DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPFBLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	10/03/2022 - 10/14/2022
	FEI NUMBER 3010977634

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Chandrakant Kathote, Site Head Vice President - Operations

FIRM NAME	STREET ADDRESS
Lupin Limited (Biotech Division)	Village-Ghotawade, Taluka-Mulshi
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pune, Maharashtra, India 412115	Drug Substance and Drug Product Manufacturer

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DURING AN INSPECTION OF YOUR FIRM I (WE) OBSERVED:

Observation 1: Aseptic monitoring for fill line, Filling and Closing Machine, equipment I.D. EQP/DPD/001 is not adequate. On 07 October 2022, during setup and manufacture of (b) (4) drug product, Batch (b) (4) I (WS) observed the following:

a. Settling plates positioned within the RABS are located on the (b) (4) of the filling machine and are replaced (b) (4) (b) (4) with manufacture possible up to (b) (4) that would include (b) (4) open (b) (4) interventions in settling plate exchange. The design of the environmental monitoring process is inadequate to minimize the number of RABS (b) (4) open interventions that may impact product quality.

b. During exchange of the environmental monitoring settling plates, the technician sanitized their gloved hands after the (b) (4) settling plate exchange, followed by environmental monitoring, finger dab to media plate after the (b) (4) settling plate exchange. Personnel environmental monitoring is only representative of the last settling plate exchange.

Observation 2: You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area you classified as Grade A.

In May 2022, a settle plate in the surrounding (b) (4) area resulted in (b) (4) CFU for which a microbial identification is still pending. The same monitoring day, one personnel that performed cleaning in the filling suite, received Out of Alert gown monitoring results at (b) (4) CFUs. Aerococci Viridans, an organisms recognized as a significant human pathogen was identified. No further testing was performed to determine if the organism can be captured by swab sampling ((b) (4) % of surface samples are collected by swabs in the RABS), through sterility testing, and media fill.

Observation 3: Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically,

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a. The RAB Filling Line used to fill (b) (4) DP, is classified as grade A and the surrounding (b) (4) area (under a LAF) is also classified as Grade A, but the surrounding (b) (4) area is not monitored to Grade A standards. For example,

i. Nonviable particle monitoring is not performed under dynamic conditions. (b) (4) nonviable monitoring sample is obtained in static condition, (b) (4) the (b) (4) of filling set up.

ii. Active air samples are not obtained under dynamic conditions. Only (b) (4) active air sample is obtained in static condition, (b) (4) the (b) (4) of filling set up.

iii. Settle plates are only placed near the (b) (4) at the return air filter.

b. Active air samplings is not conducted under dynamic conditions, during filling operations, in the RABs filling line.

c. Personnel that perform interventions into the RABS unit are not always monitored upon completion of the intervention. For example, the RABs unit and the surrounding (b) (4) area are both treated as Grade A and therefore movement between the two spaces are not treated as separate areas during equipment set up. The person performing equipment set up continuously place sterile components into the RABs unit and reach out of the RABs unit to reach for another sterile component. The personnel that are participating in equipment set up are not glove monitored until they exit the (b) (4) area, although multiple RAB (b) (4) are opened and closed for equipment set up.

d. Sterilized components (stoppering dispensing components) are unwrapped outside the RABs filling line in the supporting (b) (4) area. Stopper (b) (4) equires opening the RABs where the port is exposed to the surrounding (b) (4) area. In addition, stopper bags are opened in the (b) (4) area prior to loading into the RABs stopper shoot.

e. There is no environmental monitoring in areas that are frequently touched or have heavy traffic manufacturing personnel activity. For example

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i. (b) (4) handles are not monitored
ii. The handle to open the shoot for stopper discharge is not monitored
iii. The Human Interface Monitor is not monitored.
iv. The location where personnel perform weight checks is not monitored by settle plates and surface monitoring is not performed.

f. There is no monitoring for anaerobic organisms. The (b) (4) DP (b) (4) are filled with a (b) (4)

Observation 4: Protective apparel, such as head and face covering was not worn as necessary to protect the drug product from contamination. Specifically,

On 07 October 2022, I (WS) observed the setup of the fill line, Filling and Closing Machine, equipment I.D. EQP/DPD/001 for (b) (4) drug product manufacture, Batch (b) (4) A fill operator was observed in Grade A space with a small area of exposed skin at the goggle hood interface. The hood was inadequately fitted to the head and face, with a portion of the hood fabric not positioned under the goggle leaving the exposed area of skin.

Observation 5: Growth promotion testing of swabs used to collect environmental monitoring samples does not reflect routine incubation requirements for environmental monitoring samples. Growth promotion testing is performed by incubating samples at (b) (4) temperature, (b) (4) whereas routine incubation requires incubation from 20-25C for three days followed by 30-35C for an additional two days.

Observation 6: A building and raw material in support of (b) (4) drug substance intermediate and (b) (4) drug substance and drug product manufacture are not adequately controlled. Specifically,

a. Your raw (b) (4) for manufacture is (b) (4) with a Lupin Limited pumping station located at (b) (4) by property lease. Oversight of the pumping station is by (b) (4) and purchase order, with no contract agreement. There is no procedural control or access control for the facility, with the facility not secure.

b. Your GMP raw (b) (4) area does not have limited access.

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Observation 7: The qualified state of a manufacturing utility system is not maintained. Specifically, Your GMP raw (b) (4) system includes but is not limited to the addition of (b) (4) (b) (4) by pump. The dispense pumps have not been calibrated since qualification in 2019.

Observation 8: The qualification of a facility system for (b) (4) drug product manufacture is deficient. Specifically,

According to protocol PVP/024-07, Protocol for Performance Verification (PV) of Drug Product Manufacturing Department (HVAC), Effective Date 08/08/22, Section 9.6, Airflow direction test, , airflow visualization and smoke pattern testing is to be conducted to show the actual airflow pattern throughout the cleanroom. On 07 October 2022, I (WS) observed an area of Grade B space without direct HEPA filtration adjoining Grade A space for Room (b) (4) fill line, Filling and Closing Machine. Smoke visualization testing for the Grade B area, smoke applied at (b) (4) level was not conducted in assurance airflow is uniform and without turbulence to the (b) (4) return.

Observation 9: Training to perform assigned function in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess is deficient. Specifically,

SOP_PNB_DP_025646, Washing and Cleaning of Auxiliary Items, v6, 19 September 2022 provides instruction for manual cleaning of drug product contact equipment. Training is read and understand and questionnaire, with training not including OJT, qualification nor requalification.

Observation 10: Procedures for decontamination of material and components going into the classified clean manufacturing rooms are not sufficient to prevent contamination. For example,

a. Fungal contamination of the media preparation and (b) (4) preparation areas in the microbial manufacturing area in September 2021 was found to be related to improper decontamination of material during transfer from warehouse to manufacturing areas. (b) (4) samples were found with out of action limit fungal counts from plates exposed on 17 September 2021 and previously on 09 September 2021. Corrective actions did not include ensuring

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decontamination procedures supported the recommendation from the disinfectant efficacy studies.

b. The procedure for decontamination of material going from a lower grade environment to a higher grade environment (i.e., going from grade C to grade B) is not defined in the sanitization procedure, SOP PNB_DP_026281, Material Movement in Drug Product Manufacturing Department. For example, the procedure does not provide a minimum contact time for disinfectants as defined in the Report on Disinfectant Efficacy Test Validation. Disinfectants (b) (4) require a minimum of (b) (4) contact time and (b) (4) requires a minimum contact time of (b) (4)

Observation 11: Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis. Specifically, the following raw materials do not receive an identification test upon receipt and are accepted based on the review of the COA:

a. (b) (4) used during (b) (4) of (b) (4) does not receive an identification test upon receipt. Two lots that did not receive an identification test have been found with color not meeting specification upon dispensing of the raw material lots.

b. (b) (4) is used in the (b) (4) downstream manufacturing process.

The number of containers to be sampled is not based upon appropriate criteria. Specifically, there is no justification for the sample size for dimensional testing of (b) (4) The specification for the (b) (4) requires (b) (4) units to be tested for dimensions, but routinely, only (b) (4) units are tested for dimensions.

Requirements that must be met by suppliers have not been established. Specifically, the firm does not have a quality agreement with vendors that manufacture and supply the (b) (4) and stoppers used in the manufacture of (b) (4) drug product.

Observation 12: Your examination and testing of samples did not assure that the drug product and in-process material conformed to specifications. Specifically,

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a. The (b) (4) visual inspection defect sets used to challenge personnel during qualification for inspection of (b) (4) mL and (b) (4) mL (b) (4) are made up with (b) (4) with no defects and (b) (4) with defects. The fluid present in non-defective (b) (4) is not free flowing and are easily identifiable versus defective (b) (4) which are filled with free-flowing fluid.

b. Personnel are required to obtain eye exams as part of the visual inspection qualification process. The visual examinations do not always include a test for near visual acuity.

Observation 13: Your examination and testing of samples did not assure that the drug product and in-process material conformed to specifications. Specifically,

a. The (b) (4) visual inspection defect sets used to challenge personnel during qualification for inspection of (b) (4) mL and (b) (4) mL (b) (4) are made up with (b) (4) with no defects and (b) (4) with defects. The fluid present in non-defective (b) (4) is not free flowing and are easily identifiable versus defective (b) (4) which are filled with free-flowing fluid.

b. Personnel are required to obtain eye exams as part of the visual inspection qualification process. The visual examinations do not always include a test for near visual acuity.

Observation 14: Failure to perform a thorough investigation, make a record of the conclusions and follow-up of an unexplained discrepancy or a failure of a lot or unit to meet any of its specifications. Specifically,

Vendor Complaint Notification # 200016475 was initiated 08 April 2021 when raw material was found with an abnormal color. During dispensing of (b) (4) batch # (b) (4) for the manufacture of (b) (4) the material was found to be (b) (4) in color instead of (b) (4) per specification. A complaint was filed with the vendor and the vendor investigation was completed on 06 May 2021. The vendor confirmed the defect and reported other similar complaints were received. A deviation investigation was not initiated to determine product impact.

a. Product impact was not performed as required by SOP_MUM_CQA_009791, Handling of Vendor Complaints, which requires "Based on Vendor investigation /CAPA site QA - Head / Manager will review and evaluate the

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impact of vendor complaint on stocks available at site and previously used stocks." (b) (4) lot # (b) (4) was previously used in the manufacture of (b) (4) # (b) (4) which was used to manufacture (b) (4) Drug Substance # (b) (4) The DS lot was used in the manufacture of (b) (4) Drug Product # (b) (4)

b. (b) (4) batch # (b) (4) was not quarantined until 02 September 2021 and the vendor was not blocked until 20 December 2021.

Observation 15: An equipment system cleaning specification is inadequate. Specifically,

In microbiological downstream manufacturing for (b) (4) drug substance intermediate manufacture, you have a set a conductivity rinsate specification of ≤ (b) (4) µS/cm in cleaning validation for the (b) (4) liter and (b) (4) liter Processing Vessels. The specification is inconsistent with the capability of the cleaning process and cleaning validation results.

Observation 16: The batch production and control records are deficient in that they do not include documentation of batch investigations performed. Specifically,

a. Deviation # DEV-PN-775-20-0001 was initiated when temperature excursion occurred in the 2-8°C cold room which was storing one (b) (4) Solution lot, one (b) (4) Solution lot, one (b) (4) (b) (4) Solution lot, and fifteen (b) (4) Drug Substance lots. The individual lots were not linked with the deviation and therefore there is no history of temperature excursion for the lots in storage.

b. Deviation investigations were not initiated when two raw material lots, (b) (4) lot (b) (4) and # (b) (4) were found a different color than specification for appearance, at time of dispensing for manufacture of (b) (4) The event was addressed as a vendor complaint, but no product impact assessment was made for previous use of the lot. (b) (4) lot # (b) (4) was previously used in the manufacture of (b) (4) ot # (b) (4) which was used to manufacture (b) (4) Drug Substance # (b) (4) The DS lot was used in the manufacture of (b) (4) Drug Product # (b) (4)

Observation 17: Standard operating procedures in support of manufacture are deficient or are not followed.

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Specifically,

a. The procedure for decontamination of material going from a lower grade environment to a higher grade environment (i.e., going from grade C to grade B) is not defined in the sanitization procedure, SOP PNB_DP_026281, Material Movement in Drug Product Manufacturing Department. For example, the procedure does not provide a minimum contact time for disinfectants as defined in the Report on Disinfectant Efficacy Test Validation. Disinfectants (b) (4) require a minimum of (b) (4) contact time and (b) (4) requires a minimum contact time of (b) (4)

b. Vendor complaint investigation # 200016475 was initiated 08 April 2021 and vendor completed the investigation on 06 May 2021. Per SOP # 009791, "Based on Vendor investigation /CAPA site QA - Head / Manager will review and evaluate the impact of vendor complaint on stocks available at site and previously used stocks." This was not performed in the case of vendor complaint investigation for # 200016475.

c. Under REP/PQ/MFG/455, Report on Performance Qualification of Glass (b) (4) EQP/MFG/455, 02/11/2019, you validated an equipment dirty hold of (b) (4) Procedure EOP_PNB_MI-_44507, Operation and Cleaning of Glass (b) (4) v2, Effective date 25 May 2022 fails to include the equipment dirty hold time limit.

d. Under QC/SR/21-009-00, 06/04/2022, Report for Cleaning Validation and Hold Time Study Raw Material Sampling Tools, you validated an equipment dirty hold time of (b) (4) SOP_PNB_QC_017312, Raw Material Management, v7.0, Effective date 29 September 2022 fails to include the equipment dirty hold time limit.

e. On 11 October 2022, I (WS) observed (b) (4) on the floor near the (b) (4) drain line of the (b) (4) storage and distribution system EQP/ENG/074 and below the (b) (4) plant (EQP/ENG/073). Procedure EOP_PNB-EN-046950, Operation of (b) (4) Plant (Make-(b) (4) Model-(b) (4) 11 October 2022 fails to include a routine walk through in verification for absence of (b) (4) system leaks.

f. According to SOP_PNB_QC_026786 (3.0), Indent, Receipt and Handling of Quality Control Chemicals and Solvents, effective date, 03 March 2022, "Store the Toxic/Hazardous/corrosive chemicals/reagents in a separate location and handle these as per MSDS of the respective material". We (YW and YL) observed (b) (4)

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(b) (4) a toxic chemical on a laboratory shelf, along with other chemicals, in RM/PM Testing Lab-1/Room 6318 of QC Laboratory in Building B during a laboratory tour on 06 October 2022. Based on your provided (b) (4) Material Safety Data Sheet (MSDS), (b) (4) belongs to "very toxic hazardous materials", and the associated storage conditions are "Tightly closed; Dry; Keep in a well-ventilated place; and Keep locked up or in an area accessible only to qualified or authorized persons". The SOP was not followed, with the toxic chemical not adequately stored.

Observation 18: Equipment and a manufacturing area used in drug substance and drug product manufacture are not maintained in a good state of repair. Specifically,

a. The Microbiological Drug Substance Facility, (b) (4) Preparation Area Change Room was observed with deteriorated sealant at a wall corner (b) (4) with deteriorated sealant at a (b) (4) vall plate interface within (b) (4) preparation. A similar occurrence was observed in (b) (4) Entry for deteriorated sealant at a wall (b) (4) interface.

b. On 11 October 2022, I (WS) observed (b) (4) on the floor near the (b) (4) drain line of the (b) (4) storage and distribution system EQP/ENG/074 and below the (b) (4) plant (EQP/ENG/073).

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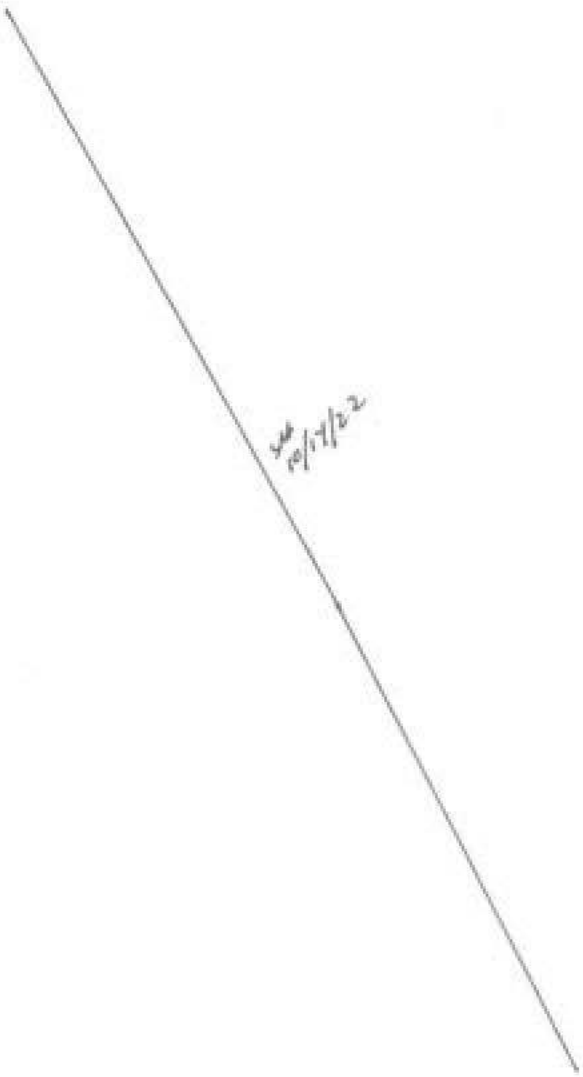

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