THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TMDA

Tanzania Medicines & Medical Devices Authority

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TNS PHARMA PVT LTD, SACHIN, SURAT, INDIA
PUBLIC GMP INSPECTION REPORT

January, 2026

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	TNS PHARMA PVT LTD
Corporate address of the manufacturer	Plot No. 4232, Road No. 42, Sachin GIDC, Sachin, Surat, 394230 Telephone number: +91 9825018791 Website/email address: info@tnspharma.com www.tnspharma.com
Inspected site	
Name & address of inspected manufacturing site, if different from that given above	Same as above
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	18th-19th November, 2024
Type of inspection	Pre - registration GMP Inspection
Introduction	
General information about thethe company and the site	The company was engaged in the manufacturing of general and steroid oral solid dosage forms (tablets, hard gelatin capsules)
History	TNS Pharma PVT Ltd was subsidiary of Trident Lifeline Limited which was commissioned in 2021. It was engaged in manufacturing of oral solid dosage (OSD) i.e tablets, hard gelatine capsules, and dry powder for suspension. The facility was inspected and approved by the Food and Drug Control Administration, Gujarat State, India, FDA Ghana (in 2024) and TMDA (in 2024).

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	None
Out of scope	None
Production lines inspected by TMDA	The inspection covered manufacturing lines for general and steroids formulations in form of tablets and capsules.
Abbreviations	**Meaning**
AHU	Air Handling Unit
CAPA	Corrective Actions and Preventive Actions
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Air
HVAC	Heating, Ventilation, and Air Conditioning
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
ETP	Effluent Treatment Plant
FDA	Food and Drug Authority
QMS	Quality and Management System
SMF	Site Master file
AMV	Analytical Methods Validation
GIDC	Gujarat Industrial Development Corporation

Part 2: Summary of the findings and comments

1. Personnel

The facility had an adequate number of qualified and experienced staff to execute their responsibilities. The heads of quality assurance, quality control and production had sufficient academic qualifications to carry out their duties. The Head of Quality Control and Production were independent in fulfilling their responsibilities as evidenced through a review of their job descriptions and organization chart.

The facility conducted induction training to new employees and on job training. On job training was conducted once in a year as per the annual calendar in place, records were verified.

All new employees were subjected to pre-employment check up while the already employed personnel were subjected to medical check in line with the SOP. Records for selected employees working in production and QC were verified and found to be adequate.

Generally, high level of personnel hygiene was observed. Personnel found at various key areas within the facility were dressed in clean factory uniforms.

2. Premises

a. Layout and Design

The facility was one storey build such that;

Ground Floor consisted of manufacturing; packing areas, Effluent Treatment Plant (ETP) and scrap yard. Mezzanine floor consisted of Quality Control Laboratory and Quality Assurance Offices. First floor consisted of warehouse for raw materials and packaging materials, finished goods store and administration offices. Terrace area had utilities (HVAC and Water Treatment Plant) and engineering offices.

The facility was designed, constructed, and maintained to suit the operations that were carried out and facilitate easy cleaning and sanitation. The walls of the manufacturing premises were made of reinforced concrete cement (RCC) and painted with easy to clean epoxy paints. Interior surfaces including floors, roofs, walls, and covings were smooth and free of cracks and crevices in order to allow easy cleaning and sanitation.

The production areas were provided with flushed doors and windows. Calibrated temperature and pressure monitoring devices were provided in the facility and were all within the specified limits. The entry of raw materials was different from the entry of personnel into manufacturing areas to minimize mix-up and contamination. Electrical supply and adequate lighting were provided in production areas to ensure smooth manufacturing operations and accurate functioning of the equipment.

3. Sanitation and Hygiene

Facilities sanitation and hygiene were maintained in line with respective procedure. External surroundings were maintained at an acceptable level of cleanliness. Adequate male, female and visitors change rooms were provided with lockers, sanitizers, shoe covers, etc. Entry and exit gowning procedures were displayed in appropriate places and were properly followed.

Rodent traps and insect - cuters were provided to ensure maximum protection against the entry of insects and pests.

4. Production

a. Tablets Production Line

Production of tablets was done on the ground floor. Dispensing was done under LAF then dispensed materials were transferred to the dispensed day-store in the manufacturing area using SS trolleys and covered in plastic bags. The manufacturing process involves stages i.e sifting, wet/dry granulation, drying, and blending and compression. The critical quality attributes of the compressed tablets were monitored for description, average weight, uniformity of weight, disintegration time, hardness and friability. Compression machines were fitted with dust extractors and metal detectors.

Packaging lines were properly segregated to prevent the risk of mix-ups. The name and batch number of the product under the packaging were displayed at the packaging station.

b. Capsules production Line

The manufacturing process for capsules included stages i.e dispensing, sifting of raw materials, blending, capsule filling by a machine fitted with metal detectors and weight checker followed by packaging

Generally manufacturing was observed to be conducted in line with the validated parameters. Generally manufacturing processes were initiated as per the BMR and

sequence of manufacturing process was followed and recorded in the BMR. Line clearance was performed as per respective procedures; checklists were properly filled.

5. 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. The QC laboratory had sufficient number of trained personnel with appropriate qualifications and experience responsible for analysis and release of dosage forms, active ingredients, raw materials, intermediates, packing materials and environmental monitoring. Modern analytical instruments were available, the same were found qualified/calibrated. Tests were performed according to written procedures, records were verified.

The facility performed both accelerated and long-term stability studies in line with the respective procedures and protocols. Stability chambers for different climatic conditions were available and were calibrated. Products were properly arranged in the chambers and were easily traceable. Reference and working standards were properly stored and were easily retrieved.

6. 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.

7. Water Treatment System

The water treatment plant sourced water from the Gujarat Industrial Development Corporation (GIDC). The raw water was chlorinated using Sodium Hypochlorite, then dechlorinated with Sodium Metabisulfite dosing. The treated water was then passed through a softener and fine filter to trap suspended solids. Purified water (PW) was generated through a single pass RO membrane and Electro de-ionization module, and stored in a half jacketed, insulated SS316L storage tank. The final PW was subjected to UV sanitization before passing to a loop system for circulation. Periodic monitoring of water for pH and conductivity, as well as microbial quality testing, was conducted. The water system was cleaned and sanitized in line with procedure No. TNS-ENSOP/006/01, using hot water at 80-85°C temperatures. The cleaning and sanitization

records were kept in the respective logbook and were found to be adequately executed as per the documented schedule.

8. Heating, Ventilation, and Air Conditioning

The HVAC system was installed on the facility's mezzanine floor, consisting of 16 Air Handling Units (AHUs) to maintain filtered fresh air, temperature, relative humidity, and pressure differentials. These AHUs were designed to supply controlled air with 90% recirculated air and 10% fresh air through l0, 3, and 0.3microns HEPA filters. Return air risers were provided with filters of a 10-micron rating and 90.00% efficiency. All AHIJs had specific identification and proper labeling. Regular cleaning of AHU filters was performed at a well-established cleaning area, and HEPA filters were re-qualified. Routine monitoring of the system was conducted, and the HVAC system's documentation was reviewed. Maintenance for AHUs was conducted quarterly and annually, with records available for review. Preventive maintenance and calibration status labels were all in place.

9. Document Review

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. During inspection, various documents were reviewed and were found to be in line with the respective SOP's. SOPs were presented at vantage areas in and were properly followed. Records were observed to be up to date, document review was done in timely manner as per the procedures. All documents were generally filled and managed manually.

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, a decision on the compliance of **TNS PHARMA PVT LTD Plot No. No. 4232, Road No. 42, Sachin GIDC, Sachin, Surat, 394230, Gujarat, India was considered to be operating at an acceptable level** with TMDA Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, 2023; for the manufacturing and packaging **of general and steroid Oral Solid Dosage forms (tablets and hard gelatin 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. TMDA (2003). Tanzania Medicines and Medical Devices Act, Cap 219.
2. TMDA (2023). Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition.
3. Tanzania Medicines and Medical Devices (Good Manufacturing Practices Enforcement) Regulations GN No. 295.
4. TMDA Good Manufacturing Practices Manual and SOPs.
5. TNS PHARMA PW Ltd, India, TNS/SMF/2023/0.