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Prequalification Unit Inspection Services
WHO INSPECTION REPORT

Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	IPCA Laboratories Limited
Corporate address of manufacturer	IPCA Laboratories Limited 48, Kandivli Industrial Estate Kandivli (W) Mumbai, 400 067, Maharashtra, India
Name & Address of inspected manufacturing site if different from that given above	IPCA Laboratories Limited, P.O. Sejavta Dist. Ratlam – 457 001 Madhya Pradesh, India DUNS Number: 862179827
Synthetic Unit /Block/ Workshop	IBD-IX, IBD-X, IBD-XII
Inspection details	
Dates of inspection	6-8 October 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	IPCA Ratlam manufacturing site produces active pharmaceuticals, intermediates and finished pharmaceutical products (oral and injectable dosage forms) for domestic and international markets.
General information about the company and site	IPCA Laboratories Limited was established in 1949. The total number of employees is approximately 15000 and the number of products marketed all over the world is approximately 120. In India it has manufacturing facilities at Kandla, Indore, Pithampur, Athal, Piparia, Dehradun, Sikkim and Ratlam licensed to manufacture (Sterile) liquid and dry powder Injectables (aseptically prepared and terminally sterilized ampoules and vials), Oral Solid Dosage Forms Liquid Oral Dosage Forms and Dry Suspensions. Products manufactured at the site comprise Generic & Proprietary Medicines and active pharmaceutical ingredients for Human Use only. Though the FPP and API manufacturing shared the same site, the production facilities, the personnel and the QMS was separate.
History	The manufacturing facility has been regularly inspected by the WHO PQ Inspection Services. The last on-site WHO Geneva GMP inspection was conducted in 2024. In addition, the facility has been inspected by national

	competent authorities of regulated markets e.g. USFDA, ANVISA, TGA Slovenia (EU).
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: – Quality management system – Personnel and training – Buildings and facilities – Qualification and validation – Production and packaging operations – Quality control laboratories – Warehouse – Utilities
Restrictions	None
Out of scope	The scope of the inspection was limited to the APIs listed below and submitted for the WHO Prequalification. Other APIs were out of the scope of this inspection.
WHO APIs (including WHO API or APIMF numbers) covered by the inspection	– Amodiaquine (APIMF030) – Lumefantrine (APIMF042) – Artesunate (APIMF081) – Artemether (APIMF163) – Dihydroartemisinin (APIMF233)
Abbreviations	**Meaning**
AHU	Air handling unit
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CoA	Certificate of analysis
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
GMP	Good manufacturing practices
HEPA	High efficiency particulate air
HPLC	High performance liquid chromatography
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
KF	Karl Fisher
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
OQ	Operational qualification
PLC	Programmable logic controller

PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RO	Reverse osmosis
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer

Part 2	**Summary of the findings and comments**

1. Quality management

Quality Manual

The Quality Manual described the quality management system, the participation of management and appropriate personnel. The document encompassed the organizational structure, procedures, processes and resources, activities necessary to ensure confidence that the API will meet its intended specifications for quality and purity, provision that all quality-related activities should be defined and documented.

The quality unit was independent of production and fulfilled both quality assurance (QA) and quality control (QC) responsibilities. It was responsible for the following functions.

- Releasing or rejecting raw materials, intermediates, packaging and labelling materials, APIs.
- Reviewing completed batch production and laboratory control records of critical process steps before release of the API for distribution.
- Making sure that critical deviations are investigated and resolved.
- Internal audits (self-inspections) are performed.
- Approving intermediate and API contract manufacturers (at corporate level).
- Change control investigation.
- Complaint investigation.
- Equipment maintenance and calibration program.
- Stability program.
- PQR preparation and approval.
- Reviewing all production batch records.
- Approval of the GMP core documents.

The quality manual was updated as per change control, covering amongst updating on EDMS, organogram, ONE-lab software.

Deviation management

SOP specifies that any deviation from established procedures should be documented and explained. All deviations should be investigated, and the investigation and its conclusions should be documented. The number of deviations recorded since the last inspection with risk-based real cases were discussed.

Risk management

The risk assessment was performed for the entire manufacturing process starting with the raw materials until final packing (Quality Risk Management). The QRM used quality tool as FMECA.

Two QRM cases were discussed.

CAPA management

CAPAs were managed in TrackWise software according to written SOPs.
The CAPA investigations triggered by a validated OOS related to the inspected product was discussed.

Release of RMs, PMs, intermediates, APIs

The release procedure of the raw materials, intermediates and APIs and the persons authorized to perform was described in SOPs.
No materials can be used for manufacturing process or released for distribution or before satisfactory completion of evaluation by the quality unit. The material management system had the function to prevent usage of any material not released by the QA.

Antimicrobial resistance through preservation of the environment

There was a common antimicrobial resistance prevention study in place for the whole site including formulations and API manufacturing. AMR QRM was prepared to assess the potential of AMR at the site. The study concluded that the risk was under control and all measures were taken to prevent the antimicrobial resistance.

Internal audits

Regular internal audits are performed in accordance with an approved schedule. Audit findings and corrective actions are documented and brought to the attention of the responsible management of the firm. Agreed corrective actions were completed in a timely and effective manner. Self-inspection plans for 2025 IBD-X and IBD-XII site were discussed.

Management Review

Management Review was performed according to written SOP, in reference to the ICH Q10 guideline. Management Quality Review Meetings (MQRM) were held quarterly under the leadership of the President of Corporate Quality. The agenda contained a standardized set of quality metrics that were submitted by the sites prior to the meeting. Minutes of the meeting were published by Corporate. The presentation included the following main items.

- Audits
- Customer Feedback - Complaints, returns & recalls
- Product Quality Performance - OOS, OOT, Deviations, Laboratory investigations, Stability,
- batches released & rejected
- Supplier Qualification & Management - Starting and packaging material approvals & rejections, Vendor qualification

- Infrastructure & Resources – Facilities, Validation & Qualifications, Manpower, Training
- The metrics for OOS, OOT, Deviations, and change controls

APQR

The APQRs were compiled according to the annual plan, but the execution of APQR calendar was recorded paper based.
The details of the last APQR documents were discussed in detail.

2. Personnel

General

The staff (permanent and temporary) in the production: IBD-IX: 52, IBD-X: 84, IBD-XII: 72 with 3 shifts.
Organization charts (the general for the corporate and the site and for the QC department) were available and discussed. The responsibilities of all personnel engaged in the manufacture of intermediates and APIs were specified in job descriptions. The job descriptions of the following staff members were discussed:

- QA manger
- QC manger
- Production IBD-XII
- Assistant general manager
- Engineer Manager

Training

The training of the staff was regularly conducted by qualified individuals and covered operations that the employee performs, and GMP as it relates to the employee's functions.
Records of training were maintained. Training system was periodically assessed.
The Annual plan for PPA (IBD-XII) and the training file of the following staff members were discussed.

- QC analyst
- Engineer
- QA assistant
- Production operator IBD-X

Personnel hygiene

Personnel were wearing clean clothing suitable for the manufacturing activity with which they are involved, and this clothing was changed when appropriate (Entry/Exit in Clean Area at IBD-IX,X,XII). The clothes were to be changed at least daily or even more frequently as appropriate. The laundry was managed in-site. Additional protective apparel, such as head, face, hand and arm coverings, was worn, when necessary, to protect intermediates and APIs from contamination. Personnel avoided direct contact with intermediates or APIs. The SOP on Personnel hygiene was bilingual (Hindi and English).

Medical health check

All personnel, prior to employment, had to undergo an initial health examination. Thereafter regular health examinations were carried out every year. Personnel conducting visual inspections had to undergo periodic eye examinations every six months according to, Medical examination of employee.

3. Buildings and facilities

Design and construction, layouts

Buildings and facilities used in the manufacture of intermediates and APIs in the scope of the inspection were as follows: IBD-XII, IBD-XII, PPA-04, IBD-XII, PPA-03 IBD-XII, PPA-05, IBD-IX, IBD-X and IBD-XII.

Ventilation, air filtration and exhaust systems were provided, where appropriate with control of air pressure, microorganisms (if appropriate), dust, humidity, and temperature, as appropriate to the stage of manufacture where APIs are exposed to the environment. Permanently installed pipework were identified. The change rooms were provided with mobile hand wash facilities and hand dryer.
The powder processing areas were used for one product at a time, following a well-defined product line to prevent cross-contamination (see above).

Classification of controlled areas

The powder processing areas were supplied with AHUs through HEPA filter and qualified as equivalent to "Class D". The areas were subject to regular requalification and continuous monitoring (manual data recording). Drains were provided with an air brake and prevented back-siphonage. The drains were filled up with sanitizer.

Facility cleaning, sanitation and maintenance

Written procedures defined responsibility for sanitation and described the cleaning schedules, methods, equipment and materials to be used in cleaning buildings and facilities.
The SOPs on facility cleaning (including controlled areas) and the on preparation of disinfectant solution and its use for cleaning in final crystallization were discussed.

Water systems

The water generation and purification system were validated, the quality of process water was specified and regularly monitored.

- Water specification
- Operation SOP
- Layout
- Monitoring (on-line and off-line) protocol and reports
- Sanitization SOP and reports
- Alert handling

Different types of water were used for various operations during manufacturing processing and cleaning of equipment.
Raw water/Potable water: from different sources like bore well water was analyzed for chemical and microbiological tests as per in-house specifications.
Purified water (or demineralized water as called in some of the documentation) was prepared in two water generation plants. The purified water used at the IBD-IX, IBD-X and IBD-XII facilities was generated by the Purified Water Plant 01.
The system consisted of resin bed with RO, UF, having capacity of 20 m3/hour. The water was supplied to 16 API plants and the QC laboratory. The water was circulated in the purified water storage tanks

and the loops (IBD-I, IBD-II, IBD-III, IBD-IV, IBD-V, IBD-VI, IBD-VII, IBD-IX, IBD-X, IBD-XI, IBD-XII, IBD-XIII, IBD-XIV, IBD-XIX, IBD-XXIII, IBD-XXIV).
The Water Generation System-02 was out of the inspection scope.
Test results for the return loop point and the trend analysis were discussed.

HVAC
The number of AHUs in the facilities under the scope of the inspection: IBD-IX: 4, IBD-X: 6, IBD-XII: 7
The powder processing areas and the centrifuge cubicles for final products were supplied with filtered air through 0.3-micron filters. Differential pressure was maintained in the controlled areas having minimum 20 air changes/hour. The recirculation rate was 90% and fresh air was 10%.
The HVAC/FFAV system periodic verification protocol and reports of PPA-03 and PPA-04 areas were discussed (Filter Integrity/Differential pressure/Temperature/Non-viables/Viables/Air Change rate).

Changes since the previous inspection
The facility changes were discussed in details.

Compressed air and nitrogen
The validation and periodic verification of compressed air and nitrogen gas was summarized in SOP.
Chemical test was done once per year, microbiological was done every 6 months.
The recent test results/COAs were discussed.

4. Process equipment

Design and construction
Equipment used in the manufacture of intermediates and APIs were adequate size, and located for its intended use, cleaning, sanitization and maintenance. Major equipment (e.g. reactors, storage containers) and permanently installed processing lines were identified. Production equipment was to be used within their qualified operating range. A set of current drawings for equipment and critical installations (e.g. instrumentation and utility systems) was available. Equipment Maintenance schedules and procedures (including assignment of responsibility) were established. Written procedures were established for cleaning of equipment and its subsequent release for use.

The main process equipment was as follows.

- Stainless Steel Reactor
- Glass-lined reactor
- Dryer (STD and Vacuum)
- Rotocone Vacuum Dryer
- Agitated Nutsche Filter cum Dryer
- Nutsche Filter
- Sifter
- Multimill
- Micronizer

Cleaning validation
Acceptance criteria for residues and the choice of cleaning procedures and cleaning agents were defined and justified.

The SOP described the procedure of cleaning validation. There was no cleaning validation study performed since the previous WHO inspections. The continuous cleaning process performance review was due in every 5 years.

Qualification of process equipment

The process equipment were qualified according to the general policy defined in the VMP.
The qualification records of the newly installed X-ANFD-03A (agitated nutsche filter dryer) were discussed.

Calibration of the measuring devices

Control, weighing, measuring, monitoring and test equipment were calibrated according to written procedures and schedule. The devices were categorized as critical or non-critical. The calibration was due annually for critical and in every 2nd year for non-critical. The current calibration status of equipment was verifiable. The qualification records of the measuring devices belonging to the newly installed ANFD (agitated nutsche filter dryer) were discussed: Pressure gauge, Vacuum gauge, Pressure transmitter, Temperature sensor, Multichannel scanner. The equipment was calibrated by an external service provider (calibration laboratory). All the equipment were listed on the annual calibration planner in the LIMS.

Maintenance program

The general maintenance procedure was summarized in SOP. The maintenance records of the agitated nutsche filter dryer were discussed. The maintenance was due in every quarterly as described in the form. The records of the last 2 maintenance were discussed.

Computerized systems

The computerized systems were basically managed at corporate level with the contribution of the local IT staff. The list of GMP-related computerized systems was available indicating complexity and criticality of the computerized application hence the depth and scope of the validation.
The suitability of computer hardware and software to perform assigned tasks was demonstrated by qualification. Computerized systems had controls to prevent unauthorized access or changes to data and equipped with permanent audit trail. Written procedures were available for the operation and maintenance of computerized systems. Data protection measure (backup) was established.
All the critical instrument i.e. HPLC/GC/GC-MS/IR/UV-VIS/LC-MS used in quality control laboratory were connected to the computerized system operated networking and complying with 21CFR part 11 Requirements. For example:

- Chromatographic Data System (CDS).
- "TrackWise" for managing investigation of Deviation, Corrective and Preventive Actions (CAPA), Change Control Management, Handling of Product Complaints, Out of Trend (OOT) and Out of Specification (OOS) as per SOP, "Operation of the Trackwise Software".
- Laboratory Information Management System (LIMS),
- ONE Lab Software for complete electronic execution of analysis workflow and integration with CDS, supporting material management, like test execution, review, approval. It was reintegrated with various instruments and data captured from instruments.
- Electronic Document Management System (EDMS) Software for workflows like CSOP, SOP, Specification, BPCR, Investigation, Quality Risk Management (QRM) and Worksheet,
- Learning Management System,

The progressive report of stability and calibration module integration with One-Lab was discussed. The following documents were discussed.

- User management and system policy for Empower 3 software
- User privilege of Empower 3, (Administrator, IT Administrator, Analyst, QA)
- Format for User requirements specification for factory talk view SCADA system for data monitoring and logging in the bulk drug & finished goods warehouse.
- User requirement specification for SCM
- SCM manage (Commercial, Costing, Inventory, Master, QC, Production),
- Operation qualification protocol for SCM system for API
- SCM inventory module, Annexure 1 of OQ report

Back-up and archiving were managed according to Veritas NetBackup Procedure. Types of storage medium for data backup (EMC DATA DOMAIN-MSDP storage -VERITAS flex) daily, weekly, monthly, yearly. The annual backup was cloud-based for infinite time. The software operated by the Company were categorized as low risk (36 months validity for GAMP category 1-5), medium risk (24 months validity for GAMP 4, 5 category) and high risk (18 months validity for GAMP category 4, 5) as defined.

The SCM system was classified as category 5 high risk and should be validated in every 18 months.

5. Documentation and records

Documentation system

The site QA and the IPCA Corporate Quality Assurance (CQA) had shared functions in terms of the document management system. The corporate was issuing SOPs at corporate level, applicable to the sites. Besides, revised the specifications, test methods. The site QA was responsible for generation, control, revision, issue, withdrawal and implementation of local documents. The following corporate level SOPs were applicable for both the API and FPP production:

- Training management system
- Medical examination
- Quality policy
- Deviation management and investigation
- Corrective and preventive actions
- Quality Risk Management

The SOPs were prepared, approved and revised in the EDMS system. The documents were archived for a well-defined period of time and recorded. The retention period of the main documents:

- Batch production reprocess 11 years
- Logbooks 6 years
- VMP 8 years
- SMF 8 years
- QM 8 years
- Internal audits 6 years

The archiving room (Controlled document storage area) was visited and found appropriate.

Archive

GMP related documents were to be controlled (prepared, reviewed, approved and distributed) according to written procedures in paper or electronic form. The retention periods and the way of archiving for documents was specified.

Batch documents

Master production instructions for all manufacturing steps were prepared, dated and signed and distributed for production in a controlled way. Batch production records included information relating to the production and control of each batch. Documentation of completion of each significant step in the batch production records (batch production and control records) was reviewed and approved as part of the batch release process. The batch numbering system was defined in SOP.

Data integrity risk assessment (DIRA)

Data integrity risk was assessed by SOP. Accordingly, all risks were evaluated as low. The existing controls are satisfactory; no further measures or mitigation was required.

6. Material management

There were written procedures in place describing the receipt, identification, quarantine, storage, handling, sampling, testing and approval or rejection of materials. Upon receipt and before acceptance, incoming materials were examined visually and sampled according to the sampling protocol. All the materials were identified and labelled with the status indicated. Sampling methods specified the number of containers to be sampled, which part of the container to sample, and the amount of material to be taken from each container. Sampling was conducted at defined locations (sampling booths). The dispensing/weighing happened under appropriate (equivalent to Class D environment) conditions.
The identification of the materials during the processing included the following information: material name and/or item code; receiving or control number; weight or measure of material. The processing status of equipment and facilities were indicated. The time limits and the storage conditions were subject to risk assessment and reflected in the BMRs, specifications. Suppliers of critical materials were regularly evaluated. The list of approved suppliers was available (see relevant section).
The material management records of a raw material were discussed.

7. Production and in-process controls

Written procedures were established to monitor the progress and control the performance of processing steps. The carry over of the residual material is avoided by means of validated cleaning processes and well-defined cleaning hold-times.
The executed batch manufacturing record of selected batch was discussed.

8. Packaging and identification labelling of APIs and intermediates

The receipt, identification, quarantine, sampling, examination and/or testing and release and handling of packaging and labelling materials is described in written procedures. Packaging and labelling materials conformed to established specifications. Records were maintained for each shipment of labels and packaging materials. The containers provided proper protection during transportation and storage. Written procedure was in place on the control (issuance and reconciliation) of the printed labels. The labelling procedures were controlled ensuring that the correct packaging materials and labels are used. The examination of the labels was part of the packaging process. APIs to be transported outside of the company premises were packed, sealed and labelled.

9. Storage and distribution

Materials were stored in a manner to prevent degradation, contamination and cross-contamination and under controlled conditions. Environmental condition (storage temperature) was controlled and recorded. Access to the storage areas (including printed labels) was restricted to authorized personnel. Raw and packaging materials, intermediates and APIs were formally released before consumption or dispatch.

10. Laboratory controls

General

Documented procedures described sampling, testing, approval or rejection of materials and recording and storage of laboratory data. The quality of the raw materials, intermediates, APIs, labels and packaging materials was assured by testing against the approved specifications, sampling plans using validated test procedures. The laboratory was equipped with the proper instrumentation: HPLC, GC, GC/MS, LC/MS, UPLC, XRPD, FTIR, UV-VIS spectrophotometer, TOC analyzer, Particle Size Analyzer, Air Sampler, Stability Chamber, Autoclave, Incubators. Laboratory testing was documented by the analyst on the test specific e-forms and reviewed by a supervisor.
Authentic certificates of analysis were issued for each batch of released and dispatched API. The provided information included the name of the API, batch number, date of release, expiry/retest date, criteria, test results date and sign of the approver.
Reference standards were received from reliable sources. Records were maintained on the receipt, storage and use in paper logbooks. Reference standards without officially recognized certificate were qualified in-house.

OOS investigations

OOS results were documented and investigated according to a written procedure.
Cases were selected risk-based and discussed.

Retention samples

Reserve samples of each batch of API were retained for one year after the expiry date or for three years after the batch has been completely distributed by the manufacturer. Reserve samples of KSM were retained for three years from date of release. The reserve samples were stored in packaging system with proper protection and in a quantity sufficient for at least two full analyses. The retention sample room was managed by the QA Department.

Test records

Laboratory records were maintained as part of the documentation system. The test records of an inspected product were discussed. The issued CoA was in line with the Quality specification.

Microbiology laboratory

The following SOPs and records were discussed.

- SOP on sample management
- Logbook for double door autoclave
- Chemical and microbiology testing of water.
- Microbiological; examination of non-sterile products API
- Test results for PW return loop point
- Trend analysis results for the selected period.

11. Validation

Validation Master Plan

The company's overall policy, intentions and approach to validation, including manufacturing process, cleaning procedures, analytical test methods, in-process control test procedures, computerized systems were described in the VMP. The validations were based on written validation protocols approved by the quality unit. The validation report cross-referenced the validation protocol summarized the results obtained.

Process validation

Manufacturing process validations were completed before the commercial distribution of the API.
Critical process parameters were controlled and monitored during process validation. Systems and processes were periodically evaluated. There was no process validation performed since the last WHO inspection. The periodic review of the process performance was due in every 5 years, the continuous process verification biannually according to SOP. The recent Process Verification Reports (CPV) of the products in the scope of the inspection were discussed.

Stability testing

The stability characteristics of APIs were monitored by the ongoing testing program. Stability samples were stored in market stipulated containers. At least the following batches were placed on stability: the first three commercial production batches then at least one batch per year. Expiry or retest dates were supported with stability testing data. The stability testing was regulated at corporate level. The running stability protocols and the test results of the inspected product were discussed.
The hold-time study results were available and discussed.

12. Change control

A formal change control system was established to evaluate all changes that may affect the production and control of the intermediate or API. The SOP covered the identification, documentation, review, approval of changes in manufacturing processes, (including raw materials), specifications, analytical test methods, facilities, utilities, equipment (including computer hardware and software. The potential impact of the proposed change was evaluated. Changes were classified depending on their nature and extent and the effects these changes may have on the process.
List of changes were reviewed.

13. Rejection and re-use of materials

Intermediates and APIs failing to meet established specifications were rejected and quarantined according to written procedure.
Materials do not conform to standards or specifications were allowed to be reprocessed repeating chemical or physical manipulation steps as part of the standard manufacturing process.
Batches to be reworked should be subjected to appropriate evaluation, testing, stability testing if warranted and documentation to show that the reworked product is of equivalent quality to that produced by the original process. Recovery (e.g. from mother liquor or filtrates) of reactants, intermediates or the API was described in the approved procedures, including testing against the quality specifications.
It was stated by the Company, that no reprocess or rework was allowed for the WHO batches without preliminary approval by the PQ assessment team.

14. Complaints and recalls

Complaints

All quality-related complaints should be recorded and investigated according to a written procedure. Records of complaints should be subject to the internal audit, management review and trend analysis. The recall procedure designated the involved staff and the process flow. The procedure covered the information sharing with the Corporate QA, the concerned authorities and the WHO.

Product recall

According to SOP the recalls were classified as

- Class 1: Serious adverse health consequences or death, to be completed within 72 hours.
- Class 2: temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote., to be completed within 5 calendar days.
- Class 3: unlikely to cause adverse health consequences, to be completed within 10 calendar days.

Drugs products for which the license were suspended should be classified as class 1 and notification for regulatory authority within 24 hours. No recall was recorded from last inspection 02/2024.

15. Contract manufacturers (including laboratories)

The vendor qualification and the performance review was managed at Corporate level. There was no new vendor selected and qualified since the last WHO inspection. The list of qualified vendors was available.

Miscellaneous	
Samples taken	NA
Assessment of the site master file	The Site Master File with the Annexes was submitted before the inspection.
Annexes attached	NA

Part 3	**Conclusion – Inspection outcome**

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection including the observations listed in the Inspection Report, ***Ipca Laboratories Limited,*** located at ***P.O. Sejavta Dist. Ratlam – 457001 Madhya Pradesh, India*** was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for active pharmaceutical ingredients guidelines.

All the non-compliances observed during the inspection that were listed in the full report were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR. This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of GMP guidelines referenced in the inspection report

1. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. ***Short name: WHO TRS No. 957, Annex 2***
   https://www.who.int/publications/m/item/annex-2-trs-957

2. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   https://www.who.int/publications/m/item/trs986-annex2

3. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4. https://www.who.int/publications/m/item/trs-1025-annex-4

4. Good manufacturing practices: guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report. Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS 1019, Annex 3***
   https://www.who.int/publications/m/item/trs1019-annex3

5. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations.
   Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
   http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

6. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 957, Annex 1
   https://www.who.int/publications/m/item/trs957-annex1

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
   Short name: WHO TRS No. 957, Annex 3
   https://www.who.int/publications/m/item/trs957-annex3

8. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 2. ***Short name: WHO TRS No. 1044, Annex 2***
   TRS 1044 - 56th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

9. WHO guidelines on transfer of technology in pharmaceutical manufacturing. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4. ***Short name: WHO TRS No. 1044, Annex 4***
   TRS 1044 - 56th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

10. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex 9***
    https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs961-annex9-modelguidanceforstoragetransport.pdf?sfvrsn=b80e925f_5

11. 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.
    Short name: WHO TRS No. 961, Annex 2
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. ***Short name: WHO TRS No. 961, Annex 14***
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