LICENSING AND ENFORCEMENT DIVISION

PUBLIC cGMP INSPECTION REPORT OF PHARMACEUTICAL MANUFACTURER:

Name of Company: IPCA Laboratories (Pvt) Ltd

1.0 General information

1.1 Name of Inspected company	IPCA Laboratories Ltd
1.2 Physical address	P.O. Sejavta, Ratlam - 457001 (Madhya Pradesh), India
1.3 Corporate address	48, Kandivli Industrial Estate, Kandivli (West) Mumbai - 400067 (Maharashtra), India
1.4 Summary of the main activities performed	Manufacture of Oral Solid Dosage Forms (Tablets), Sterile Active Pharmaceutical Ingredients and Sterile Formulations (Dry Powders for injection (vials) and Ampoules), Oral Liquid dosage forms (Suspensions and Dry Syrups), and semi-solid dosage forms (Ointments)
1.5 Scope of Inspection	Product based inspection to verify compliance to cGMP guidelines for the Manufacture of Oral Solid Dosage Forms (Tablets) and Small Volume Parenterals – Dry Powders for Injection (Vials) and Solutions for Injection (Ampoules).
1.6 Purpose of Inspection	To ascertain cGMP compliance for the products already registered and those which have been submitted for registration with the Medicines Control Authority of Zimbabwe (MCAZ)
1.7 Inspectors	Mr. Tendai Samkange – **Lead Inspector** Mr. Clive S. Kamhoti – **Co-inspector**
1.8 Date of Inspection	27th to 29th March, 2025

2.0 Abbreviations List

Abbreviation	Full Form
AHU	Air Handling Unit
API	Active Pharmaceutical Ingredient
APQR	Annual Product Quality Review
BMR	Batch Manufacturing Record
BMS	Building Management System
BFS	Blow-Fill-Seal
CAPA	Corrective and Preventive Action
CFM	Cubic Feet per Minute
cGMP	Current Good Manufacturing Practice
DEU	Dust Extraction Unit
DPI	Dry Powder for Injection
EMS	Environmental Monitoring System
FDV	Forced Draft Ventilation
FPS	Finished Product Specification
HEPA	High-Efficiency Particulate Air
HMI	Human-Machine Interface
HVAC	Heating, Ventilation, and Air Conditioning
LIMS	Laboratory Information Management System

Abbreviation	Full Form
MCAZ	Medicines Control Authority of Zimbabwe
OOS	Out of Specification
OOT	Out of Trend
OSD	Oral Solid Dosage
PD	Pressure Differential
PQR	Product Quality Review
SOP	Standard Operating Procedure
TOC	Total Organic Carbon
TRS	Technical Report Series (WHO)
USP	United States Pharmacopeia
WFI	Water for Injection
WHO	World Health Organization

3.0 Summary

3.1 Brief summary about the facility

IPCA Laboratories Ltd, P.O. Sejavta, Ratlam - 457001 (Madhya Pradesh), India, site was used for the manufacture of Oral Solid Dosage Forms (Tablets), Sterile Active Pharmaceutical Ingredients and Sterile Formulations (Dry Powders for Solution for Injection and Small Volume Parenteral Solutions for Injection - Ampoules), Oral Liquid Dosage Forms (Suspensions and Syrups), and Semi-Solid Dosage Forms (Ointments).

The Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate audited the blocks manufacturing Oral Solid Dosage Forms (Tablets) and Sterile Dry Powders for Solution for Injection (vials) and Small Volume Parenteral Solutions for Injection (ampoules). The audit was conducted from the 27th to 29th of March 2025.

3.2 General Information about the Company and the Site

This was a routine inspection of the site by the Medicines Control Authority of Zimbabwe (MCAZ) Inspectorate, to support the continuous registration of products in Zimbabwe. The inspection was product-based and focused on the products that are distributed on the Zimbabwean market, as listed in the table below.

Product	Dosage Form	Registration number
Losartan Potassium, 100mg	Tablets	2015/12.3.5/4981
Hydrochlorothiazide & Losartan Potassium 12.5mg/50mg	Tablets	2015/12.3.5/4980
Atenolol; Chlortalidone	Tablets	2010/12.3.2/4623
Leflunomide 20mg	Tablets	2019/3.3/5899
Atenolol 100mg	Tablets	2002/12.3.2/4051
Atenolol 50mg	Tablets	2002/12.3.2/4050
Bisoprolol 10mg	Tablets	2018/12.3.2/5630
Bisoprolol 5mg	Tablets	2018/12.3.2/5629
Roxithromycin 150mg	Tablets	2001/7.2.5/3922
Chlortalidone 12.5mg	Tablets	2017/12.5.1/5360
Chlortalidone 25mg	Tablets	2017/12.5.1/5359
Etodolac 400mg	Tablets	2017/3.1/5385
Gliclazide 80mg	Tablets	2003/17.7/4179
Artesunate 60mg	Injectable	2021/7.5/6190
Artemether; Lumefantrine 20/120mg	Tablets	2020/7.5/6063
Artemether; Lumefantrine	Tablets	2017/7.5/5320
Losartan Potassium 25mg	Tablets	2004/12.3.5/4257
Losartan Potassium 50mg	Tablets	2004/12.3.5/4258
Amoxycillin Trihydrate; Clavulinic Acid 250/62.5MG	Tablets	2017/7.1.2/5470
Amoxycillin Trihydrate; Potassium Clavulanate 125/31.25MG/5ML	Powder for suspension	2021/7.1.2/6178
Metoprolol Succinate 50mg	Tablets	2013/12.3.2/4802
Simvastatin 10mg	Tablets	2001/12.8/4005
Simvastatin 20mg	Tablets	2002/12.8/4057

The inspection was conducted over three (3) days. The first day involved an introduction and

company presentation meeting attended by senior members of the IPCA Laboratories Ltd 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.

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

Walk-through Inspection

Production tour

The tour of the OSD and sterile production areas was done. All the products under the scope of the inspection were manufactured on different floors.

Batch Manufacturing Records

The batch manufacturing records of products in the scope of the inspection were reviewed and considered to be satisfactory. They were prepared in accordance with 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 (3) batches were considered for validations triggered by major and critical changes.

Cleaning Validation

The cleaning validations SOP and protocol describing the approache 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. Equipment-based SOPs for preventative maintenance. The frequency of PM for production equipment was based on several 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.

Change Control 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 was done.

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.

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.

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, **IPCA Laboratories Ltd,** located at **IPCA Laboratories, Ltd, P.O. Sejavta, Ratlam - 457001 (Madhya Pradesh), India** was considered to be operating at an acceptable level of compliance with cGMP guidelines for the manufacture of Oral Solid Dosage Forms (Tablets); Sterile Dry Powders for Solution for Injection packaged in glass vials and Small Volume Parenteral Solutions for Injection packaged in glass ampoules.

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