DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	2/14/2022-2/25/2022* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Peter E. Nero, Director of Pharmacy	
FIRM NAME Central Admixture Pharmacy Services, Inc.	STREET ADDRESS 2200 S 43rd Ave
CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85043-3909	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:

Production System

OBSERVATION 1

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 failed to include the large red container as used under dynamic conditions during normal operations. On 02/18/22, during production of Rocuronium 10 mg/ml 5 ml syringes, lot (b) (4), we observed a large red container placed in the middle of the ISO 5 hood where the sterile operator was performing aseptic manipulations. The large red container was being used as a catch bin for caps being removed from vials. The large red container was not included in the smoke study conducted on 05/22/21 as part of the qualification of the ISO 5 hoods.

B. Your firm failed to demonstrate laminar airflow during the qualification of your ISO 5 hoods based on your smoke studies. During the review of the smoke study video provided during the inspection with file name "(b)(4)", dated 05/22/21, we observed multiple instances of turbulent airflow around equipment and materials inside the ISO 5 hoods. The turbulent airflow was observed under static and dynamic conditions. Also, the smoke studies do not include all sterile syringe operations.

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	Christopher M Jenner, Investigator Gunneet Kaur, Investigator	X Gunneet Kaur Investigator Signed By 2003283692 Date Signed 02-25-2022 13 57 57	2/25/2022

There is no guarantee of continuous laminar airflow shown by your smoke studies, and it does not represent all normal sterile operations at your facility.

OBSERVATION 2

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, your firm does not adequately maintain your ISO 5 hoods used to produce sterile drug products. On 02/16/22 and 02/18/22, we observed scratches on the back wall of the ISO 5 hoods during production of del Nido Formula (Plasmalyte) 1052.8 ml, lot (b) (4), and Rocuronium 10 mg/ml 5 ml syringes, lot (b) (4), respectively. The scratched surfaces do not appear to be smooth and easily cleanable for aseptic operations.

Laboratory System

OBSERVATION 3

Laboratory records do not include a record of all calculations performed in connection with the test.

Specifically, your firm failed to establish an adequate written procedure that specifies how to calculate assay results for retesting amino acids. Written procedure titled Amino Acid Analysis Test, number (b)(4) (b)(4), version 4.0, effective date 05/24/21, section 14.6 reporting results, states "(b)(4) (b)(4) (b)(4)" On 02/22/22, your Chemist Team Lead

stated she does not record the calculations and cannot recall how the calculations were performed to release Trophamine 4%/Dextrose 10% w/ Ca Gluc and Heparin, 250 ml, lot (b) (4), and finished product Trophamine 4%/Dextrose 10%, 250 ml, lot (b) (4). The Chemist Team Lead demonstrated at least two ways to perform the calculation that might have been used; however, one of the demonstrated ways showed an out-of-specification (OOS) result. Total Parenteral Nutrition (TPN) products that require retesting to invalidate an OOS uses this calculation. There is no guarantee after assay testing that reported results are accurate for the release of finished sterile drug products.

OBSERVATION 4

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. Your firm failed to adequately control finished product assay testing data. On 02/16/22, we observed the Chemist Team Lead having unrestricted privileges, including creating and deleting data, on the (b)(4) software. The (b)(4) software is used to capture finished product assay results used to release finished sterile drug products.

B. Your firm failed to adequately control adjustments to the date and times recorded on your assay testing data. On 02/16/22, we observed the date and time could be altered on Ultra Performance Liquid Chromatography (UPLC) data by changing the computer system's date and time. There are no controls in place to prevent laboratory personnel from altering the date and time on UPLC data used to release finished sterile drug products.

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Facilities and Equipment System

OBSERVATION 5

Equipment and utensils are not maintained at appropriate intervals to prevent malfunctions that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, your firm failed to maintain the (b)(4) system used for sterility testing. On 02/17/22, we observed the (b)(4) system, asset ID # (b) (4), being past due for (b)(4) calibration. The system was installed on 01/15/2021 with an (b)(4) calibration interval of (b)(4) from installation. The (b)(4) system is used for sterility testing for all finished sterile drug products.

Quality System

OBSERVATION 6

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, your firm failed to follow your written procedure titled Notification of Quality Events, number SOP-CAPS-4000693, version 10.0, effective date 11/08/21, used for reporting and documenting quality events.

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For example, we observed NQE reports related to particles in solution and yield percentage stating tracking and trending was performed; however, no adequate data was available for review during the inspection. Also, 10 out of 12 NQE reports related to complaints exceeded due dates without adequate justification.

The quality system for reporting and documenting quality issues is out of control.

***DATES OF INSPECTION**

2/14/2022(Mon), 2/15/2022(Tue), 2/16/2022(Wed), 2/17/2022(Thu), 2/18/2022(Fri), 2/22/2022(Tue), 2/24/2022(Thu), 2/25/2022(Fri)

X Christopher M Jenner
Investigator
Signed By: Christopher M. Jenner -S
Date Signed: 02-25-2022 13:58:28

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christopher M Jenner, Investigator Gunneet Kaur, Investigator X Gunneet Kaur Investigator Signed By: 2003283692 Date Signed: 02-25-2022 13:57:57	2/25/2022

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."