LICENSING AND ENFORCEMENT DIVISION

PUBLIC cGMP INSPECTION REPORT OF PHARMACEUTICAL MANUFACTURER:

Name of Company: Scilife Pharma (Pvt) Ltd

1.0 General information

1.1 Name of Inspected company	Scilife Pharma (Pvt.) Ltd.
1.2 Physical address	Plot # FD-57/58, -A2, Korangi Creek Industrial Park (KCIP), Karachi – Pakistan
1.3 Corporate address	Plot # FD-57/58, -A2, Korangi Creek Industrial Park (KCIP), Karachi – Pakistan
1.4 Summary of the main activities performed	Manufacture of the following finished pharmaceutical dosage forms: a. Oral solid dosage forms - (coated and uncoated tablets, capsules, powders. b. Capsules for inhalation c. Dry powders for suspension d. Creams and Ointments e. Oral solid dosage forms – Psychotropic tablets
1.5 Scope of Inspection	Product based inspection to verify compliance to cGMP guidelines for the manufacture of the following dosage forms: a. General Oral solid dosage forms - (coated and uncoated tablets, capsules, oral powders in sachets). b. Inhalation Powders in Capsules c. Dry powders for suspension
1.6 Purpose of Inspection	To ascertain cGMP compliance for the products submitted for registration with the MCAZ.
1.7 Inspectors	Mr. Tendai Samkange – **Lead Inspector** Mr. Clive Simbarashe Kamhoti – **Co-inspector**
1.8 Date of Inspection	10th – 12th March 2025

2.0 Abbreviations List

Abbreviation	Expanded Form
cGMP	Current Good Manufacturing Practices
MCAZ	Medicines Control Authority of Zimbabwe
WHO	World Health Organization
PIR	Public Inspection Report
GMP	Good Manufacturing Practices
AHU	Air Handling Unit
HVAC	Heating, Ventilation, and Air Conditioning
CFM	Cubic Feet per Minute
HEPA	High-Efficiency Particulate Air
GRN	Goods Receipt Note
ERP	Enterprise Resource Planning
SOP	Standard Operating Procedure
BMR	Batch Manufacturing Record
BPR	Batch Packing Record
APQR	Annual Product Quality Review
PQR	Product Quality Review
CAPA	Corrective and Preventive Action
LD50	Lethal Dose 50
RO	Reverse Osmosis
LOD	Loss on Drying
RSD	Relative Standard Deviation
NMT	Not More Than
NLT	Not Less Than
Q	Quantity (in dissolution testing)
DT	Disintegration Time
FAT	Factory Acceptance Test
SAT	Site Acceptance Test
TSA	Tryptic Soy Agar
SDA	Sabouraud Dextrose Agar
RODAC	Replicate Organism Detection and Counting
CFU	Colony Forming Unit
RH	Relative Humidity
FMEA	Failure Mode and Effects Analysis
FMECA	Failure Mode, Effects, and Criticality Analysis
HPLC	High-Performance Liquid Chromatography
TLC	Thin-Layer Chromatography
TAMC	Total Aerobic Microbial Count
TYMC	Total Yeast and Mold Count

E. Coli	*Escherichia coli*
S. Aureus	*Staphylococcus aureus*
B. Subtilis	*Bacillus subtilis*
C. Albicans	*Candida albicans*
A. Niger	*Aspergillus niger*
SP	Sampling Point
PM	Preventative Maintenance
R&D	Research and Development
MCC	Microcrystalline Cellulose
HMI	Human-Machine Interface
EM	Environmental Monitoring
MLT	Microbial Limit Test
GPT	Growth Promotion Test

3.0 Summary

3.1 Brief summary about the facility

Scilife Pharma (Pvt) Ltd located at Plot # FD-57/58, -A2, Korangi Creek Industrial Park (KCIP), Karachi – Pakistan was inspected. The site manufactures of Oral solid dosage forms - (coated and uncoated tablets, capsules, powders), Capsules for inhalation, Dry powders for suspension, Oral solid dosage forms – Psychotropic tablets, Creams and Ointments.

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**
Sitagliptin/Metformin (50/1000mg)	Tablets	Pending Registration

The inspection was conducted over three (3) days. The first day involved an introduction and company presentation meeting attended by senior members of the Scilife Pharma 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 current relevant 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,
- **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 inspection report

4.0 Systems Summaries

Walk-through Inspection

The raw material receiving area was maintained in a good state of repair with a weather shield for material protection upon receipt. The same receiving area was used for active materials, excipients and packaging materials, and a receiving checklist was available wherein several parameters such as integrity and temperature conditions were checked upon receipt.

All the products under the scope of the inspection were manufactured in the same floor using the same equipment train except for the corticosteroid capsules which had their own dedicated equipment train.

Blister packing parameters such as forming temperature, sealing temperature and speed were controlled and monitored.

Air Handling Units (AHU)

The air handling units at the facility 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.

Microbiology Laboratory
Access to critical testing areas was through change rooms. The background to the MLT area was classified as Grade D and the testing was being conducted in a biosafety cabinet with laminar air flow. The approach to growth promotion testing of media was considered generally satisfactory.

Batch Record Issuance
The procedure for issuance of batch processing and analytical records was reviewed. There was provision for intimation to QA department for issuance of the desired records. QA department was the custodian of the master copy of the batch records. Issued batch records would be logged in bound, paginated and serialized logbooks. The procedure for numbering of batches of products manufactured at the site was reviewed.

Batch Manufacturing Records
The batch manufacturing records of products in the scope of the inspection were reviewed and considered to be satisfactory. Some products in the scope were packaged in Alu-Alu blisters. For Aluminum blister foil, a chemical identification test for aluminum was employed and FTIR test for lacquering material.

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 we well defined. Three batches were considered for validations triggered by major and critical changes.

Cleaning Validation
The documents describing the approach to cleaning validations were reviewed and considered to be satisfactory.

Preventative maintenance program
The site preventative maintenance program was reviewed. There was a generalized SOP for preventative maintenance and equipment-based SOPs for preventative maintenance. The frequency of PM for production equipment was based on factors such as frequency of breakdowns, criticality of equipment *et cetera*.

Vendor approval
The SOP for vendor approval for Raw and packaging materials was reviewed. The roles and responsibilities of the Head QA was clearly outlined in the procedure and included overseeing vendor audits. There was provision for vendor rating and disqualification.

Quality Control
The COAs for products of concern were reviewed. The COAs had a unique identifier number. Tests executed on site included: Description, Identification, Average Weight, Weight Variation, Disintegration Time, Assay, Dissolution (Q), Uniformity of Dosage Unit, Degradation Products, Water Content and Microbiology Test for TAMC, TYMC and *E. Coli*.

Complaints Handling
The Complaints handling procedure was reviewed. The functions of QA and other departments were clearly outlined in the procedure. Complaints were classified as class I, II and III depending on severity and the timelines for resolving each class were stipulated. There was provision for trending and investigating complaints.

Quality Risk Management System
The SOP for Quality Risk Management was reviewed. There was a provision for setting up a QRM cross functional team. The risk management methods and tools were stated and evidence of application was provided. There was provision for periodic risk review in the SOP.

Purified Water System
The purified water system was inspected. The source water would go through reverse osmosis to generate RO water which was then further purified using ion exchange with anionic, cationic and mixed resin beds. Purified water for pharmaceutical use was claimed after the ion-exchange processing stage.

Change Management
The procedure for Change Control management was reviewed. Changes were managed through an electronic system, from initiation up to approval and verification of change. Effectiveness of the change was then verified three months after implementation of change.

Stability Monitoring
The procedure for stability monitoring of products was reviewed. There was a program in place for on-going stability monitoring.

Area Qualifications/HVAC qualification
Qualification of cleanrooms was in line with ISO 14644 guidelines.

Environmental Monitoring program

The Environmental Monitoring program SOP was reviewed. Active Air sampling was the main method of monitoring cleanrooms and was done once every month. Tryptic Soy Agar (TSA) was the main media.

Disinfectant Qualification
Disinfectant Qualification studies were reviewed. The disinfectants were used on a rotational basis. The was consideration of a sporicidal agent amongst the approved disinfectants.

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, **Scilife Pharma (Pvt) Ltd , Plot # FD-57/58, -A2, Korangi Creek Industrial Park (KCIP), Karachi – Pakistan**, was considered to be operating at an acceptable level of compliance with cGMP guidelines for the manufacture of General Oral Solid Dosage Forms (Tablets, Hard Gelatin Capsules and Oral Powder Sachets), Inhalation Powders in Capsules and Dry Powders for Suspension.

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