THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

HEBEI TIANYUAN PHARMACEUTICAL CO. LTD, SHIJIZHUANG CITY, CHINA
PUBLIC GMP INSPECTION REPORT

January, 2026

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Hebei Tianyuan Pharmaceutical Co. Ltd
Corporate address of manufacturer	Plot No.34 Changsheng Street, Lequan District, Shijizhuang City, Hebei Province, China
Inspected site	
Name & address of inspected manufacturing site if different from that given above	NA
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	21st -22nd October, 2024
Type of inspection	Pre-registration GMP Inspection
Introduction	
General information about the company and site	The company was located at Plot No.34 Changsheng Street, Lequan District, Shijiazhuang City, Hebei Province, China and was engaged in manufacturing of and packaging of veterinary medicines; • General formulations in form of Liquid injection, Bolus /Granules /Water soluble powder, oral solution and Injectable granules, • Penicillin products in form of liquid injection • Chinese traditional medicines
History	The company was established in 1999. It was inspected and approved by National Regulatory Authority and Ethiopia Agricultural Authority.
Brief report of the activities undertaken	
Areas inspected	Inspection covered: • Pharmaceutical Quality System • Production System • Facilities and Equipment System • Laboratory Control System

	• Material System • Packaging and labelling System
Restrictions	None
Out of scope	None
Production lines inspected by TMDA	General formulations; • Liquid injectables (LVP & SVP) production lines • Oral soluble powder production line • Bolus production line
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

There was sufficient number of personnel to carry out production and quality control activities.

Job descriptions were provided to key personnels and there were independent in performing their duties. Among other duties batch release was done by the Quality

Assurance Head. Staff were trained on GMP norms including general hygiene principles before employment and while on job.

It was also confirmed that personnel were subjected to medical check up inline with the available procedure records were verified.

2. Premises

a. Layout and Design

The facility was comprised of seven main buildings, namely building 1, 2,3,4,5,6 and 7. Each building was dedicated for different production lines. The buildings were made of reinforced cement concrete (RCC) frame structure. Inside finishing of the manufacturing areas followed GMP requirements. Access to production areas was access controlled to authorized personnel only. The layout and design were generally adequate enough to provide unidirectional flow of manufacturing activities as well as movement of personnel and materials to minimize risk of errors, permit effective cleaning and avoid cross contamination.

b. Sanitation and Hygiene

The facility was located in an environment with minimum risk of contamination to surroundings, materials as well as manufactured products. The general cleanliness in the production area, quality control room and storage areas were sufficient and satisfactory where the cleaning procedures were documented in SOP and confirmed to be validated. Entry and exit procedures were displayed at appropriate place and were properly followed. General cleanliness in the production, quality control and storage areas were deemed sufficient and satisfactory.

3. Production

The facility had three production line namely; injectable line, oral soluble powder line, and oral bolus line. Manufacturing process were validated; routine manufacturing was performed in line with the validated parameters. Sequence of manufacturing activities was followed and recorded in the BMRS. The facility was not engaged in contract manufacturing. There was a procedure for reprocessing with requirement of approval before reprocessing was conducted.

4. Quality Control

The facility had a quality control (QC) laboratory which was divided into different sections such as chemical laboratory, instrumentation rooms, microbiology section,

traditional medicines, stability room, and retained sample room. It was responsible for analysis and release of raw materials, intermediates, packaging materials, finished products, water, stability samples, as well as conducting environmental monitoring. The QC laboratory had sufficient number of trained personnel with appropriate qualifications and experience. Modern analytical instruments were available, the same were found qualified/calibrated. The facility performed both accelerated and long-term stability studies in line with the respective procedures and protocols. Products were properly arranged in the chambers and were easily traceable. Reference and working standards were properly stored and easily retrieved. Most of the laboratory tests were conducted on site while some were contracted out.

5. Equipment

The facility was provided with sufficient number of equipment and instruments, appropriately for the manufacturing and quality control operations carried out. The layout and design permitted effective cleaning thus preventing the risk of cross contamination build - up of dust or dirty. Calibration and preventive maintenance were performed according to the established schedules. Equipment was adequately cleaned and sanitized as per validated cleaning and available sanitization procedure; records were verified. Preventive maintenance, calibration and cleaning status labels were in place.

6. Water Treatment System

The water treatment system at the facility was designed, installed, qualified and maintained properly as per SOP, capable of generating pure water and water for injection.

Bacterial growth and stagnancy of the purified water was prevented by continuous circulation through heat exchanger. The quality of both water for injection and pure water was monitored for chemicals and microbials, online monitoring of conductivity and flow rate. Preventive maintenance, sanitization, and re qualification was performed as per procedures in place, records were verified.

7. Heating, Ventilation, and Air Conditioning

Heating, ventilation, and Air conditioning systems was installed at the facility to supply filtered fresh air and maintain adequate temperature, relative humidity and pressure differentials. There were 5 AHUs, which were designed to supply 30-40% fresh air and 60-70% return air. Classified areas were maintained at room temperature of NMT 25^{0}C and relative humidity of NMT 65%, pressure differential of NLT 10Pa and NLT 30 air

changes per hour to ensure containment and prevention of airflow reversal. All classified areas were fitted with calibrated monitoring devices to ensure temperature, relative humidity and differential pressure were within the required limits before and during operations. To ensure efficiency of the system preventive maintenance and requalification was performed as per the procedure in place, records were verified

8. Document Review

The review of documents proved that, the company had a good documentation system as documents were designed, prepared as per the GMP requirements. The same were prepared, approved, signed and dated by appropriate responsible personnel and were distributed with care. During inspection, various documents were reviewed and were found to be in line with the respective SOPs. SOPs were presented at vantage areas in and were properly followed. Records were observed to be up to date; document review was done in timely manner as per the procedure

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 Part 2 and 3, **Hebei Tianyuan Pharmaceutical Co. Ltd** located at **Plot No.34 Changsheng Street, Luquan District, Shijiazhuang City, Hebei Province, China** was considered to be complaint with TMDA Good Manufacturing Practices Guidelines for Veterinary Medicinal Products (2022) **for production of general veterinary medicines in form of liquid injectable (LVP& SVP), oral soluble powder and bolus.**

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. The Tanzania Medicines and Medical Devices (Good Manufacturing Practice Enforcement) Regulation, 2018.
3. Good Manufacturing Practices Guidelines for Veterinary Medicinal Products (2022).
4. TMDA, RIMS 2.0.
5. SMF - Hebei Tianyuan Pharmaceutical Co. Ltd.