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 Hoover, AL 35244-2918	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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)

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

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."