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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
WHOPIR
Active Pharmaceutical Ingredient Manufacturer

<table>
<tr><th>Part 1</th><th>General information</th></tr>
<tr><td colspan="2">Manufacturers details</td></tr>
<tr><td>Name of manufacturer</td><td>MSN Pharmachem Private Limited.</td></tr>
<tr><td>Corporate address of manufacturer</td><td>MSN House, Plot No.: C – 24, Sanath Nagar Industrial Estate, Sanath Nagar, Hyderabad, Telangana, Pincode: 500 018, India.
Phone: +91-40-30438600, Fax: +91-40-30438798.</td></tr>
<tr><td colspan="2">Inspected site</td></tr>
<tr><td>Name & Address of inspected manufacturing site if different from that given above</td><td>MSN Pharmachem Private Limited.,
Plot No. 182 to 186, 192-A, 193 to 197 & 212/A, B, C, D, Phase-II,
IDA Pashamylaram, Pashamylaram (Village), Patancheru (Mandal),
Sangareddy District, Telangana, Pin code-502 307 India

GPS coordinates: 17.541765° N, 8.180526° E</td></tr>
<tr><td>Synthetic Unit /Block/Workshop</td><td>
<table>
<tr><th>Product</th><th>Stage</th><th>Manufacturing Block</th></tr>
<tr><td rowspan="6">Oseltamivir Phosphate [Route Code-OT]</td><td>OMP1</td><td>C-Block & G-Block, J-Block & 2A-Block</td></tr>
<tr><td>OMP2</td><td>B-Block, C-Block, J-Block, G-Block, 2A-Block & 2D-Block</td></tr>
<tr><td>OMP3</td><td>B-Block, C-Block, E-Block, D-Block & G-Block, J-Block, 2A-Block & 2D-Block</td></tr>
<tr><td>ORT1</td><td>A-Block, B-Block, D-Block, G-Block, 2A-Block & 2D-Block & 2B-Block</td></tr>
<tr><td>ORT2</td><td>A-Block, C-Block, D-Block, G-Block, 2A-Block, 2D-Block & 2B-Block</td></tr>
<tr><td>ORT3</td><td>B-Block, B-Block Clean Room-2, K-Block, K-Block Clean Room-2, E-Block, E-Block Clean Room-2, 2B-Block & 2C-Block, 2C-Block Clean Room-2</td></tr>
<tr><td rowspan="2">Moxifloxacin Hydrochloride [Route Code-MM]</td><td>MXM1</td><td>J-Block, B-Block & G-Block</td></tr>
<tr><td>MXM2</td><td>J-Block, E-Block & E-Block Clean Room-2, B-Block & B-Block Clean Room-2</td></tr>
</table>

N.B.: Block-D Dismantling has been initiated w.r.t Change Control No. 03-C-G-25-355 and effective date: 27 December 2025.</td></tr>
<tr><td>Manufacturing license number</td><td>07/MD/AP/2006/B/R – Dated 23/01/2006 valid through 22 January 2031</td></tr>
</table>

Inspection details	
Dates of inspection	2 – 4 February 2026
Type of inspection	Routine inspection
Inspection record Number	INSP-API-2020-0115
Introduction	
Brief description of the manufacturing activities	Manufacturing of Intermediates and Active Pharmaceutical Ingredients (APIs). No Manufacture of hazardous substances, cephalosporins, beta-lactams, hormones, cytotoxins or veterinary took place at the site.
General information about the company and site	MSN Pharmachem Private Limited, Pashamylaram facilities belongs to MSN Group of companies. The manufacturing facilities are authorized to manufacture of Active Pharmaceutical Ingredients and its intermediates only. The facilities are situated about 35 kilometres from Hyderabad city in the state of Telangana state, India. MSN Pharmachem Private Limited, established in the year 2004 and started the manufacturing operations in the year 2005. The Total area of the facilities is 43,298.09 m^2.
History	**Regulatory Authority** / **Date(s) of Inspection** USFDA, USA — 14 – 18 May 2018 Health Canada, Canada — 14 – 18 May 2018 Ministry of Industry and Trade, Russian Federation — 13 – 14 December 2018 Ministry of Industry and Trade, Russian Federation — 18 – 20 December 2019 WHO, desk assessment — 28 – 31 July 2020 ANVISA, Brazil — 11 – 14 July 2022 USFDA, USA — 17 – 21 April 2023
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Documents reviewed, including but not limited to: • Quality management • Personnel • Buildings and facilities • Process equipment • Documentation and records • Material management • Production and in-process controls • Packaging and identification labelling of APIs and intermediates • Storage and distribution • Laboratory controls • Validation • Change control • Rejects and reuse of materials • Complaints and recalls • Contract manufacturers (including laboratories)

	Site visited: • Production blocks • Warehouses • QC laboratories • HVAC system • Water system • QC laboratories including chemical and microbiological • Stability chambers and retained samples area.
Restrictions	NA
Out of scope	Products and/or processes and facilities that are not under the scope of the WHO prequalification program.
WHO APIs (including WHO API or APIMF numbers) covered by the inspection	• Moxifloxacin (hydrochloride) API related to several WHO prequalified finished pharmaceutical products (FPPs) including e.g., TB414, TB415, TB230, TB263, TB341, TB342, TB349, and TB376. • Oseltamivir (phosphate) related to several WHO prequalified finished pharmaceutical products (FPPs) including e.g., IN018, IN019 and IN020.
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
HVAC	Heating, ventilation and air conditioning
IR	Infrared spectroscopy
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
PSD	Particle size distribution
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
WFI	Water for injection

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

1. Quality management

A documented system for quality assurance was established, with procedures covering key quality elements in place. The Quality Department was divided into QA and QC and was separate from the Production Department. Operations were specified in written form and critical GMP requirements were essentially met.

Quality manual AQM-001/02, effective date: 28/4/2025, was reviewed. Senior management commitment was in place to ensure implementation of PQS as per objectives, roles and responsibilities.

SOP for numbering, preparation, review, approval, control, distribution, issuance, archival and destruction of documents in eDMS, where eDMS was used for SOPs and associated formats, investigation reports, APQRs, specification of methods of analysis and annual summary reports.

Product Quality Review (PQR)

PQRs were performed according to SOP for "Annual product quality review". The PQR preparation was performed in eDMS. The SOP indicated that the APQR should be completed within 90 days from the

end of calendar year or scattered for a rolling 12-months review period as per established schedule for distinct codes of products. In-process parameters were only trended. Statistical process control including calculations of 3-Sigma and CpK were applied to data of final API specification and stability indicating tests. CpK > or equal to 1.33 was considered for capable process and less than 1.33 should trigger assessment and justification. The 2024 and 2025 APQR schedule were available.

The following APQRs were reviewed, and the content of the PQR included:

- APQR Moxifloxacin hydrochloride (monohydrate) (MM), review period Jan 2024-Jan 2025.
- APQR – Oseltamivir Phosphate-03-OT-APQR-2024-0001-001, Jan2024-Jan2025.
- APQR Moxifloxacin hydrochloride (monohydrate) (MM), review period Jan 2023-Dec 2023.
- APQR – Oseltamivir Phosphate- Jan2023-Dec 2023.

Deviations:

The SOP for managing deviations was in place. The SOP provided for deviations to be classified into critical, major and minor.

In-process control results not meeting specifications were defined to be handled as OOS using the OOS related procedure.

A couple of deviations were spot-checked.

Management review (MR)

The SOP for "Management review meeting" was checked. MR was required to be performed quarterly with attendance of senior management. The report of the MR meeting related to Q3/2025 was reviewed. The intimation letter with meeting agenda and the respective minutes of the meeting were available.

Internal Audit (self-inspection):

The SOP for internal audit was in place. The annual plan for 2025 was checked. Audit report for Block 2C production unit was conducted as per schedule.

Quality risk management (QRM)

The SOP for "Quality Risk management" was available. The QRM was utilized in various aspects across the product lifecycle. Failure mode effects analysis (FMEA) and other quality risk management methodologies were described in the procedure. Post implementation risk assessment was done if overall priority was medium or high. A QRM periodic review was indicated to be done every 5 years. A risk assessment log (risk register) was kept per each individual product: for Oseltamivir, and for Moxifloxacin HCL.

Several risk assessment reports were spot-checked.

Product release

Product release was managed according to the "Batch release" SOP. The release of "API or intermediate" was the responsibility of QA. Starting materials were released by QC.

QA manager and delegated persons were responsible for the final review of all the relevant documents including BMR, BPR and batch testing records for the finished API release according to the procedure. List of authorized personnel for batch release included 12 persons from QA.

2. Personnel

There were approximately 1028 staff working on site. In general, personnel had the necessary qualification and practical experience. Personnel interviewed during the inspection had sufficient knowledge of GMP standards. Responsibilities of staff and their duties were well documented.

Personnel qualification

There was an adequate number of personnel qualified by appropriate education, training and experience to perform and supervise the manufacture of intermediates and APIs. The responsibilities of all personnel engaged in the manufacture of intermediates and APIs were specified in writing in the form for job descriptions. Same applied to personnel supervising the manufacturing operations including QA staff.

Personal hygiene

In general, as observed during the site tour and witnessing of actual manufacturing activities, personnel followed good sanitation and hygiene practices. Proper gowning was observed before access to production and control areas.

3. Buildings and facilities

Production

In general, buildings and facilities used in the manufacture of intermediates and APIs were located, designed, and constructed to facilitate cleaning, maintenance and operations as appropriate to the type and stage of manufacture. Buildings and facilities had adequate space for the orderly placement of equipment and materials to prevent mix-ups and contamination. Facilities were designed to minimize potential contamination. Cleanrooms were utilized for final processing of the finished APIs.

The flow of materials and personnel through the building or facilities were designed to prevent mix-ups or contamination. In addition, it was established, as per the procedure for avoiding cross contamination, that one single API can be processed in cleanroom areas. In most cases, with few exceptions which were managed through procedural controls, personnel airlocks were separate from materials airlocks.

Several blocks (located at plot No. 182 to 186, 192-A, 193 to 197) were added for the production of Oseltamivir intermediate and API in 2023. These were covered during the site visit where actual manufacturing operations were observed. Block 2C clean rooms, dispensing areas and micronization rooms and RM, API and intermediate warehouses. Also, Block 2 A was visited where intermediate production took place.

The SOP for avoiding cross contamination mandated that one single product be processed within one cleanroom area in order to avoid the risk of cross contamination. Product changeover cleaning followed by line clearance were necessary to be performed in case of introducing or changing the processed product at the cleanroom areas.

QC laboratories

Laboratory areas were separated from production areas.

Quality control laboratory –2 served as an in–process control lab for Blocks 2 manufacturing areas A, B, C and D. All other testing were done in QC lab-1 which was located at the older plot 212/A, B, C, D, Phase-II, IDA Pashamylaram. The premises and facilities of the QC laboratories were adequate, in general.

Utilities

In general, all utilities impacting the product quality of the products (e.g. steam, gases, compressed air, and heating, ventilation and air conditioning) were qualified and appropriately monitored.

Nitrogen

For the APIs of relevance to WHO PQP, no nitrogen was used in manufacturing.

Water

Water used in the manufacture of the APIs was of purified water (PW) quality and was demonstrated to be suitable for its intended use. Water treatment equipment was qualified and the PW generation system was validated and monitored with appropriate action limits.

The purified water layout was reviewed. The testing reports of the routine monitoring of the PW were spot checked.

Annual quality review of PW system showed that the quality of PW used for different manufacturing activities was maintained well within the specification limits (USP) during the review period. Alert and action limits were set.

Lighting

Adequate lighting was provided in all areas to facilitate cleaning, maintenance, and proper operations.

4. Process equipment

Design and construction

Production equipment was of good standard and appeared to be well maintained. Spot-checks on differential pressure gauges indicated that equipment and devices were timely calibrated. The workflow in the facility was appropriately designed, and the equipment appeared to be installed to facilitate production and reduce the risk of contamination and mix ups. All production equipment reviewed was identified as to its content or purpose with cleanliness status identified by appropriate labels.

Equipment maintenance

The SOP for preventive maintenance along with preventive maintenance schedule which was prepared annually with 6-month frequency for all equipment were established.

Preventive maintenance schedule for 2025 for Block 2 C was checked.

HVAC maintenance

The SOP for performance verification of cleanrooms was reviewed. The frequency of cleanroom requalification was set in agreement with ISO 14644 and WHO guidelines on HVAC systems. Example HVAC requalification was spot-checked and found satisfactory.

Calibration

The SOP for internal and external instrument calibration was in place. The SOP provided for classification of measuring instruments into critical, non-critical and indicative. The frequency of calibration of these different instruments varied between 6 months and 24 months (excluding 5 years for solvent storage tanks calibration). For standard weights, the frequency of regular calibration was set for once every 24 months.

Computerized systems

The SOP for computerized system qualifications and validations was in place. Periodic data retrieval verification of database in LIMS and e-DMS was done in January every year as per SOP. E-DMS system was operated, and privileges control was in place as per SOP for operation of document management system.

5. Documentation and records

Documentation system and specifications

In general documents were designed, prepared, reviewed, and distributed properly. Documents were approved, signed, and dated by the appropriate responsible persons. Records were made or completed when any action was taken.

The documentation reviewed during the inspection indicated that there were two types of SOPs (corporate and site specific). An eDMS was in place for the issuance, revision and monitoring of SOPs. Specifications were established and documented for raw materials, intermediates, and APIs as well as labelling and packaging materials.

Equipment cleaning and use of records

In general, Records and logbooks of equipment use, cleaning, sanitization and maintenance were available and checked during the site tour.

Master production and control records

The SOP for preparation of batch production records and cleaning records was reviewed. Master Template for BPR was checked. Product specific master BMRs were available.

Batch production and control records

Batch production and batch packaging records were available. The following records were spot-checked:

- Batch production record of moxifloxacin stage 2.
- Batch packaging record of moxifloxacin finished API.
- Batch production record of moxifloxacin stage 2.
- Batch packaging record of moxifloxacin finished API.
- Batch production record of micronization and sifting for moxifloxacin finished API.

Equipment logbooks were also cross checked for alignment with batch records.

6. Materials management

Receipt and quarantine

The SOP for raw material receipt, inspection and handling at warehouse was reviewed.

Handling of receiving, storage and reconciliation of key starting material (KSM) batches was done manually through bin cards. Labels for quarantine were generated by warehouse, while labels for approved and released RM were generated by QC.

Example from received shipment of materials was checked as per procedure and found satisfactory for key starting material for Oseltamivir received from MSN life science Unit II.

Sampling and testing of starting materials and finished APIs

Several warehousing areas were designated for the storage of raw and starting materials, intermediates, finished APIs as well as packaging and labelling materials.

The SOP for Sampling and handling of all RM, packaging material, IPC samples, intermediates and drug substances was in place. The QC team was responsible for implementing the SOP. Warehouse and production coordinated with QC team to conduct the sampling activities as per the relevant procedures.

Sampling was done under LAF in clean rooms in warehouse and clean rooms, grade D, in production areas.

Storage

The SOP for raw material, packaging material, sampling, storage and handling was reviewed. Lists of different RM storage conditions were available. Storage of RM was done in ambient conditions. Temperature was monitored twice daily and monthly average was recorded. Logbooks for RM warehouse 2c and area I were checked. The temperature range assigned for storage of raw material stored at room temperature was 15°C – 45°C.

The SOP for assigning of manufacturing date and retest/expiry period for finished API, intermediates and recovered solvent was reviewed and found that storage conditions for RM was defining room temperature as (ambient condition: temperature prevailing in working area) as per reference USP <659> entitled “storage and packaging requirements” (revised Dec 2025).

Supplier management

The list of corporate approved suppliers for key starting materials for products in scope was available.

The SOP for supplier qualification was in place. AARTI pharma Labs Ltd. audit report, supplier for Moxifloxacin key starting material was checked. Audit was conducted as part of periodic onsite audit.

7. Production and in-process controls

In general, different production and in-process control activities were well controlled and documented in the respective batch records. Weighing and other critical operations (excluding printing and attaching finished API labels) were performed by production and witnessed by QA. Prior to use, production personnel verified that the materials were those specified in the batch record for the intended intermediate or API. Actual yields should be compared with expected yields at designated steps in the production process. Expected yields with appropriate ranges were established and verified. Deviations from manufacturing operations associated with critical process steps should be investigated to determine their impact or potential impact on the resulting quality of affected batches

The SOP for process validation was reviewed where blending was detailed in this procedure.

8. Packaging and identification labelling of APIs and intermediates

There were written procedures describing the receipt, identification, quarantine, sampling, examination, testing and release and handling of packaging and labelling materials.

Packaging and labelling facilities were inspected immediately before use to ensure that all materials not needed for the next packaging operation had been removed. This examination (line clearance) was documented in the batch packaging records as well as the room/equipment logbooks.

Labelling operations were designed and performed in such a way to prevent mix-ups. Labelling operations were performed at cleanrooms close to the finished API storage facilities.

Labels, including printing operations, were independently controlled and managed by the QA team. Finished API labels were printed by and attached to finished API drums by QA team and the same was verified by production team.

SOP for packaging and handling of finished products was in place. FP/saleable intermediates packaging and release checklist for Oseltamivir phosphate was checked. Packaging was done in warehouse clean room –1. Packaging labels and reconciliation records were checked.

9. Storage and distribution

Warehousing procedures

SOP for handling and storage of intermediates was in place. The procedure included steps for sampling, dispensing, packaging, and labelling. Oseltamivir intermediate ORT-1 was stored at 2°C – 8°C. Intermediates were packed using triple laminated bag sealer.

Storage of finished API and intermediate was done in areas with controlled temperature in the range of 15°C – 25°C. Daily Temperature monitoring was conducted. Logbooks for monitoring temperature were checked.

The SOP for temperature mapping of facilities and equipment, applicable for ambient and controlled storage areas. Temperature mapping study protocol for warehouse –02 and Report were discussed. Temperature mapping study protocol and report for cold room in warehouse 2 for storage of Oseltamivir intermediate at 2°C – 8°C were discussed.

Distribution procedures

APIs and intermediates were only be released for distribution to third parties after they have been released by the quality assurance team as per the batch release procedure. Special transport or storage conditions were stated on the label. A system was in place by which the distribution of each batch of intermediate and API can be readily determined to permit recall, when needed.

10. Laboratory controls

Adequate laboratory facilities, along with adequate equipment and instruments, were available at the disposal of the QC team. Different QC activities were performed at the QC unit or outsourced to qualified third parties (contracted laboratories) as per established procedures. The performed QC activities were documented in analytical sheets, whether in paper or in electronic format using an established LIMS.

Physicochemical Laboratory

The SOP for analytical data review and SOP for good chromatographic practices were established. Both procedures provided for modification of processing methods and integration parameters after review and approval by QA.

A logbook was established for modifying processing methods. The logbook indicated few cases of modifying processing methods and the same were spot-checked.

The list of HPLC aborted runs between Jan 2024 and Dec 2025 was also reviewed.

The SOP for audit trail review for chromatographic and non-chromatographic data systems was in place. It provided for two types of audit trail namely batchwise and periodical audit trail. The latter was conducted on monthly basis. Both types were conducted as per established templates in LIMS system. The last periodic audit trail was spot-checked. In addition, several batchwise audit trails were spot-checked.

The Privileges and access rights matrix of the HPLC software and LIMS were spot-checked.

OOS/OOT management

The SOP for handling OOS results was in place. The SOP provided for phase 1a (initial), phase 1b (laboratory including hypothesis testing as applicable), phase II (manufacturing and laboratory) and phase III (extended) investigations.

The list of OOS cases in the last three years was reviewed.

Stability study

A hold time study was performed for the wet material for moxifloxacin. Similarly, a hold time study was performed for the wet material for oseltamivir. The storage condition for holding the wet material was indicated as “room temperature”.

Expiry and retest dating

The SOP for assigning of manufacturing date and retest/expiry period was established and implemented. The procedure provided for definition of manufacturing date based on the date of the last operation (normally the drying operation).

Reserve/retention samples

Appropriately identified reserve samples of each batch of API were retained for a minimum of 7 years. The reserve sample were stored at an access controlled area within the QC facilities. Reserved API samples were kept in the same packaging system in which the API was stored. Sufficient quantities were retained to conduct at least two full analyses.

Microbiological laboratory

No microbiological testing was performed at MSN Pharmachem. Microbiological testing of materials, and products as well as water analysis and environmental monitoring were outsourced to MSN Rudraram. The latter site was inspected by WHO in connection with some WHO prequalified products.

Environmental Monitoring and microbiological testing

SOP for microbial EM of cleanroom areas was in place. The K-block cleanroom 2 microbiological EM summary report was reviewed and showed no out-of-limits.

11. Validation

The master validation plan was reviewed. A plan was in place on quarterly basis for different validation and qualification activities. In Q1/2026, PV and CV for Oseltamivir were planned considering the additional process equipment (addition of new blocks to meet the product demand).

Validation documentation

There was an established requirement for documentation of the validation and qualification activities, including through protocol and related reports. The template of the qualification and validation reports included dedicated sections for approval, conclusion and deviations (if any).

Qualification

Installation and qualification protocol and report for triple laminated sealer for dispatching products in 2C block was discussed.

Process Validation (PV)

The SOP for PV was in place. The procedure guided different stages of PV, including process design, process qualification and continued process verification. The SOP also provided for different PV approaches, including prospective and concurrent PV. Modern approach of continued process verification (CPV) was considered, rather than the traditional revalidation approach. 25 API batches were needed to perform CPV on quarterly basis using Cp, CpK and 3 sigma evaluation. If no enough batches were produced, accumulation of data of batches produced over earlier quarter or quarters was considered.

The PV protocol and report for moxifloxacin stage 1 (intermediate) were reviewed. The PV was initiated to address the modified manufacturing process as well as the addition of a new vendor of KSM. Three consecutive intermediate batches were considered during the PV.

The PV protocol and report for moxifloxacin stage 2 (API) were reviewed. Similar to the intermediate, This PV of the API was initiated to address the modified manufacturing process as well as the addition of a new vendor of KSM. Three consecutive API batches were considered during the PV. The three API batches were produced using the three intermediate PV batches.

In addition, a new KSM vendor was added to the list of approved suppliers as per change control. The vendor qualification process involved comparison study at the R&D level considering three batches of commercialized API and R&D batches produced using three KSM batches from the new supplier; quality and yield level evaluation.

Periodic review of validated systems

Continued process verification (CPV) was performed using Cp, CpK and other statistical process control tools. Manufacturing processes were reviewed on annual basis as part of the APQR.

Cleaning Validation (CV)

An SOP for CV was in place. The SOP defined five types of cleaning namely (1) batch to batch cleaning, (2) product changeover cleaning, (3) periodical cleaning, (4) cleaning before maintenance, and (5) cleaning after maintenance. Acceptance criteria were selected among the most restrictive calculations based on (1) general limit which was set for 10 ppm, (2) therapeutic daily dose, (3) Permissible daily exposure, (4) and toxicological data. The latter toxicological data was considered in case of absence of TDD and PDE data. Three batches were considered for this CV and the cleaning method was found to be efficient in cleaning different equipment.

12. Change control (CC)

A procedure for change management was available. CC Classification according to specified matrix and timelines of CC management were in place and extension of time was allowed for only 3 times after then CC should be cancelled. Trending of CC was performed as per SOP. Trending report for 2024 was available and 2025 was under draft. CC Trends were done per product.

13. Rejection and re-use of materials

Rejection

The SOP for handling of rejected materials was in place and was applied to raw and packaging materials. Rejected material register for 2025 was checked and no rejection for raw and packaging material took placed in 2025. Rejected materials were stored in segregated and secured areas.

Reprocessing & Reworking

The SOP for reprocessing and reworking was in place. As per the mentioned procedure, quality failed returned batches, recalled batches and OOT batches can be reprocessed/reworked based on investigation, recommendation and approval by QA head. The procedure also indicated that reprocessed and reworked batches should be enrolled into the stability monitoring programme.

As per procedure for release of products, reworked batches cannot be dispatched to WHO and other regulated markets. Reprocessed batches, on the other side, could be released if reprocessing process was approved in the DMF.

Batch production record reprocessing register for Oseltamivir phosphate in 2025, showed that some batches were reprocessed. One case was checked.

For Moxifloxacin HCL monohydrate, no reprocess was approved in the DMF and no reprocessed batches were executed accordingly.

Recovery of materials and solvents

The SOP for recovery of solvents and materials was in place. The SOP indicated the list of products for which recovered solvents was possible. Neither moxifloxacin nor oseltamivir was among the mentioned list as no recovered solvent was possibly used during the manufacturing process.

Returns

The SOP for handling of returned goods was in place. The SOP covered returns for commercial or quality reasons. As per the procedure, QA should review the handling and storage declaration from the concerned customer and the returned batch should be tested by QC. Returned batches passing testing upon return could be further reprocessed, reworked and dispatched.

Annual return trend analysis report for 2025 was reviewed. Return good record was spot-checked. Return good summary report was reviewed. Materials were checked and tested and further dispatched to other customers.

14. Complaints and recalls

Complaint:

The SOP for market complaint management was in place. Repeated complaints were considered if repeated within 12 months period of receiving complaints. Register for complaints 2023, 2024 and 2025 were checked. No complaint for Moxifloxacin HCL monohydrate in 2023, 2024 and 2025. Annual trend analysis for market complaints for Jan-Dec 2025 was checked.

Several complaints were spot-checked.

Recall:

The SOP for recall was in place. Mock recall was done every 3 years +/- 3 months. In general, no recalls were conducted by the manufacturer. Register for recall for 2025 was checked.

15. Contract manufacturers (including laboratories)

No contract manufacturing was implemented by MSN Pharmachem for the production of Moxifloxacin HCL monohydrate or Oseltamivir (phosphate).

The SOP for qualification of contract service providers was in place. The QC laboratory agreement between MSN Pharmachem private LTD. and MSN central analytical laboratories located in MSN laboratories private limited manufacturing site in Rudraram. An audit report was reviewed.

As per the quality agreement, API, intermediate, raw materials and working reference standards were in scope for testing. MSN central lab was in charge of microbial analysis for cleanroom environmental monitoring, water testing, ICP-MS, ICP-OES, PXRD, Nitrates and nitrites. Also, analytical method validations, monograph evaluations and standard qualifications were in scope of the agreement.

Miscellaneous	
Samples taken	NA
Assessment of the site master file	The SMF was received prior to the commencement of the inspection and it was found acceptable, in general.
Annexes attached	NA

Part 3	**Final 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, **MSN Pharmachem Private**

Limited located at **Plot No. 182 to 186, 192-A, 193 to 197 & 212/A, B, C, D, Phase-II, IDA Pashamylaram, Pashamylaram (Village), Patancheru (Mandal), Sangareddy District, Telangana, 502 307 India,** was considered to be operating at an acceptable level of the WHO guideline on Good Manufacturing Practices (GMP) for active pharmaceutical ingredients.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	**List of GMP guidelines referenced in the inspection report**

1. WHO good manufacturing practices for 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
   https://www.who.int/publications/m/item/trs986-annex2

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

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