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	07/21/2026-07/31/2026* FEI NUMBER 3032406608

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shixian Wang, Director of Operations

FIRM NAME	STREET ADDRESS
CD Pharmacy, LLC dba Red Rock Pharmacy	863 W 450 S Ste 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Springville, UT 84663-2299	producer of sterile and nonsterile drugs

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

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, a technician identified a suspected glass particle in one vial during visual inspection of Liraglutide Injection, 6 mg/mL, lot 042026CH01, BUD 07/19/26. The OOS investigation authorized a technician to recover, (b) (4) and then fill the solution as Liraglutide Injection, 6 mg/mL, lot 051426CR26, BUD 08/12/26. There is inadequate stability data to support the approximately 90-day BUD assigned to the (b) (4) lot that was originally formulated and (b) (4) on 04/20/26. The new BUD is 24 days beyond the original 90-day BUD for the solution. There was no confirmation of the particle identity or its source. Your firm dispensed (b) (4) units from the (b) (4) lot. Examples include Rx #(b) (6), (b) (7)(C) delivered 07/15/26; Rx (b) (6), (b) (7)(C), delivered 07/10/26; Rx (b) (6), (b) (7)(C), delivered 07/08/26; and Rx (b) (6), (b) (7)(C), delivered 06/03/2026.

OBSERVATION 2

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

Specifically, media fill procedures and executed records do not reflect the various production activities I watched. Your firm currently aseptically fills about (b) (4) vials per day, and filled about (b) (4) lots of sterile injectable drugs in the previous two years.

A. Media fills do not simulate the most challenging production conditions. I watched (b) (4) technicians simultaneously fill, stopper, and cap vials from two lots inside the same ISO 5 hood during filling of multiple lots from Semaglutide Injection, 2.5 mg/mL stock solution lots 072126CRS1, 072126CRS2, and 072226CH-S25-01; and Tirzepatide-Methylcobalamin Injection, 17 mg-100mcg/mL stock solution lots 072126CR-TM17-01 and 072726CH-TM17-01. Technicians fill, stopper, and cap vials independently during media fill.

B. Technicians used dehydrated (b) (4) modified with (b) (4) during the most recent media fills for (b) (4) technicians in July 2026. The manufacturer's information indicates this (b) (4) is intended for the selective enrichment of enterohemorrhagic E. coli in foods in a laboratory setting. Growth promotion on the manufacturer's certificate of analysis document growth of several types of *E. coli* and inhibition of *P. aeruginosa*. Growth promotion did not include the other yeast, mold, and bacteria microorganisms required by USP standards. The (b) (4) did not appear suitable for use as the culture medium during media fills for aseptic filling sterile injectable drugs in an ISO 5 hood.

AMENDMENT 1

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C. There was inadequate justification not to include 2R vials which are the highest volume vial used for sterile drugs.

D. Technicians do not always verify the (b) (4) of (b) (4) prepared in-house for media fills meets the manufacturer's specification range.

E. ~~Technicians do not always follow the dehydrated culture media to (b) (4) ratio provided by the manufacturer to prepare (b) (4) for media fills.~~

OBSERVATION 3

Smoke studies were inadequately performed under dynamic conditions.

Specifically,

A. One technician, one syringe, and one vial present in the ISO 5 hoods during the smoke studies conducted in January 2026 was not representative of routine production. Items I observed in the hood during filling of multiple lots from Semaglutide Injection, 2.5 mg/mL stock solution lots 072126CRS1, 072126CRS2, and 072226CH-S25-01; and Tirzepatide-Methylcobalamin Injection, 17 mg-100mcg/mL stock solution lots 072126CR-TM17-01 and 072726CH-TM17-01 include: (b) (4) technicians, one repeater pump, (b) (4) (b) (4) bags and tubing hanging from the IV bar, one tray of glass vials, one bag of stoppers, one bag or caps, multiple forceps, a sleeve of (b) (4) plates, and other items.

B. Operations within the ISO 5 hood and ISO 7 buffer room were not representative of routine production conditions. One technician simulated puncturing a vial septum while one person held the handheld smoke generator during the smoke study. Conditions I observed that were not evaluated during the smoke study include (b) (4) technicians filling, stoppering, and capping vials simultaneously in the same ISO 5 hood.

C. Insufficient smoke was introduced into the primary workspace to adequately confirm unidirectional airflow within the ISO 5 horizontal airflow hood.

OBSERVATION 4

Materials were exposed to lower than ISO 5 quality air.

Specifically, I observed several sterile items exposed in the ISO 7 buffer room during filling of multiple lots from Semaglutide Injection, 2.5 mg/mL stock solution lots 072126CRS1, 072126CRS2, and 072226CH-S25-01; and Tirzepatide-Methylcobalamin Injection, 17 mg-100mcg/mL stock solution lots 072126CR-TM17-01 and 072726CH-TM17-01.

A. Technicians remove sterile wipes from the package and place them on top of the package on a table in the ISO 7 Hood Room (buffer room). I saw wipes remain exposed to the environment for more than one hour and observed multiple bags of caps placed directly on top of the wipes. Technicians sprayed sterile (b) (4) on these wipes and used them to disinfect surfaces inside the ISO 5 hoods.

B. Forceps purchased sterile were stored exposed in the ISO 7 buffer room for an indefinite amount of time, sanitized with (b) (4) (b) (4), and then used to put stoppers into filled vials of semaglutide injection.

C. (b) (4) trays used as a direct contact surface for vials and stoppers inside the ISO 5 hood are sterilized in-house and then remain exposed in the ISO 7 buffer room for an unspecified amount of time.

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OBSERVATION 5
Personnel were observed using a non-sterile tool during sterile production and manually touching a sterile product contact surface.

Specifically,

A. Forceps purchased sterile were stored exposed in the ISO 7 buffer room for an indefinite amount of time, sanitized with (b) (4) and then used to put stoppers into vials filled from Semaglutide Injection, 2.5 mg/mL stock solution lot 072726KH-S25-01.

B. One technician's gloved hand directly touched the pile of stoppers on the tray multiple times throughout the filling process for vials filled from Semaglutide Injection, 2.5 mg/mL stock solution lot 072726KH-S25-01.

C. Technicians removed the paper liner from the manufacturer's tray of vials, flipped the vials over onto a (b) (4) tray, and then placed the paper liner directly on top of the vials as a cover during filling. Technicians occasionally placed the vial-contact side of the paper onto tubing connected to the repeater pump, the bag of stoppers, the (b) (4) tray, and other surfaces inside the ISO 5 hood that were not frequently sanitized.

OBSERVATION 6
Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

Specifically, I observed aseptic technique deficiencies during filling of multiple lots from Semaglutide Injection, 2.5 mg/mL stock solution lots 072126CRS1, 072126CRS2, and 072226CH-S25-01; and Tirzepatide-Methylcobalamin Injection, 17 mg-100mcg/mL stock solution lots 072126CR-TM17-01 and 072726CH-TM17-01.

A. Multiple technicians filled Semaglutide Injection and Tirzepatide Injection using tubing connected to the repeater pump without a filling needle. The lack of filling needle required the technician to place their gloved hand directly over every vial during filling. The technicians' gloved (b) (4) hands moved over the opening of every vial as they filled the row from (b) (4) to (b) (4)

B. Technicians poured a portion of the rubber stoppers from the manufacturer's bag onto (b) (4) trays inside both ISO 5 (b) (4) airflow hoods:

i. (b) (4) technicians simultaneously and continuously reached over a pile of about (b) (4) stoppers on a nonsterile tray. They used approximately 5-inch-long forceps to pick up stoppers and seat them into filled vials of Semaglutide Injection.

ii. Technicians placed the bag with the remaining stoppers between the HEPA filters and the exposed stoppers. The approximately 1.5-foot-tall bag blocked HEPA filtered air from covering the stoppers on the tray. Some of the stoppers were underneath the bag.

iii. Technicians covered the stoppers with the empty stopper bag, placed a bag of vial caps on top of the stoppers, removed the bag of caps, uncovered the stoppers, and then used the stoppers during filling of Tirzepatide Injection. The stoppers were blocked from first-pass HEPA filtered air about two minutes.

iv. A technician placed forceps directly onto the pile of stoppers on the tray. The forceps were previously placed on the ISO 5 hood critical work area and placed on the tray.

v. The stoppers remained exposed inside the ISO 5 hood for multiple hours while filling, surface sampling between lots,

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sanitation of work surface between lots, and capping vials occurred in the same hood.

C. Technicians maintain their head and torso inside the ISO 5 hoods while filling Semaglutide Injection and Tirzepatide Injection.
D. Technicians rested their forearms on the primary compounding area inside both ISO 5 hoods while filling vials of Semaglutide Injection and Tirzepatide Injection. This body position could cause air to deflect off the technician and back into the workspace.
E. (b) (4) technicians were manually capping stoppered Semaglutide Injection vials inside the ISO 5 hood while another technician was actively filling vials for the next lot of Semaglutide Injection approximately two feet away inside the same ISO 5 hood. The technicians' movements were not slow and deliberate. The capping process potentially generates particulates. Stoppers were also exposed inside the hood about 1 foot away from the capping process.
F. Technicians routinely made quick, broad movements while working collaboratively inside the ISO 5 hoods during filling.
G. Technicians moved briskly throughout the ISO 7 buffer room and opened the door next to the ISO 5 hood multiple times during active filling.

OBSERVATION 7

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically, a technician repeatedly placed their gloved hand on the edge of the work surface in the ISO 5 hood for up to two minutes at a time during filling of Semaglutide Injection, 2.5 mg/mL, lot 072726KH-S25-01. Approximately half or more of the gloved hand was outside of the ISO 5 hood and then reentered without sanitizing with sterile (b) (4)

OBSERVATION 8

Inadequate post-use filter-integrity testing on filters used to sterilize drug products.

Specifically, the (b) (4) digital pressure gauge, S/N (b) (4) attached to the (b) (4) tester has been in-use about three years but has not been calibrated to confirm the accuracy of readings for this critical test. Personnel record pressure readings from this gauge during (b) (4) tests for all sterile drug lots. Examples of drug lots produced and dispensed after (b) (4) testing with this gauge include:

- Semaglutide Injection, 2.5 mg/mL, lot 061526CH06
- Semaglutide-Glycine Injection, 5 mg-2mg/mL, lot 060826CH02
- Tirzepatide-Methylcobalamin (MB12) Injection, 8.5 mg-100 mcg/mL, lot 060526KH12
- Liraglutide Injection, 6 mg/mL, lot 051426CR26

OBSERVATION 9

Personnel inadequately sanitized gloves to prevent contamination.

Specifically, technicians repeatedly failed to thoroughly sanitize gloved hands during filling of multiple lots from Semaglutide Injection,

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2.5 mg/mL stock solution lots 072126CRS1, 072126CRS2, and 072726KH-S25-01; and Tirzepatide-Methylcobalamin Injection, 17 mg-100mcg/mL stock solution lot 072126CR-TM17-01.

A. A technician sprayed their gloved hands with sterile (b) (4) , immediately placed their wet gloves into the ISO 5 hood, and then vigorously rubbed their gloved hands together while another technician actively filled vials of Semaglutide Injection.
B. Technicians wiped gloved hands, bags of stoppers, bags of caps, and trays of empty vials with sterile (b) (4) , but did not allow the gloves or other items to dry before placing them into the ISO 5 hood.
C. A technician dropped a utensil on the floor, picked up the item with a gloved hand, sanitized gloves with sterile (b) (4) and then continued production in the ISO 5 hood without changing the gloves.

OBSERVATION 10

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

Specifically,

A. The technician did not change wipes with sufficient frequency during the deactivation and decontamination process of capsule equipment, utensils, and the BSC after producing Clomiphene Capsules, lot 07282026RW01. The technician used one approximately (b) (4) inch wipe to decontaminate the entire interior of the BSC and used one wipe to decontaminate all the parts of the capsule equipment.
B. The technician did not deactivate and decontaminate the pen used to record capsule weights in the batch record during production of Clomiphene Capsules, lot 07282026RW01.

***DATES OF INSPECTION**

7/21/2026(Tue), 7/22/2026(Wed), 7/23/2026(Thu), 7/24/2026(Fri), 7/27/2026(Mon), 7/28/2026(Tue), 7/29/2026(Wed), 7/30/2026(Thu), 7/31/2026(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."