THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

DAR AL DAWA DEVELOPMENT AND INVESTMENT CO. LTD, JORDAN

PUBLIC GMP INSPECTION REPORT

March, 2025

General information about the company

Manufacturers details	
Name of manufacturer	Dar Al Dawa Development and Investment Co. LTD
Corporate address of manufacturer	Nadur -Prince Hashem Bin Al-hussein Street twenty Kilometers South West of Amman, Jordan Tel: +9626222200 Website: www.dadgroup.com
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	Plant 1, Main Plant, Cephalosporin Plant, Penicillin Plant
Inspection details	
Date of inspection	13th - 14th May 2024
Type of inspection	GMP - Renewal Inspection
Introduction	
General information about the company and site	The facility was located at Nadur- Prince Hashem Bin Al-Hussein Street, 20km south-west of Amman. Dar Al Dawa Development and Investment Co. LTD was established on 1975 by the Jordanian Ministry of Trade and Industry as a Pharmaceutical Public shareholding company with license No. 75.
History	The facility was inspected and complied with GMP requirements and had a valid GMP certificate issued by the Jordan Food and Drug Administration, Certificate number 2/16/ML/3/2023 issued on 12/6/2923 which is

	valid until November 2026. The site was inspected and approved by other NMRAs such as HPRA Ireland in June,2023, Oman MOH 2021, Bahrain 2021, Yemen (Aden) 2022, UAE 2022, Kuwait MOH 2022, FDA - Libya 2023.
Brief report of the activities undertaken	
Areas inspected	Areas inspected include external surroundings, utilities, warehouses manufacturing areas and quality control laboratory. In particular, the following GMP quality elements were covered; ~~areas were inspected:~~ • Qualification and validation • Complaints and recalls handling • Vendor evaluation • Contracts Management • Premises design and layout ~~and hygiene~~ • Sanitation and hygiene • Personnel • Equipment • Production • Quality control • Documentation
Restrictions	
Out of scope	Production lines whose products are neither applied for registration nor registered in the country
Production lines inspected by TMDA	The inspection covered the following production lines; Penicillin a. Cephalosporin solid dosage forms - capsules, tablets and dry powder for suspension b. Sterile and non-sterile topical

	preparations - Eye/nose/ear drops, sprays and medicated shampoo c. General oral suspension d. General semi solid dosage forms - suppositories, cream, ointment and gels e. General solid dosage forms - capsules, pellets, tablets, sachets
Abbreviations	**Meaning**
AHU	Air Handling Unit
cGMP	Current Good Manufacturing Practices
HPLC	High Performance Liquid Chromatograph
HVAC	Heating, ventilation and air conditioning
TMDA	Tanzania Medicines and Medical Devices Authority
QC	Quality control
NMRA	
HPRA	
JD	
RO	

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had adequate number of personnel who were qualified, competent and experienced to carry out all tasks in their respective departments and each was provided by job description in-line with their qualification and position in the organization. Appointment letters and JDs for key personnel were reviewed and found to define responsibilities relevant to each position. The Production and Quality Control heads were independent from each other in executing their duties as supported by the organization chart. Quality Control and Quality Assurance Managers reported to Head of Quality.

Training records were reviewed and showed that, training was conducted as per established program. All new personnel were subjected to pre-job training at the time of joining. On-job training was provided to each department team member at regular interval as per program.

Medical examination was conducted to all staffs at time of joining and periodically thereafter as supported by records. General personal hygiene was observed as noted during inspection; every changing area had crossover bench, locker, pictorial illustration of gowning procedures, hand washing and disinfection facilities. Personnel were observed to follow the gowning procedures.

2. Premises

a. Layout and Design

The facility had four plants namely; plant 1, main plant, cephalosporin plant and penicillin plant. Production of beta-lactam products was performed in dedicated blocks. The premises was designed in a way that it prevents entry of rodents and insects. Arrangement of various rooms allowed for unidirectional flow of materials, process and personnel. The premises was adequately designed to facilitate effective cleaning and maintenance.

b. Sanitation and Hygiene

Cleanliness was maintained in all four manufacturing blocks. Cleaning was done as per procedures and supported by records. Change rooms to facilitate personnel hygiene were provided for all production areas. Minor issue with regards to cleanliness of materials hoist was raised and rectified. Direct contact was avoided between the operators' hands, starting materials, primary packaging materials, intermediate and bulk products.

3. Production

a. Production Line Semisolid line (Ointments, creams and gels) – Plant 1

Production processes were validated. All manufacturing stages such as dispensing of raw materials, mixing of excipients and active ingredient as well as filling were recorded in the BMR. In-process checks were conducted at regular interval whereby for semi-solid preparations, these included tests for pH, appearance and viscosity. Line clearance was conducted and approved by QA prior the start of production. Records in the BMR were made contemporaneously as observed for Nobacin Skin ointment batch number 0055 which was found at the preparation stage.

b. Production Line II Suppository line – Plant 1

This production line was also housed in plant 1. During inspection filling of Diclogesic 12.5mg suppository batch number 8664 was ongoing, appropriate in-process checks to include resistant to rupture (kg), softening time, disintegration time, weight and leak tests were performed at regular interval as per BMR. Records were reviewed and no issue was observed.

c. Production Line III Liquid Production Line - Plant 1

During inspection, filling of desloratadine syrup batch number BN 0130 was ongoing. Before filling, bottles were cleaned by compressed air. Procedures for operation of filling process was reviewed, document for production of these products were maintained in BMR which were verified during the inspection. Tests which were performed after preparation included viscosity rate, PH value and density. In process control test included appearance, filling volume or weight, leak test, torque test and temper evident done after every 1 hour

d. Production Line IV General sterile line (Eye/nose/ear drops) - Plant 1

During inspection, this line was under upgrading and there was no activity, procedure for monitoring temperature and humidity and procedure for cleaning and operating of filter integrity tester was in place.

e. Production Line V Oral Solid Dosage line (Tablets, capsule, dry suspension and sachet powder) – Main plant 1

Cephalosporin production was in separate block. During inspection the ongoing activity was filling. There was online dedusting, capacity of filling machine per hour was 25,000 capsules. Filling machine had 16 filling nozzles. Records for temperature and humidity were available and reviewed

4. Quality Control

The facility had two quality control laboratories for cephalosporin and for other products. Laboratories were equipped with qualified and calibrated instruments and equipment for testing samples of raw materials, finished products, water and environmental monitoring. There were also calibrated stability chambers for performing real time and stability studies as per program, records were verified and no issue was observed. Retained samples were stored in the retained sample room where environmental conditions were monitored.

5. Equipment

Equipment was qualified as supported by the performance Qualification report for coating machine. Requalification was performed at regular intervals as per established procedures and criteria. Measuring, weighing, recording instruments were serviced and calibrated at pre-specified intervals and records maintained. To ensure satisfactory functioning, critical instruments such as weighing balances were checked daily or before use. Maintenance of equipment were done periodically as per schedule and records maintained.

6. Purified water System

Municipal water was used as source water which was stored in the 350m^3 concrete underground reservoir. Water was purified through a series of treatment to include sand filter to remove the suspended solids, chlorination for disinfection, RO then collected to the PW water tank. Water was monitored for pH and conductivity on daily basis. Sanitization of WTP including PW storage tank and distribution loop were performed as per procedure. Annual water review was conducted and records maintained.

7. Heating, Ventilation and Air Conditioning

The facility had a total of 35 AHUs supplying to various areas in four plants. All air ducts were labelled for identification, Magnehelic gauges were provided for controlling pressure differentials in production areas and the same were functioning properly. Calibrated temperature and pressure monitoring devices were also provided in the facility. Preventive maintenance of AHUs, calibration of temperature and humidity sensors, pressure gauge transmitter and filter check were conducted as per schedule and supported by records.

8. Document Review

Documents were dated and signed by the appropriate personnel as per GMP requirements. Documents were reviewed and found prepared, authorized and distributed to vantage areas. They were properly adhered to and records were maintained.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection and assessment of compliance report, **Dar Al Dawa Development and Investment Co. LTD. Located at Nadur- Prince Hashem Bin Al-Hussein Street twenty Kilometers south west of Amman, Jordan,** was considered to be operating at an **acceptable** level of compliance with TMDA GMP Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition 2023 for the production of **Cephalosporin product solid dosage form** "capsules, tablets and dry suspension", **General sterile product in form of** (eye, nose & ear drops), semi-solid (Ointment, cream, suppository and gel) and **liquid dosage form** (topical spray solution, syrup, suspension and medicated shampoo), **General solid dosage form** "capsules, tablets and dry suspension".
This TRIP 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. Dar Al Dawa Development and Investment Co. LTD GMP Inspection report
2. TMDA, (2023), Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition 2023
3. GMP Inspection Report forms No. TMDA/DMC/MCIE/F/036 Rev #: 02
4. Dossiers
5. TMDA, (2019) Tanzania Medicines and Medical Devices Act, Cap 219
6. Dar Al Dawa Development and Investment Co. LTD SMF CM87001 Version 6 2024
7. TMDA (2018) Good Manufacturing Practices Enforcement Regulations, GN 295
8. TMDA SOP for conducting the inspection of pharmaceutical manufacturing facilities; TMDA/DMC/MCIE/SOP/008, effective date April 2022.
9. TMDA RIMS 2.0