TMDA/DMC/MCIE/F/001

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

ASTRA LIFECARE (INDIA) PVT LTD
PUBLIC GMP INSPECTION REPORT

December, 2020

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Astra Lifecare (India) Pvt Limited
Corporate address of manufacturer	Plot 57P, Sarkhej Bavla Highway, Village Rajoda 382220, Taluka: Bavla Dist., Ahmmedabad, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	10th -12th August, 2019
Type of inspection	Renewal inspection
Introduction	
General information about the company and site	Astra Lifecare (India) Pvt Limited is located on Plot 57P, Sarkhej Bavla highway, in Village Rajoda 382220, Taluka; Bavla Dist., Ahmedabad, India. It is bordered with Gallops Industrial park from east and south, national highway no. 48 from west and a green farm from north. The facility is engaged in manufacturing and packaging of beta lactam oral solid dosage forms (tablets and capsules) and non-beta lactam solid dosage forms (tablets, capsules and pessaries).
History	The facility had been issued with cGMP certificate no. 1802653 by the Gujarat state FDA and it also possesses a manufacturing license to manufacture oral solid dosage forms no. G/25/1715 and G/28/1204 for production of beta and non-beta lactam tablets and capsules for human use. The plant had also been inspected, approved and issued marketing authorization in different African countries including Uganda, Kenya, Ethiopia, D.R Congo and Malawi.
Brief report of the activities undertaken	
Areas inspected	Areas inspected were external surroundings, production areas and storage area for starting materials, packaging and finished goods, quality control laboratory and utilities.

	The inspection also verified the qualification of key personnel and training, premises layout, design, sanitation and hygiene, state of the buildings and equipment used in various manufacturing operations, laboratory instruments, complaints handlings and recalls, self-inspection, documentation, qualification and validation as well as production and quality control practices.
Restrictions	The inspection focused on the production lines for the products registered and requested to be registered in Tanzania
Out of scope	Lines for which application for product registration has not been submitted to TMDA
Production lines inspected by TMDA	Manufacturing and packaging of beta lactam (penicillin) in form of tablets and capsules and non-beta lactam solid dosage forms (tablets, capsule and pessaries)
Abbreviations	**Meaning**
AHU	Air Handling Unit
CAPA	Corrective Actions and Preventive Actions
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Air
HVAC	Heating Ventilation and Air Conditioning
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SS	Stainless steel
TMDA	Tanzania Medicines and Medical Devices Authority

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had adequate number of qualified personnel in different operational activities at the facility. Delegation of responsibilities for QC, QA and production were clearly indicated on their job description. All key personnel posts were occupied by full time, qualified and experienced personnel and they were independent in fulfilling their responsibilities.

The facility had a procedure for training of personnel, training schedule and respective training records. Trainings which were conducted include induction and periodic trainings. Medical checkup for new employees and

annual checkup for all working employees was conducted as per the facility medical checkup procedure.

2. **Premises**

The facility had five main blocks dedicated to different operational activities such as administration and quality control block, utilities block, beta lactam (penicillin) block and block I & block II for non-beta lactam formulations.

Layout and Design

The manufacturing plant was properly designed to allow logical flow of material and personnel. Interior surface such as walls, floors and ceiling were smooth and free from cracks to avoid accumulation of dust and permit easy cleaning and disinfection. All buildings were constructed using reinforced concrete cement structure and cement plastered brick walls.

Sanitation and Hygiene

Procedure for gowning and pictorial demonstration was in place and all employees were provided with appropriate clean factory gowns and protective gears. Changing rooms were adequate in size provided with step over benches, bins for keeping used and clean gowns, and facilities for hand washing and sanitization.

Availability of air lock, monitoring of pressure differentials, use of dedicated facilities, cleaning between campaign productions and appropriate use of air supply were measures taken to prevent possibilities of contamination and/or cross contamination on site. Received raw and packaging materials were dedusted as per procedure before transferring to storage areas.

Pest and rodent control were done as per the company specified procedure. Generally, the external environment and buildings were clean, properly maintained and well designed to minimize risk of contamination and allow good sanitation.

3. Production

The facility had three production blocks; one block dedicated to manufacture beta lactam products in form of tablets and capsules and two separate

blocks namely non- beta lactam block I & II for non-beta lactam products in form of tablets, capsules and pessaries.

Each building had receiving areas for raw materials as well as storage areas. Materials were received, de-dusted and verified as per respective SOP. The storage areas were partitioned and demarcated for storage of quarantined materials, under test and approved materials.

Received materials were allocated in the storage areas depending on their nature and sampling was done as per procedure. Sampling and dispensing rooms were available and installed with Reverse Lamina Air Flow booths. The material and personnel had separate entries to the facility.

There was adequate number of personnel in production floor. Sufficient measures including line clearance as per procedure and validated cleaning procedures were used to avoid mix up and prevent cross contamination.

4. Quality Control

Quality control laboratory was composed of chemistry, instrumental and microbiology sections. The laboratory was well equipped and designed to suit operations carried out. All equipment was calibrated, maintained and qualified. The quality control laboratory was mainly used for testing of raw materials, packaging materials, in process and finished products.

The microbiology laboratory was designed to have a separate functional area that was appropriate for conducting sensitive tests, such as sterility, BET and bio burden tests.

Materials received from the warehouses were sampled as per SOP and tested as per product specification. Pharmasuit software was used in preparing certificate of analysis and release of analytical results. Records were maintained and easily traceable.

There were three stability study chambers in the quality control area, stationed in a separate room. The first chamber was for 30 ± 2 ^{0}C/65% ± 5%RH storage condition, the second was for 30 ± 2 ^{0}C/75% ± 5%RH and the last one was for 40 ± 2 ^{0}C/75% ± 5%RH.

Retention samples were maintained in a room which was equipped with air conditioner. The temperature was monitored and recorded as per the respective standard operating procedure.

Volumetric solutions and working standards were prepared, stored, standardized and handled as per procedure.

There were technical agreements drawn between parties including contract laboratories for testing APIs, intermediates and finished products testing where needed.

5. Equipment

The facility had sufficient number of production equipment which were designed, installed, qualified and maintained to suit the operations carried out. The design and location of equipment also facilitated effective cleaning and avoided chances of contamination and cross contamination.

6. **Water Treatment System**

The facility sourced water from the bore well which was stored in a tank. The stored water was passed through multi grade sand filter, softener, RO I, RO II and electoral deionization unit. Purified water was then stored in SS water storage tank and distributed through SS pipes to points of use through UV light system. PH and conductivity were monitored online and microbial quality testing was performed as per plan.

7. Heating, Ventilation and Air Conditioning

Heating, Ventilation and Air Conditioning (HVAC) systems were suitably designed to maintain adequate temperature, relative humidity and pressure differentials to prevent contamination and/or cross contamination. The systems had adequate number of Air Handling Units (AHU) serving penicillin and general formulation blocks. All AHUs were qualified and properly maintained.

The AHUs that supplied air to the critical areas were provided with terminal HEPA filters. Dispensing and sampling activities were carried out under reverse lamina flow units to prevent contamination. The systems also used air mix up of 10% fresh air and 90% returned air.

8. Document Review

A documentation system was in place to guide production and control of products. These included Updated Site Master File, Validation Master Plans (VMP); Standard Operating Procedures; standard testing procedures, qualification and validation protocols and reports.

There were corresponding records in form of reports, forms, checklists, logbooks, registers maintained as evidence of compliance with the procedures and specifications.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection and CAPA submitted, the production lines for manufacturing of general pharmaceutical products (tablets, capsules and pessaries) and penicillin production line (tablets and capsules) at **Astra Lifecare (India) Pvt Ltd Plot 57P, Sarkhej Bavla Highway,, Village Rajoda Dit, Ahmedabad, India** were considered to be operating at an acceptable level of compliance with EAC GMP Compendium.

This report shall be valid for three (3) years from the date of approval unless forms and operations herewith are changed or the site is no longer considered to be in compliance with current GMP requirements.

Part 4: References

1. Compendium of Good Manufacturing Practices (GMP) Technical Document for Harmonization of Medicines Regulation in the East African Community, Version: September 2014.
2. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority, Dar es Salaam, Tanzania.
3. Tanzania Medicines and Medical Devices Act, Cap 219.
4. Astra Lifecare (India) Pvt Ltd GMP inspection report, August, 2019
5. Astra Lifecare (India) Pvt Ltd CAPA report, 2019