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REV.#. 01

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

BLISS GVS PHARMA LTD, PALGHAR INDIA
PUBLIC GMP INSPECTION REPORT

January, 2026

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	Bliss GVS Pharma Ltd
Corporate address of the manufacturer	Survey No102, Hyde Park, Saki Vihar Road, Andheri (East), Mumbai.
Inspected site	
Name & address of inspected manufacturing site, if different from that given above	Bliss GVS Pharma Ltd, Survey No. 43 – 44 Vevoor Village, Palghar 401404, India
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	30th – 31st January, 2025
Type of inspection	Pre – Pre-Registration GMP Inspection
Introduction	
General information about the the company and site	Bliss GVS Pharma Ltd (Plot number 43 and 44) is one of the three (3) units/facilities owned by Bliss GVS Pharma Ltd. The facility was located about 105 kms from Mumbai international Airport,18km from the Mumbai Ahmedabad national railway and 3kms from Palghar railways station. It was engaged in manufacturing and packaging of general formulations in the form of tablets, capsules, and dry powder for syrup/ suspension.

History	The facility was inspected and licenced by the Local National Regulatory Authority. It was also GMP inspected and approved by other foreign medicines regulatory bodies namely NDA Uganda. EFDA Ethiopia, Rwanda FDA, Madagascar, National Agency for Medicines and Medical Devices of Romania, NAFDC Nigeria, FDA Ghana, PPB, Kenya, PMRA Malawi, ZAMRA Zambia and MCAZ Zimbabwe.
Brief report of the activities undertaken	
Areas inspected	Inspection covered: • Pharmaceutical Quality System • Production System • Facilities and Equipment System • Laboratory Control System • Material System • Packaging and labelling System
Restrictions	The inspection focused on production lines for tablets and capsules.
Out of scope	None
Production lines TMDA inspected by	General formulations in the form of tablets and capsules.
Abbreviations	**Meaning**
AHU	Air Handling Unit
CAPA	Corrective Actions and Preventive Actions
cGMP	Current Good Manufacturing Practices
HEPA	High Efficiency Particulate Air

HVAC	Heating, Ventilation, and Air Conditioning
HPLC	High-Performance Liquid Chromatography
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
FMECA	Failure Mode Effects and Critical Analysis
BMR	Batch Manufacturing record
FTA	Fault Tree Analysis
QMS	Quality Manufacturing System
QRM	Quality Risk Management
HACCP	Hazard Analysis And Critical Control Point
VMP	Validation Master Plan
FPP	Finished Pharmaceutical Product

Part 2: Summary of the findings and comments

Personnel

The facility had an adequate number of qualified and experienced staff to execute their responsibilities. The Head of Quality Control and Production were independent in fulfilling their responsibilities as evidenced through reviewed job descriptions and organization chart.

Employees were imparted with induction and continual training in line with procedure in place. Induction training was given to new employees while refresher (GMP) training was provided to on-the-job personnel annually. Training plan and records were reviewed and found to meet the requirements.

Employed personnel were examined once per year including eye examination for personnel doing visual inspection. Medical records were in place. Records for some personnel were sampled and reviewed and found to be adequate.

High level of personnel hygiene was noted; the changing rooms, gowning procedures; hand sanitizer and pictorial illustrations were in place. were Personnel were trained on hygiene procedures and observed adhering to them.

1. Premises

a. Layout and Design

The the layout was observed designed to provide a unidirectional flow of manufacturing processes to minimize the risk of mix-ups and cross-contamination.

The facility had one building with two (2) floors such that;

Ground floor (GF) consisted of warehouses, manufacturing area for tablets, capsules and dry syrup, sampling and dispensing areas;

first floor consisted of Quality Control Laboratory, Quality Assurance, QA; documentation room, Retention sample room, Stability room, WTP, HVAC, manufacturing area for semisolids (under qualification), and the administration block.

The buildings were constructed with reinforced concrete cement. The flooring was made concrete and covered with epoxy. The door, windows and light fixures were flushed. Covings were provided at the junction of the wall-to-wall, wall-to-floor and wall-to-ceiling to facilitate easy cleaning and sanitization. Filtered air was supplied to warehouses, production and QC Lab through the air handling units installed. Calibrated temperature and pressure monitoring devices were also provided in the facility. Electrical supply and adequate lighting were provided in all areas to ensure smooth manufacturing operations and accurate functioning of the equipment.

b. Sanitation and Hygiene

High levels of sanitation and hygiene were generally observed in all areas, including the surroundings. Separate male and female change rooms were available and were provided with airlocks, lockers and toilets.

Eating, drinking, tobacco chewing, and smoking were prohibited in manufacturing, processing, storage, and laboratory areas. Direct contact was avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk products.

Rodent traps and insect-cutters were provided to ensure maximum protection against the entry of insects and pests. Validated cleaning and sanitization procedures of rooms and equipment were in place and properly followed.

2. Production

Materials

The facility had separate receiving and dispatch bay. After receipt materials, were dedusted, weighed quarantined area and later sampled for QC analysis as per procedure in place. There were dedicated sampling and dispensing booth (RLAF) or different materials. Temperature and RH were monitored in the storage areas and records were verified. Materials that were light sensitive and hygroscopic were properly handled. The correct colour coding was provided in the materials storage areas to prevent mix ups. The space for storing materials was also adequate and status labels were well applied for materials. Printed packaging materials were also found stored in a secure room under lock and key. Dedicated areas were provided for storage of rejected, expired, returned and recalled materials

Tablets and capsules production Line

There were separate entries for materials and personnel to production areas. Access to production areas was restricted to authorized personnel only.

Manufacturing of tablets involved the following stages; dispensing of material, sifting of material, dry mixing, granulation, wet milling, drying, sizing, mixing, lubrication, compression, in process quality check, coating, and packaging. For capsules after lubrication, capsule filling, was done followed by packaging and labelling. Critical process parameters and critical quality attributes were monitored at each stage and records were verified. Holding time for materials at different stages was adhered as per established procedures and hold time studies that was performed. Line clearance was performed as per respective procedures; checklists were properly filled. Checks on yields and reconciliation of quantities were carried out and variations in the percentage yield of the product were observed. Packaging lines were properly segregated to prevent the risk of mix-ups.

Generally manufacturing processes were initiated as per the BMR and sequence of addition of ingredients/raw materials was followed and recorded in the BMR.

3. Quality Control

The facility had a quality control (QC) laboratory which was separated from production areas. The QC laboratory was divided into different sections such as chemical laboratory, instrumentation rooms, microbiology section, stability room, and retained sample room. Sufficient number of trained personnel with appropriate qualifications and experience was available to carry out analysis of raw materials, packaging materials, intermediates and finished products. Modern analytical instruments were available, the same were found qualified/calibrated. The facility performed both accelerated and long-term stability studies in line with the respective procedures and protocols. Products were properly arranged in the chambers and were easily traceable. Reference and working standards were properly stored and easily retrieved.

4. Equipment

The manufacturing facility was provided with adequate equipment which were generally designed, constructed installed, located and maintained to fit the purposes of the operations to be carried out. The layout and design permitted effective cleaning thus preventing the risk of cross contamination build - up of dust or dirty. Calibration and preventive maintenance were performed according to the established schedules. Equipment was adequately cleaned and sanitized as per validated cleaning and available sanitization procedure; records were verified. Preventive maintenance, calibration and cleaning status labels were in place.

5. Water Treatment System

The facility had a Water Treatment Plant (WTP) whose source of water was borewell. Water was treated in two stages i.e primary treatment and secondary treatment. The bore water was first dosed with sodium hypochlorite, followed by chlorination, multigrade filter, ultrafiltration system with a 25micron bag filter and then collected to 10KL tank. The water was then passed through softener then collected in 10KL tank; from the tank it was then passed through 5micron cartridge filter followed by reverse osmosis (RO), then was collected to 10KL RO product tank and used as feed water for secondary treatment. The pretreated water then passed through heat exchanger, then stored into 2KL RO feed tank (10KL ss 316L), followed by ozonation, UV light, RO2, electro deionization (EDI), then water was collected into PW Storage tank (3KL SS316L). Purified water was then distributed to user points under closed loop. Online monitoring was done for conductivity, temperature, TOC and flow rate. UV light burning hours was also monitored, records were in place.

PW was supplied to production areas through electro polished pipelines made up of SS 316L. The entire system was cleaned and sanitized as per procedure records were verified. Sampling and testing of water for chemical and microbiology was also done as per procedure; records were in place. Preventive maintenance of the system was also done as was verified form the availed records.

6. Heating, Ventilation, and Air Conditioning

The facility had an HVAC system for supplying clean filtered air to various areas of production and maintaining pressure differential across rooms to prevent cross-contamination. There were 71 air handling units (AHUs) of which some were installed with dehumidifiers. All the AHUs were integrated with the Building Management System (BMS) which helps in controlling required temperature, RH and differential pressure as per the area requirements. AHUs were provided with mixed air units; each cycle has 10% fresh and 90% return air. Air changes in production areas was maintained at NLT 20 air changes /hr. Temperature and relative humidity for manufacturing areas were monitored to be NMT 25^0C and NMT 60% RH. Magnehelic gauges and sensors were placed between filters to monitor their performance and in the rooms, digital displays were provided to monitor temperature, RH and differential pressure in both processing and non – processing areas. Preventive maintenance SOPs were in place, filter cleaning procedures were validated and the qualification document for the HVAC system were available in support of functionality and suitability of the system.

7. Document Review

The facility used paper based and electronic methods of documentation. The review of documents proved that, the company had a good documentation system as documents were designed, prepared as per the GMP requirements. The same were prepared, approved, signed and dated by appropriate responsible personnel and were distributed with care. Records were observed to be up to date, document review was done in timely manner as per the procedures. Electronic data management and processing system were password protected which restricted their usage and only authorized personnel were responsible for managing the system.

Part 3: Conclusion

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, Bliss GVS Pharma Ltd, Survey No. 43 – 44, Vevoor Village, Palaghar 401404, India is considered to be operating at an acceptable level of compliance with TMDA GMP Guidelines, 2023 for manufacturing of for manufacturing general formulations in form of tablets and capsules.

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. Tanzania Medicines and Medical Devices Act, Cap 219.

2. TMDA *Good manufacturing practices SOPs*, Tanzania Medicines and Medical Devices Authority.

3. Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities; 2nd edition, January 2025.

4. TMDA, (2018)., Tanzania Medicines and Medical Devices (Good Manufacturing Practices Enforcement) Regulations GN No. 295.
5. TMDA, RIMS 2.0

6. Bliss GVS Pharma Ltd, Survey No. 43 – 44, Vevoor Village, Palaghar 401404, India, SMF No. SMF/PL3/05 effective from 30th December; 2024.