DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. FDA CDER/OPQ/OS IAB, Attn: Mr. Concepcion Cruz White Oak Building 51, Room 4316 10903 New Hampshire Avenue Silver Spring, MD 20993 Industry Information: www.fda.gov/oc/industry	June 30 - July 6, 2016
	FEI NUMBER 3005906909

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Snehal Sheth, Site Head and General Manager - Manufacturing

FIRM NAME	STREET ADDRESS
Lupin Limited	Block 21, Village Dabhasa; Taluka: Padra
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
District Vadodara, 391 440 Gujarat, India	Manufacturer, Distributor

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) (WE) OBSERVED:

Observation 1:

The firm failed to validate disinfectant and sanitization procedures used in the clean controlled manufacturing areas and did not ensure that product quality is not compromised.

For example,

A. The firm has fumigated the Plant (b) (4), the clean controlled Powder Processing Areas, (b) (4) times in 2014, 2015, and 2016 with (b) (4) disinfectant solution according to SOP AMP-044-02, titled "Fumigation in Powder Processing Area", effective date 6/25/2016, after microbiological environmental monitoring alert levels were exceeded. The Powder Processing Areas are used in finished API production, for example for (b) (4) (b) (4) and (b) (4) USP. When fumigation is to be done, the (b) (4) solution is aerosolized to cover the entire area of a room. The firm removes equipment and product stored in the room prior to fumigation, but when product in (b) (4) drums cannot be removed from the room, the procedure states the drums "shall be covered properly as to avoid cross contamination."

The firm did not do the following prior to implementing the fumigation procedure:
- Validate the sanitization to ensure that the method used to cover the product drums prevents contamination of the product from the fumigation agents.
- Establish that product quality is not impacted from the fumigation.
- Record in the fumigation logs which product in drums were left in the rooms.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Roger F. Zabinski Jose A. Lopez Rubet	Roger F. Zabinski, Investigator Jose A. Lopez Rubet, Chemist	07/06/2016

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. FDA CDER/OPQ/OS IAB, Attn: Mr. Concepcion Cruz White Oak Building 51, Room 4316 10903 New Hampshire Avenue Silver Spring, MD 20993 Industry Information: www.fda.gov/oc/industry	June 30 - July 6, 2016
	FEI NUMBER 3005906909

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Snchal Sheth, Site Head and General Manager - Manufacturing

FIRM NAME	STREET ADDRESS
Lupin Limited	Block 21, Village Dabhasa; Taluka: Padra
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
District Vadodara, 391 440 Gujarat, India	Manufacturer, Distributor

B. The following disinfectant and sanitization protocols and reports, used in the clean controlled Powder Processing Areas where products such as (b) (4) and (b) (4) USP are produced. These protocols were prepared at (b) (4) sites, such as at the (b) (4) and (b) (4) sites, and were used without validation at the Dabhasa site:

- Disinfectant Validation Protocol, VAP/DIS/VAL/08/15, effective 8/13/15 for the use of disinfectants such as (b) (4); completed at the (b) (4) site.
- Disinfectant Validation Report, VAP/DIS/VAL/08/15, effective 9/25/15, for the use of (b) (4); completed at the (b) (4) site.
- Validation protocol, titled "Evaluation of Efficacy of Sanitizing Agent (in vivo studies)", AMV/10/79/00, effective 3/31/08, for the use of sanitizing agents such as (b) (4) completed at the (b) (4) site.
- Validation report, titled "Evaluation of Efficacy of Sanitizing Agent (in vivo studies)", AMV/10/79/00, effective 7/29/08, for the use of sanitizing agents such as (b) (4) completed at the (b) (4) site.

Observation 2:

The firm failed to perform specific identification tests on the vendor supplied (b) (4) that is used to create an (b) (4) for the bulk packaging of APIs.

Specifically, your firm's receipt of the (b) (4) material, used in the (b) (4) of your firm's (b) (4) drug substance packaging was accepted for use with supplier provided COA for the raw material, in lieu of testing of the raw material for conformity with all appropriate written specifications, without performing at least one specific identity test on the raw material and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Roger F. Zabinski Jose A. Lopez Rubet	Roger F. Zabinski, Investigator Jose A. Lopez Rubet, Chemist	07/06/2016