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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	Mangalam Drugs and Organics Limited (Unit-1)
Corporate address of the manufacturer	Rupam Building, 3rd Floor 239, P D' Mello Road, Near GPO Mumbai - 400 001 Maharashtra India Tel: +912262616200/6300/8787 Email: contactus@mangalamdrugs.com
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	Mangalam Drugs & Organics Limited Unit-1, Plot no.187, 2nd Phase, GIDC, Vapi–396195 Valsad, Gujarat India D-U-N-S Number: 67-573-8285 Latitude : N 20°22'10.7511" Longitude : E 72°55'47.6646"
Unit /Block/ Workshop	Plant 1E & Warehouse (Block 07) Plant 1A (Block 10) Plant 1D (Block 09) Plant 1B (Block 13)
Manufacturing license number	G/725
Inspection details	
Dates of inspection	7-10 October 2025
Type of inspection	Routine inspection
Introduction	
Brief description of the manufacturing activities	Mangalam Drugs and Organics Limited, Unit-1, consists of several buildings within the premises, namely: - Raw Material, Finished product warehouse, and production Plant 1E (Block 07) - Production Plant 1A (Block 10) - Production Plant 1D (Block 09) - Production Plant 1B (Block 13) - Plant 1C (Recovery Plant) (Block 42)

	- Liquid and Hazardous Store (Block 11) - Quality Control (Block 02A, 03A, 03B & 03C) - Quality Assurance (Block 03) - Utility Building (Block 35) - E&S (Block 34) - Admin Building (Block 35A) Mangalam Drugs and Organics Limited is involved in the manufacture of non-sterile APIs and intermediates. No other manufacturing activities, including those related to sensitizing substances, animal-origin materials, high-potency drugs, beta-lactams, steroids, hormones, toxic substances, radioactive materials, or veterinary products, are carried out at the site. Furthermore, the company does not manufacture pesticides, and no non-pharmaceutical activities are conducted at the site.
General information about the company and site	Mangalam Drugs and Organics Limited (MDOL), Unit-1, commenced operations on 17 April 1977. MDOL (Unit-1) held a valid manufacturing license issued by the Food and Drugs Control Administration (FDCA), Gujarat State, India, for the manufacture of APIs (bulk drugs) under Rules 73 and 83. MDOL is engaged in the manufacture of non-sterile APIs and intermediates in accordance with cGMP principles and applicable regulatory requirements. The company imports certain raw materials from various countries, such as China and Vietnam. It was noted that the necessary documentary procedures were followed for the execution of these activities. MDOL exports APIs to various countries across Africa, Asia, and Europe via air and sea routes.

History

In the past five years, the site has been inspected by the following authorities:

Name of the Authority	Dates of inspection	Scope of inspections	Outcome
WHO	21-24/06/2022	Plant 1E (Block 07) Plant 1A (Block 10) Plant 1D (Block 09) Plant 1B (Block 13) Plant 1C (Recovery Plant) (Block 42) Quality Control & Microbiology Lab (Block 02A, 03A, 03B & 03C)	Compliant
FDCA; Gujarat	13/07/2022, 14/07/2022 & 06/09/2022	Plant 1E (Block 07) Plant 1A (Block 10) Plant 1D (Block 09) Plant 1B (Block 13) Plant 1C (Recovery Plant) (Block 42) Quality Control & Microbiology Lab (Block 02A, 03A, 03B & 03C)	Approved

The site had been previously inspected by the WHO in 2011, 2014, 2018, and 2022. The latter inspection covered both Unit I and Unit II.

A list of changes implemented since the last inspection was provided for the inspectors' review.

Brief report of inspection activities undertaken – Scope and limitations

Areas inspected	• Pharmaceutical Quality System • Facilities and Equipment (in warehouses, production blocks, QCL & Microbiology laboratories) • Utilities • Production • Quality Control laboratories, including Microbiology laboratory • Packaging and Labelling • Product Release • Review of the respective documentation
Restrictions	Not applicable
Out of scope	APIs not related to the WHO prequalification programme
WHO APIs (including WHO API or APIMF numbers) covered by the inspection	APIMF100, Lumefantrine APIMF134, Amodiaquine (hydrochloride) APIMF135, Artesunate APIMF138, Artemether APIMF149, Piperaquine phosphate APIMF151, Dihydroartemisinin

	APIMF204, Tenofovir disoproxil fumarate APIMF356, Sulfadoxine APIMF380, Primaquine phosphate APIMF405, Pyronaridine phosphate (This API was not covered by the previous WHO inspections)
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
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
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	Non conformity
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
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 brief presentation of the factory was provided at the opening meeting. The presentation provided an overview of Mangalam Drugs and Organics Limited (Unit-1), including its history, facilities, manufacturing capabilities, and regulatory compliance. It highlighted the company's focus on producing non-sterile APIs, mainly antimalarial products, in accordance with cGMP and international standards. The presentation also covered the site's quality systems, utilities, Environment, Health, and Safety (EHS) measures, and Corporate Social Responsibility (CSR) activities.

The previous audit report was reviewed with reference to the corresponding CAPA report.

MDOL had implemented a Quality Management System aligned with ICH, WHO TRS, and Schedule M requirements. The system was managed by an independent Corporate Quality Assurance department, overseeing QA, QC, and Microbiology functions to ensure compliance, product quality, and continuous improvement across both units. Responsibilities included document control, deviation and CAPA management, product release, validation, and data integrity, with all quality activities required to be recorded contemporaneously and governed under an approved Data Integrity and Data Governance procedure.

Product Quality Review

Regular quality reviews of APIs were conducted to verify process consistency. These reviews were performed and documented annually in accordance with the respective SOP.

The following Annual Product Quality Reviews (APQRs) were spot-checked:

- Pyronaridine Phosphate (APIMF 405)
- Artemether (APIMF138 _ AMR-1D Plant)
- Primaquine Phosphate (APIMF380_Plant 1D)
- Lumefantrine (APIMF100)

The observations related to the PQR were adequately addressed in the respective CAPA plan.

Quality risk management

The SOP for Quality Risk Management was reviewed. The procedure described a systematic approach for assessing, controlling, communicating, and reviewing risks to the quality of drug substances throughout their lifecycle. It defined the roles and responsibilities of relevant units and staff and outlined the process steps, including Risk Assessment, Hazard Identification, Risk Analysis, Risk Evaluation, Risk Control, Risk Acceptance, Risk Communication, and Risk Review.

Risk management tools included FMEA, FMECA, FTA, HACCP, and PHA. The SOP established defined ranking systems for severity, occurrence, and detection, and the Risk Priority Number (RPN) was calculated by multiplying these three factors.

Risk registers for 2023, 2024, and 2025 were reviewed.

Management review

The respective SOP established that Management Reviews were to be conducted twice a year to ensure that responsible management was informed of serious GMP deficiencies, regulatory inspections, product defects, complaints, recalls, and related actions. The outcome of the most recent Management Review, conducted on 28 July 2025, was evaluated to verify the execution of the review and the actions taken. The list of attendees and the report were available and reviewed. It was verified that the SOP was adequately implemented and that the table of actions, along with the respective responsibilities, were clearly defined.

Deviations & Handling CAPA

Deviations were managed in accordance with the respective SOP, which defined the procedure for identifying, initiating, handling, controlling, evaluating, investigating, approving, and closing deviations. A deviation register was maintained, with a new logbook issued each year and the previous one formally closed. The register included details such as the date of initiation, deviation number, originating department, description of the deviation, category, status (approved or rejected), and relevant authorization information.

Randomly selected deviations were reviewed during the inspection.

It was verified that the deviation form included provisions for documenting the reason or justification for the deviation, corrective actions, investigation details, root cause analysis, impact assessment, and, where applicable, the requirement for a risk assessment.

The applicable SOP described the procedure for the initiation, evaluation, assignment, verification, validation, completion, and effective implementation of Corrective and Preventive Actions. The procedure was applicable to all activities related to or supporting CAPA initiation, including deviations, OOS/OOT results, self-inspections, regulatory audits, product complaints, product recalls, laboratory incidents, APQRs, batch failures, management review recommendations, and risk management activities.

Randomly selected CAPAs were reviewed during the inspection. As per the established procedure, not all deviations resulted in a CAPA, depending on their nature and impact.

It was noted that separate CAPA registers were maintained for different sources, including deviations, market complaints, returned goods, OOS, and OOT, as indicated in the respective index on the first page of each logbook.

The observation related to the management of deviation and CAPA was adequately addressed in the respective CAPA plan.

Product release

The release of APIs at MDOL was carried out in accordance with the respective SOP, with the Head of QA holding final responsibility for product release. Certificates of Analysis were prepared on the company's letterhead by QC personnel, verified by the Head of QC, reviewed by QA, and finally approved and signed by the Head of QA. All personnel involved were qualified science graduates.

Before release, QA reviewed the batch manufacturing records, analytical test reports, and customer requirements, and performed a physical inspection of the finished goods, verifying container condition, labeling, sealing, and cleanliness. The transport vehicle was also inspected to ensure cleanliness and the absence of contamination risks. Any abnormalities identified during the inspection were immediately communicated, and corrective actions were implemented before approval. Upon satisfactory verification of all documentation and inspections, QA signed the release intimation, and the material was authorized for dispatch.

Internal audit

Regular internal audits were conducted to verify compliance with GMP principles for APIs in accordance with the applicable SOP and an approved annual schedule. The inspection plans for 2024 and 2025 were reviewed and found to be up to date, with completion dates indicated for each audit.

The self-inspection report for the Microbiology Department, dated 25 August 2025, was reviewed, and it was confirmed that the auditors were independent of the department.

Audit findings and corresponding corrective actions were documented and communicated to the responsible management. Corrective actions were implemented in a timely manner. Auditors had received relevant training, and observers participated in audits for training purposes, becoming eligible to serve as auditors after completing five audits.

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

2. Personnel

Personnel qualification

There was an adequate number of personnel qualified by appropriate education, training, and/or experience to perform and supervise the manufacture of intermediates and APIs. The responsibilities of all personnel involved in manufacturing activities were defined in their respective job descriptions.

Training records of randomly selected personnel and topics were reviewed during the inspection. Records of training were properly maintained, and the effectiveness of training was periodically evaluated.

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

Personnel hygiene

Personnel hygiene, clothing, and waste disposal were described in the respective SOP. Another procedure outlined the entry and exit procedure for the Powder Processing Area of Plant 1A.

Procedures for employee medical examinations were established.

One example of a contractual employee was reviewed to verify the corresponding training records and medical examination evidence.

Personnel wore clean clothing appropriate to the manufacturing activities in which they were engaged, and garments were changed as necessary. Additional protective apparel, including head, face, hand, and arm coverings, was used when required to prevent contamination of intermediates and APIs.

Direct contact between personnel and intermediates or APIs was avoided. Smoking, eating, drinking, chewing, and food storage were restricted to designated areas separate from manufacturing zones.

Personnel with infectious diseases or open lesions were not permitted to perform tasks that could compromise API quality. Any individual identified, either through medical examination or supervisory observation, as having an apparent illness or open lesion was excluded from relevant activities until the condition was resolved or qualified medical personnel confirmed that participation would not affect product quality or safety. In such cases, employees were required to request sick leave.

3. Buildings and facilities

Design and construction

Buildings and facilities provided adequate space for the proper placement of equipment and materials, thereby minimizing the risk of mix-ups. The flow of materials and personnel within the facilities was appropriately designed to prevent contamination and cross-contamination.

Defined areas or equivalent control systems were established for the following activities:

- Receipt, identification, sampling, and quarantine of incoming materials pending release or rejection;
- Quarantine of intermediates and APIs prior to release or rejection;
- Sampling of intermediates and APIs;
- Holding of rejected materials prior to further disposition (e.g., return, or destruction);
- Storage of released materials;
- Production operations;
- Packaging and labelling operations; and
- Laboratory operations.

Washing and toilet facilities were located separately from, but conveniently accessible to, manufacturing areas. Adequate facilities for showering and changing clothes were provided where appropriate.

Laboratory areas and operations were physically separated from production areas. In-process sampling was performed within the operational areas by production operators, whereas sampling of materials and finished goods was conducted by the Quality Control Laboratory personnel. Tools used for powder sampling were randomly selected and inspected during the visit to the QCL.

Utilities:

Purified Water System:

Water used in the manufacture of APIs was tested for suitability in accordance with the SOP, which described the sampling and analysis procedures for purified, Millipore-purified, and potable water. The SOP also defined the sampling locations and schedule.

The yearly trend report for purified water for 2024, covering all sampling points, was available and showed no OOS results. The purified water system used GIDC (Gujarat Industrial Development Corporation) water as the potable source. The water was filtered and purified through sequential treatment steps, including sand filtration, softening, cartridge filtration, ultrafiltration, and RO + EDI processing.

Purified water was stored in a stainless-steel jacketed tank connected to a closed-loop circulation system operating continuously to prevent microbial growth. An online TOC meter was installed at the end of the loop. The RO membranes and the water distribution loop were sanitised regularly at controlled temperatures to maintain microbiological quality.

The analyzer device in the water generation system room, used for measuring TOC, was calibrated. The calibration certificate dated 11 February 2025 was available and reviewed. The same applied to the conductivity device. Calibration records for the velocity meter and intensity meter were also available and reviewed.

HVAC system
The HVAC system – AHU supplying filtered air to Block E – production area was visited and inspected. The inspection included verification of the air supply source, filtration system, distribution lines, and point-of-use outlets. The adequacy of maintenance, monitoring, and control measures for ensuring the quality of air supplied to the area was also reviewed.

HVAC qualification included installed filter leakage test and filter integrity testing, airflow tests – volume and velocity, air pressure differential test, airflow direction test, and air flow visualization test, microbial airborne and surface contamination test, temperature measurement test, relative humidity test, recovery test, and containment leakage test. The video of the airflow and direction test was shown.

Vacuum Pump Systems were visited. The Vacuum system for the Rotocone dryer was assessed. The system created a low-pressure environment to remove moisture from intermediate APIs. Key components included a vacuum pump, a condenser for solvent recovery, and a receiver.

The nitrogen and compressed air systems were not inspected due to time constraints.

The observation related to building and utilities was adequately addressed in the respective CAPA plan.

4. Process equipment

Randomly selected equipment and processing areas were randomly visited and inspected to verify that they had adequate design, size, and capability for their intended use. It was also verified that the equipment and areas were suitably located within their respective premises.

The observations related to process equipment were adequately addressed in the respective CAPA plan.

Design and construction
The equipment used in the manufacture of intermediates and active pharmaceutical ingredients (APIs) was of appropriate design, adequate size, and suitably located for its intended use. The equipment was constructed so that product-contact surfaces did not alter the quality of intermediates or APIs beyond official or established specifications. However, evidence indicated deficiencies in maintenance and cleaning practices.

Production equipment was used only within its qualified operating range.

Equipment maintenance and cleaning
Control, weighing, measuring, monitoring, and test equipment critical to assuring the quality of intermediates or APIs were calibrated in accordance with approved written procedures and an established calibration schedule.

Schedules and procedures, for example, the “Preventive maintenance” schedule, which included the assignment of responsibilities and defined frequencies, were established. Furthermore, procedures were in place for the cleaning of areas and equipment, such as SOP for General

Cleaning Procedure and Schedule in Production Areas. Furthermore, SOPs were established for the cleaning of equipment and its subsequent release for use in the manufacture of intermediates and APIs. The cleaning procedures were available and reviewed during the inspection. Randomly selected SOPs were examined to verify that the relevant procedures were appropriately included. (Refer to Cleaning Validation section.)

Where equipment was assigned to continuous production or campaign production of successive batches of the same intermediate or API, it was cleaned at appropriate intervals. Non-dedicated equipment was cleaned between the production of different materials. Acceptance criteria for residues, as well as the selection of cleaning procedures and cleaning agents, were defined and justified.

Equipment was identified with respect to its contents and cleanliness status by appropriate means. It was noted that the Nutsche filter used in Block 1D was under repair, and a job order had been issued on 4 October 2025 for the respective equipment due to improper fitting of the top cover.

Computerized system validation

GMP-related computerized systems were required to be validated, with appropriate qualification of hardware and software, to ensure suitability for their intended functions in accordance with the applicable SOP. Another procedure, Periodic Review of Computerized System, was established for computerized systems used in the QC department. It was noted that no electronic systems were utilized for production activities, and all computerized systems recorded on the inventory list were related solely to the QC laboratory.

Adequate controls were implemented to prevent unauthorized access or modification of data and to ensure data completeness. Any change to data was required to be traceable through the audit trail, including the previous entry, the identity of the individual making the change, and the date of the modification. Where manual data entry was applied, additional verification of accuracy was required.

Written procedures were established for the operation, maintenance, and change control of computerized systems, such as the GxP-related computerized system inventory. Changes were required to be formally authorized, documented, tested, and recorded to demonstrate that the system remained in a validated state. The privileges assigned to the Administrator and Reviewer in the chromatography software system were reviewed and verified to be consistent with their respective job responsibilities, and it was confirmed that any changes, including those related to security configuration, would be captured in the audit trail.

In cases where system breakdowns or failures could result in the permanent loss of records, a backup system was provided in accordance with SOP for Electronic Data Backup and Restoration on Standalone Analytical Instruments. The site utilized two servers for backup purposes—one onsite and the other offsite, located at Unit 2—as part of its disaster management program. Processes were in place to verify that electronic records remained readily retrievable.

5. Documentation and records

All documents related to the manufacture of intermediates or APIs were prepared, reviewed, approved, and distributed in accordance with the applicable SOPs. Documents were maintained in paper form.

The issuance, revision, replacement, and withdrawal of all documents were controlled in accordance with approved procedures, with revision histories duly maintained. For example, SOP for Issuance and Control of Batch Manufacturing Records, Analytical Test Reports, Formats, Registers, and Logbooks was in place. Records such as the BMR/BPR of Primaquine and logbooks were randomly selected and found to be satisfactory.

A procedure for Control of Documents was established for the retention of all relevant documents. Retention periods for these documents were specified. This procedure was applicable to the preparation, revision, review, approval, authorization, distribution, retrieval, obsolescence, archival, control, maintenance, and destruction of all quality-related documents and records at Mangalam.

Process flow diagrams and master formulae for each intermediate and API were prepared, dated, and signed by one person and independently checked, dated, and signed by a person from the Quality Unit to ensure uniformity from batch to batch.

Batch production records

Batch production records were prepared for each intermediate and API and included complete information on the production and control of each batch. Each batch production record was checked before issuance to ensure it was the correct version and a legible, accurate reproduction of the corresponding master production instruction.

The BMR and BPR for Primaquine were randomly reviewed and verified to confirm that the original data were maintained, all in-process test data were complete and contemporaneous, and entries were appropriately signed and dated. A second person verified the accuracy and completeness of the records, reflecting an integrity check.

These records were assigned a unique batch or identification number, dated, and signed at the time of issuance. Documentation of the completion of each significant step in the batch production records included all required information.

Review and approval of batch production and laboratory control records, including packaging and labelling, were performed in accordance with SOP for Issuance and Control of Batch Manufacturing Records, Analytical Test Reports, Formats, Registers, and Logbooks.

Batch production and laboratory control records for critical process steps were reviewed and approved by the Quality Unit prior to the release or distribution of an API batch. Deviation, investigation, and OOS reports were required to be reviewed as part of the batch record review, before batch release.

6. **Materials management**Receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of materials were performed in accordance with the respective SOPs. A system was established for the evaluation of suppliers of critical materials. Materials were purchased in accordance with agreed specifications from suppliers approved by the Quality Unit. Upon receipt and prior to acceptance, each container or grouping of containers of materials was visually examined in accordance with the applicable SOP.

   Sampling and testing of incoming production materials
   At least one test to verify the identity of each batch of material was performed. Samples were representative of the batch of material from which they were taken. Sampling methods were defined in SOP for Sampling Procedures. This SOP was applicable to all sampling activities performed by the QC laboratory and specified:
   - the number of containers to be sampled,
   - the part of the container from which the sample was to be taken, and
   - the quantity of material to be collected from each container.

   The decision on the number of containers to sample and the sample size was based on a documented sampling plan, which took into consideration the criticality and variability of the material, the supplier's historical quality performance, and the quantity required for testing. The sampling plan ensured that representative samples were obtained to provide a reliable basis for material evaluation and release decisions.

   Storage
   Materials were handled and stored in a manner that prevented degradation, contamination, and cross-contamination. Materials stored in drums or bags were kept off the floor and suitably spaced to allow adequate cleaning and inspection.

   Materials were stored for durations that did not adversely affect their quality, and stock rotation was controlled to ensure that the oldest material was used first. The status of the materials was displayed on boards hung in the warehouse area, indicating details such as date of receipt, batch number, and retest date, until their dispatch to the production plants or to the client.

   Batch numbering system and BMR management
   A batch numbering system was established to uniquely identify each material, intermediate, and finished product. Therefore, the BMR management system was maintained in a state of control, as a unique and traceable numbering system was utilized.

7. **Production and in-process controls**Process flow diagrams and process maps for the manufacturing stages were available and reviewed. The overall process design was found to be consistent with the respective master production instructions. Each stage defined the sequence of material additions, process parameters, and associated CQAs to ensure product consistency and control.

   It was noted that process parameters such as mixing speed and temperature were not always defined in the process flow diagrams. However, the manufacturing instructions included stepwise operations, in-process checks, and acceptance criteria to ensure reproducibility of the process.

Processing operations included defined stages of reaction, separation, drying, and milling. Critical process steps were supported by in-process controls such as clarity, TLC, pH, water content, and loss on drying, to ensure that intermediates met predetermined specifications before progressing to the next stage.

Alternative equipment, such as fluid bed dryers, Rotocone vacuum dryers, or tray dryers, was used for drying operations as per process requirements. The selection and use of equipment were consistent with validated processes, and control of process parameters was documented in batch records.

In-process controls were performed at appropriate stages, and the results were documented and verified by authorized personnel. Batch production records contained details of critical steps, in-process tests, and the corresponding results. The documentation review related to Pyronaridine triphosphate demonstrated that production activities were carried out in accordance with approved instructions, and process controls were adequately implemented to ensure batch uniformity and compliance with established specifications.

Production operation

Raw materials used for the manufacture of intermediates and APIs were weighed and measured in accordance with the applicable SOPs. The weighing and measuring devices employed were of appropriate accuracy for their intended use.

Critical weighing, measuring, and subdividing operations were controlled. Prior to use, production personnel verified that the materials corresponded to those specified in the batch record for the intended intermediate or API. Actual yields were compared with expected yields at defined stages of the production process. Expected yields, with appropriate ranges, were established based on historical laboratory, pilot-scale, or manufacturing data.

Where time limits were specified in the master production instructions, they were adhered to ensure the quality of intermediates and APIs. Any deviations were documented and evaluated in accordance with the applicable procedures.

Intermediates held for further processing were stored under appropriate conditions to ensure their continued suitability for use.

Monitoring of the progress and control of processing steps that could impact the quality attributes of intermediates and APIs was performed in accordance with the applicable SOP. In-process controls and their corresponding acceptance criteria were defined in the respective documentation, based on data obtained during process development or from historical manufacturing experience.

The raw material and intermediate warehouse, finished API and intermediate warehouse, and drum yard were visited during the inspection. Blending operations for batches of intermediates and APIs were inspected to verify that they were performed in accordance with approved procedures and recorded in the respective batch records. The purpose, rationale, and control measures for blending were defined to ensure batch homogeneity and consistency of quality.

Contamination control:
Residual material carry-over into successive batches of the same intermediate or API was controlled to ensure it did not affect product quality. Potential residues, such as those remaining in processing vessels, centrifuge bowls, or micronizers, were required to be managed through defined cleaning and control procedures to prevent the transfer of degradants or microbial contamination that could alter the impurity profile.

Nitrosamine
A declaration assessing the potential presence of nitrosamine impurities in Pyronaridine tetraphosphate was presented. The assessment was based on EMA and USFDA guidance on nitrosamine control and considered factors such as nitrosating agents, contaminated or recycled materials, cross-contamination, degradation, and potential contributions from solvents and water. Vendors of starting materials were required to provide nitrosamine risk declarations.

It was noted that the report was concluded in 2025, with reference to the 2024 USFDA Guidance for Industry update.

The evaluation concluded that there was no probability of nitrosamine formation or enhancement in the Pyronaridine Tetraphosphate API. The absence of N-Nitroso-Pyrrolidine, N-Nitroso-Ethylisopropylamine (NEIPA), and N-Nitroso-Diisopropylamine (NDIPA) was confirmed through testing.

The observations related to production and in-process control were adequately addressed in the respective CAPA plan.

8. Packaging and identification labelling of APIs and intermediates

General:
SOP for “Receipt, Handling, and Storage of Packing Materials” was established to describe the processes for receipt, identification, quarantine, sampling, examination and/or testing, release, and handling of packaging and labelling materials.

Packaging and labelling materials were confirmed to conform to established specifications. Materials not meeting these specifications were rejected to prevent their unintended use. The use of transparent and black LDPE bags was randomly verified during the inspection. The drum and secondary packaging areas were also visited.

Records were maintained for each shipment of packaging and labelling materials, documenting receipt, examination or testing, and the corresponding acceptance or rejection status.

Packaging materials

Containers used for intermediates and APIs provided adequate protection against deterioration or contamination during transportation and recommended storage conditions. Containers were clean and, where required, sanitized to ensure suitability for use. They were non-reactive, non-additive, and non-absorptive, ensuring that the quality of intermediates and APIs remained within specified limits.

The containers for intermediate usage were cleaned in accordance with documented procedures, and all previous labels were removed or defaced.

Label issuance and control

Label issuance, storage, and control were carried out under the supervision of QA. The label used for Primaquine, along with its reconciliation records, was randomly selected and verified during the inspection.

9. Storage and distribution

The warehouse was equipped with an operational air curtain at the entry, and gowning requirements were clearly displayed. Materials were received, checked, and dedusted in accordance with the applicable SOP. Approved vendor and delivery vehicle checklists were completed as part of the receipt process. Following verification and dedusting, materials were labelled as “Quarantine.”

Sampling of key starting materials was performed under RLAF using dedicated, identified tools. The balance used for sampling and dispensing was verified daily and calibrated monthly, with calibration status clearly indicated.

Materials were stored in designated areas under suitable conditions. The warehouse for chemicals was not temperature-controlled, while the primary packing material store was maintained below 25 °C, with temperature monitored and recorded twice daily.

Dispensing operations were performed in the warehouse under RLAF, following defined cleaning procedures. Equipment and utensils were cleaned with 2% l Labolene solution and dried at 60 ± 5 °C.

Finished products were stored in the designated finished goods store, where each container was appropriately labelled with product name, batch number, drum number, manufacturing and expiry dates, weights, and storage conditions.

10. Laboratory controls

The independent Quality Unit had adequate laboratory facilities. Laboratory records were maintained according to established requirements.

Specifications, sampling plans, and test procedures ensured compliance with quality and purity standards. Specifications included impurity controls (organic, inorganic, residual solvents) and, where applicable, microbiological purity.

Authentic certificates of analysis were issued for each batch of intermediate or API on request.

Sample receiving and distribution

Procedures were established for the receipt, registration, storage, and distribution of samples. Samples received were verified against accompanying documentation, appropriately labelled, and logged in the sample register. Distribution to the respective testing units was carried out under controlled conditions to ensure sample integrity. Records of sample receipt, distribution, and disposal were maintained in accordance with the applicable SOPs.

Testing of starting materials, intermediates, and APIs

For each batch of intermediate and API, appropriate laboratory tests were performed to verify compliance with established specifications.

The results of selected analyses were reviewed on the respective instruments to confirm accuracy, audit trail integrity, and corresponding logbook entries, including:

- Identification testing by IR using Perkin software for a selected batch.
- Purity and impurity testing by GC for a selected batch.
- Identification and assay testing by HPLC for a selected batch.

An impurity profile was established for each API, describing both identified and unidentified impurities typical of the validated production process.

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

OOS management

Deviations were documented and explained as per established procedures. OOS results were investigated in accordance with SOP for “Handling of OOS Results”. This procedure was applicable to OOS results obtained during analysis, material or product review, as well as for stability and holding time study samples in the QCL.

Two logbooks were maintained for documenting OOS incidents:

- Stability study, raw material, and packaging material
- Finished product, intermediate, and recovered solvent/material

A randomly selected case, related to Pyronaridine tetraphosphate, was reviewed. The OOS was observed in the test for related substances (by HPLC) using Method 1. A hypothesis/investigative testing was conducted, and justification was documented in accordance with the procedure.

Retention samples

Reserve samples were retained for potential future evaluation of API batch quality and not for ongoing stability testing. Appropriately identified reserve samples of each API batch were kept for one year after the expiry date assigned by the manufacturer.

Reserve samples were stored in the same packaging system as the API or in a system that was equivalent to or more protective than the marketed packaging, under controlled temperature and humidity conditions using a hygrometer. Sufficient quantities were retained to conduct at least

two full compendial analyses or, when no pharmacopeial monograph existed, two full specification analyses.

A separate SOP was in place for retention samples, specifying a retention period of the expiry date plus one year.

Stability study

The stability chambers were visited during the inspection. Six stability chambers integrated with the appropriate software application were installed, including one standby unit, two chambers for 2–8 °C storage, and one for accelerated conditions. A spot-check for the presence of Primaquine samples under long-term stability study and Pyronaridine samples under accelerated conditions was verified.

A documented, ongoing stability testing program was established to monitor the stability characteristics of APIs. The results were used to confirm appropriate storage conditions and to verify assigned retest or expiry dates, in accordance with SOP for “Stability Study”. This procedure was applicable to stability and holding time studies for intermediates and finished APIs.

Stability reports were randomly selected and reviewed.

Microbiology laboratory

Entry to the microbiology laboratory was through a designated gowning room, where gowning requirements were clearly displayed. The laboratory layout included areas for media preparation, autoclaving, microbiological testing, and incubation.

An autoclave was used for sterilization at 115–121 °C. Records for the load autoclaved on 9 October 2025 were reviewed and found complete. The equipment was calibrated and qualified annually as per the applicable SOP.

Media preparation and sterilization were performed in accordance with the respective SOP. The media hold time was established at seven days for both liquid and solid media.

Growth promotion testing and maintenance of microbial cultures were conducted per the respective SOP. Reference cultures (ATCC strains) were maintained under defined storage and incubation conditions, and records for viability, purity, and identification were available and reviewed.

Incubators, hot air ovens, and refrigerators were managed as per the applicable procedures. Mapping studies and alarm challenge tests were conducted semi-annually, and backup arrangements were defined.

The laminar air flow cabinet used for culturing and subculturing was operated under the respective procedures.

The document related to the LDPE Bag Analytical Test Report for Microbiological Analysis was reviewed. The testing was performed on an annual basis. The report included relevant product and batch details such as the name of the manufacturer and supplier, batch number, date of receipt, date of sampling, quantity sampled, date of testing, date of release, and the corresponding analytical report number. The microbial testing included the determination of Total Aerobic Microbial Count (TAMC), Total Yeast and Mould Count (TYMC), and specified organisms, including Escherichia coli, Salmonella abony, Pseudomonas aeruginosa, Staphylococcus aureus, and bile-tolerant Gram-negative bacteria.

The observations related to the Microbiology laboratory were adequately addressed in the respective CAPA plan.

Environmental monitoring

Environmental monitoring was performed in accordance with the established procedures. The defined monitoring frequencies were once every 15 days for settle plates, once every three months for active air sampling, and once a month for contact plates.

Trend data reports for 2024 were reviewed. Results for the sifting and packing rooms were within the established limits, indicating effective environmental control.

11. Validation

Validation documentation

The following documentation was reviewed:

- SOP for "Validation of Computerized Systems"
- Validation Master Plan (VMP) for 2025

Systems and processes were periodically evaluated to confirm continued validated status. Revalidation was not required when no significant changes had occurred, and quality reviews demonstrated consistent production of material meeting specifications. Validation and qualification of critical systems, including computerized systems, processes, and analytical methods, were performed to ensure the reliability and integrity of generated and managed data.

Process validation documentation

SOP for "Process Validation" was reviewed. The procedure defined the minimum requirements for validation and revalidation of manufacturing processes for marketed intermediates and APIs, outlining responsibilities, documentation, and the requirement for both validation protocols and reports.

The process validation protocol for Pyronaridine Tetraphosphate (PNT) was reviewed. It included equipment qualification, analytical method validation, CPPs, CQAs, IPCs, sampling plans, and process parameters for all manufacturing stages. Supporting data on calibration, maintenance, utilities, raw materials, and training were also documented.

The corresponding validation report was available and reviewed.

Continuous Process Verification (CPV)
The objective of CPV was to ensure ongoing assurance that manufacturing processes remained in a validated state of control during commercial production. The program aimed to detect deviations and variability by monitoring process trends, CPPs, and quality attributes of in-process, intermediate, and finished products. Data were evaluated to assess process stability and capability against the validated state. Continuous monitoring and sampling of critical parameters were established during process validation, with signals such as deviations, complaints, OOS/OOT results, yields, stability data, and APQR outcomes included in the evaluation.

Equipment qualification
The qualification and calibration documentation of selected equipment were reviewed to verify their suitability for intended use.

The observations related to the equipment qualification were adequately addressed in the respective CAPA plan.

Cleaning validation
Cleaning validation was performed in accordance with the respective SOP. The validation covered three consecutive batches under worst-case conditions, considering equipment complexity, solubility of residues, cleaning parameters, and MACO limits. Product-wise equipment utilization matrices for Pyronaridine and its intermediates were reviewed and verified. Values used in MACO calculations were derived from public data and MSDS information, and separate targets were defined for swab and rinse samples.

The respective documentation was reviewed to verify cleaning validation activities in Block 1E after the production of Pyronaridine.

Cleaning validation between campaigns
Cleaning procedures were validated with emphasis on process steps posing the highest risk of contamination or carry-over to API quality. Each API was treated as a worst-case scenario, and the cleaning validation was performed to reflect actual equipment usage.

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

Validation of Analytical Methods
Analytical method validation and verification were conducted in accordance with the established procedures and applicable guidelines (ICH Q2(R2). Pharmacopeial methods were verified, while non-pharmacopeial and in-house methods were validated. Parameters such as specificity, accuracy, precision, linearity, robustness, and detection limits were evaluated. Methods were revalidated or reverified as required following any changes or at predefined intervals, with all activities performed under change control and appropriately documented.

Although no specific SOP was in place for analytical method development, method development activities and related experiments were recorded in designated reports and subsequently validated in accordance with the applicable procedure.

12. Change control

A formal change control system was established in accordance with the applicable SOP to evaluate all changes that could impact the production and control of intermediates or APIs.

Proposals for changes relevant to GMP were drafted, reviewed, and approved by the concerned departments and the Quality Unit. The potential impact of each proposed change on the quality of intermediates or APIs was evaluated. A defined classification procedure was applied to determine the level of testing, validation, and documentation required to support changes to validated processes. Changes were classified based on their nature, extent, and potential impact, and scientific judgment was applied to determine the need for additional testing or validation. During implementation, all affected documents should be revised accordingly.

Change control registers were maintained separately for each type of change. Change control forms were issued and managed individually for Corporate QA (multi-site) and site-specific changes.

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.

Change control requests were randomly selected and reviewed.

13. Rejection and re-use of materials

Rejection

Intermediates and APIs that did not meet established specifications were clearly identified and placed under quarantine. Reprocessing was permitted where appropriate and justified. The final disposition of all rejected materials was documented in accordance with the applicable procedures.

Reprocessing and reworking

Only reprocessing of validated process steps was performed, while reworking operations were not conducted at the site.

Recovery of materials and solvents

Not covered during this inspection.

Returns

See section “Storage and distribution.

14. Complaints

Quality-related complaints were recorded and investigated in accordance with SOP for "Market Complaint", which was applicable to all complaints received at Mangalam. A complaint record was randomly selected and reviewed.

Complaint records contained the name and address of the complainant, contact details of the reporting person, the nature of the complaint (including API name and batch number), the date of receipt, and details of initial and follow-up actions with corresponding dates and responsible persons. The records also included the response provided to the complainant, the response date, and the final decision regarding the affected intermediate or API batch. All complaint records were retained for trend analysis to assess frequency and severity and to determine the need for additional corrective or preventive actions.

15. Contract manufacturers (including laboratories)

A list of approved laboratory contractors was available, comprising 16 laboratory facilities.

Management of contract services was performed in accordance with the applicable SOP, which described the procedure for identification, assessment, inspection, evaluation, approval, and management of outsourced contract services from external agencies.

A written and approved contract was established between the contract giver and the contract acceptor, clearly defining the respective GMP responsibilities and quality obligations of each party.

The contract permitted the contract giver to participate in or support any regulatory or client audit of the contracted facility to verify GMP compliance. The audit of one of the laboratories was verified, and the respective audit report was reviewed.

Where subcontracting was permitted, the contract acceptor did not delegate any work to a third party without prior evaluation and written approval from the contract giver, in accordance with the terms of the agreement.

Vendor management

The vendor management policy described the procedures for identification, development, qualification, approval, disqualification, and requalification of vendors for raw and packaging materials used in the manufacture of APIs and intermediates. Lists of approved vendors for each material were available.

A random verification was performed.

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

Miscellaneous	
Samples taken	*NA*

Assessment of the site master file	Site Master File was provided and reviewed.
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, ***Mangalam Drugs and Organics Limited (Unit-1)***, located at ***Mangalam Drugs & Organics Ltd., Unit 1, Plot No 187, 2nd Phase, GIDC, Vapi, Gujarat, 396 195; 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-eighth 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-sixth 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. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
Short name: WHO TRS No. 961, 957), Annex 1
http://www.who.int/medicines/publications/44threport/en/

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.
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

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 artemisinin 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. Fiftieth 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. Fiftieth 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-fourth 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-fourth 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-fourth 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