

LICENSING AND ENFORCEMENT DIVISION

PUBLIC cGMP INSPECTION REPORT OF PHARMACEUTICAL MANUFACTURER:

Name of Company: Kwaliti Pharmaceuticals Ltd., Amritsar Unit II

1.0 General information

1.1 Name of Inspected company	Kwaliti Pharmaceuticals Ltd.
1.2 Physical address	Unit II, Village Nag Kalan, Majitha Road, Dist. Amritsar, Punjab- India
1.3 Corporate address	6th Mile Stone, Village Nag Kalan, Majitha Road, Dist. Amritsar, Punjab- India
1.4 Summary of the main activities performed	Manufacture of Beta Lactam Oral Solid Dosage forms including tablets and capsules, powder for oral use (sachets), dry powders for oral suspensions, and Sterile products for dry powder injections (vials).
1.5 Scope of Inspection	Product-based inspection to verify compliance with cGMP guidelines for the Manufacture of Beta Lactam Sterile products (Dry Powder Injections).
1.6 Purpose of Inspection	To ascertain cGMP compliance for the products that are pending submission for registration with the Medicines Control Authority of Zimbabwe (MCAZ) 1. Cloxacillin 500mg injection 2. Ampicillin 500mg injection 3. Benzylpenicillin 5 MU 4. Imipenem and Cilastatin 250mg/250mg injection
1.7 Inspectors	Mr. Sly Mutyavaviri- Lead Inspector Ms. Ashley Verenga- Co-Inspector
1.8 Date of Inspection	29 th to 30 th April, 2025

2.0 Abbreviations list

Abbreviation	Full form
ACPH	Air Changes Per Hour
AHU	Air Handling Unit
BMR	Batch Manufacturing Record
BPR	Batch Packing Record
cGMP	Current Good Manufacturing Practice
DHU	Dehumidification Unit
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HEPA	High Efficiency Particulate Air (filter)
HPLC	High Performance Liquid Chromatography
HVAC	Heating, Ventilation, and Air Conditioning
LAF	Laminar Air Flow
MCAZ	Medicines Control Authority of Zimbabwe
NVPC	Non-Viable Particle Count
PQR	Product Quality Review
RABS	Restricted Access Barrier System
SOP	Standard Operating Procedure
TRS	Technical Report Series (WHO)
WHO GMP	World Health Organization Good Manufacturing Practice

3.0 Summary

3.1 Brief summary about the facility

Kwality Pharmaceuticals Ltd. is a pharmaceutical manufacturing facility located in Amritsar, India. The company has been granted licenses to manufacture selected finished products by the Food and Drug Administration (FDA) of Chandigarh, Punjab, following a technical evaluation of the documents and facilities. The facility is engaged in the manufacture of various drug products. The manufacturing activities are carried out in compliance with current Good Manufacturing Practice (cGMP) guidelines as specified under Schedule M of the Drugs and Cosmetic Act, 1940, Good Laboratory Practice (GLP) (Schedule L-1), and World Health Organization (WHO) Good Manufacturing Practice (GMP). The raw materials used in the manufacturing process are sourced through registered traders/suppliers.

The facility holds a drug manufacturing license issued by the State Food & Drug Control Administration Chandigarh Punjab (India). The licenses issued by the FDA are valid for a period of 5 years, after which they are subject to renewal. The site is dedicated to the manufacturing of various dosage forms of Beta Lactam Drugs. The products manufactured include tablets and capsules, powder for oral use (sachets), dry powders for oral suspensions, and dry powder injections (vials). These different types of products are designed to cater to diverse patient needs and preferences, ensuring a range of treatment options for various medical conditions.

3.2 General Information about the Company and the Site

This was a new inspection of the facility to ascertain cGMP compliance for the products listed below that are pending submission for registration with the Medicines Control Authority of Zimbabwe (MCAZ).

1. Cloxacillin 500mg injection
2. Ampicillin 500mg injection
3. Benzylpenicillin 5 MU
4. Imipenem and Cilastatin 250mg/250mg injection

The inspection was conducted over two (2) days by the MCAZ. The first day involved an

introduction and company presentation meeting attended by senior Kwaliti Pharmaceuticals Ltd. Unit II team members and the MCAZ inspectorate. The scope of the inspection was then confirmed. Afterwards, the inspection started with document review, which was followed by a tour dry powder injection production line, the HVAC system, raw materials and finished goods warehouse. The second day started with an intensive document review session, followed by inspection of the chemistry and microbiology laboratories. Finally, a closing meeting was attended by senior members of the Kwaliti Pharmaceuticals Unit II team and the MCAZ inspectorate, in which an interim inspection report was presented and discussed.

The inspection was conducted with reference to and in accordance with the WHO Good Manufacturing Practices detailed in the Technical Report Series 986, Annex 2 of 2014, among other current relevant guidelines. The inspection was conducted in an open and cooperative atmosphere.

GMP inspections of the site within the last five years

The manufacturer had only been inspected by the Indian regulator and had no prior inspection history with other regulatory authorities for the sterile dry powder injection production line.

3.3 Products registered in Zimbabwe

There are currently no products registered in Zimbabwe.

3.4 Products currently under evaluation for registration in Zimbabwe

The products listed below have dossiers pending submission for registration with the Medicines Control Authority of Zimbabwe (MCAZ).

1. Cloxacillin 500mg injection
2. Ampicillin 500mg injection
3. Benzylpenicillin 5 MU
4. Imipenem and Cilastatin 250mg/250mg injection

3.5 Areas inspected (*Not exhaustive*)

- **Quality Management:** Product Quality Review (PQR), Quality Risk Management, Deviation control, finished product and starting material batch release, Contract agreements and Supplier approval.
- **Materials Management:** Receipt, handling, quarantine, sampling, release, reject, temperature (and humidity) monitoring and dispensing.
- **Good Practices in Production:** Production areas, production equipment, documentation and instructions, sanitation cleaning and maintenance, batch records, calibration, contamination control, in process controls.
- **Quality Control:** Review of test procedures and specifications.
- **Utilities:** HVAC, Purified Water, Compressed Air system
- **Environmental Monitoring:** EM programme
- **Equipment qualification** and preventive maintenance

3.6 Utilities

1. Water Purification system
2. HVAC system
3. Compressed Air System

3.7 Documentation reviewed

As listed in the final inspection report.

3.8 System Summaries

Annual Product Quality Review

The procedure for Annual Product Quality Review was reviewed. It indicated that APQR was to be completed within GMP timelines, covering raw materials, in-process checks, finished product testing, stability data, utilities, and technical agreements, amongst many other items.

Vendor Approval

The approved vendor lists for raw materials and packaging materials were reviewed. Vendor qualification involved questionnaires, sample analysis, onsite audits by certified auditors, and quality technical agreements. Raw material samples complied with specifications, and packaging vendors such as those supplying vials and rubber stoppers were audited and contracted. Overall, vendor approval processes included documentation, audits, and agreements to ensure compliance with quality standards.

Environmental Monitoring

Environmental monitoring in manufacturing areas, warehouses, and laboratories included viable techniques such as swabs, contact plates, and settle plates, with exposure times and sampling locations clearly defined. Non-viable particles were monitored using air samplers during each operating shift. Personnel monitoring was conducted through gloved finger dabs and checks at designated body locations. Trend reports were prepared monthly, and isolates from the environment were documented.

Change Control

The change control system covered temporary and permanent modifications across documents, products, materials, systems, facilities, and equipment. Risk assessments were performed, and changes were evaluated by a multidisciplinary committee with quarterly trend monitoring.

Batch Manufacturing Record (BMR)

A sample of a BMR was reviewed and this included verification of the bill of materials, potency adjustment provisions, line clearance, environmental monitoring, and tracking of canister residence times through dynamic passboxes.

Filling Area

Filling operations were conducted using appropriately qualified equipment. Records included machine assembly details, fill volume verification, NVPC monitoring, yield reconciliation,

viable particle monitoring, and finger dab checks. Sterile paper was used during operations, and interventions were documented.

Batch Packing Records (BPR)

Packing records included line clearance, material codes in the bill of materials, and in-process checks during packaging.

Warehouse

The warehouse featured weather protection, receipt checklists, vehicle inspections, satellite sample verification, and weight checks. Daily balance verification was recorded, and temperature monitoring was performed twice daily with continuous logging and cold room data downloads.

Dry Powder Injection

Processes included vial decartoning with light verification, defect display, and vial washing prior to depyrogenation using defined washing cycles.

HVAC Area

The facility was equipped with AHU/DHU systems with an Environmental Monitoring System with alarms. A dedicated, self-contained filter washing area with exhaust was available, along with bubble airlocks to support contamination control.

Contamination Control Strategy

The contamination control strategy was available and this incorporated all the key elements as provided by the WHO TRS 1044 Annex 2.

HVAC Design

The HVAC system included recirculant air with terminal and exhaust HEPA filters, supported by air showers at exits.

Recovery Studies

Validation studies confirmed no cross-contamination in monitored areas. Analytical methods for trace detection were validated, and recovery studies demonstrated acceptable results.

Qualifications

Tunnel qualifications were performed semiannually, covering all the critical process parameters as defined by the guidelines.

Area Qualification

HVAC was qualified and requalification was conducted periodically with well-defined parameters.

Media Fill Studies

Media fill studies were conducted using defined media types on scheduled intervals, with justification provided for media selection. Worst-case conditions were defined. Both shifts were covered, interventions documented, and inspectors qualified. . Reports were verified to demonstrate compliance with aseptic process simulation requirements.

Wet Chemistry

Sample management was supported by software systems that generated and tracked certificates of analysis, with manual options also available. Logbooks for finished product and stability samples were maintained, and sample integrity was verified upon receipt.

HPLC Room

Three HPLC systems with multiple detectors operated under validated software platforms, supported by automatic server backups.

Evaluation of Worksheets

Raw data for product testing were verified, including chromatograms and system suitability. Working standards were qualified, characterized, and tracked through consumption logbooks. Parameters such as assay, water content, related substances, and column performance were documented. Audit trails were reviewed weekly, supported by SOPs and logbooks. Stability and hold-time studies for working standards were performed, and laboratory events were logged and investigated.

Stability Program

Stability studies were conducted according to SOPs, with the first batch of each year included in the program. A master schedule and monthly stability plan were maintained.

Microbiology Area

The microbiology laboratory included a Grade B sterility test room with pass boxes, double-door autoclaves, and membrane filtration methods. Controlled buffer zones supported contamination control during sterility testing.

Complaints

The Quality Assurance Department managed complaints, logged them, and categorized them as critical, major, or minor. Investigations included testing retained samples, reviewing batch records, and analyzing stability data, with corrective and preventive actions implemented by relevant departments. Findings were documented, and responses were provided within defined timelines.

Recalls

The recall system provided for both voluntary and statutory recalls, initiated due to regulatory directives, customer complaints, or internal findings. Recalled products were identified, stored securely, and assessed for appropriate disposition, with regulatory approval sought when required.

4.0 Conclusion

Based on the areas inspected, the people met, and the documents reviewed, including the observations listed in the Inspection Report, **Kwality Pharmaceuticals Ltd., Amritsar Unit II, Village Nag Kalan, Majitha Road, Dist. Amritsar, Punjab- India** was considered to be operating at an acceptable level of compliance with WHO TRS cGMP guidelines for the manufacture of Beta Lactam Sterile products (Dry Powder Injections).

All the non-compliances observed during the inspection those listed in the full report were addressed by the manufacturer to a satisfactory level prior to the publication of the MCAZ PIR.

The site will be reinspected 3 years from the date of the last inspection in line with the risk-based reinspection frequency determination.

5.0 References

1. WHO good manufacturing practices for pharmaceutical products: main principles. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Eight Report* Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
2. WHO Good Manufacturing Practices: water for pharmaceutical use. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six Report*. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
3. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report* Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5, Annex 9
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
4. Supplementary guidelines on good manufacturing practices: validation. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report*. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
5. WHO good practices for pharmaceutical microbiology laboratories. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report*. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2 <http://www.who.int/medicines/publications/pharmprep/en/index.html>
6. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. *WHO Expert Committee on specifications for pharmaceutical preparations. Forty-third report*. Geneva, World Health Organization, 2009. (WHO Technical Report Series, No. 953), Annex 2 <http://www.who.int/medicines/publications/pharmprep/en/index.html>

7. WHO guidelines on quality risk management. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report* Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
8. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty Ninth Report* Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 3
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
9. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty Ninth Report* Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4
<http://www.who.int/medicines/publications/pharmprep/en/index.html>
10. WHO Expert Committee on Specifications for Pharmaceutical Preparations. *Forty-fourth report of the WHO Expert Committee on specifications for pharmaceutical preparations*, World Health Organization, 2010 (WHO Technical Report Series 957, 2010), Annex 1
<http://www.who.int/medicines/publications/pharmprep/en/index.html>

