DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	4/13/2026-4/22/2026* FEI NUMBER 1000110990

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Benjamin T. Ewald, Vice President of Sterile Operations

FIRM NAME	STREET ADDRESS
Alcami Carolinas Corporation	4221 Faber Place Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Charleston, SC 29405-8510	Drug Manufacturer

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:
QUALITY SYSTEM

OBSERVATION 1

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

Specifically,

Your visual inspection training does not utilize vial sizes representative of those used in commercial production. Personnel trained on non-representative vial configurations are not adequately qualified to perform visual inspection on production units.

For example:

1. Product (b) (4)): Production uses (b) (4) vials; training uses (b) (4) vials
2. (b) (4) ((b) (4)): Production uses (b) (4) vials (b) (4) capacity); training uses (b) (4) vials ((b) (4) capacity)

OBSERVATION 2

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

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	Steven A Brettler, Investigator - GDUFA Sonya M Edmonds, Investigator	X Steven A Brettler Investigator - GDUFA Signed By: STEVEN A. BRETTLER -S Date Signed: 04-22-2026 16:21:56	4/22/2026

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Specifically,

Your Quality Unit failed to perform adequate and thoroughly investigations for complaints involving (b) (4) Injection (b) (4)) and/or the (b) (4) (b) (4) Injection, (b) (4) . During the review of at least six (6) complaint investigations, there was a deficiency identified in terms of the review and/or performance of retain inspections for both the (b) (4) drug product and/or (b) (4) .

OBSERVATION 3

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

Your policy, POL61, Aseptic Process Simulation, Effective 04 Feb 2025 is not adequate as it states in step 6.17.5 that, "Individuals qualified on a (b) (4) are considered qualified on (b) (4) line." Each aseptic processing line requires an independent media fill qualification specific to each line's actual manufacturing conditions.

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically,

Your Standard Operating Procedure (SOP) 70956 titled "Operation of Line (b) (4) Tester" with an effective date of 08 December 2025 does not adequately describe in writing in regards to handling and tracking invalid or "aborted" (b) (4) tests. There was at least one (1) instance identified where an

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operator aborted a (b) (4) test with the pressure reading of 1099 Pa, which is below the acceptable pressure range of (b) (4) Pa, and there was no documented reason within the batch record for the following process validation (PV) batch, (b) (4) for (b) (4) Injection, (b) (4) (b) (4) ((b) (4) for (b) (4) Injection, (b) (4)

LABORATORY SYSTEM

OBSERVATION 5

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. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically,

Data generated from your (b) (4) meter (Equipment #A33770A), density meter (Equipment # A33678A), and Osmometer (Equipment #A33764A) utilized for (b) (4) (e.g., (b) (4) and (b) (4)), In-Process density testing, and In-Process osmolarity testing (Last vendor performed calibration in January 2025) respectively are transcribed (b) (4) from their displays into your laboratory information systems ((b) (4) and (b) (4)) and/or reports, the following deficiencies were identified:

1. Failure to ensure the original instrument-generated data includes verification by a second person.
2. Failure to ensure the original raw data from the instruments is retained in a retrievable format for later review, verification, or audit purposes.

OBSERVATION 6

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

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You have not adequately qualified your density meter (Equipment #A33678A) and osmometer (Equipment #A33764A), used in your analytical laboratory for in-process testing of (b) (4) (b) (4) Injection (b) (4) and/or (b) ((b) (4) Injection (b) (4) All (b) (4) Process Validation (PV) batches utilized this density meter and osmometer for testing. The following deficiencies were identified:

1. Failure to perform a Performance Qualification to demonstrate it performs appropriately for its intended use.
2. Failure to ensure the density meter is enrolled in a routine calibration program utilizing certified reference standards at defined intervals.

OBSERVATION 7

The establishment of laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit and reviewed and approved by the quality control unit.

Specifically,

A. Your Quality Unit failed to establish, document, and/or follow adequate risk assessments to scientifically justify the following:

A1. There was no written risk assessment documented for the lack of sterilization for the caps and seals for Line (b) (4) at the time of inspection

A2. There was no written risk assessment documented for the lack of air flow visualization studies in terms of demonstrating unidirectional airflow within the capping area which is located in room M107 (Grade C) at the time of inspection

A3. Risk Assessment (RSK) 503 titled "Risk Assessment for the interventions on Filling Line (b) (4)

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- CHS" with an effective date of 15 May 2025 on page 25-26 of 49 states that for the risk assessment for Pump tubing adjustment for (b) (4) loading that all vials that were present in the zone during the intervention go to the reject station; however, your SOP 70637 titled "Set Up and Operation of Line (b) Filling Line" with an effective date of 15 December 2025 on pages 95-96 of 136 state that for the pump tubing adjustment for (b) (4) loading to reject any vials if first air is broken over them. Your SOP is not aligned with your risk assessment, which requires a more stringent approach to control potential contamination.

B. Your Quality Unit failed to perform an air visualization study (smoke study) for the following interventions that could be applied to any given batch on Line (b) (4)

B1. Stopper Adjustment or Removal
- (b) (4) Loading Determination: Major

B2. Adjustment of (b) (4)
- (b) (4) Loading Determination: Major

B3. Product Spill Clean Up
- (b) (4) Loading Determination: Critical

B4. Adjustment of (b) (4)
- (b) (4) Loading Determination: Major

B5. Weight Check Calibration of Tare and Gross Scales
- (b) (4) Loading Determination: Major

C. There was no documentation available at the time of inspection that demonstrated your Quality Unit identified the following instances of first air interruption during interventions performed in an air

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visualization study (smoke study) for Line (b)(

C1. Pump Tubing Adjustment or Filler Install (b) (4) , Filling Assembly, Filling Needles

- The tubing was observed on the air visualization video to cross over some of the opened vials in the (b) (4) for Line (b)(

C2. Stopper Port Bag Replacement or Addition of Stoppers

- Operator (b) (4) hand in the (b) (4) was seen crossing over stoppers and interrupting first air pass in the (b) (4) for Line (b) (4

***DATES OF INSPECTION**

4/13/2026(Mon), 4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu), 4/17/2026(Fri), 4/20/2026(Mon), 4/21/2026(Tue), 4/22/2026(Wed)

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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."