THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GMH ORGANIC, UNIT II, INDIA
PUBLIC GMP INSPECTION REPORT

March, 2025

General information about the company

Manufacturers details	
Name of manufacturer	GMH Organic- Unit II
Corporate address of manufacturer	Plot No. 1, Village Kunjhal, Jharmajri, Baddi, Distt. Solan, Himachal Pradesh, India Tell: +91-6398745451 Emai: narinder@gmh.co.in www.gmh.co.in
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	Unit II
Inspection details	
Date of inspection	2nd – 3rd May, 2024
Type of inspection	Pre-registration inspection
Introduction	
General information about the company and site	The company, GMH Organic plant Unit II was commissioned in April, 2022. The company was exclusively dedicated for manufacturing of Cephalosporin dry powder for injection. It had a valid manufacturing license no. MB/21/1157 (Form No. 28) dated 13th

	October, 2021 issued by the Drugs Licensing and Controlling Authority, Baddi Distt. Solan, Himachal Pradesh India for manufacturing of Cephalosporin products in form of dry powder for injection.
History	The facility had valid GMP certificate no. HFW-H(DRUGS) 88/21 issued by Health and Family Welfare Department, Himachal Pradesh, India. The facility was also inspected and approved by other national authority such as EU-GMP (February, 2023), PPB-Kenya (March, 2023), NDA-Uganda (March, 2023), EFDA-Ethiopia (July, 2023), SFDA-Saudia Arabia (October, 2023) and MOH-Uzbekistan (January, 2024).
Brief report of the activities undertaken	
Areas inspected	Areas inspected include external surroundings, utilities, receiving and storage areas for raw materials, raw materials receiving area and finished products, production areas, quality control laboratory and documents review
Restrictions	None
Out of scope	Production lines for the products which have not been registered or applied for registration in Tanzania
Production lines inspected by TMDA	Production line for cephalosporin dry powder for injection
Abbreviations	**Meaning**

GMP	Good Manufacturing Practices
EU	European Union
NDA	National Drug Authority
TMDA	Tanzania Medicines and Medical Devices Authority
QC	Quality control
QA	Quality Assurance
LAF	Laminar
API	Active Pharmaceutical Ingredients
RO	Raw Water
UV	Ultraviolet
WFI	Water for injection
WTP	Water Treatment Plant
PW	Pure Water
AHU	Air Handling Unit
HVAC	Heating, ventilation and air conditioning

Part 2: Brief summary of the findings and comments

1. Personnel

The company had sufficient number of qualified and experienced personnels. The organization chart of the facility highlighted various positions and their responsibilities well described in job descriptions. Key positions in production, quality assurance and quality control were occupied by full time employees as revealed in their appointment letters. The heads of production and quality control were totally independent from each other. Batch release was clearly assigned to the head of quality assurance/his designee and the same was evidenced in the job description.

Review of the records for Trainings revealed that all staff were undergoing training as per respective areas of work. Training schedule and records for 2024 were availed and accepted.

Employees were medically checked on recruitment and then once annually. Tests performed were clearly defined in the procedure and visual tests were conducted to personnel involved in visual inspection activities.

2. Premises

a. Layout and Design

The facility was located, designed, constructed, adapted and maintained to suit the manufacturing operations carried out. There was one main production block which was constructed with RCC. Walls and ceiling in processing areas were provided with modular partition for easy cleaning. Covings were provided between ceiling-wall, wall-wall and wall to floor. Interlock doors were provided for entrance in the manufacturing areas. Electrical fittings were well concealed.

Rooms were arranged so as to allow for logical flow of production activities, a materials and personnel in unidirectional flow.

b. Sanitation and Hygiene

The facility was positioned in an environment that presents minimum risks of causing contamination of materials as well as products. The surrounding was observed to be good state and well maintained. Cleaning status labels were affixed to equipment, machines and production rooms accordingly. The facility was also designed and equipped to ensure maximum protection against the entry of insects and pests.

Procedures for personnel hygiene and clothing was in place. Separate primary change room were provided for male and female. Secondary and tertiary gowning with provision of sterile gowns was provided for personnel entering core manufacturing areas and microbiology laboratory.

3. Production

a. Production Line for Cephalosporin Dry Powder for Injection

Sampling and dispensing of raw materials were performed as per procedures. Line clearance was performed before any manufacturing/packing process begin and status labels were affixed on equipment and rooms. Production line was well equipped with GMP model types of equipment. The equipment's were well designed, installed, located and maintained to suit the operations carried on and permit for effective cleaning. Equipment qualification records availed and verified during inspection. Calibration and preventive maintenance labels were also stacked on all equipment

including weighing balances. Equipment SOPs, logbooks, maintenance and cleaning records were availed and found well maintained.

Manufacturing was done as per validated process and each stage contemporaneously recorded in the BMR. Critical process parameters and were monitored throughout the process as verified for Moncef (Ceftriaxone Sodium) 1 G injection which was found under filling and packing process during inspection. In-process quality control checks such as average weight, uniformity of weight, reconstitution, leak test, label coding, carton and shipper weight, were done as per BMR/BPR.

4. Quality Control

The QC laboratory had procedure for inward, outward, analysis and release of RM, PM, FG and stability samples. After receipt, samples were verified against accompanied documents and entered into respective sample register. Securely storage area was provided in the QC lab. Test request was review and samples was assigned to qualified analyst. Analysis were performed using validated methods as verified in the reviewed validation reports. Working standards were prepared in the lab and qualified against pharmacopeial refence standards supported by the records. All reference standards were well managed and stored in the refrigerator at 2 – 8°C. Current controlled specification in-line with the compendial requirements were used at the facility.

Retained sample were transferred to respective area and details entered into control sample inward register and arranged accordingly on the racks. Retained samples were kept for one year after expiry. Controlled samples were checked for physical parameters after every six months. Stability samples were also entered in the respective register and charged in the stability chamber as per stability program

5. Equipment

The equipment was well designed, installed, located and maintained to suit the operations carried on and permit for effective cleaning. Equipment qualification records availed and verified during inspection. Calibration and preventive maintenance labels were also stacked on all equipment including weighing balances. Equipment SOPs, logbooks, maintenance and cleaning records were availed and found well maintained

Preventive maintenance and calibration schedule was prepared annually. Preventive maintenance for critical manufacturing and quality control equipment/instrument were performed quarterly.

6. Purified water System

The facility had water treatment system which was suitably designed, maintained, calibrated and monitored. The system was designed to produce 10m3/hr and had two treatment stages (pretreatment and purification). Borewell was a source of water collected in underground tank of 100KL capacity.

Pretreatment phase starts with an online Sodium hypochlorite dosing before raw water being feed into storage tanks of 10KL capacity. Then raw water was pumped through multigrade filter and softener. Online dosing with antiscalant, NaOH and SMBS and soft water collected into RO feed tank of 0.5KL capacity and also supply into cooling tower, chiller, micro lab, production autoclave and boiler.

Purification phase included soft water passing through cartilage filter 5µ, 1st RO, 2nd RO, EDI and finally generated PW which was collected in SS tank of 3KL capacity. PW was stored at ambient temp (15-24°C) and in a continuous loop system. PW pass through UV before distribution to user points.

Sanitization of water storage tanks and loop system in PW line was done quarterly at a temperature above 85°C for 30 minutes whereas in WFI system was performed once in a month at temperature of 121°C for 30minutes. WFI and PW system were kept in a continuously circulation at temperature above 80°C and ambient (NMT 25°C) respectively. CIP/SIP were applied during cleaning and sterilization of the WTP system. Parameters such as TOC, pH and conductivity were monitored online and verified.

7. Heating, Ventilation and Air Conditioning

The HVAC was designed, installed, qualified, maintained and operated to ensure suitable manufacturing conditions as well as working conditions for operators. All critical processing areas were supplied with dedicated AHUs. Temperature was set at NMT 25°C whereas in blending & filling rooms relative humidity was maintained at NMT 30%.

Schematic diagram displayed on AHU and physical inspection conducted revealed that fresh air entered AHU where it passed through filter (10µ), cooling coil, heating coil, blower, 5µ and finally through terminally located HEPA filters 0.3 µ (99.997%). HEPA filters were located in core processing area, sterility room, manufacturing supporting area. Pressure differential was suitably maintained at 5-20Pa between adjacent area to prevent cross contamination. All AHUs were of recirculation type supplied with 10% fresh air and 90% recirculated return air that passes through filters installed in the return risers. The AHU was designed and qualified to provide NLT 90 air changes per hour in grade B area. Preventive maintenance was performed at regular interval as per procedure.

8. Document Review

Documents were designed, prepared signed and dated by the appropriate responsible persons as per GMP requirements. They were properly adhered 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, **GMH Organic-Unit II** located **at Plot No. 1, Village-Kunjhal, Jharmajri, Baddi, Distt. Solan, Himachal Pradesh, India** was considered to be operating at **an acceptable level** of compliance with TMDA Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities; 1st Edition, April, 2023 for production of Cephalosporins type of formulation in form of Sterile Dry powder for injection.

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.Gmp Inspection Report, GMH Organic. Unit II, Jharmajri, Baddi, Distt. Solan, Himachal Pradesh- 173205, India

2.Tanzania Medicines and Medical Devices Act, Cap 219

3.The Tanzania Medicines and Medical Devices (Good Manufacturing Practice Enforcement) Regulation, 2018

4.The Tanzania Medicines and Medical Devices Authority Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities; 1st edition, April 2023,

5.TMDA Good manufacturing practices SOPs, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania.

6.Site Master File Document no GMH/SMF-01 effective 2/06/June, 2022