DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	8/18/2025-9/5/2025* FEI NUMBER 3009590582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rachel C. Schwartz , Director of Pharmacy

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	6580 Snowdrift Rd Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allentown, PA 18106-9331	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 followed.

Specifically,

A. Your firm discontinued use of the (b) (4) system in May 2025, which previously provided continuous non-viable particulate monitoring within ISO Class 5, 7, and 8 areas. Since discontinuation, over (b) (4) batches have been manufactured using the (b) (4) particle counter as an alternative. Per SOP-CAPS-4000582, the (b) (4) collects only (b) (4) non-viable particulate samples per session, providing intermittent rather than continuous monitoring in ISO 5 areas where sterile drug products are compounded.

B. Per SOP-CAPS-4000710, each of the (b) (4) ISO 7 compounding corridors is monitored only (b) (4) (b) (4) for viable and non-viable particulates, despite active use across (b) (4). Since January 2024, 47 alarm and action level excursions for viable CFU recoveries have been documented across ISO 7 air, surface, and personnel monitoring samples.

OBSERVATION 2

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FIRM NAME Central Admixture Pharmacy Services, Inc.	STREET ADDRESS 6580 Snowdrift Rd Ste 100
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18106-9331	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established and documented.

Specifically,

A. The firm failed to demonstrate reproducibility of the (b) (4) Microbial Detection System used for sterility testing of drug products compounded in IV bags. The firm's (b) (4) Microbial Detection System Results Data from (b) (4) Microbial Detection System Performance Qualification (PQ) for Sterility Testing of (b) (4) Products Summary Report" #V0184 was generated by testing drug product in the presence of ATCC organisms. This performance qualification was done with (b) (4) samples from (b) (4) in (b) (4) by the same analyst on the same day with the same microbial preparation. This validation was performed by and approved by your Quality Validation Manager on 10/18/2019. Additionally, the environmental isolate used as representative flora during the method validation was an environmental isolate from the (b) (4) in (b) (4) not the actual 503B production sites in Allentown, PA.

B. The (b) (4) Microbial Detection System is designed to warn the user of microbial growth via the generation of (b) (4) as a biproduct of microbial metabolism. Your firm failed to take into consideration whether the system is adequate for the detection of obligate autotrophic bacteria that consume (b) (4) during metabolism.

The method transfer study for the (b) (4) Microbial Detection System, "Sterility Method Transfer Verification of (b) (4) Products Final Report" (b) (4) is deficient; lacking an evaluation of inter- laboratory variation; a sufficient number of representative test articles (e.g., (b) (4) (b) (4)) used by the originating and receiving laboratories; comparative

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studies to evaluate accuracy and precision; product inhibition studies; evaluation of multiple media and diluents, limit of detection, limit of quantitation, and microbial growth conditions to evaluate worst case scenarios for spore forming and slow growing microbes, and difficult to grow environmental isolates.

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

Your firm's 100% visual inspection process is deficient. Since August 2024, there have been approximately 94 cases of first Acceptable Quality Level (AQL) failures, primarily for particulates ((b) (4)) and leaking bags ((b) (4)), and seven second AQL failures involving compounded aseptically filled products. The detection of visible particulate matter and leaking containers following your 100% visual inspection demonstrates that the inspection program does not consistently detect product defects prior to release.

OBSERVATION 4

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically,

Incoming components and drug product containers used in drug products compounded for intravenous administration are not tested or inspected. Materials are accepted based on the suppliers certificate of analysis, without sampling and examination. Examples of materials used without appropriate evaluation

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include empty and filled diluent bags used as final product containers for compounded IV drug products, including but not limited to the products listed in the table below.

The firm has received multiple complaints of leaking bags, and drug product diluent IV bags have been identified as a potential source of particulate.

Additionally, components used as active pharmaceutical ingredients (APIs) are accepted based on supplier's certificate of analysis, without conducting at least one specific identity test. Materials accepted without appropriate testing include but are not limited to APIs used in the compounding of products listed in the table below.

Product Code (NDC)	Product Name
7128560431	Oxytocin (b) (4) units/1000 mL NS
7128560301	Epinephrine 2 mg/250 mL D5W
7128570111	Phenylephrine 25 mg/250 mL NS
7128502111	Maintenance 4:1 Low K (30 mEq) in Plasmalyte A 1047
7128581001	Heparin (b) (4) units/500 mL NS
7128504311	Trophamine 3.5%/Dextrose 10% w/ Heparin 250 mL
7128501121	Maintenance 4:1 Low K (40 mEq) Plasmalyte/Trometh 1000 mL
7128560551	Diltiazem 125 mg/125 mL NS
7128500061	Reperfusate NO K 477.5 mL
7128590051	del Nido Formula (Isolyte) 1052.8 mL
7128502061	Induction 4:1 High K (48 mEq) in Ringer's 522.8 mL
7128560921	Phenylephrine 40 mg/250 mL NS
7128560741	Vancomycin 1.25 gram/250 mL NS

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7128502051	Maintenance 4:1 Low K (12 mEq) in Ringer's 504.8 mL
7128502121	Induction 4:1 High K (30 mEq) in Plasmalyte A 542 mL
7128500011	Microplegia (MSA/MSG 0.91 Molar) 125 mL
7128501111	Induction 4:1 High K (50 mEq) Plasmalyte/ Tromethamine
7128501031	Maintenance 4:1 Low K (20 mEq) 810 mL

OBSERVATION 5

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

Specifically,

Your procedure SOP-CAPS-4000582 "Environmental Monitoring-503B" allows for non-viable particulate (NVP) sample retesting without investigation following alert or action level excursions in ISO 5, 7, and 8 areas. Specifically, Section 6.10.4.A states that no investigation is required if (b) (4) (b) (4) NVP samples collected after an alert or action alarm fall below the excursion threshold at the same location.

Since January 2025, your firm has documented 8 instances of NVP excursion events where no investigations were initiated, instead relying on this retesting protocol. When questioned, your firm explained that this resampling practice provides "a more representative snapshot of the environment."

This practice allows potentially significant environmental excursions to go uninvestigated by using retesting to override initial alert and action level results.

THIS OBSERVATION WAS PREVIOUSLY CITED IN 2023

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*DATES OF INSPECTION

8/18/2025(Mon), 8/19/2025(Tue), 8/20/2025(Wed), 8/21/2025(Thu), 8/22/2025(Fri), 8/25/2025(Mon), 8/26/2025(Tue), 8/27/2025(Wed), 8/28/2025(Thu), 8/29/2025(Fri), 9/03/2025(Wed), 9/05/2025(Fri)

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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."