DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	11/04/2024-11/15/2024 FEI NUMBER 3008563008

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
Aruna Koganti, Vice President Clinical and Regulatory Affairs

TO: FIRM NAME	STREET ADDRESS
Exela Pharma Sciences LLC	1245 Blowing Rock Blvd
CITY, STATE, ZIP CODE, COUNTRY Lenoir, NC 28645	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility / Sterile Drug Manufacturing 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/WE OBSERVED:

OBSERVATION 1

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up. Specifically,

503B Outsourcing facility

A. (b) (4) media lot (b) (4) used for release sterility testing of Sodium Acetate failed initial growth promotion testing. Your firm invalidated two tests of this lot of media and passed the third test without scientific justification. The initial test was performed on (b) (4) retested on (b) (4) and retested (b) (4) with passing results on (b) (4). Your firm's investigation, QE-000487, states that human performance was determined to be the root cause of the failed testing events. Your firm stated that there was no product impact based on this investigation. Your firm did not document any specific human error identified when testing the FTM media. FTM Lot (b) (4) was used in sterility testing of Sodium Acetate lot (b) (4) (b) (4) and (b) (4) Your firm released these lots of Sodium Acetate for distribution as follows:

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Compounded lot of Sodium Acetate	Packaged lot of Sodium Acetate	Date Released	Date(s) shipped	BUD
(b) (4)				11/30/2024
				12/31/2024
				12/31/2024
				9/30/2023

In addition, the following other test media were inadequately investigated after failing growth promotion results, as documented in investigation QE-000487. (b) (4) ot (b) (4) ot (b) (4) and (b) (4) lot (b) (4) These growth promotion media were retested once with passing results and were included in investigation QE-000487. No root cause was determined for any of the growth promotion failures.

Drug Manufacturer ((b) (4)

B. Your firm failed to adequately investigate conductivity out of specification (OOS) results for your (b) (4) unit that feeds your (b) (4) system. Review of your EM Trend Analysis excursions Quality Events (QE) reports of the (b) (4) conductivity indicated that after phase (b) (4) failures, new samples were collected and retested with passing results without performing a root cause analysis or initiating a CAPA. Retesting of the (b) (4) system was executed multiple times for the (b) (4) conductivity water samples, yielding failing results every time and with multiple collection samples. Maintenance to the (b) (4) system took approximately (b) (4) sampling, retesting and continuous out of specification results failing for the issue to be resolved.

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C. Root cause analyses in some of the laboratory investigations Quality Events such as QE-000594 and QE-000622 were found to be deficient. These records lack scientific rationale and supporting evidence to support the root cause established due to the investigational process that was used.

D. During the review of the laboratory investigations in (b) (4) System since July 2024, I observed that 48% out of a total of 89 Quality Events (QE); 43 of the laboratory investigations resulted in invalidated test results due to human error. Failure to establish and maintain adequate laboratory controls do not ensure the accuracy and reliability of test results.

OBSERVATION 2
The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically,

Drug Manufacturer
Your firm filled Sodium Bicarbonate Injection, USP lot (b) (4) ANDA 211091, in Augusta facility grade A, B, C, and D areas that were tagged as "QA HOLD". This lot was filled in Augusta facility on 11/6/2024. Quality hold was placed on the entrance to the " (b) (4) " line on (b) (4) The quality hold was placed on the room while waiting for (b) (4) HEPA certification to be completed and reviewed.

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OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed. Specifically,

Drug Manufacturer

A. Your firm failed to adequately perform Disinfectant Efficacy Studies for (b) (4) and (b) (4) on Sterile Nitrile Gloves, RPT-002136, Version: 1.0 Effective Date: 24 March 2022. No contact time was documented for the sterile nitrile glove study performed and a dilution error was carried over the repeated study and justified as not impacting the study due to a (b) (4) log reduction (Log (b) (4) rather than Log (b) (4). (b) (4) log reduction was attributed to a lower bacterial concentration.

Drug Manufacturer

B. Your firm has not demonstrated that (b) (4) disinfectant is adequately used. For example, Surface Disinfectant Efficacy Studies contracted to challenge disinfectant efficacy testing of (b) (4) against Candida albicans did not meet the (b) (4) criteria for test surfaces: (b) (4) (b) (4) and (b) (4). The disinfectant criteria passed criteria for all other surfaces challenged in the disinfectant efficacy study. Disinfect is readily available to use at your facility for the passing criteria surfaces. However, written instructions restricting of use (b) (4) disinfectant were not instructed in your procedures for (b) (4) and (b) (4) surfaces.

Drug Manufacturer

C. Your firm failed to detect leaks found in (b) (4) water system in the (b) (4) Facility. I observed the (b) (4) and the (b) (4) holding tank ((b) (4)) leaking with water puddles

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accumulated around tank and under the tank. (b) (4) water tank supplies the compounding tank during batch production of aseptic and (b) (4) products.

503B Outsourcing Facility and Drug Manufacturer

D. Your firm failed to detect visible damages on your sterility (b) (4) For example, during visual inspection of the sterility (b) (4) we noticed that the (b) (4) had a big crack on it. Microbiology Manager explained that (b) (4) of the (b) (4) is performed (b) (4) Sterility Test (b) (4) Cleanroom Technology Asset# (b) (4) is used to perform sterility testing of finished and in-process drug products which maintains an ISO Class 5 environment and uses (b) (4) access for process manipulation. Additionally, procedure "SOP-000552 Containment (b) (4) and Maintenance Program, Doc Version: 4.0, Effective Date: 02 Aug 2024" and "SOP-000188 Operation, Calibration, and Maintenance of the (b) (4) Exela Asset (b) (4) Doc Version: 6.0, Effective Date: 20 Sep 2024" do not include instructions for (b) (4) unit damage inspection, it only requires (b) (4)

Drug Manufacturer

E. Your firm failed to demonstrate adequate personnel monitoring during post-cleaning procedures after manufacturing of Ephedrine Sulfate Injection, USP (5.0 mg/mL), 5 mL COC Syringe, 400 L Batch, (b) (4) ine (b) (4) Lot : (b) (4) Date: (b) (4) For example, in room (b) (4) I observed (b) (4) operators performing cleaning of floors, inside and outside the Sterility (b) (4) The operator sweeping the floors bumped into the corner (b) (4) of the (b) (4) I also observed operators' finger, hand, and head (personnel monitoring) environmental contact plate sampling via (b) (4) efore exiting the room. Operator (b) (4) by (b) (4) on operators' (b) (4) Operator (b) (4) on the (b) (4) (b) (4) During personnel monitoring, I noticed that (b) (4)

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plate was not firmly pressed on operator's head and contact time was very brief. During the finger sampling the operators (b) (4) fingers but the palm of the hand did not seem to be efficiently sampled on RODAC plate.

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OBSERVATION 4

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy and completeness. Specifically,

503B Outsourcing Facility and Drug Manufacturer

Your firm failed to perform contemporaneous two-person check during reading and data entry of environmental (b) (4) plates in the (b) (4) system. A single operator reads environmental plate counts, takes pictures of positive counts (no pictures are taken of negative counts), enters results in the (b) (4) system and later results are reviewed and verified by QC personnel. There is no assurance that the operator has entered data accurately (missed or misread plates counts) at time of reading. In addition, miscounted plates were observed in the microbiology lab on 11/6/2024. Miscounted colony forming units are as follows:

Plate number	Sample location	Sample date	Sample type	Number of Colony Forming Units (cfu) on plate	Analyst count
(b) (4)	(b) (4)	10/31/2024	Active viable air	10cfu	8cfu
		10/31/2024	Active viable air	11cfu	10cfu
		10/31/2024	Active viable air	4cfu	3cfu

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OBSERVATION 5

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,

Drug Manufacturer ((b) (4)

A. Your firm failed to generate accurate and complete records in a legible, original or a true copy of electronic records suitable for inspection and review. During the implementation of (b) (4) System, version (b) (4) completed on (b) (4) under the following change controls:
   a. Change Control # (b) (4) and (QE-000194- (b) (4) for Phase (b) (4)
   b. CR-12459 (b) (4) for Phase (b) (4)
   c. QE-000584 (b) (4) for Phase (b) (4)

   The affected data transition from (b) (4) system, during Phase (b) (4) and completed on (b) (4) (b) (4) it was noted that the format used to present laboratory investigations, deviations, change controls, and other critical quality documentation is not conducive to effective review. The information presented is displayed in metadata format in a tabular layout, which does not assure that the data is readable and complete.

B. The implementation of Phase (b) (4) was deficient is due to failure to perform complete back up of the data that was previously generated under (b) (4) system prior to the implementation of (b) (4) System, version (b) (4) This deficiency compromises the integrity and availability of these records. A true copy of the original data (which includes associated metadata) and should be in original format compatible with the original data during the transition from (b) (4) software to (b) (4) System on (b) (4)

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C. Your firm uses a non-validated system (Excel workbooks) to manage the stability samples inventory, these controls should include audit trails to ensure accuracy and integrity of data presented on these workbooks. In addition, the same issue was observed for the storage of drug product defects. It is not acceptable to store electronic records that allows for manipulation without creating a permanent record.

OBSERVATION 6

The calibration of instruments and recording devices is not done at suitable intervals in accordance with an established written program. Specially,

Drug Manufacturer (b) (4)

A. Calibration certificates for the Analytical balances (Asset ID # QC2209 and Asset ID # QC2493) and Top loading balance (Asset ID#(b) (4) located in the QC Chemistry Laboratory, were found to be deficient. The reproducibility test in the calibration certificates for these balances do not meet the required specifications to ensure suitability of the balances before use. These analytical and top loading balances are used for weighing reference standards and solution preparation for testing of raw materials, in-process, and finished products.

B. Analytical balance, (Asset ID# QC2209), located in the QC Chemistry Laboratory was observed to have poor maintenance (i.e. appeared to have rust/corrosion, displayed defective side doors that did not open as expected). This analytical balance is used for weighing reference standards and samples used for evaluation and release of manufactured products that use data generated by analytical balance (i.e. raw data weights).

C. pH meter (Asset ID# (b) (4) located in the R&D Laboratory was not evaluated for the offset requirements as per reference test method. A review of the pH meter calibration logbook ID: (b) (4) from 05 JUN 24 to current showed that in multiple instances the offset results failed to

meet acceptance criteria (b) (4) According to SOP-000454: "Use, Calibration, and Maintenance of the (b) (4) Document Version: 4.0, Effective Date: 22 Aug 2024, only the slope criteria was used during the pH meter calibration, while the offset requirement is not considered as part of the calibration requirements to determine the suitability of the instrument before use.

D. Storage conditions and controls of laboratory reference standards were found to be inadequate. For example, laboratory reference standards located in the dry reagent room and in the laboratory refrigerator Asset ID# QC2456 were not segregated from reagents and test solutions to prevent possible mix-ups and contamination. Additionally, no traceability of the reference standards were used in the analytical test's reports (Bottle ID), only lot number was used. Furthermore, no written procedure is in place for the use of (b) (4) System for the distribution and procurement of standards.

E. Dry reagent room lacks temperature mapping studies and temperature monitoring system to ensure storage conditions remain unaffected and uniform to avoid possible impact to reference standards stored in the room. Currently, there is no assurance that the room remains uniformly at room temperature conditions. Analytical Chemistry Director stated that there is no temperature mapping studies performed for the reagent room.

F. Sample management room used for storage of laboratory raw material, in-process, release, and stability samples for chemical testing. Analytical Chemistry Director stated that the room had been previously mapped but not fully implemented. Temperature monitoring is performed with a (b) (4) and document (b) (4) and (b) (4) (b) (4) There is no assurance that temperature excursions are accurately detected and documented.

G. Retain Sample Room SMRY-1599 report for temperature mapping studies and temperature verification monitoring system is inadequately installed. Your system cannot assure that retain samples maintain uniform conditions in the area. Locations of temperature probes have not been properly placed to accurately detect uniformity in the room. Current mapping study could lead to undetected temperature variations that may impact the integrity of samples stored in the room.

OBSERVATION 7
Laboratory records do not include complete records of any testing and standardization of laboratory standard solutions. Specifically,

Drug Manufacturer
Your firm failed to have analytical data to support the stability of Resolution Solution used during the sample analysis of a sterile product identified as: Tranexamic Acid Injection, 10mg/mL, 100 mL IV Bag (i.e. Lot# (b) (4) Released on: 13 AUG 2024. According to laboratory record (Book: (b) (4) the resolution stock solution was prepared in (b) (4) and it has been used for the evaluation and further release of manufactured batches of this Tranexamic Acid Injection. This resolution solution is a combination of Tranexamic Acid Related (b) (4) and Tranexamic Acid for which the Tranexamic Acid standard solution has been identified as stable for (b) (4) (Document: QCMET-000179). Your firm indicated that as per SOP-QC-000075: "Procurement, Receipt, Storage, and Expiration Dating of Laboratory Chemicals", Document Version 2.0, Effective Date: 09 Feb 2021. As per Table 1 – General Expiration Dating Guidelines the Resolution/Identification/Sensitivity Solutions Expiration Date is Indefinite (with suitable chromatography and chromatographic requirements met), or if it is indicated in analytical test method or compendial procedure. There is no scientific rationale to support that a resolution solution is stable indefinitely, such as a continuous monitoring nor assessment of the

chromatographic behavior of this resolution solution since the initial use on 2021 to support that statement and stability of the resolution solution.

OBSERVATION 8

Established laboratory control mechanisms are not followed and documented at the time of performance. Specifically,

Drug Manufacturer (b) (4)

A. Retain samples for commercial products and raw materials were not stored in their designated locations as required by SOP-000024: "Quality Assurance Retain Management", Document Version: 8.0, Effective Date: 16 May 2024. Samples identified in (b) (4) inventory log as being located on the (b) (4) and (b) (4) shelves were not found. Your Retain Manager was unable to locate it. Additionally, the room was cluttered, with retain samples and raw materials stored in a packed manner, which may have contributed to the difficulty in locating the samples and increased the risk of misplacement or improper storage. For example:

Product Name	Exela Lot Number	Qty	Storage Location
Pentamidine Isethionate for Injection (150mg/mL, 2mL fill)300mg/vial, 10mL Vial (Finish Drug Product)	(b) (4)		
Streptomycin for Injection, USP, 200mg/mL, 1g/vial, 10mL vial (Finish Drug)			
20mL Vial, Clear, Type I Glass Tube (Raw Material)			

B. Your firm failed to have GMP equipment segregated from Research and Development (R&D). For example, during the review of analytical data of Tranexamic Acid Injection, 10mg/mL, 100 mL IV Bag (i.e. Lot# (b) (4) Released on (b) (4) and Sodium Bicarbonate Injection, USP, 84 mg/mL, (1 mEq/mL), 50 mL Vial (i.e. Lot# (b) (4), Released on: (b) (4) I observed analyst used pH meter (Asset ID# RD9058) located in the R&D laboratory. Instrument is used for the evaluation and lot release of manufactured drug product batches. The inductively coupled plasma optical emission spectroscopy (ICP-OES, Asset ID# QC2514) is used for R&D but is located in the QC Raw Material Laboratory. It was not identified as R&D equipment.

C. (b) (4) Stability Chamber (Asset ID# QC2489) located in the Clinical Lab Room is not limited to authorized personnel only. Uncontrolled room allows access to Corporate, QA-India, API, Facilities, Utilities, Validation, and other personnel. Stability chamber (Asset ID# QC2489) was found unlocked, allowing easy access to drug manufacture stability sample products stored in chamber. Additionally, (b) (4) Stability Room (Chamber) located in the ground floor of Stability Room was also found to be accessible to unauthorized personnel from Facilities, Corporate and other departments to access the stability samples located in room.

OBSERVATION 9There is no written testing program designed to assess the stability characteristics of drug products. Specifically,

503B Outsourcing Facility

Your firm does not have stability data to support a 6-month expiration date for Sodium Chloride Injection 0.9% Injection, USP packaged in 500mL polypropylene IV bags. Your firm produced (b) (4) (b) (4) batches of Sodium Chloride in (b) (4) IV bags in (b) (4) and placed them on stability for potential

503B compounding. This study was performed using (b) (4) bag size with a fill volume of (b) (4) This study data was produced using different equipment, compounding/filling rooms, and packaging configurations than the current Sodium Chloride Injection 0.9%, USP being compounded at your firm. The current Sodium Chloride Injection 0.9% USP batches are packaged in 500mL polypropylene IV bags with a 500mL fill volume and a batch size of (b) (4) Your firm used the data from the 2017 study to justify a 6-month expiration on the current Sodium Chloride Injection 0.9% USP being compounded. In addition, your firm has not performed any sterility testing on Sodium Chloride IV bags currently being compounded.

OBSERVATION 10

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions. Specifically,

503B Outsourcing Facility (b) (4)

A. Your firm's visual inspection qualification (b) (4) s inadequate.

i. Your firm's visual inspection kit used during qualification is not representative of the visual inspection process. Your firm's visual inspection (b) (4) s comprised of (b) (4) vials of a variety of vials sizes ranging from (b) (4) These vials also contain a variety of products depending on the vial size. During visual inspection of a production batch the visual inspection process is performed on (b) (4) and (b) (4)

ii. Your firm's qualification (b) (4) does not contain all defects found in production lots. For example, your firm's defect classifications are missing from the following vial qualification (b) (4) The clear vial inspection (b) (4) does not include critical defects; gross high fill and gross low fill. The clear vial inspection kit does not include major defect: empty unit. The clear vial inspection (b) (4) does not include minor defects: check/chip in container and air lines in container. Your firm's IV bag qualification (b) (4) does not include critical

defects: gross high fill, gross low fill, and discolored solution. Your firm's IV bag qualification kit does not include major defect: damaged hanger eyelet.

B. Your firm's visual inspection qualification process is inadequate.

i. Your firm pulls challenge defect vials to be used for qualification from a pool of defects (b) (4) with no process to assure that visual inspectors are qualified on an appropriate range of defects found in products. During review of your firm's visual inspection qualification documents for visual inspectors, your firm did not qualify each visual inspector for all defects found in production including fill volume, discolored solution, glass particulate matter, missing crimp, white particulate matter, and black fiber.

ii. The visual inspection speed was not appropriately qualified for speed. Your firm's procedure requires an inspection (b) (4) per vial. During qualification one inspector finished inspecting vials in an average of (b) (4) per vial, which is faster than the inspection procedure requires. In addition, during inspection of production vials/IV bags your firm does not document the total number of vials/IV bags inspected by each inspector to confirm that time spent inspecting vials is within the qualified speed.

C. Your firm's library of defects is not indexed and is not verified to have all representative defects from production.

OBSERVATION 11

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The statistical quality control criteria fail to include appropriate rejection levels. Specifically,

503B Outsourcing Facility

Your firm has a (b) (4) overall reject limits for visual inspection, individual defect categories do not have reject limits. Your firm does not open investigations unless an overall (b) (4) visual inspection reject rate is reached. Your firm rejected 69 cracked vials, which are considered a critical defect, from lot (b) (4) of Sodium Acetate Injection, 100mL vials without opening any investigation. Your firm also rejected 79 cracked vials from lot (b) (4) of Sodium Acetate Injection, 100mL vials without opening any investigation.

OBSERVATION 12

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the holding of rejected components, drug product containers and closures before disposition. Specifically,

Drug Manufacturer

Your firm failed to properly handle reject drug products. For the example, during the inspectional walkthrough of your Reject Room (Reject Cage), I found you did not have a logbook or a physical inventory in place of materials stored in the cage. Your Quality Assurance Manager, stated material stored in cage is verified (b) (4) However, it is not documented nor there is written instructions for (b) (4) in your procedure "Handling of Rejects, SOP-000035 Doc Version: 4.0 Effective Date: 01 Aug 2024". Additionally, In-process rejects or finished rejects cannot be physically identified due to incorrect labels affixed on rejects. Your SOP lacks a defined list of reject materials that can be stored in the area. For example, Media Fill rejected samples were found in the area but not included as one that should be in that area. Furthermore, among the

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CITY, STATE, ZIP CODE, COUNTRY Lenoir, NC 28645	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility / Sterile Drug Manufacturing Facility

rejected In-process drug products, there was a red reject rectangular box labeled Sodium Chloride 0.9%, 500 mL IV Bag,(b) (4)Batch, Line (b) (4)Augusta, 503B, Catalog # (b) (4) Lot# (b) (4) ocated on the second shelf of the cage that was directly dripping (leaking) on a pallet with a Finished Product Inventory Log sheet FRM-000156, Doc Version: 4.0, Effective Date: 29 Jul 2024, Controlled Copy ID# CC-FRM-000156-(b) (4)placed on top of the pallet

OBSERVATION 13

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the receipt, identification, storage, and withholding from use of components, drug product containers, and closures pending sampling, testing, or examination by the quality control unit before release for manufacturing or packaging. Specifically,

Drug Manufacturer

Your firm failed to record storage conditions during the receipt of Active Pharmaceutical Ingredients (APIs). There is no assurance that drug substance has been kept under the right temperature conditions before and after receipt. During review of the Raw Material Disposition Report (FRM-000046 Doc Version: 12.0, Effective Date: 28 Dec 2023, Controlled Copy ID# CC-FRM-000046-(b) (4) I found storage conditions are not indicated as required in the report. Warehouse operator stated that raw material is not received with a data logger and no time entry is recorded upon receipt of drug substance (only date). Manufacturer's label on raw material indicates raw material API should be kept refrigerated at (b) (4)

OBSERVATION 14

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE	LTW MTZ JMC	Logan Williams, Investigator Santos Camara, Investigator Megan Ziegler, Investigator Joan Cantellops, Chemist	11/15/2024

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	11/04/2024-11/15/2024 FEI NUMBER 3008563008

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
Aruna Koganti, Vice President Clinical and Regulatory Affairs

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The labels of your outsourcing facility's drug products are deficient.

503B Outsourcing Facility

1. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:
   a. The dosage form

   Examples of your drug product labels that do not contain this information, include but are not limited to:

   - Midazolam HCl in 0.8% Sodium Chloride 50mL
   - Midazolam HCl in 0.8% Sodium Chloride 100mL

OBSERVATION 15
Written production and process control procedures are not followed in the execution of production and process control functions. Specifically,

Your firm's process validation for (b) (4) used in (b) (4) Sodium Chloride Injection 0.9%, USP were performed using (b) (4) and not using product. There is no data to assure that the sterilization process is effective when the (b) (4) is performed on compounded drug products.

***DATES OF INSPECTION**
11/04/2024 (Mon), 11/05/2024 (Tues), 11/06/2024 (Wed), 11/07/2024 (Thu), 11/08/2024 (Fri), 11/11/2024 (Mon), 11/12/2024 (Tues), 11/13/2024 (Wed), 11/14/2024 (Thu), 11/15/2024 (Fri)

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE		Logan Williams, Investigator Santos Camara, Investigator Megan Ziegler, Investigator Joan Cantellops, Chemist	11/15/2024

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."