

**Prequalification of Medicines Programme
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Product Manufacturer**

The report is the property of the organization responsible for performing the inspection.

Part 1: General information about the inspection

Name of manufacturer	Matrix Laboratories Limited Unit OSD (Tablets and capsules, including Pilot plant)
Physical address	F4 & F12 Malegaon MIDC Sinnar Nashik, 422113. India.
Postal address	As above.
Telephone number	+ 91 2551.230092
Fax number	+ 91 2551.230924
Summary of all the activities performed by the manufacturer	Manufacturer and packer of oral solid dosage forms coated and uncoated tablets and capsules.
Dosage forms and type of products	
Scope and type of inspection	Specific GMP inspection, related to the data verification
Pharmaceutical dosage forms	Tablets (coated and uncoated) and hard gelatin capsules
Date of inspection	10 and 11 August 2009.
Programme	Prequalification Programme: Priority Essential Medicines

Part 2: Summary

The manufacturing site of Matrix Laboratories Limited located in Nashik, Maharashtra, India, was inspected by a WHO prequalification inspection team on 10 and 11 August 2009.

General information about the company and site

The manufacturing site was located about 180 km from Mumbai. The company employed about 451 staff members (164 at production and 166 at Quality assurance) at the time of the inspection. API manufacturing facilities were located at:



Unit I	Kazipally, Hyderabad India
Unit II	Astrix Laboratories, Kazipally, Hyderabad India
Unit III	Jeedimetla, Hyderabad India
Unit VII	Pashamylaram, Hyderabad India
Unit VIII	Vizianagaram at Vishakapattanam, India Concord Biotech, Ahmed- bad, India
Mchem Pharma,	Xiamen, China

The production of the tablets and capsules concerned was done in Nashik facilities. These facilities started their activities in March 2001.

History of WHO and/or regulatory agency inspections

This was the third inspection by WHO, Geneva at this site. Site was inspected by US FDA, UK MHRA and various other authorities.

Focus of the inspection

This was a special inspection, where some systems were being inspected focusing mainly on material management, quality control and documentation.

After arrival, the inspectors introduced themselves and exchanged business cards with company representatives. The inspection team briefly explained the functioning of the prequalification program including assessments, inspections, WHOPIRs and NOC procedures. The company made a brief presentation of its activities.

The inspectors requested several documents to start the documentation review. These included (for above mentioned products)

- Annual products quality review reports (APQR)
- API specifications,
- Batch manufacturing records
- Validation protocols and reports and source data;
- Complaints register
- Deviations register
- Change control register
- Code change management SOP and record
- SOPs
- Analytical reports
- Stability study protocols

The different recipes for products were checked to see which API code is used in the product e.g. PEPFAR and WHO.

It was verified that the approved APIs were used in batches produced and supplied as WHO prequalified products.

Following procedures and related documents were reviewed (for above mentioned products)

- Annual product reviews (APR):
- Process validation reports and links to batch documents
- Process validation source data (samples, chromatograms)
- Stability program and raw data (samples, chromatograms)
- Batch Manufacturing Records
- Master document code numbers and versions
- Deviations
- Change control
- Complaints
- Out of Specifications
- Material codes for APIs
- Certificates of analysis for API and FPP
- Specifications for API and FPP
- Analytical test methods for API and FPP
- SAP management
- Transfer of codes
- Use of correct API (code) in batches
- List of performed vendors audits
- Vendors audit reports
- SOP's:
 - "Procedure for material transfer"
 - "Complaints"
 - "Recalls"
 - "Conducting stability studies"
 - "Preparation of certificate of analysis"
 - "Testing of raw materials "
 - "Sampling of raw materials"
 - "Handling of blend uniformity results"
 - "Vendor approval and evaluation"

Validation and stability protocols/reports were reviewed together with batch manufacturing records (BMR) and analytical raw data. This included verification of API used, codes, approved suppliers against the approved suppliers list (ASL). Analytical raw data was inspected, including chromatograms and calculations.

Tabulated data was verified against analytical raw data and chromatograms were inspected.

Vendor audits

Vendor audits were performed in accordance with SOP and audit schedule. Audit reports were available for inspection. It was noticed that one person performed audit of two manufactures of API's in one day. In total manufacture of eight API's were audited.

SAP system

The SAP system was inspected for the various codes for selected APIs. Checks were made to verify which code API was used in which batches of products. Print outs of codes were requested as well as batches received, batches used in products and transfer of codes were checked.

Complaints

Reported no complaints in 2008, even though WHO had made aware of a complaint from a customer that the batches could not be delivered due to lacking key starting materials and breakdown of HPLCs. (The complaints received at HQ are not filtered through to the production unit and logged as a complaint)

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, **Matrix Laboratories Limited Unit OSD, F4 & F12 Malegaon MIDC Sinnar, Nashik, 422113 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.