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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	**Alembic Pharmaceuticals Limited (API Unit I)**
Corporate address of the manufacturer	Alembic Road, Vadodara – 390 003, Gujarat, India
Name & address of inspected manufacturing site if different from that given above	Village Panelav, P.O. Tajpura, Near Baska Taluka, Halol, District Panchmahal, 389350, Gujarat State, India
Synthetic unit /Block/ Workshop	Plant 01A & B (Stage-I) Plant 01A, Plant 04 & Plant 06B (API) Plant 06B (Hydrogenation & Methanol recovery)
Dates of inspection	21-25 July 2025
Type of inspection	Initial GMP inspection
Introduction	
Brief description of the manufacturing activities	Alembic's API Unit-I was located at Panelav, Baska, and Halol. The site was located approximately 40 km from Vadodara Airport. The site was divided into 09 (nine) plants, with seven plants engaged in APIs and intermediate manufacturing, and two plants for manufacturing intermediates only.
General information about the company and site	Alembic Limited was established in 1907 in Vadodara, Gujarat, India. The company is engaged in the manufacturing of intermediates, drug substances, and formulations. Alembic Pharmaceuticals Limited, API Unit-I, at Panelav, was commissioned in the year 1996. Previously, it was known as Darshak Limited, which was later renamed to Alembic Pharmaceuticals Limited, API Unit-I, Panelav, in 2011.
History	This is the first WHO PQ inspection of Alembic Pharmaceuticals Limited, Unit I. The national and international regulatory authorities have regularly inspected the manufacturing site. In May 2025, the USFDA conducted an unannounced inspection.
Areas inspected	The following areas were inspected: 1. Quality management 2. Personnel, hygiene, sanitization, and training 3. Production and packaging operations 4. Quality control and microbiology laboratories 5. Process equipment, instruments, and computerized systems

	6. Utilities, including purified water and air handling units 7. Validation, including process, cleaning, and computerized systems 8. Material management
Restrictions	None
Out of scope	The inspection was limited to Azithromycin API manufactured at API Unit-I, while other APIs manufactured at API Unit-I were out of scope for this inspection. Also, other API Units on the same site were out of the scope.
WHO APIs covered by the inspection	Azithromycin API for Azithromycin 500mg tablets (NT020)
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original, and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CIP	Cleaning in place
CoA	Certificate of analysis
CpK	Process capability
DQ	Design qualification
EDI	Electronic deionization
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
GMP	Good manufacturing practices
HEPA	High-efficiency particulate air
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
HVAC	Heating, ventilation, and air conditioning
IQ	Installation qualification
KF	Karl Fisher
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MR	Management review
NC	Non conformity
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance

PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer

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

1. Quality management

Alembic's Unit-I, API manufacturing site, implemented a quality management system in accordance with national and international GMP standards. Quality management encompasses the organizational structure, procedures, processes, and resources to ensure the API meets its intended quality and purity specifications. The quality unit was independent of operations and was responsible for QA and QC. The Head of Global Quality was responsible for both QA and QC, whereas the Head of Business Development and Operations (API) was responsible for API operations. These heads were supported by site-level personnel for both quality and operations. The job descriptions of the key personnel responsible for releasing intermediates and APIs were specified. The site has been using several enterprise-level applications, including:

Sr. No	Software Name	Application
1.	SAP	For material management
2.	Documentum	For document management
3.	LIMS	Laboratory information management system
4.	LMS	Learning management system
5.	D scheduler	Scheduling activities
6.	TrackWise	For QMS

The company started using TrackWise in November 2024. The first module covered change controls. This was followed by modules on CAPA, deviations, OOS, OOT, market complaints, and internal audits. The remaining modules, including recalls and supplier qualification, are to be implemented. Several applications and software have been recently implemented, and some are currently under development/implementation.

The SOP for the annual product quality review of API manufacturing sites was discussed. The procedure was recently revised to improve the process flow chart, add a D-scheduler, and use a statistical tool, among other changes. The responsibilities of QA and production personnel were defined. The scope was limited to finished APIs and saleable intermediates. The APQR schedule for the Jan-Dec 2024 and July-June 2024 periods was reviewed, and various products were divided accordingly. The responsibilities for the plant head and the head/designee QA were not described.

The SOP for quality risk management (QRM) was reviewed. The procedure stated that risk assessment should be performed when introducing equipment, instruments, facilities, systems, or QMS. A cross-functional team performed the risk assessment. The procedure was applied to the API and formulation facility of Alembic, and risk was assessed using both qualitative and quantitative evaluation. Additionally, the procedure described the use of several tools, including Risk Ranking & Filtering (RRF), HACCP, and FMEA.

The SOP for Deviation Management was reviewed, which provided a flowchart describing the procedure for handling deviations. The deviations were categorized into critical, major, and minor. The procedure applied to unplanned deviations, whereas planned deviations were handled through temporary change controls.

The SOP for Quality Management Review was reviewed. The QMR meeting was held quarterly and attended by the department head and the managing director. The last MR took place on July 16, 2025, and was attended by more than 40 personnel. The meeting minutes were recorded. It was recommended that the manufacturer draft an agenda for the meeting and record minutes that included the discussion and the way forward.

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

2. Personnel

According to the company's presentation, the total number of employees working at Unit-I was 950, while approximately 500 contracted staff were engaged in various non-GMP activities.

The SOP for Personal Hygiene and Health was reviewed. The SOP for entry/exit and gowning procedures for the powder processing and final crystallizer area was reviewed. It stated that gowns should be worn before entering the classified areas.

The SOP for Training Management was discussed. The new employee received the induction training, and the respective department head would ensure job-specific training. The learning management system (LNS) and Documentum (D2) were integrated, and employees were assessed upon completion of training. Training modules would be prepared only for those topics that lacked a specific procedure. The refresher training was given once every three years.

The job descriptions of the key personnel were reviewed and found adequate.

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

3. Buildings and facilities

Unit I, Panelav was involved in the manufacturing of APIs and intermediates with a total area of 87,271 m^2 and spread over the following departments and areas:

Total built-up area	33,479 m^2
Manufacturing Area	12,996 m^2
QC /QA	2,595 m^2
Warehouse	6,078 m^2
Admin	184 m^2
Others	8,738 m^2

Unit I was further divided into nine plants for the manufacturing of various APIs and intermediates. Plants 1, 4, and 6 were used to manufacture Azithromycin Dihydrate. A centralized warehouse, quality control, and quality assurance supported the manufacturing of Azithromycin Dihydrate.

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

4. Process equipment

Unit I was equipped with several process equipment, including stainless steel reactors, Hastelloy reactors, glass-lined reactors, an agitated nustch filter, a centrifuge, pressure filters, sparkle filters, a vacuum dryer, a fluid bed dryer, a tray dryer, a mill, a micronizer, a sifter, and a blender. The preventive maintenance program was implemented using D-scheduler.

The calibration tags were available on equipment, such as pressure gauges or temperature sensors, indicating the last calibration date and the due date for the next calibration. The pressure gauges were calibrated once every 2 years.

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

5. Documentation and records

The documents were prepared, reviewed, approved, and distributed using the Documentum D2 system. The SOPs, specifications, testing procedures, batch manufacturing records (BMRs), and laboratory records were managed in Documentum D2. The batch numbers were issued automatically using the SAP system. A separate BMR was prepared for reprocessed batches. Most of the key SOPs were prepared by corporate QA and included the next review date (3 years).

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

6. Materials management The procedure for the receipt, identification, quarantine, storage, handling, sampling, testing, approval, or rejection of the materials was in place. The SOP for vendor qualification of RM/PM of API sites described various materials, including KSM, non-KSM, advanced intermediates, and packaging materials (primary and secondary). The qualification process included the purchasing department identifying the supplier, requesting three samples for testing, sending the samples to the PDL before requesting a questionnaire, and conducting an on-site audit. The KSM, advanced intermediate, and primary packaging material manufacturers were subject to an on-site audit every 3 years. For the remaining materials, qualification was based on the questionnaire. The suppliers were assessed yearly based on the number of batches supplied and their compliance status. The input material used to manufacture the Azithromycin starting material was audited by a third-party auditing agency in 2024, and the report was provided.

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

7. Production and in-process controlsAPI Unit-I was a multiproduct manufacturing site that produced more than 50 different APIs and intermediates of various therapeutic categories. These APIs and intermediates were manufactured in 9 different plants within Unit I. The KSM for Azithromycin was manufactured in-house. Azithromycin was manufactured in two stages: stage I for the intermediate and stage II for the API. The batch sizes for Stage I were 200 kg, 350 kg, and 400 kg, whereas those for Stage II were 300 kg.

Plant 01 was spread over two floors, the first floor for synthesis and the ground floor for the unit operations. Plant 06 was used for the hydrogenation reaction, whereas Plant 04 was used for the powder processing of Azithromycin. The material lift/hoist was used to transfer materials from the warehouse to the production area. The materials were stored in the intermediate storeroom before being charged into the reactors for synthesis. A non-dedicated powder transfer system was used to charge the materials. The reactor was used for Azithromycin, and a cleaning procedure was in place (batch-to-batch, periodic cleaning, and product changeover). At the time of the inspection, Batch No. was being manufactured in the synthesis area. The ground floor housed a centrifuge, tray dryer, and fluid bed dryer. The centrifuge bag was discarded after the campaign was completed, but it could have been used for up to 40-45 batches. The integrity of the centrifuge bag was verified. The batch No was being centrifuged during the visit. Similarly, a tray dryer was used for drying a batch of Azithromycin. An FBD option was also available. In Plant 06 for the hydrogenation reaction, the in-process material was charged through the PTS. Batch No. was being produced in this area, and the BMR was available.

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 personnel and visitors were required to wear a gown (over-gowning) and sanitize their hands before entering the classified area. The pressure differential was maintained at a minimum of 6 Pa. The area was maintained at a temperature below 27°C, and humidity was monitored for information purposes only. The material was transferred from one stage to another through the corridor. The dynamic passbox was used to receive packaging materials and to transfer the finished APIs.

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

9. Storage and distribution

A warehouse was available for the receipt of starting materials, intermediates, and packaging materials. Separate receiving and dispatch bays were provided. Upon receipt of the incoming materials, an inspection was performed using a checklist before the materials were stored. The warehouse management system (WMS) was used to manage incoming materials, whereas no physical labels were used to indicate the materials' status. The WMS was interfaced with the SAP system. The materials were sampled under the RLAF booth, having a separate MAL and PAL. The materials were stored at temperatures below 45°C, below 25°C, and between 2°C and 8°C, based on the storage requirements of the respective materials.

The finished goods store for API-I was maintained at NMT 25ºC. The area was temperature-mapped, and one hot spot was identified for regular monitoring. It was noted that the colour of the HDPE containers used to pack the finished APIs was starkly different. The integrity of the finished API was maintained appropriately using unique seal numbers.

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

10. Laboratory controls

The QC laboratory was divided into two buildings: the QC and QA buildings. The samples were received, logged into the LIMS, and stored in a controlled environment. Separate personnel were responsible for managing the incoming samples, including raw materials, in-process materials, intermediates, and finished products. The QC laboratory had 210 employees, of whom 165 performed analyses. The LIMS was interfaced with the SAP system. The incoming samples were required to be tested within 30 days. The analysis was directly recorded on LIMS, without the use of a physical analytical worksheet. The analytical balances were connected with the LIMS.

The out-of-specification (OOS) procedure was discussed. The procedure was recently revised following the implementation of TrackWise for the OOS model. The flowchart was provided in the procedure describing the investigation in a phased manner. Hypothesis testing was performed to rule out any obvious laboratory error before repeat testing was performed.

The reference and working standards for Azithromycin and related impurities were verified and found to be adequately stored and maintained. The Azithromycin working standard was prepared in accordance with the Azithromycin EPCRS 5.0, and 100 vials were prepared for single-use. A one-year expiry date was assigned to the working standard. A mixture of all known impurities and a system suitability solution was used from the EPCRS, Batch 5.0 and 3.0, respectively.

The laboratory was equipped with seven stability chambers for conducting studies under various conditions. The annual stability study program was in place, and samples were stored at various time points. Azithromycin batches were stored at 30°C and 75% relative humidity as part of the annual stability studies.

Retention samples were stored under the QA's supervision using the simulated packs. The retention samples were stored for up to 6 years, including the 3 years after the last distribution. A split air conditioner was used to maintain a temperature below 25°C.

The microbiology laboratory was located in a separate building serving the API I and II. The microbiology laboratory was responsible for carrying out testing related to environmental monitoring, water, and finished API. Separate autoclaves were provided for media preparation and disposal of media plates. The cultures were handled under the biosafety cabinet, and laminar airflow (LAF) was used for testing water, environmental, and finished APIs. The background for the LAF was classified as ISO 7, whereas testing was performed under an ISO 5 environment.

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

11. Validation

The SOP for Validation Master Plan/VMP outlines the policy for validation and qualification. It included areas such as process performance qualification, cleaning validation, verification, computer system validation, and other regions. Additionally, the Validation Master Plan outlines the responsibilities of various departments.

The SOP for Process Performance Qualification/PPQ was reviewed, and it was noted that a lifecycle approach was used. The entire process was divided into three stages, wherein three batches were taken for PPQ. The process design (Stage I) was primarily handled at the R&D site, where products were developed before being transferred to the production site. The PPQ was triggered by a change in batch size, KSM, process optimization, or equipment. The sampling plan criteria were described in the SOP. The third stage, namely, continued process verification (CPV), was handled through the Minitab software. The critical in-process parameters (IPC), final in-process test results, yield, and critical quality attributes (CQA) were monitored. A separate procedure was used for managing the CPV. The processes were revalidated once every 5 years regardless of any changes.

The SOP for cleaning validation and verification of API manufacturing was discussed. The cleaning procedure was divided into three types of cleaning (batch-to-batch, periodic cleaning, and product changeover). Cleaning validation was not required for batch-to-batch cleaning. The MACO was calculated using the PDE values. The cleaning validation was performed every 5 years, including changes to equipment, process, and MACO.

The SOP for PQ & requalification, air flow pattern, and recovery study of the HVAC system was reviewed. The initial qualification included air velocity, air changes per hour, HEPA filter integrity, non-viable particle count, airflow pattern, recovery test, and viable airborne particle count. In the event of requalification, air velocity, ACPH, HEPA integrity, NVPC, and Differential pressure are to be checked biannually, except for the airflow pattern, which is to be checked every two years. Viable monitoring for routine production was performed quarterly.

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

12. Change control

The Change Control Procedure was reviewed, and it has been managed in TrackWise since November 2024. The user department classified the changes as temporary and permanent, whereas QA categorized them as major and minor. The user department performed an impact assessment. The implementation timelines were described, and the system gave a prompt or flag for the due date. The change control form provided basic information before initiating a change control and applied to the facility, product, equipment, materials, processes, systems, and documentation.

Between 2023 and 2024, a total of 36 change controls were raised for Azithromycin. In 2025, 3 change controls were raised for Azithromycin. One change control related to the increase in batch size for Azithromycin Stage I was reviewed, and it was noted that it was raised on March 12, 2025. Some of the action items have been completed, whereas the rest are in progress. The RA reviewed the proposed change and recommended filing a variation/notification with the US, Europe, Canada, the EDQM, and other relevant authorities.

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

13. Rejection and re-use of materials

The SOP for managing recovered solvents was reviewed. If solvent recovery is less than 70%, it will be discarded; otherwise, it will be used if it meets the specifications. The manufacturer confirmed that solvent recovery was performed on-site at the solvent recovery plant (SRP), and as such, no outsourcing was involved in the recovery of solvents. The recovered solvents should be used for the same API, and if used in intermediate manufacturing, they can be used at the same stage or an earlier stage. The recovered solvents were handled using a separate batch manufacturing record.

The SOP for reprocessing of APIs and intermediates was discussed. The reprocessing was performed when the material did not meet the QMS requirement (OOS, OOT). A checklist was used to assess the request for reprocessing before it was executed. If required, the reprocessed sample was placed for a stability study. An e-log was maintained for the reprocessing.

No reworking was performed by the manufacturer, as confirmed by the manufacturer.

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

14. Complaints and recalls

The SOP for Market Complaints was reviewed. The complaints were categorized into critical, major, and minor. The timelines were established for different types of complaints. The complaints were received directly from their customers (primarily FPP manufacturers). As part of the complaint investigation, the retention sample was tested, and the customer was also asked to send the sample along with a photograph of the sample, the method of analysis, and other information. The analysis results were shared with the complainant.

The company confirmed that there had been no recall of Azithromycin Dihydrate. Recall was made for another API from Alembic's formulation facility located near the Alembic API site. Based on the stability study of that API, OOS was reported; hence, it was decided to recall it from their formulation facility.

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

15. Contract manufacturers (including laboratories)

The manufacturer confirmed that no part of the Azithromycin manufacturing was contracted out. Although the on-site quality control laboratory was adequately equipped with various instruments, a few of the contracted laboratories were designated as backups. These laboratories were evaluated to ensure they meet GMP requirements.

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, ***Alembic Pharmaceuticals Limited, API Unit-I***, located at ***Village Panelav, P.O. Tajpura, Near Baska Taluka, Halol, District, Panchmahal, 389350, Gujarat State, 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
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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***
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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.
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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***
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