

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314		DATE(S) OF INSPECTION 8/24/2026-9/8/2026* FEI NUMBER 3010589333	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Valerie L. Zacny, Director of Quality			
FIRM NAME Right Value Drug Stores LLC		STREET ADDRESS 8400 Esters Blvd Ste 190	
CITY, STATE, ZIP CODE, COUNTRY Irving, TX 75063-2217		TYPE ESTABLISHMENT INSPECTED 503B 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 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed. Specifically, your firm failed to perform adequate smoke study videos of the biological safety cabinets (BSC) in room (b) (4) in a dynamic state to demonstrate unidirectional airflow and proper environmental controls during actual operating conditions. Your current practice is to perform aseptic filling operations in room (b) (4) with (b) (4) BSCs ((b) (4)) operating simultaneously. However, the smoke study videos provided, titled "Workers (b) (4) ISO 5 Hood During Fill," did not demonstrate that: - Unidirectional airflow is maintained during simultaneous operation of (b) (4) BSCs - Air patterns prevent contamination of critical surfaces - Personnel movements and interventions do not disrupt the aseptic environment This is a repeat observation.			
OBSERVATION 2 Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Specifically, Your he firm fails to perform dissolution testing and hardness/friability testing as part of estradiol pellets batch release. The specification and batch release criteria are limited to potency assay and endotoxin testing. Since 06/01/2025 through this inspection period, approximately 260 of the (b) (4)			
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		DATE ISSUED 9/8/2026	

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batches of the following products manufactured were released without dissolution or hardness/friability testing.

NDC	Product	Specification
73271-0006-01	Estradiol 6 mg Pellet (E6)	(b) (4)
73271-0010-01	Estradiol 10 mg Pellet (E10)	
73271-0125-01	Estradiol 12.5 mg Pellet (E12.5)	
73271-0015-01	Estradiol 15 mg Pellet (E15)	
73271-0018-01	Estradiol 18 mg Pellet (E18)	
73271-0020-01	Estradiol 20 mg Pellet (E20)	
73271-0022-01	Estradiol 22 mg Pellet (E22)	
73271-0025-01	Estradiol 25 mg Pellet (E25)	
73271-0375-01	Estradiol 37.5 mg Pellet (E37.5)	
73271-0050-01	Estradiol 50 mg Pellet (E50)	

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

A. Your Quality Unit failed to implement corrective actions across all affected master batch records. For example, Master Batch Record 5.351 (Testosterone Cypionate 200 mg/mL with Miglyol, 30 mL, version 5) was revised to require documentation of filling and vent needles replaced during filling to address black particulate matter. However, this corrective action was not implemented across all affected master batch records.

- 5.311: Testosterone Cypionate 200 mg/mL with Miglyol

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5.321: Testosterone Cypionate/ Propionate 200/10 mg/mL with Miglyol 5.341: Testosterone Cypionate 200 mg/mL, 5 mL This is a repeat observation B. Your Quality Unit failed to approve Annual Product Review (APR) reports by the due dates required by SOP 4.130.1, Annual Product Review Periods and Due Dates, version 4. All APR reports due in 2025 were approved after the dates required by the procedure. For example: - The APR for Estradiol Pellets, covering June 2024 through May 2025, was due in (b) (4) 2025 but was not approved until 05/06/2026. - The APR for Testosterone Cypionate 200 mg/mL in Miglyol Oil, 30 mL, covering July 2024 through June 2025, was due in (b) (4) 2025 but was not approved until 05/22/2026. This is a repeat observation C. Your Quality Unit failed to ensure Environmental Monitoring reports met the requirements of SOP 4.093, Environmental Monitoring Reports, version 2. For example: (b) (4) reports (meeting minutes) failed to include all required metrics, such as percent recovery for ISO 5 and ISO 7 and alert/action limit performance and lacked quality management approval. - The (b) (4) 2025 Environmental Monitoring Report, covering the (b) (4) ending December 31, 2025, was not approved until August 25, 2026. At the time of the inspection, no (b) (4) Environmental Monitoring reports for 2026 had been approved. This is a repeat observation D. Your Quality Unit failed to complete vendor qualification before using a contract laboratory, to perform microorganism identification services as required by SOP 4.050, Vendor Qualification, version 4. For example:			
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- On 07/30/2025, your Director of Quality sent qualification documents to (b) (4), (b) (4), to begin qualification for antimicrobial testing and microorganism identification services. Your firm began using their services on 08/05/2025, before qualification was complete. (b) (4) signed the qualification documents on 07/31/2026.

Microorganism identification results from unqualified laboratory were used to make quality decisions, including batch disposition, for investigations involving microbial growth.

OBSERVATION 4

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

Specifically,

A. Equipment Calibration: Procedure 2.020, Equipment Calibration, version 4, does not include the requirement to adequately investigate the impact of equipment found out of tolerance. For example:

- The most recent calibration certificates for analytical balances 19-00004 (serial # (b) (4), located in (b) (4) and 19-00013 (serial (b) (4), located in (b) (4) showed "out of tolerance" results. These balances are used as part of pellet compounding and vialing operations. No associated deviation or impact evaluation was performed.

B. Environmental Monitoring: The firm does not have a clear and robust method for tracking and trending microbial recoveries over time, resulting in inadequate monitoring of the ongoing presence of various molds in the clean rooms. For example:

- Mold recoveries in the pellet compounding/pressing suite (b) (4) increased from 0.9% in (b) (4) to 24.4% in (b) (4) with Penicillium and Aspergillus species identified (IR-2025-043).
- Mold recoveries facility-wide increased from 8% in (b) (4) 2025 to 33% in (b) (4) 2025. No justification, trend report, or investigation to identify the most probable cause and corrective actions was completed.

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OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm failed to perform environmental monitoring as required in SOP 4.090, Environmental and Personnel Monitoring Program, version 7, section 7.1. This includes data, and evaluation supporting continuous (b) (4) non-viable particle sampling in ISO 5 and ISO 7 areas, regardless of batch manufacturing activities.

OBSERVATION 6

Test devices are deficient in that instruments not meeting established specifications are used.

Specifically, analytical balance (b) (4) calibrations and/or (b) (4) verifications do not cover the full bracketed range of use for the pellet process weights ((b) (4) to (b) (4) For example:

- Analytical balance 19-00003 (serial (b) (4)) was calibrated on 04/13/2026 at (b) (4) to (b) (4). This balance is used for the pellet compounding process in (b) (4)

This is a repeat observation

***DATES OF INSPECTION**

8/24/2026(Mon), 8/25/2026(Tue), 8/26/2026(Wed), 8/27/2026(Thu), 8/28/2026(Fri), 8/31/2026(Mon), 9/01/2026(Tue), 9/02/2026(Wed), 9/03/2026(Thu), 9/04/2026(Fri), 9/08/2026(Tue)

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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."