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REV.#. 01



THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

MEDREICH LIMITED UNIT VII, BANGALORE - INDIA
PUBLIC GMP INSPECTION REPORT

Date: March, 2025



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General information about the company

Manufacturers details	
Name of manufacturer	MEDREICH LIMITED UNIT VII
Corporate address of manufacturer	Sy. No. 11-15, Poojaramanahalli Village, Hosakote, Taluk, Bangalore, Karnataka
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	Unit VII
Inspection details	
Date of inspection	21 st - 22 nd October, 2024
Type of inspection	Renewal GMP Inspection
Introduction	
General information about the company and site	<p>Medreich Limited is a pharmaceutical company which has been 100% acquired by Meiji Seika Pharma Co. Ltd, Japan, and is its subsidiary since February, 2015. Medreich Unit VII was located at Sy No.11, 12, 13, 14 and 15 Poojaramanahalli Village, Bangalore Rural Dist-562114.</p> <p>Medreich Unit-VII site was licensed to manufacture tablets, sachets, and hard gelatin capsules under the terms of its manufacturing license issued by drugs control Department of Karnataka, India.</p>
History	The manufacturing site was also inspected and approved by other NMRA including FDA (Ghana), MHRA (UK), TGA (Australia), PMDA (Japan) and ANVISA (Brazil).

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	This was a renewal GMP inspection to verify the compliance with GMP requirements after the previous TMDA Inspection which was conducted in December, 2018 whereby the facility complied with the TMDA GMP requirements.
Brief report of the activities undertaken	
Areas inspected	External surroundings, Raw material receiving area, Raw material and Packaging materials warehouses, Production areas, Packing area, Finished goods store, quality control laboratory and utilities
Restrictions	The inspection focused on production lines for products registered in Tanzania
Out of scope	Production lines whose products have not been applied for registration in Tanzania
Production lines inspected by TMDA	General Oral Solids in form of tablets, sachets, and hard gelatin capsules
Abbreviations	Meaning
AHU	Air Handling Unit
ASRS	Automated Storage and Retrieval System
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Air
HVAC	Heating Ventilation and Air Conditioning
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
TMDA	Tanzania Medicines and Medical Devices Authority



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Part 2: Brief summary of the findings and comments

1. Personnel

The facility had adequate number of qualified and experienced personnel in different operational activities. Delegation of responsibilities for QC, QA and production were clearly indicated on their job description. All key personnel posts were occupied by full time, qualified and experienced personnel and they were independent in fulfilling their responsibilities.

The facility had a procedure for training of personnel, training schedule and respective training records. Trainings which were conducted include induction and periodic trainings. Medical checkup for new employees and annual checkup for all working employees was conducted as per the facility medical checkup procedure.

2. Premises

a. Layout and Design

The premises were designed and constructed to meet unidirectional flow of material to avoid cross contamination. 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 up and cross contamination. The buildings were provided with change rooms with proper gowning instructions.

b. Sanitation and Hygiene

High levels of sanitation and hygiene were generally observed in all areas, including the surroundings. Change rooms with adequate size were provided for both gender, each equipped with appropriate cabinets for storage of clothing and factory gowns. The procedures for entry and exit in different production areas were also in place, including adequate gowning and de-gowning procedures supported with pictorial presentation.



SOP for cleaning and its validation was verified whereas, the cleaning protocol and relevant records were checked and found to be updated and properly maintained.

3. Production

The facility was dedicated for manufacturing of General products (oral solid dosage forms) in form of tablets, capsules and sachets. Manufacturing processes were initiated in accordance with instructions in the BMR. Critical process parameters and critical quality attributes were monitored during production

There was a Standard Operating Procedure (SOP) for receiving of materials and list of qualified vendors at the vantage area. All incoming materials were generally controlled (quarantined, sampled, tested, released or rejected).

Raw and packaging materials were received, examined, de-dusted and stored in quarantine area. Sampling was done in designated area using clean equipment in and appropriate sampling technique to avoid contaminating the anticipated product. The materials were tested under QC department before being released to the production area.

The production areas were designed to fit the operations carried out while facilitating effective cleaning and maintenance to avoid cross-contamination and buildup of dust or dirt. Qualification and validation of equipment, manufacturing processes and quality control testing methods were generally performed. Personnel were instructed to carry out procedures as directed by the specific operating SOPs, and this was verified in the records made during manufacturing process.

4. Quality Control

The facility had Quality Control laboratory responsible for testing of raw materials, packaging materials and finished products against documented pharmacopeia or in-house specifications using validated analytical procedures. The laboratory was using Quality Laboratory Management System (QLMS) software integrated with the SAP system.

The microbiology laboratory was responsible for conducting environmental monitoring, finished products/ raw material testing and water testing. Quality Control Laboratory (QC) was designed and equipped with facilities for chemical, instrumental and microbiological testing. All of the instruments and equipment used in the quality



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control laboratories were periodically calibrated and labeled with calibration status labels.

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

The facility had sufficient and required number of production equipment and machines which were designed, located, installed, qualified and maintained to suit the operations carried out. The design facilitated effective cleaning and avoidance of recess to prevent chances of contamination and cross contamination. Equipment cleaning was performed as per SOPs. Production equipment were maintained inhouse by qualified maintenance staff as per preventive maintenance schedule.

Equipment log books, SOPs, calibration records and qualification reports were verified and found to be acceptable.

6. Purified water System

The source of raw water was bore well. Raw water was treated to generate portable water and then passed through Chemical Sanitization Reverse Osmosis (CSRO) Ozonization, UV, Heat Sanitization Reverse Osmosis (HSRO), EDI to produce Purified Water (PW). 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 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.

Generally, water treatment system was properly functioning, suitably designed, maintained and monitored.



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7. Heating, Ventilation and Air Conditioning

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. All AHUs were qualified and properly maintained.

8. Document Review

The facility had Standard Operating Procedures for all activities performed. Various documents were prepared, reviewed, 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, including the observations listed in Part 2 and 3 above **Medreich Limited Unit VII** located at **Sy. No. 11-15, Poojaramanahalli Village, Hosakote, Taluk, Bangalore Rural District, Karnataka, India** was considered to be operating at an acceptable level of compliance with TMDA GMP Guidelines for Human Medicines for the production of general pharmaceutical formulations in the form of oral solid dosage forms (tablets and capsules).

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.



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Part 4: References

1. TMDA, (2003)., Tanzania Medicines and Medical Devices Act, Cap 219.
2. TMDA (2023)., Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition, Dodoma, Dar es Salaam
3. TMDA (2018)., Tanzania Medicines and Medical Devices (Good Manufacturing Practices Enforcement) Regulations GN No. 295.
4. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority Dar-es-Salaam, Tanzania.
5. Medreich Unit VII- Site Master File with number U7-SMF-156
6. Previous TMDA GMP Inspection for Medreich Unit VII
7. WHO Technical Report Series (WHO TRS)