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Prequalification Team Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)

Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Olon Active Pharmaceutical Ingredients India Private Limited**
Corporate address of the manufacturer	Unit No. 2801A, 28th Floor, Plot No. D-33, 0207, Rupa Renaissance, Juinagar, MIDC Road, TTC Industrial Area, Navi Mumbai 400705, Maharashtra, India
Name & address of inspected manufacturing site if different from that given above	Plot No: L-1, L-21 to L-28 & L-44, Additional Phase MIDC, Raigad District, Mahad, Maharashtra 402 301 India
Synthetic unit /Block/ Workshop	Rifa Plant, including – Fermentation Plant – Synthesis Plant with Rifampicin final processing
Dates of inspection	2-5 September 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Olon API India Pvt. Ltd has two manufacturing plants for the manufacture of APIs. One plant (termed the Rifa plant) is used to manufacture Rifampicin, Rifaximin, and Rifamycin O Pure (an intermediate only). The second plant, referred to as the VI (vertically integrated) plant, is used for manufacturing non-Rifa products. The Rifa plant was commissioned in 1997, and the VI plant was commissioned in 2007. The milestones of the sites are summarized as follows: - 1997-2000 Dedicated facility for Rifampicin established by a joint venture of CKD (Korea) and CIBA Geigy - 2001-2004 Become part of the Novartis Group - 2005 Integration into Sandoz API Business Unit - 2007 API (VI) Plant established and start of operation - 2008-2012 Pilot Plant established - 2019 Become Olon Active Ingredients India - 2023 Rifa Plant capacity increased by the addition of 5 fermenters - 2024 Plant (VI) capacity increased

	- 2025 Additional line for Rifaximin
General information about the company and site	Olon Group is in the development and production of active pharmaceutical ingredients (APIs) for CDMO and generic markets, integrating chemical synthesis and biological processes. Olon has a global network of 14 manufacturing sites and 9 R&D centres, with 2,600 employees, including 350 highly experienced and qualified R&D experts. Olon API India Pvt. Ltd is a company of the Olon S.p.A. Group, Italy.
History	Authority inspections WHO 2007 TGA 2009 USFDA 2010 WHO 2012 TGA 2014 USFDA 2014 ANVISA 2016 TGA 2017 WHO 2019 TGA 2021 PMDA 2022 USFDA 2023 EDQM Distant
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management - Personnel, health, sanitization, and training - Equipment/instruments calibration and qualification - Process validation, cleaning validation, computerized system validation - Material management and supplier qualification - Production and packaging operations - Quality control, including the microbiology laboratory
Restrictions	None
Out of scope	- API (VI) plant - Rifaximin synthesis and final processing areas (in Rifa Plant)
WHO APIs covered by the inspection	1. Rifampicin (non-compacted grade, APIMF 113a) 2. Rifampicin (compacted grade, APIMF 113b)
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
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

Quality Management System (QMS)

The QMS was managed by the QA Department. The development and operation of the system were assisted by the corporate quality assurance. The QA was responsible for the following activities:

- Preparation and approval of the APQRs, vendor/supplier approval procedure, managing GMP documentation, deviation management,
- OOS management, complaint management, CAPA Management, batch release, product recall, handling of returned goods, change control management, procedure (SOPs) management, and training management.

Product quality review (PQR)

The SOP for annual product quality review/APQR was discussed. The personnel's responsibilities were defined in the procedure. The procedure stated that, as per the FDA guideline, APQR was integrated with the continued process verification (CPV). The SOP instructed the use of Minitab to calculate the PpK (Process Performance Index) and described the acceptance criteria. Twenty-five batches were required for calculating PpK. The APQR preparation plan was available and covered various APIs and intermediates.

Quality risk management/QRM

The QRM procedure was discussed. The risks were assessed both quantitatively and qualitatively, and responsibilities were clearly outlined in the procedure. The qualitative risk assessment encompassed high, medium, and low rankings based on the severity, likelihood of occurrence, and ease of detection. The quantitative risk analysis was conducted using a range of tools, including FMEA, PHA, PRA, HACCP, and cause-and-effect diagrams. The procedure provided an example of FMEA, whereas the other tools have not been utilized. Risk review was performed every 5 years, where applicable.

Management review meeting

The QA was responsible for organizing the management review meetings. The site leadership team was responsible as the management representative. The SOP for the quality management system was reviewed, which stated that the site quality committee meeting is held quarterly. The purpose of this meeting was to maintain and improve the effectiveness of the QMS for product quality and GMP compliance. The meeting covered all matters related to QMS, KPIs, review of GMP compliance, corporate policies, and other relevant areas.

Antimicrobial resistance/AMR

The samples were collected after treatment from liquid, solid waste, and composed Mycelium, and tested for Rifa-B, and were reported as nil. Estimation of Rifampicin API content in effluent was performed by Intertek, and HPLC chromatograms were provided, confirming the absence of Rifampicin content before waste was discharged from the RC (reaction clarify) outlet. In addition, the manufacturer performed an antibiotic assay on the composed Mycelium for Rifamycin-B content and reported a result of nil.

Batch release
The intermediates and APIs were released by three persons, each of whom was delegated by the Quality Head listed in the "Delegation List". The release was managed using a checklist that contained the production and quality control items to be reviewed.

Handling of deviations
The SOP specified that any deviation from established procedures should be documented and explained. Critical deviations should be investigated, and the investigation and its conclusions should be documented in accordance with Handling of Deviations. The deviations were recorded, reported in a deviation investigation form, and categorized as critical, major, or minor. The main data on deviations, including their unique identification numbers, were recorded in the logbook.

CAPA management
Corrective and preventive actions were triggered by deviations, OOS/OOE/OOT results, customer complaints, and laboratory incidents. The process and records contained a problem description, root cause analysis, action plan, implementation plan, and an effectiveness evaluation.

Self-inspections
Regular internal audits were performed in accordance with an approved schedule. Audit findings and corrective actions were documented and presented to the firm's responsible management. Agreed, corrective actions were completed in a timely and effective manner. Internal audits were conducted annually, covering all GMP-relevant facilities and activities in accordance.

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

2. Personnel

The manpower
Manufacturing operations were continuous across 3 shifts. Department organization charts were available and up to date. The personnel involved in the GMP activities related to the Rifampicin manufacturing at the site were as follows: Quality Unit (58), Rifa Synthesis (31), Fermentation (27), SRP (Rifa and VI, 8), SCM (Warehouse, 7), SCM (Planning, Dir. Purchase, 2), Engineering (42), HSE (8), MS&T (19), CDMO (5), Human Resources (2), Information & Technology (1), and Helpers (10).

Job descriptions
The responsibilities of all personnel involved in the manufacture of intermediates and APIs were specified in job descriptions and aligned with the organizational charts. The job descriptions for the Deputy General Manager, Quality, the Quality Manager, Jr. Executive, Production, and Jr. Technical Assistant, Production were discussed.

Training and personnel qualifications
Staff training was conducted regularly by qualified individuals in accordance with the SOP: Training, Qualification, and Certification of Personnel. It covered the operations the employee performs and GMP as it relates to the employee's functions. Records of training were maintained. The training system was periodically assessed.

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

3. Buildings and facilities

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 sufficient space for the orderly placement of equipment and materials, preventing mix-ups and contamination. Ventilation, air filtration, and exhaust systems were provided, where appropriate, with control of air pressure, microorganisms, dust, humidity, and temperature, as necessary for the stage of manufacture, particularly when APIs were exposed to the environment. Permanently installed pipework was identified. Defined areas and control systems were in place for storage, processing, and quality control activities, as well as auxiliary, toiletry, and change facilities. The changing, washing, and toilet facilities were provided for personnel equipped with water, soap or detergent, and air driers. The washing and toilet facilities were located separately from the manufacturing areas but were easily accessible to the manufacturing areas.

Water system

The purified water system was fed by potable water (treated municipal water). In the pretreatment plant, the water was treated with a softener, a UV lamp, a 5 µm cartridge, a UF membrane, NaOH, SMBS, an antiscalant, and RO membranes, followed by DEI, and then stored in the 600 kl PW tank. The system capacity was 2000 LPH (litres per hour). The PW system was qualified, including IQ/OQ and PQ, in both the 1st and 2nd Phases. The PQ 3rd phase was still ongoing.

Nitrogen

The product (rifampicin) was highly sensitive to oxygen; therefore, the final processing steps and the primary packaging were carried out in a closed system under nitrogen. The nitrogen was generated at the nitrogen plant (located at the Rifa utility), which was common to the site, and distributed to the Rifa Plant via a separate loop. The nitrogen quality was continuously monitored (online) and regularly tested (offline, according to the schedule) against the quality specification parameters.

Air handling systems

HVAC Systems were in place to assure a controlled environment in classified areas. The powder processing activities were carried out in a classified area (ISO 8). The final processing areas of the Rifa Plant were supplied by four air handling units, ensuring an ISO 8/GMP Class D environment with the final filtration by HEPA EU-13. The air was recirculated with 10% fresh air. The temperature was <25 ºC, Air Changes Per Hour NLT 20. Environmental monitoring was scheduled to occur every four months. The qualification was due annually or every other year, as defined in the SOP.

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

4. Process equipment

The inventory of the main process equipment

- Fermentation Plant: Five Fermenters 100 M3 each, Three seed Fermenters, Three pilot Fermenters, and Two Rotary filters.
- Synthesis Plant: MSGL and SS vessels (6 to 16 M3), ANFD (1000, 6000 & 7000 L), and Double Cone Dryer (2000, 2500 & 4000L).

Calibration

The measuring devices were regularly calibrated according to the annual plan as managed by the SAP system. The calibration records of the temperature sensor TERA-321 and the temperature transmitter TTRA-321 were discussed. The calibrations were due every 6 months. The certificates from the last calibration (dated April 18, 2025) were discussed

Maintenance management

The maintenance and qualification program was managed by the SAP system, reflecting the equipment maintenance SOPs and protocols.

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

5. Documentation and records

Written instructions were in place regarding the preparation and handling of instructions and records. Preparation of the documents was supported by formal change control. Document identification was driven by the defined and listed document types. The documentation system was basically paper-based. Electronic document handling for SOPs, training records, and change controls was available only through the electronic document management system. Documents were stored and archived in the archive rooms.

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

6. Materials management The materials were identified by material codes generated in the SAP system according to SOP PP00001, v.0001, as follows:

- 701 with 5-digit serial: Final product (API)
- 704 with 5-digit serial: Intermediates
- 708 with 5-digit serial: Raw materials
- 709 with 5-digit serial: Packaging materials

Apart from the SAP codes, there were “legacy codes” used, generated, and implemented even before the launch of the SAP system.

Upon receipt and prior to acceptance, incoming materials were visually examined and sampled in accordance with the sampling protocol. Cross-contamination from the tanker was avoided through tanker dedication, a cleaning certificate, and testing for trace impurities. All the materials were identified and labelled with the indicated status. Sampling methods specified the number of containers to be sampled, the part of the container to be sampled, and the amount of material to be taken from each container.

Sampling was conducted at defined locations (sampling boots). The dispensing/weighing happened under appropriate conditions. The identification of materials during processing included the following information: material name and/or item code, receiving or control number, and weight or measure of the material. The processing status of equipment and facilities was indicated. The time limits and the storage conditions were subject to risk assessment and reflected in the BMRs and related specifications. Suppliers of critical materials were regularly evaluated. The list of approved suppliers was available

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

7. Production and in-process controls The upstream and downstream processes were performed in the Fermentation Plant, including the following process steps:

- Culturing in a round-bottom flask
- Pilot, seed, and main fermentation
- Rotary vacuum filtration
- Precipitation of the filtrate

The inspectors visited the Rifampicin powder processing area (PPA). Biometric access was provided before entering the PPA. The process equipment was of appropriate capacity and design, capable of performing the synthesis and subsequent crystallization, filtration, and drying steps. The final processing steps, including compaction (optional), milling, blending, sifting, and primary packaging of Rifampicin API, were performed in a controlled (Grade D) area within a closed system under a nitrogen atmosphere. An oxygen monitoring system was installed in the final rooms where nitrogen was used. Alarm and evacuation setpoints were set.

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

8. Packaging and identification labelling of APIs and intermediates

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

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

9. Storage and distribution

Materials were stored in a manner that prevented degradation, contamination, and cross-contamination, and under controlled conditions as required. The storage facilities were available for the storage materials under appropriate conditions (e.g., controlled temperature and humidity when necessary). Environmental conditions were controlled and recorded. Access to the storage areas (including printed labels) was limited to authorized personnel. Raw and packaging materials, intermediates, and APIs were formally released before consumption or dispatch. The materials were stored in the following warehousing facilities:

- Cold storage of -20°C ± 5°C, Cold storage of 2°C to 8°C, Ambient storage
- Controlled storage NMT 25 ^{0}C
- Separate storage area for hazardous chemicals & flammable materials
- Overhead Tanks for solvent storage (2 Tank Yards)

The storage conditions of the materials within the scope of the inspection were ambient (for raw materials) and NMT 25°C for APIs. The transport conditions were supported by a transport risk assessment.

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

10. Laboratory controls

The quality unit, comprised of QA and QC, was visited on the last day of the inspection. The quality unit was spread over two floors, the ground floor occupying the QA office, stability chambers, retention sample area, and microbiology laboratory. The first floor housed the physical, chemical, and instrumentation sections of the QC lab.

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

11. Validation

The validation master plan and the corresponding SOP were discussed. The VMP included validation and qualification activities for equipment, instruments, systems, and processes. Annually, VMP was prepared, and validation activities were identified in the respective annexures. The validation team within MS&T was responsible for coordinating the validation and qualification activities. The annual VMP was approved by the QA.

The protocols and reports for process, cleaning, and analytical method validation were reviewed.

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

12. Change control

The changes were controlled in accordance with the SOP. The process steps included: Phase IA (Proposal for Change), Phase IB (Change Opening), Phase II (Change Input Assessment), Phase III (Activity Management), and Phase IV/V (Change Approvals at Different Levels). The number of changes in 2025: 612 (across all sites), 35 (at the Rifa Plant). The change control records of the new PW system (PWS-02) were discussed.

13. Rejection and re-use of materials

The definition and process for product reprocessing or rework were outlined in the Procedure for Reprocessing and Reworking of Materials. The reprocessed/reworked batches had a batch number with the suffix RP/RW. The Company claimed that no rework practice was in place. The rejection of the material depends on the outcome of the batch release.

14. Complaints and recalls

The quality complaints were investigated in accordance with SOP and recorded in the Investigation form. The customer's report was received by the Customer Service Department or the QA Department. The investigation timeline for the various phases, including customer feedback, was defined. Preliminary assessment: not more than 5 days, investigation: 5 days for critical and 30 days for major and minor.

15. Contract manufacturers (including laboratories)

The company did not outsource any manufacturing activities.

The quality control laboratories and service providers were qualified in accordance with SOP.

The vendors of materials, service providers, and contract laboratories were qualified in accordance with SOP.

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, ***Olon Active Pharmaceutical Ingredients India Private Limited***, located at ***Plot No: L-1, L-21 to L-28 & L-44, Additional Phase MIDC, Raigad District, Mahad, Maharashtra 402 301, India*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines for APIs.

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 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***
   http://www.who.int/medicines/publications/44threport/en/

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 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

4. 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

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

6. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 957, Annex 1
   http://www.who.int/medicines/publications/44threport/en/

7. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
   Short name: WHO TRS No. 957, Annex 3
   http://www.who.int/medicines/publications/44threport/en/

8. 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

9. 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

10. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex* 9**
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
    Short name: WHO TRS No. 961, Annex 2
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. ***Short name: WHO TRS No. 961, Annex 14***
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

13. 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/

14. 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/

15. 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

16. 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

17. 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

18. 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

19. 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/

20. 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

21. 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

22. 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

23. 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

24. Points to consider when including Health-Based Exposure Limits (HBELs) 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 1033, Annex 2***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations¨

25. 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 1033, Annex 3***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

26. 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 1033, Annex 4***
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations