of the (b) (4) vials filled, one vial resulted in microbial growth. After this media fill failure, your firm continued to produce sterile drugs without implementing corrective and preventive actions during a six-month time frame.

2. On 03/08/2018, a media fill batch was performed using, (b) (4) mL vials in ISO 5 classified Hood #5. Of the (b) (4) vials filled, one vial resulted in microbial growth. After this media fill failure, your firm continued to produce sterile drug products without implementing corrective and preventative actions.

B. There is no hold time data to support that depyrogenated vials, sterilized stoppers and wipes that are used during the production of sterile drugs can be stored for indeterminate amount of time in your ISO 7 and ISO 8 areas.

C. In addition, the validation study "VALIDATION OF HOLD TIME FOR STERILIZED GLASSWARE, UTENSILS & SUPPLIES", VAL-SC-05.5002.01, addresses hold times for stoppers and other (b) (4) items used in sterile drug production. Yet this study does not address the following issues. For example:

1. No simulation of taking stoppers and other items out from the (b) (4) during the defined storage times.
2. The sample for bio burden detection were only incubated for (b) (4) while sterility testing requires an incubation time of (b) (4) .
3. The process does not appear to be part of a media fill simulation.

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	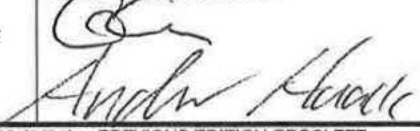	Kenneth O. Gee, Investigator Andrew K. Haack, Investigator	08/02/2018

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OBSERVATION 4

ISO-5 classified areas were not certified under dynamic conditions. Specifically, uni-directional airflow was not verified under operational conditions.

Specifically,

Your dynamic smoke study for ISO 5 classified Hood #2 and the ISO 5 (b) (4), which demonstrates laminar airflow for the process of transferring vials from Hood #2 to your(b) (4), is inadequate in that it is not representative of your process, and objects that block airflow over the vials were observed. Furthermore, the video you provided cannot be adequately evaluated. For example, in the video your provided:

A. No stoppers are present on the vials in the video you provided. Your process is to (b) (4) on vials as you transfer them from Hood #2 into the(b) (4).

B. You move vials (b) (4) as part of the process to transfer vials from Hood #2 to your(b) (4) While vials move (b) (4) During this transfer, the flow of uni-directional air to the vials may be interrupted.

C. The amount of smoke present in the video is insufficient to visualize uni-directional airflow in the region of the vials.

OBSERVATION 5

Vermin was observed in an area immediately adjacent to your production area.

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	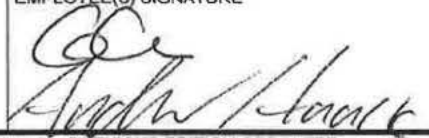	Kenneth O. Gee, Investigator Andrew K. Haack, Investigator	08/02/2018

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Specifically,

On 07/09/2018 we observed:

A. Seven apparent ants along the floor wall-junction of the east wall; and on the north wall of the pre-gown room, identified as room 101. This room is where non-sterile hairnets and masks are donned. In addition, this room leads to the ISO 8 classified gowning room, where your operators don sterile gowns, hoods, and boots before entering the sterile suite.

B. Additionally, on 07/09/2018 one apparent ant was observed on the outer surface of an FDA Investigator's sterile hood in the ISO 8 classified gowning room. This observation was made after he had exited the ISO 7 classified room where he observed the production of "TESTOSTERONE CYPIONATE/ENANTHATE OIL INJECTION 126/54 MG/ML INJECTABLE", lot 180709@21.

OBSERVATION 6

Personnel conducted aseptic manipulations in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically,

We observed a sterile technician using poor aseptic technique by placing his head and body into an ISO 5 classified (b) (4) laminar flow hood, identified as Hood #5, while dispensing a drug purporting to be sterile after performing the fina(b) (4) step. The drug being dispensed was "TESTOSTERONE CYPIONATE/ ENANTHATE OIL INJECTION 160/40 MG/ML INJECTABLE", lot 180709@23.

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OBSERVATION 7

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically, (b) (4) from your (b) (4) (b) (4) is used as an ingredient in the production of (b) (4), non-sterile drug products. Regarding this, the following issues were observed:

A. Your firm does not perform any microbial testing of the (b) (4) (b) (4) by your (b) (4) (b) (4) Additionally, your SOP, (b) (4) (b) (4) Operation, SOP-SC-01.1676.02, is deficient as the procedure does not require you to perform any microbial testing of the (b) (4) (b) (4) by your (b) (4) (b) (4).

B. Your SOP (b) (4) (b) (4) Operation, SOP-SC-01.1676.02, requires that (b) (4) and (b) (4) be monitored, yet from 03/08/2018 to 07/16/2018 your firm has only monitored (b) (4) Your firm has not conducted any analytical (b) (4)) testing of the (b) (4) (b) (4) through your (b) (4) (b) (4) between the dates 09/11/2017 and 03/08/2018. For example, "TETRACAINE HCL TOPICAL 2% SOLUTION", lot 180212@21, made on 02/12/2018, RX (b) (6), shows "(b) (4) " was used as an ingredient.

C. The (b) (4) (b) (4) (b) (4) used to (b) (4) (b) (4) has not been qualified and validated. For example, "TETRACAINE 2% TOPICAL SOL", lot 180129@15, made on 01/29/2018, RX (b) (6), shows (b) (4) (b) (4) " was used as an ingredient.

OBSERVATION 8

The written stability testing program is not followed.

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Specifically,

Your firm has not conducted any stability studies to establish Beyond Use Dates (BUD) for your non-sterile drug products. For example, we observed: "TETRACAINE HCL TOPICAL 2% SOLUTION" of lot 180212@21, produced on 02/12/2018 where a BUD of 05/13/2018 was applied. You have no assurance that this BUD is appropriate.

This is a repeat observation from the 2015 FDA inspection.

OBSERVATION 9

You have not established appropriate Beyond Use Dates for your products.

You used stock solutions with 180 day (six-month) beyond use dates (BUD) as an ingredient in the production of sterile drug products. These following stock solutions were stored at room temperature in the ISO 7 classified clean room:

A. (b) (4) , lot:(b) (4) , prepared on: 02/26/2018, BUD: 08/25/2018

B. (b) (4) , lot(b) (4) , prepared on: 02/12/2018, BUD: 08/12/2018

These stock solutions were used in the production of "FOLIC ACID INJECTION BENZYL ALCOHOL 10 MG/ ML INJECTABLE", lot 180515@2 on 05/15/2018, RX(b) (6) , with BUD of 08/12/2018 at room temperature.

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	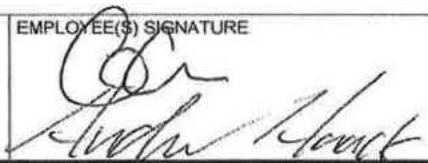	Kenneth O. Gee, Investigator Andrew K. Haack, Investigator	08/02/2018

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OBSERVATION 10

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

A. On 07/09/2018, we observed a gap, approximately 1/4 inch by 1/2 inch, under the south door that opens to a hallway leading to the unclassified pre-gown room.

B. On 07/18/2018, in the ISO 8 classified prep room, we observed a lack of backflow protection devices on the sink where municipal water and (b) (4) (b) (4) is supplied. Water from these supplies are used to wash equipment and utensils used in the production of sterile drug products; and (b) (4) - (b) (4) (b) (4)

DATES OF INSPECTION
*7/09/2018(Mon), 7/10/2018(Tue), 7/11/2018(Wed), 7/12/2018(Thu), 7/13/2018(Fri), 7/16/2018(Mon), 7/17/2018 (Tue), 7/18/2018(Wed), 7/19/2018(Thu), 7/20/2018(Fri), 7/31/2018(Tue), 8/01/2018(Wed), 8/02/2018(Thu)

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