THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TMDA

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GLENMARK PHARMACEUTICALS LTD, BADDI, DISTRICT SOLAN, HIMACHAL PRADESH, INDIA

PUBLIC GMP INSPECTION REPORT

MARCH, 2025

General information about the company

Manufacturers details	
Name of manufacturer	Glenmark Pharmaceuticals Ltd
Corporate address of manufacturer	Same as below
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Village Kishanpura, Baddi -Nalagarh, Tehsil Baddi, District Solan, (H.P.) -1, 173205, India
Unit/ block/ workshop number	Unit I
Inspection details	
Date of inspection	23rd & 24th September, 2024
Type of inspection	GMP Renewal Inspection
Introduction	
General information about the company and site	The company was engaged in manufacturing, packaging, and quality control of: - • General Formulations in form of Oral Dosage Forms (Tablets and Capsules) • General formulations in form of Oral Liquids in form of syrups and suspension • General External Preparations (creams, ointment and lotion)
History	Glenmark Pharmaceuticals Limited was involved in Research and Development, manufacture and marketing of pharmaceutical products since 1977. The facility was set up in 2005 and commissioned in 2006 for production of General Oral solid dosage forms (OSD) in form of tablets, capsules, liquids and semi-solid dosage form (Creams, Ointments and Lotions) at Unit 3 intended for different markets. The facility had a valid

	manufacturing license/permit and GMP certificate issued by State Drugs Controller, Controlling cum Licensing Authority, Baddi, Solan.
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, Compressed air and Effluent Treatment Plant) 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) and; • External preparations line (creams, lotions and Ointments)
Abbreviations	**Meaning**
HVAC System	Heating, Ventilation and Air Conditioning System
SOP	Standard Operating Procedures
SS	Stainless Steel
AHUs	Air Handling Units

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. A review of the qualifications of key personnel along with those stationed at key areas was performed during the 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 us 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), liquid and semi-solid dosage forms (creams, ointments and Lotions). All manufacturing processes were performed and recorded according to the instructions in the batch production records.

a. Production of External Preparations

The block was dedicated for the manufacturing of Semi 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. Production of Oral Solid dosage form (tablets and capsules)

This block was dedicated for production of oral solid dosage in form of tablets and capsules. Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production and records were maintained.

c. Production of syrup

The production of the liquid dosage form was done at different floors. 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 was maintained inhouse by qualified maintenance staff as per preventive maintenance schedule.

6. Purified water System

There was separate Water Treatment plant for each block. The source of raw water was bore well. Raw water was treated to generate portable water and then to double pass reverse osmosis system. The purification system was also comprised of UV lights whereby light intensity was monitored and recorded. Th e 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 above 80°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.

7. Heating, Ventilation and Air Conditioning.

   Each production block had 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, **Glenmark Pharmaceuticals Limited, Village Kishanpura, Baddi-Nalagarh Road, Tehsil, Baddi, District: Solan, 173 205, Himachal Pradesh, India** was considered to be operating at **an acceptable** level of compliance with TMDA GMP Guidelines for Human Medicines for the production of **General Oral Dosage Forms (tablets and Liquids) and External Preparations (Creams, Lotions and Ointments).**

This report shall be invalid if the forms and operations herewith are changed or if the site is no longer considered to in compliance with current GMP requirements.

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-01-29.

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