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	7/7/2025-7/17/2025*
	FEI NUMBER 3009107538

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amit Sareen, Site Head and Sr. Vice President - Manufacturing

FIRM NAME	STREET ADDRESS
Lupin Limited	Unit 3, Plot No. M-2 & M2-A, SEZ, Phase II, MISC Zone, Apparel Park, Dist Dhar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, Madhya Pradesh, 454775 India	Human 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

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

Your firm lacked appropriate testing of components used in the manufacture of your drug product. For example, you lacked a specific identify test to detec (b) (4) in all shipments, containers, and lots of (b) (4) before use in the manufacturing of (b) (4) Cream. Approximately (b) (4) batches of (b) (4) (b) (4) Cream manufactured and shipped to the US are within the (b) (4) expiry period including but not limited to batches (b) (4) (b) (4)

OBSERVATION 2

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

Specifically,

Your firm received 107 complaints citing that the (b) (4) on the (b) (4) was difficult to open but failed to determine a root cause or perform confirmatory testing to verify the reported issue. For example, Complaint DPC-ID-166-23-4135, DPC-ID-166-23-6164, and DPC-ID-166-24-1508, along with associated FAR-ID-166-24-0003, all reported difficulty opening the (b) (4) on the (b) (4) (b) (4) Despite the recurring nature of the defect, your firm did not conduct functional testing on retained samples or returned units to confirm the problem or assess the potential impact on usability and patient access to medication.

OBSERVATION 3

Written procedures are not established that describe the in-process controls and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically,

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Lisa L Flores, Office of Global Policy and Strategy Employee
Rafeeq A Habeeb, Investigator

X Lisa L Flores
Office of Global Policy and Strategy Employee
Signed By: 2001625756
Date Signed: 07-17-2025 11:52:02

DATE ISSUED
7/17/2025

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A. Your firm uses a single, general SOP for reviewing electronic data including audit trails across multiple computerized systems used in GMP operations, such as filling system, (b) (4) manufacturing vessel, (b) (4) machine, (b) (4) (b) (4) and (b) (4) machine.

This SOP does not include or reference system-specific instructions, such as:

1. Identifying critical audit trail events relevant to each system (e.g., parameter changes, alarm acknowledgments, aborted runs, manual interventions).
2. Locating and interpreting audit trail entries specific to each software/system architecture.
3. Documenting and justifying the audit trail review performed per system.

During interviews, we observed inconsistent audit trail review practices, with staff relying on experience rather than documented procedures. The SOP does not differentiate between systems, functionalities, or risk levels, nor does it specify review triggers or expectations per equipment.

B. Quality Assurance (QA) employees lack independent login access to manufacturing equipment software and were found to rely on Information Technology (IT) employee assistance to access these systems during (b) (4) audit trail reviews. This practice compromises the independence of QA oversight.

C. During batch release, QA employees do not review audit trails directly on the manufacturing equipment but instead review only printed copies provided by the operations department.

D. Your firm failed to adequately document parameters related to (b) (4) sample collection, specifically failing to record the time (b) (4) samples were collected and documented when sampling should be done from a (b) (4) as the point of use.

***DATES OF INSPECTION**
7/07/2025(Mon), 7/08/2025(Tue), 7/14/2025(Mon), 7/15/2025(Tue), 7/16/2025(Wed), 7/17/2025(Thu)

X Rafeeq A Habeeb
Investigator
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EMPLOYEE(S) SIGNATURE
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7/17/2025