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	8/18/2025-9/5/2025* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark A. Caylor, Director of Operations	
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:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

The firm has failed to ensure reliable and reproducible quality production of sterile drug products manufactured by admixture compounding of active ingredients into intravenous (IV) bags and syringes and released to market. The firm has reported recurring non-conformances (NC) and notice of quality events (NQE) from July 2023 to August 2025 for defective units of IV bag drug products. Defects include particulate matter in solution (PM-S), particulates embedded (PM-E), delamination of external layer of IV bag, uncapped or leaky IV injection ports, leaking bag, defective component, or damaged labels.

A. From April 2024 – August 2025, over 212 out of 1096 non-conformances (20%) were for failed 1st or 2nd Acceptable Quality Limit (AQL) visual inspection for particulate matter (PM-S and PM-E) inside the bags. Additionally, your firm reported 30 non-conformances for delamination or crinkles in the outer plastic lining of the IV bags for the same period.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Roger F Zabinski, National Expert Homero W Aguilar, Microbiologist X Roger F Zabinski National Expert Signed By: Roger F. Zabinski -S Date Signed: 09-05-2025 11:19:33	9/5/2025

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	8/18/2025-9/5/2025* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark A. Caylor, Director of Operations	
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

For the three months from 5/19/2025 – 8/18/2025, the firm manufactured (b) (4) batches of drug products in IV bags and syringes, but 30% of the batches manufactured were rejected due to defects including particle matter, IV bag delamination, IV bag or syringe leaks, or other reasons, resulting in low final batch yields. High number of defects has been a recurring issue for the past 1-2 years. Of the (b) (4) batches released during this three month period, (b) (4) batches (33%) had yields below the firm's (b) (4)% specification limit, sometimes as low as 6% final yield. The low yield batches were released inconsistent with the firm's specification and without scientific justification to support that the portion of the batches released were free of defects.

B. The firm's compounding procedures SOP-CAPS-4000717, 31.0, 6/09/2025, Repeater Pump Procedure; and SOP-CAPS-4000768, 17.0, 5/20/2025, APEX Compounding Procedure 503B; require (b) (4)% or greater finished product yield. A non-conformance must be initiated for batches with a final yield below that specification. But the low yield limits are not enforced by the firm's Quality Unit. The firm does not use alert and action limits, instead only requires that a non-conformance investigation be opened for each low yield batch occurrence. The non-conformances are evaluated on a risk-based approach but lack scientific justification, root cause analysis, or effective corrections (CAPAs).

C. The root cause and resolution of recurring non-conformances from 2023-2025 has not been resolved. Some batches that have been released to market have final yields as low as 6-20%, with 80-94% of the units rejected for defects including external bag delamination, visible particulates, or other defects. The firm has not established orthogonal detection methods that are more accurate including liquid particle analysis, filtration and microscopic analysis, or other tests. The firm instead has relied on (b) (4) methods of 100% visual inspection and AQL sampled visual

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Roger F Zabinski, National Expert Homero W Aguilar, Microbiologist	X Roger F Zabinski National Expert Signed By: Roger F. Zabinski -S Date Signed: 09-05-2025 11:19:33	9/5/2025

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	8/18/2025-9/5/2025* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark A. Caylor, Director of Operations	
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

inspection. The non-conformance investigations were inadequate in that the firm has not shown that the units released to market are free of visible particles that may be difficult to see, sub-visible particulates, or bag defects. Some of the (b) (4) low batch yield products released to market include:

					Number of Major and Critical Defects in Batch		
Batch #	**Product**	**Manufacture Date**	**Total Reject %**	**Final Yield %**	**Particles**	**Delamination**	**Leaks, other**
36-276932	Heparin 4,000 units in 0.9% Sodium Chloride 1000 mL Release Date: 7/22/2025 Expiration Date: 9/19/2025	6/16/2025	94%	6%	1	542	2
36-277831	Heparin 4,000 units in 0.9% Sodium Chloride 1000 mL Release Date: 8/22/2025 Expiration Date: 10/24/2025	7/21/2025	82%	18%	1	479	0
36-277832	Heparin 5,000 units in 0.9% Sodium Chloride 500 mL Release Date: 8/21/2025 Expiration Date: 10/24/2025	7/21/2025	43%	57%	10	240	0
36-277739	Oxytocin 30 units added to 0.9% Sodium Chloride 500 mL Release Date: 8/11/2025 Expiration Date: 9/16/2025	7/18/2025	64%	36%	22	348	0
36-277334	Phenylephrine HCl 100 mcg/mL in 0.9% Sodium	7/01/2025	16%	84%	87	0	1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Roger F Zabinski, National Expert Homero W Aguilar, Microbiologist	X Roger F Zabinski National Expert Signed By: Roger F. Zabinski -S Date Signed: 09-05-2025 11:19:33	9/5/2025

	Chloride 10 mL in 10 mL Syringe Release Date: 8/05/2025 Expiration Date: 9/29/2025						
36-277632	Vancomycin 1.25 gram added to Dextrose 5% 250 mL Release Date: 8/05/2025 Expiration Date: 10/08/2025	7/10/2025	11%	89%	44	10	3

D. The firm's Visual Inspection Procedure 503B, SOP-CAPS-4000688, version 16, effective 5/28/2025, is deficient in that it does not specify the 100% visual inspection and AQL visual inspection limits for critical, major, and minor defects. The number of defects are recorded in the batch records and categorized at particles, delamination, leaks, or cosmetic, but the defects are not specified in terms of critical, major, or minor.

E. The firm's warehouse packaging procedure is to pack whole boxes of (b) (4) x 1L IV bags or (b) (4) x 500mL IV bags and any units that do not comprise a full box will be rejected, but these are not defect units.

For example, Heparin 4,000 Units/1000 mL NS (normal saline), batch 36-276932, had (b) (4) units (bags) released, packaged in (b) (4) bags per box. Non-conformance (NC) investigation, NC-10471 for low batch yield, was opened for this batch and was listed as major. There was one defect for particles, 542 defects for bag delamination, and 2 leaking bags. The NC-10471 states that all bags with defects were identified and rejected and the investigation concluded no impact to the conforming bags released. However, there is no scientific evidence to conclude that all defects

were identified and rejected. The firm did not have stability data or filter / microscopic analysis of approved units to determine if there were unseen particles or if more particles were generating over time.

Oxytocin 30 units/500mL NS, batch 36-277739, had three non-conformances opened: NC-11121, Critical, for Failed 1st AQL Delamination; NC-11122, Major, for low batch yield; and NC-11147, Critical, for frequent low batch yield and defects. Some of the defects for this batch included: 17 units rejected for particulate matter in solution (PM-S); 5 rejects for particulate matter embedded on the inside of the bag (PM-E); 348 defects for bag external delamination; 6% defects for particles, 91% for delamination, and 3% for other. After the 64% of rejected units, the remaining 36% of the batch was released, but other than visual inspection there was no evidence to support that all defect units were removed.

Heparin 4,000 Units/1000 mL NS, batch 36-275247, had a high final yield 96%, but had 3 rejects for particles, 2 leaking bags, and 3 units rejected for warehouse packaging limit. This batch received a consumer complaint from a hospital pharmacy on 5/28/2025, for 4-5 leaking bags, indicating that the inspection process does not catch all defects.

OBSERVATION 2

Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

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	8/18/2025-9/5/2025* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark A. Caylor, Director of Operations	
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

Each batch of diluent IV bags including Normal Saline (NS), 5% Dextrose in Water (D5W), and other diluents, are not tested by 100% visually inspection, strict AQL visual inspection, or other Quality Control tests to ensure the materials are free of foreign particles and meet the specifications of sterility, endotoxin, and other specifications, prior to adding drug products such as Heparin, Oxytocin, Phenylephrine, or other drugs. Change request CR-04984 has been recently initiated in August 2025 to create an Incoming Inspection SOP. SOP-CAPS-4000530, for Material Receiving, Handling, and Storage – 503B covers the initial receiving and shipment inspection in the warehouse but there is no procedure or current process developed yet at the firm to complete 100% visual inspection of the IV diluent bags prior to use in compounding.

The firm has reported more than 212 non-conformances for failed 1st and 2nd AQL visual inspection and low batch yields of finished product IV bags and syringes due to bag defects and visible particulate matter in solution. The firm used a third party laboratory and have identified the visible particles in the drug/diluent solution as polystyrene and polypropylene from the IV bags. The firm has observed the same defects of visible particles, leaks, and bag delamination in the incoming raw material diluent IV bags, but the firm does not have incoming raw material quality control checks to prevent the defective bags from being used in the production process. The firm uses commercially distributed IV bags of diluents including Normal Saline and D5W from their parent company, BBraun, but per the firm's Corporate VP of Quality Assurance for BBraun and CAPS, the firm has not reported complaints to the supplier for the particle matter defects of the IV bags to enable the supplier to initiate investigations and take corrective actions. This is an issue that has reoccurred from at least April 2024 to August 2025, and has not been fully investigated.

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Roger F Zabinski, National Expert Homero W Aguilar, Microbiologist	X Roger F Zabinski National Expert Signed By: Roger F. Zabinski -S Date Signed: 09-05-2025 11:19:33	9/5/2025

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	8/18/2025-9/5/2025* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark A. Caylor, Director of Operations	
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

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 and syringes. The firm's (b) (4) Microbial Detection System Results Data from "(b) (4) Microbial Detection System Performance Qualification (PQ) for Sterility Testing of CAPS 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) (b) (4) by (b) (4) on (b) (4) with (b) (4). 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 CAPS (b)(4) in (b)(4) not the actual 503B production site in Phoenix, AZ.

B. The (b) (4) Microbial Detection System is designed to warn the user of microbial growth via the generation of CO_2 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 CO_2 during metabolism.

C. The method transfer study for the (b) (4) Microbial Detection System, "Sterility Method Transfer Verification of CAPS Products Final Report" RPT-CAPS-4000110 is deficient; lacking

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Roger F Zabinski, National Expert Homero W Aguilar, Microbiologist	X Roger F Zabinski National Expert Signed By: Roger F. Zabinski -S Date Signed: 09-05-2025 11:19:33	9/5/2025

an evaluation of inter-laboratory variation; a sufficient number of representative test articles (e.g., same lot(s) of drug substance or drug product) used by the originating and receiving laboratories; comparative 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 4

Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

Your firm failed to thoroughly investigate three (b) (4) Microbial Detection System sterility test failures (OOS-00055, OOS-00070, & OOS-00104) for Heparin 4000 units/1000 mL NS (NDC: 7022-1) between 04/2025 and 06/2025. Investigations into these discrepancies included review of materials used and employee interviews. The isolates recovered were identified as *Bacillus circulans* in April and *Chaetomium globosum* between 05/2025 & 06/2025. The investigations failed to address any aspects downstream of production, but not limited to, visual inspection, sample chain of custody, and media sterility.

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not fully followed.

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	8/18/2025-9/5/2025* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark A. Caylor, Director of Operations	
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

Specifically,

The firm's Quality Unit is not taking effective measures to respond to discrepancies in materials, production, inspection, and other systems to ensure consistent, reliable, quality products are made for market distribution.

A. The firm's Quality Procedures, Quality Unit, and Site Leadership are new with personnel in leadership positions at the site for less than 1 year. The firm had multiple quality system restarts between 2023-2025. The firm has used 2-3 databases for recording Notice of Quality Events (NQE), Nonconformances (NC), Out of Specifications (OOS), Complaints/ Adverse Drug Events (ADEs), change controls, and deviation investigations (DEV), and other quality events. The firm's management has reported that procedures for quality oversight of the firm have been evolving between 2023-2025. Trending of quality evens has been inconsistent from customer service reports that only include select limited number of quality events; to (b)(4) Quality System Management Reviews that only start from January 2025 to present. Personnel at the firm stated that they would not address quality or facility trends prior to their employment or January 2025. Quality event trends from July 2023 – December 2024 were not available.

B. Real time trend and corrections of deficiencies appears inadequate. The firm relies on assistance from employees of CAPS or BBraun not located at this site, but there does not appear to have bene adequate support provided across the corporate network to ensure that personnel at the local site have the expertise to evaluate if any data, tests, or validation reports for complex systems are adequate. The Quality Unit members lack the experience to conduct trend analysis using (b) (4) pivot tables, or other metrics to respond to non-conformances, process deficiencies,

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	8/18/2025-9/5/2025* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark A. Caylor, Director of Operations	
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

inspection of incoming raw materials, and AQL inspection failures for the finished product. The firm's local Quality Unit lacks expertise to evaluate the (b) (4) sterility testing system.

C. Retrospective analysis via Annual Product Reviews are not done routinely. The last APR was for all products by type, or family of products, was in 2023 and took 9 months to complete: CAPS Annual Product Review Data Collection for Data Preliminary Review, for period 1/1/2023-12/31/2023, completed 9/13/2024.

D. Repeat deficiencies have occurred and corrections from 2023-present have not been effective. Corrective actions have sometimes involved multiple variables changed simultaneously, resulting in new unforeseen deficiencies, for example the failed AQL review.

E. Records associated with drug production and distribution and within the retention period for such records were not made readily available for authorized inspection and required multiple corrections. Per the firm's management, the local site Quality Unit is not able to access and query some specific batch manufacturing data generated at this site but stored in the database programs Lance. Instead, the staff at the local site must request information through the corporate IT department personnel. The firm has not yet implemented a database that will allow local sites to access their own data.

F. The Quality Unit has not assured the quality of the products released. The firm uses 100% visual inspection of product to remove defects but has not resolved the root cause issues that cause the defects – leaky bags, delamination of the external layers of the IV bags, plastic particles inside of

the IV solution, and others. The firm uses a process of initial 100% product visual inspection, followed by 1st AQL visual inspection, a 2nd 100% visual inspection, and a 2nd AQL inspection to remove defects from the batch. This process of repeat inspections indicates testing into compliance.

The firm has not established strict alert or action AQL limit controls for when to reject a batch. A failed 1st AQL or low batch yield only requires a nonconformance investigation, but scientific evidence is lacking in the investigations to support batch release.

The firm has not explored additional product inspection methods such as filtration / microscopic examination of the solution or liquid particle analysis to determine if there are difficult to see particles that are missed after 100% and AQL visual inspections.

OBSERVATION 6

Established standards, sampling plans and test procedures are not followed.

Specifically,

A. Per the firm's management and non-conformance investigations, the firm's finished product visual inspection test procedure, SOP-CAPS-4000688, is deficient and not fully followed. This visual inspection test procedure, SOP-CAPS-4000688, states that inspectors will have a (b) (4) minute break after (b) (4) minutes of product inspection. DEV-001194 opened on 6/24/2025 considered changing the inspection time to 30 minutes with a 5 minute break, but the inspection procedure has not been updated. Non-conformance NC-10409, 7/02/2025, states that Heparin 4,000

Units/1000 mL NS, batch 36-276932, had 2 visual inspection sessions that exceeded the (b) (4) minute maximum for continuous visual inspection.

B. Per the firm's management, the environment for Visual Inspection and Labeling Area (VILA) in an ISO-8 corridor and the AQL visual inspection area in the warehouse are deficient and do not allow optimal inspection to detect particles and other defects in IV bags and syringes. The firm has over 212 non-conformances for visual inspection deficiencies and failed 1st and 2nd AQL visual inspections of finished product. The firm opened investigations DEV-000890 on 11/20/2024 and DEV-001194 on 6/24/2025 for the high number of failed AQL visual inspections.

C. The visual inspection procedure SOP-CAPS-4000688 that states IV bags and syringes will be (b) (4) for (b) (4) so that particles may be easier to detect. During the walk-through inspection of the firm's visual inspection VILA area, we observed employees inspecting IV bags and syringes of drug products. The employees routinely did not (b) (4) the IV bags and syringes and syringes. Some of the product visual inspections observed included Heparin 4,000 units in 1L NS lot 36-278220; Oxytocin 30 units/500mL lot 36-278320; and Cardioplegia Solution del Nido Formula lot 36-278669.

OBSERVATION 7

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically,

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	8/18/2025-9/5/2025* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark A. Caylor, Director of Operations	
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

The firm does not have a procedure for supplier material verification testing. The firm does not perform quality control testing at least annually to confirm specifications, including purity, potency, sterility, and other specifications, to confirm the material Certificate of Analysis and verify the supplier reliability for drug active ingredients used for admixture compounding of finished drugs in IV bags and syringes, including but not limited to, Heparin, Oxytocin, Phenylephrine, Lidocaine, Rocuronium Bromide, and other drug active ingredients. Supplier qualification and reporting is deficient to ensure that all starting materials conform to specifications prior to use in production.

OBSERVATION 8

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

Specifically,

The firm's procedure SOP-CAPS-4000820, 7.0, 12/15/2024, (b) (4) Continuous Environmental Monitoring System Operation is deficient in that it allows the use of manual non-viable and viable active air environmental monitoring equipment to be used in the event of a system failure for the (b) (4) Continuous EM monitoring. The manual non-viable and viable active air environmental monitoring equipment do not operate continuously and do not monitor the entire aseptic compounding operation.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Roger F Zabinski, National Expert Homero W Aguilar, Microbiologist	X Roger F Zabinski National Expert Signed By: Roger F. Zabinski -S Date Signed: 09-05-2025 11:19:33	9/5/2025

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	8/18/2025-9/5/2025* FEI NUMBER 3014307835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark A. Caylor, Director of Operations	
FIRM NAME	**STREET ADDRESS**
Central Admixture Pharmacy Services, Inc.	2200 S 43rd Ave
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Phoenix, AZ 85043-3909	Outsourcing Facility

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), 9/05/2025(Fri)

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Roger F Zabinski, National Expert Homero W Aguilar, Microbiologist	X Roger F Zabinski National Expert Signed By: Roger F. Zabinski -S Date Signed: 09-05-2025 11:19:33 Homero W. Aguilar -S Digitally signed by Homero W. Aguilar -S Date: 2025.09.05 11:33:43 -07'00'	9/5/2025

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."