

WHO PUBLIC INSPECTION REPORT Finished Product Manufacturer**WHO PUBLIC INSPECTION REPORT
(WHOPIR)****Finished Product Manufacturer****Part 1: General information**

Name of Manufacturer	Micro Labs Ltd
Unit number	ML-08
Production Block	NA
Physical address	15/A, II Phase, Kumbalgodu Industrial Area, Bangalore, 560 074, INDIA
Contact address	Mr. S.M. Mudda, smm@microlabs.in Executive Director, Technical & Operations
Date of inspection	19 to 21 July 2012
Type of inspection	Follow up inspection
Dosage forms(s) included in the inspection	Tablets
WHO product categories covered by the inspection	Tablets
Summary of the activities performed by the manufacturer	Manufacturing, packaging, quality control and batch release of FPP oral solid dosage forms (tablets and capsules).

Part 2: Summary

General information about the company and site

Micro Labs Limited was established in 1973. It has 14 facilities and most of the facilities are located around Bangalore. Out of 14 sites, 4 Micro Labs sites have been approved by the UK MHRA, while 2 sites each have been approved by the Health Canada and MCC, South Africa and one site had been approved by the USFDA. It was noted that an on-site USFDA inspection of Micro Labs, another manufacturing site manufactures ophthalmic is scheduled from 23 July 2012 for 7 working days.

The facility inspected was **ML-08** of Micro Labs Limited 15/A, 2nd Phase, Kumbalgodu Industrial Area , Bangalore 560 074, India. According to the presentation by the company at the start of the inspection, Kumbalgodu (ML-08) site was commissioned in 2005 and it had been upgraded in 2010-2011.

The factory site of Micro Labs Limited at Kumbalgodu, Karnataka, is about 25km from Bangalore city.

History of WHO and/or regulatory agency inspections

This is the third WHO inspection on this site. The last WHO inspection on this site was held in January 2012, which resulted in non-compliance.

A follow up inspection was conducted in July 2012 at the Kumbalgodu site to verify the implementation of CAPAs.

Focus of the inspection

The inspection focused on the production and control of Ethambutol / Isoniazid / Pyrazinamide / Rifampicin 275/75/400/150mg tablet (TB223) product. The inspection covered all the sections of the WHO GMP text, including premises, equipment, documentation, materials, validation, sanitation and hygiene, production, quality control and utilities.

Inspected Areas

- Quality assurance
- Good manufacturing practices for pharmaceutical products
- Sanitation and hygiene
- Qualification and validation
- Complaints
- Product recalls
- Contract production and analysis
- Self-inspection, quality audits and supplier's audits and approval
- Personnel
- Training

- Personal hygiene
- Premises
- Equipment
- Materials
- Documentation
- Good practices in production
- Good practices in quality control

2.1 QUALITY ASSURANCE

A system for quality assurance was appropriately established after the first inspection held in January 2012 and covered all the basic elements of GMP including Change Controls, Deviation Management, Product Quality Review and Quality Risk Management. In addition, more emphasis was given on the qualification and validation of equipment and processes respectively. An organization chart was reviewed and found to be acceptable.

2.2 GOOD MANUFACTURING PRACTICES (GMPs) FOR PHARMACEUTICAL PRODUCTS

Good manufacturing practices were improved from the initial inspection. The necessary resources were generally provided. Manufacturing steps were recorded in batch manufacturing and packaging records. Instructions and procedures were generally written in clear and unambiguous language. Qualifications and validations were performed, adequate premises and equipment were available for production, in-process controls and storage, and operators were trained.

During the follow up inspection, it was also noted that more staff were recruited to carry out various GMP task.

2.3 SANITATION AND HYGIENE

The entry and exit procedures were improved and provided clear instructions and pictorial presentations. In general, premises and equipment were maintained at an acceptable level of cleanliness.

2.4 QUALIFICATION AND VALIDATION

There were number of issues noted from the process validation and cleaning validation documents. Similarly, equipment were not adequately qualified which were eventually corrected.

2.5 COMPLAINTS

Complaints and other information concerning potentially defective products were reviewed according to a written procedure.

2.6 PRODUCT RECALLS

The SOP on Product recall was briefly reviewed and was found to be acceptable.

2.7 CONTRACT PRODUCTION AND ANALYSIS

Production operations were not contracted out. Some analytical tests were contracted out to outside contract laboratories. Also, it had been found that stability studies of the domestic products were conducted at the R&D center.

2.8 SELF INSPECTION AND QUALITY AUDIT

The SOP and schedule for self-inspection was reviewed and found to be acceptable.

2.9 PERSONNEL

After the initial inspection held in January 2012, the manufacturer had recruited more personnel with the necessary qualifications and practical experience. Job descriptions of key personnel were checked. The personnel met during the inspection appeared to be competent and experienced.

2.10 TRAINING

Following the initial inspection held in January 2012, the company had done a commendable job by organizing various on-site trainings for the staff conducted by internal and external trainers. It was recommended to carry on with this initiative and also ensure these training were evaluated by the trainers.

2.11 PERSONAL HYGIENE

The entry/exit procedures had been improved by displaying larger and clearer photographic instructions in the change rooms.

2.12 PREMISES

A brief tour of the premises (red and white production, technical/utility and quality control laboratory) indicated satisfactory compliance with WHO GMP for finished pharmaceutical products.

2.13 EQUIPMENT

In general, the equipment seen during the inspection of production areas appeared to be acceptable and well maintained.

2.14 MATERIALS

In general, the materials were arranged in the warehouse in a clean, tidy and orderly manner.

2.15 DOCUMENTATION

In general, there was an improvement seen in the control and clarity of documentation. In particular, various key SOPs had been revised to provide greater detail and clearer instructions. Also, the company had introduced hard bound log books to replace loose sheet logs, however in one exception, it was noted during the inspection of the dispensing usage log that loose sheets were still being used.

2.16 GOOD PRACTICES IN PRODUCTION

There was no production activity being undertaken at the time of inspection. It was stated that the company is awaiting WHO Prequalification approvals before they start the production operations.

In general, the production areas inspected (white and red areas) were found to be clean and tidy. As the packaging activities were not being carried out at the time of inspection, it is recommended that this be covered during the next routine inspection.

2.17 GOOD PRACTICES IN QUALITY CONTROL

A brief visit to the QC laboratory revealed that all observations from last inspection had been corrected. This included the installation of a degasser for dissolution tester and the installation of Empower software for two Shimadzu HPLC systems. Also, the pooling of composite raw materials samples had been relocated to the sampling area.

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 Inspection Report, as well as the corrective actions taken and planned, **Micro Labs Ltd, Kumbalgodu (ML-08)** was considered to be operating at an acceptable level of compliance with WHO GMP guidelines.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.