



**WHO PUBLIC INSPECTION REPORT
(WHOPIR)**

Finished Product Manufacturer

Part 1: General information about the inspection

Name of manufacturer	Micro Labs Limited
Physical address	92, SIPCOT Industrial Complex, HOSUR - 635 126 TAMIL NADU INDIA
Postal address	As above
Telephone number	+91-4344-276618
Fax number	+91-4344-277261
Summary of all the activities performed by the manufacturer (e.g. manufacturing, packing). Indicate dosage forms and type of products (e.g. tablets; penicillin or cephalosporin containing products)	Manufacturer and packer of oral solid dosage form products - tablets and hard gelatin capsules No penicillins or cephalosporins are produced.
Scope of inspection	General and Product Specific GMP inspection with data verification.
Date of inspection	18 – 21 May 2009
Programme	Prequalification of Medicines Programme

Part 2: Summary

The manufacturing site of Micro Labs Limited, located in Hosur, India was inspected by a WHO prequalification inspection team on the above mentioned days.

General information about the company and the site. History of WHO or regulatory agencies' inspections

Micro Labs limited had 14 manufacturing facilities.

The inspection was a joint inspection between UNICEF and WHO, Geneva.

The company produces non-sterile products for sale in India as well as products for export. The manufacturing areas are split into 3 different manufacturing units on the above address, which all manufacture non-sterile oral solid dosage forms.

Micro Labs manufacturing pharmaceutical products since 1973 for domestic and export markets.

The total number of personnel was 138.

WHOPIR:

Micro Labs Limited, India

18 – 21 May 2009

Focus of the inspection

The focus of this inspection was to verify production and quality control activities for above mentioned products and to assess compliance with WHO GMP.

2.1. Quality Assurance (QA)

The company's quality assurance system was based on a quality manual and number of SOP's. A review of the quality manual for unit ML03 did not give rise to any comments.

The procedure for change control, the procedure for handling of deviations and the procedure for incident reporting were reviewed and found satisfactory.

2.2. Good manufacturing Practices for Pharmaceutical products

Good manufacturing practices were implemented and generally maintained. Qualification and validation were performed.

2.3 Sanitation and Hygiene

No notable concerns were identified during the inspection.

2.4 Qualification and Validation

The key elements of the qualification and validation program were defined and documented in Validation Master Plan (VMP).

2.5. Complaints

Dealing with complaints was specified in a written SOP. The complaints register was maintained. A person responsible for the handling of complaints was designated.

2.6 Product Recalls

The system to recall the products from the market was in place. The authorized person responsible for the execution and coordination of recalls was designated.

2.7 Contract production and analysis

Manufacturing activities were not contracted out.

2.8 Self inspection and Quality Audits

The company has performed regular self inspections. A review of the programme did not give rise to any comments. Deviations are followed up.

2.9 Personnel

In general, the personnel met and interviewed during the inspection were experienced, skilled and conscientious.

2.10 Training

The training needs were identified and training was organized as per the written SOP. The training effectiveness was evaluated by questionnaires and some open questions.

2.11 Personal Hygiene

No notable concerns were identified during the inspection of the production areas and the level of hygiene observed was considered satisfactory.

2.12 Premises

The buildings and facilities used for manufacture and quality control were located, designed, and constructed to facilitate proper cleaning, maintenance and production operations. The layout, design and maintenance of the three units are in general relative similar.

2.13 Equipment

Process equipment was installed and maintained in a manner that minimized the risk of error and contamination. Modern production equipment and analytical equipment appear to be suitable for their intended use.

The HVAC systems in each unit generally consist of many separate and independent units. Final filtration of air is through HEPA in all areas. Production areas are classified as class 100000. Non-viable particle count as well as microbiological monitoring of production areas are carried out at regular intervals.

2.14 Materials

Materials were properly quarantined, stored and released by QC.

2.15 Documentation

In general, the documentation system was established and maintained, documents were approved, signed and dated by appropriate responsible persons, regularly reviewed and kept up to date.

2.16 Good practices in production

Handling of materials and products was done in accordance with written procedures and was recorded. Access to production premises was restricted. In-process controls were performed within the production area.

2.17 Good practice in Quality Control

Good Practice in Quality Control were generally implemented and maintained. Adequate facilities, personnel and approved procedures were available.

Part 3: Conclusion

Based on the facilities inspected, the personnel met and the documents reviewed, and considering the inspection observations listed in the inspection report, Micro Labs Limited, located 92, SIPCOT Industrial Complex, HOSUR - 635 126 TAMIL NADU

INDIA, India, was considered to be operating at an acceptable level of compliance with WHO GMP.

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.