TMDA/DMC/MCIE/F/001

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

(MANEESH EXPORTS (EOU)
INDIA
PUBLIC GMP INSPECTION REPORT

Date: 11th December, 2020

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Maneesh Exports (EOU)
Corporate address of manufacturer	Navi Mumbai 400703, India
Inspected site	
Name & address of inspected manufacturing site	Plot D-16/7, TTC Industrial Area, MIDC Turbhe, Navi Mumbai 400703, India
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	17th -18th December, 2018
Type of inspection	Pre-registration inspection
Introduction	
General information about the company and site	Maneesh Exports (EOU) is a subsidiary of Maneesh Pharmaceuticals Ltd which was established in 1985. It manufactures penicillin in form of tablets, capsules, dry suspension and dry powder for injection. The facility was set up in 2003 at Navi Mumbai, the plant started manufacturing of tablets, capsules and dry syrup/suspension and dry powder injection started on 2008. The facility had a valid manufacturing license number KD 381 in form 28 for manufacturing of dry powders for suspension, capsules, tablets and dry powder for injection (Beta lactam) issued by state FDA.
History	This was the pre-registration inspection conducted by TMDA. The site was approved by the state FDA and the certificate was valid to 24/06/2021. It was also approved by PPB-Kenya, FMHACA- Ethiopia, FDA- Ghana, NAFDAC- Nigeria, Ivory Coast, ANVISA-Brazil, Austrian Health Authorities and Ministry of Health Ukraine.

Brief report of the activities undertaken	
Areas inspected	The areas inspected were external surroundings, utilities, production area starting from incoming raw material warehouse, manufacturing areas to the finished products warehouses, quality control laboratory and documentation.
Restrictions	The inspection focused on lines used to manufacture products which were applied for registration in Tanzania
Out of scope	Penicillin dry powder for injection line.
Production lines inspected by TMDA	Lines for manufacturing of penicillin in form of capsules, tablets, dry syrup/suspension.
Abbreviations	**Meaning**
AHU	Air Handling Unit
BMR	Batch Manufacturing Record
EAC	East African Community
EOU	Export Oriented Unit
GMP	Good Manufacturing Practice
SOP(s)	Standard Operating Procedure(s)
TMDA	Tanzania Medicines and Medical Devices Authority
WTP	Water Treatment Plant

Part 2: Brief summary of the findings and comments

1. Personnel

The facility has sufficient number of qualified and experienced personnel to carry out the task of production, quality control and quality assurance. Individual responsibilities were defined and clearly narrated in their job description. Key post such as Quality assurance head, Quality control head and production head were occupied by full time personnel and were present during inspection. The heads of production and quality control were independent of each other in fulfilling their responsibilities.

Personnel interviewed and record checked reflected that they were aware of the principles of GMP. Initial training and on job continuous GMP training were conducted as per procedure. Records were availed and verified. Medical examination of employees was conducted as per SOP and records for the same were reviewed and accepted.

2. Premises

i. Layout and Design

The facility layout was designed to provide logical flow of materials and personnel. The buildings were constructed with reinforced cement concrete materials. The floor in non-sterile manufacturing area was in kota stone. The walls were in fabricated stainless steel sheet sandwiched with insulation between the stainless steel sheets. Corners of wall-wall, floor-wall, and wall-ceiling were coved to permit cleaning. Changing rooms were available in areas before entering production area, sampling and dispensing area. Airlocks were available and all fitting and fixtures such as doors, windows, tube lights, AHU inlets and exhaust fans were flushed inside in symmetry with wall to avoid accumulation of dust

Warehouse was well designed and maintained to allow orderly storage of materials. It had receiving bay and partition inside/ labeled as quarantine areas, under test area, approved area and rejected area. It was also equipped with sampling and dispensing booth for sampling and dispensing materials. All the areas had adequate space and equipment were properly placed. Rodents and insect were controlled from entering the facility.

ii. Sanitation and Hygiene

The external surrounding, manufacturing areas and warehouse were inspected and found to be clean. Entry and exit procedures were in place and they were being followed. SOP for cleaning were found in vantage areas and cleaning method validation was conducted. Changing rooms were in place provided with SOP, pictorial presentation and personnel outfits. Personnel and material airlock with interlocking doors were also in place.

3. Production

The manufacturing plant was engaged in the manufacturing of beta lactam (penicillin) products in form of tablets, capsules, dry syrup/suspension and powder for injection. The focus of the inspection was on the production line I (tablets and capsules) and production line II (dry syrup/suspension). The facility had receiving bay for receiving incoming raw materials and materials were received and verified as per SOP. Materials were sampled as per procedure and assigned label either quarantine, under test, approved or rejected and stored in their appropriate area. Records were available and reviewed. Packaging materials were properly stored and label reconciliation was performed thus suggesting that there was no risk of mix up. All ongoing processes were identified by status labels. In process quality check were performed and verified in BMR. Production was carried out by competent and qualified personnel.

4. Quality Control

The quality control department was divided into wet chemistry, instrumentation and microbiology section. The laboratory had sufficient space, well equipped and maintained to minimize mix up and cross contamination. Stability chambers as well as sample retention rooms were available.

Testing of raw materials, packaging materials and finished products were performed within the facility and some of the analytical tests were sub contracted to authorized laboratories. Reference standards, working standards, standardized volumetric solutions, reagents and volumetric solutions were prepared, handled and stored as per requirements.

SOPs applicable to activities carried out in the laboratory, qualification report of analysts and equipment log books and stability study reports were available and reviewed. Microbiology laboratory was clean, equipped, isolated and managed by qualified personnel.

5. Equipment

The facility had sufficient and required number of production equipment and machines which were designed, located, installed qualified and maintained to suit the operations carried out. The design facilitated effective cleaning and avoidance of recess to prevent chances of contamination and cross contamination.

6. Water Treatment Plant

WTP was well designed, qualified and properly maintained. Municipal water was used as feed water for generation of purified water. Routine water sampling was conducted as per procedure and records were availed. Purified water was maintained in a continuous loop circulation. Sanitation of WTP was conducted and records were verified.

7. Heating, Ventilation and Air Conditioning
The heating, ventilation and air condition system was designed and installed to supply filtered fresh air and re-circulated air. Temperature, relative humidity and pressure differential were monitored and records were verified. Positive pressure was maintained in the corridor compared to the manufacturing area to prevent cross contamination. Records for preventive maintenance, filter integrity and cleaning were availed and verified.

8. Document Review

Documentation system was in place to guide production and control of products. These included Validation Master Plans (VMP); Standard Operating Procedures; Batch Manufacturing and Packaging Instructions and records; specifications of starting materials, packaging materials, packaging components, intermediates and finished products; standard testing procedures, analytical records and certificates of analysis; 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, including the observations listed in inspection report the production lines for manufacturing and packing of **Penicillin in form of tablets, capsules and dry syrup/suspension at Maneesh Exports (EOU) Plot D-16/7, TTC Industrial Area, MIDC Turbhe, Navi Mumbai 400703, India** was considered to be operating at an **acceptable** level of compliance with EAC GMP guidelines.

This report shall be invalid if the forms and operations herewith are changed or if the site is no longer considered to be in compliance with current GMP requirements.

Part 4: References

1. EAC- *Good Manufacturing Practice Compendium, (2014), Technical Documents for Harmonization of Medicines Regulation in the East African Community*
2. TMDA *Good manufacturing practices inspection manual and SOPs*, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania.
3. Tanzania Medicines and Medical Devices Act, Cap 219.
4. Maneesh Exports (EOU) CAPA assessment report.