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	8/5/2026-8/18/2026* FEI NUMBER 3015826782

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Courtney M. Nix, Pharmacist In Charge

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

OBSERVATION 1

There is a lack of HEPA-filtered air and an inadequate HEPA filter coverage or airflow over the critical area to which sterile drug product is exposed.

Specifically, on (b) (4), after the manufacture of tirzepatide for injection 26mg/ml lot 08052026(b) (4) and tirzepatide/cyanocobalamin for injection 26 mg/2mg per ml lot 08052026(b) (4), the (b) (4) (b) (4) laminar flow hood (ISO-5) was operating with a pressure gauge reading of zero, indicating a failure to maintain the positive pressure required to protect the critical aseptic processing area from the influx of lesser quality air.

You failed to use an appropriate anti-microbial preservative to prevent microbial proliferation within containers of multi-dose sterile drugs.

Specifically, (b) (4) bulk stock solutions of drug products, such as tirzepatide, are stored in unclassified areas and repeatedly introduced into the ISO-5 environment over a (b) (4) period to draw up patient-specific syringes. This workflow repeatedly exposes the bulk container closure system to unclassified air during storage and introducing contamination risks with each re-entry. You are using (b) (4). This can only inhibit bacterial proliferation; it is not bactericidal and does not provide protection against mold contamination.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joanne E King, Investigator Roger F Zabinski, National Expert	X Joanne E King Investigator Signed By: 1300174867 Date Signed: 08-18-2026 14:45:30	8/18/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	8/5/2026-8/18/2026* FEI NUMBER 3015826782

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Courtney M. Nix, Pharmacist In Charge	
FIRM NAME Carolina Infusion, LLC	STREET ADDRESS 95 Bees Creek Rd
CITY, STATE, ZIP CODE, COUNTRY Ridgeland, SC 29936-7540	TYPE ESTABLISHMENT INSPECTED Sterile and Non-Sterile Drug Manufacturer

Furthermore, your in-house sterility and endotoxin testing is deficient. Your firm is conducting sterility testing within the same ISO 5 hood simultaneously with the production of drug product intended to be sterile, such as tirzepatide. This is not appropriate for aseptic processing or laboratory testing. The in-house sterility and endotoxin test method development does not evaluate for product interference (e.g., from the use of (b) (4)). This calls into question the validity of your test results.

OBSERVATION 2

The Cleanroom areas contain dust-collecting overhangs without adequate and frequent cleaning.

Specifically, on 08/05/2026, visible dust was observed on the inside of the clean room door windowpane adjacent to the (b) (4) ISO-5 (b) (4) laminar flow hood in the non-hazardous compounding cleanroom (b) (4) which is used to produce sterile non-hazardous drug products.

Throughout the cleanroom suites, doors and viewing windows feature decorative molding with ridges and ledges. These surfaces are not smooth, or easily cleanable, contributing to particulate accumulation and potential microbial contamination in close proximity to production activities for drug product intended to be sterile.

Additionally, wall insulation was exposed and open to the mezzanine and warehouse area. This insulation was on the exterior of the generator room, the exterior of the ante room hallway, and the exterior of the hazardous compounding room (b) (4) The mezzanine and stairs leading to the mezzanine were composed of particle generating wood particle board. In some locations, on the mezzanine, the air ducts were not connected to an exterior venting system.

OBSERVATION 3

Inadequate (b) (4) on (b) (4) used to sterilize drug products.

Specifically, on (b) (4) after the manufacture of tirzepatide for injection 26 mg/ml lot 08052026(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joanne E King, Investigator Roger F Zabinski, National Expert	X Joanne E King Investigator Signed By: 1300174867 Date Signed: 08-18-2026 14:45:30	8/18/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	8/5/2026-8/18/2026* FEI NUMBER 3015826782

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Courtney M. Nix, Pharmacist In Charge	
FIRM NAME Carolina Infusion, LLC	STREET ADDRESS 95 Bees Creek Rd
CITY, STATE, ZIP CODE, COUNTRY Ridgeland, SC 29936-7540	TYPE ESTABLISHMENT INSPECTED Sterile and Non-Sterile Drug Manufacturer

and bulk tirzepatide/cyanocobalamin for injection 26 mg/ 2mg per ml lot 08052026(b) (4) we observed that the (b) (4) was not performed since the gauge used to test the (b) (4) appeared to be out of calibration and stuck on the pressure reading of approximately 18 PSI. This resulted in the following:

- tirzepatide for injection 26 mg/ml lot 08052026(b) (4) was rejected on 8/6/2026.
- bulk tirzepatide/cyanocobalamin for injection 26 mg/ 2mg per ml lot 08052026(b) (4) was reprocessed on (b) (4) .

OBSERVATION 4

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, the bulk tirzepatide/cyanocobalamin for injection 26 mg/2 mg per ml lot 08052026(b) (4) was reprocessed when the (b) (4) was not performed due to a pressure gauge malfunction. This reprocessing combined the contents of (b) (4) approximately (b) (4) bulk drug vials which were then (b) (4) and tested for endotoxin and sterility. This reprocessing was performed on (b) (4) and the beyond use date assigned was 9/19/2026.

OBSERVATION 5

Smoke studies were inadequately performed under dynamic conditions.

Specifically, the smoke studies taken on 1/27/2025 in your ISO-5 (b) (4) laminar flow hoods and bio safety cabinets did not fully demonstrate laminar flow. These smoke study videos were 4 to 18 seconds long and recorded by (b) (4) . The video does not show the air flow over the critical sterile drug product preparation areas and the air flow patterns for hoods that are located across from each other. Compounding room (b) (4) contains (b) (4) ISO 5 biosafety cabinets positioned facing each other, approximately 2-3 feet apart. One hood is designated for nuclear blood tagging, and the other is used for the production of testosterone cypionate injectable product intended to be sterile. No smoke study has

been conducted to demonstrate that the airflow from one hood does not interfere with the airflow of the other. The smoke study videos also did not include the most dynamic conditions of use such as (b) (4)

OBSERVATION 6

The facility is designed and/or operated in a way that permits poor flow of personnel or materials.

The warehouse / material receiving and product shipping area was found to have the following deficiencies:

- Open insulation and unfinished construction was observed in the warehouse on the wall between the cleanroom and warehouse.
- A recycling room at the back of the main warehouse / material receiving and shipping room is used for cleaning and storing the lead containers (pigs) used for shipping the radiopharmaceutical patient doses (syringes). In this recycle room, we observed that the firm is storing lead shipping containers (pigs) and radioactive waste such as Technetium Tc99m, Gallium Ga68 Netspot labeled containers, and Iodine I-123 capsules. The firm is disassembling (b) (4) radioactive generators used for production of Technetium Tc99m. Plastic containers, lead, metal and residue from these items was observed in this recycle room. Dead roach(es), dust and debris was also observed in this recycle room.
- The firm lacks controls to prevent cross contamination of lead, lead particles, and other debris from the recycle room through the rest of the facility.
- A door connects the warehouse / material receiving and shipping room directly to the non-sterile compounding processing and pharmacy orders packaging room. A door connects the warehouse to the employee break room and front hallway, administrative area, and compounding area front entrance. These doors from the warehouse lack controls to prevent

cross contamination from the recycle room, warehouse, and mezzanine areas from being introduced to the compounding non-sterile processing room. The only controls from preventing insanitary cross contamination to the main compounding cleanrooms and nuclear-pharmacy cleanrooms is the ante room.

OBSERVATION 7

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.

A. Specifically, testosterone compounding (a highly potent hormone), chemotherapy reconstitution (hazardous drugs), and blood radiolabeling (biohazardous material) are all performed within the same cleanroom (b) (4) using (b) (4) hoods in close proximity. There is no physical separation between the biohazardous blood handling area and the areas where non-blood products are handled. Furthermore, a shared supply table was observed containing materials for both testosterone compounding and blood radiolabeling activities, demonstrating inadequate dedication and segregation of equipment based on risk.

Each of these high-risk activities requires fundamentally different decontamination approaches—blood-borne pathogen decontamination, hazardous drug deactivation, and hormonal drug decontamination, respectively. The firm has not demonstrated through documented procedures or supporting evidence that the shared room, work surfaces, and equipment are adequately cleaned and decontaminated when transitioning between these activities. The performance of highly potent, hazardous, and biohazardous operations in the same unsegregated space, without

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	8/5/2026-8/18/2026* FEI NUMBER 3015826782

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Courtney M. Nix, Pharmacist In Charge	
FIRM NAME Carolina Infusion, LLC	STREET ADDRESS 95 Bees Creek Rd
CITY, STATE, ZIP CODE, COUNTRY Ridgeland, SC 29936-7540	TYPE ESTABLISHMENT INSPECTED Sterile and Non-Sterile Drug Manufacturer

demonstrated decontamination controls, represents a significant, unmitigated risk for cross-contamination whereby sterile drug products may have been rendered injurious to health.

B. Specifically, the ante room gowning includes use of non-sterile lab personnel protective equipment including shoe covers, a short lab coat, hair net, face mask, hand washing, non-sterile gloves, and use of (b) (4) or (b) (4) disinfectants for the gloved hands. There is no method for detecting and controlling cross contamination such as swabbing and analytical lab testing for particles, lead particles, and other chemicals.

OBSERVATION 8

Lack of and Inadequate routine environmental monitoring in the ISO 5 area and classified areas.

Your staff stated they perform (b) (4) surface sampling within the ISO 5 and ISO 7 area after cleaning and disinfection. Sampling after cleaning does not accurately represent your production environment. Additionally, your staff also stated and demonstrated that when (b) (4) plates are unavailable, the firm's procedure is to use (b) (4), (b) (4) on a surface, and then (b) (4) that (b) (4) onto an (b) (4) plate as EM surface sampling. A (b) (4) alone will not efficiently lift or release microorganism from a (b) (4) surface on to an (b) (4) plate compared to a pre-saturated swab. This method also does not include the use of neutralizing buffer which is necessary to neutralize residual disinfectants. This calls into question the validity of your test results.

OBSERVATION 9

Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joanne E King, Investigator Roger F Zabinski, National Expert	X Joanne E King Investigator Signed By: 1300174867 Date Signed: 08-18-2026 14:45:30	8/18/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	8/5/2026-8/18/2026*
	FEI NUMBER 3015826782

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Courtney M. Nix, Pharmacist In Charge

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

Specifically, on 08/06/2026 during cleaning activities of the (b) (4) laminar flow hood ISO5 in cleanroom (b) (4) the upper torso of a pharmacist was observed entering the ISO 5 hood, disrupting the unidirectional airflow intended to protect the sterile field.

OBSERVATION 10

Vermin or other animals or evidence of their presence was observed in the areas adjacent to production areas.

Specifically, on 08/05/2026, dead roaches were observed in the recycling room located at the back of the main warehouse, which is adjacent to areas with direct access to the compounding rooms. We observed each day of this inspection that bird feces were located on the ground outside your facility front door which could be tracked into your front office area and on to other areas within the facility.

***DATES OF INSPECTION**

8/05/2026(Wed), 8/06/2026(Thu), 8/07/2026(Fri), 8/10/2026(Mon), 8/11/2026(Tue), 8/12/2026(Wed), 8/13/2026(Thu), 8/14/2026(Fri), 8/18/2026(Tue)

Roger F. Zabinski -S
Digitally signed by Roger F. Zabinski -S
Date: 2026.08.18 14:50:55 -04'00'

Roger F. Zabinski, National Expert / CSO

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joanne E King, Investigator Roger F Zabinski, National Expert X Joanne E King Investigator Signed By: 1300174667 Date Signed: 08-18-2026 14:45:30	8/18/2026

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."