TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

PRINCE PHARMACEUTICALS CO. LTD, MWANZA, TANZANIA

PUBLIC GMP INSPECTION REPORT

November, 2022

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Prince Pharmaceuticals Co. Ltd
Corporate address of manufacturer	NA
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Prince Pharmaceuticals Co. Ltd Plot No. 4/1, Buhongwa Industrial Area, P.O BOX 11415, Mwanza
Unit/ block/ workshop number	NA
Inspection details	
Date of inspection	28-29th June, 2022
Type of inspection	Routine GMP inspection
Introduction	
General information about the company and site	Prince Pharmaceuticals Co. Ltd is located in Plot No. 4/1, Buhongwa industrial area which is almost 14KM from Mwanza city off Shinyanga road. The facility is engaged in manufacturing of general internal preparation in form of; Oral dry powder, oral liquid (syrup and suspension) and External preparation in form of; Cream/Ointments, Liniments, lotion and emulsion
History	Prince Pharmaceutical Co. Ltd is a local pharmaceutical industry in Tanzania which 100% owned by local Tanzanians business entrepreneurs The facility was constructed from 2012 and started its operations in March, 2014. The facility is registered by TMDA with a valid business permit This was a routine GMP inspection as scheduled by TMDA in order to oversee the level of compliance with the EAC GMP guideline

Brief report of the activities undertaken	
Areas inspected	External surrounding, Water storage tanks, Effluent treatment plant, scrap yard, sideway warehouse, manufacturing and packaging areas, finished products warehouse, Utilities, quality control laboratory
Restrictions	The inspection focused on the production lines for the products registered in Tanzania
Out of scope	Lines for which application for product registration had not been submitted to TMDA
Production lines inspected by TMDA	Oral liquids dosage form, Oral rehydration salts and External preparations
Abbreviations	**Meaning**
AHU	Air Handling Unit
EAC	East African Community
ETP	Effluent Treatment Plant
FAV	Forced Air Ventilators
GMP	Good Manufacturing Practice
HVAC	Heating Ventilation and Air Conditioning
NEMC	National Environmental Management Council
ORS	Oral Rehydration Salt
RLAF	Reverse Laminar Air Flow
SMF	Site Master File
SOP	Standard Operating Procedure
TMDA	Tanzania Medicines and Medical Devices Authority
WTP	Water Treatment Plant

Part 2: Brief summary of the findings and comments

1. **Personnel**

The facility had a sufficient number of personnel to carry out their assigned duties. Review of organization chat revealed that key personnel namely Quality assurance, Quality control and Production managers were permanently employed and had qualification and experience required for performing their duties.

Quality control and Production personnel were independent from each other in executing their jobs. Training schedule was in place and the selected records for employees confirmed that they were initially trained on GMP principles on recruitment and On Job Trainings were conducted as per training procedure number SOP-QA-014.

Medical examination to employees was conducted during recruitment and once on annual bases as it was shown in the SOP for Medical examination policy No. SOP-HR-003.

2. Premises

The facility had one (1) main manufacturing block and all manufacturing processes were carried out at the ground floor. Raw materials and finished goods warehouses were also located at the ground floor. The first floor was used for quality control laboratory, stability chambers, conference room, offices and service floor for utilities.

i. Layout and Design

The manufacturing block was constructed by concrete and cements blocks plastered to make it smooth and painted with emulsion paint. The production corridor, rooms and quality control areas were partitioned by using clean modular panels for easy cleaning.

The floor, junctions between floors and walls, walls and ceilings were covered with epoxy to facilitate easy cleaning.

Generally, the layout and design of the building permitted unidirectional flow of manufacturing processes with separate entries for personnel and materials.

ii. Sanitation and Hygiene

Personnel involved in the manufacturing activities were found in clean factory uniforms and there were separate entries for personnel and materials. Entries for both personnel and materials were controlled. Cabinets for keeping street gowns and shoes, step over benches and sanitization with Methylated Spirit 70% were provided in change rooms.
All wastes generated in the facility were channeled to the effluent treatment plant for further treatment and disposal and the same was used for gardening.

3. Production

Raw materials were received, de-dusted using vacuum cleaner and weighed using calibrated weighing balance. SOP for receiving raw materials was at the vantage area.
Raw materials, in process and finished products were sampled, tested and released according to procedures.

Separate entries for personnel and materials to production areas were provided. Personnel change rooms were provided with Methylated Spirit 70% for hand sanitization, cross over benches and cupboards for storing street shoes and clothes.

i. **Oral Liquids Dosage Form.**

Floor in the production rooms were epoxy painted, clean and of adequate size. Personnel entered through an airlock with interlocking doors. Mixing tanks which were jacketed stainless steel equipped with propeller were used for mixing materials. Filling and sealing was achieved through an automatic filling and sealing machines respectively and products were visually inspected for presence of any particle as well as volume check.

ii. **Oral Rehydration Salt**

There was an airlock for personnel before entering the powder blending room. Temperature and humidity monitoring devices were observed in production and filling areas. Rooms and equipments cleaning were conducted as per the written procedures.

iii. **External Preparation**

Cream manufacturing room had three (3) tanks for water phase, wax phase and mixing tank and hygienic pump fixed at the bottom of the cream manufacturing tank. The pump was covered to avoid dust accumulation. All the processes and documents were available and well documented.

4. **Quality Control**

Quality control laboratory composed of three (3) sections namely microbiology, wet chemistry, chemical and instrument. Other sections included hot room, chemical storage room and stability chambers. Primary and secondary changing rooms were available prior entering into the Microbiology Section.

The laboratory was equipped with enough equipments, apparatus and personnel to carry out different laboratory activities. Working standards were properly prepared and stored. Reagents and chemicals were well labeled with their opening dates. Protective gears including eye wash and emergency shower were available

The facility had two (2) stability chambers designed to suit zone IVB climatic condition for both real time (30±2°C 75 ± 5% RH) and accelerated (40±2°C 75 ± 5% RH). Products were well arranged and the list of products in the chamber was available.

5. **Equipment**

The facility was equipped with modernized equipments and machines to pursue different functions related to manufacturing and quality control. Equipments were labeled and had logbooks.

Among the available instruments were Mixing tanks, automatic bottle washing machines, automatic filling machine, automatic sealing machine, octagonal blender, vibrio sifter machine, automatic pouch filling machine, HPLC, UV/VIS spectrophotometer, Dissolution apparatus, Disintegration tester, Friability tester, Autoclaves and Reverse laminar.

At the facility equipments were designed to facilitate effective cleaning and to prevent chances of contamination.

6. Purified water System

The source of water used in the facility was from municipal-MWAUWASA and get collected and stored in the HDPE storage tank with capacity of 45,000 Liters and underground storage tanks with capacity of 320,000 liters.

Raw water was transported to the plant and collected into 1000 liters HDPE tank then treated by chlorination, anti-scaled and passed through multimedia filter, carbon filter, 5µ filter, membrane filter and then reverse osmosis system to produce RO water which was then channeled to the EDI system and UV lamp for sterilization to produce purified water which were stored in the 1000 litres SS 316 tank and finally passed through UV before being supplied to user points. Conductivity and PH were monitored through online and offline systems.

Water direction flow arrows, logbook for sanitization of water treatment plant were available and the same was found adequate. There were seven (7) sampling points which were well labeled.

7. Heating, Ventilation and Air Conditioning

The facility had a total of seven (7) Air Handling Units and four (4) Forced Air Ventilators (FAV). Each AHU supplied to dedicated processing area which were coded and labeled with direction of air flow clearly identified.

The system was installed with primary filters (efficiency 90% and 10µ filter) and supplied air through Secondary filters (efficiency 99% and 5µ filter) then finally to terminal HEPA filters placed at the plenum (efficiency 99.997% and 0.3µ filter) to ensure acceptable quality of air in the clean area (class D).

Pressure differential was set to provide positive pressure in the production room relative to the corridor.

Pressure monitoring devices were installed outside of each processing room in the manufacturing areas and across the 10 micron filter and a 5 micron filter for monitoring filter integrity. There was a dedicated area for filter cleaning and procedures for cleaning.

8. **Document Review**
   A number of documents were reviewed which included manufacturing license, quality manual, organization chart, batch manufacturing records, validation master plan, preparation of protocols and reports validation, qualification reports, analytical method validation, cleaning validation.
   Most documents were properly written with sufficient information to allow activities

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, **Prince Pharmaceuticals Co. Ltd Plot No. 4/1, Buhongwa Industrial Area,** P.O BOX 11415, **Mwanza** was considered to be operating at an acceptable level of compliance with East African Community GMP guidelines.

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. 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. Prince Pharmaceutical Co. Ltd GMP Inspection report June, 2022.
4. Prince Pharmaceutical Co. Ltd Corrective Action and Preventive Action report May, 2022
5. Tanzania Medicines and Medical Devices Act, Cap 219.