DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	1/14/2025-1/24/2025* FEI NUMBER 3015826782

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Melissa J. Etheridge, President

FIRM NAME	STREET ADDRESS
Carolina Infusion	95 Bees Creek Rd
CITY, STATE, ZIP CODE, COUNTRY Ridgeland, SC 29936-7540	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

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

Materials were exposed to lower than ISO 5 quality air.

Specifically,

A. The (b) (4) swabs used to collect samples of compounded drug products intended for sterility testing were observed to have been opened and placed in the ISO 7 area. For example:

- On 1/15/2025, during the compounding of TRI-MIX 30/2/40 Injectable, Lot# 01152025@(b) (4) BUD 2/10/2025, it was observed that the operator filtered a drop of the solution intended to be sterile onto a swab that had been opened and exposed to the ISO 7 hallway while being carried to the ISO 5 Biological Safety Cabinet (BSC), Equipment ID 49302 located in Compounding Room (b) (4)

- On 1/15/2025, during the compounding of TEST CYP/DHEA (SESAME) 200 mg/2.5 mg/ml, Injectable Lot# 01152025@(b) (4) BUD 2/14/2025, it was observed that the operator opened a new bag of swabs to collect samples; however, during the cleaning of the ISO 5 Laminar Airflow Hood (LAFH), the opened bag of swabs was placed on a cart in the ISO 7 Compounding Room (b) (4) and would be used to perform testing inside the ISO 5 hood for the next batch of drug product intended to be sterile.

Your firm has not reported any positive growth; however, there is no assurance that the current method used for sterility testing of finished drug products is effective. Additionally, these cotton swabs may release particles during aseptic processing.

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	Taichun Qin, Investigator X Taichun Qin Investigator Signed By: 2001324646 Date Signed: 01-24-2025 08:43:34	1/24/2025

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B. Sterile wipes and mop wipes used to clean the interior surfaces of the ISO 5 LAFH were stored in open bags, leaving them exposed to ISO 7 areas and they were not fully saturated with (b) (4) (b) (4) before being introduced into the ISO 5 hoods. For example, on 1/16/2025, during the compounding of Gemcitabine 1g/50 mL, Lot# 2408201, it was observed the operator placed a wipe from an open bag in the ISO 7 compounding room into the ISO 5 Biological Safety Cabinet (BSC), Equipment ID: 3S-15-BR-4886 to hold supplies, but it was not fully saturated with (b) (4)

C. On 1/14/2025, during the tour of the ISO 7 sterile compounding room, unused capped sterile syringes were observed stored in an open bag on a cart. These syringes were intended for use in future batches.

OBSERVATION 2

Inadequate routine environmental monitoring in the ISO 5 area.

Specifically,

Environmental monitoring (EM) of the ISO 5 LAFH and BSC is inadequate. Air sampling for environmental monitoring in each ISO 7 compounding room is conducted (b) (4) by a third-party company; however, active air monitoring and the use of settle plates have never been conducted in these ISO 5 areas. There are (b) (4) ISO 5 LAFHs in Compounding Room (b) (4) and (b) (4) ISO 5 BSCs in Compounding Room (b) (4)

OBSERVATION 3

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

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The media fill process does not fully simulate the production of sterile compounded drugs. Your firm conducted a media fill every (b) (4) using a purchased kit to aseptically transfer a non-sterile solution from (b) (4) control vials to (b) (4) vials through a (b) (4). While this media fill process simulates the production of vial products, it does not account for the production of pre-filled syringes. For example, your firm produced (b) (4) pre-filled syringes of Semaglutide/Cyanocobalamin 9/2 mg/mL injection (Lot# 012122025@ (b) (4) dated 1/21/2025, with a BUD of 2/20/2025); however, the media fill process does not simulate the production of sterile pre-filled syringes.

OBSERVATION 4

Smoke studies were inadequately performed under dynamic conditions.

Specifically,

Your firm has no documented evidence demonstrating that the smoke study in the ISO 5 LAFHs or BSCs was conducted under dynamic conditions. The smoke study is performed (b) (4) by a third-party company. For example, the most recent smoke study, conducted on 12/30/2024, showed that the system meets the unidirectional airflow requirements as specified in the Unidirectional Airflow Test Protocol; however, no information, records, or videos demonstrating the smoke study was conducted under dynamic conditions were available for review.

OBSERVATION 5

Hazardous drugs and Highly potent drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

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A. The sterile compounding operators do not clean the ceiling area (with or without HEPA filter grids) inside the ISO 5 LAFHs or BSCs. For example, on 1/15/2025, after completing the compounding of TEST CYP/DHEA (SESAME) 200 mg/2.5mg/ml, Injectable Lot# 01152025@(b)(4) BUD 2/14/2025, the operator did not clean the ceiling area of the ISO 5 BSC (Equipment ID: 99302), a shared piece of equipment used for producing sterile hazardous drug products, biological products, and for radiolabeling blood cells. Additionally, the operator did not clean the interior surfaces of the front shield of the ISO 5 LAFH during the end-of-day cleaning in Compounding Room (b)(4)
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B. On 1/14/2025, during the compounding of Testosterone, 350 mg/ml gel, Lot# 01132025@(b)(4) BUD 2/17/2025 inside the BSC in the non-sterile Compounding Room (b)(4) it was observed that the paper towel used to wrap and stabilize a balance wheel inside the BSC appeared dirty, could not be effectively cleaned, and remained dirty throughout the inspection.

OBSERVATION 6

Lack of disinfection of supplies at each transition from areas of lower quality air to areas of higher quality air.

Specifically,

A. The operator did not thoroughly disinfect supplies, such as needle packages, with (b) (4) before introducing them into the ISO 5 LAFH from the ISO 7 area. On 1/14/2025 and 1/15/2025, during the compounding of Sermorelin Acetate Injection, 1 mg/ml, Lot# 01142025@(b)(4), BUD 2/28/2025 and TEST CYP/DHEA (SESAME) 200 mg/2.5 mg/ml, Injectable Lot# 01152025@(b)(4) BUD 2/14/2025, the operator sprayed multiple needle packages while holding them together in her hands with (b) (4), leaving the contact surfaces between the needles insufficiently disinfected.

B. The paper-like bag containing (b) (4) cotton swabs, used to sample sterile products for microbiology testing, was not disinfected prior to being introduced into the ISO 5 LAFH or BSC given

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that disinfecting the bag with (b) (4) might potentially cause false negative results if a cotton swab came into contact with the (b) (4) On 1/15/2025, the following observations were made:

- During the compounding of TRI-MIX 30/2/40 Injectable, Lot# 01152025@(b)(4) BUD 2/10/2025, the operator dropped an unopened bag of cotton swabs on the floor and immediately placed it inside the ISO 5 LAFH without disinfecting the bag's surfaces.

- During the compounding of TEST CYP/DHEA (SESAME) 200MG/2.5MG/ML, Injectable, Lot# 01152025@(b)(4) a hazardous drug product, the operator carried an opened bag of cotton swabs through an ISO 7 hallway into the compounding room containing the ISO 5 BSC, without disinfecting the bag before introducing it into the ISO 5 BSC.

***DATES OF INSPECTION**

1/14/2025(Tue), 1/15/2025(Wed), 1/16/2025(Thu), 1/17/2025(Fri), 1/20/2025(Mon), 1/21/2025(Tue), 1/22/2025(Wed), 1/23/2025(Thu), 1/24/2025(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."