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WHO Prequalification Unit (PQT) - Inspection Services Team (INS)
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Guilin Pharmaceutical Co., Ltd. – API**
Corporate address of manufacturer	Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd Building A, No. 1289, Yishan Road, Shanghai, 200233, China (People's Republic of)
Name & address of inspected manufacturing site if different from that given above	API-I and II No 43 Qilidian Road Guilin, Guangxi 541 004 China (People's Republic of)
Synthetic unit /Block/ Workshop	API-I (Artemether, Artesunate, and Dihydroartemisinin/DHA) API-II (Sulfadoxine and Pyrimethamine)
Inspection details	
Dates of inspection	17 to 19 April 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Guilin Pharmaceutical Co., Ltd.'s API manufacturing facility consists of three workshops. The API Workshop I (API-I) manufactures Artesunate, Artemether, and Dihydroartemisinin (DHA). API Workshop II (API-II) manufactures Sulfadoxine, Pyrimethamine, and Bumetanide, while API Workshop III (API-III) manufactures Levamisole HCl.
General information about the company and site	Guilin Pharmaceutical Co., Ltd. has been a member of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. since 2003. The manufacturer is engaged in manufacturing OSD, Injections, and APIs; the inspection focused on the manufacturing of APIs in workshops API-I and API-II. The API-I and API-II workshops were located in the northwest section of the manufacturing area at No. 43 Qilidian Road, Guilin.
History	Guilin Pharmaceutical Co., Ltd. has been regularly inspected by the WHO Prequalification Inspection Services, with the last inspection conducted from September 25 to 28, 2023.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: 1. Quality management system 2. Personnel, hygiene, and training

	3. Production and packaging operations 4. Quality control laboratory 5. Chemical warehouse 6. Purified water system
Restrictions	None
Out of scope	APIs other than those listed in the scope of the inspection were out of the scope of this inspection.
WHO APIs covered by the inspection	APIMF181 – Artemether – API-I APIMF278 – Pyrimethamine – API-II APIMF279 – Sulfadoxine – API-II APIMF355 – Artesunate – API-I APIMF459 – Dihydroartemisinin – API-I

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

The Guilin API manufacturing site implemented a quality management system following national and international GMP standards. The quality management encompasses the organizational structure, procedures, processes, and resources to ensure that the API meets its intended specifications for quality and purity. The quality unit was independent of production and fulfilled QA and QC responsibilities. The Vice President of Quality was responsible for both QA and QC overall. The job descriptions of the key personnel responsible for releasing intermediates and APIs were specified. The following quality management elements were reviewed:

Annual product quality review (APQR)

The SMP of APQR for APIs was reviewed, and it was noted that QA was responsible for reviewing the APQR. A review was conducted on the batches manufactured between January 1 and December 31. It included a review of production batches, materials used, process parameters, OOS, deviations, CAPA implemented, equipment qualification, change controls, regulatory commitment, reprocess, rework, recovery of solvents/materials, stability study, complaints, returned product, and contract activities. A schedule was prepared at the beginning of the year, and the review is expected to be completed by March-April next year. The schedule included 15 APIs manufactured in API-I, II, and III workshops. The manufacturer used JMP statistical software to calculate the process capability and control charts. The CpK was calculated using 25 or more batches manufactured during the review period (≤CpK 1.0, ≥1.00 and ≤1.33, and ≥1.33).

Deviation management

The SMP for deviation handling provided guidance on handling deviations, encompassing areas such as raw materials, products, process programming, specifications, facilities, utilities, environmental control, metrological calibration, validation, and all related aspects of quality. The deviations were logged in the Excel spreadsheet by the QA.

CAPA management

The SMP for CAPA was discussed. It was noted that the manufacturer has established a CAPA system to investigate and take corrective and preventive actions for observations arising from deviations, recalls, OOS/OOT, complaints, PQRs, risk assessment, rejection, self-inspection, or external inspections, process performance (CpK), and quality monitoring trends. The CAPA closure depended on the size of the activities planned for implementation. The CAPA coordinator was responsible for ensuring the timely implementation of activities in accordance with the established timeline. The Excel spreadsheet was used to keep track of the implementation of CAPA. As part of the quarterly quality management review meeting, updates on CAPA, along with other QMS elements, were presented and discussed.

Management review/MR

The SOP for MR was discussed, and it was noted that it was performed every quarter, including whenever required due to major quality incidents. Five major elements were included in the review: the quality system, product quality review, QC laboratory performance, supplier chain reliability, and regulatory affairs. The QMS and QA managers would organize a management review meeting, which would be attended by personnel from various departments. The meeting minutes were recorded, and action items will follow the CAPA. The Q4 and annual management review meeting report was discussed.

Quality Risk Management/QRM

The SMP for QRM was reviewed, and it was noted that the procedure was applied throughout the product's lifecycle, including the use of raw materials, APIs, excipients, solvents, packaging materials, labels, and all aspects related to drug quality. The QA was responsible for performing overall QRM in the company using the Failure Mode and Effects Analysis (FMEA). Risk Priority Number (RPN) was determined based on Probability (P), Occurrence (O), and Severity (S). Risks associated with manufacturing products in a multipurpose manufacturing site were considered in the 2023 HBEL assessment. The RA report of the API-II Workshop for products manufactured in the shared facility was discussed.

Self-inspection

The SMP for self-inspection of the QA system was reviewed, specifying that internal audits should be conducted annually. The procedure was contradictory in that it further included a risk assessment, which determined that for low-risk category areas, based on the previous self-inspection, the frequency can be 48 months. Audit findings were categorized into three categories: critical, major, and minor, with clear definitions for each. Another SOP described the qualifications and requirements of auditors. The requirements for a team lead were 3 years of working experience in quality, production, and regulatory affairs. As stipulated by the SOP, the audit team shall be independent of the department being audited, ensuring that teams are not assigned to audit their own departments to avoid conflict of interest. Timelines to close out the non-conformances were dependent on the classification.

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 was 1063, which consisted of 12 senior engineers, 62 engineers, 170 assistant engineers, and 30 licensed pharmacists. There were 507 personnel in production-relevant departments (OSD/API/INJ), 63 in QA, 109 in QC, and 49 in the warehouse. Others included management staff and personnel from supporting departments.

The company had an SMP for GMP training. Training included induction on the quality management system and good manufacturing practices. Training was implemented according to the annual training plan, with each department responsible for providing technical training and evaluating the effectiveness of the training provided. On-the-job training was provided to all employees according to the annual training schedule established by department heads. The effectiveness of the training was assessed through a written examination and/or an oral assessment, with a pass rate of 80%. Those who scored less than 80% underwent retraining. The matrix of job descriptions and the training schedule for the API workshop in 2024 and 2025 were presented. The job description matrix listed training topics needed for each position and the training period for each cycle. It was mentioned that the training plan would be developed considering the matrix and other factors, such as CAPA, for any deviations, changes, or audit findings.

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

3. Buildings and facilities

The API-I workshop was located northwest of the manufacturing area on No. 43 Qilidian Road, Guilin. The building had three floors and was completed in June 2011. The first floor of the workshop was a clean area of Grade D, used for crystallization, drying, and packaging processes. The second and third floors were the general production area. The reduction and esterification processes were conducted on the 3rd floor, while the 2nd Floor was used for centrifugation, drying, and press filtration. The clean area of grade D was used for refining/ purification, drying, and packing.

The API-II workshop was located adjacent to the API-I workshop. Like API-I, it was a three-floor structure; the building construction was completed in February 2012. The workshop was a multifunctional line for APIs. API-II consists of LAPP (Large Annual Production Product) and SAPP (Small Annual Production Product) areas. WHO PQ Products (Sulfadoxine and Pyrimethamine) were manufactured in the LAPP area. The first floor in the workshop was a clean area of grade D, and the second and third floors were used as a general production area. The clean area of grade D was used for refining/ purification, drying, and packing. All workshop floors were coated with epoxy, and all rooms were separated with a color steel plate.

Each workshop had an air purification system (HVAC) dedicated to the production line. The purified water was prepared using a double-pass reverse osmosis system and an EDI water treatment system located on the second floor of the workshop API-I. Independent purified water distribution loops to API II and API-III were available.

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

4. Process equipment

Some of the major processing equipment in API-II included reaction tanks, double-cone rotary vacuum dryers, centrifuges, crystallization tanks, plate-and-frame centrifuges, precision filtration systems, and others. Written procedures were available for cleaning equipment, and the criteria were used for release in manufacturing intermediates and APIs. Equipment and utensils were cleaned, stored, and sanitized to prevent contamination or carryover of materials that could alter the quality of the intermediate or API. Equipment were identified by its contents and its cleanliness status. Equipment parts were dedicated to each product, e.g., transfer pipes and filter bags. The SOP (Briefly describe: policies, procedures, records, and any other evidence for qualification and validation, and how the validation status is monitored and maintained)SMP-ED-000006-16, dated 09/11/2024, was discussed for use, preventative maintenance, and equipment maintenance. Preventive maintenance (PM) for each piece of equipment was performed as scheduled, and records were kept.

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

5. Documentation and records

The company used four levels of documents. The Class 1 documents included the QM, SMF, job description, department responsibility, and organization chart. The Class 2 documents included the quality system management document, process procedures, and specifications. The Class 3 documents included operating procedures in QC and production, equipment verification and maintenance procedures, and batch records. The Class 4 documents included records, confirmation/ verification protocols, and reports. New documents and proposals for change or revision were partially managed using the Document Management System (DMS). Any user who proposes a new document or a revision should propose it to the DMS. Once QA approves the proposal, the user will be given access to edit the file/ document. The proposer should then submit the draft document for QA approval. Once QA approves, the document will be sent to the account of the document administrator, who will then provide the proposer with access to print the document for training purposes. The training of the documents will be conducted offline. The proposer will only report the training date to the document administrator so that the document administrator can assign an effective date. Once effective, the document administrator would print the document and distribute it. Return and distribution of the document were conducted offline. During inspection of the API Workshop, copies of blank documents (batch records, instructions, procedures) were found in the spare parts room. The documents were stored in the lock cabinet under the control of the Production Unit, which indicated a lack of control in the documentation system.

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

6. Materials management Materials were received in the receiving bay and checked according to the purchase order, including verification of whether the material came from an approved supplier. An SOP specific to each manufactured product had information on the approved supplier. Upon arrival, the purchased order was checked against the information in the SAP system. Raw and starting materials for the API manufacturing were received directly in the chemical warehouse. A separate sampling room was available for sampling chemical materials. The room's classification was controlled-not-classified (CNC), and it was equipped with different entrances for materials and people. The sampling tools for the chemical sampling room were brought in clean condition from the other sampling room in Building 2. Sampling was conducted in a sampling booth equipped with UDAF.

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 opening meeting presentation noted that Artesunate, Artemether, and Dihydroartemisinin were produced in the API-I workshop located in building 7. In contrast, Sulfadoxine and Pyrimethamine were produced in the API-II workshop in building 8. Both workshops produced other APIs of different therapeutic areas in the same workshops. Sulfadoxine and Pyrimethamine were produced on a campaign basis. To meet the demand for finished products, Sulfadoxine was manufactured before Pyrimethamine. One campaign can make 20 batches. After completing the 20 batches, thorough cleaning and batch-to-batch cleaning were performed. The key starting material/KSM (Artemisinin) was purchased from China (People’s Republic of) before manufacturing Artesunate, Artemether, and DHA.

The inspectors visited the API-II area where Sulfadoxine API was being produced. This block also produced Pyrimethamine and Bumetanide. Bumetanide was manufactured in the SAPP area, while Sulfadoxine and Pyrimethamine were manufactured in the LAPP area. The manufacturing process of Sulfadoxine consisted of several steps, including the preparation of sodium sulfanilamide, a condensation reaction, and a methoxylation reaction, followed by the final crystallization process to obtain the Sulfadoxine API. The KSM for Sulfadoxine was Sulfanilamide, which was converted into Sodium Sulfanilamide through a reaction with Sodium Hydroxide, followed by crystallization with dichloromethane, centrifugation, and drying. After the condensation and methoxylation process, crude Sulfadoxine would be obtained. The crude Sulfadoxine would be dissolved, decolorized, and then crystallized before becoming Sulfadoxine API. During the walkthrough of the API-II workshop, the inspection team confirmed the equipment used for the manufacturing process. Overall, the equipment used in the production were as per the SMP processing procedure for Sulfadoxine (SMP-QA-007114-42, dated 21 March 2025).

No manufacturing activity was carried out during the inspection in the API-I workshop.

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 primary packaging activity was carried out in the Grade D environment. At the time of the inspection, no primary packaging activity was ongoing.

9. Storage and distribution

The KSMs were stored in the chemical warehouse, while the finished API was stored in the warehouse of Building 2. A walkthrough was conducted in both warehouses. At the time of inspection, the condition met the warehouse specification. For the chemical warehouse, monitoring was performed manually, with temperature checks conducted daily. The monitoring equipment can log/record the highest and lowest temperatures for the past 24 hours. The minimum and maximum temperatures were recorded in the respective logbook. In the Building 2 warehouse, the temperature and humidity were monitored through BMS, and the person in charge was notified when an excursion was observed.

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

10. Laboratory controls

The quality control laboratory was equipped with 32 HPLCs (31 HPLCs and 1 UPLC), 4 GCs, and one each of GC-MS and LC-MS. The HPLC and GC were connected to Empower CDS, whereas the UPLC and GC-MS were connected to OpenLab (Agilent), and the LC-MS was connected to Shimadzu LabSolution. All 38 equipment were connected to the LACE acquisition server. The inspector visited the QC laboratory and verified the OOS related to Pyrimethamine Batch No. EA240538. When the sample was tested on 5-6 June 2024 with other batches of Pyrimethamine (10 batches from 530 to 539), an unknown impurity at RRT 0.811 reported 0.11% against the limit of NMT 0.10%. Since Batch No. EA240538 was tested along with other batches; the solutions were reinjected to determine whether there was any obvious error. The same batch did not meet the requirement, whereas the rest did. No retesting was performed as it was obvious that the mentioned batch did not meet the criteria. The affected batch was rejected and reprocessed. The reprocessed batch was tested and met the criteria. The system audit trail was verified, and initial and reprocessed batch analysis entries were found. The analysts could view the audit trail but were unable to make any changes to it. The backup was performed every 2 hours (incremental), whereas the IT department conducted a full backup weekly. Additionally, IT verified the daily completion of the backup. Additionally, the restoration process was outsourced to Waters, which was performed annually. The restoration process included verification of the number of projects, the number of data files, the completeness of each data file, and the readability of each data file based on sampling. There was no QA involvement to ensure sample size, and samples were selected using a risk-based and objective process. The central server and standby server were located in the admin building, while another server was placed in the warehouse for disaster recovery purposes.

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

11. Validation

The VMP was prepared in accordance with local GMP regulations, WHO guidelines, and references from other regulatory agencies. The VMP described the validation philosophy, confirming that qualification and validation activities should be performed before commercializing the products. The roles and responsibilities were also described in the VMP. The VMP covered HVAC, water, pure steam, compressed air systems, and other areas.

The processes were validated based on the approved protocols, and reports were available.

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

12. Change control

The SMP for change control outlines the procedure for handling changes. It was applied to all changes, starting from the technology transfer of new products, product commercialization, manufacturing, and product discontinuation. The change controls were logged into a spreadsheet. The changes were reviewed.

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 procedure for reprocessing and reworking, along with its implementation, was reviewed. The procedure applied for the reprocessing and reworking of unqualified intermediates, bulk products, finished products, returned products, recalled products, or complaint products for API and FPP. According to the SMP, the expired OOS product should not be reprocessed or reworked. For a product to be reprocessed or reworked, the root cause of the product failure must be investigated, and the associated risk must be assessed before a decision is made.

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

14. Complaints and recalls

The SMP for handling customer complaints was discussed. The complaints were categorized into three classes: Class 1 (critical), Class 2 (major), and Class 3 (minor). One logbook was maintained for all complaints related to APIs and FPPs (sterile, non-sterile, TCM).

Recalls were managed using SMP for product recall management. Recalls could be initiated for both voluntary and compulsory reasons. If there were no recalls for 2 years, a mock recall would be conducted. Guilin Pharmaceutical has not had any recalls for the past 5 years. Moreover, the API manufactured by Guilin Pharmaceutical was used for internal use only.

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

15. Contract manufacturers (including laboratories)

The company did not outsource any manufacturing activity for PQ APIs. The site master file mentioned that it has conducted contract testing, among other things, for X-ray Diffraction (Crystal Form parameter) and Scanning Electron Microscopy (Morphology parameter) for the testing of Artesunate, Pyrimethamine, Sulfadoxine, Dihydroartemisinin, and Artemether.

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, ***Guilin Pharmaceutical Co., Ltd***, located at ***API-I & II, No. 43, Qilidian Road, Guilin, Guangxi, China (People's Republic of)*** 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