DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER U.S. Food & Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 04/28/2025 to 05/02/2025* FEI NUMBER 3004126703
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Sudhir K. Vaid, Chairman & Managing Director	
FIRM NAME Concord Biotech Limited	STREET ADDRESS 1482-1486, Trasad Road
CITY, STATE, ZIP CODE, COUNTRY Dholka Ahmedabad, Gujarat, India 382225	TYPE ESTABLISHMENT INSPECTED API Manufacture

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

Failure to clean equipment and utensils to prevent contamination or carry-over of a material that would alter the quality of the intermediates and API beyond the official or other established specifications.

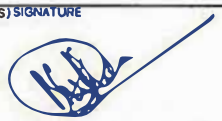
Specifically,

During my walkthrough inspection of your manufacturing Plant (b) (4), I observed (b) (4) residues on the agitator and around the walls of a (b) (4) # (b) (4)1. I also observed (b) (4) particles on the bottom of the (b) (4) According to the logbook your firm performed after use cleaning on (b) (4) and (b) (4) cleaning on (b) (4) This (b) (4) utilized in the (b) (4) operation of (b) (4) Active Pharmaceutical Ingredient.

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Nibin Varghese, Investigator	05/02/2025

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Your firm failed to verify the microbiological results by a second person at the time of documentation. The colony counts of incubated plates for the determination of Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) tests performed for finished Active Pharmaceutical Ingredient (API) release is not verified by a second microbiologist to ensure the accuracy of the reported results. Your *SOP No: MQ/SOP/028: Microbiological Testing of Active Pharmaceutical Ingredients, Revision.02, Effective Date: 05/01/2023* is deficient in defining the second verification of the microbiological results.

OBSERVATION 3

Failure to exercise sufficient controls over computerized systems to prevent unauthorized access or changes to data and failure to have adequate controls to prevent omission of data.

Specifically,

Your firm failed to exercise sufficient controls over computerized systems to prevent unauthorized access. I observed the following deficiencies, but are not limited to:

a) Your firm utilizes multiple standalone electronic balances (ID#CBL/QC/BAL -17 & ID#CBL/QC/BAL -20) in the Quality Control (QC) Laboratory. I observed that analyst can login with common username "operator" to the system. I also observed that unique usernames can be created on these balances. This instrument is also capable for storing test data electronically. The accuracy of data record on these forms were not reviewed by your quality unit.
b) Your Quality Assurance department utilizes a computer ID #CS/QA/C/002 for the issuance of batch records to production department. Your firm utilizes a common username "CBL\qa" and password to login to the computer system.

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		Nibin Varghese, Investigator	05/02/2025

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OBSERVATION 4

Failure to ensure that water used in the (b) (4) manufacturing steps of a non-sterile API intended for a sterile drug product is monitored and controlled for total microbial counts, objectionable organisms, and endotoxins.

Specifically,

Your firm manufacture (b) (4) USP API intended for sterile (b) (4) product (b) (4) Injection. Your firm utilizes (b) (4) Water (b) (4) in the manufacturing steps, especially with the (b) (4) steps. Your firm failed to test the (b) (4) for endotoxins.

*** DATES OF INSPECTION**

04/28/2025 (Mon), 04/29/2025 (Tue), 04/30/2025 (Wed), 05/01/2025 (Thu) and 05/02/2025 (Fri)

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		Nibin Varghese, Investigator	05/02/2025