THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

MICROLABS LIMITED (ML14) LTD

PUBLIC GMP INSPECTION REPORT

March, 2025

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Micro Labs Limited (MI-14)
Corporate address of manufacturer	Plot No. 113-116, 4th Phase KIADB, Bommasandra Industrial Area, Bangalore-560-099, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	9th & 10th December 2024
Type of inspection	GMP Renewal Inspection
Introduction	
General information about the company and site	Micro Labs has a presence in over 50 countries with operations in 25 and markets products across multiple therapeutic areas. It has multiple manufacturing facilities in India, including locations in Bommasandra, Hosur, and others. These plants are designed to meet GMP standards.

History	In 2006, Micro Labs Limited (ML14) was commissioned in Bommasandra, Bangalore, India. The plant was designed to manufacture Ophthalmic and Sterile Oral Liquids products in Blow Fill Seal Containers, Three three-piece containers and Liquid Injectable products in ampoules and vials. The Government of Karnataka licensed the plant for manufacturing ophthalmic solutions and small-volume parenteral injections.
Brief report of the activities undertaken	
Areas inspected	The inspection of the facility was conducted according to the plan that was discussed and agreed upon. The inspected areas are such as production area where the flow of production was traced from the incoming raw materials warehouses to the FPP. The inspection also verified the qualification personnel involved in various lines of production, premises layout, design and sanitation, and equipment used in various manufacturing, packaging, and quality control operations.
Restrictions	None
Out of scope	Lines whose products are not applied for market authorization
Production lines inspected by TMDA	The inspection focused on manufacturing lines for solutions for injection in ampoules/vials small volume parenteral in the form of ophthalmic solution (BFS and three-piece containers
Abbreviations	**Meaning**
AHU	Air Handling Unit
CAPA	Corrective Actions and Preventive Actions
cGMP	Current Good Manufacturing Practices
HEPA	High Efficiency Particulate Air

HVAC	Heating Ventilation and Air Conditioning
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
RPN	Stainless steel
BMR	Batch Manufacturing record
QMS	Quality Manufacturing system
QRM	Quality Risk Management
APQR	Annual quality product review
CQA	Critical quality attributes
CPP	Critical processing parameter
COA	Certificate of Accuracy

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had a documented organogram and job responsibilities of personnel. The organogram highlighted the names of the management team and heads of various departments and sections within the facility. There was an adequate number of personnel working in various departments, including warehousing, production, utilities, and QC. The Key personnel were full-time time in which head of production and head of QC were independent of each other during the execution of their duties.

Training for recruited and on-the-job which included topics such as cGMP, safety, and hygiene, was provided as per documented SOPs regularly via a learning management system monthly. In addition, QC personnel received additional training on QC equipment and analytical method validation.

Employees were subjected to pre-employment and periodic medical examinations as per documented SOP, and those involved in visual inspection were qualified and regularly examined for eyesight. Records were maintained.

2. Premises

The facility manufacturing area was constructed with a reinforced concrete cement (RCC) frame structure and concrete blocks with smooth finished walls from outside and sand finish on the exterior surface. The flooring of storage, secondary packing and ancillary areas was of polished smooth stone. In the processing areas, dispensing, sampling, and primary packing areas, self-levelling epoxy floor was provided. The joints of walls with the ceiling and floor had been coved.

3. Layout and Design

The facility had one (1) production block, which included two (2) production lines. The block comprised of ground floor dedicated to a warehouse for storage of raw materials, packaging materials, quarantine room, approved raw material room, sampling rooms, dispensing rooms, manufacturing areas for small volume parenteral in injection, BF and three-piece line.

4. Sanitation and Hygiene

Sanitation and hygiene were observed in all areas, including the surroundings, premises, equipment, and personnel. The facility was fenced to prevent unnecessary entrants, with gates installed with an electronically controlled system. Insect and rodent traps were provided at various points of the building to prevent the entry of insects, pests, birds, vermin, and rodents. In addition, the premise was situated in an environment that presented minimal risk of contamination of raw materials and finished products.

Personnel were provided with appropriate protective garments, and during and after gowning toward entry to the production and packaging areas, personnel washed and sanitized their hands by using sanitizer in rotational bases. Personnel in all production areas were observed to be properly dressed with clean, fully covered garments and gloves as safety gear. This suggested that personnel hygiene was well maintained.

The production rooms were visibly clean and well maintained according to the laid down validated procedure. This was evidenced in the reviewed area cleaning log books.

5. Quality Control

The facility maintained a comprehensive Quality Policy aligned with cGMP to ensure consistently high-quality products. The Quality Assurance (QA) department monitored the quality system through testing, validation, calibration, and audits. The QA team implemented the Quality System Policy, covering raw materials, in-process materials, packaging, and finished products, including stability studies and corrective actions. The quality system incorporated self-inspections, vendor audits, process validation, in-process testing, and managed investigations, deviations, and complaints. Annual product quality reviews included trend analysis of critical quality attributes and thorough investigation of deviations, complaints, and recalls to continuously improve the quality system.

The facility had 16 stability chambers that included accelerated stability study (40 ± 2 °C/75 ± 5% RH and real time stability study at 25 ± 2 °C/60 ± 5% RH, zone IVB climatic conditions 30 ± 2 ^{0} C/75 ± 5% RH, intermediate stability study at and 30 ± 2 ^{0} C/65 ± 5% RH. The facility also had cold rooms (2 to 8 °C) for products requiring a cold chain. The chambers were verified to be calibrated and well maintained, as evidenced in the chamber usage logbook. In addition, there was an approved procedure for the arrangement and management of the products in the stability chamber.

6. Equipment

Equipment was calibrated and maintained as per SOP No. QAP/MLCM/0020-006. It was described at monthly, quarterly, half-yearly, and yearly maintenance frequency was implemented based on the subjected equipment. This was all done to reduce errors during the process of production to increase efficiency and efficacy production.

7. Water Treatment System

The facility had designed, installed, qualified, validated, operated, and maintained a Water Treatment Plant (WTP) for the generation and distribution of Purified Water System (PW) as per the laid down procedure in place for the operation of purified water storage and distribution system. Water quality was continuously monitored using online conductivity meters installed in the return loop line for each storage tank. Both Purified Water and Water for Injection complied with USP, BP, and IP standards.

Water was continuously checked for total microbial count according to the sampling plan in place. The procedure for sampling of water, sampling plan for water, and analytical results were in place as evidenced in the water sampled November and

December 2024 for routine, monthly, quarterly, and annual water quality trend analytical results reviewed during the inspection and was found satisfactory.

8. Heating, Ventilation, and Air Conditioning

Heating, Ventilation, and Air Conditioning (HVAC) systems were suitably designed to maintain adequate temperature, relative humidity, and pressure differentials to prevent contamination and/or cross contamination. The systems had an adequate number of Air Handling Units (AHU) serving penicillin and general formulation blocks. All AHUs were qualified and properly maintained.

The AHUs that supplied air to the critical areas were provided with terminal HEPA filters. Dispensing and sampling activities were carried out under reverse-lamina flow units to prevent contamination. The systems also used an air mix of 10% fresh air and 90% returned air.

9. Document Review

A document review was conducted per SOPs to ensure no cross-contamination from previous batches. Verified equipment cleanliness, area sanitation, and functional HVAC systems. Production and QA personnel confirmed clearance via checklists and documentation. In the dispensing process, raw materials were dispensed by qualified personnel under reverse laminar flow to prevent contamination.

Separate entry points for materials (via pass box) and personnel (via change rooms) maintained hygiene. All activities (dispensing, production, checks) were recorded in the Batch manufacturing record. QA verified and signed off on-line clearance, material reconciliation, and process steps. This review confirms adherence to GMP standards, emphasizing cleanliness, compliance, and systematic documentation.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Part 2 and 3, **Micro Labs Limited, Plot No. 113-116, 4th Phase KIADB, Bommasandra Industrial Area, Bangalore-560-099, India** was considered to be operating at an acceptable level of compliance with TMDA Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities; 1st Edition April, 2023 for production of general pharmaceutical formulations in form of small volume parenteral, in liquid injectables (ampoules and vials) and ophthalmic solutions.

This report shall be valid for three (3) years from the date of approval unless forms and operations herewith are changed or the site is no longer considered to be in compliance with current GMP requirements.

Part 4: References

1. Tanzania Medicines and Medical Devices Act, Cap 219.
2. The Tanzania Medicines and Medical Devices (Good Manufacturing Practice Enforcement) Regulation, 2018.
3. The Tanzania Medicines and Medical Devices Authority Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities; 1st edition, April 2023.
4. TMDA Good Manufacturing Practices Manual *and SOPs*, Tanzania Medicines and Drugs Authority, Dar-es-Salaam, Tanzania.
5. Site Master File Document No. SMF:ML14:036 Effective date 17/07/2024
6. TMDA RIMS