

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

12420 Parklawn Drive, Room 2032
Rockville, MD 20857

DATE(S) OF INSPECTION

5/21/2025-5/30/2025*

FEI NUMBER

3005210225

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Rajesh Kshirsagar, Chief Operating Officer

FIRM NAME

Micro Labs Limited

STREET ADDRESS

Plot No. S-155 to S-159 & N1, Phase III &
Phase IV, Verna Industrial Estate

CITY, STATE, ZIP CODE, COUNTRY

Verna, Goa, 403722 India

TYPE ESTABLISHMENT INSPECTED

Drug Product 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

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

On April 24, 2025, your firm increased the (b) (4) range for the drug (b) (4) stage and increased the (b) (4) range for the (b) (4) stage in the manufacturing process of (b) (4) (b) (4) ng, which is used to produce (b) (4) Capsules (b) (4) mg (b) (4) ng. The new ranges exceeded what was used during process validation, completed on August 24, 2021. The table below outlines the changes made for (b) (4) stages.

(b) (4)

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Tamil Arasu, Investigator - Dedicated Drug
Cadre
Lauren N Howard, Investigator

X

Tamil Arasu
Investigator - Dedicated Drug
Cadre
Signed By: 2001563486
Date Signed: 05-30-2025
10:57:00

DATE ISSUED

5/30/2025

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Rajesh Kshirsagar, Chief Operating Officer			
FIRM NAME Micro Labs Limited		STREET ADDRESS Plot No. S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate	
CITY, STATE, ZIP CODE, COUNTRY Verna, Goa, 403722 India		TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer	
To date, re-validation has not been performed using the new (b) (4) range and new (b) (4) range. (b) (4) batch of (b) (4) mg, batch number (b) (4) has been manufactured using the unvalidated ranges.			
OBSERVATION 2 There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed. Specifically, Your attributed root causes for Out of Specifications (OOS) and Laboratory Incident investigations are not adequately justified with scientific evidence. For example, OOS-ML06-2024-0014 (PR ID: 43233): An OOS result of (b) (4)% (Specification limit: (b) (4)% - (b) (4)%) was obtained during in-process test for assay by HPLC at the compressed tablet stage of (b) (4) Tablets (b) (4) mg (Batch # (b) (4) OOS result was invalidated, and your firm attributed a potential root cause that concluded, "error during weighing and incomplete transfer of sample (b) (4) into the volumetric flask". However, this conclusion was not adequately supported with evidence and justified. This in-process (b) (4) Tablets batch was used to manufacture (b) (4) batches (b) (4) of (b) (4)			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tamil Arasu, Investigator - Dedicated Drug Cadre Lauren N Howard, Investigator		DATE ISSUED 5/30/2025 Tamil Arasu Investigator - Dedicated Drug Cadre Signed By: 2001563486 Date Signed: 05-30-2025 10:57:00

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Rajesh Kshirsagar, Chief Operating Officer			
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(b) (4) Tablets USP (b) (4) mg (b) (4) mcg (b) (4) - OOS-ML06-2025-0014 (PR ID: 96524): OOS result of (b) (4) % (Specification limit: Between (b) (4) % and (b) (4) %) was obtained for (b) (4) content in dissolution test at (b) (4) stage at (b) (4) time point (Product: (b) (4) Capsules (b) (4) mg / (b) (4) mg, Batch # (b) (4)). You have confirmed the OOS, but no root cause has been identified. However, you have proposed to implement (Change control # 107081) a corrective action which states, "Use cleaned (b) (4) for each (b) (4) stage and whenever (b) (4) is observed". The same batch also gave an OOS (OOS-ML06-2024-0105, PR ID: 87142) for content uniformity and you invalidated the OOS result, attributing the root cause for an analyst error in transferring the sample. However, this conclusion was not adequately supported with evidence. - LIR-ML06-2025-0096 (PR ID: 95575): This laboratory incident investigation was initiated due to the finding that during the dissolution testing of (b) (4) Tablets (b) (4) mcg, additional peak was observed at retention time about (b) (4) (about RRT (b) (4) in sample solution for Batch # (b) (4)). Your investigation conclusion, "analyst might have used uncleaned test tubes for sample collection or could be due to dissolution vessels not rinsed with (b) (4) following the cleaning with (b) (4) solution" is not supported with evidence as the HPLC peak pattern did not match with the peaks of detergent (b) (4).			
*DATES OF INSPECTION 5/21/2025(Wed), 5/22/2025(Thu), 5/23/2025(Fri), 5/26/2025(Mon), 5/27/2025(Tue), 5/28/2025(Wed), 5/29/2025(Thu), 5/30/2025(Fri)			
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Lauren N Howard
Investigator
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