DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
ORA OPQO HQ, Room #2032 12420 Parklawn Drive, Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	09/16/2019-09/20/2019 FEI NUMBER 3002807512

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Vijay A. Kothiwale, Site Head & Senior Vice President Manufacturing

FIRM NAME	STREET ADDRESS
Lupin Limited	T-142, M.I.D.C. Tarapur Via Boisar
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tarapur, Thane, Maharashtra, 401506, India	API 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 I OBSERVED:

OBSERVATION 1

Failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

a. The investigation regarding the metal particle contamination in (b) (4) USP is deficient. Deviation # DEV-TA-535-19-0009 (dated March 23, 2019) was initiated based on the presence of foreign particles during the sampling of (b) (4) USP, batch (b) (4). Based on your investigation, the contaminants were identified as metal particles which could originate from (b) (4) (b) (4) and blender (BL-9501). The batch (b) (4) was identified as the mother batch of the affected batch, which was blended on March 21, 2019 using the blender, (b) (4). The investigation was never extended to all other (b) (4) API batches manufactured during the production campaign using this equipment train between the major cleaning schedules. For example, the major cleaning schedule of blender BL-9501 was between (b) (4) and about (b) (4) batches were blended during this production campaign. Your Quality team did not include all the batches manufactured during the campaign for a risk evaluation. There is no assurance that API batches such as, but not limited to (b) (4) USP, (b) (4) (b) (4) blended after the affected batch, without performing a major cleaning, are free of metal particles. These batches were distributed for the manufacturing of U.S market products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Unnee Ranjan, Investigator	09/20/2019

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b. Damage was noticed on (b) (4) of the (b) (4) Equipment ID # (b) (4) on June 18, 2019 after completion of (b) (4) process of the product (b) (4) USP batch, (b) (4) However, no risk assessment was conducted on other API batches (b) (4) using the affected (b) (4) since the last preventive maintenance was performed (April 29, 2019). There is a lack of assurance that API batches such as, but not limited to (b) (4) USP (b) (4) (b) (4) (b) (4) using the affected (b) (4) are not impacted. In addition, the production department failed to document the incident within the executed batch record or in the associated equipment log.

For the API batches listed above in part A and B, no metal detection was performed prior to release. As of the current inspection the firm does not have a metal detector.

OBSERVATION 2

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

The documentation of controls during manufacturing of (b) (4) USP is deficient. It was observed that the batch manufacturing record was not provided with sufficient controls required for the (b) (4) of (b) (4) USP. The manufacturing operators change the (b) (4) of (b) (4) based on the nature of (b) (4) API material without proper guidance in the batch record or approval from the Quality group. (b) (4) USP batches manufactured in 2019 for U.S market were (b) (4) using (b) (4) Equipment ID (b) (4) using various (b) (4) (b) (4) between (b) (4) The actual (b) (4) used for batch (b) (4) process was not documented as part of executed batch records. The (b) (4) was found changed by initiating work orders to Engineering Department without involvement from the Quality Department.

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OBSERVATION 3

There was a failure to handle and store cleaned utensils in a manner to prevent contamination.

Specifically,

a. On September 16, 2019, the storage of cleaned non-dedicated utensils was found deficient. For example, cleaned utensils such as, but not limited to scoops, measuring vessels and solvent weighing containers were stored in an emergency exit corridor together with (b) (4) drums containing (b) (4) The drums were found labeled as "To be cleaned" (b) (4) batch (b) (4)

b. On September 16, 2019, I observed an umbrella stored inside the equipment cleaning room. As per a manufacturing operator, this room is regularly used for the washing of (b) (4) bags used for (b) (4) (b) (4).

***DATES OF INSPECTION**

9/16/2019(Mon), 9/17/2019(Tue), 9/18/2019(Wed), 9/19/2019(Thu), 9/20/2019(Fri).

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