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Prequalification Unit Inspection Services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Finished Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Swiss Pharma Nigeria Ltd. (Swipha)
Corporate address of the manufacturer	No. 5 Dopemu Road, Agege, Lagos, 100273, Nigeria
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/block / workshop number	Pharma plant
Inspection details	
Dates of inspection	01 - 05 September 2025
Type of inspection	Routine inspection
Introduction	
Brief description of the manufacturing activities	• Manufacturing of oral solid dosage forms (coated and uncoated tablets) and liquid dosage forms (syrups and suspensions). • Distribution of imported products.
General information about the company and site	In 1976, Swiss Pharma Nigeria Limited (Swipha) was incorporated as Roche Nigeria Limited. In August 1999, the company was renamed as Swiss Pharma Nigeria Limited (Swipha). In 2017, Swipha was acquired by Biogaran, a subsidiary of Servier. In October 2024, Swipha was acquired by Micro Labs Limited. The site is located in Dopemu, adjacent to the Dopemu flyover on the Lagos-Abeokuta Expressway, within the Agege Local Government Area of Lagos State.
History	The site has been inspected by the WHO PQT team in September 2022 and February 2024. The site was regularly inspected by the National Agency for Food and Drug Administration and Control (NAFDAC).
Brief report of inspection activities undertaken - Scope and limitations	
Areas inspected	Documents reviewed: • Quality management • Data integrity • Change control

	• Deviations and CAPAs • Sanitation and hygiene • Qualification and validation • Complaints • Product recalls • Contract production, analysis and other activities • Self -inspection and supplier audits • Personnel • Training • Personal hygiene • Facilities and utilities • Materials management • Equipment • Documentation and records • Production and in-process controls • Laboratory controls Visited the following areas: • Pharma plant • Warehouse • QA building, which housed the QC laboratories - Physicochemical and Microbiological • Utilities - HVAC, Water system, Compressed air system • Stability chambers • Retention samples
Restrictions	The inspection was restricted to the manufacturing of the product in the WHO PQ program.
Out of scope	Products and facilities outside of the WHO PQ program.
WHO product numbers covered by the inspection	DI014 Zinc (sulfate) Tablet, Dispersible 20mg MA180 Pyrimethamine/Sulfadoxine Tablet 25mg/500mg
Abbreviations	**Meaning**
ADE	Acceptable daily exposure
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
AP	Authorized person
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
CAPEX	Capital expenditure
CC	Change control
CFU	Colony-forming unit
CIP	Cleaning in place
CoA	Certificate of analysis

CpK	Process capability
CPP	Critical process parameter
CQA	Critical quality attribute
DIRA	Data integrity risk assessment
DQ	Design qualification
EM	Environmental monitoring
FMEA	Failure modes and effects analysis
FPP	Finished pharmaceutical product
FTA	Fault tree analysis
FTIR	Fourier transform infrared spectroscopy
GMP	Good manufacturing practices
GPT	Growth promotion test
GRN	Goods received note
HBEL	Health-based exposure limit
HEPA	High efficiency particulate air
HMI	Human-machine-interface
HPLC	High performance liquid chromatography (or high performance liquid chromatography equipment)
HVAC	Heating, ventilation and air conditioning
IQ	Installation qualification
IR	Infrared
KPI	Key performance indicator
LAF	Laminar air flow
LIMS	Laboratory information management system
MA	Marketing authorization
MACO	Maximum allowable carryover
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MR	Management review
NC	Non conformity
NRA	National regulatory agency
OOS	Out of specification
OOT	Out of trend
OQ	Operational qualification
P&ID	Piping and instrumentation diagram
PDE	Permitted daily exposure
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PPQR	Periodic product quality review
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PSD	Particle size distribution

PW	Purified water
PV	Process validation
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
RFT	Right first time
RH	Relative humidity
RO	Reverse osmosis
RS	Reference standard
SMF	Site master file
SOP	Standard operating procedure
SS	Stability study
STP	Standard test procedure
TOC	Total organic carbon
URS	User requirements specifications
UV	Ultraviolet
UV-VIS	Ultraviolet-visible spectrophotometer

Part 2	**Summary of the findings and comments (where applicable)**

1. Pharmaceutical quality system

A documented system for quality assurance was established, with procedures in place that cover key quality elements. The Quality department was divided into QA and QC and was separated from the Production department. Operations were specified in written form, and critical GMP requirements were essentially met. The procedures reviewed and discussed during the inspection were generally of an acceptable standard; however, in some cases, improvements are sought.

Product quality review

The SOP on "Periodic Product Quality Review (PPQR)" outlined the purpose, scope, responsibility and procedure. QA coordinated and administered the PPQRs. Final PPQR reports were reviewed using a standardized checklist.

The following PPQRs were reviewed:

1. DI014 Zinc (sulfate) Tablet, Dispersible 20mg
   No commercial batches of DI014 Zinc (sulfate) Tablet have been produced and supplied to the market since the product was PQed in May 2023.

2. MA180 Sulfadoxine Pyrimethamine (SP) 500mg/25mg Tablet, uncoated
   Commercial batches have been produced since the product was PQed in August 2024.

Quality risk management (QRM)
A QRM system was implemented according to a documented SOP. Failure Modes Effects Analysis (FMEA) was commonly used as a tool and a "Risk Register" was maintained.

Risk assessments pertaining to Process Validation (PV) of SP tablets and data integrity risks associated with standalone chromatogram instruments in the QC laboratory were reviewed.

DIRA (Data Integrity Risk Assessment)
The procedure on data integrity applied to all GxP data and outlined ALCOA principles and data governance. Electronic QC data was managed in accordance with documented SOPs. User group privileges were defined and documented.

Management review (MR)
According to the documented SOP. MR meetings were to be held twice a year. These meetings covered communication on deviations, changes, Right First Time (RFT), Corrective and preventive Actions (CAPAs), and identified areas for improvement, etc. Attendance by senior management of the company was required.

The meeting was held in April 2025. The presentation, prepared by QA, was available. The senior management and department heads participated in the MR meeting. Attendance records were available. Key Performance Indicator (KPI) monitoring was checked. The meeting minutes documented areas for improvement.

Change control
Change controls were managed in accordance with a documented SOP. The procedure detailed two different types of changes:

- Major change
- Minor change

Change control was the responsibility of the QA/Compliance Team. A Change Control Team was appointed, comprising delegates from all departments who were tasked with conducting the impact assessment of the proposed changes, implementing approved changes, and providing reports on the changes implemented. A Change Control Committee evaluated and approved all changes for implementation. Action plans were required to be executed and closed within one year of initiation. Change Control Log Sheets were maintained. Examples of change controls were checked.

Deviations
The SOP on deviation and incident handling described the process for managing deviations. Trend analysis was performed. Deviation Registers and examples of deviations were reviewed.

Corrective and preventive actions (CAPA)
The CAPA SOP outlined the process for initiating and documenting CAPAs, conducting root cause analysis, proposing actions, implementing within defined timelines, and verifying completion by QA prior to closure. Effectiveness checks were required post-closure.

OOS/OOT

OOS/OOT procedures were in place. OOS registers were maintained, and examples of OOS were checked.

Product release

Product release was managed in accordance with a documented SOP. The Authorized Person (AP) was responsible for the final review of all the relevant documents, including Batch Manufacturing Records (BMR), Batch Packaging Records (BPR), and batch testing records, prior to releasing finished products. The batch release procedure was verified.

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Sufficient human resources, suitable facilities, and the necessary equipment and utilities were in place to support the current level of FPP operations. Manufacturing activities were performed in accordance with the procedures defined and recorded in the BMRs and BPRs. The personnel were appropriately qualified and adequate training was conducted.

3. Sanitation and hygiene

Sanitation and hygiene procedures were established and implemented, covering personnel, premises, equipment and apparatus, production materials and containers, as well as cleaning products.

4. Qualification and validation

Validation master plan (VMP)

The company maintained a policy to qualify and validate the manufacturing facility. The VMP for 2025 was reviewed, and reference was made to a continuous process validation approach.

Process validation (PV)

The SOP covering PV was checked. The procedure described that the process validation activities were carried out in three stages:

- Stage 1: Process Design
- Stage 2: Process Qualification
- Stage 3: Continued Process Verification

The PV of MA180 Pyrimethamine/Sulfadoxine Tablet 25mg/500mg was checked and discussed.

Cleaning validation

Cleaning validation was conducted using a risk-based approach. Worst-case products were selected based on solubility, toxicity, Health Based Exposure Limit (HBEL), including Acceptable Daily Exposure (ADE) and Permitted Daily Exposure (PDE), and batch size. Cleaning procedures were validated using swab sampling and validated analytical methods. Acceptance criteria included visual cleanliness, Maximum Allowable Carryover (MACO) limits, microbial specifications, and verification for detergent residue. Hold times and cleaning types were defined in SOPs, and documentation was maintained via labels, certificates, and checklists.

Equipment Cleaning Risk Assessment and Cleaning Validation Report for a granulator were checked.

Computer system validation

Computerized systems were utilized in the QC laboratory to network Gas Chromatography (GC) and High-Performance Liquid Chromatography (HPLC) instruments and in material management, stock and status control. The computerized system validation was conducted in accordance with the policy described in the VMP. The computerized system validation was spot checked.

5. Complaints

Complaints concerning potentially defective products were managed in accordance with a documented SOP which outlined the required actions in response to product defect complaints.

A designated QA person (Documentation Process Improvement Supervisor) was assigned responsibility for complaint handling and decision-making, supported by adequate personnel. The Quality Manager/Authorized Person (AP) was informed of all complaints. All complaints were recorded in a "Product Complaint Logbook". An example of complaint handling was checked.

6. Product recalls

An SOP was established to enable prompt and effective recall of products from the market that were known or suspected to be defective. The responsibility for executing and coordinating all product recall activities was assigned to the Quality Manager/Authorized Person (AP), with support from designated personnel to ensure timely and effective implementation.

The effectiveness of the recall arrangements was tested annually by performing a mock recall and evaluating to ensure continued readiness and compliance. A mock recall report was verified.

7. Contract production, analysis and other activities

No contract production activities were utilized by the company for the products under inspection.

Contract testing laboratories were used for the PSD testing of Sulfadoxine and Pyrimethamine Active Pharmaceutical Ingredient (API). The associated quality agreement was checked.

8. Self-inspection, quality audits and suppliers' audits and approval

Self-inspections

Self-inspections were performed annually to assess the manufacturer's compliance with GMP across production and quality control activities. The Quality Manager appointed trained internal auditors with appropriate competence and impartiality. A cross-functional audit team was established jointly by the Lead Auditor (Quality Manager) and QA Compliance Head, based on job experience and relevant training.

Supplier audits

An SOP was established for vendor management. A "Master List of Approved Vendors" was maintained. An annual evaluation of approved suppliers was performed in accordance with the documented SOP. The audit report on the API supplier of Pyrimethamine and Sulfadoxine was checked.

9. Personnel

An organizational chart was maintained to reflect reporting lines and functional responsibilities. The manufacturer had an adequate number of personnel with appropriate qualifications and experience to support operations.

Job descriptions

Written job descriptions were issued for responsible personnel, outlining specific duties and delegated authorities.

10. Training

The SOP on training detailed the on-site training program. QA and departmental heads developed an annual schedule based on identified training needs. Annual training covered changes in cGMP requirements, newly issued or revised SOPs, and the introduction of new processes, methods, or equipment. Training records were retained following the SOP.

11. Personal hygiene

Personnel hygiene requirements were documented in an SOP. The requirements for entry into Grade D cleanrooms were clearly outlined, including pictorial drawings displayed in the changing rooms. Personnel observed in these areas were dressed in appropriate protective clothing. Direct hand contact with starting materials, primary packaging, and intermediate or bulk products was avoided.

12. Premises

Production areas

The production block was multi-product and non-dedicated. Manufacturing areas were of an acceptable standard and were suitable for the activities conducted therein. Exposed surfaces were smooth, non-porous, and intact, preventing particle or microbial buildup and enabling repeated cleaning applications. The classified areas were monitored for temperature, relative humidity and pressure differentials with a manual system for environmental control.

Storage areas

Warehouse had sufficient capacity and appropriate segregation for all material categories, including quarantined, released, rejected, returned, and recalled items. Environmental conditions such as temperature and humidity were controlled and manually monitored. The receiving and dispatch bays were separated and adequately protected from weather exposure. Pest control procedures were implemented.

Quality Control areas

QC laboratories (Chemistry and Microbiology) located within the QA building were physically separated from production areas. The Chemistry laboratory had adequate storage space provided for samples, reference standards, solvents, reagents, and records. Retention samples were kept in a secure room. Stability chambers were located in different buildings. The Microbiology laboratory was separated from the Chemistry laboratory.

HVAC system

The HVAC system, which provided filtered air to the Grade D cleanrooms, was briefly visited and spot-checked. The following documents were checked:

- HVAC Zoning Layout Drawing
- HVAC Pressure Cascade Drawing
- Re-qualification Report for Cleanroom Validation (HVAC) approved in January 2025.

Water system

The water system was briefly visited. The Piping and Instrumentation Diagram (P&ID) of the PW system was checked. The water system produced potable water and purified water (PW). The sanitization of the PW system was performed periodically. The system was controlled between 20°C and 25°C. Total Organic Carbon (TOC) and conductivity were monitored online, and pH was monitored offline. Samples were tested chemically and microbiologically.

Compressed air

The compressed air unit serving the production block (clean zone) was briefly visited. The system included air compression with a refrigerant dryer and several filtration steps. The P&ID of compressed air, Performance Requalification Report for Compressed Air and Specifications for compressed air were checked.

Lighting

Lighting was adequate in all areas visited during the inspection.

13. Equipment

Equipment installed in the production block was multi-purpose and each piece of equipment had a unique identification number. The equipment appeared to be of suitable design and construction for its intended purpose.

Equipment maintenance and cleaning

The equipment viewed during the inspection appeared to have been suitably maintained and in good condition. Equipment status labels were present. The preventive maintenance schedule was available, and implementation was monitored.

14. Materials

The SOP on the receipt and management of goods was checked. Upon receipt of incoming materials at the Receiving Bay, each consignment was checked using a checklist. Raw materials were weighed, dedusted and labelled. The raw materials were stored in the “Raw Material Quarantine” area. Deliveries containing multiple batches were treated as separate batches for sampling, testing, and release.

GRNs forwarded to QC for sampling. The SOP on raw material sampling included a sampling guide, sampling plan and examples of quarantine, released and rejected labels. Sampling was performed by trained QC personnel in an ISO 8 Sampling Booth located in the Warehouse. Samples were analyzed per the approved specifications. If approved, labelled with a green “RELEASED” label and material transferred to the “Approved Raw Material” area. Non-conforming materials were

labelled with a red "REJECTED" label, and the material was transferred to the secure "Rejected Material" area.

A walkthrough the "Quarantine Finished Goods/Approved Finished Goods/Approved Packaging Material" area was conducted.

Temperature mapping
An SOP was in place detailing the procedure for conducting temperature mapping.

15. Documentation

The documentation system was designed, prepared, reviewed and distributed following written procedures. Approved, signed, and dated specifications and test methods were available for starting materials, packaging components, and finished products. Documentation was primarily maintained by a manual system, with some data managed in a computerized system. An SOP on data management defined the retention period for data/records.

Batch numbering system and BMR management
The procedures on batch numbering for manufactured products and issuance, receipt, storage, and destruction of batch production record, were reviewed. Authorized master formulae were available for commercialized products. Batch manufacturing records (BMRs) were maintained for every batch produced. The management of batch numbering of reprocessed batches and product code allocation was checked and discussed.

16. Good practices in production

The production facility was visited. The production for SP tablets for the domestic market was in operation at the time of inspection. Tablet manufacturing steps, including material dispensing, granulation, compression, primary, secondary packaging areas and finished product storage rooms, at the site were inspected. Manufacturing records of the products under production were spot-checked and found to be acceptable.

In-process control was conducted within the IPC laboratory located inside the production facility. Appropriate testing equipment was available to support routine IPC activities.

The manufacturing processes were performed and recorded according to instructions in the batch production records.

Zinc Sulfate Dispersible Tablet 20mg production has not been performed since it was PQed in May 2023.

Reprocess and rework
The SOP on reprocessing procedure for bulk, intermediate and finished products, was reviewed. The document described procedures for reprocessing of bulk, intermediate and finished products that do not conform to established specifications. A "Reprocessing Register" was maintained for reprocessed batches. Reworking of products was not permitted.

Return of products
Returned goods were defined as finished products that did not meet customer specifications, showed breakage/damaged packaging or were considered non-compliant.

17. Good practices in quality control

The QC function was independent of other departments. QC laboratories were physically separated from production areas and housed in a separate building, with the Chemistry laboratory and Microbiology laboratory located in separate areas.

Sample receiving and distribution of samples
An access-controlled area for sample reception was available. The "Sample Register", and the records for receipt and distribution, was examined. The traceability of raw data was available in the sampling records.

Testing of starting material and finished products
The procedure for testing and release of Sulfadoxine API were spot-checked. For WHO PQed SP tablets, samples were taken from the primary packaging line. The reference substance for the related substance test of SP tablets was checked and discussed.

Instrument calibration
Calibration status and records of several QC instruments were checked. Instruments were serviced and calibrated at predefined intervals and records were maintained. Instrument calibration labels indicated the date of calibration and servicing and the recalibration due date. Balances of an appropriate range and precision were available.

Retention samples
Retention and retained samples were stored in a secure, temperature-controlled room maintained below 25°C and separate from other areas. The SOP on finished product retention samples management was checked. The "Retention Sample Register" and samples of each batch were kept. Annual checks were performed in accordance with the procedure. Retention samples were retained 1 year beyond expiry, in marketed packaging.

Stability studies
Stability chambers were located in a separate room, separate from other areas. The company had stability chambers for long-term and accelerated stability studies at the conditions of 40°C/75% RH, 30°C/75% RH and 25°C/60% RH. Chambers were qualified in accordance with the in-house procedure.

SP PV stability study samples batches inward in the chamber controlled at 30°C/75% RH were recorded. The SP PV batches were completed in 2025, and stability study data were spot checked with no OOS reported.

Microbiology laboratory

Microbiological testing was performed by qualified microbiologists with experience in microbiology. The following microbiological testing was undertaken:

- Testing of oral solid and liquid dosage forms
- Testing of raw materials and primary packaging materials
- Testing of Potable water and PW
- Personnel monitoring
- Environmental monitoring

Media was prepared in-house using PW. Growth promotion tests were conducted on every batch and media performance was assessed. Reference cultures used were traceable to ATCC collections. Reference cultures were subcultured once to create stocks and working stocks were not subcultured more than five passages.

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, ***Swiss Pharma Nigeria Ltd***., located at ***No. 5 Dopemu Road, Agege, Lagos, 100273, Nigeria*** 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 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
   https://www.who.int/publications/m/item/trs986-annex2

2. 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
   https://www.who.int/publications/m/item/annex-2-trs-957

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
   https://www.who.int/publications/m/item/trs-1025-annex-4

4. 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 1019, Annex 3
   https://www.who.int/publications/m/item/trs1019-annex3

5. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3.
   Short name: WHO TRS No. 943, Annex 3
   http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

6. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1.
   Short name: WHO TRS No. 957, Annex 1
   https://www.who.int/publications/m/item/trs957-annex1

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
   https://www.who.int/publications/m/item/trs957-annex3

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
   TRS 1044 - 56th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

9. WHO guidelines on transfer of technology 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
   TRS 1044 - 56th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

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
https://cdn.who.int/media/docs/default-source/medicines/norms-and standards/guidelines/distribution/trs961-annex9-modelguidanceforstoragetransport.pdf?sfvrsn=b80e925f_5

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
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs981-annex2-who-quality-risk-management.pdf

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
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs981-annex3-who-variations-prequalified-product.pdf?sfvrsn=809e81b_2

15. 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
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs992-annex4.pdf?sfvrsn=2a1980f0_2

16. 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
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs992-annex5.pdf?sfvrsn=99aedfbe_2

17. 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**
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs966-annex10.pdf?sfvrsn=5d94f486_2

18. 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
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1010-annex8-who-gmp-heating-ventilation-airconditioning.pdf?sfvrsn=c77698e2_0

19. 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
https://extranet.who.int/pqweb/sites/default/files/documents/TRS1010_Annex10.pdf

20. 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

21. 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

22. Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 6.
Short name: WHO TRS No. 1025, Annex 6
https://www.who.int/publications-detail/978-92-4-000182-4

23. 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/m/item/annex-2-trs-1033

24. 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

25. 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