



## **WHO PUBLIC INSPECTION REPORT**

### **(WHOPIR)**

#### **Finished Product Manufacturer**

#### **Part 1: General information**

Name of Manufacturer	Meditab Specialities Pvt. Ltd
Unit number	N/A
Production Block	N/A
Physical address	J-4/2, Addl. MIDC, Satara -415004 Maharashtra India
Contact address	As above
Date of inspection	19 to 22 April 2011
Type of inspection	Routine GMP inspection
Dosage forms(s) included in the inspection	Oral solution Oral suspension
WHO product categories covered by the inspection	Antiretroviral oral solutions and oral suspension
Summary of the activities performed by the manufacturer	Production, quality control and release of oral solution and oral suspension and Ayurvedic formulation.

## **Part 2: Summary**

### ***General information about the company and site***

The manufacturing site of Meditab Specialities Pvt.Ltd is located about 275 km from Mumbai, the nearest airport is at Pune.

Meditab Specialities Pvt Ltd is a company was established in year 1998. With effect from August 2<sup>nd</sup>, 2010, the M/s Mediorals Laboratories at Satara was taken over by M/s Meditab Specialities Pvt. Ltd., Mumbai. The company's name has been changed from Mediorals to Meditab since then. Meditab Specialities has manufacturing facilities at different locations such as Satara, Goa & Daman.

Products produced at the Satara site included oral liquid and nasal inhaler formulation. Nasal inhaler is an Ayurvedic formulation. All products were manufactured in one unit.

### ***History of WHO and/or regulatory agency inspections***

The Satara site was previously inspected by the following agencies MHRA (Medicines and Healthcare Products Regulatory Agency) UK, MCC (Medicines Control Council) Republic of South Africa, TGA (Therapeutic Goods Administration), Australia, The State Institute for Drug Control , Slovak Republic, NDA (National Drug Authority), Uganda, TFDA (Tanzania Food and Drug Authority), Tanzania, Ministry of Health and Social Services, Namibia, PMPB (Pharmacy, Medicines & Poisons Board ), Malawi, Pharmacy & Poisons Board (PPB), Kenya and WHO, Geneva.

### ***Focus of the inspection***

The inspection focused on the production and control of prequalified products. 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***

- Documentation
- Quality Management System
- Validation and Qualification
- HVAC System
- Purified Water System
- Receiving areas of materials
- Warehousing areas (starting and packaging materials)
- Sampling and dispensing areas
- Solution and suspension Production areas
- Quality control laboratory (packaging, chemistry, instruments, reference standards, Stability chambers and microbiology)

## 2.1 QUALITY ASSURANCE

There was a quality assurance system in place that covered all the relevant aspects of the WHO GMP guidelines. Production and control operations were specified in written form, deviations were reported, investigated and recorded, and responsibilities of key personnel were described in job descriptions. Product Quality Review was performed according to the SOPs.

Documents and records listed as below have been reviewed during this inspection.

- Organization chart
- Job description
- Training procedure
- Product Quality Review (PQR)
- Quality risk management
- Product list
- Complaints
- Recalls
- Deviations
- Change control
- Approved suppliers list
- Document Control
- Contracts / agreements
- Specifications and analytical reports for selected batches, source data including assay calculations, IR and chromatograms;
- Primary and secondary standards;
- Stability schedules and test reports;
- Retention samples and records;
- Media and Incubators;
- Validation Master Plan
- Process validation, cleaning validation protocols and validation report of selected equipment
- IQ, OQ, PQ data for filling machine.
- Batch Manufacturing Records and Batch Packaging Records
- HVAC preventive maintenance programme
- Water system

## 2.2 GOOD MANUFACTURING PRACTICES (GMPs) FOR PHARMACEUTICAL PRODUCTS

In general, principles of Good Manufacturing Practices were implemented and followed. 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. Qualification and validation were performed.

### **2.3 SANITATION AND HYGIENE**

A satisfactory level of sanitation and hygiene was practised. There were systems implemented to minimize the risk of contamination and cross-contamination to an acceptable level. Cleaning procedures and records for premises and equipment were available. Cleaning validations were performed.

### **2.4 QUALIFICATION AND VALIDATION**

The validation policy of the company was documented in a validation master plan. The validation master plan covered both - FPP and API. Protocols and reports for the qualification and validation were available for the equipment and processes checked during inspection.

Validation studies were conducted in accordance with predefined and approved protocols and written reports summarized the results and the conclusions reached.

### **2.5 COMPLAINTS**

Complaints were handled, investigated and reviewed according to the established procedure and considered acceptable.

### **2.6 PRODUCT RECALLS**

There were no recalls on record.

### **2.7 CONTRACT PRODUCTION AND ANALYSIS**

The technical agreement was reviewed.

### **2.8 SELF INSPECTION AND QUALITY AUDIT**

System was in place and appropriately followed.

### **2.9 PERSONNEL**

An organizational chart was available. Individual responsibilities of key personnel were defined in job descriptions. Quality assurance and quality control departments were independent from production.

### **2.10 TRAINING**

The procedure for training listed the introductory training for new employees as well as the on-going training of existing staff. On-going training was carried out according to a training schedule.

### **2.11 PERSONAL HYGIENE**

An acceptable level of personal hygiene was observed. Direct contact was avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk

product. Personnel were wearing clean body coverings appropriate to the duties they performed, including appropriate hair covering. Used clothes were stored in separate closed containers until properly laundered.

Employees had to undergo a health examination prior to employment as well as annually monitoring for hormone levels. Records were available for inspection.

## **2.12 PREMISES**

In general, the premises were found to be designed, constructed, maintained and cleaned to suit the operations carried out and facilitate sanitation. The logical flow of materials and personnel was ensured. The HVAC system was suitably designed, installed and maintained. The purified water system was appropriately installed and was validated.

## **2.13 EQUIPMENT**

Equipment was located, designed, maintained and cleaned to suit the operations at satisfactory level. The layout and design of equipment also aimed to minimize the risk of errors and permitted effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of products.

## **2.14 MATERIALS**

Materials were generally procured, received, stored, sampled, dispensed and used in an appropriate manner according to the GMP recommendations.

## **2.15 DOCUMENTATION**

The company had a clearly designed, completed, controlled and authorized documentation system including SOPs, specifications, protocols, reports as well as other related documents. These were, in general, acceptable.

## **2.16 GOOD PRACTICES IN PRODUCTION**

In general, production activities were performed in accordance with SOPs and batch documentation as well as principles of GMP. Access to production premises were restricted to authorized personnel.

## **2.17 GOOD PRACTICES IN QUALITY CONTROL**

The quality control unit was responsible for sampling, specifications and testing, and for the organization, documentation and release procedures which ensure that the necessary and relevant tests were carried out and that materials were not released for use, nor products released for sale or supply, until their quality had been judged to be satisfactory.

There was:

- adequate facilities,
- personnel;

- approved procedures for sampling, inspecting, and testing starting materials, packaging materials, and intermediate, bulk, and finished products, and for monitoring environmental conditions for GMP purposes;
- samples of starting materials, packaging materials, intermediate products, bulk products and finished products were taken by methods and personnel approved of by the quality control department;
- Records were made demonstrating activities performed.

### **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, Meditab Specialities Pvt. Ltd, J-4/2, Addl. MIDC, Satara -415004, Maharashtra India 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.