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	2/18/2025-2/27/2025* FEI NUMBER 3011688532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Haleigh J. Wilkes, Quality Manager/Pharmacist in Charge (PIC)

FIRM NAME	STREET ADDRESS
Eagle Pharma Outsourcing LLC	2200 Riverchase Ctr Ste 675
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hoover, AL 35244-2918	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 I OBSERVED:

OBSERVATION 1

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

Specifically,

A. Your firm management failed to conduct a smoke study for the design of the ISO 5 Filling Cleanroom, which contains an open (b)(4) flow ISO 5 LAFU and an enclosed ISO 5 Filling System to ensure adequate airflow for the prevention of possible contamination.

B. During a review of your firm's vial filling machine (VFM) dynamic smoke study dated (b)(4) located within your ISO 5 Filling cleanroom, I observed turbulent eddy currents created while (b)(4) rubber stoppers into the designated carousel in the presence of non-stoppered vials. During observation of vial filling for the drug product, Triamcinolone Acetonide 50mg/mL, Lot # (b) (4) , Expiry 2/20/2026, the rubber stopper carousel was refilled in the presence of open vials, which has the potential of becoming contaminated with particulate matter from the sterilized stopper bag. The vial filling machine is not designed with a protective barrier overtop the non-stoppered filled vials that are being processed. **This is a repeat observation.**

C. Your firm's procedure, Environmental Monitoring, P.15.12, which include an environmental sampling map, failed to include contact surfaces within the (b)(4) used to transfer drug components and production equipment between ISO 7 Laboratory (Formulation) Cleanroom and ISO 5 Filling Cleanroom as part of your environmental monitoring program for the control of contamination. **This is a repeat observation**.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 02-27-2025 15:34:45	2/27/2025

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OBSERVATION 2
Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, your firm's environmental sampling technician was observed poor sterile re-gowning techniques within your firm's ISO 7 (b)(4) used during aseptic processing by leaning against the wall rendering the gown non-sterile prior to entry into the ISO 5 Filling room for vial filling of the drug product, Triamcinolone Acetonide 50mg/mL, Lot # (b) (4) , Expiry 2/20/2026.

OBSERVATION 3
Equipment and utensils are not sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, your firm's environmental sampling technician failed to disinfect stainless steel pan containing EM sampling plates and particle counter prior to transfer from the (b)(4) connecting the ISO 7 Lab Cleanroom and the ISO 5 Filling Cleanroom. **This is a repeat observation**.

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, during observation of vial filling for the drug product, Triamcinolone Acetonide 50mg/mL, Lot #(b) (4) , Expiry 2/20/2026, I observed an approximate 2-inch diameter hole within the stainless-steel plate used to cover the (b)(4) beaker containing the bulk drug product creating a potential foreign particulate entry point. The center hole remained uncovered within your firm's ISO 7 Lab Cleanroom, during transfer, and while undergoing vial filling within the ISO 5 Filling Cleanroom. At no time during formulation, bulk drug cleanroom transfer, and filling was the hole covered.

OBSERVATION 5

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The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically,

A. Your firm's procedures, Daily Procedures and Job Responsibilities for Eagle Pharma Employees, P1.10.8; and Personnel Training and Evaluation, P1.20.5 failed to define and document the responsibilities of the Visual Inspection Technician, who performs the inspection of finished sterile drug products. Your firm's PIC stated the role was created during the 4th Quarter of 2024 and she has failed to adequately update your firm's procedure to reflect the new position.

B. Your firm's procedure, Visual Inspection of Finished Drug Products, P.20.10 is inadequate. For example, the procedure fails to define and document responsibilities for a Visual Inspection Technician.

***DATES OF INSPECTION**

2/18/2025(Tue), 2/19/2025(Wed), 2/20/2025(Thu), 2/21/2025(Fri), 2/24/2025(Mon), 2/25/2025(Tue), 2/26/2025(Wed), 2/27/2025(Thu)

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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."