TMDA/DMC/MCIE/F/001

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

KAIRUKI PHARMACEUTICALS INDUSTRY LIMITED
PUBLIC GMP INSPECTION REPORT

November, 2022

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Kairuki Pharmaceuticals Industry Limited (KPIL),
Corporate address of manufacturer	P. O. Box 65300, Dar es Salaam
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Kairuki Pharmaceuticals Industry Limited (KPIL), Plot No. 192, Zegereni Industrial Area, Kibaha, Coast Region
Unit/ block/ workshop number	None
Inspection details	
Date of inspection	17th – 18th March, 2022
Type of inspection	Pre-registration GMP Inspection
Introduction	
General information about the company and site	Kairuki Pharmaceuticals Industry Limited is the subsidiary of Kairuki Health and Education Network which is designed for manufacturing of Large Volume Parenteral for human use.
History	The facility had obtained the premise registration number TAN 0121 D REG 0051 issued by the Tanzania Medicines and Medical Devices Authority in 2021 for the manufacturing of large volume parenteral.
Brief report of the activities undertaken	
Areas inspected	The following areas were inspected; Raw materials, packaging materials and finished goods warehouse, manufacturing area, utilities, quality control laboratory and documentation.
Restrictions	NA
Out of scope	None

Production lines inspected by TMDA	Large volume parenterals
Abbreviations	**Meaning**
BMS	Building Management System
HEPA	High Efficiency, Particulate Air
HVAC	Heating, Ventilation, Air Conditioning
GMP	Good Manufacturing Practices
LAF	Laminar Air Flow
RO	Reverse Osmosis
SOP	Standard Operating Procedures
QC	Quality Control
WTP	Water Treatment Plant

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had adequate number of personnel with appropriate qualifications and experience in the manufacturing and quality control activities. Heads of quality assurance, quality control and production were independent from each other as described in the company organogram and job descriptions which were verified during inspection.

Training was provided to personnel as per the respective SOPs and records reviewed demonstrate that induction and on job training were conducted by the facility including cGMP and technical trainings.

SOP for medical examination of personnel was adequate, medical examination was carried out prior to employment and during employment. Medical examination records were verified and found to be sufficient.

2. Premises

i. Layout and Design

The premises was suitably located, designed, constructed and maintained to suit the operations carried out.

The facility had seven (7) blocks dedicated for manufacturing activities, administration, general warehouse and utilities. The buildings were built with concrete and partitions were of modular panels. Covings were observed between walls and floors, walls and roofing to permit effective cleaning. Doors and windows were flashed with glaze view

glass paned for easy cleaning. There was a separate entry for man and materials in the storage, sampling and manufacturing areas.

Building Management System (BMS) had been installed to enhance monitoring of the temperature, relative humidity and pressure differentials.

ii. Sanitation and Hygiene

Adequate level of sanitation and hygiene was observed on the site, written procedures and cleaning records for all critical areas. Primary and secondary change rooms were provided with step over benches, lockers and toilets.

Sampling was done in the sampling booth under LAF to avoid direct contact between the operator's hands and starting materials.

Waste management from the manufacturing facility had been approved by the National Environment Management Council of Tanzania.

3. Production

The facility was involved in the production of terminally sterilized large volume parenteral for human use under terminal sterilization. Raw materials and packaging materials were received and dedusted then stored in the respective warehouse after QC testing and approval.

Manufacturing was carried out in block 1 and the operations were initiated as per the BMR; sequence of activities was followed and properly recorded. Manufacturing processes consisted of mixing and filling. The bottles used for filling were prepared by blowing technique and then rinsed before filling. This was followed by terminal sterilization of the finished product. In process quality control checks were done.

4. Quality Control

The quality control laboratory consisted of; wet chemistry section, physical chemical section, instrumentation section, microbiology section and rooms for stability chambers and retention samples.

Stability chambers were available including the stability chamber for long term studies at zone IVB ($30^0C\pm 2^0C$/ 75% ± 5%RH). Stability study protocol, log books, SOP and reports were verified.

Microbiology laboratory was located in the QC laboratory and had the following sections; incubator room, sterility area, media disposal, microbial limit testing, media

preparation and washing rooms. There was a provision for change room before entering the lab and sterility room. Samples were transferred to adjacent rooms via pass boxes.

Reference and working standards used for analysis of the finished products were found stored according to the storage instructions. Retained samples were stored in a clean room with an appropriate storage condition, records were verified.

5. Equipment

The facility was equipped with sufficient number of production equipment and machines, which were designed, located, installed, qualified and maintained to suit the operations carried out and effective cleaning. All equipment had identification numbers and preventive maintenance records which were reviewed and found to be satisfactory.

6. Purified water System

The facility had installed purified water system sourced from a bore hole. Pretreatment of raw water was done through passing it in multi grade sand filters, activated carbon and reverse osmosis then collected in a pretreatment tank.

Collected potable water is further treated by passing to the softener then transferred to reverse osmosis for purification and stored in a temporary SS tank. RO water passes through secondary RO to electro-deionization system and stored in SS tank as purified water. All materials from water treatment plant were of SS316 L nature. The records for qualification of the water treatment system were in place.

7. Heating, Ventilation and Air Conditioning

The facility had installed HVAC system and there were nine (9) air handling units (AHUs) located in the backyard of the production block. These AHUs were dedicated to specific areas to minimize cross contamination and positive pressure. The core process room was supplied with controlled air passage through pre-filter then 0.3 – 5-micron filter then HEPA filter. The AHUs recirculate 90% return air with 10% fresh air. Extractor fans have been installed in the raw materials and finished goods warehouses, WTP and sterilization unit. Records for installation and operational of the HVAC system was available and were reviewed.

8. Document Review

A documentation system was in place to ensure that all documents required for GMP compliance were available. Some of the reviewed documents included Validation Master Plans; standard operating procedures; Batch Manufacturing and Packaging records; environmental monitoring reports, analytical records and certificates of analysis; qualification and validation protocols and reports. All documents were

prepared, reviewed and approved by authorized personnel and provided evidence of conformity to GMP requirement.

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 report, Kairuki Pharmaceuticals Industry Limited (KPIL), Plot No. 192, Zegereni Industrial Area, Kibaha, Coast Region, was considered to be operating at an acceptable level of compliance with EAC – GMP guidelines for manufacturing of large volume parenteral.

This TPIR will remain valid for three (3) years from the date of approval for GMP compliance provided that the outcome of any inspection conducted during this period is positive.

Part 4: References

1. EAC, (2014), Compendium of Good Manufacturing Practices (GMP) Technical Documents for Harmonization of Medicines Regulation in the East African Community.
2. TFDA, (2008), Good manufacturing practices guidelines for pharmaceutical, Tanzania Food and Drugs Authority, Dar-es-Salaam, Tanzania.
3. TFDA Good manufacturing practices inspection manual and SOPs, Tanzania Food and Drugs Authority, Dar-es-Salaam, Tanzania.
4. Tanzania Medicines and Medical Devices Act, Cap 219.
5. Kairuki Pharmaceuticals Industry Limited, Site Master File
6. GMP Inspection Report for Kairuki Pharmaceuticals Industry Limited, 2022