MDA/DMC/MCIE/F/001

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA

Tanzania Medicines & Medical Devices Authority

NAARI PHARMA PRIVATE LTD, INDIA

PUBLIC GMP INSPECTION REPORT

11th December, 2020

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Naari Pharma Private Limited
Corporate address of manufacturer	Plot No. 30, Galaxy, 1st Main Road, JP Nagar, 3rd phase, Bangalore-560078, India
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Plot No. 14-16, 55-57, Sector-5, IIE Pantnagar, Rudrapur (Udham Singh Nagar), India
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	10^{th} – 11^{th} June, 2019
Type of inspection	Renewal Inspection
Introduction	
General information about the company and site	Naari Pharma Private formerly known as Jagsonpal Pharma Limited is a subsidiary of Tenshi Life Sciences Private Limited Company. The company was issued with drug license number 11/UA/2009, 12/UA/SC/P-2009 valid until 2021 by the Drug Control and License Authority of India to manufacture hormone in form of tablets The facility is located in an industrial area Pantnagar Distt, Udham Singh Nagar Uttarakhand.
History	The facility was issued GMP certificate by the local NMRA This was the renewal inspection conducted to verify if the facility still operated under GMP requirements following the previous inspection that was conducted in 2014. The facility had also been inspected and approved by other NMRA from Uganda, Kenya, Ethiopia, Nigeria and Ukraine.
Brief report of the activities undertaken	
Areas inspected	External surroundings, utilities, raw materials and packaging materials warehouses, manufacturing areas, finished goods warehouse, and quality control laboratory.)
Production lines inspected by TMDA	Hormones Oral Solids in form of Tablets.

Abbreviations	Meaning
TMDA	Tanzania Medicines and Medical Devices Authority
R&D	Research and development
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
TOC	Total Organic Carbon
UV	Ultraviolet
RO	Reverse Osmosis
HVAC	Heating Ventilation and Air Conditioning
AHU	Air Handling Unit
EAC	East African Community

Part 2: Brief summary of the findings and comments

1. Personnel

The company had adequate number of personnel required for pharmaceutical manufacturing with appropriate qualification and experience. Key posts for Quality Assurance manager, Production manager and Quality Control manager were occupied by full time, qualified and experienced individuals each with separate responsibilities as per their job descriptions. Production, quality control and quality assurance sections were independent of each other as indicated on the company organization chart.

Personnel in the production area were found to observe good hygienic practices, as evidenced from records scrutinized. Induction and on job GMP training was conducted as per SOP No. QA051, revision 04 and records for training plans, schedules, types of training, attendance and other items necessary for staff training were verified. Company employees prior to and during employment undergo medical examination as per SOP No. AD010, version 01 and the human resource department was responsible for this.

2. Premises

The facility was made up of four (4) separate blocks; block I was designated for production of hormone solid dosage form (hormone block) and raw material warehouse. Block II was for the production of general solid dosage formhormone solid

dosage form packing, secondary packaging hall, FPP warehouse, engineering and R&D department. Block III and IV housed the QA, QC laboratory, administration department and utilities respectively.

Layout and Design

All blocks were roofed with reinforced cement concrete. The slabs were RCC construction using bricks and cement with adequate pest and vermin control treatment done on the plinth. Walls were plastered with smooth finish paint, added with antifungal acrylic paint in block-2. Flooring was epoxy coated in production rooms. The QC laboratory floor was coated tiles and epoxy, clean rooms. Block-1 walls were made of PPGI double skin modular panel, the walls were characteristically featured with PPGI double skin modular panel. Windows were double glazed and all doors were made of aluminum frames with glass and aluminum laminated boards galvanized with steel PU coated/GI powder coated panels with insulation. Wall-wall and wall-ceiling junctions were coved to prevent dust accumulation.

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 qualified cabinets and benches 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.

Warehouses were provided with sampling and dispensing booths fitted with laminar air floor cabinets. Entry and exit point to core production area were provided with air shower facilities. The design and layout of the facility permitted unidirectional flow of materials and personnel.

Generally, the premises were designed to ensure the logical flow of materials, personnel and activities performed.

3. Production

All incoming materials (raw materials) were received in the warehouse located in block I,II, dedusted and stored in dedicated areas as per SOP, raw materials are initially sampled before allocated for storage. API and excipients had separate sampling and dispensing booths, with effective control of material and man entry, all activities conducted in these areas were under laminar air flow.

Entry and exit to production block was as per SOP No. PR002 and there were provisions for the change rooms, cross over benches, disinfectants and pictorial illustrations for gowning and de-gowning procedures. Production equipments were well designed and located to suit the manufacturing and packaging operations. All equipments had preventive maintenance status labels.

Packaging line was also equipped with automatic machines for packaging processes, there were also proper separation between the packaging lines to avoid mix-ups. In-process quality control tests were done, and results and records verified were found to be adequate.

There was a logical flow of manufacturing processes observed from the material warehouse to the manufacturing areas. Relevant documents for use in respective areas were provided and were descriptive of the process they detail in an updated manner.

4. Quality Control

The Quality Control laboratory for the facility was located in block III and performed analytical tests of starting materials, intermediate and finished products. Personnel working in the laboratory were adequate and qualified to carry out analytical tests.

All major necessary equipments for testing pharmaceutical products were available, key equipments for microbiology laboratory such as incubators, autoclaves, sterilizers, microscope etc to facilitate microbiological testing of both raw materials and finished pharmaceutical products were available. Instruments and devices were calibrated and subjected to preventive maintenance according to written procedures and records of calibration were verified. Analytical methods and manufacturing processes were validated as Validation Master Plan and records were reviewed.

Walk in stability chambers were available at the QC laboratory for conducting stability studies at a climatic zone conditions as per written procedure. Products were observed to be stored in the chambers as required, log books were also verified.

Separate areas for storage of retained raw materials and finished products were available and the records for the inventory control were kept and maintained as per written procedure.
The overall quality system was found reliable and consistent.

5. Equipment

The facility was deemed to have 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 also facilitated effective cleaning and avoidance of recess to prevent chances of contamination and cross contamination.

6. Water Treatment Plant

The facility was installed with a water treatment plant for the purpose of supplying purified water for production uses. Water was sourced from the ground (bore well) and processed through several stages prior to generation of purified water. multi-grade

filter, softener was the initial pathway, followed by RO-1, EDI, conductivity, UV TOC (for the purpose of reducing the TOC level). The purified water was stored in SS tanks, tested for chemical attributes, conductivity and microbiological parameters as per SOP.

The system consisted of 13 sampling units (apart from user point) and 22 user points, arrows showing direction of water flow were indicated, schematic drawings as well as the SOP for water treatment and daily records were also verified and approved to be adequate as per GMP requirements.

7. Heating, Ventilation and Air Conditioning

The HVAC system was designed and installed (to each block) to supply filtered fresh and re-circulated air. The facility had a total of 55 AHUs distributed among the blocks depending on their functional capabilities and were qualified through design, installation, operational and performance qualification.

Regular validation of the HVAC system and AHUs as per validation master plan was conducted to ensure the desired air supply is maintained, whereas temperature and humidity sensors were provided in all supplied rooms to monitor performance of these systems.

8. Document Review

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, **Naari Pharma Private Limited located at Plot No. 14-16, 55-57, Sector-5, IIE Pantnagar, Rudrapur (Udham Singh Nagar), India** was considered to be operating at **an acceptable** level of compliance with EAC GMP guidelines for the production line of oral solid dosage form namely hormones uncoated tablets.

This TPRI 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. TFDA, (2008), *Good manufacturing practices: guidelines for pharmaceutical*, Tanzania Food and Drugs Authority, Dar-es-Salaam, Tanzania.
3. TFDA *Good Manufacturing practices manual and SOPs,* Tanzania Food and Drugs Authority, Dar-es-Salaam, Tanzania
4. Naari Pharma Private Limited Site Master File.