

**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

8/27/2018-9/11/2018*

FEI NUMBER

3004378804

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Bhavya B. Sharma, Director of Pharmacy

FIRM NAME

Central Admixture Pharmacy Services Inc

STREET ADDRESS

7935 Dunbrook Rd Ste C

CITY, STATE, ZIP CODE, COUNTRY

San Diego, CA 92126-6322

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

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

Specifically,

The firm has not adequately established proper aseptic technique in the (b) (4) of the contents from drug product vials or in the sealing of IV bags during filling.

For example,

- a) On 08/29/18, during the walkthrough of the facility, I observed (b) (4) different techniques employed for the (b) (4) of the contents from drug product vials by (b) (4) different technicians working within separate ISO Class 5 hoods. The (b) (4) step is performed (b) (4) utilizing (b) (4) to extract the contents of finished drug vials. Sterile tubing with a (b) (4) is used to (b) (4) of each drug vial. This process is repeated (b) (4) the vial contents into a (b) (4) for compounding. Only one of the (b) (4) techniques appeared to fully allow for first air from the HEPA filters provided (b) (4) to (b) (4) the (b) (4) of the vial unencumbered during the (b) (4) step. The other (b) (4) techniques blocked first air exiting from the HEPA filter with either the vial or gloved hand.

- b) On 08/27/18, during the walkthrough of the facility, I observed an operator working in ISO Class

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Joey V Quitania, Investigator

DATE ISSUED

9/11/2018

Joey V Quitania
Investigator
Signed By: Joey V. Quitania -S
Date Signed: 09-11-2018 14:36:48

X

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5, Hood 11. The technician was filling and sealing IV bags, Fentanyl 10mcg/mL in 0.9% Sodium Chloride 100mL, Lot# 1700000120531. The IV bags were filled utilizing a repeating pump and scale within ISO Class 5. After filling, the filled IV bag is (b) (4) transferred out of ISO Class 5 and heat sealed utilizing a heat sealer located adjacent to the hood, but within the ISO Class 7, (b) (4) cleanroom. The technician was observed entering and exiting the ISO Class 5 workspace for each IV bag unit. The operation was inadequate in that entry and exits from the ISO Class 5 workspace was not minimized.

OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

The design of the facility and operations in the ISO Class 7, (b) (4) Room, does not always provide adequate spacing. Due to the orientation of the hoods and carts used during production along with the position of personnel working in the room, there may not always be adequate space for personnel to move from one end of the room to the other.

For example, it was observed on 08/27/18 that a technician rolling a support cart was unable to pass through from one end of the room to the other without disrupting production in two separate ISO Class 5 hoods. The two technicians working in the ISO Class 5 hoods had to re-position their support carts in order for the other technician to pass. The firm's (b) (4) room houses (b) (4) ISO Class 5 hoods which are used to aseptically produce sterile drug products.

OBSERVATION 3

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

Specifically,

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Environmental Monitoring of the ISO Class 5 hoods is not adequate to assure cleanroom operations are met during operations. The (b) (4) ISO Class 5 hoods in the firm's cleanrooms ((b) (4) and (b) (4) rooms) are routinely monitored each (b) (4) per day (non-viable particulate air, viable particulate air, and worksurfaces) to represent (b) (4) shifts in a (b) (4) work day. Samples may be collected at static or dynamic conditions depending on the operations in each hood at the time of sampling.

OBSERVATION 4
Written procedures are lacking which describe in sufficient detail the receipt of components, drug product containers and closures.

Specifically,
The firm's written procedure, SOP-CAPS-4000157, vers 10.0, "Material Receiving Handling and Storage", eff 03/01/2016 is inadequate in that it does not require the confirmation of receipt of a Certificate of Analysis or the review of Certificate of Analysis for sterile container/closures and components.

For example, on 08/30/18, the firm received empty sterile 250ml IV bags, Mft Lot# (b) (4). There was no Certificate of Analysis received with the shipment of empty IV bags to establish the sterility conformance of the lot. In addition, there is no record to document the checks performed in the release of materials. The 250ml IV bags are used as the final container in products aseptically produced by the firm with no (b) (4) sterilization step.

OBSERVATION 5
Procedures for the preparation of master production and control records are not described in a written procedure.

Specifically,

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Batch records prepared by production are not controlled to prevent the unauthorized printing in whole or part. There is no mechanism to detect the re-printing the batch record.

OBSERVATION 6

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically,

Loose leaf worksheets are used to document UPLC sample preparation and testing. Laboratory analysts print out or make copies of worksheets used to document sample preparation and testing. There is no mechanism to assure that all laboratory raw data has been retained.

***DATES OF INSPECTION**

8/27/2018(Mon), 8/28/2018(Tue), 8/29/2018(Wed), 8/30/2018(Thu), 8/31/2018(Fri), 9/06/2018(Thu), 9/11/2018(Tue)

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