

LICENSING AND ENFORCEMENT DIVISION

FINAL cGMP INSPECTION REPORT OF PHARMACEUTICAL MANUFACTURER:

Emcure Pharmaceuticals (Pvt) Ltd

1.0 General information

1.1 Name of Inspected company	Emcure Pharmaceuticals (Pvt) Ltd
1.2 Physical address	Lane No- 3, Phase-II, SIDCO Industrial Complex, Bari Brahmana, Jammu, Jammu and Kashmir, 181133, India
1.3 Corporate address	Lane No- 3, Phase-II, SIDCO Industrial Complex, Bari Brahmana, Jammu, Jammu and Kashmir, 181133, India
1.4 Summary of the main activities performed	Manufacture of oral liquid and oral solid dosage forms
1.5 Scope of Inspection	Product based inspection to verify compliance to cGMP guidelines for the manufacture of oral liquid and oral solid dosage forms
1.6 Purpose of Inspection	To ascertain cGMP compliance for the products which are registered in Zimbabwe and currently under registration with the MCAZ.
1.7 Inspectors	Martha Mwatseteza – Lead Inspector Onias Hove- Co-Inspector
1.8 Date of Inspection	11 th -13 st August 2025

2.0 Abbreviations List

Abbreviation	Expanded Form
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AHU	Air Handling Unit
BMR	Batch Manufacturing Record
BPR	Batch Processing Record
CV	Cleaning Validation
EM	Environmental Monitoring
FPP	Finished Pharmaceutical Product
HPLC	High-Performance Liquid Chromatography
HVAC	Heating, Ventilation, and Air Conditioning
MACO	Maximum Allowable Carry Over
MCAZ	Medicines Control Authority of Zimbabwe
PDE	Permitted Daily Exposure
PQ	Performance Qualification
PQR	Product Quality Review
QA	Quality Assurance
SOP	Standard Operating Procedure
TD	Therapeutic Dose
TRS	Technical Report Series
WHO	World Health Organization

3.0 Summary

The inspection constituted a product-based evaluation designed to verify the manufacturer's adherence to current Good Manufacturing Practice (cGMP) requirements for the production of oral solid and liquid dosage forms. Over a three-day period, the inspectorate team reviewed the facility's quality management system, batch records, validation protocols and standard operating procedures (SOPs). Documentation review encompassed critical control points such as raw-material receipt and testing, in-process monitoring, equipment qualification, cleaning and maintenance logs, and stability-testing data.

Concurrently, an on-site tour of the production and ancillary areas was conducted, during which active manufacturing lines were observed under routine operating conditions. The inspectors evaluated in real time the implementation of batch release controls, sampling procedures and environmental monitoring results to ensure that process parameters remained within predefined acceptance criteria. The inspectors then held an inspectors' meeting in which findings from the inspection were discussed and there was consensus on the inspection findings.

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

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

3.1 Summary about the facility

The manufacturing facility located in Jammu operates as a dedicated site with two distinct production blocks. One block is designated for the manufacture of tablet and capsule dosage forms, while the other is dedicated to the production of oral liquid formulations. At the time of the inspection, the site had several products which were registered in Zimbabwe, alongside additional products currently undergoing evaluation for registration. The details of the registered products and those under registration are provided below.

S. No.	Name of Product	Generic Name	Registration status
1.	Sevcar 400 Tablets	Sevelamer Carbonate Tablets 400mg	Registered
2.	Sevcar 800 Tablets	Sevelamer Carbonate Tablets 800mg	Registered
3.	Vifex syrup	Salbutamol Sulphate, Bromhexine hydrochloride and Guaifenesin Syrup 1mg/2mg/50mg	Registered
4.	Dexpure Tablets	Dexrabeprazole Sodium Tablets 10mg	Registered
5.	Orofer Syrup	Iron [III] Hydroxide Polymaltose Complex Syrup 50mg	Registered
6.	CALOSHELL 500 TABLET	Calcium and Colecalciferol Tablets 500mg	Registered
7.	Orofer Capsules	Iron [III] hydroxide polymaltose Complex & Folic Acid BP Capsules 100mg/550mcg	Registered
8.	Deshist	Desloratadine Oral Solution 0.5 mg/ml	Under registration

3.2 General Information about the Company and Site

The site is located at Lane No- 3, Phase-II, SIDCO Industrial Complex, Bari Brahmana, Jammu, Jammu and Kashmir, 181133, India. This was a routine inspection of the facility by Emcure Pharmaceuticals (Pvt) Ltd. *Final cGMP Inspection Report, 11th August - 13th August 2025*

the MCAZ inspectorate. The company was previously inspected by the Medicines Control Authority of Zimbabwe (MCAZ) in 2022. The first day activities comprised of an introductory meeting in which the MCAZ Inspectorate and the Emcure team introduced themselves. This was followed by a projected Emcure Company power-point presentation. Thereafter the scope of the inspection was defined, both parties agreed on the blocks to be inspected. Immediately after, extensive document review commenced. Later in the day a walk-through inspection was conducted, for the raw material warehouse and the oral liquids manufacturing block.

Second day activities encompassed further document review and the inspection of the oral solid dosage forms block and the utility blocks (HVAC system and Water Purification). Quality control laboratories chemistry section and the microbiology section for both blocks were inspected on the third day. The inspectors then held an inspectors' meeting in which findings from the inspection were discussed and there was consensus on the inspection findings.

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,
- **Environmental Monitoring:** EM program
- **Equipment qualification** and preventive maintenance

3.4 Utilities

- a. Water Purification system
- b. HVAC system

3.5 Documentation reviewed (*Not exhaustive*)

Refer to the final report.

4.0 Summary of Systems

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Pharmaceutical Quality Systems

Product Quality Review (PQR)

The Standard Operating Procedure (SOP) for Product Quality Review was submitted for review. The key pharmaceutical quality system parameters have been considered. All the parameters were in state of control.

Vendor Qualification

The SOP for vendor approval was submitted for review. The approach to qualification, requalification and disqualification of vendors was evaluated. All the necessary declarations were being submitted as part of the vendor qualification. The approach to ongoing vendor monitoring was reviewed.

Complaints

The procedure for handling complaints was submitted for review. The procedure provided for receipt, root cause identification and CAPA provision. The timelines from receipt to closure were specified. The logs of complaints were reviewed. Examples of complaints were reviewed to show the application of the SOP. The approach to handling of complaints was satisfactory.

Product Recall

The procedure for product recall was submitted for review. The classes of recall and the depth of recall were reviewed. The timelines for handling the different classes were specified. The SOP provided for execution of mock recalls. The mock recalls were reviewed for their effectiveness.

Self-Inspections

The procedure for self-inspection was reviewed. There was provision of a self inspection calendar. There was provision for internal auditors. There was a procedure for qualification of these auditors. The SOP provided for CAPA production.

Deviations

The SOP for deviations handling was submitted for review. There was provision of categorizing the deviations according to their impact. Timelines for closure of deviations were specified. The logs of deviations and trend reports of deviations were submitted for review.

Change Control

The SOP for change management was submitted for review. There was provision of a multidisciplinary approach to change management. The log of changes were submitted for review and examples of quality impacting changes were reviewed. The handling of changes was satisfactory.

Quality Risk Management

The SOP for Quality Risk Management (QRM) was reviewed. The different types of risk tools were specified and circumstances they would be used were specified in the SOP. Examples of executed risk assessments were submitted for review and these were following the procedure.

Warehouse.

The procedure for receiving raw materials was reviewed. The approach to storage of printed packaging materials was evaluated. Procurement of starting materials was being done from approved vendors. The SOP for receipt of materials was submitted for review. There was provision of dedusting, weight verification, sampling and dispensing. The SOPs for sampling and dispensing were submitted for review. The sampling areas and the dispensary areas were inspected, and these were in a good state of maintenance.

Batch manufacturing records

SOP for handling, issuance and receipt of BMR documents was submitted for review. There was provision for QA oversight in the BMR issuance process. There was provision for the doer and checker concepts. Data integrity principles were being observed in the batch records. The line clearance procedures were well executed. Examples of batch manufacturing records were submitted for review, and these were satisfactory.

Facility tour

The compounding, tableting, packing (blister and bottle), liquid compounding, filling and bottle packing areas were inspected. The compounding, encapsulation and visual inspection areas were inspected.

Batch manufacturing records

SOP for handling, issuance and receipt of BMR documents was submitted for review. There was provision of an intimation slip from production to QA. There was provision for doer and checker concepts. Data integrity principles were being observed in the batch records. The line clearance procedures were well executed. Examples of batch manufacturing records were submitted for review and these were satisfactory.

Water System

A comprehensive analysis of the water system including the layout, sanitization procedures, preventative maintenance, trends analysis and environmental monitoring were evaluated. The records were satisfactory. The annual water trend reports for the online monitored parameters were reviewed and these were satisfactory.

HVAC

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The AHUs were inspected. The SOPs for handling the primary and secondary filters were submitted and these were satisfactory. Preventive maintenance schedules and records were also submitted for review. Preventive maintenance program for the dust extractor was reviewed. The filter cleaning procedure was also reviewed and was found to be satisfactory.

Qualification and Validation

Cleaning validation

The facility's approach to cleaning validation was evaluated. The MACO calculations, PDE reports and the approach to cleaning verification was submitted for review.

Process validation (PV)

The approach to process validation was reviewed. The SOP for CPV was established and implementation was verified.

Area qualification reports

SOP for Preventative maintenance of air handling unit was submitted for review. Key parameters such as non-viable particle counts, air changes per hour, room recovery, HEPA leakage tests had been considered. AHU Qualification for AHU #3 and #6 were also reviewed.

Equipment qualification

The qualification protocol and report for the capsule filling machine were reviewed. The protocol and report for the bottle filling machine were reviewed.

Quality Control

Chemistry Laboratories

The procedure for sample receipt and management was reviewed. The sample storage areas were inspected and were found to be generally satisfactory.

HPLC room

The HPLC room was inspected. The SOP for operation and calibration of HPLCs was submitted for review. The approach to handling of columns and calibration of the HPLCs was reviewed.

Audit trail review

The SOP for review of electronic data and audit trail in laboratory was submitted for review. This was satisfactory.

Specification, working standard and reference standards

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The SOP for specifications, handling of working standards and reference standards was submitted for review. These were being handled satisfactorily.

Glassware cleaning

The SOP for cleaning laboratory glassware was submitted for review. The approach to handling of the detergents was verified.

Stability

The SOP for stability monitoring was submitted for review. The stability chambers were inspected. Examples of stability protocols for the products under consideration were submitted for review.

5.0 Conclusion

Based on the areas inspected, the people met, and the documents reviewed including the observations listed in the Inspection Report, **Emcure Pharmaceuticals (Pvt) Ltd, located at Lane No- 3, Phase-II, SIDCO Industrial Complex, Bari Brahmana, Jammu, Jammu and Kashmir, 181133, India**, was operating at a level of compliance with cGMP guidelines for the manufacture of General oral solid dosage forms and oral liquids.

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.

6.0 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>

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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>