THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

KAIRUKI PHARMACEUTICALS INDUSTRY LIMITED, ZEGERENI, KIBAHA, COAST REGION

PUBLIC GMP INSPECTION REPORT

July, 2024

General information about the company

Manufacturers details	
Name of manufacturer	Kairuki Pharmaceuticals Industry Limited (KPIL),
Corporate address of manufacturer	Plot No. 192, Zegereni Industrial Area, Kibaha, Coast Region. P. O. Box 65300, Dar es Salaam, Tanzania
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Plot No. 192, Zegereni Industrial Area, Kibaha, Coast Region. P. O. Box 65300, Dar es Salaam, Tanzania
Unit/ block/ workshop number	Not applicable
Inspection details	
Date of inspection	9th – 12th July 2024
Type of inspection	Routine GMP inspection
Introduction	
General information about the company and site	Kairuki Pharmaceuticals Industry Limited (KPIL) is located at plot No. 192, Zegereni Industrial Area, Kibaha Municipal in Coast Region and approximately 60 km from Dar es Salaam city. It is a subsidiary of Kairuki Health and Education Network (KHEN) which also had other branches dealing in health business within Tanzania The Facility is engaged in manufacturing and packaging of General formulations in form of Large Volume Parenterals (LVP) for human use.
History	The facility has been issued with manufacturing license No. TMDA0121/D/0030 and business permit No. TAN 0124 D LIC 0166 for manufacturing pharmaceutical

	products for human use from Tanzania Medicines and Medical Devices Authority. It also holds a GMP Certificate No. TMDA 0122 D GMP 0002 valid until 12th July 2025 The site has been GMP inspected by other foreign medicine regulatory authorities namely Pharmacy and Poisons Board (PPB), Kenya and Medicines Regulatory Authority of Malawi and issued with GMP certificates no. PPB/ GMP/F/2023/032 valid until 11th April 2026 and PMRA/cGMP/084/001 valid until 08th February 2025 respectively.
Brief report of the activities undertaken	
Areas inspected	External surroundings, utilities (water treatment plant and HVAC), quality control Laboratory, starting and packaging materials warehouses and manufacturing areas.
Restrictions	The inspection focused on manufacturing line for general formulations in the form of Large Volume Parenteral (LVP).
Out of scope	None
Production lines inspected by TMDA	General formulations in the form of Large Volume Parenterals (LVP).
Abbreviations	**Meaning**
AHU	Air Handling Unit
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
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 and experienced staff in different operational activities to execute their responsibilities 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 Quality Assurance Manager was responsible for all quality issues including batch review and release.

Employees were imparted with induction and continual training on GMP as per company procedure and training program; interviews and records indicated that they were aware of GMP, company policy and procedures. Medical examination for new employees and annual checkup for all working employees including eye examination for personnel doing visual inspection was conducted as per the facility medical checkup procedure.

2. Premises

a. Layout and Design

The facility was designed and constructed to suit the operations to be carried out and consisted of buildings or blocks to cater for manufacturing (production, QCL and HVAC, water treatment unit), administration, materials warehouse, water treatment plant, power backup generations and compressed air production.

The buildings were constructed with reinforced concrete cement. The flooring in the warehouse was made up of concrete cement while in production areas was made of polyvinyl chloride (PVC). Covings were provided at the junction of the wall-to-wall, wall-to floor and wall-to-ceiling to facilitate easy cleaning and sanitization. The ceilings were smooth and light fixtures were flushed with the ceilings. Adequate changing rooms for personnel provided with airlocks; facilities for the storage of clothes, hand washing, disinfectants, toilets, gowning and de-gowning procedures. Electrical supply, lighting, temperature, humidity and ventilation were verified and found appropriate for manufacture, functioning of equipment and storage of materials and finished products.

Generally, the layout was observed designed to provide a unidirectional flow of manufacturing processes to minimize the risk of mix-ups and cross-contamination.

b. Sanitation and Hygiene

High levels of sanitation and hygiene were generally observed in all areas, including the surroundings. Change rooms with adequate size were provided for both sexes, each equipped with appropriate cabinets for storage of clothing and factory gowns. The

procedures for entry and exit in different production areas were also in place, including adequate gowning and de-gowning procedures, as supported with pictorial presentation.

Cleanness of the processing area and equipment were maintained as per the procedure in place. In order to facilitate effective cleaning, detergents were used for area cleaning in rotation bases as per the defined frequency and cleaning records were maintained.

3. Production

The facility was dedicated for manufacturing of general formulations in form of Large Volume Parenteral (LVP) for human use. The inspected area include production line for sterile solutions for infusion (LVP). There were separate entries for materials and personnel to production areas. Access to production area was restricted to authorized personnel whose names were displaced at entry point of each production module.

Manufacturing operations were carried out in the designated and well segregated areas equipped with all necessary equipment to facilitate production operations and to prevent mix- up and cross contamination. Manufacturing areas were labelled to indicate the type of activities to be carried out.

To prevent cross contamination sampling and dispensing booth were provided with separate material and personnel entry. Manufacturing processes were initiated as per the BMR, sequence of activities was followed and properly recorded. In process control was performed in the production area. Packaging lines were also equipped with automatic machines and proper separations between the packaging lines was provided to avoid mix-ups.

Generally, the manufacturing processes followed unidirectional flow, thus minimizing the risk of cross contamination and mix ups.

4. Quality Control

The facility had Quality Control laboratory which was independent and separated from the production areas. The laboratory was divided into two major sections i.e. wet chemical analysis, instrumentation and microbiology. It was spacious enough to avoid mix-ups and cross- contamination and was provided with adequate suitable storage space for the storage of samples and reference standards, reference micro-organisms, reagents and records.

The Quality Control Laboratory (QC) was designed and equipped with facilities for chemical, instrumental and microbiological testing. The laboratory had sufficient number of qualified personnel with appropriate knowledge and experienced to carry out quality control activities.

The laboratory was responsible for testing raw materials, excipients, packaging materials, finished products, stability samples, water and environmental monitoring. It was also responsible for the preparation of specifications, test methods, test and volumetric solutions, analytical method verification, calibration, maintenance and performance qualification of analytical instruments.

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.

Equipment log books, SOPs, calibration records and qualification reports were verified and found to be acceptable.

6. Purified water System

The facility sourced water from the bore hole. Raw water was pre-treated by passing through a multigrade sand filter, activated carbon tank, and reverse osmosis to produce portable water which was then pumped into the water treatment plant for further treatment to produce soft water and later passed through secondary RO to the Electro deionization (EDI) system to produce Purified Water (PW) and finally stored in the SSL 316 tank with the capacity of 8000 Liters. To obtain water for injection, purified water was used as a source which was passed through a multi column distillation unit and WFI was collected in SS316L 8,000Lt tank at > 80°C which was under continuous circulation.

Cleaning and sanitization of storage tanks and distribution loop was done as per the procedure. Online monitoring pressure gauges, pH, temperature sensors, and conductivity sensors, routine sampling and testing for chemical and microbiological attributes were performed and records were maintained.

Generally, water treatment system was properly functioning, suitably designed, maintained and monitored.

7. Heating, Ventilation and Air Conditioning

Heating, Ventilation and Air-conditioning (HVAC) system was suitably designed, installed and qualified to maintain adequate temperature, relative humidity and pressure differential within the facility to prevent contamination and/or cross contamination. The system had a total number of four (4) Air Handling Units (AHUs) designed to have air changes depending upon process requirement

The AHUs that supplied air to the critical areas were provided with terminal HEPA filters. Relevant records for preventive maintenance and performance qualification were all reviewed and proved the suitability and functionality of the system.

8. Document Review

The review indicated that the facility had a documentation system for the procedures, records, specifications and policies to support quality management and quality assurance. Most of the documents were available to define specifications and procedures for all materials, manufacturing methods and testing of starting materials and finished products.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed,and considering the findings of the inspection **Kairuki Pharmaceutical Industry Limited 192, Zegereni Industrial Area, Kibaha Municipal, Coast Region** was considered to be operating at an acceptable level of compliance with TMDA GMP Guidelines for Inspection of Human Medicinal Facilities for manufacturing and packaging of Large Volume Parenteral (LVP)

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. Tanzania Medicines and Medical Devices Act, Cap 219
2. TMDA Good manufacturing practices SOPs, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania.
3. Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities; 1st edition, April 2023,
4. TMDA, (2018)., Tanzania Medicines and Medical Devices (Good Manufacturing Practices Enforcement) Regulations GN No. 295. Tanzania Medicines and Medical Devices Authority. Government Printer, Dar es Salaam, Tanzania,
5. TMDA, RIMS 2.0
6. Kairuki Pharmaceutical Industry Limited, Plot no. 192, Zegereni Industrial Area, Kibaha Municipal, Coastal Region, SMF No. KPIL/SMF/01 effective from 22/09/2023 to 21/09/2025.