DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	5/5/2025-5/12/2025*
	FEI NUMBER 3029456823

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sandeep Raktate, President - India and Ireland Operations

FIRM NAME	STREET ADDRESS
Amneal Pharmaceuticals Private	Plot No. 15,16,17 PHARMEZ Special Economic Zone, Sarkhej-Bavla N.H. No 8a; Vil: Matoda
CITY, STATE, ZIP CODE, COUNTRY Tal. Sanand, Ahmedabad, Gujarat, 382213 India	TYPE ESTABLISHMENT INSPECTED Sterile Finished Drug Manufacturer

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

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

Your firm failed to adequately qualify your (b) (4) Filling Machine, Equipment ID No. SM-2044, located in the (b) (4) Filling Line of the (b) (4) Unit (b) (4) building, which is used to manufacture (b) (4) Injection, (b) (4) mL. During Performance Qualification (PQ) of the (b) (4) (b) (4) Filling Machine, fill weight verification was performed using the data generated from the (b) (4) and a calibrated, standalone analytical balance, Equipment No, SM-2046. Upon review, it was noted that the qualification did not establish a criterion for variation between individual units weighed on the (b) (4) against those weighed on the analytical balance. The qualification did not contain traceability to the (b) mg challenge/standard weight used in the (b) (4) calibration. The acceptance criteria for (b) (4) in the Qualification Protocol was (b) (4) mg to (b) (4) mg, with (b) (4) runs of (b) (4) total (b) (4) respectively. All (b) (4) runs contained units that experienced significant variability in fill weights recorded from the (b) (4) against those from the analytical balance, for example:

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	Marcellinus D Dordunoo, Investigator X Marcellinus D Dordunoo Investigator Signed By: MARCELLINUS DORDUNOO -S Date Signed: 05-12-2025 13:23:58	5/12/2025

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(b) (4)

[redacted]

No investigation was initiated to determine the source of the variability in the fill weights, assess the impact/risk, and subsequently propose a mechanism to control variation relative to the assessed risk. No specific trend was observed. The acceptable range for fill weight spans (b) (4) mg, and a (b) (4) mg (maximum) variation was observed during review. Although no investigation was performed, the dynamic nature of the (b) (4) fill weight verification has inherent variability due to (b) (4) [redacted] The data generated during the PQ, indicates that there can be (b) (4) that meet the fill weight specification per the (b) (4), but are under or over filled when weighed (b) (4). In a "worst case" scenario, (b) (4) with fill weights all the way

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down to (b) (4) mg, as a lower theoretical limit, and as high as (b) (4) mg as an upper theoretical limit, could subvert detection and be deemed acceptable based on the fill weights recorded by the (b) (4) In routine manufacturing operations, there is no secondary verification of the fill weight, and therefore no mechanism to detect significant under/over fills.

OBSERVATION 2

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

Specifically,

A. The (b) (4) Filling Line, located in the (b) (4) Unit (b) (4) production block contains Grade A/B (Unidirectional Airflow/UAF), and C areas for production operations. However, your firm performs no routine or periodic personnel monitoring in any of the classified areas of the (b) (4) Filling Line. There is no mechanism or data, by which to determine if adequate cleanroom behavior is employed by production/Quality personnel who enter classified areas. Production personnel routinely enter the Grade A/B (UAF) areas to transfer sterile equipment and to perform environmental monitoring.
B. Airflow Visualization studies (smoke studies) for The Grade A/B (UAF), did not include demonstration of airflow patterns under dynamic conditions. specifically, operator entry/exit and performance of environmental monitoring were not simulated and assessed.

***DATES OF INSPECTION**

5/05/2025(Mon), 5/06/2025(Tue), 5/07/2025(Wed), 5/08/2025(Thu), 5/09/2025(Fri), 5/12/2025(Mon)

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