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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	KPC Pharmaceuticals, Inc.
Corporate address of manufacturer	KPC Pharmaceuticals, Inc. No.166 Keyi Road, High and New Technology Development Zone, Kunming City, 650100, Yunnan Province P. R. China.
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	KPC Pharmaceuticals, Inc. Qigongli, West Suburb, Kunming City 650100, Yunnan Province, P. R. China.
Synthetic Unit /Block/ Workshop	No.4 Phytochemistry Plant (PCP4)
Inspection details	
Dates of inspection	9-13 June 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	Production and quality control of small volume injections, freeze-dried powder for injection, tablets, hard capsules, soft capsules, granules, APIs, active substances (including psychotropic), pharmaceutical precursor chemicals, traditional Chinese medicines, and herbal extractions.
General information about the company and site	KPC Pharmaceuticals, Inc. was established in 1951. The company has one joint venture, eight subsidiary companies, one drug research institute, and one manufacturing center. The WHO PQed API product, Artemether was manufactured in a dedicated block.
History	This was the 6th WHO PQT inspection.
WHO products covered by the inspection	APIMF125, WHOAPI-125 Artemether
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	• Quality Management System • Production block • Warehouse • Utilities: Water system, nitrogen system and HVAC • Quality Control Laboratory

	• Microbiological Laboratory
Restrictions	The scope of the inspection was restricted to the API in the WHO PQ program
Out of scope	API areas and FPP areas which are not under the scope of prequalification
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BER	Batch Analysis Record
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	Nonconformity
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
QP	Qualified person
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
WFI	Water for injection

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

1. Quality management

KPC's production and quality were overseen by management, manufacturing, and quality control teams. Processes are documented, and the quality department operates independently from production. Authorized staff release intermediates and APIs, with all quality activities recorded and deviations investigated. Internal audits were scheduled, and a risk assessment process was in place.

Annual Product Quality Review

The annual product quality review was conducted annually and covered raw materials, testing results of semi-finished and finished products, out-of-specification batches, validation and qualification performed, complaints, recalls, returned products, yields, reworks/reprocesses, registration status, contract manufacturing, self-inspection, critical process parameters, deviations, change control, stability studies, environmental and water testing results, and a review and conclusion of the previous year.

Organogram

The Organogram listed the KPC departments indicating the company hierarchy and reporting lines.

Management review (MR)

Management review meetings covered communication on deviations, changes, adverse reactions, and inspection findings. The President or Deputy President chaired the MR committee, which was conducted via written reports contributed by relevant managers.

Quality Risk Management

The Quality Risk Management system was implemented with FMEA tools commonly used. Risks reviewed included shared facilities, validation, change control, deviation handling, complaints, material management, process control, and data integrity throughout the lifecycle of the drug substance. Potential risks were identified and assessed using scientific knowledge.

The 2024 Risk Register was confirmed, and several risk assessments were reviewed and found acceptable.

Deviations

Deviation management followed a predefined procedure. Deviations were identified and categorized as Critical, Major, or Minor. Recorded deviations underwent an assessment of their impact on data integrity and corresponding corrective actions were implemented. Investigations were scheduled within a defined timeline. The process involved collaboration with the Quality Assurance (QA) team following completion of the root cause investigation. Some deviation investigations were reviewed.

CAPA

According to the SOP, the CAPA system addressed corrective actions from sources such as deviations, audits, reviews, incidents, monitoring, complaints, recalls, validations, qualifications, and maintenance. CAPA effectiveness was assessed biannually by reviewing deviations, documentation, operations, complaints, and related issues.

Internal audit / Self inspections

Self-inspections covered all GMP-related areas in the company. An annual plan and the 2024 self-inspection schedule, along with the multi-discipline team structure, were reviewed. Inspections address personnel, facilities, materials, equipment, documentation, quality control and assurance, product distribution, complaints, recalls, sanitation, previous inspection outcomes, and corrective actions. After each self-inspection, a corrective action plan and timelines are set.

Product release

The Director of Quality, serving as KPC's Qualified Person, held responsibility for authorizing the release of finished products. For each active ingredient, a Release Certificate was prepared. Batch release protocols for Artemether were outlined in the relevant standard operating procedures (SOPs) and encompassed Dihydroartemisinin, Artemether crude, and Artemether API. Upon completion of batch review, release documentation was submitted to the Qualified Person for final approval. Records of product releases were maintained both in paper format and within a computerized system.

Data Integrity

A procedure detailed the company's policy and requirements for data integrity. It was applicable to both manual and electronic data management, describing the ALCOA principles. Additionally, the company maintained a Data Integrity Risk Assessment Document.

Pharmaceutical quality system

A Corporate Quality Manual was available and included the following:

- The concept of quality management (QM)
- The KPC model of QM, which incorporated input from relevant parties and outlined requirements for continuous improvement
- Implementation of QM objectives and enhancement of post-market monitoring focused on patient safety, with defined responsibilities in areas such as quality, Quality Assurance, and Pharmacovigilance.

2. Personnel

An adequate number of qualified trained and experienced personnel were available. Responsibilities (job descriptions) were specified in writing.

Job descriptions

The verified job description for the Quality Director and Qualified Person was signed and accepted, covering responsibilities such as production and material release. The job description for the Chemist in the Production Unit and QA system support was also evaluated and found accepted.

Training

Production staff received regular, ad hoc, and onboarding training, which was evaluated by written exams. An annual assessment identifies training needs.

Production staff attended regular training on GMP, legislation, production processes, material management, SOPs, and microbiology. Verified training records for selected staff, including the Self-inspection team lead and quality control analysts, were accepted.

Hygiene

The procedure addressing personnel hygiene was verified. The SOP included a pre-employment medical examination overseen by Human Resources, as well as annual health checkups. These assessments cover general health etc. Individuals with open wounds were not permitted to enter the factory.

3. Buildings and facilities

Buildings and facilities used in the manufacture of intermediates and APIs and specific the dedicated block for Artemether production 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 buildings and facilities provided sufficient space to ensure the organised placement of equipment and materials, thereby minimising the risk of mix-ups and contamination. The movement of materials and personnel within the premises was structured to further reduce the potential for mix-ups or contamination.

A grade D clean zone was used for final crystallization, drying, and packaging of the API. The air purification system consisted of preliminary, medium efficiency, and high efficiency particulate air filters which were found acceptable.

Quality control laboratories were separate from production blocks.

Water system

Purified water (PW) was produced by reverse osmosis (RO), with pre- and post-treatment by filtration and UV, respectively. Weekly disinfection covered both the PW collection tank and distribution loop. The system operated at room temperature, with online monitoring of conductivity and flow rate, and offline checks of pH and TOC. SOP set microbiological action and alert limits. PW specifications included endotoxin limits, with annual review confirmed. Final return/supply points and use points were sampled and tested following the defined schedule.

HVAC

A single air handling unit (AHU) supplied the filtered air to clean rooms. The plenum included primary, secondary and HEPA filters, with pressure differentials monitored for filter condition. HVAC and clean room qualifications were performed annually. Regular OQ and PQ checks of HVAC and clean rooms were completed. The operation procedure for AHUs was reviewed.

Gasses

Nitrogen gas was applied directly to product following in house procedure.

Solvent Storage

The storage area for solvents used in Artemether production was inspected. Labels on incoming materials as well as in-house material testing and release procedures were reviewed and found acceptable.

4. Process equipment

Equipment for producing Artemether intermediates and APIs was dedicated, properly designed, adequately sized, and correctly located for intended use, cleaning, sanitization, and maintenance. Contact surfaces did not impact product quality, and processing lines were clearly identified. A number of procedures for equipment management were reviewed and found acceptable.

Cleaning frequency of equipment was described as daily cleaning and periodical cleaning. Cleaning of the Artemether production area was manual, with the clean hold time and dirty hold time been validated and specified. The cleaning of clean areas was defined as daily cleaning, weekly cleaning and monthly cleaning. The two disinfectants used were exchanged regularly.

Equipment calibration
Equipment calibration was spot checked for balances used in QC. The Calibration certificate of one of the balances was checked and found accepted.

5. Documentation and records

Documents related to the manufacture of intermediates or APIs were prepared, reviewed, approved and distributed according to written procedures. The issuance, revision, superseding and withdrawal of all documents was controlled with maintenance of revision histories.

The company utilized a document management system (DMS) to control certain documents, including SOPs, QC forms and original testing records, production process instructions, and specifications and auxiliary laboratory records such as SOP attached templates, balance logbooks, maintenance records. Other documents, such as batch records and QA forms and records, were managed manually. Documentation management procedures were outlined in specific SOPs.

A random verification of document control within the DMS system was conducted. The review confirmed that the processes for document preparation and distribution were managed appropriately.

Batch numbering and BMR management
Batch numbers for Artemether were assigned according to a specific SOP using a unique sequence of numbers. Reprocessed/reworked batches were indicated in the batch number. Batch Manufacturing Records (BMRs) followed a specific procedure which was authorized by QA.

Batch analysis record management
The management of specifications of raw materials, intermediates and final products were described in SOPs.

6. Materials management Written procedures describing the receipt, identification, quarantine, storage, handling, sampling, testing and approval or rejection of materials were available.

Sampling of the raw materials, intermediates and finished products was performed according to procedures with sampling of the packaging materials performed according to the procedure on "Sampling of packaging material used for Artemether API." Cleaning, drying and storage of the sampling tools were defined.

Handling of rejected incoming materials, out of expiration date materials as well as rejected finished products and intermediates were defined in SOPs which were acceptable.

Receipt and storage
Materials received in the warehouse were checked for the order suitability and its physical condition. Checklist logbook for the incoming material was available.

List of approved suppliers was available. Artemisinin starting materials were stored under appropriate conditions which was monitored manually. Records were available. The warehouse was equipped with pest control traps and UV lamps.

Sampling: raw materials and packaging materials
Sampling of the raw materials, intermediates, finished products and packaging materials was performed according to the applicable procedures. Cleaning, drying and storage of the sampling tools were defined in the SOP on "Cleaning and disinfection of sampling tools".

Dispensing

The dispensing of materials was carried out in the dedicated Artemether workshop. The warehouse dispatched materials to the workshop utilizing the distribution form within the SAP system.

Dispensing records for Artemisinin were verified. The Workshop maintained stock cards and forms documenting dispensing, weighing, and distribution, which enabled traceability of starting material usage in the production of the API.

Supplier Qualification

Risk assessment classifies materials as main or non-main. Suppliers/manufacturers of main materials required a vendor audit performed periodically. An annual review of all material suppliers, which includes a comprehensive supplier assessment, was conducted. A spot check was performed on the Annual Review of All Material Suppliers.

7. Production and in-process controls The production block of Artemether was dedicated. Raw materials were weighed and measured using appropriately accurate devices. The Company divided the artemether production into various steps. Intermediate substances and crude material were staged in the dedicated block prior to additional processing. The areas dedicated to Artemether manufacturing were inspected.

Environmental Monitoring and Testing Overview

Environmental monitoring for the facility's clean zones was conducted according to SOPs.

Contamination control

Contamination control for production was covered in SOP. Contamination risk in the intermediate drying room was reviewed.

8. Packaging and identification labelling of APIs and intermediates

Written procedures describing the receipt, identification, quarantine, sampling, examination and/or testing and release and handling of packaging and labelling materials were available.

No packaging took place during the inspection. Label sampling, examination, and release procedures were inspected. The following documents were checked:

- "Label management" that defined the procedure of request, storage, usage and destruction procedure".
- "Production procedure of packaging"
- "Label receival and storage"
- "Control of packaging material"
- " Label, leaflet and box" standard.

Product labels were prepared by the assigned production personnel in accordance with procedures. The labels were affixed to drums by the production operator, and one label was placed on the BPR.

9. Storage and distribution

Materials were stored under proper conditions, with records kept accordingly. Quarantine, rejected, returned, or recalled materials were stored in separate areas.

Finished API products were stored in the specified warehouse. The company used a building management system with each room monitored by probes with continuous recording to track warehouse temperatures.

10. Laboratory controls

Physicochemical laboratory

Samples were received in the laboratory as outlined in SOP with information uploaded to the Document Management System. Quality control facilities and procedures for sampling, testing, material approval or rejection, and data management were in place, along with relevant specifications and test plans. Sampling for artemether was checked and found accepted.

The QC laboratory utilized software programs for HPLCs, GCs, UV, and IR spectrophotometers, etc., while the *DMS* managed documents and *SAP* handled material management.

The preparation of the HPLC mobile phase was reviewed. Records were available and found acceptable.

OOS

OOS results were investigated and handled according to SOP addressing "Investigation of Out of Specification Results" and SOP "Investigation for microbial data deviation in QC".

At any stage, if the cause is identified and confirmed, the investigation may be concluded, and OOS (Out of Specification) results can be classified as valid or invalid. Deviations and action plans were documented. The final decision regarding the product was determined by Quality Assurance (QA). A Certificate of Analysis (CoA) will be issued to indicate whether the product conforms or does not conform. According to SOP for release, if the CoA indicates that the product was non-conforming, then the handling of the product was addressed according to the management of rejected products. Several OOSs investigations were inspected and investigations verified.

Stability studies

An on-going stability study for Artemether was conducted according to *S*OP. One batch of each year was chosen at random for on-going stability studies.

Stability study samples were stored in a controlled refrigerator for long-term stability assessment and in a stability chamber for accelerated stability testing. The long-term stability samples kept in the controlled refrigerator for WHO grade Artemether batches. All testing was performed in accordance with the specified protocols. The stability testing for the product were inspected and found to be satisfactory.

Retention samples

Samples of starting materials, intermediates, and finished products were retained in QC, as described in SOP. The retention samples were stored using the same or similar packaging materials as those used in the production (intermediate) and for the market (starting materials and APIs).

Retention samples of Artemether were kept in a refrigerator located in the stability study room, which was equipped with an alarm system to notify the person in charge if there were deviations from the required conditions.

Laboratory equipment

The company had the necessary testing instrument needed for the testing as per specification, among others, IR spectrophotometer, HPLC, GC, UV spectrophotometer, and X-ray powder diffractometer. During the inspection, testing related to HPLC and GC for assay, related substances, and residual solvents was reviewed.

Microbiology Laboratory

Microbial limit testing and microorganism identification were taken place under defined conditions. Microbiological media preparation followed written procedures. The lab used ready-to-use media for environmental monitoring, stored in a dedicated room, with suitability and documentation verified prior to acceptance.

QA personnel who were stationed in QC unit received product samples for testing, which were then distributed for analysis. Microbiology personnel collected environmental and water samples directly for immediate testing.

11.Validation

The Validation Master Plan addressing process validation for 2025 was available. Multiple validation master plans were in place, covering areas such as training, qualification, analytical processes, the GMP project master plan, and cleaning validation, with SOPs specifying the types of validation to be performed. Revalidation of the WHO Grade Artemether process was finalized in 2024.

Process validation

The process validation submitted to WHO PQT in 2024 was inspected.

Analytical Method Validation

The Analytical Method Validation for Artemether WHO grade was reviewed. Parameters evaluated included precision, intermediate precision, repeatability, linearity, accuracy, robustness, limit of quantitation (LOQ), specificity, and solution stability. The validation found that all parameters met established criteria.

Cleaning Validation

The SOP on “Cleaning validation” was reviewed. The facility and equipment in the manufacturing area were dedicated for Artemether production. The cleaning revalidation interval was defined.
The risk assessment report for cleaning validation was reviewed and the periodic cleaning validation report for the purification process was examined. The acceptance criteria for Artemether residue were established. Various equipment cleaning timelines following validation were defined. The analytical method used to detect residues was reviewed.

Computerised system validation

Computerized systems were not used for production control. Software systems were implemented in Material and product management, document management and QC lab for HPLC and GC networking. The “Computerized System Validation Procedure" was checked.

Qualification

Dust collector located in weighing room was inspected together with the operational qualification report.

12.Change control (CC)

Change control system was established to evaluate changes that may affect the production and control of the intermediate or API. CC on Computer systems include hardware, software, data. Changes were classified as critical, major and minor changes. Critical changes were reported at management review meetings.

13.Rejection and re-use of materials

Reworking

Reworking was addressed as per SOP “Handling of Out of Specification Products”. Reworking for Artemether was not allowed.

Rejection and Reprocessing
SOP "Handling of Unqualified Material and Product" was reviewed. According to the procedure, any rejected product will be either destroyed, disposed of, or subjected to reprocessing or reworking following the completion of a deviation investigation.

Recovery of Solvents
Only fresh solvents were used in artemether production; recovered solvents from production were not reused in other company units. Recovered solvents were prohibited in all API production.

Returns
SOP "Self-production API return" was inspected. The returned APIs were placed in the quarantine section of the cold warehouse.

14.Complaints and recalls
Once a quality complaint was verified, an investigation was conducted, and customer feedback was provided. This included reviewing batch production, intermediates analysis, finished product analysis, and sales records. Preventive actions were implemented following approval by the Director of Quality, with QA assessing adequacy and effectiveness. All records were maintained by Quality Assurance.

Complaints were classified into 4 types: Severe complaints, Important and minor complaints and Others. Complaints could lead to further investigation and recall of product. Complaints could be received via a company hotline. A complaints investigation team was established. The 2025 complaints register was reviewed. One major complaint was reviewed as part of the inspection.

Recalls
The QA Department was responsible for submitting investigation reports and recall plans to Regulatory Agencies. The recall process was implemented, monitored, and documented as required. A mock recall was conducted every two years, if necessary, with the effectiveness of recall arrangements periodically evaluated. Recalls were categorized as Class I, II, or III, and can be either voluntary or mandatory. Communication procedures included publishing on the company website news section within 24 hours for Class I recalls, reporting to National Drug Authorities and WHO, and informing the product marketing platform to discontinue product use.

15.Contract manufacturers (including laboratories)
An annual audit plan was established. QA was responsible for the follow-up of corrective and preventive actions implemented by suppliers as per SOP "Quality Audit for Supplier". The director of quality provided final approval for new suppliers according to SOP "Quality Management for Supplier".

Contracts (TA agreements - production, quality control and services)
Quality Agreement was signed with vendor/ supplier after initial audit if the company was deemed satisfactory and can be updated. Some contract agreements were verified.

Part 4	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, ***KPC Pharmaceuticals, Inc., No.4 Phytochemistry Plant*** located at ***Qigongli West Suburb, Kunming City 650100, Yunnan Province, P. R. China*** was considered to be operating at an acceptable level of compliance with WHO good manufacturing practices for active pharmaceutical ingredients.

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.

The WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 5	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. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052, Annex 4. **Short name: WHO TRS No. 1052, Annex 4**
   http://whqlibdoc.who.int/trs/WHO_TRS_1052_eng.pdf?ua=1

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. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 2. **Short name: WHO TRS No. 1044, Annex 2** http://whqlibdoc.who.int/trs/WHO_TRS_1044_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
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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

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