THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TMDA

Tanzania Medicines & Medical Devices Authority

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

CCL PHARMACEUTICAL (PVT) LIMITED, LAKHPAT, LAHORE-54770, PAKISTAN

PUBISHING GMP INSPECTION REPORT

January, 2026

Part 1: General information about the company

Manufacturers details	
Name of manufacturer	CCL Pharmaceutical (Pvt) Limited
Corporate address of manufacturer	62-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, Pakistan. Telephone number: +9242111225678 Website: mail.ccl@cclpharma.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	24th – 25th October 2024
Type of inspection	Renewal inspection
Introduction	
General information about the company and site	The was incorporated in Pakistan in April 1985 under the companies Ordinance 1987 as a private limited company and was principally engaged in the manufacturing and sale of all sorts of medicines, drugs and allied activities. The facility manufactured General Oral solid Dosage forms (tablets and capsules), oral liquid(syrups), dry powder suspension, and sterile liquid injections in form of SVP and steroid products in form of capsules.
History	The facility was inspected and licensed by the Local National Regulatory Authority. It was inspected and approved Certifying board such as NDA (Uganda), PPB (Kenya), Ministry of Health Uzbekistan and SGS United Kingdom.
Brief report of the activities undertaken	

Areas inspected	The inspection covered manufacturing lines for general oral solid dosage forms (tablets and capsules)
Restrictions	Restriction was emphasised to the scope of inspection. i.e inspection of general oral solid dosage forms (tablets and capsules) production line.
Out of scope	None
Production lines inspected by TMDA	Manufacturing lines for general oral solid dosage forms (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
SS	Stainless steel
TMDA	Tanzania Medicines and Medical Devices Authority

Part 2: Brief summary of the findings and comments

1. Personnel

The facility had sufficient number of personnel to carry out different activities. An organogram stipulating different positions in the company was available and was verified. Key personnels were provided with job descriptions and employment letters. Employees were imparted with induction and on the job training appropriate to their duties and responsibilities after training assessment as per training SOP in place. All personnels were subjected to pre-employment and on the job medical examination as

was evidenced from the availed records. SOP for hygiene and health of employees was available and was adhered to. In all areas personnel were observed wearing clean uniforms and maintained good hygienic practices during production operation.

2. Premises

a. Layout and Design

The facility was designed, located, constructed and maintained to minimize errors and avoid cross contamination and permit effective cleaning.

Ground floor consisted of change rooms, raw materials warehouse, oral liquid manufacturing area, OSD manufacturing area for tablets and capsules, packing and finished good warehouse.

First floor consisted of Injectables production areas (ampoules and vials), packing materials store, granulation areas for OSD, and general Dry powder for suspension (GDS) area.

Second floor had the utilities, (HVAC and WTP).

The premises were constructed with reinforced cement concrete and the walls, floors and ceilings were constructed by using hard non-porous and non-shedding materials with smooth finish to facilitate effective cleaning. All doors and windows were flushed and have a smooth finish. Door interlocking system mechanism was provided in all critical areas to avoid aerial contamination.

b. Sanitation and Hygiene

High levels of sanitation and hygiene was observed in all areas including the surrounding, premises, equipment and personnel.

Entry of insects, pests, birds, pests, vermin and rodents were prevented by insects and rodents' traps that were located at various points of the building.

Entry to the manufacturing area was controlled and adequate sanitation procedures was followed through provision of primary and secondary changing rooms which were provided with facilities for hand washing, sanitizer, crossover benches, cabinets, bins etc. Gowning and de-gowning procedures including pictorial diagrams were in place and were properly followed. Cleaning and disinfection of sterile and non-sterile production areas was done ain line with the respective procedures and records were verified.

3. Production

Materials

Incoming raw materials and manufactured finished products were quarantined after receipt until release for use. Materials were found stored under required temperature and RH. Cold storage facilities were provided for APIs that required cold environment. There were dedicated and secured areas for storage of expired, rejected and recalled, and printed packaging materials.

General Tablets and Capsules Production Line

The manufacturing process was done according to instructions and recorded in the Batch Production Record (BMR). Before batch production line clearance was adequately conducted together with pre-operation monitoring, records were in place.

Manufacturing activities properly carried out from dispensing to packaging. Separate dedicated production areas for steroids and general formulations were provided to prevent risk of cross contamination.

All critical stages including sieving, feeding of API and excipient in the granulator, dry and wet granulation, drying, sieving, blending and tablets compression or capsules filling, and packaging were carried out as per validated procedures. In process checks at each stage of production were all recorded in the executed BMRs.

Reworking/reprocessing was conducted once approved in line with respective procedures. There were no any contracted-out manufacturing activities.

4. Quality Control

The facility had a quality control (QC) laboratory which was separated from production areas.

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. Accelerated and long-term stability studies were carried out based on the established protocol and stability results were maintained in the LIMS. Products were properly arranged in the chambers and were easily traceable.

Reference and working standards were properly stored and easily retrieved. Retained samples were observed to be stored at appropriate storage conditions according to the documented procedure in place and the room was well maintained for temperature and relative humidity.

5. 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.

6. Water Treatment System

The facility had water treatment plant for generation of Purified water and Water for Injection. To obtain purified water the source water was passed through filtration, softener, RO, and deionizers, then was distributed to production area through loop system. WFI was then obtain by passing the PW through multicolumn distillation, then under UV lamp to the user points. Both chemical and microbial parameters were monitored to ensure quality of the water. Preventive maintenance, sanitization and qualification were performed in line with the respective procedures, records were in place.

7. Heating, Ventilation, and Air Conditioning

The facility had HVAC system which consisted of 33 AHUs, dehumidifiers and ventilation units. Each core production room was supplied with dedicated AHU. Temperature was controlled and maintained within 15-25^{0}C while humidity was controlled if required. Limits of temperature and humidity were designed for all products processing areas along with installation of dehumidifiers in critical areas. Calibrated thermohygrometer and magnehelic gauges were installed in all processing areas for routine monitoring of temperature, relative humidity and differential pressure respectively. The system was subjected to revalidation and return filters were cleaned

after every product change. Filter integrity test was also performed as pe the SOP, records were verified.

8. Document

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, including the observations listed in Part 2 above **CCL Pharmaceuticals(Pvt) Limited,62-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, Pakistan** was considered to be operating at an acceptable level of compliance with TMDA GMP Guidelines for Human Medicines for the production of **general pharmaceutical formulations in forms 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 Authority (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition.

2. CCL Pharma Limited site Master File number CCL-SMF-16.

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

4. Tanzania Medicines and Medical Devices Act, Cap 219.

5. Tanzania Medicine and Medical devices Authority GMP Inspection Report 5th - 6th September, 2019 and corresponding CAPA response.