

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA/ORR/OPQO HQ, Room #2032 12420 Parklawn Drive Rockville, MD 20857 Industry information: www.fda.gov/oc/industry Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 04/29-05/03/2024 & 05/06-08/2024
	FEI NUMBER 3002806702

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Mr. Amol Sarmandal, Director-Technical Services

FIRM NAME Cipla Ltd.	STREET ADDRESS Plots D-7, D-22, D-27, M.I.D.C. Taluka-Daund
CITY, STATE AND ZIP CODE Kurkumbh Maharashtra 413802 India	TYPE OF ESTABLISHMENT INSPECTED API and Finished (b)(4) Dosage 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) (WE) OBSERVED:


**QUALITY SYSTEM**

**OBSERVATION 1**

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Your firm failed to follow document control procedures. For example, during the walk-through of the stability chambers of drug substances, located in the (b)(4) of the warehouse Unit (b)(4) we observed an uncontrolled document named "SAMPLE LOCATION CHART", used for the location of the stability samples in chamber (b)(4) 033. Furthermore, your firm also had uncontrolled "SAMPLE LOCATION CHART" sheet for the following chambers: (b)(4) 84, (b)(4) 111, (b)(4) 93 and (b)(4) 201. SOP Document Control, 1035-G-004, Version: 13.0, Effective Date: March 29, 2024, states in that document should have been stamped "UNCONTROLLED COPY" with Sign:, Date:, Time: and Valid up to: Date:. Validity of "Uncontrolled" document shall be (b)(4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  Haitao Li	EMPLOYEE(S) NAME AND TITLE (Print or Type) Santos E Camara, Investigator Haitao Li, Chemist	DATE ISSUED 05/08/2024
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