THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

MICRO LABS LIMITED (ML-07) LIMITED
PUBLIC GMP INSPECTION REPORT

March, 2025

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Micro Labs Limited (MI-07)
Corporate address of manufacturer	121-124, 4th Phase KIADB, Bommasandra Industrial Area, Bangalore-560099, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	Manufacturing block
Inspection details	
Date of inspection	12th & 13th December, 2024
Type of inspection	GMP Renewal Inspection
Introduction	
General information about the company and site	The facility was engaged in the manufacturing of cephalosporin pharmaceutical formulations in the form of oral solid dosage forms (tablets, capsules) and dry syrups.
History	Micro Labs Limited (MI-07) was commissioned in the year 2004. The plant was located at Bommasandra Industrial Area, Anekal (Taluk), Bangalore, Karnataka (India), which was 25 km from Bangalore city capital of Karnataka State (India). The facility was designed for the manufacturing of Cephalosporin products such as oral solid dosage forms (tablets, capsules) and dry syrups
Brief report of the activities undertaken	
Areas inspected	The inspection the surroundings of the facility were inspected and a walk through the production areas where the flow of production was traced from the incoming raw materials warehouses, manufacturing, packaging areas to the finished goods warehouse, Quality Control (QC) laboratory and utilities including the water treatment plant, HVAC system, compressed air, and pure steam generation system
Restrictions	None

Out of scope	Lines whose products are not applied for market authorization
Production lines inspected by TMDA	Inspection of the production system was focused on production lines for the manufacturing of cephalosporin pharmaceutical formulations in solid dosage forms (tablets, hard gelatine capsules) and dry syrups.
Abbreviations	**Meaning**
AHU	Air Handling Unit
CAPA	Corrective Actions and Preventive Actions
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Air
HVAC	Heating Ventilation and Air Conditioning
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SS	Stainless steel
TMDA	Tanzania Medicines and Medical Devices Authority

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had a documented organizational structure and job responsibilities, with qualified and experienced personnel in key positions like QA, Production, and QC, who were independent of each other. An adequate number of personnel works in various departments, including warehousing, production, utilities, and QC. Training, including cGMP, safety, hygiene, and on-job training relevant to SOPs, was conducted regularly via a learning management system every month. Furthermore, QC personnel received additional training on QC equipment and analytical method validation.

Employees undergo pre-employment and periodic medical examinations, including cephalosporin sensitivity tests for relevant personnel, and those involved in visual inspection are qualified and regularly examined for eyesight.

2. Premises

The facility manufacturing area was constructed with a reinforced concrete cement (RCC) frame structure and concrete blocks with smooth finished walls on the 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, a self-leveling 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 three (3) 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, primary packing materials store, finished goods stores, and secondary packing materials store.

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. Production

The production system at the facility focuses on manufacturing cephalosporin formulations (tablets, capsules, and dry syrups). Before each batch, thorough line clearance was conducted and recorded in the Batch Manufacturing Record (BMR). All manufacturing activities, from dispensing to production, including in-process checks, are documented in the BMR. Batch record reviews showed checks on yields and reconciliation of quantities, with variations accounted for. The dispensing of raw materials was performed by qualified personnel under RLAF, with measures to prevent contamination. Separate entry of materials and personnel was maintained, and the dispensing area was clean and well-maintained. Materials were transferred to the production area through a dynamic pass box.

6. 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 systems 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 six (6) stability chambers for conducting accelerated stability study (40 ± 2°C/75 ± 5% RH and real time stability study at 25 ± 2 °C/60 ± 5% RI-I, zone IVB climatic conditions 30 ± 2 °C/75 ± 5% RH, intermediate stability study at 30 ± 2 ° C/65 ± 5% RH. The facility also had cold rooms maintained at 2 to 8° C for products requiring a low, cold condition. 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 chambers.

7. Equipment

The facility had a sufficient number of production equipment, which were designed, installed, qualified, and maintained to suit the operations carried out. The design and location of equipment also facilitated effective cleaning and avoided chances of contamination and cross-contamination.

8. 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 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 water, the sampling plan for water, and the analytical results were in place as evidenced in the water sampled in November and December 2024 for routine, monthly, quarterly, and annual water quality trend analytical results reviewed during the inspection was found satisfactory.

9. 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.

10. Document Review

A documentation system was in place to guide the production and control of products. These included Updated Site Master File, Validation Master Plans (VMP), Standard Operating Procedures, standard testing procedures, and qualification and validation protocols and reports.

There were corresponding records in the form of reports, forms, checklists, logbooks, and registers maintained as evidence of compliance with the procedures and specifications. Its documentation system for the procedures, records, specifications, and policies were observed to support quality management and quality assurance activities

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. 121-124, 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 cephalosporin pharmaceutical formulations in form of tablets, hard gelatine capsules and dry syrups

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/ML07/33 Effective date 22/06/2024
6. TMDA RIMS