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	02/24/2025-02/28/2025 FEI NUMBER ~~3009882550~~ 3030133758

NAME AND TITLE OF TO WHOM REPORT ISSUED

Mrs. Manorama Avinash, Executive Director

FIRM NAME	STREET ADDRESS
Cdymax (India) Pharma Private Limited	Plot Nos. 20 and 169, Sy. No's 132, 243, & 244, Bommasandra Jigani Link Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bangalore, Karnataka, 562106, India	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 I OBSERVED:

OBSERVATION 1

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

A. (b) (4) Microbial Enumeration Test (a release test) method suitability did not include scientifically supported conclusion that the method is most suitable at (b) (4) product dilution. Per pharmacopeia requirement, the lowest possible dilution factor of the drug product must be used. Your method suitability did not include sample preparation such as at (b) (4) dilutions to justify the use of a higher dilution at (b) (4)

B. The (b) (4) is a raw material used for the manufacturing of (b) (4) (b) (4) Your firm's (b) (4) monitoring is deficient in that the isolate identification is not appropriately performed. SOP-MBGN-023-04 requires to record and compare representative isolate colony morphology to the in-house isolate library for further species identification. In 2024, a total of (b) (4) samples were collected for monitoring. You have only 4 documented records that show

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	Eileen A. Liu -S Digitally signed by Eileen A. Liu -S Date: 2025.03.03 10:47:20 -08'00'	**Eileen A. Liu, Investigator**	03/03/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 ORAPHARMInternational483responses@fda.hhs.gov	02/24/2025-02/28/2025
	FEI NUMBER ~~3009882550~~ 3030133758

NAME AND TITLE OF TO WHOM REPORT ISSUED

Mrs. Manorama Avinash, Executive Director

FIRM NAME	STREET ADDRESS
Cdymax (India) Pharma Private Limited	Plot Nos. 20 and 169, Sy. No's 132, 243, & 244, Bommasandra Jigani Link Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bangalore, Karnataka, 562106, India	Drug Manufacturer

isolate morphology observation were performed. You do not have records for the other (b) (4) observations you supposedly performed.

C. The viable environmental monitoring (EM) for your production area is deficient in that the EM isolate identification is not appropriately performed. Specifically, SOP-MBGN-023-04 requires to record and compare representative EM isolate colony morphology to the in-house isolate library for further species identification. In 2024, a total of (b) (4) viable EM samples were collected from the production location (b) (4) where (b) (4) room are located. You have only 1 documented record to show that colony morphology observation was performed. You do not have records for the other (b) (4) observations you supposedly performed.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	Eileen A. Liu -S Digitally signed by Eileen A. Liu -S Date: 2025.03.03 10:47:44 -08'00'	**Eileen A. Liu, Investigator**	03/03/2025