LICENSING AND ENFORCEMENT DIVISION

PUBLIC cGMP INSPECTION REPORT OF PHARMACEUTICAL MANUFACTURER:

Name of Company: Qualigens Pharma Private Limited

1.0 General information

1.1 Name of Inspected company	Qualigens Pharma Private Limited
1.2 Physical address	M/s. Qualigens Pharma Private Limited Survey No. - 151/2, Umbre, Khopoli-Pali Road, Taluka-Khalapur, Dist. : Raigad - 410203, Maharashtra State, India.
1.3 Corporate address	M/s. Qualigens Pharma Private Limited Survey No. - 151/2, Umbre, Khopoli-Pali Road, Taluka-Khalapur, Dist. : Raigad - 410203, Maharashtra State, India.
1.4 Summary of the main activities performed	Manufacture of Oral Solid Dosage forms (Tablets and Capsules)
1.5 Scope of Inspection	Product based inspection to verify compliance to cGMP guidelines for the Manufacture of Oral Solid Dosage forms – Tablets
1.6 Purpose of Inspection	To ascertain cGMP compliance for the products which have been submitted for registration with the Medicines Control Authority of Zimbabwe (MCAZ)
1.7 Inspectors	Mr. Tendai Samkange – **Co-inspector** Mr. Clive S. Kamhoti – **Lead Inspector**
1.8 Date of Inspection	31st March to 1st April, 2025

2.0 Abbreviations List

Abbreviation	Full Form / Meaning
cGMP	Current Good Manufacturing Practice(s)
GMP	Good Manufacturing Practice(s)
WHO	World Health Organization
MCAZ	Medicines Control Authority of Zimbabwe
APQR	Annual Product Quality Review
PQR	Product Quality Review
CAPA	Corrective and Preventive Action
SOP	Standard Operating Procedure
BMR	Batch Manufacturing Record
OOS	Out-of-Specification
QA	Quality Assurance
QC	Quality Control
CQA	Corporate Quality Assurance (inferred from "Asst. Vice President, CQA")
RA	Regulatory Affairs
R&D	Research and Development+
PDE	Permissible Daily Exposure
FMEA	Failure Mode and Effects Analysis
Cpk	Process Capability Index
SPC	Statistical Process Control

Abbreviation	Full Form / Meaning
HR	Human Resources
HRD	Human Resources Department (prefix for SOP)

Abbreviation	Full Form / Meaning
OSD	Oral Solid Dosage
API	Active Pharmaceutical Ingredient
RMG	Rapid Mixer Granulator
FBD	Fluidized Bed Dryer
LOD	Loss on Drying
CPP	Critical Process Parameter
HVAC	Heating, Ventilation, and Air Conditioning
AHU	Air Handling Unit
RLAF	Restricted Access Barrier System (RABS) Laminar Airflow or Recirculating Laminar Airflow (context suggests a unidirectional airflow cabinet/booth)
HEPA	High-Efficiency Particulate Air (filter)
PW	Purified Water
RO	Reverse Osmosis
TOC	Total Organic Carbon
USP	United States Pharmacopeia
LCMS/MS	Liquid Chromatography with Tandem Mass Spectrometry

Abbreviation	Full Form / Meaning
PCS/PTS	Product Contact Surface / Parts (inferred from context)
FPM	Feet Per Minute
CFU	Colony Forming Unit
UV	Ultraviolet

3.0 Summary

3.1 Brief summary about the facility

Qualigens Pharma Private Limited, Survey No. - 151/2, Umbre, Khopoli-Pali Road, Taluka-Khalapur, Dist. : Raigad - 410203, Maharashtra State, India. Qualigens Pharma Private Limited is used for the manufacture of Oral Solid dosage forms (Tablets and Capsules).

The Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate audited the block manufacturing Oral Solid Dosage forms. The audit was conducted from the 31st of March to the 1st of April, 2025. The company had been previously audited by other regulatory agencies as shown in the non-exhaustive list below.

Country	Agency
Malta	Malta Medicines Agency
South Africa	SAHPRA
Russia	The Ministry of Health of the Russian Federation (Minzdrav)
India	WHO/FDA GMP

3.2 General Information about the Company and the Site

This was an initial inspection of the site by the Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate, to support registration of products in Zimbabwe. The inspection was product-based and focused on the products that were intended for the Zimbabwean market, as provided below:

Product	Dosage Form	Registration number
Methocarbamol 750mg (Mylospas)	Oral Solid Dosage Form - Film-Coated Tablets	Pending Registration

The inspection was conducted over two (2) days. The first day involved an introduction and

company presentation meeting attended by senior members of the Qualigens Pharma Private Limited team and the MCAZ inspectorate.

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 relevant current guidelines. The inspection was conducted in an open and cooperative atmosphere.

3.3 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

3.4 Utilities

a. Water Purification system
b. HVAC system
c. Compressed Air System

3.5 Documentation reviewed *(Not exhaustive)*

As stated in the final report

4.0 System Summaries

Batch Manufacturing Records

The batch manufacturing records of products in the scope of the inspection were reviewed and considered to be satisfactory. All the process parameters were recorded in the BMR and in process sampling was done at specific intervals to monitor the critical quality attributes for the products as well as process endpoints.

Cleaning Validation

The documents describing the approached to cleaning validations were reviewed and considered to be satisfactory.

Air Handling Units

The service area was inspected. The AHUs located in the service area had capabilities for temperature and humidity control. There was provision for cleaning of G4 filters, whilst F6 and F9 filters were changed based on differential pressure changes. HEPA filters were changed once yearly.

Water System

There was a procedure in place for microbiological analysis of purified water, potable water and raw water. There was microbiological testing for Total Viable Count Testing and specified microorganisms, namely, Escherichia Coli, Salmonella, Pseudomonas Aeruginosa and Staphylococcus Aureus.

Annual Product Quality Review

The annual product quality review (APQR) for products of interest were reviewed. The PQR included a review of all the product quality review elements stated in WHO TRS 986 Annex 2 guidelines.

Process Validation

The process validation protocols and reports of products in the scope of the inspection were reviewed. The acceptance criteria were well defined. Three batches were considered for validations triggered by major and critical changes.

Retention Samples

An inspection of the retention samples room was conducted. A sample of the product submitted to Zimbabwe (MCAZ) for registration was reviewed.

5.0 Observations

As stated in the final report

6.0 Conclusion

Based on the areas inspected, the people met, and the documents reviewed including the observations listed in the Inspection Report, **Qualigens Pharma Private Limited, located at Survey No. - 151/2, Umbre, Khopoli-Pali Road, Taluka-Khalapur, Dist. : Raigad - 410203, Maharashtra State, India** was considered to be operating at an acceptable level of compliance with cGMP guidelines for the manufacture of General Oral Solid Dosage Forms.

All the non-compliances observed during the inspection 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 **2 years** from the date of the last inspection in line with the risk-based reinspection frequency determination.

7.0 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 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, 2018 (WHO Technical Report Series, No. 1010), Annex 8, https://www.who.int/publications/m/item/Annex-8-trs-1010

3. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3 https://cdn.who.int/media/docs/default-source/medicines/norms-and standards/guidelines/production/trs1019-annex3-gmp-validation.pdf?sfvrsn=9440a5c_0&download=true

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