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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	**Jiangsu Puxin Pharmaceuticals Co Ltd**
Corporate address of the manufacturer	No.1 Chenli Road, Chemical Park, Binhai Economic Development Zone, Jiangsu, China
Name & address of inspected manufacturing site if different from that given above	No.1 Chenli Road, Chemical Park, Binhai Economic Development Zone, Jiangsu, China GPS Details: Latitude: 34.29020, Longitude: 120.08310; DUNS Number: 527539103
Synthetic unit /Block/ Workshop	Workshop 1, Workshop 2, Workshop 3, Workshop 6, Workshop 7, Workshop 8
Dates of inspection	11-15 August 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Historically, the site manufactured API intermediates and key starting materials for distribution. These activities were later expanded to include the manufacture of APIs (Lamivudine, Nirmatrelvir, Zidovudine, Emtricitabine-FTC, Tenofovir disoproxil fumarate, and Tenofovir alafenamide fumarate) for commercialization. The company's customers included API manufacturers, FPP manufacturers, wholesalers in the EU/EEA, the USA, China, South America, and India.
General information about the company and site	Jiangsu Puxin Pharmaceuticals Co., Ltd., a wholly owned subsidiary of Shanghai Desano Pharmaceuticals Co., Ltd., was established in 2006 and operates at No. 1 Chenli Road, Chemical Park, Binhai Economic Development Zone, Jiangsu, China. Jiangsu Puxin maintains large-scale production capabilities for intermediates used in ARV APIs, including Zidovudine, Emtricitabine, Tenofovir Disoproxil Fumarate, and Lamivudine. As a critical supplier in the global HIV/AIDS drug supply chain, Puxin helps to ensure access to affordable ARV medications in LMICs. With three APIs successfully registered, Puxin is transitioning to a commercial-scale API manufacturer, further strengthening its role in the worldwide ARV API supply.
History	The site has been inspected regularly by the WHO PQ inspection services. The last PQ inspection was conducted in 2019. Additionally, the site was inspected by the USFDA in March 2024 for Crude Zidovudine and PMPA.

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Quality management - Personnel, job description, training - Buildings and facilities - Process equipment - Documentation and records - Material management, including warehousing - Production and in-process control - Validation - Change control - Rejection and reuse of materials - Complaints - Contracting out and vendor qualification - Facility tour covering o Quality control laboratory, including stability chambers o Workshop B04-4 (Zidovudine Crude) o Workshop A03-6 (Zidovudine and TDF powder processing area) o Workshop E05 (PMPA) o Warehouses, including a tank farm o Utilities o Document archives
Restrictions	None
Out of scope	The APIs and intermediates not under the WHO PQ program were outside the scope of this inspection.
WHO APIs covered by the inspection	1. APIMF049 (Zidovudine) APIMF202 (Emtricitabine)**Intermediates manufactured by Jiangsu Puxin:** 1. ((2R, 5S)-5-(4-Amino-5-fluoro-2-oxo-2H-pyrimidin-1-yl)-[1,3]-Oxathiolane-2-carboxylic acid, 2S-isopropyl-5R-methyl-1R-Cyclohexyl ester) (FCE) for **APIMF039** (Emtricitabine) 2. Crude zidovudine for **APIMF049** (Zidovudine) 3. (2R,5S)-((1R,2S,5R)-2-isopropyl-5-methylcyclohexyl) 5-(4-amino-5-fluoro-2-oxopyrimidin-1 (2H)-yl)-1,3-oxathiolane-2-carboxylate, (FCME) or **APIMF061** (Emtricitabine) 4. 9-R-phosphonomethoxy propyl adenine (PMPA) for **APIMF150** (TDF) 5. FCME for **APIMF165** (Emtricitabine) 6. FCME for **APIMF202** (Emtricitabine) 7. PMPA for **APIMF208** (TFD) 8. PMPA for **APIMF512** (TAF) 9. 3-Azabicyclo[3.1.0]hexane-2-carboxylic acid, 3-[(2S)-3,3-dimethyl-1-oxo-2-[(2,2,2-trifluoroacetyl)amino]butyl]-6,6-dimethyl-, (1R,2S,5S) for **APIMF469** (Nirmatrelvir)
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

Jiangsu Puxin 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 operations and fulfilled QA and QC responsibilities. The Quality Director (qualified person) was responsible for QA, QC, and regulatory affairs (RA), whereas the Production Director was responsible for the manufacturing operations and reported to the Deputy GM. The job descriptions of the key personnel responsible for releasing intermediates and APIs were specified.

The SOP for product quality review was reviewed. The APQR was prepared by the production & QC team, reviewed by the QA, and approved by the Qualified Person. The purpose of the APQR was described, and the scope was applied to marketable pharmaceuticals, intermediate products, and recycled materials. The site manufactures three APIs (Zidovudine, Emtricitabine, and TDF) and intermediates (FCE, CME, PMPA, and crude Zidovudine) for the WHO market. It was noted that Emtricitabine and TDF had not yet been commercialized. The APQR was performed on a calendar basis and should be completed by 31 March every year. The process capability index was calculated using an Excel Spreadsheet, and the criteria were described in the procedure. CpK criteria were inappropriately defined, with values less than 1.0 and 1.33 considered to meet the requirement.

The SOP for quality risk management was reviewed. The risk management procedure was applied to the product lifecycle, and tools such as FMEA, HACCP, and HAZOP were described in the procedure. The FMEA tool using the RPN was described in detail, covering severity, occurrence, and detectability.

Quality Management Review (QMR)

The SOP for quality management review outlined the purpose, scope, responsibilities, requirements, procedures, and other details. The QMR was conducted at least once per year. The last QMR was held on 30 June 2025. The meeting was chaired by the General Manager, Mr Yang, and was attended by the department heads and QA. Various items were discussed during the meeting, including recruiting staff and purchasing equipment and instruments. The identified items will be assigned to the relevant personnel/department and followed up on.

The SOP for evaluating and releasing products was reviewed. The procedure was applied to the release of finished APIs, finished intermediates, recycled products, and recycled solvents. The procedure identified four personnel from QA to release the products, including the QA manager and the QA supervisors. The release procedure was based on an extensive checklist used to verify the completeness of batch production/packaging and laboratory records. As part of the release procedure, the QA reviewer visited

the QC laboratory to verify the audit trail. A separate procedure was in place for the quality control laboratory to approve or reject incoming materials.

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

2. Personnel

The manufacturing operations were carried out in three shifts. The distribution of the staff in the different areas:

- Production (248), QA (11), QC (31), Warehouse (22), R&D (11), Engineering (34), HR & Ad Environment (44), Commercial (3), Finance (6), Information Management (9), Others (5)
- Total staff (465)

The responsibilities of personnel engaged in GMP activities were specified in job descriptions. The following job descriptions were discussed:

- Workshop 1 production manager (Clean area director)
- QA manager (temporarily taking the vice QA manager function)
- QA director
- General manager

Staff training was regularly conducted by qualified individuals and covered the operations the employee performs and GMP as it relates to the employee's functions (SOP GS-1001.08). Training records were maintained paper based. The training system was periodically assessed.

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. Facilities were designed to minimize potential contamination. The flow of materials and personnel through the buildings or facilities were designed to prevent mix-ups or contamination. There were defined areas and control systems in place for storage, processing, and quality control activities, along with auxiliary, toiletry, and change facilities. The changing, washing, and toilet facilities were provided for personnel equipped with water as appropriate, soap or detergent, air driers, or single-use towels. The washing and toilet facilities were separate from, but accessible to, manufacturing areas.
The production area covered about 27490 m2, of which the clean area is about 900 m^2. Layouts and flow charts of the controlled areas showed the room classifications and pressure differentials between adjoining areas, and indicated the production activities (e.g., compounding, filling, storage, packaging) in the rooms. The final processing areas (crystallization, drying, blending/crushing, and packing) were supplied by two AHUs designed in accordance with the China National Standard Code for the design of pharmaceutical industry clean rooms (and ISO 14644).

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

4. Process equipment

Equipment used in the manufacture of intermediates and APIs were of an adequate size, and located for its intended use, cleaning, sanitization, and maintenance. Major equipment (e.g. reactors, storage containers) were identified. Production equipment was to be used within its qualified operating range. A set of current drawings for equipment and critical installations (e.g. instrumentation and utility systems) was available. Equipment Maintenance schedules and procedures (including assignment of responsibility) were established. Written procedures were established for the cleaning of equipment and its subsequent release for use. Control, weighing, measuring, monitoring, and test equipment were calibrated according to written procedures and schedule. The equipment's current calibration status was verifiable. The list of process equipment, the recent qualification statuses, and the requalification due dates were documented in the Validation Master Plan according to the SOPs for the Qualification and Validation Program and Qualification of Equipment.

5. Documentation and records

GMP-related documents were paper-based and were controlled (prepared, reviewed, approved, and distributed) according to written procedures. The retention periods and the archiving process for documents were specified. The document management program was described in GS-0002.10, 18/07/25, including instructions for issuing batch records. The batch record was issued after a request from production to QA was received. The copies were made from the master record, and every page was stamped with the batch number. The QA maintained the logbook for each product. A copy of the issued BPR may be issued if the production reported concerns to QA. A deviation was raised before issuing another batch record.

The specifications and test methods for Zidovudine, Emtricitabine, Tenofovir DF, PMPA, Crude Zidovudine, and FCME were briefly reviewed. The manufacturer confirmed that all test parameters had been validated by the QC laboratory.

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

6. Materials management Written procedures were in place for receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of materials.

- Receipt, storage, and distribution of purchased materials.
- Receipt, storage, and distribution of manufactured materials.

Upon receipt and before acceptance, incoming materials were visually examined and sampled in accordance with the sampling protocol. All the materials were identified and labelled with the status indicated. Sampling methods specified the number of containers to be sampled, which part of the container to sample, and the amount of material to be taken from each container. Sampling was conducted at defined locations. 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 deficiencies raised in this section have been adequately addressed and will be verified during future PQ inspections.

7. Production and in-process controls The inspectors visited the synthesis and powder processing areas (PPA) related to the APIs in the scope of the PQ inspection. The batch records were available at the point of use. There was not much manufacturing activity in the synthesis area. Centrifuges inside the PPA area were found to be poorly maintained. Upon inspection of the "cleaned" centrifuges, it was found that these centrifuges were not adequately cleaned. Overall, there were issues with the cleaning procedure, the clean/dirty hold time, and the cleaning validation. Some of the doors were not adequately closed, resulting in a differential pressure below the specified limit (more than 10Pa). The area where blending and packaging were carried out was also found to be inadequate due to maintenance and size.

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 labeling 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. The 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

The storage facilities were available for the storage materials under appropriate conditions (e.g., controlled temperature and humidity when necessary). Environmental conditions were recorded when controlled. The storage conditions for the solid raw material warehouse, the liquid material warehouse, the hazardous materials warehouse, and the package materials warehouse were ambient, without temperature or humidity control. The storage conditions in the final product warehouse were set to 10-30 °C. Materials were stored to prevent degradation, contamination, and cross-contamination, and under controlled conditions if required. 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. Before shipment, a security seal with the company's logo and unique serial number was used as a tamper-proof seal for the packages. The general description and function of warehousing and storage facilities are listed in Section 3. The A02 and B02 warehouses were divided into two separate sections:

- A02: 1) "West solid" for storage of solid materials under uncontrolled conditions, including retention samples for starting materials and intermediates (locked cage), 2) "Packing materials".
- B02: 1) "API" for APIs and retention samples (locked cage), 2) "East solid warehouse". The TDF, requiring a cold chain, was stored in an isolated, air-conditioned container.

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

10. Laboratory controls

The laboratory has 32 staff members responsible for conducting physical, chemical, instrumentation, validation, and microbiology testing of the incoming materials, intermediates, and finished APIs. The main QC laboratory was located on the 2nd floor of the admin building, whereas the microbiology laboratory was on the 3rd floor. The retention samples were stored in the warehouse under QC supervision. The samples for raw materials, finished APIs, and intermediates were collected by the QC personnel, whereas in-process samples were collected and sent by the production personnel. Separate samples were collected and sent to the microbiology laboratory for testing. The laboratory runs in three shifts. The logbooks were used to record incoming samples before they were assigned to the analyst for testing. The laboratory was equipped with 13 HPLCs, 6 GCs (2 with headspace), 1 FTIR and 1 UV-Vis spectrometer, and 7 analytical balances. The calibration was performed in-house and by the external service provider on a periodic basis. The analytical balances were connected to the printers, and the username and password were given to each user.

Working and reference standards

The working standards were prepared by the QC laboratory. The working standards for Zidovudine and TDF were verified. For Emtricitabine, the primary reference standard, USPRS, was used. The standards used for GC analysis were also verified.

Stability chambers

The laboratory was equipped with 4 stability chambers (25/65%, 25/60%, 40/75% and 2-8°C). As part of the yearly calibration of the stability chambers, alarms were also challenged. The stability samples for TDF stored at 2-8°C were verified and found satisfactory. Emtricitabine samples were stored at 30% and 65%.

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

11. Validation

The qualification and validation master plan for 2025 was reviewed. The table of contents included the overview, purpose, scope, basic validation requirements, acceptance standards, plan, and schedule. The VMP included the qualification of instruments and equipment, validation of processes, cleaning and analytical methods, and computerized systems. The environmental monitoring and personnel qualification were not part of the VMP.

Computerized system validation

The SOP for computerized system validation referenced ISPE GAMP 5. The management procedure for computer system software provided guidance on ensuring that relevant computer systems operated in a stable, safe, and reliable manner to maintain data accuracy.

The SOP for cleaning principles described the cleaning methods for production sites, equipment, appliances, etc. The cleaning procedure was divided into three types: batch cleaning, level 1 cleaning, and level 2 cleaning.

The SOP for process validation described that processes should be revalidated once every 5 years. The SOP stated some of the contents of the continued process verification

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

12. Change control

The SOP for change control provided guidance on implementing changes related to vendor, plant, facility, equipment, cleaning procedures, method analysis, processes, key personnel, and computerized systems. The procedure was not explicit in ensuring changes related to the introduction of a new intermediate and API. A flowchart in the procedure allowed any department to initiate changes, and QA provided the change control number, classification, and risk assessment. The changes were classified into major, moderate, and minor. Once the change control was approved and implemented, an impact assessment would be performed. The procedure did not require a timeline for the change control closure.

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

Handling of rejected materials and products was in accordance with SOP Handling and control of rejected material. Intermediates and APIs that failed to meet established specifications were rejected and quarantined in accordance with the written procedure. Materials that do not conform to standards or specifications may be reprocessed, with chemical or physical manipulation steps repeated as part of the standard manufacturing process. The reprocessing was always based on the OOS and reprocessing investigations recorded on the appropriate forms, using the same process as defined in the manufacturing instruction/batch processing record. Batches to be reworked should be subjected to appropriate evaluation, testing, and, if warranted, stability testing, and documented to show that the reworked product is of equivalent quality to that produced by the original process.

14. Complaints and recalls

Quality-related complaints should be recorded and investigated in accordance with a written procedure. Records of complaints should be subject to internal audit, management review, and trend analysis.

15. Contract manufacturers (including laboratories)

The purchasing department selected suppliers based on the established material specifications. The materials were categorized according to their criticality as follows:

- Type 1: Starting materials
- Type 2: Process solvents, reagents, primary packaging materials
- Type 3: Secondary packaging materials and other materials

The vendor qualification process depended on the material type and may include the following: manufacturer's COA, Questionnaire, Sample testing, Pilot production, On-site audit, and Technical agreement. Supplier requalification was due every 5 years. The suppliers' performance was continuously monitored and summarized in the Annual Product Quality Reviews.

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, **Jiangsu Puxin Pharmaceuticals Co., Ltd**, located at **No.1 Chenli Road, Chemical Park, Binhai Economic Development Zone, Jiangsu, China** 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