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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Pharmaceutical Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**MSN Laboratories Private Limited**
Corporate address of the manufacturer	MSN House, Plot No.: C-24 Industrial Estate, Sanath Nagar, Hyderabad - 500 018, Telangana INDIA
Name & address of inspected manufacturing site if different from that given above	Formulations Division, Unit-II, Survey Nos. 1277, 1319 to 1324, Nandigama (Village & Mandal), Rangareddy (District), Telangana 509228, India
Unit/block/workshop number	Block D (General OSD)
Dates of inspection	16-20 June 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	The factory is situated at Sy. No. 1277 & 1319 to 1324, Nandigama Village & Mandal, Rangareddy District – 509 228, Telangana, and about 45 kilometers from Hyderabad. The manufacturing site was spread across various manufacturing blocks, with Block D used to manufacture WHO-prequalified and under-assessment products. Block C was dedicated to oncology products, whereas Block G was used for manufacturing immunosuppressants and OSD in separate areas.
General information about the company and site	MSN Laboratories Private Limited, Formulations Division, Unit-II, Nandigama, is a unit of MSN Laboratories Private Limited and is part of the MSN Group of Companies, established in 2003. MSN Group comprises a number of API manufacturing plants, finished dosage facilities, and a separate dedicated Research and Development centre.
History	The last on-site GMP inspection was performed in March 2017. In May 2020, a desk assessment was conducted based on the 2019 US FDA inspection.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Pharmaceutical quality system - Personnel and training - Qualification and calibration of equipment and instruments - Validation (cleaning, process, analytical, and computerized system) - Visit to the warehouse - Visit to the quality control laboratory, including the microbiological

	laboratory - Visit to production and packaging areas - Visit to the air handling units and the purified water system
Restrictions	None
Out of scope	The products and areas for non-WHO-prequalified products were out of scope for this inspection.
WHO products covered by the inspection	1. Moxifloxacin tablets 400mg (TB341) 2. Levofloxacin tablets USP 250mg (TB338) 3. Levofloxacin tablets USP 500mg (TB339) 4. Levofloxacin tablets USP 750mg (TB340) 5. Darunavir film-coated tablets 400mg (HA723) 6. Darunavir film-coated tablets 600mg (HA724) 7. Darunavir film-coated tablets 800mg (HA725) 8. Oseltamivir phosphate hard gelatin capsules 30mg (IN018) 9. Oseltamivir phosphate hard gelatin capsules 45mg (IN019) 10. Oseltamivir phosphate hard gelatin capsules 75mg (IN020) 11. Bedaquiline 100mg tablets (TB395) 12. Molnupiravir capsules 200mg (CV030, under assessment)
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original, and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
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
GPT	Growth promotion test
HEPA	High-efficiency particulate air
HPLC	High-performance liquid chromatography
HVAC	Heating, ventilation, and air conditioning
IQ	Installation qualification
LAF	Laminar air flow
LIMS	Laboratory information management system

MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media fill Test
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
SIP	Sterilization in place
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. Pharmaceutical quality system

A documented quality assurance system was established, with procedures covering key quality elements. The quality department was divided into QA and QC and separated from the production department. Operations were documented, and critical GMP requirements were essentially met. The procedures reviewed and discussed during the inspection were generally acceptable. The manufacturer used various electronic systems for quality management, document management, learning management, material management, laboratory management, and others. The following quality system elements were reviewed and found to be adequate:

Management review

MRMs were responsible for evaluating the effectiveness of the pharmaceutical quality system and were governed by the SOP. The MRMs were conducted monthly, quarterly, and annually, according to an

established schedule and agenda. The Quality Assurance Head served as the management representative and meeting chairman; other members of management included the Heads of the respective departments.

Annual product quality review

The APQRs were prepared for the calendar year (Jan-Dec) and should be completed by the end of March each year. The procedure provided a template that included various elements in line with the WHO GMP main principles. The CpK was calculated for critical process parameters (CPPs), whereas for the remaining test parameters, a 3-sigma (UCL/LCL) approach was used, and graphs were prepared. The Excel Spreadsheet was used to prepare a graphical presentation. The Cp and CpK calculation was performed using 30 batches; in addition to 3-sigma, Cp and CpK for assay and yield were calculated using Minitab software. If fewer than 30 batches are manufactured, batches from the previous year will be considered.

Deviations

Deviations were managed in the Caliber QAMS system in accordance with the SOP for reporting, investigating, and closing deviations.

Corrective and Preventive Action (CAPA)

A procedure for implementing CAPA in the caliber was in place and reviewed. The procedure was linked to various QMS elements that could require CAPA, including internal audits, APQR, market complaints, recalls, and deviations, among others. Provisional CAPAs were proposed by members from the respective departments, reviewed by the department heads, and approved by QA.

Change control procedure (CCP)

Change management was described in two procedures: one for permanent changes and one for temporary changes. Changes were managed in the caliber QAMS and classified as minor, moderate, or major based on the impact on the system or product quality. Impact assessments were required to be conducted by cross-functional departments prior to Head QA's approval of changes.

Quality risk management

The procedure was applicable for identifying possible risks associated with a drug product or with the processes used to develop, manufacture, distribute, inspect, and submit drug products throughout their life cycle, manufactured on-site. The procedure also described various methods (FMEA, FTA, FMECA, HACCP, HAZOP, PHA, etc). The FMEA tool described the use of severity, occurrence, and detectability, and the calculation of the Risk Priority Number (RPN).

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources, including adequate premises, equipment, and utilities, were provided to support the current operational level of finished pharmaceutical products manufacturing activities. The manufacturing processes followed procedures as defined and documented in the BMRs. The personnel were appropriately qualified. The manufacturing facility where WHO-prequalified and under-assessment non-sterile products were produced was a shared facility. Particularly, Block D was used for WHO products.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

3. Sanitation and hygiene

The manufacturer followed sanitization and hygiene practices, as noted during the review of various procedures, including entry and exit procedures for employees and visitors to the production and warehouse. Similarly, the SOP for handling garments outlined the gowning management procedure.

4. Qualification and validation

The Validation Master Plan for Unit II provided a high-level overview of the validation activities, overall intentions, and on-site approaches. The document was applied to all qualification/validation activities carried out at Unit-II, Nandigama. The overall responsibility for validation activities rests with the QA, with support from user departments, including engineering, production, and laboratory. The content of the VMP included facility qualification, utility & equipment qualification, water system, calibration, preventive maintenance, process validation, hold time study, reprocess and rework, computerized system validation, temperature & RH mapping study, cleaning validation, analytical method validation/verification, transportation study, personnel qualification, etc. A risk-based approach (direct and indirect impact system) was used for the equipment/system qualification. The periodic requalification of equipment and systems was conducted every 5 years. The manufacturer requalified the AHUs between 12 and 24 months, depending on the test type. For the compressed air and nitrogen, assistance was sought from an outside party. The calibration activities were carried out by the manufacturer and an outside party, as required. The engineering team calibrated the production equipment and systems, whereas the QC personnel calibrated the laboratory equipment. The source of the purified water is bore water, and its qualification was conducted in three phases. The process validation was performed in three stages. Stage I was conducted by the R&D; Stage II was performed by the site, involving three batches; and Stage III was performed using a 3-sigma approach.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

5. Complaints

Market complaints were handled in accordance with the SOP. The procedure applied to a broad range of complaint types, including those related to manufacturing, packaging, product purity, safety, efficacy, counterfeit concerns, and adverse drug reactions. The procedure provided instructions on receiving, registering, investigating, applying CAPA, communicating with customers, and closing complaints in the Caliber QAMS.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

6. Product recalls

The product recall and rapid alert procedures outline the steps to be taken when withdrawing defective products or batches from the market. According to the procedure, the recall decision was made by the company's Head of Quality Management. Recalls were classified as voluntary or statutory, and, depending on the risk to the patient's health, categorized as Class I, II, or III. The depth of the recall was

defined in the SOP class (consumer/patient level, retail level, wholesale level, and hospital level), and this was linked to the recall class. A rapid alert system was described for Class I recalls. Root cause investigation and CAPA were required for all recalled products. The procedure also described conducting mock recalls to test the effectiveness of recall arrangements on an annual basis, in case no actual recalls had been conducted.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

7. Contract production, analysis, and other activities

The manufacturer confirmed that no part of the production related to WHO prequalified products was contracted out. The manufacturer used some of the contracted laboratories to test certain products where on-site testing was not feasible.

8. Self-inspection, quality audits and suppliers' audits, and approval

Self-inspections were conducted at least once every year to cover all GMP-related areas. Ad hoc self-inspections could also be conducted in response to critical complaints, recalls, deviations, and in advance of external inspections. An annual schedule was prepared by QA in consultation with the Departmental Heads. A list of auditors, based on experience and qualification, was maintained by QA. Self-inspection reports were followed by appropriate CAPAs, which were to be discussed at monthly management meetings.

9. Personnel

More than 2000 staff members were working on the site. The drug license number 5/MN/TS/2014/F/G, issued on 24 August 2024, included the list of approved analytical chemists (instrumentation, wet analysis, and microbiology) and manufacturing chemists.

10. Training

A training program, governed by SOP, was in place for all employees at the company and managed in the Nichelon 5 CMS software. The SOP described various types of training, including induction training, on-the-job training involving newly revised or updated SOPs, GMP training, specific training, external training, and technical training. A training schedule was required to be prepared in the last month of the year for the following year. The SOP also described training for casual employees on general and job-specific procedures relevant to their areas of operation. Trainers were selected by the Head QA/QM in consultation with the Departmental Head, based on their qualifications and experience.

11. Personal hygiene

The personnel were trained in hygiene practices as described under Section 3. The personnel were required to enter the manufacturing facility through the designated changerooms. The gowning instructions were displayed at the changerooms, and facemasks, shoe covers, hairnets, and gowns were provided. An adequate washing facility was available before entering the manufacturing areas.

12. Premises

The site consisted of three manufacturing blocks: Block C, Block D, and Block G. These blocks were designed to manufacture products for all global markets. The manufacturing unit was constructed of brick and cement, and the roofs were reinforced concrete. The floors in the production area, warehouse

area (including raw material storage areas and dispensing areas), and microbiology lab were of epoxy. Block D, under the scope of this inspection, was divided into the following areas:

- Ground Floor: RM, PM, FG Storage Areas and Packing Lines
- Mezzanine Floor: Conference hall, Offices, QA Office, Document Archival
- First Floor: Manufacturing & Packing Lines and Quality Control Laboratory
- Second Floor: Quality Control Laboratory, PW system & Utility

In general, the premises were adequately designed and well-maintained at the time of the inspection.

13. Equipment

The requalification records for the octagonal blender, following its transfer from Blending Room 7 in Block D to the Granulation Room 7 in Block D, were selected for review. The requalification report included a re-verification of the equipment installation, verification of its operational range, and verification of its HMI interface, as reported in the CSV. The quarterly preventive maintenance records were also reviewed.

14. Materials

Material receipt operations included inspecting the vehicle, inspecting and dedusting material containers, verifying weight, verifying related documentation such as certificates of analysis, packing lists, invoices, challans, and the qualification status of the supplier and vendor, as well as conducting a physical inspection of material labels, batch, and expiry details. An electronic checklist in the SAP software was used to document these checks. Temperature and relative humidity were controlled and monitored using calibrated data loggers at predefined hot spots in the various rooms of the warehouse. Maximum values recorded were spot-checked during the inspection and were observed to be within the set limits.

15. Documentation

Documents such as SOPs, protocols, and reports at the site were handled through the document management system (DMS), which was controlled by the QA unit. Procedures were in place for preparing, revising, and distributing documents through the DMS. Executed batch manufacturing and packaging records related to commercial products were maintained as manual records and stored in the document archive facility, at level 2 of the D-block. The retention period for various document types was described in the SOP.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

16. Good practices in production

The inspector visited the manufacturing areas of Block D. Building D was broadly divided into the ground floor (warehouse) and the first floor (manufacturing areas). Hand-washing and toilet facilities were provided before entering the changerooms. Separate changerooms were provided for casual personnel and staff. After removing street clothes and footwear, the personnel enter the first changeroom, which is maintained as unclassified. The personnel were provided with shoe covers, aprons, hairnets, beard masks, and crossed over the bench. The instructions were displayed to remove jewelry, watches, and mobile phones, and gowning instructions were provided. The biometric and card access were provided before entering the manufacturing areas. The garments were washed/ironed by an outside party.

The temperature and relative humidity, differential pressure, and pressure cascading (40 mm for corridors, 30 mm for MAL/PAL, and 20 mm for core processing areas) were maintained using manual thermohygrometers and magnehelic gauges. Granulation four (4) was equipped with a sifter, RMG, FBD, co-mill, bin blender, tilting device, and other necessary equipment. The granulation, compression, coating, and capsulation areas were equipped with separate MAL and PAL. There were 14 granulation areas and eight compression machines of different makes and capacities. For the compression machines, the in-process checks, including group weight, individual weight, thickness, hardness, friability, and disintegration time, were conducted by the IPQC and production at regular intervals. The metal detector was challenged at the start and end of the compression operation, as well as after any breakdown. Some of the production equipment has a clean-in-place (CIP) facility, whereas the rest uses clean-out-of-place (COP).

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

17. Good practices in quality control

The quality control laboratory for testing raw, finished products, and packaging materials was located on the 1st and 2nd floors of Block D. Additionally, the central laboratory, located on the 2nd floor of Block G, was used for nitrosamine testing and other tests. The microbiology laboratory was located on the first floor of C block. Generally, the quality control laboratory was appropriately organized and equipped. Separate sections were maintained for the receipt and storage of samples, wet chemistry, storage of chemicals and glassware, and instrumentation. A LIMS software was installed at the laboratory and used to manage the receipt, registration, allocation, testing, and review of test results. Samples were received, registered in LIMS, and stored in chambers of controlled temperature and relative humidity prior to allocation to different analysts. Most analytical equipment, such as weighing balances, HPLCs, GCs, dissolution testers, and pH meters, were interfaced directly with the LIMS software, limiting direct analyst intervention in recording analytical test results. Access to the LIMS software was controlled through unique user IDs and passwords with defined user privileges.

The deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

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, ***MSN Laboratories Private Limited***, located at ***Formulations Division, Unit-II, Survey Nos. 1277, 1319 to 1324, Nandigama (Village & Mandal), Rangareddy (District), Telangana 509228, India,*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

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 WHO 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-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. ***Short name: WHO TRS No. 986, Annex 2***
   https://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

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***
   untitled (digicollections.net)

3. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 3.
   Short name: WHO TRS No. 1033, Annex 3
   9789240020900-eng.pdf (who.int)

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
   https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

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**
   https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

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
   https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

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
   https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

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 3.
Short name: WHO TRS No. 957, Annex 3
https://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

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
https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

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
https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

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***
https://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

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***
https://digicollections.net/medicinedocs/#d/s21438en

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
https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

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
https://digicollections.net/medicinedocs/#d/s20177en/

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
https://digicollections.net/medicinedocs/#d/s20175en/

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. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS No. 1019, Annex 3***
https://digicollections.net/medicinedocs/documents/s23697en/s23697en.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***
Essential Medicines and Health Products Information Portal (digicollections.net)

20. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
Short name: WHO TRS No. 992, Annex 6
https://www.who.int/publications/m/item/who-recommendations-for-quality-requirements-when-plant-derived-artemisinin-is-used-as-a-starting-material-in-the-production-of-antimalarial-active-pharmaceutical-ingredients---trs-992---annex-6

21. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4. ***Short name: WHO TRS No. 1033, Annex 4***
9789240020900-eng.pdf (who.int)

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 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. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**
https://digicollections.net/medicinedocs/documents/s23699en/s23699en.pdf

25. Points to consider when including Health-Based Exposure Limits in cleaning validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 2. **Short name: WHO TRS No. 1033, Annex 2**
9789240020900-eng.pdf (who.int)

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**
9789240001824-eng.pdf (who.int)

27. 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. 1025), Annex 3. ***Short name: WHO TRS No. 1025, Annex 3***
https://www.who.int/publications-detail/978-92-4-000182-4

28. 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