TMDA/DMC/MCIE/F/001

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

MEDREICH LIMITED, UNIT 8, BANGALORE, INDIA

PUBLIC GMP INSPECTION REPORT

10th December, 2020

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Medreich Limited – Unit 8, India
Corporate address of manufacturer	Medreich House (Corporate office) 12/8, Saraswithi Ammal Street, Maruthi Seva Nagar, Bangalore -500 033, India
Inspected site	
Name & address of inspected manufacturing site	Medreich Limited – Unit 8 Survey No. 14 &15, Gundarahali Village Sulibele Hobli, Hoskote Taluk, Bangalore Rural Dist – 562 114 Karnataka India.
Unit/ block/ workshop number	Unit 8
Inspection details	
Date of inspection	8th – 10th December, 2018
Type of inspection	Pre- Registration Inspection
Introduction	
General information about the company and site	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 8 is located at survey No. 14 & 15, Gundarahali Village Sulibele, Hobli Bangalore. Unit 8 is dedicated for manufacturing of Beta Lactam formulations in form of Oral Solid Dosage hard-shell gelatin capsules, tablets and dry powder for syrups and suspensions. Medreich Unit 8 was issued manufacturing license No. KTK/28/418/2014 by Drug Controller for the State Government of Karnataka, India. The license was valid up to 27th July, 2019.
History	Medreich Unit 8 was also inspected and approved by other NMRA including FDA (Ghana), PPB (Kenya), NAFDAC Nigeria, MHRA (UK) and TGA Australia

	This was the first GMP inspection conducted by TMDA to verify compliance to cGMP requirements following the application for registration of their products in Tanzania.
Brief report of the activities undertaken	
Areas inspected	The inspection covered all the sections of the WHO GMP text, including quality assurance, sanitization and hygiene, complaints and recalls, self-inspection, personnel, training, personal hygiene, premises and equipment, materials, documentation, qualification and validation, production, quality control and utilities.
Restrictions	None
Out of scope	None
Production lines inspected by TMDA	Manufacturing line for beta lactam oral solid dosage forms i.e., tablets, capsules and dry powder for syrup and suspension.
Abbreviations	**Meaning**
AHU	Air Handling Unit
CAPA	Corrective and Preventive Action
EAC	East African Community
GMP	Good Manufacturing Practices
HVAC	Heating, Ventilation and Air Conditioning
IPQC	In Process Quality Control
QA	Quality Assurance
QC	Quality Control
QLMS	Quality Laboratory Management System
SOP	Standard Operating Procedures
RLAF	Reverse Laminar Air Flow
VMP	Validation Master Plan

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had sufficient number of qualified and experienced personnel to carry out the tasks of production and quality assurance. Key posts for technical personnel were occupied by full time, qualified and experienced individuals with responsibilities fully defined in their job descriptions. Heads of Production and Quality Control and their subsequent sections were independent of each other as indicated on the company organization chart.

GMP training programs and schedules were as per facility SOPs, as evidenced in the training records for employees availed. Medical checkups were conducted both, during initial employment and as a routine procedure.

2. Premises

Layout and Design
The facility had one main block with three floors suited for production, quality control and administrative proceedings.

Interior surfaces (walls and floors) of storage and production areas were constructed with suitable materials that permit effective cleaning and sanitation. The production areas were made of smooth epoxy painted floors with coved corners. Electrical supply, lighting, temperature, humidity and ventilation were verified and found appropriate for manufacture, functioning of equipment and storage of materials and finished products.

Adequate and spacious warehouses were provided with separate storage areas for quarantine, under test, approved, and rejected materials. The layout was designed to provide adequate space for logical flow of materials and segregated movement of personnel working in the production areas.

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 sexes, 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, as 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

Raw and packaging materials were received in the main warehouse, and following approval, stored in their designated storage areas. The production areas had their own sampling and dispensing rooms, each provided with separate entry for man and materials, and operated under RLAF that was adequately maintained.

The manufacturing block had a sub-store where approved material was taken before production and its own IPQC room. Manufacturing processes were generally defined and reviewed to match the process flow chart for raw materials, packaging materials and production. The manufacturing process was traced and verified to follow unidirectional flow of manufacturing activities. 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 manufacture.

4. Quality Control

The QC laboratory was divided into sections; chemical analysis, instrumentation, microbiology section, stability room and controlled sample room, all of which were handled by qualified and competent personnel. The lab was equipped and designed to suit all operations conducted, i.e., testing of raw materials, packaging materials, in-process and finished products. Instruments and equipment's were calibrated and qualified according to written procedures, whereas tests and records for such process were maintained as per SOP to ensure consistency in quality of operations conducted. Analytical methods were validated and records were maintained, as evidenced by ease in traceability in the QLMS installed software.

The microbiology laboratory was designed in a manner that suffices GMP requirements, with adequate equipment, machines and reserved sample rooms. Procedures and records for various tests, including water monitoring and sampling were traced and reviewed.

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

6. Water Treatment Plant

The water treatment plant was sufficient, in terms of guaranteeing continuous source of water, purification and storage coupled with continuous circulation at ambient temperature. The distribution system was considered adequate and appropriate, ensuring all areas of production are supplied with purified water.

The procedure for water monitoring was in place. Sampling points were observed and frequency of sampling was mentioned, review of the preceded records proved that routine analysis conducted was sufficient to establish annual trending and evaluation of the systems performance and water quality.

Purified water was analyzed chemically and microbiologically as per schedules & frequency and records maintained. Cleaning and sanitization of purified water and distribution system was performed on scheduled frequency as per procedure. Qualification documents for the plant was also availed and proved that the system was working as expected.

7. Heating, Ventilation and Air Conditioning

The HVAC systems were designed to operate in a qualified manner that facilitated production without contamination. All the AHUs were qualified through design, installation, operational and performance qualification.

All the critical areas, i.e., dispensing, sampling and manufacturing suites were provided with AHUs comprised of filters as required for such areas. Based on verification of records (calibration status, maintenance status and filter integrity), all the pressure gauges were calibrated and maintained. Cleaning protocols, validation master plan, qualification protocol and preventive maintenance plan for the system were in place.

All AHUs were clearly labelled to indicate the supplied rooms, direction of airflow and, were in proper functioning conditions. Maintenance and servicing of AHUs was done in accordance with SOP in place, whereas procedures for monitoring and maintenance were in place as verified with the records taken.

8. Document Review

A documentation system was in place to guide production and control of products. These included Validation Master Plans (VMP); Standard Operating Procedures; Batch Manufacturing and Packaging Instructions and records; specifications of starting materials, packaging materials, packaging components, intermediates and finished products; standard testing procedures, analytical records and certificates of analysis; qualification and validation protocols and reports. There were corresponding records in form of reports, forms, checklists, logbooks, registers maintained as evidence of compliance with the procedures and specifications.

Documents were found to be adequately prepared and controlled as per requirement of the quality management system in place. Prepared documents were approved and authorized for use, distributed to all vantage areas of use, well descriptive and directive. The review proved that the company had a documentation infrastructure that supports quality management and quality assurance as expected in a pharmaceutical manufacturing facility.

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 the report and assessment of CAPA, **Medreich Limited – Unit 8, Survey No. 14 &15 , Gundarahali Village Sulibele Hobli , Hoskote Taluk, Bangalore Rural Dist – 562 114 Karnataka India** was considered to be operating at **an acceptable level** of compliance with EAC Compendium of GMP for the Manufacturing of Beta lactam oral solid dosage forms i.e., tablets, capsules and dry powder for syrup and suspension.

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.***

Part 4: References

1. EAC- *Good* Manufacturing *Practice Compendium, (2014), Technical Documents for Harmonization of Medicines Regulation in the East African Community*
2. TMDA *Good* Manufacturing *Practices Regulations, Manual and SOPs*, Tanzania Medicines and Medical Devices Authority, Dar es Salaam, Tanzania.
3. Medreich Limited – Unit - 8 Site Master File.
4. Tanzania Food and Drugs and Cosmetics Act, Cap 219.