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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 12420 Parklawn Drive, Room 2032<br>Rockville, MD 20857 | 1/30/2025-2/7/2025* |
| | FEI NUMBER<br>3004495158 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Rajesh Kshirsagar, Chief Operating Officer

| FIRM NAME | STREET ADDRESS |
|---|---|
| Micro Labs Limited | Plot No 16 and 24, Veerasandra Industrial Area |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Bengaluru, Karnataka, 560100 India | Finished Drug Products Manufacturer (b) (4) (b) (4) |

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:**
QUALITY SYSTEM

## OBSERVATION 1

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

Specifically,

Your Quality Unit lack oversight on the control and management of GMP documents that are critical in ensuring drug products manufactured and tested at your site are safe and effective. For example, at the initiation of this inspection on 30-Jan-2025, we observed that one of your housekeeping personnel was rushing to remove large black color plastic scrap bags from the main QC Chemistry laboratory. This scrap bag was collected for our evaluation. Subsequently, large number of transparent plastic bags along with few silver and green color plastic bags containing black color scrap bags were found in the main scrapyard of your facility. The evaluation of these scrap bags revealed large number of torn and few intact pieces of GMP documents indicative of original records, raw data, and metadata such as "Leak Tester Results" printouts, pH meter printouts, signed and dated chromatographic sample set sequences, chromatograms, specification, test procedures, along with handwritten calculations, weights, and documentations in *"blue color ink pen"* on uncontrolled papers and pH meter printouts. Many of these documents were crumpled upon tearing into pieces and not all torn pieces could be found from the scrap bags. Per your Quality Assurance Procedure (QAP) No.: QAP/MLCM/0110-001, Titled: "Good

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Documentation Practice", Effective date: 16-Jan-2024, section: 5.2.1.2 *"blue ballpoint pen"* is used for recording of GMP documentation.

There is also a lack of Quality Unit oversight on employee practices of documenting GMP data on uncontrolled white paper and later disposing of these papers by tearing into pieces inside scrap bags. Among multiple sections violated by destroying GMP documents, procedure QAP/MLCM/0110-001, Titled: "Good Documentation Practice", section: 5.2.1.4 refers to *"Data shall be recorded directly on the designated records, by the person who performs the activity"*, and sections: 4.3 and 4.4 refers to ALCOA and ALCOA+ principles to ensure integrity of data and Good Documentation Practices. These expectations about ALCOA and ALCOA+ principles are also emphasized in sections 4.2 and 4.3 of your procedure No.: QAP/MLCM/0064-006, Titled: "Handling and Control of Data Integrity", Effective date: 18-Apr-2024.

Upon putting together some of the torn pieces of documents with the help of your employees, your Quality Unit management stated the torn pieces belonged to original record, raw data and metadata pertaining to QC and packaging units and these documents should not have been destroyed. The evaluation of some of these GMP documents revealed serious deficiencies relating to lack of your Quality Unit oversight on employees' practices while conducting tests to ensure integrity of data. For example, but not limited:

**A.** Torn printouts relating to "LEAK TESTER RESULTS" were observed inside the scrapyard. These printouts were relating to Leak Test Apparatus ID: PR707, batch numbers: (b) (4) and (b) (4) printout date: 28/01/2025 (28-Jan-2025), Time: 16:07, Product: (b) (4) (b) (4) mg (b) (4) ml (b) (4)

The evaluation of these torn pieces of Leak Test Result printouts along with this apparatus electronic data log entries (audit trail) revealed the following:

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1. There is no user level privilege and no access control established for your Leak Tester ID: PR707 and additional (b) (4) similar leak test detectors to ensure its usage is restricted to assigned trained employees only for data reliability. These standalone instruments can retain only last (b) (4) (b) (4) test results, but not the batch number and number of samples analyzed details for those (b) (4) (b) (4) tests. Further, the batch number and number of sample details could be modified on a later date without keeping track of the changes made through the system audit trail.

   On 31-Jan-2025, your Packaging Supervisor stated that Test Result (b) (4) relating to batch number (b) (4) dated 28-Jan-2025, time: 16.07 was manually edited to reflect test completed for batch number (b) (4) on 29-Jan-2025 without verifying the (b) (4) batches have the exact same matching details relating to results, number of samples, testing time and date. Your Packaging Supervisor stated the printout was destroyed into small pieces and disposed in the plastic scrap bag due to matching test results for (b) (4) different batches i.e. (b) (4) (b) (4) The torn pieces of printouts relating to these batches were found from the main scrapyard of your firm.

2. On 31-Jan-2025, we observed "Leak Tester Results" printout for date 30/01/2025 (30-Jan-2025), Time: (b) (4) was missing in your batch packaging record for batch (b) (4) The entry pertaining to this missing printout was found in your standalone Leak Tester ID: PR707 data storage. Your Packaging Operator (b) (6) mislead us by providing conflicting information as follows:

   On 31-Jan-2025, (b) (6) demonstrated Leak Test Apparatus performance check that he performed on 30/01/2025 by using (b) (4) filled bottles from rejected bottles crate (b) (4) Upon asking the reason for using rejected bottles for conducting Leak Test Apparatus performance check. (b) (6) (b) (6) apologized for using rejected bottles and stated he should not have used rejected bottles.

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stated that the Leak Test printout was disposed in the scrap due to incorrect number of sample entry in the printout. Later, on the same day, (b) (6) stated that he conducted leak performance test without any bottle and simply took printout depicting (b) (4) sample (reflective of (b) (4) bottles) were used for conducting leak tester performance check. According to (b) (6) this printout was destroyed and disposed in the scrap.

On 03-Feb-2025, (b) (6) stated that he only switched on Leak Test Apparatus and did not conduct Leak Tester performance check.

Moreover, your Quality Unit management provided conflicting information stating that (b) (6) is not responsible for conducting leak test performance check and that he is not trained on testing samples for leak test. However, on 31-Jan-2025, (b) (6) stated that he conducted Leak Tester performance check (b) (4) as a part of one of his (b) (4) responsibilities. The training records of (b) (6) reflected that he was trained on "Operation of Leak Test Apparatus" procedure ML11/SOP/QAGN/0016.

3. Your firm has no documented procedure established to provide stepwise instructions for conducting Leak Test Apparatus performance check that is critical in ensuring operational capabilities of your leak tester and consistency among your employees that conducted leak tester performance check.

**B.** pH meter printout for Meter S/N V12116, dated 29-Jan-2025, time 13:43:04 with pH reading of (b) (4) (b) (4) was found in the scrap storage area.

According to your QC Microbiologist, pH meter printout was disposed in the scrap due to measurement of pH at incorrect (b) (4) According to your procedure number OAP/MLCM/0083, Titled: "Microbiology Media Management", the sterilized media (b) (4) prior to measuring

the pH.

**C.** pH meter printout with instrument details in the header containing handwritten calculations in blue ink pen for (b) (4) and (b) (4) medias on the front side of this paper and the back side contained handwritten calculations for (b) (4) and (b) (4) medias was found in the scrap storage area.

According to your QC Micrologist, the calculations were done on pH meter printout for media batches (b) (4) (b) (4) and (b) (4) Further, the calculations were written on pH printout to determine the quantity of media to be prepared based on number of samples for testing and based on the weight of materials determined upon calculation the materials were weighed and the printout containing calculation (metadata) was disposed in the

LABORATORY CONTROL SYSTEM

**OBSERVATION 2**

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

Specifically,

Your (b) (4) test procedure (b) (4) for Relative Content of (b) (4) (b) (4) by GC-FID is deficient and the analyses conducted according to this test procedure does not ensure integrity of test results. Some examples include:

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**A.** You failed to investigate potential practices of testing either sample test solution as standard test solution or vice versa to get favorable test results each time the analyses was conducted to determine the content of (b) (4) in (b) (4) by GC-FID.

During the inspection, we observed chromatographic patterns for your routinely analyzed (b) (4) (b) (4) test samples were exactly matching upon overlay of sample test solution injection against reference standard solution injection and blank (b) (4) injection against blank (b) (4) solution injection for sample set sequences evaluated for the period of 21-Jan-2023 to 07-Jan-2025. The evaluation of overlay chromatograms of these solutions showed significant differences in the chromatographic patterns during analytical method verification. The differences were indicative of the solution compositions and its characteristics as a result of components used in the preparation of these solutions. Therefore, the matching chromatographic pattern of these solution injections during routine (b) (4) analyses were indicative of potential for compromised test solution integrity for these solutions based on the evaluation of your analytical method verification chromatographic data.

**B.** There is no documented stepwise instruction mentioned in your (b) (4) test procedure (b) (4) for Relative Content of (b) (4) by GC-FID for the preparation of blank (b) (4) and blank (b) (4) solutions. The accuracy with which these solutions are prepared is critical to determine the chromatographic pattern for testing integrity and disregard any peak obtained due to these solutions while calculating relative content of (b) (4) (b) (4) in (b) (4)

**C.** Your Quality Unit lacked oversight on the use of qualified reference standard in conducting QC tests. For example,

On 06-Jan-2025, we observed your QC Analysts used non-compendial grade (b) (4) (b) (4) as a reference standard to conduct analytical method verification and routine analyses of

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(b) (4) for Relative Content of (b) (4) by GC-FID. This was in deviation of your (b) (4) test procedure (b) (4) which requires the use of USP grade (b) (4) reference standard (RS)/working standard (WS). Further, your Quality Unit Manager stated that they have never qualified and evaluated purity of (b) (4) (b) (4) materials for use as reference standards. Moreover, the evaluation of manufacturer label for (b) (4) indicated that material is *"For R&D use only. Not for drug, household, or other uses"*.

**D.** The potential for lack of testing integrity is due to the fact that none of your (b) (4) QC Analysts that are conducting this analysis are qualified and trained on performing this complex test that includes multiple steps of (b) (4) solution for analyses which according to your Analysts takes over (b) (4) for each sample test solution, standard solution, and blank (b) (4) solution preparation.

On 06-Jan-2025, your QC Manager stated that they have not trained Analysts on conducting Relative Content of (b) (4) test by GC-FID.

## OBSERVATION 3

Deviations from written test procedures and laboratory mechanisms are not recorded and justified.

Specifically,

On 30-Jan-2025, we observed your Quality Unit failed to evaluate and investigate your QC employees' practices of using *"inhibit integration"* timed event while processing chromatographic (HPLC and GC) sample set sequences to disregard unknown peaks. For example,

Your Quality Unit revised procedure number QAP/MLCM/0112-003, Titled: "Empower 3

Chromatographic Data Management" on 13-Jan-2025 to include instructions for not using the *"inhibit integration"* timed event. This revision was implemented without evaluating previously generated data in the Empower 3 software prior to implementation of the revised procedure. During the evaluation of randomly selected chromatographic sample set sequences, we observed your QC Analyst had applied *"inhibit integration"* timed event for sample set name: (b) (4) TAB_ (b) (4) for batch number: (b) (4) product: (b) (4) mg Tablets that was analyzed on 19-May-2023 to block a (b) (4) unknown peak at about (b) (4) from getting integrated. On 07-Feb-2025, your QC Manager stated that they investigated the (b) (4) unknown peak and found that it belongs to (b) (4) API which is one of the active components in this product. However, there was no evaluation done to assess the impact of (b) (4) peak elution on the shoulder of (b) (4) peak to ensure test result reliability for (b) (4) content in your product.

FACILITY AND EQUIPMENT SYSTEM

**OBSERVATION 4**

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,

During the facility walkthrough on January 31st, 2025, we observed that your Quality and Production Units lacked oversight on the adequate cleaning and maintenance of equipment that are used in the manufacturing of drug products at your site. For example,

1. The (b) (4) belt number PR 049 had an unidentified piece of debris on top of the conveyor belt. The debris had a (b) (4) appearance and was approximately (b) (4) to (b) (4) mm in length and (b) (4) to (b) (4) mm in width. Your equipment cleaning record shows that type A (product to product)

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cleaning was performed and checked on January 28, 2025, and type C (wipe with dry (b) (4) cloth) cleaning was performed and checked on January 29, 30, and 31, 2025.

2. The (b) (4) number PR 058 had a piece of unidentified debris positioned between the (b) (4) The debris had a (b) (4) appearance and was approximately (b) (4) to (b) (4) mm in length by (b) (4) to (b) (4) mm in width. Your equipment cleaning record indicates that type A cleaning was carried out and checked on January 31, 2025.

3. The (b) (4) number PR 654 (b) (4) port was left uncapped. An unidentified piece of debris was observed on top of the (b) (4) port. The debris had a (b) (4) appearance and was approximately (b) (4) to (b) (4) cm in length and (b) (4) to (b) (4) mm in width. Your equipment cleaning record shows that type A cleaning was performed and checked on January 29, 2025, and type C cleaning was performed and checked in January 30, and 31, 2025.

These equipment are used by your firm as a part of the production process to make drug products for the U.S. market, which includes (b) (4) tablet USP (b) (4) mg (Product code (b) (4)

***DATES OF INSPECTION**
1/30/2025(Thu), 1/31/2025(Fri), 2/03/2025(Mon), 2/04/2025(Tue), 2/05/2025(Wed), 2/06/2025(Thu), 2/07/2025(Fri)

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