THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TMDA
Tanzania Medicines & Medical Devices Authority

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

USV PHARMACEUTICALS, BADDI, SOLAN, H.P - 173 205, INDIA
PUBLIC GMP INSPECTION REPORT

January, 2026

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	USV Private Limited,
Corporate address of the manufacturer	Arvind Vithal Gandhi Chowk, BSD Marg, Govand, Mumbai, Maharashtra, India, 400088.
Inspected site	
Name & address of inspected manufacturing site, if different from that given above	Khasra No. 1342/1/2, Hilltop Industrial Area Jharmari, Baddi, Solan, H.P - 173 205, India Telephone no: +91 9816619996, +91 1795271450
Unit/ block/ workshop number	N/A
Inspection details	
Date of inspection	12 - 13 September 2024
Type of inspection	Pre - Registration GMP Inspection
Introduction	
General information about the the company and site	USV Private Limited (Jharmajri, Baddi plant) is one of the seven facilities owned by USV Private Ltd. The facility was established in 2010 and was engaged in manufacturing of oral solids dosage forms in form of tablets and granules. It was about 45km from Chandigar (Union Territory) towards Norh East and was well connected by Road to Chandigarh and Shimla.

History	The facility holds a valid GMP Certificate issued by the State Drug Controller, Controlling cum Licensing Authority, Baddi Distt. Solan [H.P] 173205, India. It has also been GMP inspected and approved by the National Institute of Pharmacy and Nutrition, Hungary.
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	Only tablet production line was inspected.
Out of scope	None
Production lines inspected by TMDA	The inspection of the production system focused on production lines for manufacturing General formulations in the form of tablets.
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
FMECA	Failure mode effects and criticality analysis

TMDA	Tanzania Medicines and Medical Devices Authority
HACCP	Hazard analysis and critical control
HPLC	High-Performance Liquid Chromatography
TLC	Thin-layer chromatography

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 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. eLIMS software was available for training management, records were in place.

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 to be adhered to.

2. Premises

a. Layout and Design

The facility was designed, constructed and maintained to suit the operations that were carried out and facilitate easy cleaning and sanitation.

The facility had one building with four floors such that; ground floor consisted of administration section, cafeteria, ETP, warehouse, sampling and dispensing areas, first floor consisted of quality assurance, retained samples room and stability chamber room, second floor consisted of QA section, manufacturing and packaging areas, third floor consisted of QC laboratory and purified water system and 4th floor consisted of the HVAC system.

The buildings were constructed with reinforced concrete cement. The flooring was made of polished kota (terrazzo) stone with epoxy joints. 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.

3. Production

Materials

There were separate entries for materials and personnel to production areas. Access to production areas was restricted to authorized personnel only. Raw and packaging materials were received, examined, de-dusted, weighed, quarantined and tested as per the requirement.

Dedicated sampling and dispensing booth (RLAF) for actives, excipients, packaging materials and liquid materials were provided. Temperate and RH were monitored in the storage areas and records were verified. Provisions were available for handling of light sensitive and hygroscopic materials. 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.

Production line of tablets

Manufacturing was observed to be conducted in line with the validated parameters. Tablets manufacturing involved the following stages; dispensing, milling, sifting, dry mixing, wet granulation, drying, milling and sizing, mixing, lubrication, compression, coating, inspection and packaging. Manufacturing of light sensitive products was carried out under sodium light lamps and material were sealed in black polyethylene bags.
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.

4. 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 for different climatic zones 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

5. Equipment

The 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. The equipment was calibrated and maintained as per the available plan, records were verified. 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. Qualification documents were available in support of functionality and suitability of the equipment.

6. Water Treatment System

Water Treatment Plant (WTP) was available whose source of water was borewell. From the borewell, water was treated with chlorine, multigrade sand filter; then passes through 40microns cartridge filter, ultrafiltration, RO1, ozonator, 5micron filter, UV, 5micron filter RO2, EDI and then stored in the purified water tanks (SS 316L 10KL capacity) 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.

Purified water was supplied to production areas through electro polished pipelines made up of SS 316L. The entire system was cleaned and sanitized as per procedure using hot water of above 80 °C for 1hr. Sampling and testing of water for chemical and microbiology was also done as per procedure in place, records were in place.

7. Heating, Ventilation, and Air Conditioning

The facility had an HVAC system that supplied clean, filtered air to production areas and maintained pressure differences across rooms to prevent cross-contamination. It had 49 air handling units (AHUs), 6 ventilation systems, and 22 dust extraction systems. The AHUs used mixed air units with 10% fresh air and 90% return air. Fresh air passed through various filters, with air changes in production areas maintained at 20 per hour. Magnetic gauges monitored filter performance and pressure differences across rooms. 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.

8. Document Review

The facility used both paper-based and electronic methods of documentation. Documents 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. Electronic data management and processing system were password protected which restrict their usage and only authorized personnel were responsible for managing the system. SOPs were found at vantage areas and were properly followed; records were also in place.

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 USV Private Limited, Khasra No. 1342/1/2, Hilltop Industrial Area Jharmajri, Baddi, Solan, H.P - 173 205, India with TMDA GMP Guidelines for Inspection of Human Medicinal Facilities for manufacturing oral solid dosage forms in form of tablets and granules will be made after the manufacturer's response to the observations has been assessed.

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.

3. Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities; 1st edition, April 2023.

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

5. 5. TMDA, RIMS 2.0

6. USV Private Limited, Khasra No. 1342/1/2, Hilltop Industrial Area, Jharmajri, Village Bhatoli Kalan, Baddi, Tehsil Nalagarh, District Solan, Himachal Pradesh, SMF No. JSMF-OOI effective from 27/02/2024 to 27/02/2026.