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 ORAPHARMInternational483responses@fda.hhs.gov	03/21/2023-03/29/2023
	FEI NUMBER 3007549629

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 – 2, Plot No. M2 and M2A, SEZ, Phase II, Misc. Zone, Apparel Park, Dist. Dhar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, Distt. Dhar – 454775, MP, India	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

Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

On 09/16/2021 during stability study sample analysis of (b)(4) Solution (b)(4) % Batch (b)(4) (9-Month Long Term), (b)(4) test result did not comply with specification limit. The observed test result was (b)(4) % (b)(4) while the Limit was NMT (b)(4) % (b)(4) OOS-IO-153-21-0027 was initiated on 09/16/2021. The (b)(4) investigation did not identify any errors. Hence, the Out of Specification (OOS) result stood valid. The (b)(4) manufacturing investigation concluded that surface imperfections/aberration observed on some (b)(4) of QC Batch (b)(4) have led to product loss under conditions of stability study at (b)(4) orientation. However, this batch of (b)(4) underwent a successful incoming material inspection when they were received at the warehouse and was released by your QA on 09/11/2020. No issues of surface imperfections/aberration were reported at that time.

Your firm performed Impact Assessment and the subject OOS Batch (b)(4) was recalled (RCL/IN2/21/04 10/18/2021). (b)(4) more batches of (b)(4) Solution (b)(4) % ((b)(4) (b)(4) were also recalled (RCL/IN the same batch (b)(4) batch. The investigation further identified the defective (b)(4) Batch (b)(4)

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was also used to manufacture (b) (4) Solution (b) (4) % Batches (b) (4) (b) (4) (b) (4) The above batches were in the U.S. market and within expiry at the time of this OOS investigation. Your firm lacked adequate justification for allowing the above (b) (4) mpacted (b) (4) batches (manufactured using defective (b) (4) batch) to remain in the U.S. market until expiration.

OBSERVATION 2 (Repeat)

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,

A. Your firm failed to document deviations/equipment failures occurring during manufacturing and packaging in the batch record, initiate investigations, including risk assessments, and appropriate corrective and preventive actions (CAPAs) into the breakdown of critical process equipment/critical breakdown notifications in the (b) (4) manufacturing area for several US marketed products in

(b) (4)

You recorded 1695 breakdown notifications from January 2019 to March 2023 for (b) (4) (b) (4) and 64 breakdown notifications for (b) (4) However, you investigated 41 breakdown notifications for (b) (4) and 7 breakdown notifications for (b) (4)

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Total Breakdown Notification for (b) (4)	1695
Total Notification Investigated	41
% Investigated for (b) (4)	2.41%
Total Breakdown Notification for (b) (4)	64
Total Breakdown Notification Investigated for (b) (4)	7
% Investigated for (b) (4)	10.9%

B. Deviation investigations are not thoroughly investigated by your firms and appropriate actions are not taken to prevent recurrence . For example,

a) Deviation #DEV-IO-136-20-0062 revealed that a foreign filled capsule was found by your inspector during the visual inspection of (b) (4) Capsules (b) (4) mg, Batch no. (b) (4) in Inspection (b) (4) area on October 20, 2020. The investigation revealed the foreign empty capsule was supplied in your shipment by your vendor and is a different specification. You utilized the (b) (4) capsule Batch # (b) (4) where the foreign capsule was found to encapsulate (b) (4) other batches of (b) (4) Capsules (b) (4) mg Batch # (b) (4) that were released to the US market. However, you failed to file a field alert report (FAR).

(b) (4)

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(b) (4) [redacted]

b) **Deviation #DEV-IO-136-22-0003:** Manufacturing data was not captured in the data acquisition software for (b) (4) [redacted] (b) (4) [redacted] 303) during the manufacture of (b) (4) [redacted] tablets (b) (4) [redacted] mg Batch # [redacted] (US market). You lost manufacturing data for 10 minutes (b) (4) [redacted] which is a critical step according to your Manager of (b) (4) [redacted] Production and stated there was no product impact. However, this is a recurring deviation and you initiated an ineffective CAPA (CAP-IO-136-21-0022) for manufacturing data previously lost and where you proposed to capture data manually in the batch records.

c) **Deviation #DEV-IO-136-19-0034:** During (b) (4) [redacted] activity of Lot- (b) (4) [redacted] for product (b) (4) [redacted] of (b) (4) [redacted] (b) (4) [redacted] mg for [redacted], Batch # (b) (4) [redacted] (b) (4) [redacted] tablets (b) (4) [redacted] mg and (b) (4) [redacted] mg Batch No. (b) (4) [redacted] production person noticed that (b) (4) [redacted] was not started at the time of (b) (4) [redacted] (b) (4) [redacted] in (b) (4) [redacted] material. You attributed the root cause to human error where you stated the operator might have missed to switch the "ON" power button although you stated in the investigation report there was no identification available whether the (b) (4) [redacted] was on or off. However, you failed to interview the operator prior to reaching the root cause and the batch record does not delineate any instructions for the operator regarding turn on/off the switch.

C. Your firm failed to implement controls to support the integrity of your data. You recorded 16 breakdown notifications where manufacturing data was not captured in the data acquisition software for some manufacturing and packaging equipment during batch operations for the following US marketed products. However, you only investigate one out of (b) (4) [redacted] of the breakdown. In addition, you released all the batches.

Notification	Description	product name	Batch no.

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(b) (4)

[redacted]

In addition, you recorded two repeated critical breakdown notifications (Notification (b) (4) [redacted] where data was not captured and (b) (4) [redacted] were aborted. Notification (b) (4) [redacted] occurred

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during the manufacturing of [redacted] Tablets USP [redacted] mg Batch # [redacted] for the US market. However, you failed to investigate the reason and take appropriate action to prevent recurrence for Notification [redacted]

D. Assigned root causes for laboratory OOS result are not always scientifically justified. Specifically,

a) OOS/C/19/IN2/SS/014 was initiated on 07/27/2019 for the OOS result observed in dissolution test analysis in product [redacted] Tablets USP [redacted] mg Batch [redacted] at 3 months (M) long term (LT) stability study. An observed OOS result of [redacted]% for Tablet [redacted] at [redacted] time point did not pass the specification limit of No Less Than (NLT) [redacted]% of the labelled amount as per USP requirement. One of your hypothesis studies demonstrated that wrong filter usage and without discarding aliquots would cause a similar OOS result. The investigation thus concluded the OOS result was attributed to laboratory error (human error). However, your investigation did not contain confirming information because the conclusion of wrong filters used was not substantiated by the analyst interview and the filters had been discarded. No [redacted] manufacturing investigation was conducted. The observed OOS result was invalidated, re [redacted] sults were within specification, and Batch [redacted] (Mfg. [redacted]) remained in the U.S. market with an expiration date of 01/31/2021.

b) OOS/C/20/IN2/SS/004 was initiated on 04/30/2020 for the OOS result observed in the Related Substances test of [redacted] Tablets USP [redacted] mg Batch [redacted] during stability study at 24 M [redacted] An individual unspecified impurity res [redacted] f [redacted]% was OOS for the specified limit of No More Than (NMT) [redacted]%. The hypothesis study and investigation concluded the root cause for unknow impurity peak was due to contamination of sample solution with [redacted] during sample preparation. However, the contamination was not admitted by the analyst. Further, the assigned root cause referenced an unrelated OOS investigation, where an experiment was conducted by [redacted] during sample preparation. No different probable contamination sources were assessed. The root cause that [redacted] contamination attributed to the observed impurity in Batch [redacted] was unsupported. No [redacted] manufacturing investigation was conducted. The observed OOS result was invalidated, [redacted] esults were accepted, and Batch [redacted] (Mfg. [redacted]) remained in the U.S. market with an expiration date of 01/31/2021.

c) OOS/C/20/IN2/SS/006A was initiated on 06/28/2020 for the OOS result observed in the Assay test of [(b) (4)] Capsules USP [(b) (4)] mg/[(b) (4)] mg Batch [(b) (4)] during stability study at 3M [(b) (4)] Assay test result of [(b) (4)]% for [(b) (4)] content was OOS for the specified limit of [(b) (4)]% of label claim. The [(b) (4)] content result of [(b) (4)]% was within specification. The hypothesis study and investigation concluded the root cause for the observed OOS result was due to improper shaking during sample solution preparation. However, the assigned root cause was unsupported because the analyst stated applicable STP was followed. Further, Investigation Study PR- OOS/C/20/IN2/SS/006/02 demonstrated the different combinations of [(b) (4)] did not produce passing results on the batch. Your firm lacked scientific justification that improper shaking attributed to only [(b) (4)] OOS result. The observed OOS result was invalidated, retest results were accepted, and Batch [(b) (4)] (Mfg. [(b) (4)] remained in the U.S. market with an expiration date of 12/31/2021.

OBSERVATION 3 (Repeat)

Written records of investigation of a drug complaint do not include the findings of the investigation and the follow-up.

Specifically, your complaint investigations are deficient. You have received several repeated market complaints for [(b) (4)] [(b) (4)] Tab USP [(b) (4)] mg (US Market), [(b) (4)] Capsules [(b) (4)] [(b) (4)] Tablets USP [(b) (4)] mg, [(b) (4)] mg, [(b) (4)] Tablet USP [(b) (4)] mg [(b) (4)] and [(b) (4)] Tablets for the marketed finished products in the U.S.A. In all resulting investigations, you co ese complaints are unconfirmed. However, our inspectional walkthroughs and some of the investigations revealed some of the foreign tablets are actually manufactured at your facility and are being filled into capsule products. However, you have not taken any effective measures to prevent recurrence.

A. You received several complaints for foreign tablets/capsules including two complaints for [(b) (4)] [(b) (4)] Capsules USP (Complaint #DPC-IO-134-21-0041 on July 19, 2021 and DPC-IO-134-22-0069 on July 1, 2022) where the complainant reported that a foreign tablet with no marking

were found in a sealed bottle. You concluded in your investigations that they did not occur at your facility which were unconfirmed. However, I observed you processed Deviation #DEV-IO-136-20-0062 where a foreign filled capsule with different marking was found by your visual inspector during visual inspection of product (b) (4) Capsules (b) (4) mg, batch no. (b) (4) in Inspection (b) (4) area on October 20, 2020.

In addition, we observed during our inspectional walkthroughs that your packaging lines are not equipped with a vision system for detecting foreign capsules and tablets. We also observed collected in-process samples (tablets) from (b) (4) equipment (ID #TCM303) are returned to the equipment/batch during our inspectional walkthrough on March 21, 2023.

B. You recorded at least 40 complaints for short-count/underfilled and for different products from 2019 to date. You have not taken any appropriate actions to prevent recurrence although you concluded they did not happen at your facility through deficient investigation. We observed during our inspectional walkthroughs that that you only challenge your checkweighers at the (b) (4) of manufacturing and packaging operations. In addition, we observed that you recorded 18 notifications from the equipment breakdowns for checkweighers during operations where the checkweighers were not working or the (b) (4) was not working (as reported in **Observation 2**).

OBSERVATION 4 (Repeat)

Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.

You failed to monitor and ensure that personnel complete their assigned training by the due date. Training is assigned in SABA software (which was validated in 2011) and you do not assign the due dates in SABA. For example, the following personnel were assigned training in SABA and they are currently overdue. In addition, you failed to provide on-going CGMP training to contracted personnel at least (b) (4)

- Employee ID # (b) (6) (Manager, (b) (4) – Overdue on (b) (4) For New Joinee in (b) (4) Production assigned on 09/28/2016 and not yet completed.

- Employee ID (b) (6) – (b) (4) Data Integrity 2020 training assigned May 08, 2019 and not yet completed.

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not [in writing] [fully followed]. Specifically,

A. You failed to adequately classify and assess Change control #CCP-MM-941-21-0003 initiated on January 14, 2023 for upgrading the Windows operating system from 2008 to 2016. You classified the change as "Minor" where revalidation is required and did not perform an assessment of the change.

B. You have not established quality agreements with the following suppliers; (b) (4) USP (Excipient RM # (b) (4) (b) (4) (Excipient, RM (b) (4)), and (b) (4) (b) (4) Excipient, RM # (b) (4) .

Facilities & Equipment System

OBSERVATION 6

Equipment for adequate control over air pressure, humidity, temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product. Specifically, you failed to requalify the HVAC systems (HEPA) for (b) (4) Building/Unit classified as ISO Class 8 per ISO standard utilized by your firm. You requalified the HVAC for (b) (4) Building (b) (4) However, ISO 14644-2:2000 (E) states they must be performed at (b) (4) maxim time interval.

In addition, your requalification documents for HVAC system and equipment with HEPA listed below failed to include the service provider/third party who performed the requalification including their reports although the documents were approved by your Quality Assurance.

- Protocol #SP/3/044-08 (Re-qualification of HVAC of HVAC System and Equipment with HEPA filter) Study Protocol for Re-Qualification of HVAC System and Equipment with HEPA Filter 07/13/2022 effective date.
- Document #SR/3/044-02 (*Requalification of HVAC System and Equipment with HEPA Filte*r, 09/29/21 approval date).

OBSERVATION 7

Substances required for equipment operations such as lubricants and coolants come in contact with drug product containers, closures, drug product so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements. Specifically,

A. During our inspectional walkthrough of the packaging operations on March 21, 2023, we observed the firm utilizes Laminar Air Flow (ID #LAF-303) in Bulk Packing (b) (4) which is classified as ISO Class-8 during operation where the bottles are (b) (4) However, the firm does not perform testing of the (b) (4) bottles (b) (4) operations.

B. You have not established action limit, alert limit, and limit for environmental monitoring (EM) of (b) (4) which is being utilized in (b) (4) area for (b) (4) bags that are filled with raw materials going to manufacturing In addition, we reviewed several sampling for (b) (4) where you recorded the following EM testing results and you concluded that all counts mits :

- June 29, 2020 sampling: Location (b) (4) (b) (4) (b) (4) The Limit for (b) (4) states "Informative".

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Production System

OBSERVATION 8 (Repeat)

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

The Electronic Logbook (eLog) System V1.0.0 is used for Instrument, Equipment, Area Operation and Cleaning usage log for Production, Warehouse, and Quality Control departments of Lupin Limited. The eLog is not adequately controlled.

A. Your firm cannot assure us that access to the eLog system is adequately controlled. According to Annex_MUM_ITP_004403 (page of (b) (4) of SOP_MUM_ITP_004150 Rev. 4.0 (*User Management for Elog System)*, the Service Vendor/Service Engineer is assigned the same rights and privileges as the System Administrator at Lupin (Page (b) (4) where under "Admin and Security", the system administrator and service provider/vendor is able to set security profile, register new role, Set Global Profile, Register New User, Activate New User Account, Set User Account Status, Register Standard Reason, temporary password reset, etc.

B. In general, you do not document alarms in the batch records, review, investigate, assess, and trends alarms recorded in the data acquisition software during manufacturing and packaging operations at the facility. We observed on March 22, 2021, the HMI screens for (b) (4) 308) and (b) (4) 311) located in (b) (4) (Room (b) (4) a message displayed on the scre e occurred March 17, 2023. According to your production management, these alarms are not documented and reviewed by your firm. In addition, alarms for vision systems in the packaging areas are not being recorded in the batch packaging record and investigate.

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Laboratory Control System

OBSERVATION 9

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, or followed. Specifically,

Your firm lacks sterility assurance for (b) (4) drug products already distributed to the U.S. market. Specifically, your (b) (4) conducted in the (b) (4) filling line (b) (4) Room (b) (4) is deficient in that (b) (4) bottles instead of (b) (4) bottles are being used for (b) (4) Specifically, (b) (4) (b) (4) ml bottles (b) (4) and (b) (4) ml bottes (b) (4) (b) (4) are being used to conduct (b) (4) operations. During (b) (4) these bottles are filled with growth media then incubated for 14 days. However, these (b) (4) bottles do not allow for (b) (4) visualization of microbial growth that maybe present after incubation. Your firm lacks appropriately designed visual inspector qualification program that demonstrates visual inspectors can accurately identify different degree (including low level) of microbial contamination in these (b) (4) bottles. This deficient practice of using (b) (4) bottles for (b) (4) operation has been used since the commercial distribution of (b) (4) drug product in 2012.

OBSERVATION 10

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, test procedures designed to assure that components, drug products conform to appropriate standards of identity, strength, quality and purity. Specifically,

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Your failed to test (b) (4) received from your supplier according to (b) (4) Monograph as exemplified below.

Test Performed	(b) (4) Acceptance Criteria	Lupin Acceptance Criteria
(b) (4)		

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