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	5/6/2019-5/15/2019*
	FEI NUMBER 3004995645

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Rajendra Chunodkar, President - Manufacturing Operations

FIRM NAME	STREET ADDRESS
Lupin Ltd.	28-1, Midc Industrial Area, Chikalthana
CITY, STATE, ZIP CODE, COUNTRY Aurangabad, Maharashtra, 431210 India	TYPE ESTABLISHMENT INSPECTED Manufacturer of Finished Drugs

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

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

Your firm has not documented completed investigations for the following:

A. From July 2017 until February 2019, there were (b) (4) cases ((b) (4) cases of (b) (4) (b) (4) mg; (b) (4) cases of (b) (4) (b) (4) mg; (b) (4) cases of (b) (4) (b) (4) mg) where the In-Process Control (b) (4) testing of (b) (4) tablets yielded out of specification results. Retesting was conducted but no corrective actions were taken at the time including conclusions of "No assignable cause" or "Manual Error" without documentation of the manual error. The (b) (4) tester and formulation were changed in January and August 2018, but no CAPA was developed and no follow-up action was assigned

B. No investigation was initiated for the discrepancy found with the (b) (4) Tablet Compressor showing an out of range compaction force in the end protocol compaction force statistics versus the operating messages in (b) (4) (b) (4) mg batch (b) (4) (finished goods batch (b) (4)).

C. Complaint DPC-AU-261-18-0016 consisted of human hair being embedded within an (b) (4) (b) (4) mg tablet. There was no expansion of the investigation to determine microbial contamination and impact.

OBSERVATION 2

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rumany C Penn, Investigator X Rumany C Penn Investigator Signed By: 2001148009 Date Signed: 05-15-2019 11:03:40	5/15/2019

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Specifically,

Growth promotion is deficient in that (b) (4) average colony counts obtained from the certificates of analysis are used to accept new media rather than using actual counts obtained from verified, already accepted media. This process has not been validated to show at least equivalency to USP methods.

OBSERVATION 3

Control procedures are not established which monitor the output and 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,

A. Temperature mapping studies were conducted on the finished drug product warehouses (b) (4) but did not use the data to scientifically justify the placement of the temperature data loggers. The loggers were not placed in the hot spots derived from the studies. The variability of the movement of the shelves was also not taken into account during the studies.

B. Yield limit specifications have not been established for critical manufacturing steps such as in-process (b) (4) of (b) (4) (b) (4) mg and (b) (4) mg capsules. The process was stated to have been validated but (b) (4) (b) (4) commercial batches would be needed to validate the yield specification.

***DATES OF INSPECTION**

5/06/2019(Mon), 5/07/2019(Tue), 5/08/2019(Wed), 5/09/2019(Thu), 5/10/2019(Fri), 5/13/2019(Mon), 5/14/2019(Tue), 5/15/2019(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rumany C Penn, Investigator	X Rumany C Penn Investigator Signed By: 2001148009 Date Signed: 05-18-2019 11:03:46	5/15/2019