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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT

Active Pharmaceutical Ingredient Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**Zhejiang Keming Biopharmaceuticals Co. Ltd.**
Corporate address of manufacturer	**Zhejiang Medicines Co. Ltd** 168 Mid Zhiyuan Avenue, Binhai New Area Shaoxing City, Zhejiang 312366, P.R. China
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	**Zhejiang Keming Biopharmaceuticals Co. Ltd.** 1 Dingshan Road, Yulin Subdistrict, Xinchang, Zhejiang, P.R. China
Synthetic Unit /Block/ Workshop	Workshop 3016A, Workshop 3016B, Workshop 3016, Workshop 3026 and Workshop 3036
Inspection details	
Dates of inspection	26 - 28 January 2026
Type of inspection	Initial inspection
Introduction	
Brief description of the manufacturing activities	The facility produced various food additives and dietary supplements. Rifamycin S Sodium was the first pharmaceutical intermediate made on-site. No production of allergenic pharmaceuticals, biological products, cytotoxic substances, or potent chemical drugs occur on site.
General information about the company and site	Zhejiang Kerning Biopharmaceuticals Co., Ltd. is a key subordinate enterprise of Zhejiang Medicine Co., Ltd (hereinafter referred to as ZMC) and was established in 2019. The production of Rifamycin S Sodium included abovementioned workshops, the water production system, and the supporting warehouse and testing facilities.
History	This was the first WHO PQT inspection, with no prior inspections by other authorities.
WHO products covered by the inspection	Rifamycin S Sodium used for Rifampicin (APIMF533/WHOAPI-533)
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 • Quality control laboratories • Warehouses • Water system • Steam system • Nitrogen system • HVAC system
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.
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 (where applicable)**

1 Quality management

A system for managing quality that involved participation of management and appropriate manufacturing personnel was in place. Quality-related activities were defined and documented. The quality department was independent of production department. Staff authorized to release intermediates and APIs were specified.

Quality-related activities were recorded at the time they were performed. Deviations from established procedures were documented and investigated. Regular internal audits were performed in accordance with an approved schedule. A risk assessment procedure was in place.

Product Quality Review

The SOP *Product Quality Review Procedure* was verified. Topics to be reviewed included deviations, change control, CAPA, validation, stability, inspections, and related matters. The 2025 Product Quality Review (PQR) for *Rifamycin S Sodium*, covering 01/10/2024 to 23/12/2025, was reviewed.

Management review (MR)

The SOP *Management Review Procedure* was reviewed. The Quality Director facilitated management review meetings attended by representatives from Production, IT, Engineering, Warehouse, RA, and the General Manager. The agenda encompassed training, deviations, change control, inspections, CAPA, supplier qualification, utilities, contracts, OOS/OOT, and additional relevant topics. Meeting minutes were distributed for review then approved by QA and Production, with final authorization provided by the General Manager. Furthermore, the SOP mandated quarterly reviews, with the end-of-year review reflecting the cumulative activities. The minutes from the most recent meeting were available and reviewed.

Quality Risk Management

The SOP concerning Quality Risk Management was reviewed. When implementing quality risk management activities, suitable risk analysis tools were chosen based on their specific features. The procedure identified when to use which tool. The appointment of a multi component risk assessment team was included. QA oversight was required.

The Risk assessment for the introduction of the *Rifamycin S Sodium* line to the manufacturing site was checked and discussed.

Deviations

The SOP on Deviations was reviewed. Deviations were categorized as critical, major, or minor; notably, three minor deviations may be reclassified as a major deviation. The QA Director was authorized to review and approve minor deviations. For each deviation, QA appoints an investigative team to determine the cause and root cause, as well as to conduct a risk assessment. Investigations must be completed within specified days; if this deadline cannot be met, an adjustment request should be submitted. Corrective and Preventive Actions (CAPA) for critical and major deviations required approval by the Quality Head.

The Deviation Register for 2025 was available. Investigation reports for deviations have been completed and found to be compliant.

Internal audit / Self inspections

Self-inspection was conducted in accordance with the established plan. Upon completion, a report was prepared, and any identified deficiencies were communicated to the respective department. The inspected department then proposed and implemented corrective actions. The relevant quality management offices monitored and verified the effectiveness of these corrective measures. Due to time constraints this section was not inspected in detail.

Product release

The SOP *Product release procedure* was verified. The Authorized Person released products after reviewing production, QC, and QA assessments, then signed the certificate. Company policy prohibits commercialization of any engineering, test, pre-validation batches of Intermediates.

The letter for staff responsible for product release was duly signed and dated by the General Manager. These personnel report directly to the Quality Director, who is accountable to the General Manager. The Product batch release for *Rifamycin S Sodium* was verified. Final CoAs sent to the client were dated and signed by QA manager or QP.

Change Control

The Change Control process was not conducted separately. Instead, all change control procedures were implemented after a risk assessment was carried out. This assessment covered process, facility, utilities, raw material control, supplier evaluation, process assessment, and process validation, with each aspect examined individually as part of the overall risk review. Based on this risk assessment and relevant change controls, a Contamination Control Strategy (CCS) was established to facilitate the introduction of pharmaceutical manufacturing—specifically *Rifamycin S Sodium* at the Keming site, seeing that the site primarily serves as a food and dietary supplement production facility.

Data Integrity

Data integrity was governed by a written procedure, covering both manual and electronic records. Compliance with this policy was a collective responsibility shared by all personnel. Key elements of the policy included provisions for electronic signatures and adherence to ALCOA principles.

Electronic data management incorporated a classification strategy and robust security protocols. Data backup operations were performed daily and weekly. Audit trail access was provided, and data was retained on the server. A business contingency plan was available for handling data disasters.

2. Personnel

The company maintained an organization chart that clearly distinguished the duties and reporting lines of its quality and production departments. Job descriptions were identified and available. The job descriptions of the following key personnel were reviewed:

- Quality Director, Quality Management Department
- Deputy Quality Director and Quality Manager
- Head of Quality Assurance and Responsible person for product Release

The Company employed 700 employees according to the company's SMF at the time of inspection. The number of personnel appeared adequate to the present activities. In general personnel met during the inspection are aware and follow the GMP principles with appropriate qualifications and experience.

Training

Enough qualified, trained, and experienced personnel were available to meet operational needs. The Human Resources department oversaw all aspects of training. A comprehensive training program was designed for new or transferred employees, which underwent review by both the department director and the Quality Assurance team. Training and subsequent evaluation were conducted accordingly. Assessment outcomes required approval from the department director and human resources, with final confirmation provided by Quality Assurance prior to commencement of work duties.

Hygiene

Personnel received comprehensive training in proper sanitation practices and health maintenance. Direct contact with intermediates was strictly avoided. Individuals presenting infectious diseases or open lesions on exposed skin were excluded from duties that could compromise API quality. Annual physical examinations were mandated for all employees. Those failing to meet the health criteria were restricted from tasks involving direct contact with food or pharmaceuticals. Certain roles required additional specialized medical evaluations.

3. Buildings and facilities

Buildings and facilities for manufacturing intermediates were designed and constructed for easy cleaning, maintenance, and operation suitable to each production stage. They were properly maintained and kept clean throughout the manufacture of intermediates and APIs.

The production blocks for *Rifamycin S Sodium* included Workshop 3016A, Workshop 3016B, Workshop 3016, Workshop 3026and Workshop 3036 which formed the basis of the inspection.

Water system

Drinking water and deionized water were used in the production of *Rifamycin S Sodium*. In the workshops, they were used for production, equipment cleaning, and solution preparation. The deionized water system was briefly visited.

Steam

Steam served as a sterilization agent for equipment and culture medium materials during the fermentation process. A brief inspection of the steam generator was conducted.

HVAC

The clean area classified as Class C for Rifamycin production was visited. Temperature and humidity within clean rooms were regulated by programmable logic controllers (PLCs), which controlled cooling, heating, humidification, and electric valve adjustments. The variable frequency fan delivered uniform air supply and maintained appropriate air exchange rates. The following documents were reviewed:

- SOP *HVAC operation procedure*"
- SOP *Clean groom (Area)Environment monitoring procedur*e
- E*nvironmental monitoring results for operation room applicable to Refa*.

Nitrogen

Nitrogen was produced in house with the dew point monitored. Nitrogen plant for Workshop 3036 was briefly visited during the inspection.

Sanitation and maintenance

Overall, facilities designated for the production and testing of intermediates were consistently well-maintained and remained in a clean state.

4. Process equipment

Equipment for intermediate and API manufacturing was properly designed, sized, and located for use, cleaning, and maintenance. Materials in contact did not affect product quality. All equipment was dedicated to *Rifamycin S Sodium* production.

Equipment Qualification

Equipment qualification was performed following written procedures which included:

- SOP "*Procedure for DQ*"
- SOP "*Procedure for OQ*"
- SOP "*Procedure for PQ"*

The qualification of an autoclave was checked and discussed.

Equipment maintenance

The procedure for equipment maintenance and cleaning and the SOP for handling the deionized water unit was verified.

Equipment cleaning

Equipment and utensils were cleaned, sanitized, and stored to prevent contamination or quality changes in intermediates or API. Each piece was labeled for contents and cleanliness. Rifamycin production equipment was cleaned according to a validated process.

5. Documentation and records

The site's documentation system was primarily paper based. Documents for manufacturing intermediates or APIs were drafted, reviewed, approved, and distributed per written procedures, with issuance and revision history tracked according to SOP "*Good document practices".* The SOP *"Quality related documents managemen*t" established document retention procedures.

Laboratory control records included complete data derived from all tests conducted to ensure compliance with established specifications and standards, including examinations and assays.

Batch numbering and BMR management

The batch number for Rifamycin S was assigned according to the respective production stages. A reprocessed batch was referenced in the batch number. A batch number register was maintained.

The SOP *Control procedure of production records* was available and reviewed.

6. Materials management

Materials were stored in warehouses based on temperature needs and material type. The storage facilities were intended for production materials, encompassing raw and auxiliary materials, finished products, packaging components, labels, and hazardous chemicals. The area and capacity of the storage spaces were appropriately matched to the current scale of production, with designated zones allocated for material sampling. Ample space was provided for materials, items pending testing, and finished goods, ensuring compliance with specific storage requirements. The areas were maintained in a clean and dry state, with temperature and humidity routinely monitored and controlled.

Written procedures describing the receipt, identification, quarantine, storage, handling, sampling, testing and approval or rejection of materials were available. Materials could be received either manually or by entering them into the WMS system. Warehouses for *Rifamycin S Sodium* were briefly visited. The SOP "*Material primary checking procedure*", SOP *"Sampling of materials*" and Solvent tank farm were verified.

Mapping Studies:

Temperature mapping for finished products warehouse was performed following written procedures. Data logger calibration certificates are available. The same data logger was used for both temperature and humidity measurements.

Vendor approval

The SOP for vendor approval was reviewed along with the approval process for starting materials. The vendor approval process covered auditing, quality agreements, material assessment, and document review. Supplier qualification included annual requalification, classifying suppliers as excellent, qualified, or unqualified.

7. Production and in-process controls

The production workshops were not dedicated to *Rifamycin S Sodium* manufacturing. Raw materials were weighed and measured using appropriately accurate devices. Written procedures were established to monitor the progress and control the performance of processing steps that cause variability in the quality characteristics of the intermediate. In-process controls and their acceptance criteria were defined.

All production steps were in operation during the WHO inspection. The relevant production areas were visited. Manufacturing processes were generally adequately defined. The manufacturing processes follow procedures as defined and documented in the BMRs and BPRs.

Contamination and Cross-Contamination Control

A QRM procedure was in place, structured in accordance with ICH Q9 guidelines. The procedure detailed the use of Failure Mode Effects Analysis (FMEA) along with other quality risk management methodologies. RPN (Risk Priority Number) for high, medium or low risk and the acceptance criteria were defined. Relevant risk assessment reports related to the production of *Rifamycin S Sodium* were reviewed.

8. Packaging and identification labelling of APIs and intermediates

During the visit to the production workshop, packaging/labelling operations were not carried out. According to the BMR reviewed during the inspection, line clearance was documented before and after labelling/packaging procedures.

9. Storage and distribution

Facilities were available for the storage of materials under appropriate conditions. Records were maintained of these conditions. A system was in place by which the distribution of each batch of intermediate and/or API can be readily determined to permit its recall.

10.Laboratory controls

Physicochemical laboratory

Adequate quality control facilities were provided. Procedures were in place describing sampling, testing, approval or rejection of materials and recording and storage of laboratory data. Specifications, sampling plans, and test procedures were documented and accessible.

Laboratory controls were followed and documented at the time of performance. Any departures from procedures were documented and explained. OOS results obtained were investigated and documented according to a procedure.

Reagents and standard solutions were prepared and labelled following written procedures. Reagents prepared in laboratory were appropriate labelled, expiry dates were defined for all reagents and were based on stability studies.

Primary reference standards were available. Working reference standards (WS) were appropriately prepared, identified, tested, approved and stored.

Laboratory tests were performed for each batch of Intermediate. CoAs were issued for each batch of intermediate. SOP "*Certificate of analysis template*" was verified. Final CoAs sent to the clients were dated and signed by QA manager or QP.

Documented, stability testing programme was in place. Test procedures used in stability testing were validated. Stability samples were stored in packaging that simulate the market container. Intermediate expiry / retest date was based on an evaluation of data derived from stability studies.

OOS

OOS results were investigated and handled according to *SOP Out of Specification (OOS/OOT/OOE) Investigation Procedure*. No OOS results for 2025 addressing *Rifamycin S Sodium*.

Stability studies

The ongoing stability study for *Rifamycin S Sodium* was conducted following the procedures outlined in the stability protocol and the associated testing schedule. Each year, one batch was selected for the study. The designated test intervals for these samples were 0, 3, 6, 9, 12, 18, 24, 36, and 48 months.

Retention samples

Samples of starting materials, intermediates and finished products were retained in QC as per the procedure *SOP Management of Retention Samples*. The retained samples were stored in the same or similar packaging materials to that used for market.

Laboratory equipment

All laboratory equipment had usage and calibration logbooks.

11.Validation

VMP

The SOP *Validation master plan* was reviewed. It described the validation policy and specified that VMP should be periodically reviewed. Annual VMP plan should be established in December of the year and reviewed the following January. The Validation master Plan for 2025 was available.

Process validation

Process validation was performed following written procedures. The procedures indicated that at least three consecutive batches in commercial batch size should be engaged in the process validation. Holding time study was required.

Process validation for *Rifamycin S Sodium* were verified. PV protocols, reports and PV batches were reviewed. The product Batch size was defined.

Cleaning Validation

The SOP *Cleaning validation* was verified. A risk assessment was required. The acceptance criteria were established based on

- Visual inspection
- Residue of API/intermediate
- Microbial contamination.

The site's equipment was dedicated to *Rifamycin S Sodium* production, with a cleaning validation report available. Both swab and rinse methods were used, and the most challenging areas for cleaning and sampling were identified and documented. The dirty hold time and clean hold times for equipment were established.

Analytical method validation

The "*Analytical method validation report for assay and related substance of Rifamycin S Sodium* was verified and found to be acceptable.

Computerised system validation

Computerized systems were utilized for production (Fermentation process) and the chemical laboratory. These were spot checked during the tour in a production workshop. Due to time constraints, the computerized system validation was not inspected in detail.

Computer validation for the computerised system in the warehouse was spot checked. Access control, data entry, operational confirmation, QR code printing and recognition were reviewed. The handheld reader was verified for correct displaying of information.

12.Change control (CC)

The SOP "*Change control procedure*" and flow chart were checked. The Quality Department oversaw the change request, supervise implementation, and approve the change. Changes were classified as minor, moderate and major based on nature, scope and impact on safety, effectiveness, and quality of the product. Following the change, some development work might be required such as stability studies, validation, regulatory approval, etc. The Change Control register for 2025 was available. Changes related to *Rifamycin S Sodium* were checked.

13.Rejection and re-use of materials

Rejection, reprocessing and reworking

The procedures to handle non-confirming products were available. The SOP "*Nonconforming product handling procedure*" and SOP "*Nonconforming product handling procedur*e" were verified.

Reprocessing and Reworks

Non-compliant intermediates or products were allowed one reprocessing or reworking according to the company SOP. Regulatory approval for reworked product was discussed.

Recovery of Solvents

Solvent recovery and its process validation related to *Rifamycin S Sodium* production were checked and discussed.

14. Complaints and Recalls

The complaint management process stipulated that staff receiving complaints need to promptly inform the Quality Assurance (QA) team. QA was responsible for recording, categorizing, and investigating each complaint, as well as preparing reports as required. Following an investigation, appropriate preventive and corrective actions were implemented when necessary. So far, there have been no recorded product complaints up to inspection dates, noting that only one customer from the ZMC group has been served.

Recalls

A recall procedure was in place to address potential safety hazards found in drug substances, whether through complaints or other sources. The procedure required that the Quality department works with other departments to investigate and evaluate the risks before developing a recall plan. The risk plan was reviewed by the Quality department and approved and signed by the responsible company authority. When the recall plan went into effect, the Quality department was required to inform the applicable drug regulatory authorities.
This section was not thoroughly assessed due to limited time.

15.Contracts

Quality agreements were spot checked. Contracts permitted the contract giver to audit the contract acceptor's facilities for compliance with GMP. Subcontracting was not allowed. Contract acceptor and contract giver responsibilities were clearly defined.

Examples of contracts with vendor and/or service provider were checked and discussed.

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, ***Zhejiang Keming Biopharmaceuticals Co. Ltd*** located at ***1 Dingshan Road, Yulin Subdistrict, Xinchang, Zhejiang, R.P. China*** was considered to be operating at an acceptable level of compliance with WHO GMP Guidelines.

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 three 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-eight 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**
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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. Fifties 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**
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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.
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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

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

27. WHO good manufacturing practices for excipients used in pharmaceutical preparations. Fifty-seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052, Annex 2.
Short name: WHO TRS No. 1052, Annex 2
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