

WHO PUBLIC INSPECTION REPORT

(WHOPIR)

Finished Product Manufacturer

Part 1: General information about the inspection

Name of manufacturer	STRIDES ARCOLAB LIMITED Oral solid dosage forms division
Physical address	KRS Gardens', Suragajakkanahalli Indlawadi Cross, Anekal Taluk Bangalore-South - 562 106 India
Postal address (Head Office)	As above
Telephone number (Corporate Office)	+91-80-66580600
Fax number (Corporate Office)	+91-80-66580606
Summary of all the activities performed by the manufacturer	Manufacturing and packaging of oral solid dosage form products: Tablets, hard gelatin capsules, soft-gelatin capsules.
Dosage forms and type of products	
Scope and type of inspection	Special type of inspection
Dates of inspection	21-22 November, 2009
Programme	Prequalification Program of Essential Medicines

Part 2: Summary

Background information

Strides Arcolab Limited, Oral solid dosage forms division located in KRS Gardens', Suragajakkanahalli Indlawadi Cross, Anekal Taluk Bangalore-South - 562 106 India, was inspected by a WHO prequalification team on the above mentioned dates.

For more details see previous report.

At the time of inspection, there were approximately 415 employees working on site, 34 employees were involved in Quality Assurance (QA) and 48 in Quality Control (QC) activities.

Products were manufactured in three shifts.

Focus of the inspection

This was a special inspection, where some systems were being inspected focusing mainly on material management, documentation and HVAC system. Manufacturing operations of products which are provided for the treatment of Malaria and HIV and are prequalified or under assessment in the WHO prequalification program were inspected.

Quality control operations were not covered by this inspection

History of WHO or regulatory agencies inspections

The Strides Oral Dosage Form division had been inspected and approved by various regulatory authorities, including:

- TGA (Australia)
- MHRA (UK)
- MCC (South Africa)
- ANVISA (Brazil)
- USFDA

The site was inspected previously by WHO in April 2008.

2.1. Quality Assurance (QA)

A quality assurance system was implemented and maintained. The QA unit and QC unit were independent from production. A formal system for deviation/incident management was described in writing. Deviations/incidents were recorded also in the Batch Manufacturing Records and in Batch Production Records.

The number of incident reports were reviewed and found to be acceptable.

A change control procedure and change control register were available for inspection

The number of change control forms for years 2008 and 2009 were reviewed and found to be acceptable

Quality Risk Management was implemented.

2.2. Good Manufacturing Practices

Good manufacturing practices were implemented and maintained.

2.3 Sanitation and Hygiene

The topic was not specifically covered during the inspection. No notable concerns were identified during the "walk through" the production areas.

20, avenue Appia – CH-1211 Geneva 27 – Switzerland – Tel central +41 22 791 2111 – Fax central +41 22 791 3111 – www.who.int

2.4 Qualification and Validation

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

A number of documents were reviewed and found to be acceptable.

Specific product validation protocol/report/raw data, BMR and analytical raw data were evaluated and found to be acceptable.

2.5. Complaints

Complaints were handled in accordance with an SOP.

Complaints were trended and trends were available for inspection, reviewed and found to be acceptable.

A number of complaint forms were evaluated and found to be acceptable:

A new complaint investigation form has been implemented from January 2009.

2.6 Product Recalls

Recalls were handled in accordance with a written procedure. There were no recalls since the last inspection. The last recall was executed in 2007. A dummy recall was planned for December 2009.

2.7 Contract Production and Analysis

Not covered during inspection.

2.8 Self Inspection and Quality Audits

Not covered during inspection.

2.9 Personnel

Personnel met during the inspection were experienced, skilful and conscientious.

2.10 Training

Training records for personnel working on sampling, manufacturing and quality control were reviewed and found acceptable.

2.11 Personal Hygiene

20, avenue Appia – CH-1211 Geneva 27 – Switzerland – Tel central +41 22 791 2111 – Fax central +41 22 791 3111 – www.who.int

The level of hygiene observed and the measures taken to maintain this were considered sufficient. Changing rooms were provided with photos describing the gowning procedures.

2.12 Premises

A short tour was made to the tablet and hard gelatin capsule manufacturing block and TB products manufacturing block.

Storage areas

Quarantined, rejected, recalled and returned materials and products were stored separately and securely.

Weighing and Dispensing areas

All materials used in production were dispensed in one room in separate laminar booths.

Production areas

There were separate personnel and material entrances. Temperature, relative humidity, if required, and pressure differentials were regularly monitored. In general production facilities were not maintained in a good condition, however the company explained that in the near future - manufacturing rooms, starting from changing rooms to all manufacturing areas, would be clad with solid panels (walls and ceilings). Four separate dispensing booths will be created with separate material and man entries. Doors in manufacturing areas will be replaced with press fit doors.

2.13 Equipment

Process equipment was installed and maintained in a way that minimized the risk of error and contamination.

A preventive maintenance program was in place. Production and quality control equipment was identified as to content and cleanliness status and appropriately indicated by labels.

2.14 Materials

Materials in the warehouse were handled by the SAP system.

SAP system dealt with the following activities:

- Sales order
- Purchase order
- Approved vendor list
- Goods receipt
- Goods approval
- Goods issuance
- Goods transfer
- Process order
- Goods release

20, avenue Appia – CH-1211 Geneva 27 – Switzerland – Tel central +41 22 791 2111 – Fax central +41 22 791 3111 – www.who.int

- Goods dispatch
- Goods rejections
- Goods returns
- Goods reconciliation
- Material tracking

Purchase orders were drawn up by the SAP.

Vendors for the specific products were checked in the SAP and found to be in accordance with product dossiers.

According to the explanation it was not possible to delete or change the entered data to the SAP. Entered data could only be blocked in the system by the SAP team. There were no observations made regarding SAP.

2.15 Documentation

In general, the documentation system was well established and maintained.

For general information see previous report.

2.16 Good Practices in Production

During processing, materials, bulk containers, major items of equipment, and the rooms and used packaging lines were labeled and indicated the products being processed, its strength and the batch number.

For general information see previous report.

2.17 Good Practice in Quality Control

The Quality Control laboratories were not inspected.

A number of documents were reviewed and found to be acceptable.

Utilities

The HVAC system

The inspection of the air handling system entailed a visual inspection of the equipment in the plantroom, measurement of room pressure differentials, checking supply and return grille locations for airflow patterns, checking qualification documents and drawings. In general the air handling equipment appeared to be in good condition and well maintained. The air handling systems have very basic controls, with no Building Management automated control system. Reliance was largely on maintenance adjustments and re-qualification to ensure adherence to system parameters.

Purified Water (PW) system

20, avenue Appia – CH-1211 Geneva 27 – Switzerland – Tel central +41 22 791 2111 – Fax central +41 22 791 3111 – www.who.int

The Purified water system underwent a cursory inspection following the process through from the raw water input into the system, through to the purified water loop serving the OSD block.

Part 3: Conclusion

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, STRIDES ARCOLAB LIMITED, Oral Solid Dosage forms division, KRS Gardens', Suragajakkanahalli Indlawadi Cross, Anekal Taluk Bangalore-South - 562 106 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.