THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TMDA

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GULF PHARMACEUTICALS INDUSTRIES- JULPHAR, RAS AL KHAIMAH, U.A.E

PUBLIC GMP INSPECTION REPORT

MARCH, 2025

General information about the company

Manufacturers details	
Name of manufacturer	Gulf Pharmaceutical Industries- JULPHAR
Corporate address of manufacturer	Same as below
Inspected site	
Name & address of inspected manufacturing site if different from that given above	P. O. Box 997, Airport road, Digdaga street, RAS AL KHAIMAH U.A. E
Unit/ block/ workshop number	Julphar I, Julphar IX, Julphar VI, Julphar X
Inspection details	
Date of inspection	11th , 12th & 13th December, 2024
Type of inspection	GMP Renewal Inspection
Introduction	
General information about the company and site	The facility was engaged in the manufacturing of • General pharmaceutical products in the form of solid dosage forms: tablets, capsules & powder for suspension; • Penicillin & Cephalosporins tablets, capsules & powder for suspension; • General injectables: liquid injection (ampoules & vials) and lyophilized vials; • Cephalosporins dry powder for injection; • General oral Liquid: syrup, suspension and drops, • Externals: creams, ointment and suppositories, • Recombinant injectables: Human Insulin & Erythropoietin
History	Gulf Pharmaceuticals Industries 'Julphar' was initially established in 1980 and licensed to

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History	Gulf Pharmaceuticals Industries 'Julphar' was initially established in 1980 and licensed to

	manufacture different pharmaceutical product dosage forms. The facility has 10 production units/blocks located on the same site which were progressively developed at different time intervals. Julphar had valid manufacturing license issued by the United Arab Emirates Ministry of health and Prevention (MOHAP) for Julphar (J) JI, JII, JIII, JIV, JV, JVI, JVII, JVIII, JIX, JX. The facility had been inspected by Ministry of health and Prevention for renewal of permit.
Brief report of the activities undertaken	
Areas inspected	Areas inspected included the external surroundings, raw materials warehouse, manufacturing and packaging areas, Quality control laboratory and utilities (Water Treatment Plant, HVAC system) and finished goods warehouses.
Restrictions	None
Out of scope	Production lines that had no products applied for market authorization
Production lines inspected by TMDA	• General Oral solid line (Tablets and Liquids) • Beta lactam sterile products (powder for injection) • Oral liquid dosage form (Syrup, suspension and drops) and; • Semi solids external preparations line (creams, Ointment and suppositories)
Abbreviations	**Meaning**
HVAC System	Heating, Ventilation and Air Conditioning System
SOP	Standard Operating Procedures
SS	Stainless Steel
AHUs	Air Handling Units
WFI	Water for Injection

Part 2: Brief summary of the findings and comments

1. Personnel

   The facility had the sufficient number of qualified and experienced personnel to carry out activities at the site. Review of qualifications of key personnel along with those stationed at key areas was performed during inspection. Documents such as appointment letters and job descriptions for key personnel were reviewed. Medical examination was carried out every year and pre-employment. Training was provided to all employees as per SOP in place.

2. Premises
   a. Layout and Design

   The facility was located, designed, constructed, adopted and maintained to suit the operations carried out. Interior surfaces (walls and floors) of storage and production areas were constructed with suitable materials that permit effective cleaning and sanitation. The layout of the facility allowed for the maintenance of major components from the service corridors. The entire manufacturing and warehouse areas of all blocks were designed for ventilation and filtered air was supplied through air handling units installed. All areas were provided with adequate working space for working and logical placement of equipment and materials to avoid mix ups and cross contamination. The buildings were provided with change rooms with proper gowning instructions.

   b. Sanitation and Hygiene

   There were written procedures for cleaning of manufacturing areas and equipment. All areas were cleaned daily as per respective SOP. During inspection, cleaning validation protocols and reports were reviewed and found satisfactory. All workers used appropriate gowns based on level of cleanliness of respective areas.

3. Production

   The facility produced general formulations in form of Oral Solid dosage forms (tablets, capsules and powder for suspension- Julphar I), syrup, suspension, solution and drops (Julphar VI) and Semi solids (creams, ointments, gel and

suppositories-Julphar X); Cephalosporin in form of sterile powder for injection (Julphar IX). All manufacturing processes were performed and recorded according to the instructions in the batch production records.

a. General Oral solid dosage forms (Tablets and Capsules) – Julphar I

The block was dedicated for manufacturing of Oral Solid dosage form. Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production. In process Quality control (IPQC) was conducted and parameters monitored were recorded.

b. General Liquid (syrup, suspension and drops)- Julphar VI

This block was dedicated for production of syrup, suspension and oral drops. Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production.

c. General Creams, Ointments and Suppositories- Unit X

Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production.

d. Powder for Injection (Cephalosporin) -Unit IX

Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production.

Generally, in all production blocks measures to prevent cross contamination and mix ups were in place and use of status labelling of materials and products, use of validated clean procedures, use of segregated production cubicles, positive pressure was maintained in corridors with respect to manufacturing cubicles, monitoring of pressure differentials, temperature and relative humidity, use of primary, secondary and tertiary gowning procedures before going to production areas, instituting campaign manufacturing, use of sealed double polyethylene bags and HDPE containers for storage of dispensed and in process materials with proper labelling and identification, use of dedicated sampling and dispensing booth for APIs, excipients and packaging materials, proper segregation of packaging lines and performing

line clearance before starting manufacturing and packaging operations were in place. Samples were received, registered, and distributed to analysts through the Laboratory Information Management System (LIMS). Testing was conducted as per the specifications using validated analytical procedures

4. Quality Control

Raw materials, packaging materials, in process, finished products and stability samples were tested in the laboratory. Testing was conducted as per the specifications using validated analytical procedures. The laboratory was equipped with adequate equipment for carrying out relevant tests for all products. A list of materials used as reference standards was prepared. Most of the reference solutions were prepared within the facility and evaluated against the Pharmacopoeia primary reference standards (USP, BP). Primary and Working standards were stored in refrigerator where temperature was monitored. All raw data obtained from various analyses were recorded in the approved analytical work report which were then transferred to an electronic software maintained by the facility for the generation of certificate of analysis. Class A glass wares were used in preparations of different solutions and reagents. Reagents, prepared test and volumetric solutions were handled and labelled according to written procedures.

5. Equipment

Critical manufacturing equipment were qualified, the measuring devices calibrated in accordance with Validation Master Plan. There was adequate number of equipment each with a unique identification number which were orderly placed in all production areas. Access control, alarm system and audit trail of each equipment was reviewed. Equipment cleaning was performed as per SOPs. Production equipment were maintained inhouse by qualified maintenance staff as per preventive maintenance schedule.

6. Purified water System

There was adequate number of Water Treatment plants to serve all production blocks. The source of raw water was Municipal supply. Raw water was treated to generate portable water and then passed through reverse osmosis system and finally through deionizer. The purification system was also comprised of UV lights whereby light intensity was monitored and recorded. The generated purified water was stored in SS316L storage tanks and distributed through SS pipes under UV sterilization and continuous loop system circulation at a temperature of NMT 25°C.Sampling points were

identified/labelled. The system was cleaned, sanitized and maintained as per schedule and records were verified. The system had real time monitoring devices for pressure, flow rate, conductivity and TOC readings. Moreover, the system was validated and proved to consistently produce water of desired specifications.

The purified water served as raw water for preparation of Water for injection produced by passing through multicolumn distillation units. The prepared WFI was stored in SS 316L tanks at a temperature above 80°C and supplied in closed circulation loop. Conductivity, TOC, temperature and flowrate were monitored at the return loop and recorded on the control panel. WFI distribution system was sterilized by pure steam and super-heated water at 121^{0}C as described in the SOP. Pure steam was generated from purified water and its quality was the same as WFI.

Water was continuously checked for total microbial count according to the procedure and established sampling plan in place as evidenced in the reviewed daily analytical results for return loop, monthly and annual water quality trend analytical results.

7. Heating, Ventilation and Air Conditioning

Each production block had a dedicated HVAC system which were qualified. Installed AHUs were capable of supplying filtered air into various manufacturing rooms and laboratory. AHU's were clearly labelled to indicate the supplied rooms and direction of airflow. The HVAC systems were designed to suit the area supplied. Maintenance and servicing of AHUs were done by full-time employed and qualified persons according to SOP. Magnehelic pressure gauges were installed across filters of AHUs to measure pressure differential and assurance of filter integrity.

8. Document Review

The facility had Standard Operating Procedures for all activities performed. Various documents were prepared, authorized and distributed for use as per the mother SOP. Various records were produced and maintained as per SOP. During inspection, several documents were reviewed including records and were found to be appropriately prepared, maintained and stored in accordance to the SOP.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection, **Gulf Pharmaceutical Industries – Julphar** located at **Airport road, Digdaga street, RAS AL KHAIMAH U.A.E** was considered to be operating at **an acceptable** level of compliance with TMDA GMP Guidelines for Human Medicines for the production of **General solid dosage form products (tablets & capsules) manufactured in Julphar I, General oral liquid dosage products (syrup, suspension & drops) manufactured in Julphar VI and General semi-solids external products (cream, ointment & suppositories) manufactured in Julphar X and Beta Lactam (Cephalosporin) sterile products (powder for injection) manufactured in Julphar IX.**

This TPIR will remain valid for three (3) years provided that the facility will remain compliant following any inspections conducted in the period.

Part 4: References

1. TMDA (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition, Dodoma, Tanzania

2. Site Master File No.SMF-01

3. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania

4. Tanzania Medicines and Medical Devices Act, Cap 219.

5. TMDA, Good Manufacturing Practices Enforcement Regulations (2018), Tanzania Medicines and Medical Devices, Dar-es-Salaam, Tanzania