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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
of the FPP manufacturer

Part 1	**General information**
Manufacturers Details	
Company information	
Name of manufacturer and address	Micro Labs (Hosur) 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126, India North latitude: 12º 45’ 50.8’’ N East longitude: 77º 48’ 01.8’’ E
Corporate address of manufacturer	**Micro Labs Limited** #27, Race Course Road, Bangalore – 560 001, INDIA. Tel.: +91 (080) – 22370451 to 57 Fax: +91 (080) – 22370463
Inspected site	
Address of inspected manufacturing site if different from that given above	As above
Block	Unit 3
Manufacturing license number	TN00003934 and TN00003935, issued by issued by Director of Drugs Control, Tamilnadu State, India for Manufacturing and Sales of Human Drug Products
Inspection details	
Dates of inspection	10 – 14 July 2017
Type of inspection	Routine
Introduction	
Brief summary of the manufacturing activities	Production, quality control and batch release for oral solid dosage forms tablets and capsules.

General information about the company and site

Micro Labs Limited is engaged in the manufacture of medicinal products since 1973 for domestic and export markets. Company is engaged in the manufacture of various therapeutic segments including cardiovascular, psychotropic, neurological, anti-diabetic, gynecological, gastro-enterological, dermatological and ophthalmic products. The company has a total of 14 manufacturing facilities for the manufacture of products for domestic and export markets.

SITE NAME	ADDRESS	TYPE OF OPERATIONS
MICRO LABS UNIT -3	Plot no. 92 Sipcot industrial area, Hosur -635126 Tamilnadu.	Solid oral dosage
MICRO LABS (ML-06)	Plot no. S-155 to 159 & N1, Phase-3 & Phase-4, Verna Industrial Estate, Verna, GOA-403722.	Solid oral dosage
MICRO LABS (ML-08)	No.15/A, 2nd Phase, Kumbalgodu Industrial Area, Bangalore- 560074	Solid oral dosage
MICRO LABS (ML-15)	Plot No. 43-45, KIADB, Jigani-Bommasandra ink Road Anekal Taluk, Bangalore - 560105.	API Manufacturing
MICRO LABS (ML-14)	Plot no. 113-116, 4th Phase,KIADB , Bommasandra industrial area, Anekal Taluka, Bangalore – 560099.	Sterile Ophthalmic / Injectables
MICRO LABS (ML-11)	Plot no 16, Veerasandra Industrial area, Hosur road Anekal taluka, Electronics city, Bangalore - 560100	Solid oral dosage (dedicated facility for Penicillin)

All facilities were approved by local Drugs Authority.

Micro Labs Limited, Unit-3 is engaged in the manufacture of oral solid dosage forms of medicinal products i.e. tablets coated and uncoated and hard gelatin capsules. This manufacturing facility was commissioned in the year 2003.

The location number of the facility was changed from ML03 to Unit-3 with effective from 19/10/2015 due to change in the manufacturing license number from TN/DRUGS/300 and TN/DRUGS/148 to TN00003934 and TN00003935 respectively.

Research and Development facility is located at Kudlu and Mumbai.

This manufacturing facility also includes a small-scale manufacturing area for producing scale-up batches, bio-batches and products which require small batch sizes for commercial requirements. The equipment in this area is of similar type and operating principle as that of equipment used for manufacture of commercial scale batches.

<table>
<tr><td>History</td><td>The site was inspected by WHO in December 2015

The site has been inspected by the following authorities:
<table>
<tr><th>Name</th><th>Dates of inspection</th></tr>
<tr><td>Medicines & Healthcare products Regulatory Agency (MHRA)</td><td>May 2010</td></tr>
<tr><td>Joint inspection WHO & MHRA</td><td>April 2012</td></tr>
<tr><td>MHRA</td><td>July 2014</td></tr>
<tr><td>WHO</td><td>July 2014</td></tr>
<tr><td>FDA (Local Licensing Authority, Tamilnadu, India)</td><td>December 2016</td></tr>
</table></td></tr>
<tr><td>Brief report of inspection activities undertaken</td><td></td></tr>
<tr><td>Scope and limitations</td><td></td></tr>
<tr><td>Areas inspected</td><td>See Part 2 below</td></tr>
<tr><td>Restrictions</td><td>Microbiological laboratory was not inspected</td></tr>
<tr><td>Out of scope</td><td>N/A</td></tr>
<tr><td>Abbreviations</td><td>
<table>
<tr><td>AHU</td><td>air handling unit</td></tr>
<tr><td>ALCOA</td><td>attributable, legible, contemporaneous, original and accurate</td></tr>
<tr><td>AQL</td><td>Acceptance quality limit</td></tr>
<tr><td>API</td><td>active pharmaceutical ingredient</td></tr>
<tr><td>APQR</td><td>annual product quality review</td></tr>
<tr><td>BDL</td><td>below detection limit</td></tr>
<tr><td>BMR</td><td>batch manufacturing record</td></tr>
<tr><td>BPR</td><td>batch packaging record</td></tr>
<tr><td>CAPA</td><td>corrective actions and preventive actions</td></tr>
<tr><td>CC</td><td>change control</td></tr>
<tr><td>CFU</td><td>colony-forming unit</td></tr>
<tr><td>CoA</td><td>certificate of analysis</td></tr>
<tr><td>CpK</td><td>process capability index</td></tr>
<tr><td>DQ</td><td>design qualification</td></tr>
<tr><td>EM</td><td>environmental monitoring</td></tr>
<tr><td>FAT</td><td>factory acceptance test</td></tr>
<tr><td>FBD</td><td>fluid bed dryer</td></tr>
<tr><td>FG</td><td>finished goods</td></tr>
<tr><td>FMEA</td><td>failure modes and effects analysis</td></tr>
<tr><td>FPP</td><td>finished pharmaceutical product</td></tr>
<tr><td>FTA</td><td>fault tree analysis</td></tr>
<tr><td>FTIR</td><td>Fourier transform infrared spectrometer</td></tr>
<tr><td>GC</td><td>gas chromatograph</td></tr>
<tr><td>GMP</td><td>good manufacturing practice</td></tr>
<tr><td>HACCP</td><td>hazard analysis and critical control points</td></tr>
<tr><td>HPLC</td><td>high-performance liquid chromatograph</td></tr>
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HVAC	heating, ventilation and air conditioning
ID	identity
IR	infrared spectrophotometer
IPC	In process control
IQ	installation qualification
KF	Karl Fisher
LAF	laminar air flow
LIMS	laboratory information management system
LoD	limit of detection
LOD	loss on drying
MB	microbiology
MBL	microbiology laboratory
MF	master formulae
MR	management review
NIR	near-infrared spectroscopy
NMR	nuclear magnetic resonance spectroscopy
NRA	national regulatory agency
OQ	operational qualification
PHA	preliminary hazard analysis
PM	preventive maintenance
PpK	process performance index
PQ	performance qualification
PQR	product quality review
PQS	pharmaceutical quality system
PW	purified water
QA	quality assurance
QC	quality control
QCL	quality control laboratory
QMS	Quality management system
QRM	quality risk management
RA	risk assessment
RCA	root cause analysis
RH	relative humidity
RM	raw materials
RS	reference standard
SAP	system applications products for data processing
SFG	semi-finished goods
SOP	standard operating procedure
STP	standard test procedure
T	temperature
TAMC	total aerobic microbial count
TFC	total fungal count
TLC	thin layer chromatography
TMC	total microbial count
TOC	Total organic carbon
URS	user requirements specifications
UV	ultraviolet-visible spectrophotometer
VMP	Validation Master Plan

WFI	water for injection
WS	working standard

Part 2	Brief summary of the findings and comments (where applicable)

1. Pharmaceutical quality system (PQS)

Principle

Production and control operations were specified in written form and GMP requirements were generally followed. Managerial responsibilities were specified in job descriptions. Product and processes were monitored and the results taken into account at batch release; regular reviews of the quality of pharmaceutical products were conducted.

Data integrity

The SOP "Handling and control of data integrity" was discussed. QAP described responsibilities, data integrity policy, periodic review and monitoring of data integrity policy, training, reporting, investigation and impact assessment. Data integrity issues report No XX was discussed.

Quality Risk Management

The SOP "Quality Risk Management" was discussed. The procedure described the approaches utilized in managing the risk assessment by qualitative and quantitative (FMEA) approaches. These were recorded under Quality Risk Assessment Register XX. Annual plan was established under Annual Risk Assessment Planner in which 2016 and 2017 Risk Assessment were discussed.

The risk assessments conducted for year 2016 were;

- Water system
- Complaint Management
- Document storage, retrieval and destruction
- Equipment qualification
- Cleaning validation
- Laboratory control and stability testing

The risk assessments conducted for year 2017 were;

- All instruments in QC to determine risks and controls relating to operational / functional and quality / Data reliability aspects
- Utility compressed air generation, testing and maintenance
- Risk assessment of computerized system for compliance of part 11 / Annex 11
- Training and education
- Material management: Receipt, storage, handling and dispensing of Raw Materials
- Vendor management
- Preventive Maintenance of production major equipment

Risk assessment on Cleaning Validation protocol and report XX were discussed.

Product Quality Review (PQR)

The SOP "Product quality review" was discussed. The SOP stated that in case no batches were manufactured during the review period, PQR should be prepared according to the SOP. PQR reports were prepared within 2 months from the identified review period according to the planner. Process capability was calculated using Cpk. SOP contained all sections listed in the cGMP guideline.

The following PRQs for 2016 were discussed:

- Prothionamide tablets XX mg and Isoniazid tablets BP XX mg.

Management review (MR)

The SOP "Quality system review", was discussed. Two types of review groups were specified in the procedure:

- Core quality group review. This group composed of the members from corporate quality and Unit staff. According to the SOP core quality group review meeting should be conducted once in a month
- Senior Management Review. Head of corporate QA was responsible for coordinating senior management review meetings. According to the SOP senior management review meeting should conducted once in six months.

Standard meeting agenda was specified as well as core performance indicators.

Last core quality group meeting was held on XX. Lists of participants as well as quality system review power point presentation were presented to the inspectors.

Last senior management review was held on XX. Lists of participants as well as quality system review power point presentation were presented to the inspectors. Data integrity issues were covered.

Deviations

The SOP "Handling of deviations" and its flow chart were discussed. Deviations were classified as:

- Planed
- Unplanned

and

- Critical
- Major
- Minor

Deviations were classified by QA.

Deviation registers were maintained unit wise, a register for Unit 3 was presented to the inspectors. Deviations were recorded in the BMRs/BPRs and investigation copies attached.

Deviations were trended per categories: planned and unplanned; deviation register for 2016 was discussed.

A XX number of deviation reports were discussed.

Root Cause Analysis

The SOP "Root cause management procedure" was discussed. The procedure was applicable, but not limited to investigations of deviations, non-conforming products, OOS test results, market complaints, product recalls, OOT results, self-inspection observations, PQRs, internal data reviews, validation and inspection findings. The following tools were used to identify possible root cause:

- Ishikawa
- 5 Why's

Root cause analysis was performed by team set up case-by-case.

Corrective actions and preventive action (CAPA)

The SOP "Corrective actions and preventive actions" was discussed. The SOP was applicable, but not limited to:

- Complaints
- Recalls
- Deviations
- Self-inspection/ external inspection
- Process capability analysis
- OOS/OOT
- Training etc.

CAPA system was divided in three phases:

- Phase I –Initiation, assessment and approval of CAPA
- Phase II – Implementation of CAPA, review of Implemented CAPA and closure of CAPA
- Phase III – CAPA effectiveness monitoring and closure.

CAPA registers for 2016 and 2017 were presented to the inspectors. A number of CAPA reports were discussed.

Change control (CC)

The SOP "Change control system" and its flow chart were discussed. The SOP was applicable to various GMP related changes.

Changes were classified as:

- Critical
- Major
- Minor

CC registers for 2016 and 2017 were presented to the inspectors. A number of CC reports were discussed. CC were trended, trending report for 2016 was presented to the inspectors.

2. Good manufacturing practices for pharmaceutical products

Manufacturing processes were defined and reviewed. Qualifications and validations were seen to be performed according to prepared protocols. Significant deviations from the initial protocol were recorded and investigated, root causes were determined and CAPAs were implemented where necessary. Systems were in place for handling complaints and recalling any batch of product from sale or supply.

3. Sanitation and hygiene

The company had an SOP as the basis for its approach to personal hygiene and sanitation in its production facilities. Microbial monitoring of clean room personnel was performed as part of routine batch control.

Generally, the facilities were noted to be clean and well organized during the inspection.

4. Qualification and validation

Performance qualification (PQ) report for online in process checking system (TANTRA SOFT) for compression III and bin weighing system and capsule filling machine II were discussed. Intelligent data station (IDS) was connected to all testing equipment (hardness testers, weighing balances and Vernier calipers).

Validation Master Plan (VMP)

The Validation Master Plan was discussed. There was a requirement for routine requalification at every 5 years for major equipment. The list of all the major production equipment was listed under Qualification Status of Major Production Equipment. The revalidation criteria were based any major modification to the equipment, product failure, any request from customer or regulatory agency.

Validation Master Plan for Computer Systems was presented to the inspectors. Quality Risk Assessment was implemented for the computerized system.

Process Validation (PV)

The Process Validation for specific p0roduct was discussed.

Cleaning Validation (CV)

The CV approaches as outlined in the Cleaning Validation procedure was based on the worst-case scenario. It was determined from product group matrix, equipment group matrix, Maximum Allowable Carry Over (MACO) calculation and No Observed Effect Level (NOEL). It was conducted by rinse sample method and swab sampling method. A molecule list was established under Determination of Worst Case Product, a list of Equipment Group Matrix was established for equipment complexity. The determination of Worst Case Product was discussed.

Holding Time - Equipment

A holding time study was conducted for cleaned equipment prior to use. It was discussed under Hold Time Study Protocol – Cleaned Area and Equipment and Hold Time Study Report Cleaned Area and Equipment. The holding time period determined based on the study for cleaned area and equipment is valid for 6 days.

Equipment Qualification
The qualification of equipment was conducted based on the procedure Qualification of Equipment was discussed, in which the company was practicing the traditional approach of Performance Qualification by qualifying three batches.

Computer System Validation
The company utilized Empower 3 program, an updated program for Empower 2, which was previously used to manage data collection for laboratory use. Computer system validation policy was discussed.

5. Complaints
The SOP "Handling of market complaints" was discussed. Complaints were received by complaints coordinator from the QA. Complaints were classified regarding product quality:
- Critical - class I
- Major - class II
- Minor class III

Site QA and corporate QA were responsible for complaints investigation.

Complaints register for 2016 and 2017 were presented to the inspectors. Complaints were trended; trends for 2016 were presented to the inspectors.

A number of complaints investigation records were discussed. Ishikawa diagram was used for root cause investigations.

6. Product recalls
The SOP "Product recall for export market" and its flow charts for:
- Export /WHO/ROW
- EU markets
- US markets
- Mock recall

were discussed.

Responsible person for making decision about recall was head of the corporate QA.

Recalls were classified:
- Class I - recall should be initiated within 24 hours
- Class II – recall should be initiated within 48 hours
- Class III – recall should be initiated within NMT 10 days

There were several levels of recall specified:
- Level I – consumer level
- Level II – retail level
- Level III – wholesale level
- Hospital level

SOP stated that mock recall should be performed annually.

7. Contract production, analysis and other activities

Manufacturing activities were not contracted out. A number of contract laboratories were used for some tests. As an example, technical agreement (TA) with XX was discussed. Audit was performed by General Manager QC.

List of service providers was presented to the inspectors. TA with XX – service provider for AHUs and LAFs qualification was discussed.

8. Self-inspection, quality audits and supplier audits and approval

The SOP "Self-inspection" was discussed. Inspection was carried out by a nominated multi-disciplinary self-inspection team. According to the SOP, conflict of interest should be avoided. Six systems approach was used for self-inspection. Self-inspection by on site team was performed every two months and by corporate QA once in a year.

Inspection was carried out using system wise check lists. Data integrity and electronic compliance topics were covered during self-inspection.

Inspection report was written by the team and CAPAs addressed by the inspected department, evaluated and approved by QA. CAPA implementation was also checked by QA. Non-conformances were classified as:

- Critical
- Major
- Minor

Self-inspection schedule for 2017 was presented to the inspectors.

<u>Supplier audits and approval</u>

The SOP "Vendor approval" and its flow charts for:

- Vendor approval for new materials (commercial use)
- Additional vendor approval for existing product
- Vendor approval for submission batches /commercial batches

were discussed.

The procedure was applicable to raw materials and materials that come in contact with the product used for manufacturing of solid oral dosage forms.

Vendor audit schedules for APIs, primary packaging materials and printed packaging materials for 2017 were presented to the inspectors.

Vendor audit report XX was discussed. Audit was performed by deputy manager CQA.

9. Personnel

There appeared to be an adequate number of personnel qualified to perform and supervise the manufacturing and quality control. Controls were in place to prevent unauthorized people from entering production, storage and QC areas.

Job description (responsibility) for Manager, analytical QA, responsible for materials release and Head of Department QA, responsible for product release were discussed.

10. Training

The SOP "Analysts qualification and reviewed qualification" was discussed. Analysts were trained on general GMP, safety, intersectional induction program and SOPs. Analyst's certification plan contained the following phases:

- Phase I – Wet analytical techniques
- Phase II – Instrument handling and software familiarity
- Phase III - Instrumental Techniques

Not released sample was given to the analyst under qualification and experienced analyst and afterwards results were compared. Analyst competency matrixes were presented to the inspectors. Mr. XX certification file and training card were checked.

11. Personal hygiene

All personnel, prior to and during employment, had to undergo an initial health examination. Thereafter regular health examinations were carried out every year. Direct contact between the operator's hands and starting materials, primary packaging materials and intermediate or bulk products was avoided. Smoking, eating, drinking, chewing, and keeping plants, food, drink; smoking material and personal medicines was prohibited in production, laboratory and storage areas.

12. Premises

Ancillary areas

Rest and refreshment rooms were separate from manufacturing and control areas.

Production areas

Generally, production premises were designed and constructed to facilitate good sanitation. Premises were cleaned according written procedures. Entrance to the production rooms was via change rooms. Adequate storage space was provided for in-process storage and logical positioning of equipment and materials. Generally, steps were taken to avoid contamination and cross contamination. Steps were taken to prevent unauthorized people from entering production areas.

Quality control areas

Sufficient space was given to avoid mix ups and cross-contamination. Storage space was provided for samples, reference standards, solvents, reagents and records. Steps were taken to prevent unauthorized people from entering laboratory areas.

Microbiological laboratory was separate from chemical laboratory. Laboratory was not inspected. According to the laboratory layout microbial limit test and water tests were performed in the same room under LAF and work with master strains were carried out in separate room under LAF.

13. Equipment

Generally, equipment was located, designed and maintained to suit the operations to be carried out. Design of equipment permitted adequate cleaning and maintenance to avoid contamination and cross-contamination.

In general, fixed pipework was labelled to indicate the contents and the direction of flow. Balances and other measuring equipment of an appropriate range and precision were available for production and control operations and were calibrated on a scheduled basis.

Utilities

Purified water (PW)

PW was generated using reverse osmosis. TOC and conductivity were monitored on line and in case of OOS water was rejected automatically. Water flow was continuously monitored at the return loop. Water was continuously circulated. Water system sanitization (loop and storage tank) was performed every 15 days using hot water (90 °C) for 1 hour. PW system appeared to be well maintained.

HVAC

There were 46 AHU what supplied air to the individual production cubicles. Five AHUs supplying air to the corridor was in continuously operation. Rec-circulated air was used. Filter cascade was following: G4→G4→EU7→EU8→H13. HEPA filters were terminally installed. AHUs re-qualification and HEPA filters integrity tests were performed once per year. HVAC system appeared to be well maintained.

14. Materials

Materials were received, sampled and tested according to written procedures. Materials were stored under appropriate conditions established by the manufacturer in an orderly fashion. Starting materials and packaging materials were purchased from approved suppliers. 100 % identity tests were performed on each container of the starting materials. Two sampling rooms were provided for starting materials sampling and one for primary packaging materials sampling. Sampling was done under LAF. Dispensing of starting materials was performed in two dispensing rooms under LAF. Products under quarantine/released/rejected were appropriately segregated.

IQ & OP for the SAP used for materials management was performed in XX and PQ in YY. Till the date of inspection materials management was done in parallel - paper based and SAP.

Temperature mapping report XX - winter for the raw materials warehouse was discussed.

15. Documentation

Documents were available and included QAP, SOPs, protocols and records. SOPs reviewed were generally being followed and staff appeared appropriately knowledgeable as to their content.

Non-conformance log book and BMR/BPR issuance registers were cross checked with released products lists. No discrepancies were noted.

BMR/BPRs, log books and register were controlled and issued by the QA department. These documents were paper based documents. The company explained that they are planning to introduce electronic document management tools.

The SOP “Sampling of raw materials” was discussed.

The SOP “Sampling of packaging materials” was discussed. Acceptance Quality Limit was applied for packaging materials sampling. Inspection level II was applied, defects were specified as:

- Critical
- Major
- Minor

The following SOPs were discussed:

- “Creation, completion, review of BMR/BPR and batch release”. According to the procedure analytical work records, electronic data and BMR/BPRs (each batch) were reviewed by on-site corporate QA.
- “Testing of samples and reporting results of analysis”. Analytical data was reviewed on-line by QC section head/reviewer as well as analytical work records. If no non-conformances observed, then analytical QA reviewed analytical work records and electronic data. Afterwards CoA was prepared and approved by the Head QC.
- “Rounding of significant figures and reporting of results” was discussed.
- “Empower chromatography data management system”. The SOP requested to perform audit summary report review for injection sequence for every analysis after completion. The SOP explained procedure for manual integration (MI). According to the SOP MI was allowed only for related substances, MI can be done by the Group leader by prior approval from Head QC and Head Analytical Quality Assurance (AQA)
- “Preparation, validation and usage of excel based calculation sheets” and Validation report XX were discussed. Excel sheets were used for assay, dissolution and content of uniformity calculations.

16. Good practices in production

In general production operations followed defined procedures. Handling of materials and products was done in accordance with written procedures and, recorded.

Deviations were recorded and investigated in accordance with approved procedure. Operations on different products were not carried out simultaneously or in the same room.

During processing, materials, bulk containers, major items of equipment, and the rooms and packaging lines being used, were labelled with an indication of the product or material being processed.

In-process controls are usually performed within the production area.

Time limits for storage of equipment after cleaning and before use should was stated.

17. Good practices in quality control

General

The QC function was independent from other departments. Adequate resources were available to ensure that all QC arrangements were carried out in a timely and orderly fashion. QC personnel had access to production areas for sampling and investigations as appropriate.

Samples for analysis were received and distributed by Analytical Quality Assurance.

All HPLCs and GCs were connected to the Empower 3 software and were connected to the server system. IR, NIR and UV were standalone instruments. IQ & OQ for Lab Solutions was completed and PQ was in the process during inspection. After qualification IR, UV and NIR will be connected to the Lab Solutions software.

The SOP “Handling out of specifications (OOS) test results, its flow chart, register and trends were discussed. SOP was based on MHRA guideline and specified phase I and II investigations as well as hypothesis testing.

The SOP “Handling out of trend (OOT) results” its flow chart, register and trends were discussed. There were XX OOS registered in 2016 and X in 2017.

A number of OOS investigation reports were discussed.

The SOP “Handling of laboratory deviations” was discussed. Laboratory deviations register for 2017 and trends for 2016 were presented to the inspectors.

A number of laboratory deviations were discussed.

Trending of OOS, OOT and laboratory deviations was performed quarterly.

The SOP “System suitability and bracketing of standards during the analysis” was discussed.

Stability studies

Monthly stability schedules for 2016 and 2017 were presented to the inspectors. Scheduled pull out dates and actual pull out dates were crosschecked. Spot checks showed that there was no back log for stability samples analysis. Stability records were manual, company explained that within 3 months LIMS system will be introduced.

Stability chambers were equipped with audio alarm system to laboratory, security and engineering department.

PW analysis
The SOP "Water analysis" and monthly and quarterly trends for 2016 and 2017 were discussed. Samples from PW supply and return loop were analyzed daily /chemical and microbiological analysis). All other sampling points were covered once in a month following sampling schedule. Action and alert limits were specified.

Environmental monitoring (EM)
The SOP "Environmental monitoring" and monthly and quarterly trends for 2016 and 2017 (settle plates and air samples) were discussed. Settle plates, swab method and active air sampling was used. Settle plates were exposed for 4 hours. Action and alert limits were specified.

Reference standards
Reference and working standards were available, stored in a refrigerator, usage was recorded. Working standards (WS) were qualified against pharmacopoeia reference standards. WS standards were dispensed in vials for individual use. Expiry date to WS was specified 1 year.

Retention samples
Finished products retention samples were retained expiry date + 1 year. Samples of active starting materials were retained one year beyond the expiry date of the corresponding finished product batch.

Back up of electronic data
The Empower Back up and Restoration Procedure was discussed. The data backup was conducted daily, weekly, monthly and annually. Each of the data backup was recorded in EMPOWER Backup Log. Disaster Management SOP of Laboratory Systems was discussed.

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, Micro Labs (Hosur) Unit III, located at 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126, India was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for pharmaceutical products.

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.

PART 4

List of GMP guidelines used for assessing compliance

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/
   Short name: WHO TRS No. 986, Annex 2

2. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6
   Short name: WHO TRS No. 961, Annex 6
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

3. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
   Short name: WHO TRS No. 957, Annex 2
   http://www.who.int/medicines/publications/44threport/en/

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-Ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4
   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

6. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5
   Short name: WHO TRS No. 961, Annex 5
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

7. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4
   Short name: WHO TRS No. 937, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

8. WHO Good Practices for Pharmaceutical Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1
   Short name: WHO TRS No. 957, Annex 1
   http://www.who.int/medicines/publications/44threport/en/

9. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2
   Short name: WHO TRS No. 957, Annex 3
   http://www.who.int/medicines/publications/44threport/en/

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7
    Short name: WHO TRS No. 961, Annex 7
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