

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov		DATE(S) OF INSPECTION 06/27/2022-07/01/2022
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Mr. Ashish Zitshi, Vice President – Site Head		FEI NUMBER 3008581988
FIRM NAME Cipla Limited	STREET ADDRESS 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) 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.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Dipesh K. Shah -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Dipesh Shah, CSO	DATE ISSUED 07/01/2022
	<small>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'</small>		

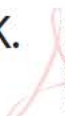
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Mr. Ashish Zitshi, Vice President – Site Head

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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) MCG and (b)(4) mcg (b)(4) USP', with effective date July 20, 2021 for its stability program.

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