TMDA/DMC/MCIE/F/001

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

PREMIUM SERUMS AND VACCINES PVT.LTD, INDIA

PUBLIC GMP INSPECTION REPORT

08 December, 2020

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	**Premium Serums and Vaccines Pvt. Ltd**
Corporate address of manufacturer	S. No. 354-1, 354-2A/1, At Post Narayangaon, Taluka-Junnar, Dist-Pune-410 504, Maharashtra, India
Inspected site	
Name & address of inspected manufacturing site	S. No. 354-1, 354-2A/1, At Post Narayangaon, Taluka-Junnar, Dist-Pune-410 504, Maharashtra, India
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	25th – 26th February, 2019
Type of inspection	Pre-registration GMP inspection
Introduction	
General information about the company and site	Premium Serums and Vaccines Pvt. Ltd is located at Narayangaon, Taluka-Junnar, Pune District about 80 Km from Pune City. The company is provided with license no. 271 and 395 issued by FDA, Maharashtra, India to manufacture plasma, bulk antiserums and finished products for tetanus and diphtheria antitoxins, snake anti-venoms and anti-rabies (both liquid and lyophilized injections).
History	The facility was inspected and approved by the FDA, Maharashtra, India and was issued with license no.271 and 395. This was the first inspection to be conducted by TMDA as pre-requisite to market their products in Tanzania.
Brief report of the activities undertaken	
Areas inspected	The areas inspected were external surroundings, utilities, production areas starting from incoming raw materials

	warehouse, manufacturing areas to the finished products warehouse, quality control laboratory and documentation.
Restrictions	None
Out of scope	None
Production lines inspected by TMDA	Line for manufacturing of plasma, bulk antiserums and filling and sealing lines for tetanus and diphtheria antitoxins, snake anti-venoms and anti-rabies (both liquid and lyophilized injections)
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
SOP	Standard Operating Procedures
VMP	Validation Master Plan
WFI	Water For Injection

Part 2: Brief summary of the findings and comments

1. Personnel

The organization chart indicating the key personnel involved in production, quality control and quality assurance was reviewed. Individual responsibilities were defined and described in their job descriptions. All departments at the site had sufficient number of personnel with appropriate qualifications and experience to perform their functions. Heads of production and quality control sections were found independent of each other as indicated on the company organization chart.

Training programs on principles of GMP and on-job trainings and schedules were as per facility's SOPs, as was evidenced in the training records for employees availed. The procedure for medical checkup was reviewed and found adequate. Medical examination was carried out prior to employment followed by periodic examination.

2. Premises

The facility had three blocks namely blood collection and plasma processing building, fill finish suite and animal laboratory house.

Layout and Design

All buildings were constructed using reinforced concrete cement foundation, smooth finish and modular panel partitions. Corners between wall to wall, floor to wall and wall to ceiling in manufacturing areas were all provided with covings. Floors in both production and other primary areas were epoxy coated. All lightings in the processing area were sunken and enclosed.

The storage areas of the facility were adequate for storage of raw materials, packaging materials and finished goods. The production areas had aluminum flushed interlocking doors. The manufacturing areas were provided with 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. Primary and secondary change rooms with crossover benches and sanitization solution were available at the entry to production areas. Gowning and de-gowning procedures and pictorial presentations were in place. Rodent traps were placed in different stations around the facility.

The production rooms and equipment were observed to be clean. SOP for cleaning and its validation was verified whereas, the cleaning protocol and relevant records were assessed and found to be updated and properly maintained

3. Production

The production scope of the facility was from the decantation of plasma from animal blood followed by processing to produce bulk quantities that are then filled for finished products. These processes were defined in two blocks, namely blood collection and plasma purification block and were concluded in the fill finish suite building.

Generally, the available resources; personnel, equipment, raw materials, containers and labels, operating procedures and the IPQ checks and control conducted by the QC

department were considered appropriate and relevant for the production scheme. Manufacturing processes were generally defined and reviewed. Instructions and procedures were generally available.

Qualification and validation of equipment, manufacturing processes and quality control testing methods were generally performed.

4. Quality Control

The facility's laboratory had sufficient space, properly arranged with critical equipment that were coded, qualified and had status label. It was divided into sections which included chemical, microbiology and biological sections. The operating procedures and log books were reviewed. Calibration and maintenance of instruments and equipment were done and records were verified. There was adequate number of analysts who were qualified and possessed relevant experience. Records for qualification of analysts were assessed and accepted.

Stability study procedures were available. Stability study registers and samples under condition of ($25\pm2^0C/60\pm5\%$, $30\pm2^0C/75\pm5\%$) and accelerated conditions of ($40\pm2^0C/75\pm5\%$) were available. The maintenance and monitoring of stability chambers including the sample retention rooms were adequately documented.

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.

6. Water Treatment plant

The water treatment plant was in place. The source of raw water used was a dam. The water treatment plant was of adequate capacity and it guaranteed continuous supply of treated water. Purified water was maintained under continuous closed loop at ambient temperature. Water for injection (WFI) was generated from purified water which was used as feed water to the multicolumn distillation plant.

The procedure for monitoring of quality of water was in place. Sampling, testing and frequency for all sampling points was identified and upon review of the preceded records, it was proven that routine analysis conducted was sufficient to establish the annual trend and evaluation of the systems performance.

Cleaning and sanitization of purified water and distribution system was performed on scheduled frequency as per procedure. Log book for cleanliness of water treatment plant was found in place. Qualification documents for the plant was also availed and proved that the system was working as expected.

7. Heating, Ventilation and Air Conditioning

Different areas of the facility were installed with a dedicated HVAC system having adequate Air Handling Units (AHUs) that were qualified through design, installation, operational and performance qualification. Pressure differentials were monitored by calibrated magnehelic gauges mounted on the AHUs and schematic drawings for each AHU were verified.

Maintenance and servicing of AHU was done in accordance with relevant SOP, monitoring records together with preventive maintenance records were checked and accepted. Dedicated area for cleaning filters was provided, SOP for filter cleaning and records were available. Qualification and re-qualification documents for the HVAC system were available.

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

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 and the assessment of CAPA , **Premium Serums and Vaccines Pvt. Ltd, S. No. 354-1, 354-2A/1, At Post Narayangaon, Taluka-Junnar, Dist-Pune-410 504, Maharashtra - INDIA** was considered to be operating at **an acceptable level** of compliance with EAC Compendium of GMP for the Manufacturing of plasma, bulk antiserums and finished products for tetanus and diphtheria antitoxins, snake anti-venoms and anti-rabies (both liquid and lyophilized injections).

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, (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. Premium Serums and Vaccines Pvt. Ltd – CAPA assessment report.