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	06/27/2022-07/01/2022
	FEI NUMBER 3008581988

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Ashish Zitshi, Vice President – Site Head

FIRM NAME	STREET ADDRESS
Cipla Limited	Plot No 9 & 10, Pharma Zone Phase II, Sector III
CITY, STATE, ZIP CODE, COUNTRY Indore SEZ, Pithampur, Madhya Pradesh 454775 India	TYPE ESTABLISHMENT INSPECTED 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

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, on June 28, 2022, during my review of cleaning validation, CUR01, 'Validation Report Cleaning of Equipment' for (b) (4) batches (b) (4) (b) (4) documents the surface area of each equipment. I asked for the raw data for the surface calculations for each equipment such as (b) (4) Accessories and Packing Machine. According to the Site Quality Assurance Head, there are no raw data for the surface area calculation for each manufacturing equipment. Because there are no raw data, there is no evidence that swab samples were actually analyzed.

OBSERVATION 2

Samples taken of drug products for determination of conformance to written specifications are not properly identified.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	Dipesh K. Shah -S Digitally signed by Dipesh K. Shah -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Dipesh K. Shah -S, 0.9.2342.19200300.100.1.1=1300184065 Date: 2022.07.01 15:48:20 +05'30'	Dipesh Shah, CSO	07/01/2022

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Specifically, on June 29, 2022, I observed (b) (4) units of (b) (4) of batch (b) (4) in the 25 degrees Celsius / 60 % Relative Humidity chamber # (b) (4) According to the Laboratory Management System (LMS) reconciliation data, the stability chamber should have had (b) (4) units of (b) (4) of batch # (b) (4) Your firm follows Protocol, PRSP/PD/DP/31005019A, document tilted, (b) (4) (b) (4) MCG and (b) (4) (b) (4) mcg (b) (4) USP', with effective date July 20, 2021 for its stability program.

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