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	3/10/2025-3/19/2025*
	FEI NUMBER 3018907202

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

FIRM NAME	STREET ADDRESS
Amneal Pharmaceuticals Private Limited	506 Survey No, Near Sachana Kalyanpura Road
CITY, STATE, ZIP CODE, COUNTRY Palli, Gujarat, 382165 India	TYPE ESTABLISHMENT INSPECTED Sterile 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 WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

On February 10, 2024, your firm opened unplanned deviation investigation UD-AL-24-0003, when (b) (4) Injection, USP (b) (4) mg/mL, batches (b) (4) and (b) (4) each failed (b) (4) visual inspection for the percentage of (b) (4) fibers in the product (major defect) exceeding the allowable limit level of (b) (4) %.

Per the deviation investigation, you determined that the vendor for the (b) (4) (lot # (b) (4) in which the product was filled, had a higher rejection rate for (b) (4) fibers than the previous (b) (4) from the same vendor.

Your firm made the decision to reject the remaining empty, unused (b) (4). However, the finished sterile (b) (4) drug product, (b) (4) Injection, USP (b) (4) mg/mL, (batches (b) (4) and (b) (4) which had already been filled into those (b) (4) was released to the U.S. market based on a third round of visual inspection and a passing AQL. Your risk assessment used to evaluate product quality for these batches failed to adequately address the known defect of (b) (4) fibers associated with this particular vendor supplied (b) (4) and the risk associated with releasing finished sterile (b) (4) drug products, which may contain (b) (4) fibers, to the market.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Anastasia M Shields, Investigator Alan A Rivera, Investigator	X Anastasia M Shields Investigator Signed By: Anastasia M. Shields - S Date Signed: 03-19-2025 04:10:35	3/19/2025

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The firm released (b) (4) additional batches of sterile (b) (4) drug product, filled into (b) (4) supplied by the same vendor, without a thorough risk assessment.

OBSERVATION 2

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

Sterile (b) (4) drug products must be essentially free of particles. Upon review of the visual inspection certification process, described in SOP AL-SM-025-001, entitled, "Procedure for Preparation of Visual Inspection Test Kit and Qualification", effective April 10, 2024, it was observed that defective (b) (4) which are part of the (b) (4) used in the qualification testing of visual inspectors, were marked with black pen verses the "good" (b) (4) which were free of marks.

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate designed to assure that conform to appropriate standards of identity, strength, quality and purity.

Specifically,

While observing preparation and reading of the Bacterial Endotoxin Test (BET) the following deficiencies were identified:

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A. On March 10, 2025, your microbiologist performing the Bacterial Endotoxin Test (BET) gel formation reading for (b) (4) Injection (b) (4) mg/mL, Batch: (b) (4) and (b) (4) Injection, Batch: (b) (4) moved the sample tubes from the incubator to the waste container in one abrupt continuous motion while inverting each sample to expel the contents of the test tube with no sufficient time to accurately inspect each sample tube for gel formation.

At the same time, a second QC Microbiologist/Analyst acting as a verifier during this test failed to accurately observe and verify the Bacterial Endotoxin Test (BET) results at the time that the task was being performed and documented. Per discussion with this analyst, the microbiologist reading the sample tubes failed to perform the task at a speed that permitted him to accurately verify the test results. Quality procedure AC-QCM-015, titled, "Role and responsibilities of Analyst, Checker, Reviewer and Approver in Microbiology Laboratory", section 5.3.3.2 states that a check by task is required where objective evidence is not available for a particular test.

B. Quality procedure IR-QA-002-001, titled, "Good Documentation Practices", section 5.3.2 states that the entries in documents shall be done contemporaneously after completion of the task by an authorized person. On March 10, 2025, your QC Microbiology Analyst failed to contemporaneously document the test results of the BET samples for (b) (4) Injection, Batch (b) (4) Your analyst was observed documenting two (2) negative sample results at the same time and assigning a passing result (gel formation) for the product positive control sample prior to observing the actual sample.

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C. Laboratory procedure AL-QCM-017, titled, "Operation and calibration of micropipette", section 5.3.1.10 states that to make tip empty completely, press down the control bottom up to the second stop (blow out). On March 11, 2025, your QC Microbiology Analyst was observed failing to completely discharge the micropipette solution into the test tubes in two occasions during the preparation of BET samples for (b) (4) Injection, Batch (b) (4) and (b) (4)

Since November, 2024, your QC Microbiology Analyst has performed the bacterial endotoxin test (BET) for (b) (4) batches, encompassing (b) (4) different sterile (b) (4) products (b) (4) (b) (4) all within expiration date and released to the U.S. Market. This QC Microbiology Analyst also performed the test for a total of approximately (b) (4) samples.

OBSERVATION 4

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

Specifically,

Your Quality Unit fails to maintain oversight on destruction of documents using a shredder. For example, on March 17, 2025, we observed white shredded pieces of documents inside shredder bin for shredder (Serial Number: 1294308) located in QA documentation room (b) (4) As per your procedure titled "Procedure for handling of papers intended to be shredded/destroyed", SOP Number: AL-QM-

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014-000, section 5.2.5 states that the QA employee should "send the collected document for destruction from user to scrap area for shredding/ destruction of the documents by using paper shredder or cutter machine". Your firm failed to send collected documents for destruction to a dedicated locked scrap area and opted to use an uncontrolled shredder observed inside the QA document room. There is no oversight from the Quality Assurance department on controlling, managing and documenting the use of the observed uncontrolled shredder located inside this department.

***DATES OF INSPECTION**

3/10/2025(Mon), 3/11/2025(Tue), 3/12/2025(Wed), 3/13/2025(Thu), 3/17/2025(Mon), 3/18/2025(Tue), 3/19/2025(Wed)

X Alan A Rivera
Investigator
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Date Signed: 03-19-2025 04:10:58

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