TMDA/DMC/MCIE/F/001

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

(MJ BIOPHARM PRIVATE LIMITED)
PUBLIC GMP INSPECTION REPORT

December, 2020

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	M.J Biopharm Private Limited
Corporate address of manufacturer	L – 7, MIDC Industrial Area, Taloja, District Raigad, 410208, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	L – 7, MIDC Industrial Area, Taloja, District Raigad, 410208, India
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	2nd - 3rd February, 2019
Type of inspection	Renewal inspection
Introduction	
General information about the company and site	MJ Biopharm Private Company started in 1999 as manufacturer of general solid dosage forms (i.e tablets and capsules), liquid for injection, cephalosporin in form of dry powder for injection and biological (insulin) in form of liquid injection. It is located at L – 7, Maharashtra Industrial Development Cooperation (MIDC) area Taloja, District Raigad, Maharashtra about 65 km from Mumbai.
History	The site was licensed by the Office of the Controller Food and Drugs Administration, Maharashtra to manufacture for sale and distribution of pharmaceutical products. It was also inspected and approved by Nigeria, Romania, South Africa, Uganda, Namibia, Kenya, Colombia and Ethiopia.
Brief report of the activities undertaken	
Areas inspected	The inspection covered external surroundings, production area, and storage area for starting materials, packaging and finished goods, quality control laboratory and utilities.

	The inspection also verified the qualification of key personnel and training, premises layout, design, sanitation and hygiene, state of the buildings and equipment used in various manufacturing operations, laboratory instruments, complaints handlings and recalls, self-inspection, documentation, qualification and validation as well as production and quality control practices.
Restrictions	Only the manufacturing facilities and activities pertaining to registered products and those under registration process were inspected.
Out of scope	Activities apart from the ones mentioned above.
Production lines inspected by TMDA	General solid dosage forms (tablets and capsules) and liquid for injection production line, cephalosporin dry powder injection and biological (insulin) production lines
Abbreviations	**Meaning**
AHU	Air Handling Unit
BMR	Batch Manufacturing Record
BPR	Batch Packaging Record
EAC	East Africa Community
FPP	Finished pharmaceutical products
GMP	Good Manufacturing Practices
HVAC	Heat, Ventilation and Air conditioning
PW	Purified Water
QA	Quality Assurance
QC	Quality Control
RLAF	Reverse Laminar Air Flow
SOP's	Standard Operating Procedure(s)
TMDA	Tanzania Medicines and Medical Devices Authority
WFI	Water for Injection

Part 2: Brief summary of the findings and comments

1. Personnel

The manufacturer had an adequate number of qualified and experienced personnel for carrying out manufacturing and quality control activities. Key posts were occupied by full time personnel with clearly defined responsibilities and job descriptions. Head of

Production and Head of Quality Control were independent from each other as indicated in the Company's Organization Chart.

Personnel were provided with GMP training on recruitment and while on job as per training procedure and schedules and were proved to be aware of GMP principles. Medical examination policy and records for employees were available and was observed that employees were examined on recruitment and on yearly basis.

2. Premises

i. Layout and Design

The premises was suitably located, designed, constructed and maintained to suit the operations which were carried out. It was designed such that there were dedicated manufacturing blocks, quality control laboratories, and HVAC system for cephalosporins and biologicals. Walls, floors and ceilings in each manufacturing block had curved angles to prevent accumulation of dust and minimize the risk of cross contamination. Reliable electrical supply and lighting were appropriate for manufacturing activities and functioning of equipment.

Generally, the layout and design of premises was suitable to ensure logical flow of materials and personnel that minimizes the risk of errors and permitted effective cleaning and maintenance.

ii. Sanitation and Hygiene

Adequate level of sanitation and hygiene were generally observed in all areas, including surroundings, personnel, premises and equipment. Separate changing rooms for ladies and gents including visitors were provided with air showers, step over benches, entrance and gowning procedures, hand washing facilities and sanitizers. Sampling booth, dispensing booth and production were provided with secondary change rooms. Personnel were provided with clean uniforms and protective gears.

Personnel and material entrances to production were provided with airlock and pressure differentials to reduce the possibility of particulate contamination. Cleaning methods for premises, equipment and filters were validated to ensure that they were effective and consistent to meet the predetermined cleaning standards and prevent cross contamination of manufactured products.

Generally, the premises was clean, properly maintained and located in environment with minimal risk of causing contamination of materials and manufactured products.

3. Production

Production areas of concern were the cephalosporin and insulin manufacturing lines. Competent personnel were available for performing and supervising all manufacturing activities. Handling of materials and products, such as receipt and cleaning, quarantine, sampling, storage, labelling, dispensing, processing, packaging, and distribution was done in accordance with written procedures and properly recorded. Environmental monitoring in production areas was done on viable and non- viable particles (settle plates, on line particle counter).

Cephalosporin production area consisted of dedicated areas for sampling and dispensing with separate material (pass box) and man entry. Sampling and dispensing booths were provided with RLAF and required secondary gowning. Core manufacturing areas were classified as A/B. It was verified during manufacturing of Ceftriaxone Injection BN. T3C300514 that all process were controlled and parameters were monitored.

Insulin manufacturing was performed in class A and the surroundings in the room was class C, while filtration was done in Class B area. Sterilization of accessories, stoppers, machine parts and manufacturing gowns was done by Autoclave while dry heat sterilization was used for ampoules, vials and cartridges.

Generally manufacturing processes for Cephalosporins dry powder for Injection and Liquid Injectable were properly defined and approved. Verification revealed that the manufacturing processes followed unidirectional flow. In process control checks were performed within the production area and record maintained in BMR and BPR. Packaging lines were also equipped with automatic machines and a proper separation between the packaging lines was provided to avoid mix-ups.

4. Quality Control

There were dedicated quality control laboratories for cephalosporins and biologicals (insulin) separated from production areas. The design of laboratories allowed sufficient space for equipment installation and analytical processes in a manner that minimizes mix-up and cross contamination. Sufficient number of personnel with appropriate qualification and experience were available for sampling, testing of raw materials, packaging materials, finished products, environmental monitoring and stability testing. Primary reference and working standards were properly stored and maintained as per requirement.

Stability chambers for different climatic zones were available. Zone 1V B climatic condition stability chambers were qualified and they were operating at (40 ± 2 ^{0} C/75± 5% RH) for

acceleration studies and (30 ± 2 ^{0} C/75 ± 5% RH) for real time studies. Retention samples were properly handled as per procedure and were stored at controlled storage condition.

All equipment/instrument were found functional, calibrated and qualified. Equipment log books, SOPs, calibration records and qualification reports were verified and found to be adequate.

5. Equipment

Sufficient number of equipment and utilities were observed during the inspection. Equipment were located, designed, constructed, adapted, and maintained to suit the operations to be carried out. The layout and design of equipment were found suitable to minimize risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and in general any adverse effect on the quality of products.

6. Water Treatment System

Water Treatment Plant was found to be suitably designed, maintained and periodically monitored. Water was produced, stored and distributed in a manner that prevented unacceptable microbial, chemical or physical contamination. Municipal and rain water was used as feed system for generating PW which in turn was used as a source of WFI. PW and WFI were stored in the 316 L stainless steel tanks and maintained in a circulation loop at 60^{0}C and 80^{0}C respectively. Dedicated storage tanks were provided for small volume parenteral and dry powder fill block with capacity that was sufficient to meet the demand.

To ensure consistent production of water of the required quality routine monitoring and sanitization of water storage and distribution systems were performed on scheduled frequency as per SOP. Monitoring, preventive maintenance and qualification records were reviewed and found satisfactory.

7. Heating, Ventilation and Air Conditioning

Heating, Ventilation and Air-conditioning (HVAC) system was installed in the facility to supply filtered fresh and re-circulated air and maintain adequate temperature, relative humidity and pressure differentials so as to prevent contamination and/or cross contamination. Servicing and maintenance of the system was done in accordance to SOP and preventive maintenances program. Approved Validation Master Plan, Qualification protocol and records, preventive maintenance plan and records were verified and confirmed that the system was properly functioning.

8. Document Review

Documents were designed and prepared as per GMP requirements and distributed with care. Documents were approved, signed and dated by the appropriate responsible persons. Documents review was done in timely manner and records kept up to date.

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 inspection report, M.J Biopharm Private Limited located at L – 7, MIDC Industrial Area, Taloja (District Raigad, 410208, India was considered to be operating at an acceptable level of compliance with EAC GMP Compendium for the manufacturing of general pharmaceutical products in form of tablets, capsules and liquid for injection,cephalosporin dry powder for injection and biological (insulin) in form of liquid injection.

This report shall be valid for 3 years from the date of approval unless forms and operations herewith are changed or the site is no longer considered to be in compliance with current GMP requirements.

Part 4: References

1. EAC, (2014), *Compendium of Good Manufacturing Practice Guidelines Technical Documents for Harmonization of Medicines Regulations,* EAC Secretariat, Arusha, Tanzania.

2. TMDA *Good Manufacturing Practices Regulations, Manual and SOPs*, Tanzania Medicines and Medical Devices Authority, Dar es Salaam, Tanzania.

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

4. MJ Biopharm – Site Master File.