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	7/7/2025-7/18/2025* FEI NUMBER 3010589333

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Valerie L. Zacny, Quality Director

FIRM NAME	STREET ADDRESS
Right Value Drug Stores LLC	8400 Esters Blvd Ste 190
CITY, STATE, ZIP CODE, COUNTRY Irving, TX 75063-2217	TYPE ESTABLISHMENT INSPECTED Outsourcing 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

A. Deviation DEV-2025-166, dated 06/19/2025, reported a high number of dark particulate defects identified during the visual inspection causing a (b) (4) major defect percentage in the sterile injectable drug product Testosterone Cypionate 200mg/ml with Miglyol, lot (b) (4), BUD 03/31/2026. Your firm identified 41 vials contaminated with dark particulates and 6 vials contaminated with filaments. A total of 60 vials were removed for critical and major defects out (b) (4) vials. No investigation was performed to identify the root cause of these dark particulates. In addition, your firm failed to analyze or characterize the dark particles that were recovered during the visual inspection process. Despite the lack of investigation, a total of (b) (4) vials were approved and released for distribution on 06/23/2025 by your firm's Quality Unit.

B. Deviation DEV-2025-170, dated 06/25/2025, reported a high number of dark particulate defects identified during the visual inspection causing a (b) (4) major defect percentage in the sterile injectable drug product Testosterone Cypionate/ Testosterone Propionate 200mg/10ml with Miglyol 30ml, lot (b) (4) BUD 03/31/2026. Your firm identified 79 vials contaminated with dark particulates and 7 vials contaminated with filaments. A total of 92 vials were removed for critical and major defects out (b) (4) vials. Your firm attributed these findings to a newer aseptic filling technician; however, no investigation was performed to identify the root cause of these

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dark particulates. In addition, your firm failed to analyze or characterize the dark particles that were recovered during the visual inspection process. Despite the lack of investigation, a total of (b) (4) vials were approved and released for distribution on 06/26/2025 by your firm's Quality Unit.

C. Deviation DEV-2025-171, dated 06/26/2025, reported a high number of dark particulate defects identified during the visual inspection causing a (b) (4) major defect percentage in the sterile injectable drug product Testosterone Cypionate 200mg/ml with Miglyol 30ml, lot (b) (4), BUD 03/31/2026. Your firm identified 54 vials contaminated with dark particulates and 5 vials contaminated with filaments. A total of 64 vials were removed for critical and major defects out (b) (4) vials. Your firm attributed these findings to a newer aseptic filling technician; however, no investigation was performed to identify the root cause of these dark particulates. In addition, your firm failed to analyze or characterize the dark particles that were recovered during the visual inspection process. Despite the lack of investigation, a total of (b) (4) vials were approved and released for distribution on 06/30/2025 by your firm's Quality Unit.

D. Deviation DEV-2025-171, dated 07/03/2025, reported a high number of dark particulate defects identified during the visual inspection causing a (b) (4) major defect percentage in the sterile injectable drug product Testosterone Cypionate 200mg/ml with Miglyol 30ml, lot (b) (4) BUD 03/31/2026. Your firm identified 48 vials contaminated with dark particulates and 5 vials contaminated with filaments. A total of 54 vials were removed for critical and major defects out (b) (4) vials. Your firm attributed these findings to a newer aseptic filling technician; however, no investigation was performed to identify the root cause of these dark particulates. In addition, your firm failed to analyze or characterize the dark particles that were recovered during the visual inspection process. Despite the lack of investigation, a total of (b) (4) vials were approved and released for distribution on 07/03/2025 by your firm's Quality Unit.

In addition to the lack of investigation, your firm has not justified the alert and action limits as defined in

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SOP 5.030, "Visual Inspection", effective date 6/11/2025, version 4.

OBSERVATION 2

Written procedures are not established that describe the in-process controls, tests and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically,

Your firm does not have validated methods or procedures for assessing the essential physical characteristics of work-in-progress (WIP) pellets stored in the WIP dry cabinet (Asset 19-00390) in the DEA cage. There are no documented validation studies demonstrating that your hormonal pellet manufacturing process consistently produces pellets meeting predetermined specifications and quality attributes after being stored in the WIP cabinet.

This is a repeat observation.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

A. Your firm failed to perform smoke study videos of the biological safety cabinets (BSC) in room H300 in a dynamic state. Your current practice is to perform aseptic filling operations in room H300 in both BSCs (19-00133 and 19-00134) simultaneously. However, the smoke study videos provided does not represent the current practice or worst-case scenario of your aseptic filling operations. Additionally, your firm's Smoke Study Evaluation – Vial Removal, GS-2024-001, date 01/06/2025, does not assess airflow visualization while both BSCs are in operation.

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This is a repeat observation.

B. On 07/08/2025, we observed your firm's pharmacy technician (designee) perform personnel monitoring sampling (b) (4) of the pharmacy technicians in both the left and right BSC, located in room H300, after aseptic filling of Testosterone Cypionate 200mg/ml with Miglyol 30ml, lot (b) (4). We observed the pharmacy technician working in the left BSC (19-00134) disinfect their gloves after batch completion but prior to sampling. Additionally, we observed the pharmacy technician working in the right BSC (19-00133) (b) (4) without applying (b) (4) or creating an (b) (4) on the (b) (4) plate, as required by SOP 4.090, effective date 12/16/2024, version 5.

C. On 07/08/2025, we observed your firm's pharmacy technician (designee) perform environmental monitoring (EM) sampling of the right BSC (19-00133) after aseptic filling of Testosterone Cypionate 200mg/ml with Miglyol 30ml, lot (b) (4) The pharmacy technician performing aseptic filling used a cleanroom wipe over the critical contact area where vials are placed to be aseptically filled. However, EM sampling performed by the designee was performed outside of the operator's critical contact areas as defined by SOP 4.090, effective 12/16/2024, version 5.

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

A. The IQ,OQ,PQ (Protocol: QUAL-2025-001) for Dry Cabinet Model (b) (4) (Asset 19-00390) was inadequate and failed to demonstrate that the equipment performs as intended for its critical function of storing work-in-progress hormonal pellets. The performance qualification conducted on 02/28/2025, documented failing results for PQ Test Case 1 Power Verification testing, which was designed to ensure the dry cabinet maintains required humidity and

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temperature parameters until the backup generator activates during power failures. The performance qualification documented failing results for PQ Test Case 4 Addition of Beakers Verification test, which was intended to demonstrate that the dry cabinet maintains interior humidity levels when additional items are introduced into the storage environment. The protocol documented after the addition of (b) (4) beakers the cabinet did not maintain the set humidity parameter. This cabinet was observed to be in used during the current inspection with more than (b) (4) beakers present in the cabinet. This protocol was submitted as a corrective action response to Warning Letter 694687, dated 12/17/2024.

B. Your firm failed to perform a temperature and humidity study of the DEA Caged storage areas used for quarantine products, quarantine chemical, and finished sterile drug products. Your firm has a single probe placed between the two separate caged areas; however, your firm's Director of Quality Assurance and Director of Operations reported that there is no scientific justification or rationale for the placement of the probe used to measure temperature and humidity in the DEA cage. Additionally, P-008 Policy on Product Storage, effective date 01/15/2025, fails to define acceptable relative humidity conditions for pellet products and sterile drug injectable products stored in the DEA cage.

This is a repeat observation

OBSERVATION 5

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing.

Specifically,

According to your firm's Pharmacy Manager and batch record step 10.7.20 and 10.5.20 states "regularly change the needle while filling, fill a maximum of (b) (4) vials before replacing the needle. If the needle becomes dull before filling (b) (4) vials, replace it as needed." However, your firm's batch record fails to adequately verify that this practice is performed consistently. For example, the batch record

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Testosterone Cypionate/ Testosterone Propionate 200/10 mg/ml with Miglyol 30ml, lot (b) (4) BUD 06/11/2026 failed to document the number of filling needles and vent needles replaced during the aseptic filling process. Your firm's Pharmacy Manager acknowledged that needle replacement is performed specifically to reduce the number of potential black particles (likely rubber coring or metal particles) in the sterile drug products and considers this process a critical quality attribute in the manufacturing/filling process. A total of (b) (4) vials were approved and released for distribution on 07/08/2025 by your firm's Quality Unit.

***DATES OF INSPECTION**
7/07/2025(Mon), 7/08/2025(Tue), 7/09/2025(Wed), 7/10/2025(Thu), 7/11/2025(Fri), 7/14/2025(Mon), 7/15/2025(Tue), 7/16/2025(Wed), 7/17/2025(Thu), 7/18/2025(Fri)

X MILTON J. DE JESUS-TAVAREZ -S Digitally signed by MILTON J. DE JESUS-TAVAREZ -S Date: 2025.07.18 12:20:05 -05'00'

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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."