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

Part 1	**General information**
Name of manufacturer	Jiangsu Jinshen Pharmaceutical Technology Co., Ltd.
Corporate address of manufacturer	Xinyu Village, Shanghu Town, Changshu 215554, Jiangsu, China 215554
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	Same as above.
Synthetic Unit /Block/ Workshop	• Building 16: Workshop 3: Synthesis • Building 2: ▪ Dissolving and decolorization area ▪ Grade D clean area
Inspection details	
Dates of inspection	13 – 16 October 2025
Type of inspection	Initial inspection
Introduction	
Brief description of the manufacturing activities	Production, quality control and release of APIs, intermediates and starting materials.
General information about the company and site	Jiangsu Jinshen Pharmaceutical Technology Co., Ltd. is located at Shanghu Town, Changshu, Jiangsu province of China. The current pharmaceutical activities on the site are only for manufacturing of Sulfadoxine API. The API was produced in different processes and quality grades. The manufacturing site is also engaged in the production of Sulfadoxine starting material in a separate area from the API production activities.
History	This was the initial WHO onsite GMP inspection. The site was regularly inspected by Suzhou Inspection Branch of Jiangsu Medical Products Administration, China, and has not been inspected by other National Regulatory Authorities (NRAs).
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document reviewed:** • Quality management • Personnel • Buildings and facilities • Process equipment

	• Documentation and records • Materials management • Production and in-process controls • Storage and distribution • Laboratory controls • Validation • Change control • Rejection and reuse of materials • Complaints and returns • Contract laboratories **Site area visited:** • Production blocks: ▪ Synthetic Workshop ▪ Clean area workshop • Quality control laboratories • Solid material warehouse • Liquid material warehouse • Printed packaging material warehouse • Water system • Nitrogen system • HVAC
Restrictions	The scope of the inspection was restricted to the API in the WHO prequalification program.
Out of scope	Products and facilities that are not under the scope of WHO prequalification program.
WHO API (including WHO API or APIMF numbers) covered by the inspection	Sulfadoxine API (internal code A05) used for FPPs.
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
BSE	Bovine spongiform encephalopathy
BTR	Batch testing 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
GPT	Growth promotion test
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
KSM	Key starting material
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MR	Management review
NC	Nonconformity
NON-CCOE	Non-chief controller of explosive
NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
RH	Relative humidity
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
TSE	Transmissible spongiform encephalopathy
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer

Part 2	Summary of the findings and comments

1. Quality management

A documented system for quality assurance was established, with procedures covering key quality elements in place. The Quality Department was divided into QA and QC and were separate from the Production Department. Operations were specified in written form and critical GMP requirements were essentially being met. Authorized person for the release of APIs was designated.

Product Quality Review

Regular quality reviews of APIs were performed according to the SOP "Product Quality review". The APQR for Sulfadoxine A05 of year 2024 was reviewed and discussed during the inspection.

Quality risk management

The SOP "Quality risk management" was reviewed. The content was based on ICH Q9. Failure mode effects analysis (FMEA) and other quality risk management methodologies were described in the procedure. The QRM was used by the company in various aspects such as introduction of a new product, cleaning validation, process validation, equipment qualification, change control, deviation, vendor qualification. 2023-2025 quality risk assessment register was available. The risk assessment reports related to WHO grade Sulfadoxine were checked.

Management Review (MR)

The SOP "Quality management review" was established to define the process for conducting management reviews and evaluating the performance of quality system. According to the SOP, MR should be conducted annually. The last MR performed in February 2025 was checked. The meeting minutes, along with the list of attendees, were available and reviewed. The minutes were prepared in accordance with the SOP.

Deviations and CAPA

The SOP "Deviation investigation and Handling" was checked. Deviations from established procedures were documented and explained. Critical deviations were investigated, and the investigations and their conclusions were documented. The SOP was applicable to the handling of deviations from procedures or standards related to the entire pharmaceutical manufacturing process. Deviation register from 2024 was checked. It specified root cause analysis, corrective actions and closure date.

Handling of CAPA

The SOP "Corrective actions and preventive actions" was applicable to all non-conformities including these occurring during the operation of the quality management system, other undesirable situations, and potential defects. CAPA register from 2024 was checked and contained information from external audits and self-inspections.

According to the SOP, CAPAs shall be classified, summarized and statistically analysed and reviewed in the PQR. CAPA administrator of QA shall record the measures to be taken in the CAPA report, including the planned completion date.

Batch release

The SOP "Product review and release" was checked. The release of APIs was the responsibility of the Qualified Person (QP). The batch release records were maintained.

Self-inspection

The SOP "Internal Audit" to ensure compliance with current cGMP was checked. This procedure covered various departments, including manufacturing, quality control, quality assurance, training, and warehouse management. The inspection schedule was established to conduct audits of each department twice a year. GMP auditor qualifications form was part of the SOP.

A checklist was used to guide the self-inspection. All findings identified were escalated to the management review meeting discussion and resolution, ensuring timely corrective actions. Last different department's self-inspection was carried in June 2025.

Data management
The following SOPs were checked and discussed during the inspection.
- SOP "Data management specification".
- SOP "Computerized system back up and archiving procedure"
- SOP "Disaster management and data restoration"
- SOP "QC laboratory Open Lab System"

2. Personnel
An organogram was documented. The Head of Production and Quality Department reported directly to the General Manager. The production and quality assurance functions were operated independently.

An adequate number of qualified trained and experienced personnel were available. The responsibilities of personnel engaged in the manufacture of intermediates and APIs were specified in job descriptions.

Training
The manufacturer had established documented training program following the written procedure. This procedure covered the identification, planning, execution, and documentation of training for personnel involved in pharmaceutical manufacturing and support activities. The training program included initial training for new employees, as well as ongoing training for all staff members. Training annual planner was available. Training effectiveness was monitored with evaluations.

Personnel hygiene
The following SOPs were checked and found to be acceptable.
- SOP4 "Personal hygiene and sickness report"
- SOP "Master hygiene plan"
- SOP "Personal health checks"

3. Building and facilities
The facilities for manufacturing and testing of Sulfadoxine API were dedicated. The production areas included chemical synthetic area and Grade D clean area.
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. Adequate space was provided for the orderly placement of equipment and materials. The classified areas were monitored for temperature, relative humidity and pressure differentials. Exposed surfaces were smooth, impervious and unbroken to minimize the shedding or accumulation of particles or microorganisms and permitted the repeated application of cleaning agents.

QC laboratories
The physio-chemical Laboratory and microbiological laboratory were separate. QC laboratories were visited and seen generally in good order and clean.

Warehouses
The following warehouses were available at the site.

- Packaging materials' warehouse, and Finished API warehouse
- Solid raw materials' warehouse
- Liquid raw materials' warehouse

Sanitation and maintenance
In general buildings used in the manufacture and testing of intermediates and APIs were properly maintained and kept in a clean condition. Written procedures were established assigning responsibility for sanitation and describing the cleaning schedules, methods, equipment and materials to be used in cleaning buildings and facilities.

Water system
Process water included drinking water and purified water. Raw city water was pretreated followed by double ROs and EDI. PW was circulated continuously in distribution loop between PW storage tank and user points.

Purified water storage tank, pipeline, the pre-treatment system and RO system were sanitised following SOP "PW system cleaning". Parameters including PH, conductivity and flow rate were monitored online. TOC was tested offline. PW system qualification was performed. Limits for total microbial count and conductivity were established. The SOP "Process water monitoring" and PW sampling plan for 2025 was checked. Till the date of inspection all test results were within alert limits.

HVAC system
The HVAC system for the clean area was briefly visited and found at good state. The temperature and humidity were controlled. Appropriate filter cascade was installed before final HEPA filters. Limits for differential pressure at the filters were specified. Monitoring of differential pressure was documented.

Environmental monitoring (EM)
The SOP "Production environmental monitoring management" was checked and discussed.

Compressed air and Nitrogen gas system
Compressed air and nitrogen system was in place. The schematic drawing of compressed air and operation procedure were checked. The system was briefly visited during the inspection.

Lighting
Adequate lighting was provided in all areas to facilitate cleaning, maintenance and proper operations.

4. Process equipment
Design and construction
Equipment used to manufacture the intermediate and API was of appropriate design, adequate size, and suitably located for its intended use, cleaning and maintenance. Equipment was constructed so that surfaces in contact with raw materials, intermediates, or APIs did not alter the quality of intermediates and APIs. All equipment was dedicated to Sulfadoxine API manufacturing.

Equipment Qualification
The equipment qualification was performed in accordance with SOP "Management procedure on premises, Facility and equipment". The procedure defined the equipment qualification and requalification requirements and frequency. Equipment was classified depend on their criticality. Requalification of equipment used for Sulfadoxine API production performed in July 2024 were checked.

Calibration of Equipment
Equipment had calibration labels, showing calibration date and due date as well as "status tags" and preventive maintenance labels. Control, weighing, measuring, monitoring, and test equipment critical for assuring the quality of intermediates or APIs were calibrated according to written procedures and as per an established schedule.

Equipment maintenance and cleaning
Schedules and procedures were established for the preventive maintenance of equipment. Written procedures were established for cleaning of equipment and its subsequent release for use in the manufacture of the intermediates and API. Equipment dirty holding time and clean holding time were established. Equipment was observed to be clean and maintained in a good status during the inspection.

5. Documentation and records
Documents related to the manufacture of intermediates or APIs were prepared, reviewed, approved, and distributed according to respective SOPs. GMP documents were stored under the responsibility of the Quality Assurance (QA) department, with appropriate access restrictions in place. Documents were retained for defined periods.

Batch numbering system and Batch production records
The SOP "Batch numbering system" was checked. A reprocessed/reworked batch was referenced in the batch number.

Master production instructions
Master production instructions were prepared, dated and approved; and contained detailed guidance on production activities.

Batch production records
The SOP "Batch production record management" was checked. Batch production records included complete information relating to the production and control of the batch. The batch production records issuance was checked and discussed. The BMRs for process validation and BMRs in operation during the visit to production were checked.

6. Materials managementA system was established for the evaluation and approval of suppliers of critical materials. Materials were procured in accordance with agreed specifications from approved suppliers. Materials were handled and stored in a manner that prevented degradation, contamination, and cross-contamination. Materials were stored under conditions and for periods that had no adverse effect on their quality and were normally controlled to ensure that the oldest stock was used first. Materials and finished API products were stored in different warehouses which were visited during the inspection.

Vendor management
The SOP "Supplier management" was checked. The procedure specified qualification and requalification of vendors supplying raw materials, process aid materials, packaging materials and contract testing. QA was responsible for formulating specifications, conducting supplier audits and subsequent re-evaluation. The supplier qualification was checked. Vendor audit schedule for 2025 and approved suppliers/manufactures list were presented. Approved suppliers list was updated regularly or whenever there were changes.

7. Production and in-process controls The production workshops were dedicated to Sulfadoxine manufacturing. Raw materials were weighed and measured using appropriately accurate devices. Different grades of Sulfadoxine APIs were produced, distinguished by coding system.

Sulfadoxine API manufacturing process and steps were defined. Blending batches of intermediates or APIs were not performed for WHO grade Sulfadoxine. All the steps were in operation during the WHO inspection. The relevant production areas were visited. Contamination control in production was checked and discussed.

8. Packaging and identification labelling of APIs and intermediates
The API product packaging was in operation during the inspection. The packaging record for the batch in operation was checked. A sample of the approved label was included/attached in the BPRs.

The SOP3-004-04 "Label verification, storage and release" was checked. The register of labels release, return and destruction was required to be maintained.

9. Storage and distribution
Warehousing procedures
Adequate facilities were available for the storage of materials under appropriate conditions. Records of these conditions were maintained.

Distribution procedures
APIs and intermediates were released for distribution to third parties only after approval by the Quality Unit.

10.Laboratory controls
The QC function was independent from other departments. QC laboratories were segregated from the production areas. The microbiology laboratory was segregated from the chemistry laboratory. Laboratory facilities were adequate and equipped with appropriate instruments. Written procedures were established and implemented for the sampling, testing, approval or rejection of materials and finished API products. Specifications, sampling plans, schedules, and test methods were in place to ensure compliance with defined quality and purity standards.

Computerised system was used to network of HPLC and GC analysis instruments. Chromatographic columns were stored in original packaging. Column register was available as well as usage register. All volumetric glassware had unique identification number and calibration certificates indicating calibration date and calibration due date.

Sample receiving and distribution
Samples were received through a designated pass-through window to the sampling room. Sample were stored in designated locked metal cabinets. Samples register was available.

Standard and reference substances
Reagents and standard solutions prepared in the laboratory were appropriately labelled. For reagents received from supplier's, the receipt, opening and expiry dates were specified. Primary reference standards were obtained, stored and used in accordance with established procedures.

Testing of starting materials, intermediates and APIs
For each batch of intermediate and API, appropriate laboratory tests were performed to confirm compliance with established specifications.

OOS/OOT management
Out-of-Specification results were investigated in accordance with the SOP "Investigation of Laboratory OOC/OOT".

Retention samples

Reserve samples were managed according to the written procedure. Samples were stored in the same packaging system as the API or in packaging that was equivalent to the marketed packaging. Sufficient quantity was retained to allow for full specification analyses. WHO retention sample register was available and checked.

Stability study

The SOP "Drug Stability study" was reviewed. Initial (long term and accelerated) stability studies and ongoing stability programme were defined. Ongoing stability studies were mandatory for the commercialised products. At least one batch from every product / specification / type of packing should be included in the programme. Specified chambers with the following conditions were used for WHO grade of Sulfadoxine API:

- T 30 °C ± 2°C, RH 75% ± 5%
- T 40 °C ± 2°C, RH 75% ± 5%

Stability study report and data of Sulfadoxine API in year 2024 was checked and discussed.

Microbiology laboratory

Microbiological laboratory was briefly visited. The laboratory was adequately equipped and appeared to be of an acceptable standard for non-sterile API products. Media preparation and sterilization followed the SOP "Media management". The media preparation record was checked.

Appropriate microbiological tests were conducted on each batch of API where microbial quality was specified. PW testing procedure, sample receiving records and monitoring results for microbiological limit were spot checked.

11.Validation

VMP

Validation master Plan 2025 was checked. The VMP described qualification and validation policy and specified that VMP should be reviewed periodically.

Process validation

Process validation was performed following SOP "Manufacturing process validation management" and SOP "Validation management". The procedures indicated that at least three consecutive batches in commercial batch size should be engaged in the process validation. The PV documents for WHO grade Sulfadoxine API were checked.

Cleaning validation:

The SOP "Cleaning validation management" was checked. The acceptance criteria were established. The facility and equipment at the site were dedicated for Sulfadoxine production. The cleaning validation report of manufacturing equipment for Sulfadoxine was available.

Validation of Analytical methods

Sulfadoxine API related analytical method validation was briefly checked.

Computerized system validation

Computerized systems were not used for production and material control with the exception of the chemical laboratory at which a computerized system was utilized.

12.Change control (CC)

A formal change control system was established to evaluate all changes that could affect the production and control of intermediates or APIs. The SOP "Change control" covered the identification, documentation, appropriate review, and approval of changes. CC were classified as:

- Critical
- Non-critical

CC register from 2023 was presented.

13.Rejection and re-use of materials

Rejection, reprocessing and reworking

SOP "Handling of non-conforming products" was checked. The SOP was applicable to non-conforming raw materials, packaging materials, intermediates and finished products. Rejected products were labelled as such, and labels were affixed to each container and stored in the rejected materials area.

According to the SOP, non-conforming intermediates and finished products could be reprocessed and reworked following the SOP "Reprocessing and rework".

Recovery of materials and solvents

The SOP "Recovered solvents/solid materials and mother liquors" was checked. Till the date of the WHO inspection no recovered solvents/solid materials were used in the production of the WHO PQ related API.

Returns

The SOP "Handling of returned products" was checked. According to the SOP, QA shall evaluate product quality based on nature of the drug, required storage conditions, time interval between shipment and return and packaging. Till the date of the WHO inspection no products were returned.

14.Complaints and recalls

All quality-related complaints, whether received orally or in writing, were recorded and investigated according to SOP "Handling of customer comments and complaints". No complaints were registered since 2021.

The SOP "Product recall" was discussed. The SOP was established to define the circumstances under which a recall of an intermediate or API should be considered. The recall procedure specified responsibilities for evaluating information, the process for initiating a recall, individuals and authorities to be notified, and the handling of recalled materials. In serious or potentially life-threatening situations, local, national, and/or international authorities were required to be notified. Mock recall was carried out periodically. The last mock recall was carried out in August 2024. Till the date of the WHO inspection, no recalls were carried out.

15.Contract testing laboratories

A list of contract testing laboratories was available. The quality agreement for development of new suppliers for Sulfadoxine was checked. The agreement defined the GMP related responsibilities.

Contract laboratories

The SOP "Supplier management", explained qualification procedure for contract testing laboratories (testing suppliers). According to the SOP, contract laboratories were qualified/approved based on different documents submitted by the laboratory e.g. business license, list of instruments, etc. Approved contract testing laboratories list was presented.

Contract production

Production operations were not contracted out for the product related to WHO prequalification programme.

Part 3	Initial 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 Jinshen Pharmaceutical Technology Co., Ltd.*** *located at* ***Xinyu Village, Shanghu Town, Changshu, 215554, Jiangsu, 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 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***

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***

3. 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 No. 1033, Annex 3***

4. 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***

5. 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***

6. 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***

7. 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***

8. WHO guidelines on technology transfer in pharmaceutical manufacturing. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4. ***Short name: WHO TRS No. 1044, Annex 4***

9. 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**

10. 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***

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***

12. 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***

13. 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***

14. 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***

15. Good Manufacturing Practices: Guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS No. 1019, Annex 3***

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**

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***

18. WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the production of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6**.** ***Short name: WHO TRS No. 992, Annex 6***

19. 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 No. 1033, Annex 4***

20. 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 TRS No. 996, Annex 10***

21. 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***

22. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2. ***Short name: WHO TRS No. 1019, Annex 2***

23. Points to consider when including Health-Based Exposure Limits 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 No. 1033, Annex 2***

24. 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***

25. 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***

26. 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***

27. WHO good practices for research and development facilities of 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 6. ***Short name: WHO TRS No. 1044, Annex 6***

28. WHO good manufacturing practices for investigational products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 7. ***Short name: WHO TRS No. 1044, Annex 7***

29. WHO good manufacturing practices for excipients used in pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 2. ***Short name, WHO TRS No. 1052, Annex 2***

30. WHO good practices for pharmaceutical quality control laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 2. ***Short name, WHO TRS No. 1052, Annex 4***