

**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 4/23/2019-5/7/2019*
	FEI NUMBER 3005199309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Shery Eghtesadi, Pharmacist in Charge

FIRM NAME Rancho Park Compounding Pharmacy	STREET ADDRESS 10587 W Pico Blvd
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CITY, STATE, ZIP CODE, COUNTRY Los Angeles, CA 90064-2333	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non Sterile Drug Products
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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**

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

Specifically,

On 4/23/2019, I observed the ISO 5 Laminar Flow Workstations (LAFWs) had visibly dirty equipment or surfaces as follows:

A. Unknown yellowish-brown stains were observed on the stainless steel surfaces on the back side and left side inside the ISO 5 LAFW (ID (b) (4)), on the top of (b) (4) curved metal hooks hung on a metal pole inside the ISO 5 LAFW (ID (b) (4)) and on two cap screws digging in a faceplate on the back side inside the ISO 5 LAFW (ID (b) (4)).

B. The HEPA filter cover positioned above the work surface inside the ISO 5 LAFW (ID (b) (4)) contained yellowish-brown spots on its surface.

C. The front glass shield of ISO 5 LAFW (ID (b) (4)) contained an unknown white layer at its joints with the LAFW on both sides and part of it was discolored.

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D. While technician (b) (6) produced 5% acetylcysteine ophthalmic solution, lot # 04232019@3 on 4/23/2019 and technician (b) (6) produced Trimix # 11C 10/1/12 Injectable Lot # 04242019@5 on 4/24/2019, they both disinfected their gloved hands using (b) (4) frequently but performed sterile operations without drying their hands.

**OBSERVATION 2**

Non-microbial contamination was observed in your production area.

Specifically,

I observed non-microbial contamination in the ISO 7 buffer room and ISO 7 anteroom at the sterile compounding lab as follows:

A. The recessed ceiling above the ISO 5 LAFW (ID (b) (4) ) in the buffer room chipped off with thin small pieces loosely adhered to a side wall. Also, the ceiling above the compounding preparation area broke off at four spots.

B. Two bolt screws in the (b) (4) beside the ISO 5 LAFW (ID (b) (4) ) was observed with yellowish-brown color. During the filling of Trimix # 11C, 10/1/12 Injectable, Lot# 04252019@11 on 4/25/2019, technician (b) (6) used his gloved hands to place a sterile (b) (4) into a (b) (4) near those two screws for filling.

C. The HEPA filter cover in the buffer room near the entrance showed yellowish color in some spots on 4/23/2019, but it was cleaned the next day.

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D. The HEPA filter cover in the anteroom above the compounding preparation area showed accumulations of yellowish-brown dirt at the joint of the frame.

**OBSERVATION 3**

Personnel conducted aseptic manipulations and placed equipment/supplies 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,

On 4/23/2019, during the sterile processing of Dexamethasone Ophthalmic Soln (Pres Free) 0.1% Drop, Lot# 04232019@5, technician (b)(6) constantly tilted sterile (b)(4) to a certain angle to facilitate (b)(4) capping sterile dropper tips (b)(4). Both of his hands and the (b)(4) were placed in the path of unidirectional airflow. The caps with dropper tips were used to (b)(4) filled (b)(4) containers inside the ISO 5 LAFW (ID (b)(4)). Technician (b)(6) operated in the same way as I observed on 4/26/2019 through a screen outside the sterile compounding lab.

**OBSERVATION 4**

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

Non-sterile wipes were used in the ISO 5 LAFWs. For example,

On 04/24/2019, technician (b)(6) sprayed (b)(4) (sporicidal), sterile water and sterile (b)(4) (b)(4) on different non-sterile (b)(4) Wipes sequentially to wipe the ISO 5 LAFWs (ID (b)(4)) after the compounding of Trimix # 11C 10/1/12 Injectable Lot #

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04242019@5 was completed. Also, a wipe was not completely covered with each of the disinfection agents.

On 04/23/2019, technician (b) (6) sprayed (b) (4) on non-sterile (b) (4) (b) (4) Wipes to disinfect surface of materials before they were introduced into the ISO 5 LAFW (ID (b) (4)) for sterile processing of Dexamethasone Ophthalmic Soln (PRES FREE) 0.1% Drop, Lot# 04232019@5.

**OBSERVATION 5**

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

On 04/25/2019, during the aseptic processing of Trimix #11C, 10/1/12 Injectable, Lot# 04252019@11, a depyrogenated (b) (4) covered with foil wrap was observed to be opened in the buffer room for disinfection of the outer surface before it was placed into the ISO 5 LAFW (ID (b) (4)). That (b) (4) was used to hold a (b) (4) and the (b) (4) used during the filling process.

**OBSERVATION 6**

The segregated production areas surrounding the ISO 5 classified aseptic processing area contained dust-collecting overhangs without adequate and frequent cleaning.

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The ISO 7 buffer room surrounding the (b) (4) ISO 5 LAFWs (b) (4) as well as the ISO 7 anteroom contain wall cable raceways that are designed to conceal cables running along walls near the ceiling, which are hard to clean and visualize the top surface. The cable raceways run through every room in the sterile compounding lab and are opened at the corners with cables exposed. Dirty was observed around the cable raceway in the anteroom.

**OBSERVATION 7**

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

On 4/23/2019, I observed technician (b) (6) donned gowning apparel improperly before she started producing 5% acetylcysteine ophthalmic solution, lot # 04232019@3 as follows:

A. While the pharmacy technician (b) (6) was washing her hands in a small sink prior to gowning, the water spilled out onto the ground. While she was gowning, the bottom of the gown touched the floor surface, including the wet spillage.

B. A string of the sterile gown touched the ground while technician (b) (6) was gowning.

**OBSERVATION 8**

Unsealed, loose ceiling tiles were observed in your cleanroom.

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Specifically,

On 4/23/2019, I observed an unsealed light cover and frame in the ISO 7 buffer room as follows:

A. The fluorescent light cover above the ISO 5 LAFW (ID (b) (4)) was cracked near the corner, leaving a gap (about a pencil size) between the light cover and the frame.

B. The right-angle frame of the fluorescent light fixture on the ceiling near the ISO 5 LAFW (ID (b) (4)) was not completely sealed.

**OBSERVATION 9**

Your facility was designed and/or operated in a way that permits poor flow of personnel and materials.

Specifically,

The gowning room inside the ISO 7 anteroom occupies an area of (b) (4) ft that includes a sink and drain, a trash bin, and an open metal shelf for the storage of sterile materials used for compounding such as (b) (4) syringes, (b) (4) water, and a small space for gowning. For example, water spills out onto the gowning area while washing hands, and gowning apparels were observed to touch the wet spillage, wall, trash bin or doorframe before technician (b) (6) moved into the ISO 7 buffer room on 4/23/2019.

**\*DATES OF INSPECTION**

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4/23/2019(Tue), 4/24/2019(Wed), 4/25/2019(Thu), 4/26/2019(Fri), 4/29/2019(Mon), 5/07/2019(Tue)

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