

WHO PUBLIC INSPECTION REPORT (WHOPIR)

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

Part 1: General information about the inspection

Name of manufacturer	Ranbaxy Laboratories Ltd
Physical address	Paonta Sahib, District Sirmour Himachal Pradesh India 173 025
Postal address	Village Ganguwala, Paonta Sahib, Dist Sirmour, Himachal Pradesh India
Telephone number	+91-1704-222834
Fax number	+91-1704- 223492
Summary of all the activities performed by the manufacturer (e.g. manufacturing, packing).	Manufacturer and packer of oral solid dosage forms
Indicate dosage forms and type of products (e.g. tablets; penicillin or cephalosporin containing products)	Tablets and HGC
Scope of inspection	1) General and Product Specific GMP inspection with data verification 2) Block A Unit I and II Pharmaceutical dosage forms: Tablet and capsule manufacturing (HGC)
Date of inspection	8 - 10 May 2007
Programme	Prequalification Programme: Priority Essential Medicines



Part 2: Summary

The manufacturing site of Ranbaxy Laboratories Ltd, India (hereafter referred to as Ranbaxy) located in Paonta Sahib, 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

See previous reports.

Focus of the inspection

The focus of this inspection was to verify the implementation of some of the corrective actions taken since the last inspection of January 2007, and to further review and assess compliance with WHO GMP. All the areas were not inspected in detail as a GMP inspection was done in recent months.

Inspection information

Day 1.

After arrival, business cards were exchanged and the company gave a presentation on the activities of Ranbaxy and the activities on site at Paonta Sahib. This was followed by a brief introduction by the inspectors on the program and prequalification. Documentation was reviewed briefly including the layout of the facility, flow of personnel and material, and the changes made since the last inspection. Various documents were then reviewed. The warehouse (Unit I) and the sampling area was then inspected.

Day 2.

The Dispensing areas were inspected. This included the excipients dispensing area with 2 booths, as well as the API dispensing area and the sifting suite with washing area. Thereafter, the different production areas of Unit I were briefly inspected (e.g. granulation, in process storage, blending, docking area and compression area). The production areas of Unit II were briefly inspected and focus was placed on the pack-



aging lines (in particular line 04 (bulk packaging) after lunch time. The general QC laboratory was then inspected focusing on specifications, release reports for a ARV product API, verification of the tests including description, ID and assay, use of reference standards, records including column and HPLC, shifts, sample registers, work allocation, and NIR validation. Training records of analysts, list of signatures and other documents were reviewed.

Day 3.

The inspection of the quality control laboratory was continued. The laboratory where stability testing was done, was inspected. The area where samples for testing were kept was inspected, as well as the instrumentation room. The stability programme, protocol and reports for a product were inspected. The water systems of Unit I and II and selected AHUs of the HVAC system were inspected. The remaining of the days was spent inspecting documentation including SOPs and records for recalls, complaints, planned preventative maintenance, vendor approval, and the NIR library and validation.

2.1. QUALITY ASSURANCE

The company had quality assurance systems in place consisting of procedures, protocols, records, reports, specifications and related documents and controls. A revised procedure for deviation management was now in use to replace several documents including an approach to deviation control, CAPA and failure investigation, however, the training and records of the SOP showed that this procedure was not fully implemented. In several cases, quality risk assessment had still not been done.

2.2 GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS

Basic principles of GMP were followed.

2.3 . SANITATION AND HYGIENE

Sanitation and hygiene was acceptable in general.



2.4 . QUALIFICATION AND VALIDATION

Qualification and validation was performed. In general, the approach was acceptable. Raw/source data was lacking in some reports. The new/amended SOP for cleaning of specific equipment was not validated.

2.5 COMPLAINTS

The SOP and reports inspected were acceptable.

2.6 PRODUCT RECALLS

The SOP was acceptable. There were no recalls in recent years.

2.7 . CONTRACT PRODUCTION AND ANALYSIS

This area was not inspected.

2.8. SELF INSPECTION AND QUALITY AUDIT

The SOP and reports inspected were acceptable.

2.9 . PERSONNEL

The training records for personnel in the quality control laboratory were reviewed and considered to be acceptable.

2.10 TRAINING

See 2.9. above.

2.11 PERSONAL HYGIENE

This area was not inspected specifically, but in general, it was considered acceptable.

2.12 PREMISES

The premises was acceptable in general, however in some areas it still lacked maintenance, appropriate provision and monitoring of pressure differentials, and risk assessment



for the activities performed in the relative area (e.g. dispensing, sifting, sampling booths (liquids and packaging materials)).

2.13 EQUIPMENT

The equipment was generally acceptable and suitable for its intended use. The use of vacuum cleaners required attention as well as labelling of equipment components/utensils and the sampling booths (e.g. those used for liquids and primary packaging materials).

2.14 MATERIALS

Handling of materials was generally acceptable. The use of poly bags and labelling was not always consistent in production steps.

2.15 DOCUMENTATION

Several documents were reviewed. Although qualification of the new areas (e.g. sampling and dispensing) was done, the reports lacked detail and raw data. Deviations were not managed appropriately in accordance with the new SOP, and the formats were not completed as required.

Part 3: Conclusion

The observations (non-compliances with the WHO guidelines) listed in the full inspection report needed to be addressed by the manufacturer and verified through evaluation of the documentation of the corrective actions (planned and implemented) submitted by the manufacturer.

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, reflected in the observations listed in the inspection report, Ranbaxy Laboratories India (Unit I and II), located in Paonta Sahib, India, was considered to be operating at an acceptable level of compliance with WHO GMP.