TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

NEOPHARMA, ABU DHABI, UAE
PUBLIC GMP INSPECTION REPORT

12th December , 2020

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Neopharma
Corporate address of manufacturer	Not indicated
Inspected site	
Name & address of inspected manufacturing site	Plot No. A-1 89-95, Industrial City of Abu Dhabi (ICAD), Mussafah, P.O. BOX 72900, Abu Dhabi, United Arab Emirates +971-2-5501000 sureshp@neopharma.com
Unit/ block/ workshop number	General Manufacturing Plant 1, 2, 3 and a dedicated beta lactam production block.
Inspection details	
Date of inspection	26th & 27th June 2019
Type of inspection	Renewal GMP Inspection
Introduction	
General information about the company and site	Neopharma L.L.C is situated in Industrial City of Abu Dhabi (ICAD), Mussafah, United Emirates. It is engaged in manufacturing of general products (hard gelatin capsules, soft gelatin capsules, tablets, powders, granules, semi solids, liquids for internal use) and beta-lactam (hard gelatin capsules, tablets and powder) The Facility had manufacturing license no. CR R044/17 valid up to 16/10/2022 issued by Ministry of Health and Prevention, UAE to manufacturer the above mentioned products
History	The facility was issued GMP certificate by the local NMRA The site has also been inspected and approved by the other medicines regulatory bodies including DPML (Ivory Coast), Pharmacy and Poisons Board (Kenya), Ministry of Health (Iraq), Gulf Central Committee-DR (Saudi Arabia), NAFDAC (Nigeria), NMPB (Sudan), MOH (Russia), FDA (Philippines) and INFARMED I.P. (Portugal).

	This was renewal inspection conducted to verify if the facility still operated under GMP requirements following the previous inspection that was conducted in 2013.
Brief report of the activities undertaken	
Areas inspected	This inspection focused on the production and control of general products (tablets, capsules, liquids, powder for oral suspension, semi-solids (cream and ointment) and powder sachet) and beta-lactam in form of penicillin (tablets, capsules and powder for oral suspension) and covered all the sections including external environment, utilities, starting materials and packaging materials warehouses, sampling and dispensing areas, production areas, finished products warehouse, quality control and document review.
Restrictions	None
Out of scope	None
Production lines inspected by TMDA	General Oral Solid (tablets and capsules) line, Oral liquid line, Powder for oral suspension line, Sachet-Oral rehydration salts line and Semi-solid dosage form manufacturing line and beta lactam inform of penicillin (tablets, capsules and powder for oral suspension)
Abbreviations	**Meaning**
BMS	Building Management System
DPML	Direction De La Pharmacie Du Medicament Et Des Laboratoires
EAC	East African Community
FDA	Food and Drug Authority
GMP	Good Manufacturing Practices
INFRAMED	Instituto Nactional da Farmaciae e do Medicamento
MOH	Ministry of Health
NAFDAC	National Agency for Food and Drug Administration and Control
NMPB	National Medicines and Poison Board
QA	Quality assurance
QC	Quality Control
SOP	Standard operating procedures
TIPR	TMDA Public Inspection Report
TMDA	Tanzania Medicines and Medical Devices Authority
TOC	Total organic carbon

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had adequate number of qualified and experienced personnel to carry out task of production and quality assurance. Review of the facility organogram and job descriptions for key personnel (Head of QA, QC and Production) confirmed that they were appropriate for their assigned duties and were independent from each other in their responsibilities. Verification of medical check-up records evidenced that employees were subjected to medical examination prior to and during employment once in a year per procedure. Personnel were subjected to induction and on job GMP training as per respective SOP. Training records were reviewed and were adequate.

2. Premises

The site consisted of block 1 for administration, block 2 General products (GP1) which was connected to the main warehouse, block 3 Beta-lactam products, block 4 general products (GP3, R&D, QA and QC), block 5 General product (GP2) and utility block.

Layout and Design

The buildings were constructed with steel structure portal frame. The walls were concrete hollow blocks and the roof was insulated with roofing materials. The modules were constructed out of clean room partitions. The clean room partitions, door and ceiling were made up of powder coated MS insulated with polyurethane. In order to facilitate ease cleaning and prevent accumulation of dust; all angles (floor to wall, wall to ceiling and wall to wall) were coved, the flooring in warehouses and production areas was epoxy painted and the doors and windows were flushed.

Adequate space was provided for orderly and logical placement of equipment and materials to avoid mix ups and cross contamination. Separate entry points for materials and personnel were provided in each block including the warehouse. Electrical supply, lighting, temperature, humidity and ventilation were appropriate for manufacturing and functioning of equipment.

i. Sanitation and Hygiene

High levels of sanitation and hygiene were generally observed in personnel, premises and surroundings. Separate change rooms for ladies and gents were available and were provided with change instructions, disinfectant and hand washing facilities. Personnel working in production were provided with neat and clean clothes with respect to clean zones. Direct contact was avoided between operator's hands and materials or products. Cleaning SOP, cleaning protocol, and record confirmed that cleaning of premises and equipment was performed as per requirements.

3. Production

The facility was engaged in manufacturing of beta-lactam products (oral solid dosage in form of tablets, capsule and dry syrup) and general products (oral dosage form in form of tablets, hard and soft gelatin capsules, semi-solid, powder, granules, oral liquid, oral

suspension and syrup. The inspected areas include general production plant 1 tablets, capsules, dry syrups, semisolids, oral liquids and oral rehydration salts, plant 2 for tablets, capsules and sachet manufacturing - oral rehydration salts, plant 3 for tablets and a dedicated beta lactam production block. Materials were received, de-dusted, and then stored in the material warehouse. Different storage areas with adequate space were provided for storing quarantine, under-test, approved and rejected material; status labels and material codes were applied in all materials. Labels were stored in a secure room under lock and key. Temperature monitoring including temperature mapping was also performed in the facility.

To prevent cross contamination sampling and dispensing booth were provided with separate material and personnel entry. Manufacturing processes were initiated as per the BMR, sequence of activities was followed and properly recorded. In process control was performed in the production area. Packaging lines were also equipped with automatic machines and proper separations between the packaging lines was provided to avoid mix-ups.
Generally, the manufacturing processes followed unidirectional flow, thus minimizing the risk of cross contamination and mix ups.

4. Quality Control

The facility had Quality Control laboratory manned by person with appropriate qualifications and experience; and equipped with instruments and procedures for sampling and testing of materials and products. The laboratory comprised of instrumentation chemical lab, stability room, and controlled samples room.

Instruments were properly kept in a separate room to protect them against electrical interference, vibration, contact with external moisture and other external factors. The same were suitably qualified and calibrated and was confirmed from the records reviewed. Microbiological testing was performed for materials, products and the environmental control in production areas.

Reference and working standards were stored and maintained according to storage instructions. Chemical reagents were prepared as per procedures; records were in place. Protective gears including eye wash and emergency showers were also available. Retention samples were properly arranged in a dedicated room and were traceable.

Stability chambers for different climatic zone condition were qualified and operating at specified temperatures and relative humidity. Records for stability studies were verified and found to be satisfactory

5. Equipment

The facility had sufficient number of equipment which were designed, located, installed, qualified and maintained to suit the operations carried out. The layout and design permitted effective cleaning thus preventing the risk of cross contamination build - up of dust or dirty.

6. WATER TREATMENT SYSTEM

The facility had a water treatment plant which was suitably designed, maintained and monitored. The system consisted of a common pretreatment system for all blocks comprising of multi grade filters & softener, and dedicated purification systems for each block comprised of RO, electro –de - ionization, and ultrafiltration, SS purified water tank maintained at ambient temperature, air vent filter of 2*microns* , Ultra Violet light and electro polished SS 316 circulation loop. Cleaning and sanitization of storage tanks and distribution pipelines was done as per the procedure. Online monitoring for conductivity and TOC, routine sampling and testing for chemical and microbiological attributes were performed and records were maintained.

Review of qualification and maintenance documents confirmed that system was suitable and working as expected.

7. Heating, Ventilation and Air Conditioning

Heating, Ventilation and Air-conditioning (HVAC) system was installed in the facility in order to supply filtered air and to maintain adequate temperature and relative humidity. Dedicated AHUs were proved to function properly and supply filtered air to various manufacturing areas. Pressure differentials, temperature and humidity were also maintained within the limits as per respective area design criteria to avoid cross contamination, ensure quality of products and functioning of equipment. Monitoring of room parameters was precisely monitored by BMS. Relevant records for preventive maintenance and performance qualification were all reviewed and proved the suitability and functionality of the system.

There were separate dedicated AHUs for Beta Lactam blocks and for General formulations block.

8. Document Review

The review indicated that the company had a documentation infrastructure consisting of procedures, records, specifications and related documentation, approaches and policies to support quality management and quality assurance. Some of the reviewed documents include; Site Master File, standard operating procedures, job descriptions and appointment letters for employees, batch manufacturing and packaging records, stability studies tests and reports, process validation protocol and reports, cleaning validation protocol and reports, analytical method validation protocol and reports,

calibration and qualification reports, preventive maintenance report and annual product quality review.

Generally, documents were detailed, well prepared, checked & approved as instructed in Master SOP.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, the observations listed in the inspection report, **Neopharma Plot No. A-1 89-95, Industrial City of Abu Dhabi (ICAD), Mussafah, Abu Dhabi, United Arab Emirates** was considered to be operating at **an acceptable level** of compliance with the East Africa Community (EAC) GMP Compendium for the manufacturing of general products (tablets, capsules, liquids, semi-solids, powder for oral suspension and powder sachet) and beta-lactam in form of penicillin (tablets, capsules and powder for oral suspension)

This TPIR will remain valid for 3 years from the date of approval for GMP compliance, provided that the outcome of any inspection conducted during the 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 inspection manual and SOPs*, Tanzania Medicines and Medical Devices Authority, Dar-es-Salaam, Tanzania.
3. Tanzania Medicines and Medical Devices Authority Act, Cap 219.
4. Neopharma Site Master File