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Prequalification Unit - Inspection Services
WHO PUBLIC INSPECTION REPORT
Active Pharmaceutical Ingredient (API) Manufacturer
WHOPIR

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Kaygee Laboratories Private Limited
Corporate address of manufacturer	203-E, Vastu Prestige, New Link Road Andheri (West) Mumbai 400053 Maharashtra, India
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	Plot No. 06, Phase II, New Industrial Area Mandideep, District Raisen, 462046 Madhya Pradesh India D-U-N-S Number: Under Process GPS coordinates: 23°05'22.1"N 77°31'38.1"E
Unit /Block/ Workshop	Block – III
Inspection details	
Dates of inspection	23-26 March 2026
Type of inspection	Initial
Introduction	
Brief description of the manufacturing activities	Kaygee Laboratories Private Limited (KLPL), established in 1988, was engaged in the manufacturing of drug substances and intermediates.
General information about the company and site	The Kaygee site formed part of Ipca Laboratories Limited. KLPL undertook contract manufacturing (job work) of active pharmaceutical ingredients and intermediates for Resonance Specialties Limited (RSL). RSL and KLPL were linked through common directorship, resulting in shared executive management and potential alignment in strategic decision-making. RSL is the holder of the Drug Master Files (DMFs) for the products within the scope of the inspection. KLPL held 6.61% equity shares of Ipca Laboratories Limited. In addition, common directorship indicates a relationship between the two entities through both ownership and management participation.

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	RSL owned the WHO-listed products and was responsible for oversight of production and associated administrative activities. RSL was represented in management with a Whole-Time Director. Ipca provided QA and QC services. All functions reported to the Chairman.
History	No stringent or WLA regulatory inspections have been conducted in the past five years.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Pharmaceutical Quality System Documentation Facilities and Equipment (including warehouses, tank farm, production blocks) Utilities Production, including the records Quality Control, including the laboratories Packaging and labelling Product Release
Restrictions	Not applicable
Out of scope	APIs not intended for WHO-related supply were not included within the scope of this inspection
WHO APIs (including WHO API or APIMF numbers) covered by the inspection	APIMF532 (Isoniazid) APIMF551 (Pyrazinamide)
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
CPP	Critical process parameters
DM	Demineralized
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
HEPA	High-efficiency particulate air

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HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
HVAC	Heating, ventilation, and air conditioning
IQ	Installation qualification
KF	Karl Fisher
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MR	Management review
NC	Nonconformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SCM	Supply chain management
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

A detailed presentation was provided at the opening meeting.

The company had an established Quality Policy committed to meeting stakeholder expectations. The Quality Policy was approved by the Director and was included in the SMF (Annexure-04).

The organization was structured with clear reporting lines from corporate leadership to site-level operations. Overall governance was provided at the corporate level, supported by senior executive roles overseeing quality, operations, and R&D. Independent Corporate QA oversight was in place, separate from manufacturing. Day-to-day site activities were managed by a Site Head, who

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reported to senior management and was supported by functional heads for QA, Production, Engineering, IT, Warehouse, QC, HR & Administration, and Purchase. The structure demonstrated appropriate segregation of quality and production responsibilities, defined accountability, and effective management oversight in line with GMP requirements.

A QMS was implemented and maintained to ensure compliance with applicable quality policies and regulatory requirements and to support continuous improvement. The QMS was aligned with ICH Q7, EudraLex Vol. 4 Part II, WHO GMP, and 21 CFR Part 11. Oversight of the QMS was assigned to the Head of QA, who reported to the VP Corporate QA.

Clear roles and responsibilities were defined for the QA department. QA department was responsible for batch release, rejection or holding of APIs and intermediates; batch documentation review and management; handling of complaints and recalls; implementation and oversight of CAPA; conduct and approval of OOS and OOT investigations; approval of validation and qualification activities; oversight of stability studies; performance of self-inspections; area clearance prior to production activities; document control and retention; management of control and retention samples; training of personnel; vendor qualification and approval; and approval of outsourced laboratories and contract manufacturers. Change control and deviation management were performed on-site as part of the QMS.

Materials were not released or used prior to completion of evaluation by the Quality Unit, unless a defined system was in place to allow such use in accordance with GMP requirements.

Procedures were in place to ensure timely communication of regulatory inspections, significant GMP deficiencies, product defects, and associated follow-up actions to responsible management. Quality-related activities were documented contemporaneously at the time of execution. Deviations from established procedures were recorded, assessed, and justified. Investigations were performed for critical deviations as required. Data integrity principles consistent with ALCOA were applied.

Self-Inspection

In order to verify compliance with GMP principles for APIs, regular internal audits were performed in accordance with the respective SOP and an approved annual audit schedule. Audit findings and associated corrective actions were documented and communicated to responsible management. Agreed corrective actions were implemented in a timely and effective manner.

Product Quality Review

Regular quality reviews of APIs were conducted to verify process consistency. These reviews were performed and documented on an annual basis.

The PQRs for Pyrazinamide and Isoniazid, covering the period from Jan 2025 to Dec 2025 and approved on 20 Mar 2026, were requested and reviewed to verify inclusion of the required assessment elements:

- Critical in-process controls and critical API test results were included and assessed.
- All batches that failed to meet established specifications were reviewed where applicable. A dedicated section for specification results was present.
- Critical deviations or non-conformances and related investigations were evaluated.

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- Changes to manufacturing processes or analytical methods were reviewed. Relevant examples are referenced in Section 12 of this report.
- Results of the stability monitoring program were reviewed and documented.
- Quality-related returns, complaints, and recalls were assessed.
- The adequacy and effectiveness of implemented corrective actions were reviewed.

The site manufactured two types of batches, including batches intended for the domestic market and batches intended for the WHO supply. Both types of batches were manufactured in Block III.

Process capability analysis (Cp/CpK) was defined as part of the site's ongoing process monitoring strategy. The established frequency for performance of the analysis was annual, with completion required within three months following the end of the review period. Where the defined timelines were not met, initiation of a deviation was required.

Gap assessments were performed by CRD-AMV-Mumbai for Isoniazid and Pyrazinamide to verify alignment between AMV, AMT, and STP.

The regulatory review of the finished product was ongoing with the WHO, and the technical agreement was found to be satisfactory.

The results of these reviews were evaluated, and an assessment was made of whether corrective action or any revalidation should be undertaken.

Quality risk management

SOP for Quality Risk Management, effective 20 Jan 2026, described the procedure for the preparation and maintenance of Risk Management Plans (RMP) and Risk Evaluation and Mitigation Strategies (REMS). The SOP provided a systematic approach to Quality Risk Management. The SOP also described the requirements for establishing and implementing risk minimization activities and for evaluating their effectiveness.

A risk register was available and was reviewed. The risk register logbook was closed annually, and a new register was opened for each year. Selected risks, including Data Integrity Risk Assessment and Nitrosamine Risk Assessment for both Isoniazid and Pyrazinamide, were reviewed and discussed.

Management review (MR)

Procedures SOP for Management Review Meetings were established and implemented to ensure that responsible management was promptly informed of significant GMP-related matters, including serious GMP deficiencies, regulatory inspections, product defects, complaints, recalls, and related follow-up actions.

Regular management reviews were conducted according to an approved schedule to evaluate site performance and to assess the need for corrective actions or revalidation of processes. The outcomes of these reviews were evaluated, and agreed actions were required to be completed in a timely and effective manner.

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The minutes of the management review meeting dated 6 Feb 2026 were available and reviewed. The meeting was conducted at a corporate level, with each manufacturing site reviewed individually and assigned a dedicated section within the action tracking table.

Deviations & Handling CAPA

Any deviation from established procedures was documented and justified. Critical deviations were investigated, and the investigations, root cause analyses, and conclusions were documented in accordance with approved procedures.

The documentation of the selected deviations was reviewed.

Product release

The Head-QA, a qualified science graduate, reviewed batch production records and analytical records and authorized the release or rejection of APIs and intermediates in accordance with the respective SOP. Batches were dispatched only after completion of analysis, record review, and formal batch release, including approval or rejection of finished products, as applicable.

A list of authorized personnel for batch release was available and reviewed. In addition to the Head-QA, the list included two other authorized QA personnel.

Observations related to this section were adequately addressed in the respective CAPA plan.

2. Personnel

Personnel qualification

The site personnel overview indicated that staffing levels and organisational structure were established to support manufacturing, engineering, quality, warehouse, administrative, and information technology functions. The distribution of personnel across these functions demonstrated adequate resourcing to support GMP operations and quality system requirements.

Records of training were maintained, and training was periodically assessed.

The observation related to training was adequately addressed in the respective CAPA plan.

Personnel hygiene

SOP for Personnel Hygiene (effective January 2026) was reviewed. The SOP required all employees to undergo induction training. It addressed requirements related to personal cleanliness, hygienic behaviors, work wear, and protective clothing, as well as health and medical requirements.

Personnel wore clean clothing appropriate for the manufacturing activities performed, and clothing was changed when required. Additional protective apparel, including head, face, hand, and arm coverings, was worn as necessary to prevent contamination of APIs. Personnel avoided direct contact with APIs. Smoking, eating, drinking, chewing, and food storage were restricted to designated areas separate from manufacturing areas.

Consultants

Not applicable.

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3. Buildings and facilities

Design and construction

During the inspection, Block III, dedicated to the production of Isoniazid and Pyrazinamide, was visited.

The buildings and facilities used for the manufacture of intermediates and APIs were appropriately located, designed, and constructed to facilitate cleaning, maintenance, and operations in accordance with the type and stage of manufacture. The facilities were designed to minimize the potential for contamination. Where microbiological specifications were established for intermediates or APIs, the facilities were designed to limit exposure to objectionable microbiological contaminants, as appropriate.

Adequate space was available for the orderly placement of equipment and materials to prevent mix-ups and contamination. The flow of materials and personnel within the facility was designed to prevent mix-ups or contamination. Facility layout drawings were available and provided for review and follow-up.

Defined areas or control systems were in place for key operations, including the receipt, identification, sampling, and quarantine of incoming materials pending release or rejection. Quarantine arrangements were established for APIs prior to release or rejection. Designated areas were available for the sampling of intermediates and APIs, and for holding rejected materials pending further disposition. Storage areas were defined for released materials. Controlled areas were also in place for production operations, packaging and labelling activities, and laboratory operations.

Adequate and clean washing and toilet facilities were provided for personnel. The washing facilities were equipped with hot and cold water, as appropriate, soap or detergent, and air dryers or single-use towels. Washing and toilet facilities were separate from manufacturing areas and were readily accessible. Facilities for showering and/or changing clothes were available where appropriate.

Laboratory areas and operations were separated from production areas.

Environmental monitoring (EM)

SOP for Environmental Monitoring of Microbiology and Production Area (effective March 2026) was reviewed. The environmental monitoring program included the use of settle plates and active air sampling. Processing rooms, including the milling and sifting areas, were classified as Grade D.

Two locations for settle plates using Soyabean Casein Digest Media and two locations for active air sampling with Soyabean Casein Digest Media were defined. These locations were established based on the initial qualification. The PQ protocol was available for review, including the justification for worst-case sampling locations. The specified microbiological limits were defined as follows:

- Settle Plates: 100 CFU/plate
- Active Air: 200 CFU/plate

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Trend reports were prepared on a quarterly basis. Reports covering the period from January to December 2025 were available for review. The reports included trend charts for each period, showing specification limits, alert limits, action limits, and individual results. No OOS results were observed for this period.

4. Process equipment

Design and construction

Equipment used in the manufacture of APIs was of appropriate design, adequate size, and suitably located to allow for intended operation, cleaning, sanitization, where applicable, and maintenance.

Equipment surfaces in contact with raw materials, intermediates, or APIs were constructed of materials that did not adversely affect product quality beyond established specifications. Production equipment was operated only within its qualified operating range.

Equipment maintenance and cleaning

Control, weighing, measuring, monitoring, and test equipment critical to assuring API quality were calibrated in accordance with written procedures and an established schedule.

Written procedures were established for equipment cleaning and for the subsequent release of equipment for use in API manufacturing. For equipment used in the manufacture of WHO products, only DM water was used for cleaning.

Randomly selected SOPs were reviewed and were found to define responsibilities for equipment cleaning, established cleaning schedules, and sanitization where applicable. The SOPs also included instructions for the removal or obliteration of previous batch identification, protection of clean equipment from contamination prior to use, inspection of equipment for cleanliness immediately before use, and the specification of the maximum allowable time between completion of processing and equipment cleaning, where appropriate.

Equipment and utensils were cleaned, stored, and, where applicable, sanitized or sterilized to prevent contamination or carry-over that could adversely affect API quality beyond established specifications.

Where equipment was assigned to continuous or campaign production of successive batches of the same API, it was cleaned at defined and appropriate intervals to prevent the build-up and carry-over of contaminants, including degradants or objectionable levels of microorganisms. Non-dedicated equipment was cleaned between the manufacture of different materials to prevent cross-contamination.

SOP for Preventions to Control Cross Contamination & Mix-Ups (API and Intermediates) (effective March 2026) was reviewed. The SOP established measures to prevent cross-contamination and mix-ups during the manufacture of APIs and intermediates, ensuring that no undesired materials, intermediates, or APIs were introduced. The procedure defined controls related to personnel hygiene, material management, facilities, utilities, equipment, housekeeping, pest control, and material movement. It also included requirements for

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environmental controls, laboratory controls, packaging and labelling operations, occupational exposure band–based handling of APIs and intermediates, PPE requirements, antimicrobial resistance assessment, and air quality monitoring.

Equipment was appropriately identified with respect to its contents and cleanliness status using suitable identification methods.

5. Documentation and records

All documents related to the manufacture of APIs were prepared, reviewed, approved, and distributed in accordance with the SOP for documentation and control. Manufacturing and quality documents were maintained in paper format at the time of inspection. It was noted that the site was in the process of implementing electronic systems.

The issuance, revision, superseding, and withdrawal of all documents were controlled in accordance with the applicable SOP. Revision histories were maintained for controlled documents.

A document retention procedure, i.e., an SOP for Document Retention Policy, effective 20 March 2026, was established for the retention of GMP-relevant documents. Defined retention periods were specified in a table titled “The Documents and Its Retention Time.”

Master (approved) labels were maintained and used for comparison with issued labels.

An SOP was in place for the preparation of Master BPCR (Batch Production & Control Record) The review and approval of batch production and laboratory control records, including packaging and labelling records, were performed in accordance with the approved Master BPCRs (Batch Production and Control Records). Batch production and laboratory control records related to critical process steps were reviewed and approved by the Quality Unit prior to the release or distribution of API batches.

Batch production records

BPCRs for each API were prepared, dated, and signed by one individual and were independently reviewed, dated, and signed by personnel from the Quality Unit to ensure consistency between batches.

BPCRs for Isoniazid were reviewed, and the inclusion of the name of the API and the applicable document reference code was verified. The records provided a complete list of raw materials and intermediates, identified by specific names or codes to ensure clarity regarding quality attributes. Accurate statements of the quantities or ratios of each raw material and intermediate, including units of measure, were documented. Where quantities were not fixed, the required calculations for each batch size or production rate were included, and justified variations were recorded.

The BPCRs specified the production location and major equipment used. Detailed production instructions were documented, including the required sequence of operations, defined process parameter ranges, sampling instructions, and in-process controls with acceptance criteria where applicable. Time limits for individual processing steps and for the overall process were specified as appropriate, along with expected yield ranges at relevant processing stages. Where applicable,

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special notations and precautions or referenced instructions were included. The BPCRs also contained defined storage instructions to ensure API suitability for use, including labelling and packaging requirements, special storage conditions, and applicable time limits.

For Isoniazid, three approved Batch Production and Control Records were in place. Documentation related to the most recent batch, dated December 2025, was reviewed and discussed during the inspection.

Original data were maintained, and all test results were complete, contemporaneous, and appropriately signed and dated. Records were independently reviewed by a second person to confirm accuracy and completeness, demonstrating data integrity oversight.

Batch records were assigned unique batch or identification numbers and were dated and signed at the time of issuance. For production, the batch number was a combination of product code, manufacturing year, month, and then a sequential serial number until the final batch number was assigned.

QA controlled the master copies of Batch Records for Production. Upon request for documentation to initiate a new batch, QA issued controlled copies that were stamped, signed, dated, and recorded in the relevant logbook before release to the production area.

Observations related to documentation and records were adequately addressed in the respective CAPA plan.

6. Materials management

Receipt, identification, quarantine, storage, handling, sampling, testing, and release or rejection of materials were performed in accordance with the applicable SOP.

Sampling activities were conducted in the designated sampling/dispensing room. When up to five containers were received, 100% sampling was performed. For consignments containing more than five containers, sampling was conducted in accordance with the $\sqrt{n}+1$ sampling plan. For bags received in quantities of up to ten, 100% sampling was applied, while consignments exceeding ten bags were sampled according to the $\sqrt{n}+1$ approach. Sampled bags, drums, or containers were appropriately labelled, and sampling status labels were affixed to each sampled unit.

A system for vendor audit and approval was established and implemented in accordance with the applicable SOP. The procedure defined the evaluation and approval of suppliers of critical materials. Materials were procured against approved specifications and were sourced only from suppliers approved by the Quality Unit.

Upon receipt and before acceptance, each container or group of containers of incoming materials was subjected to a visual examination to verify integrity and condition.

Sampling and testing of incoming production materials, including tank farms

At least one test was performed to verify the identity of each batch of incoming material.

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Vendors were audited and approved in accordance with the SOP for Vendor Audit and Approval, effective 8 September 2025. The SOP applied to suppliers of intermediates, starting materials, other raw materials, and packing materials. Supplier approval was based on an evaluation that provided adequate evidence, including a review of historical quality performance, to demonstrate the supplier's ability to consistently deliver materials meeting predefined specifications. As part of the approval process, full analytical testing was conducted on at least three batches prior to any reduction in routine in-house testing. Thereafter, full analysis was performed at defined intervals, and results were compared against the corresponding certificates of analysis. The reliability of suppliers' certificates of analysis was verified at regular intervals.

The audit report related to a vendor audit, compliance report, declarations, questionnaires, and related documentation were available for review. It was noted that the supplier had been used since the beginning of site operations and had not been fully approved in accordance with the revised version of SOP. A gap analysis was performed, and a documented justification was provided to assess whether retrospective application of the revised SOP requirements to existing vendors was required. The justification was available at the time of inspection and reviewed.

Samples were representative of the batches from which they were taken as described above. Sampling methods were defined in the respective SOP and specified the number of containers to be sampled, the portion of the container to be sampled, and the quantity of material to be withdrawn from each container. The determination of the number of containers and sample size was based on an established sampling plan that considered material criticality, material variability, supplier quality history, and the quantity required for testing.

Sampling activities were performed at designated locations using procedures designed to prevent contamination of the sampled material and to avoid cross-contamination of other materials.

Furthermore, the sampling procedure for tankers was updated through a change control request to revise SOP for Sampling, Labelling, Testing, and Release Procedure of Raw and Packing Material. The CC was initiated to incorporate revised requirements applicable to tanker sampling.

Certificates of tank cleaning issued by the vendor were available and reviewed. For each delivery, a cleaning certificate was provided indicating the tanker identification number and details of the previously loaded material. Transfer pipes were subsequently labelled to indicate dedication to specific solvents. The pipes were appropriately bagged to prevent contamination when not in use.

Storage

Materials were handled and stored in a manner that prevented degradation, contamination, and cross-contamination.

Materials stored in fiber drums, bags, or boxes were kept off the floor and, where appropriate, adequately spaced to allow cleaning and inspection. It was noted that the barrel pumps used for liquid sampling and dispensing were refurbished. The controlled area excursion of four hours was assessed and subsequently justified. A Change control was raised, and the respective draft SOP was prepared to address the updated requirements.

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Materials were stored under defined conditions and for durations that did not adversely affect quality. Stock rotation controls were in place to ensure that older materials were normally used first.

7. Production and in-process controls

Production operation

Process flow charts for Isoniazid and Pyrazinamide were provided and reviewed. The facility was inspected to verify the actual workflow against the documented process. The inspection commenced on the 2nd floor of Block III, where reactors were installed, including reactors used for hydrolysis and condensation steps. Crystallization activities, including cooling and chilling, were performed on the 1st floor, which was classified as a Class D clean room. Product transfer was carried out through closed lines, and equipment was opened only during batch-to-batch cleaning. Filtration, slurry preparation, and drying operations were conducted in a separate Class D clean area located on the ground floor, followed by milling, sifting, and packing activities. The associated washing area and quarantine room supporting this section were also inspected.

In-process sampling methods were defined in the applicable SOP and were based on scientifically sound sampling principles. Sampling plans and procedures were designed to prevent contamination of sampled material and other intermediates or APIs, and to ensure sample integrity after collection. The in-process specifications for Isoniazid were available and reviewed.

Critical weighing, measuring, and subdividing operations were controlled. Prior to use, production personnel verified that the materials conformed to those specified in the relevant batch record for the intended intermediate or API. Actual yields were monitored and compared against expected yields at predefined stages of the manufacturing process.

Time limits were defined in the master production instructions and were adhered to in order to ensure the quality of intermediates and APIs. Any deviations from established time limits were documented and evaluated in accordance with applicable procedures.

Intermediates awaiting further processing were stored under appropriate and controlled conditions to maintain their suitability for use.

The monitoring of processing steps that could impact the quality characteristics of intermediates and APIs was performed in accordance with approved SOPs. In-process controls and their corresponding acceptance criteria were defined in the production process flowcharts.

Vendor management

QA approved all raw and packing material suppliers through defined processes, including sample evaluation, trials, questionnaires, and audits in accordance with the respective SOP. Quality Agreements required prior QA approval for any major changes, and suppliers provided compliance declarations as part of the approval framework. Material management activities were performed in accordance with written procedures.

The audit report for a supplier of polyethylene bags, dated 15 January 2026, was available and reviewed. The audit documentation included the audit report, compliance report, relevant certifications, and supplier declarations.

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Blending batches of intermediates or APIs
Not applicable for WHO products.

8. Packaging and identification labelling of APIs and intermediates

General:
SOP for Labelling System and Its Control in Manufacturing Area (effective 6 March 2026) was established and implemented. The SOP described the labelling system and associated controls applicable to the manufacturing area and defined the status labels used, including those for finished products, in-process samples, rinse samples, intermediates, and accessories. The approved label formats were provided in Annex 1 of the SOP.

Packaging and labelling materials complied with established specifications. Materials that did not meet these specifications were rejected to prevent their use in unsuitable operations.

Records were maintained for each shipment of labels and packaging materials, documenting receipt, examination and/or testing, and the final disposition as accepted or rejected.

Packaging materials
SOP for Packing of Finished Products (effective 1 January 2026) was established and implemented. Containers used for packing provided adequate protection against deterioration or contamination of intermediates or APIs during transportation and under the recommended storage conditions. The containers should be clean and constructed of materials that were non-reactive, non-additive, and non-absorptive, ensuring that product quality was not affected beyond established specification limits.

An SOP describing the generation of QR code labels for API finished products was established. It was noted that the SOP was due for periodic review; however, it remained within the defined review window of ± one month at the time of inspection. The site utilized the QR code module application for the generation of QR codes.

Selected documentation related to packing materials was reviewed. All reviewed documents were current, controlled, and aligned with the applicable packing material requirements.

Label Issuance and Control
Data related to the number of bags required for each batch, including the AR number and issued quantity, were recorded in the BPR by production personnel. Each bag was weighed to record tare weight, gross weight, and net weight, along with details of the outer seal and sealing operation.

Labels were printed by production personnel and independently verified by QA/QC for placement both inside and outside the drum. In addition, a dispatch label sheet containing the barcode to be affixed to the finished product was generated and controlled as part of the packing operation.

Packaging and Labelling Operations
Packaging and labelling operations were performed in accordance with the applicable SOP, which ensured the use of correct and approved packaging materials and labels. Labelling

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activities were designed and organized to prevent mix-ups and were physically or spatially segregated from operations involving other APIs.

Labels affixed to containers of APIs included the product name or identifying code and the batch number. Where an expiry date was assigned, it was indicated on both the label and the certificate of analysis. For APIs assigned with a retest date, the retest date was indicated on the label and/or the certificate of analysis as applicable.

Packaging and labelling areas were inspected immediately before use to verify that all materials not required for the specific operation had been removed. These checks were documented in the BPR, facility logbooks, or other controlled documentation systems.

Packaged and labelled APIs were examined to confirm that all containers within the batch bore the correct labels. This verification formed part of the dispatch process, and the results were documented on the dispatch specimen label sheet.

Observations related to this section were adequately addressed in the respective CAPA plan.

9. Storage and distribution

Warehousing procedures

Facilities were available for the storage of all materials under appropriate conditions. SOP for Temperature and Humidity (effective March 2026) was reviewed. The specified storage temperature for finished APIs was NMT 30 °C.

Key starting materials were stored under ambient conditions in line with MSDS requirements. Sampling and dispensing of solid raw materials were performed in a controlled booth under RLAF, with appropriate gowning and balance controls in place. Temperature mapping was conducted per the SOP for Procedure for Temperature Mapping, effective January 2026, with winter studies completed; summer and rainy season studies were pending. Identified hotspots were determined for empty conditions and for loaded conditions, with the latter designated as the routine monitoring location.

A dedicated sampling booth was available and required additional gowning prior to entry. No hand-washing facilities were provided within the booth; however, hand sanitization was required and implemented.

A separate storage area was in place to prevent the unintentional or unauthorized use of quarantined, rejected, returned, or recalled materials until a decision regarding their future use was taken.

Distribution procedures

QA prepared the Product Release Note to formally authorize the distribution of finished goods. Finished products received from Production were stored under defined storage conditions with clear batch identification. Batch allocation was performed in consultation with QA.

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Invoices were prepared prior to dispatch, and dispatch activities were daily recorded. Distribution was carried out using authorized transporters. The warehouse ensured appropriate control of temperature and humidity and maintained stock and distribution records in accordance with SOP.

The primary packing material (polybag) was supported by a certificate of analysis in accordance with the specification, with an assigned analytical reference number. Specifications covered physical characteristics and identification by IR. A bioburden study was completed in March 2026 to assess microbial contamination of the primary packaging material; total aerobic microbial count (TAMC) and total yeast and mold count (TYMC) were within specified limits.

APIs were transported in a manner that did not adversely affect their quality.

Observations related to this section were adequately addressed in the respective CAPA plan.

10. Laboratory controls

An independent QC department was established and headed by the Head-QC. The QC department was responsible for conducting analytical and support activities, including raw material analysis, water testing, packing material analysis, in-process testing, microbiological analysis, finished product analysis and stability testing. The department also performed laboratory equipment and instrument calibration and verification, environmental monitoring, and provided analytical support for validation activities.

Scientifically sound specifications, sampling plans, and test procedures were established and implemented to ensure compliance with defined quality and purity requirements. The specifications included controls for organic impurities, inorganic impurities, and residual solvents. All specifications, sampling plans, and test procedures were reviewed and approved by the Quality Unit.

Selected analytical tests were reviewed and discussed for one batch related to Isoniazid for the WHO market.

Reagents:

Reagents and standard solutions were prepared, stored, and labelled in accordance with the applicable SOPs. Labels included relevant identification details, the preparation date, and “use by” dates where applicable. In addition, expiry periods after opening were defined and clearly indicated on the labels. Reagents in use were stored in the wet lab, and replenishment of stock was requested from the warehouse through approved requisition forms.

Chromatographic column performance was verified prior to first use in accordance with the applicable SOP. Columns that failed system suitability requirements or demonstrated unsatisfactory performance were removed from use and destroyed in accordance with established procedures.

Reference standards: (Primary and Secondary)

Primary reference standards were procured from recognized compendial sources, including EP, USP, and BP, and were appropriately documented, stored, and used in accordance with the

suppliers' recommendations. In-house primary standards (working standards) were established and qualified against the corresponding reference standards before use.

Reference standards were stored under controlled conditions in a refrigerator, which was equipped with a built-in digital thermometer. The calibration certificate for the refrigerator was available.

Sample receiving and distribution

In-process samples were placed in a designated box located outside the QC laboratory and were delivered by production personnel. A bell system was used to notify QC laboratory staff for the timely collection of samples for analysis.

Testing of starting materials, intermediates, and APIs

For each API batch, appropriate laboratory testing was performed to verify compliance with established specifications in accordance with the applicable STPs. The STP for Isoniazid Ph. Eur./BP (DMF) was available and applied for batch analysis.

An impurity profile was established for each API, describing both identified and unidentified impurities typically present in batches manufactured using a defined and controlled production process. The impurity profile documented the identity or qualitative designation of each impurity (e.g., retention time), the observed range for each impurity, and the classification of identified impurities, including inorganic, organic, or solvent-related impurities.

At defined and appropriate intervals, a mechanism was in place within the CQA framework to monitor updates to pharmacopeial requirements and other relevant regulatory or scientific information. Identified changes were evaluated and, where applicable, incorporated into the corresponding STPs.

OOS management

OOS results for finished products and intermediates were documented in dedicated logbooks. In-process OOS results were handled as deviations and were recorded within the respective BPRs. OOS numbers were assigned sequentially in chronological order, and separate OOS logbooks were maintained for each calendar year.

OOS investigations were conducted in accordance with the SOP for Out of Specification (OOS) Test Results. Laboratory controls were applied and documented in real time, and any deviations were recorded and appropriately justified. OOS investigations included data review, assessment of impact and significance, identification of root causes, definition of corrective actions, and documented conclusions. Where required, resampling or retesting was performed in accordance with approved procedures, including hypothesis-based evaluation.

An OOS case was randomly selected from the OOS register and reviewed. It was confirmed that no OOS cases were related to products manufactured for the WHO market.

The OOS investigation was conducted using a checklist and was documented in accordance with the established OOS management procedure.

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The annual OOS trend review for January–December 2025 was reviewed and discussed.

An Out-of-Trend Results procedure for APIs and intermediates was established and implemented in accordance with the applicable SOP.

Retention samples

Control samples were retained in a dedicated storage area for potential future evaluation of API batch quality and not for stability testing purposes. The storage area was monitored for temperature and humidity using a hygrothermometer. Environmental conditions were recorded daily, documenting both maximum and minimum values.

Samples were stored in their original or simulated original packaging and were appropriately labelled with all required information. The samples were retained in drums of the same type as those used for finished products. Sufficient quantities were stored to allow at least two complete compendial analyses or, where no pharmacopeial monograph was applicable, two full specification analyses.

Appropriately identified reserve samples of each API batch were retained for a period of one year after the assigned expiry date. Control samples for both Isoniazid and Pyrazinamide were available in the designated control sample storage area.

Temperature mapping data for the control sample storage area was available and reviewed. A protocol for temperature mapping of the control sample room was established, defining the study approach, duration, and inclusion of seasonal variations, namely summer, monsoon, and winter conditions. The temperature mapping study reviewed during the inspection was conducted on 7 March 2026.

Stability study

The stability chambers were located in a dedicated room adjacent to the control sample storage area. The facility housed one chamber set at 30 °C / 65% RH for long-term studies, one chamber for accelerated conditions at 40 °C / 75% RH, and one chamber maintained as a standby. Chamber conditions were continuously monitored using software, which recorded temperature and humidity parameters. Monitoring records were printed daily and reviewed for any excursions. The alarm system consisted of an audible alert.

The procedure governing stability studies for APIs and intermediates was established in the respective SOP. A documented and ongoing stability testing program was implemented to monitor the stability characteristics of APIs. Stability data were used to confirm appropriate storage conditions and to establish or verify retest periods or expiry dates.

Stability documents were randomly selected and reviewed.

Validation of Analytical Methods

SOP for analytical method validation of APIs (effective 29 July 2024) was available and reviewed. The document defined the requirements and approach for validation of analytical methods and was found to be appropriately structured and implemented.

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The analytical method validation for the determination of benzene content in Pyrazinamide by GC-HS, dated 3 November 2023, was available for review and was found to be satisfactory.

SOP for Analytical Method Transfer and Partial Re-Validation (Method Transfer) (effective 22 August 2025) was established and reviewed. The SOP defined the documented process for transfer of analytical procedures between laboratories, ensuring that the receiving laboratory demonstrated the capability to perform the transferred method as intended.

The method transfer report for Isoniazid's related substances by HPLC was available and reviewed. The report included the evaluation of the transferred parameters and concluded that the method transfer was successful. The report was approved on 30 December 2024.

Polymorphism (API Manufacturing)

Polymorph assessments were reviewed for Pyrazinamide and Isoniazid. The corresponding reports were included in the respective Drug Master File.

For Pyrazinamide, the polymorph assessment report covered three commercial batches. Evaluations were performed on initial batches and under accelerated and long-term stability conditions. The results demonstrated a consistent and predominant presence of Form α. This form was confirmed by characteristic X-ray diffraction peaks at defined 2-theta positions, indicating polymorphic consistency across batches and throughout stability studies.

For Isoniazid, the polymorph assessment report covered six commercial batches. The study included initial evaluation and stability testing under accelerated and long-term conditions. A single polymorphic form was consistently identified. Characteristic diffraction peaks confirmed uniformity of the crystalline form during manufacturing and stability testing.

Overall, control of the polymorphic form for both APIs was adequately demonstrated. Batch-to-batch consistency and stability over time were evaluated and appropriately documented.

Microbiology Laboratory

Microbiology Laboratory

The microbiology laboratory was located on the 1st floor within the QC department and was accessed through an airlock and a change room. The laboratory was observed to be clean, orderly, and well-maintained at the time of inspection. The facility comprised designated rooms for incubation, washing and decontamination, culture handling, media preparation, plate observation, and MLT. The laboratory was adequately designed and equipped to support microbiological testing of non-sterile APIs.

Equipment and Environmental Control

Four incubators operating at 20–25 °C, 30–35 °C, 40–45 °C, and 55–60 °C, together with a cold chamber maintained at 2–8 °C, were available for laboratory use. All incubators were alarmed and continuously monitored through a data acquisition system. However, a documented contingency plan for incubator failure and supporting alarm excursion studies was not available for review.

Material Transfer and Decontamination

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Dynamic pass boxes were used for material transfer between controlled areas. The washing area was equipped with a decontamination autoclave. Glassware cleaning was performed using a 1% Teepol solution. A separate sterilization autoclave was installed and had been qualified as per the respective report. Defined sterilization cycles were established for liquids at 121.1 °C for 20 min and for solids at 121.1 °C for 30 min. The use of biological indicators and chemical indicator tape was observed during sterilization activities.

Culture and Media Control

Culture handling activities were performed in accordance with the applicable SOP. Reference cultures were procured at passage 1, and identification testing was outsourced. The maximum media hold time was defined as 28 days. GPT was conducted as per the applicable SOP using pharmacopeial reference cultures and one in-house isolate. Laboratory fumigation was performed at 15-day intervals in line with the respective SOP.

Water Quality Monitoring

Demineralized water was used in the manufacture of two WHO-designated products. Water specifications included defined physicochemical parameters and microbiological requirements, namely TVAC and the absence of E. coli, Salmonella spp., P. aeruginosa, S. aureus, and Enterobacteriaceae. Water testing procedures, analytical records, and microbiological monitoring results were reviewed on a spot-check basis and were found to be acceptable.

Observations related to this section were adequately addressed in the respective CAPA plan.

11. Validation

Validation documentation

A VMP, effective 26 Feb 2026, was available at the site and was reviewed during the inspection. The VMP described the overall approach to qualification and validation activities. It defined the responsibilities of the relevant functional groups involved in validation activities and outlined the general principles, stepwise execution, and defined frequency for re-qualification and re-validation.

The VMP addressed project-related validation activities and included installation, operation, and performance qualification of equipment. It also covered qualification and validation requirements for support systems that were integral to plant operation.

The plan included all validation activities related to critical technical operations relevant to product and process controls, as well as the qualification of critical manufacturing and control equipment. It covered validation and qualification requirements for facilities, instruments, processes, analytical methods, cleaning, vendor qualification, personnel training, computer system validation, and quality review activities.

The plan also addressed validation requirements associated with significant changes to premises, facilities, equipment, or processes that could directly or indirectly impact product quality.

Re-validation of systems was performed based on the outcome of periodic review assessments. The frequency of periodic review was determined through GxP criticality assessment. The defined interval for re-validation did not exceed three years from the initial validation date.

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A validation policy was included within the VMP and was available for review.

Computerized system validation

GMP-related computerized systems were validated, and appropriate qualification of hardware and software was performed to demonstrate suitability for their intended use. Controls were implemented to prevent unauthorized access and unauthorized changes to data and to ensure data integrity and completeness.

Data changes were required to be traceable through an audit trail, capturing the previous entry, the identity of the individual making the change, and the date of the change. The audit trail functionality was available for review.

The re-validation frequency for CSV systems was defined in Annexure XII of the VMP. The annexure included information on software versions, associated instruments, and the date of the most recent qualification.

Written procedures were established for the operation, maintenance, and change control of computerized systems, including an inventory of GMP-related computerized systems. All changes were required to be formally authorized, documented, tested, and recorded to demonstrate that systems remained in a validated state.

SOP for user management of the chromatography software, effective 22 Mar 2026, was available and was reviewed. The SOP defined user management processes, including user groups and user roles. A user account request form was available to request system access, with privileges assigned in accordance with the employee's JD and granted through IT authorization.

Software global policies were also available and were used to define system functionality and access controls for the respective computerized systems.

Where system breakdown or failure could result in permanent loss of records, a data backup system was provided in accordance with SOP for the Synology backup system, effective 2 Mar 2026. The procedure included defined restoration and verification activities.

All chromatography software systems used for GC and HPLC were networked. Two standalone systems, for IR and UV-VIS, were also in use. Backup activities for both networked and standalone systems were performed using the same backup system. Data were transferred to a primary server as well as a replicate server. The data transfer process was validated.

Disaster recovery documentation was reviewed, including the disaster recovery testing qualification report for physical systems. Evidence in the form of screenshots was provided. Data restoration activities were verified and confirmed by IT, QC, and QA. Processes were in place to verify that electronic records remained readily retrievable.

Observations related to this section were adequately addressed in the respective CAPA plan.

Process validation documentation

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The manufacturing processes for Isoniazid and Pyrazinamide APIs, produced since 2023 in Manufacturing Block III, were reviewed. Process validation was performed at commercial scale for both APIs using qualified raw materials from approved sources, with defined batch sizes and campaign-based capacities. Validation reports demonstrated consistent process performance, acceptable yields, and conformance to quality attributes across consecutive batches. Sampling plans, in-process controls, final testing (assay and organic impurities), sieve analysis, density measurements, and COA review were appropriately executed. No process deviations were identified; one analytical deviation for Isoniazid related to system suitability testing was adequately investigated and corrected through retraining, reanalysis, and system improvements. Continued Process Verification confirmed all critical process parameters remained within approved limits, indicating the processes are under a state of control. Overall, the process validation studies met all acceptance criteria, and both APIs were deemed validated and suitable for routine commercial manufacture.

The company established an SOP for Gasket Management covering equipment gaskets, seals, and O-rings.

Equipment qualification

HVAC

The HVAC utility serving Block-III was inspected in detail.

AHU qualification documentation was available. SOPs for preventive maintenance and HVAC validation were reviewed. These SOPs defined test frequencies for airflow, HEPA integrity, particle counts, pressure differential, temperature/RH, recovery, airflow visualization, and viable monitoring.

HEPA integrity testing performed in the Milling and Sieving room demonstrated compliant results (≤0.01%) using a calibrated photometer. Temperature and RH testing was performed for the storage area. Recovery testing was conducted for the Nutsche filter room. In-operation particle count results were available and included a defined sampling rationale.

Autoclave

Two autoclaves were present in the Microbiology laboratory, one designated for decontamination and one for sterilization. Approved loading patterns were available for both autoclaves.

Purified Water Generation System

Demineralized water was generated by a dedicated utility system and met the same specifications as purified water as per EP.

The water treatment facility was inspected. The source water, supplied by the government from a river, was stored in a potable water tank and chlorinated prior to being transferred to the demineralization system. Monitoring conductivity, temperature, and UV intensity was in place, and records were available. The system was sanitized using water at 85 °C for one hour.

Following generation, the demineralized water was distributed through a circulation loop across the facility, including Block-III.

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Water sampling was performed in accordance with the applicable SOP, and the inspector witnessed the sampling activity.

Nitrogen system and compressed air

The nitrogen and compressed air systems were inspected. Oxygen levels in the nitrogen system were controlled within low ppm limits. Moisture was removed using a desiccant dryer with periodic thermal regeneration, and operational checks were performed to confirm appropriate system performance. Carbon Molecular Sieve maintenance and replacement intervals were defined, and pre-filtration was in place to protect the system.

Specifications for nitrogen and compressed air quality were established. Quality testing was outsourced to qualified laboratories. Microbiological monitoring was performed annually at multiple points of use using validated methods.

During qualification, critical safety and control features of the nitrogen system, including vent valve operation, were verified to function as intended when operating limits were exceeded; however, it was adequately addressed in the respective CAPA.

As numerous pieces of equipment showed deficiencies in maintenance and cleaning with respect to gaskets, the company retrospectively drafted an SOP on Gasket Management. SOP was implemented to cover all equipment gaskets, seals, and O-rings.

Observations related to this section were adequately addressed in the respective CAPA plan.

Cleaning validation:

The cleaning validation program was reviewed against the applicable requirements, which defined the requirements for validation of equipment used in the manufacture of Isoniazid and Pyrazinamide. Cleaning validation had been performed for both APIs.

Dirty equipment hold times were defined as 72 hours for wet processing equipment for both products. For dry processing equipment, hold times were established as 96 hours for Pyrazinamide and 120 hours for Isoniazid. Clean equipment hold times were established at 15 days for both APIs.

Cleaning validation was executed in accordance with a protocol. The protocol covered cleaning agent selection, solubility assessment, equipment description, surface area calculations, batch size, and defined cleaning procedures. Purified (DM) water was used as the cleaning agent. Acceptance criteria were established using multiple approaches, including 10-ppm limits, therapeutic dose calculations, and health-based exposure limits (PDE/ADE). The PDE values applied were 0.25 mg/day for Isoniazid and 0.75 mg/day for Pyrazinamide, supported by outsourced toxicological assessments.

Cleaning method validation was performed for both APIs using UV-VIS analytical methods. LOD and LOQ were established. Swab and rinse recovery studies were conducted and demonstrated acceptable recoveries within predefined limits.

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Cleaning validation reports for both products were reviewed. These reports covered campaign manufacturing, including an initial validation followed by extended production of up to 30 batches. Defined sampling locations, including the Nutsche filter, were documented.

Detailed cleaning procedures for the Nutsche filter during product changeover were selected to be reviewed. Final rinse samples were tested for pH and product residue and were found to comply with established specifications based on worst-case assessment and MACO calculations.

Relevant cleaning specifications, analytical methods, and acceptance criteria were in place. Training of personnel involved in cleaning activities was documented. Overall, the cleaning validation program was supported by defined procedures, validated analytical methods, health-based limits, and documented execution.

Observations related to this section were adequately addressed in the respective CAPA plan.

12. Change control

All system, process, equipment, and material changes were managed through the change control system in accordance with the applicable SOP. Changes were evaluated by the Technical Committee, approved by QA, and subjected to documented impact assessments to ensure that validated systems remained in a compliant state. The scope of the procedure covered all prospective changes affecting product quality and the quality system within the API manufacturing facilities.

The SOP covered the identification, documentation, review, and approval of changes related to raw materials, specifications, analytical methods, facilities, support systems, equipment (including computer hardware), processing steps, labelling and packaging materials, and computer software.

A register was maintained for each product to record change control requests. Requests were identified using a unique code in chronological order and categorized by department. Selected change control requests were randomly selected and reviewed.

Proposals for GMP-relevant changes were drafted, reviewed, and approved by the appropriate organizational units and QA. A classification procedure was applied to determine the extent of testing, validation, and documentation required to justify changes to validated processes.

Changes were classified based on their nature, extent, and potential impact on the process. Scientific judgment was applied to determine the need for additional testing and validation activities.

Observations related to this section were adequately addressed in the respective CAPA plan.

13. Rejection and re-use of materials

Rejection

Rejected materials were stored in a designated rejected area that was secured and physically segregated in accordance with the applicable SOP. The warehouse ensured that rejected materials were either returned to the manufacturer or supplier at the earliest opportunity or destroyed, as applicable.

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The Quality Control Department affixed a red sticker marked **REJECTED** to rejected materials. The sticker contained the material name, analytical report number, date of rejection, and initials of the QC chemist. The corresponding analytical report, together with the Finished Goods Transfer Note, was forwarded to the warehouse.

Reprocessing and reworking

SOP on reprocessing and reworking in APIs and intermediates (effective March 2026) was reviewed. The SOP applied to commercially established APIs and intermediates and provided clear definitions of reprocessing and reworking.

Reprocessing was defined as reintroducing an API or intermediate into the established manufacturing process to repeat approved processing steps, such as crystallization, distillation, filtration, drying, or washing. Reworking was defined as subjecting non-conforming API or intermediate material to processing steps that differed from the established manufacturing process in order to achieve acceptable quality.

The company had formally committed to the WHO that neither reprocessing nor reworking would be performed.

Recovery of materials and solvents

Methanol was the only solvent used in production.

Recovery and reuse of methanol in the manufacturing of the product were performed in accordance with the applicable SOP. The recovered solvent met established specifications and was suitable for its intended use.

14. Complaints and recalls

Complaints

SOP on customer complaints (effective July 2025) was reviewed. The SOP defined the procedures for receipt, investigation, classification, and closure of customer complaints. Roles and responsibilities were clearly assigned across relevant departments. Complaints were classified as Critical, Major, or Other, with defined timelines for investigation and response. Critical complaints required investigation within 12 calendar days, while non-critical complaints required investigation within 40 calendar days. Extensions were permitted up to two times, with maximum investigation periods of 26 days for critical complaints and 100 days for non-critical complaints.

At the time of inspection, no customer complaints related to products within the WHO scope were recorded. A complaint log was maintained. One non-WHO complaint was reviewed. The complaint was classified as minor. The corresponding investigation report was available. The investigation resulted in a CAPA, including an update to the SOP on the dispatch of finished products.

Product Recall

Product recalls were managed by the Head – QA in accordance with the respective SOP. The SOP addressed voluntary and statutory recalls and classified them as Class I, II, or III based on risk, with defined timelines and requirements for NRA notification. Recalled materials were quarantined until final disposition. No recalls had been initiated for Isoniazid or Pyrazinamide at the time of inspection.

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Mock recalls were conducted annually to assess system effectiveness, with frequency adjusted in case of an actual recall. Exercises were performed during office and non-office hours, with batch selection based on predefined risk criteria.

Mock recall protocol dated February 2026 was reviewed. A mock recall was conducted for Isoniazid IP (1200 kg). Full reconciliation of the quantity dispatched to a single customer was demonstrated, confirming effective traceability and recall capability.

15. Contract manufacturers (including laboratories)

A list of approved contract laboratories was available. QC testing was outsourced to laboratories that were authorized to perform testing of all QC samples.

The SOP on technical agreements for contract laboratories (effective September 2025) was reviewed. Valid technical agreements were in place for both laboratories, with a defined validity period of three years, and are currently effective.

No contract manufacturing activities were reported.

Miscellaneous	
Samples taken	Not applicable
Assessment of the site master file	Site Master File effective 2 February 2026 was provided and reviewed.
Annexes attached	Not applicable

Part 3	**Initial 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, ***Kaygee Laboratories Private Limited***, located at ***Plot No. 06, Phase II, New Industrial Area Mandideep, District Raisen, 462046 Madhya Pradesh, India,*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

The deficiencies observed during the inspection, as listed in the full report, were addressed by the manufacturer to a satisfactory level before 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 GMP for APIs or WHO TRS No. 957, Annex 2***
http://apps.who.int/medicinedocs/documents/s20119en/s20119en.pdf

2. 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. ***Short name: WHO TRS No. 986, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. 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.
Short name: WHO TRS No. 970, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

4. 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
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. **Short name: WHO TRS No. 1010, Annex 8**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

6. 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.
Short name: WHO TRS No. 937, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

7. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty- seventh report (WHO Technical Report Series, No. 1052), Annex 4
Short name: WHO TRS No. 1052, Annex 4

8. 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 2.
Short name: WHO TRS No. 957, Annex 2
http://www.who.int/medicines/publications/44threport/en/

9. WHO good manufacturing practices for sterile 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 6.

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Short name: WHO TRS No. 961, Annex 6
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. 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**
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. 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

13. 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

14. 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. ***Short name: WHO TRS No. 981, Annex 2***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

15. WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3. ***Short name: WHO TRS No. 981, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

16. 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***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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17. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

19. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

20. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
Short name: WHO TRS No. 992, Annex 6
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

21. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
Short name: WHO GDRMP guidance or WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

22. WHO general guidance on variations to multisource pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report. Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10.
Short name: WHO Multisource guidance or WHO TRS No. 996, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 10.
Short name: WHO TRS No. 1010, Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

24. Production of water for injection by means other than distillation. WHO Expert Committee on

Specifications for Pharmaceutical Preparations. Fifty-Forth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1015), Annex 3.
Short name: WHO TRS No. 1025, Annex 3
https://www.who.int/publications-detail/978-92-4-000182-4

25. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Forth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 4.
Short name: WHO TRS No. 1025, Annex 4
https://www.who.int/publications-detail/978-92-4-000182-4

26. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Forth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6.
Short name: WHO TRS No. 1025, Annex 6
https://www.who.int/publications-detail/978-92-4-000182-4

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