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

Part 1	**General information**
Manufacturers details	
Name of manufacturer	**S Kant Healthcare Pvt Ltd**
Corporate address of the manufacturer	3-A, Shiv Sagar Estate, North Wing, Dr. Annie Besant Road, Worli, Mumbai-400 018, India
Name & address of inspected manufacturing site if different from that given above	S Kant Healthcare Pvt Ltd 1802-1805, G.I.D.C., Phase III Vapi-396 195, Gujarat, India.
Unit/block/ workshop number	Formulation Plant
Dates of inspection	24-27 February 2025
Type of inspection	Routine GMP inspection
Introduction	
Brief description of the manufacturing activities	The manufacturing site manufactures different dosage forms, viz., Solid Oral Dosage Form (Tablets, Capsules & Oral Dry Powder (suspension)), Liquid Oral Dosage Form (Suspension, Solutions & Syrup), and Semi-Solid Dosage Form for Topical Application (Ointments, Gel & Creams).
General information about the company and site	S Kant HEALTHCARE Ltd. was established in 1996. The manufacturing site is located at 1802-1805, Phase III, G.I.D.C., Vapi, 396195, Gujarat, India.
History	This was the third PQ inspection of S Kant Healthcare. The last inspection was performed in June 2022.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The following areas were inspected: - Pharmaceutical quality system - Personnel, training, hygiene, and sanitization - Production, packaging, and finished goods stores - Quality control laboratory, including microbiology laboratory - Equipment and instrument calibration, preventive maintenance, and requalification - Supplier qualification(For example: blocks inspected, areas of interest, scope and focus of inspection) - Cleaning validation and analytical method validation - Purified water system and air handling units
Restrictions	None

Out of scope	Products and areas other than those for WHO Prequalification were outside the scope of this inspection.
WHO products covered by the inspection	1. Sulfadoxine and Pyrimethamine dispersible tablets (MA144) 2. Sulfadoxine and Pyrimethamine dispersible tablets (MA145) 3. Amodiaquine, Sulfadoxine, and Pyrimethamine dispersible tablets (MA146) 4. Amodiaquine, Sulfadoxine, and Pyrimethamine dispersible tablets (MA147) 5. Sulfadoxine and Pyrimethamine tablets (MA193) 6. Pyridoxine hydrochloride tablets 50mg (TB401) 7. Isoniazid dispersible tablets (TB405) 8. Pyridoxine hydrochloride Tablet 10mg (TB413)
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original, and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
APS	Aseptic process simulation
BMR	Batch manufacturing record
BPR	Batch production record
CC	Change control
CFU	Colony-forming unit
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
LAF	Laminar air flow
LIMS	Laboratory information management system
MB	Microbiology
MBL	Microbiology laboratory
MF	Master formulae
MFT	Media Fill Test
MR	Management review
NC	Non conformity

NRA	National regulatory agency
OQ	Operational qualification
PHA	Process hazard analysis
PLC	Programmable logic controller
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RO	Reverse osmosis
SIP	Sterilization in place
SMF	Site master file
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometer
WFI	Water for injection

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

1. Pharmaceutical quality system

The quality management system was divided into quality assurance and quality control. The QA and QC departments were independent from manufacturing. The person responsible for quality managed the overall product quality. The QA had oversight of all document control processes. The QA department conducted a product release in accordance with the material and product release procedure. Detailed descriptions of the Standard Operating Procedures (SOPs) formed part of the quality system. The QA was responsible for documents (analytical control procedures, specification sheets, manufacturing instructions, master batch records, manufacturing and batch control records, analytical methods, process validation protocols and reports, stability reports, and review of audit trails).

Product quality review/PQRs

The report was discussed, and it was noted that a validated Excel sheet was used to calculate various statistical parameters (CpK, RSD, upper control, and lower control). The procedure described how to perform statistical analysis using Annexure III. The procedure also listed various parameters to be reviewed as part of the PQR, which was found to be in line with the WHO GMP for FPP. The PQR planner was available, and various products were divided into different months as a rolling review. The PQRs for the WHO products were reviewed.

Quality risk management/QRMs

The QRM procedure was reviewed, and it was noted that the procedure was prepared in accordance with the WHO requirements. The risks were assessed following the FMEA tool.

Change control:

The procedure for handling change controls was discussed. The procedure included examples of various changes, including the introduction of new products through technology transfer. Before introducing a new product, a risk assessment should be performed to consider permissible daily exposure, solubility, and cleanability, in accordance with the change control procedure. The changes were categorized as either major or minor.

Handling of planned deviations

The SOP for planned deviations was discussed. It was noted that the company has a separate procedure for handling incidents (unplanned deviations). Planned deviations were classified as either major or minor and must be closed within three months of approval. The trend analysis for 2024 was reviewed, and it was noted that some deviations were compared with those of previous years and found to be on the lower side.

Management Review

The management review principles were described in the SOP "Management Review Report". The procedure outlined the scope of issues that should have been reviewed to conduct the management review, including, among others, OOS (Out of Specification), OOT (Out of Tolerance), vendor qualification, stability studies, quality agreements, results of external audits and inspections, and the status of actions from previous meetings. The review occurred every six months, and the Head of Quality Assurance was responsible for preparing the documentation.

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

2. Good manufacturing practices for pharmaceutical products

Good manufacturing practices were generally implemented. Necessary human and physical resources, including adequate premises, equipment, and utilities, were provided to support the current operational level of various finished pharmaceutical products. The manufacturing processes followed procedures as defined and documented in the BMRs. The personnel were appropriately qualified. A multi-product facility produces products of different therapeutic areas in various dosage forms. The products were manufactured on a campaign basis, and a cleaning validation program was implemented to ensure that there was no carryover from one product to the next.

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

3. Sanitation and hygiene

Cleaning and disinfection of areas related to production were carried out according to the SOP "Preparation of Disinfectant Solution and Cleaning and Sanitization of Process Areas and Non-Process Areas". According to this SOP, in production areas of Class D, the following disinfectants were applied rotationally: 2.5% v/v Dettol, 2.5% v/v Savlon, and 2.5% v/v Lizol. In other areas, 1% v/v Phenol was used. According to the SOP, there were two cleaning procedures: daily and monthly.

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

4. Qualification and validation

The validation master plan for the formulation plant 2025 was discussed. The VMP was prepared every year and covered areas such as personnel qualification, HVAC, utilities, water system, calibration of measuring devices, internal quality audit, computerized system validation, planned preventive maintenance, process, analytical, and cleaning validation. Periodical requalification was performed every four years and when any major change was made. The water system was qualified, and a yearly trend analysis was performed. The CSV was conducted by the outside party covering the ERP system used for material management and PLC validation of production equipment.

The SOP for process validation has been reviewed. It was noted that concurrent and prospective validation was adopted. The procedure still stated three batches to be taken for process validation. Additionally, a procedure for continuous process verification (CPV) was discussed. The CPV was performed using the Excel spreadsheet, wherein data from 30 batches were collected, tabulated, analyzed, and CpK was calculated for various stages (granulation and compression).

The SOP for cleaning validation was reviewed, and it was noted that the procedure was recently revised per WHO TRS 1033, Annex-2. The acceptance criteria were defined as visual cleaning, chemical, and microbiological contamination, which were calculated based on solubility, cleanability, highly potent APIs, strength, and toxicity, as well as toxicological evaluation (PDE). The cleaning validation protocol for Sulfadoxine 500mg and pyrimethamine 25mg tablets described the cleaning validation procedure and acceptance criteria. Three batches were selected for study, and worst-case criteria were established based on solubility, potency, cleanability, toxicological evaluation through PDE, and health-based exposure limit calculations. The cleaning agent used for the equipment cleaning was a 0.1% Sodium Lauryl Sulfate solution in purified water. The swabs were taken for microbiological and chemical testing, and the results were reported as nil.

Analytical method validation

The analytical method validation for estimating Pyrimethamine by HPLC was completed. Based on the PDE value and solubility, pyrimethamine was considered the worst-case scenario. The method validation covered specificity, accuracy, linearity, precision, recovery, robustness, and solution stability.

The SOP for computerized system validation was available. A technical agreement between S Kant and the supplier was available. The performance qualification report for LabSolutions, Version 6.129, was discussed. The CSV was performed once every three years, and it was noted that the PQ was conducted to verify user authorization, operational requirements, and audit trails. The software's functionality was verified against configuration and found to be adequate.

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

5. Complaints

The handling of market complaints was reviewed. It was noted that complaints were classified as critical, major, and minor. If classified as critical, major, or minor, the complaints must be handled within 48 hours, 15 days, and 30 days, respectively.

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

6. Product recalls

The SOP for Product Recall describes the procedures for both forced and voluntary recalls. The recalls were classified into three classes (A, B, and C). The procedure also described the maximum duration for recalling the product. The company performed a mock recall early this year by asking the distributor to provide complete traceability of the product already supplied in the country. As such, the company did not receive products in its facility except for confirmation of the quantities supplied and available at different levels (hospitals, pharmacies, healthcare workers, etc.). There has not been any recall since the last WHO PQ inspection.

7. Contract production, analysis, and other activities

The WHO prequalified and under assessment products were not contracted out for manufacturing any unit operations. The manufacturer utilized commercial laboratories to conduct some of the tests.

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

Self-inspections were conducted based on the "Internal Audit" procedure every six months in each area. The list of 34 internal auditors was available. The requirements for auditors, as specified in the SOP, included, among others:

- a minimum of four years of experience in the pharmaceutical industry,
- training in self-inspection procedures.

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

9. Personnel

The Organizational Chart for S. Kant Healthcare Ltd., Vapi 17, was reviewed. QA and QC were separate from production. The General Manager QA reported to the Associate Director, while the General Manager QC reported to the General Manager QA. The Head of Production, Engineering, and Warehouse Manager reported directly to the Site Director. The procedure "Preparation, Approval, Issuance, and Retrieval of Organizational Chart," which the QA Head approved, referred to the preparation of organizational charts for individual departments. The site's organizational chart was also prepared according to this procedure. In the manufacturing facility, 393 employees were employed, including:

Department	Number of personnel
Production	142
Quality Control	102
Quality Assurance	64
Storage & Distribution	28

Technical & Engineering Services	32
Administration	18
A&D Support	7

The job descriptions of key personnel, including the Head of Quality Control, Head of Quality Assurance, and Head of Production, were reviewed.

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

10. Training

According to the "Training of Plant Personnel", the manufacturer conducted various types of training, including:

- introduction training (for new employees),
- cGMP training (including those specified in the annual plan),
- refresher training,
- continual training,
- incidental training (e.g., related to CAPA).

The principles regarding each type were specified in the procedure. The "Annual Training Calendar for 2025" was reviewed. This plan included training for all employees.

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

11. Personal hygiene

According to the SOP "Dress Code for Employees," clothing was designated for specific areas and activities. It was color-coded, for example, Staff/Supervision – coffee-colored, and In Process Control QA – yellow-colored. The procedure for entering and exiting the production area was described in the "Procedure for Plant Entry/Exit for Employees Working in the Manufacturing Area". According to this SOP, used garments were segregated and washed at an external laundry. For hand disinfection, 70% IPA was used. Detailed procedures for specific production rooms were outlined in dedicated SOPs for those rooms, such as "Entry and Exit from Granulator Cubicle", which described the preparation of employees for work in that particular room. According to the SOP, an additional coverall and gloves were required when working in this room.

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

12. Premises

The layout and design of the premises aimed to minimize the risk of errors, contamination, cross-contamination, and mix-ups. The restrooms were separated from the manufacturing areas.

The storage areas were of sufficient capacity, and receiving and dispatch nays were separated. The weighing was carried out in the dispensing areas. For premises related to production and quality control laboratories, refer to Sections 16 and 17.

The inspector visited the purified water system and the air handling units on the service floor of the tablet manufacturing area. The service floor was well-maintained and found to be neat and clean.

Purified Water System

The purified water was produced using a combination of ultrafiltration, electrodeionization, and reverse osmosis. Additionally, a UV system was installed on the distribution line to the storage tank. The loop contained 36 user points. The water temperature in the loop was maintained at 50-60°C. According to the procedure "Sanitization of Purified Water Loop System," the purified water loop was sanitized on a weekly basis. During sanitization, the temperature was maintained at not less than 80°C for 2 hours. The record for the last sanitization of the PW loop was checked. Monitoring was conducted according to the procedure "Sampling and Analysis of Water". The microbiological laboratory staff took water samples. Daily tests were conducted from the user points, both before and after the tank. Weekly tests were conducted from all user points. The purified water was tested for compliance with the specification "Specification for Purified Water". Raw water, treated water, and potable water were also tested periodically.

HVAC system

The entire manufacturing facility was served by 105 AHUs, including 23 AHUs in the solid dosage forms area, 9 AHUs in the warehouse, and 3 AHUs in QC. Each Air Handling Unit (AHU) contained three pre-filters: a primary filter (10 µm), a secondary filter (10 µm), and a tertiary filter (3 µm). HEPA H14 filters were installed at the inlet to Grade D rooms. An exception applied to the dispensing and sampling rooms located in the warehouse area, where the HEPA filter was installed directly in the AHU as an additional filter. Between the HEPA filter and the room, a space could become a source of cross-contamination. The HVAC system in these rooms was only switched on during dispensing or sampling activities. The procedure for turning the system on and off, as well as its monitoring during routine operations, was described in the SOP "Operation of Air Handling Unit". According to the SOP "Cleaning of Filters of the HVAC System," filter cleaning was performed weekly using PW and compressed air. HEPA filters were replaced at least once every five years.

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

13. Equipment

The manufacturing areas, quality control laboratories, and utilities were well-equipped with sophisticated equipment and instruments. For equipment related to the production and quality control laboratories, refer to Sections 16 and 17.

14. Materials

The inspectors visited the warehouse and inspected various areas, including the incoming receiving bay, the quarantine area, the sampling area, the dispensing area, and others. The inspector visited the finished goods store and noted that the area had expanded significantly from the last PQ inspection. It was confirmed that temperature mapping was performed, and hotspots were identified and monitored. Upon quick inspection of the finished goods store area, various cages were available for storing recalled, rejected, and returned goods. They were found to be empty and locked.

15. Documentation

Documentation was maintained in paper form. The SOP "Document and Data Control" defined the types of system documents, including BMR, BPR, SOP, VMP, protocols, reports, and specifications. The documentation review was conducted every 3 years. The SOP reviewed all the procedures that were verified during the inspection. QA was responsible for overseeing the issuance and distribution of procedures. The distribution of the "Training for Contract Workers" procedure was reviewed. The method for numbering products and assigning serial numbers was specified in separate procedures. The serial number consisted of 8 characters. The method for assigning serial numbers was identical for all markets, except for the first letter, which defines the recipient, order, or target market, e.g., "W" for WHO.

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

16. Good practices in production

The inspectors visited the manufacturing areas and inspected the granulation, quarantine areas for storing in-process materials, compression, washing, IPQA, and coating processes. During the inspection, production activities were conducted in various granulation areas and compression machines. The inspector visited the primary packaging area and noted that the facility had expanded its packaging activities since the last PQ inspection. The facility now features 11 blister packing lines, two strip packing lines, one dedicated to dry powder, and one bulk packaging line. Cubicles 8 to 13 were used for WHO products and were equipped with separate MAL and PAL. The tablets were manually transferred to the hopper using the SS bowl, and a dust collector was built in to contain dust generated during the packaging operations. The camera challenge test was performed every 2 hours to detect broken tablets, empty pockets, black spots, and tablets of different colors. This was done at the start of the operations, any breakdown, and at the end of the shift. For the Combi-kit product (SP+AQ tablets), the company ceased deblistering/defoiling the blister. Additional controls were also implemented to ensure that there was no mix-up between SP and AQ, or vice versa. The bulk packing line number 15, which is a fully integrated line, was also briefly visited. The company informed that a feasibility study was performed, and a camera inspection system would be purchased and qualified before commercializing the products in bottle packs. The strip packing line (cubicle number 4) was also used for WHO PQ products. Though a separate MAL/PAL was not available due to design constraints, an over-gowning facility was provided before entering the area for strip packing.

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

17. Good practices in quality control

The inspectors visited the quality control laboratory and inspected various areas, including the microbiology laboratory. The QC Manager was supported by 101 staff members and temporary workers for housekeeping. The laboratory was equipped with several instruments and equipment. The laboratory had 28 HPLC systems (26 Shimadzu and 2 Agilent), 2 GC systems, a pH meter, a conductivity meter, an FTIR spectrometer, a UV-VIS spectrometer, and other equipment. The LabSolution software was used for the chromatographic data system. Since the last PQ inspection, the company has purchased some equipment and instruments (e.g., HPLC, GC, double-door autoclave, incubator, etc.). At the time of the inspection, the laboratory area was well-maintained. The incoming

samples were received and logged in the register as raw material, in-process, and finished product samples. A separate analytical reference (AR) number was assigned to incoming samples received by the microbiology laboratory. The IPQA sampled in-process and finished goods samples from the shopfloor, whereas the microbiologists sampled water samples. The microbiology laboratory was well maintained, as noted during the visit. The quality control laboratory was supported by the QA/QC reviewers, who were responsible for reviewing documents and systems.

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

Part 3	**Conclusion – Inspection outcome**

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, ***S Kant Healthcare Limited***, located at ***1802-1805, GIDC, Phase III, Vapi, 396 195, Gujarat, India*** 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 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	**List of WHO 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://digicollections.net/medicinedocs/documents/s21467en/s21467en.pdf

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***
   untitled (digicollections.net)

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
   9789240020900-eng.pdf (who.int)

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
https://digicollections.net/medicinedocs/documents/s21440en/s21440en.pdf

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**
https://digicollections.net/medicinedocs/documents/s23455en/s23455en.pdf

6. 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
https://digicollections.net/medicinedocs/documents/s20108en/s20108en.pdf

7. 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. 961, 957), Annex 1
https://digicollections.net/medicinedocs/documents/s18681en/s18681en.pdf

8. 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://digicollections.net/medicinedocs/documents/s22358en/s22358en.pdf

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
Short name: WHO TRS No. 961, Annex 6
https://digicollections.net/medicinedocs/documents/s19959en/s19959en.pdf

10. 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
https://digicollections.net/medicinedocs/documents/s18677en/s18677en.pdf

11. 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://digicollections.net/medicinedocs/documents/s18683en/s18683en.pdf

12. 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***
https://digicollections.net/medicinedocs/#d/s21438en

13. 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
https://digicollections.net/medicinedocs/documents/s18682en/s18682en.pdf

14. 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://digicollections.net/medicinedocs/#d/s20177en/

15. 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://digicollections.net/medicinedocs/#d/s20175en/

16. 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

17. 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***
https://digicollections.net/medicinedocs/documents/s23697en/s23697en.pdf

18. 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

19. 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***
Essential Medicines and Health Products Information Portal (digicollections.net)

20. 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
https://www.who.int/publications/m/item/who-recommendations-for-quality-requirements-when-plant-derived-artemisinin-is-used-as-a-starting-material-in-the-production-of-antimalarial-active-pharmaceutical-ingredients---trs-992---annex-6

21. 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***
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22. 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
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

23. 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

24. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditionning 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**
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25. 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**
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26. 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**
9789240001824-eng.pdf (who.int)

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