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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	Shouguang Fukang Pharmaceutical Co., Ltd.
Corporate address of manufacturer	No.666 Dongwaihuan Road, Shouguang City, Shandong 262700 P.R. of China.
Inspected site	
Name & Address of inspected manufacturing site if different from that given above	Shouguang Fukang Pharmaceutical Co ., Ltd Northeast of Dongwaihuan road, Dongcheng Industrial area, Shouguang city, Shandong Province, P.R. of China.
Synthetic Unit /Block/Workshop	▪ Workshop 101 ▪ Workshop 102
Inspection details	
Dates of inspection	11 – 14 November 2024
Type of inspection	Routine re-inspection
Introduction	
Brief description of the manufacturing activities	Production and quality control of APIs, Intermediates and Chemicals
General information about the company and site	Shouguang Fukang Pharmaceutical Co., Ltd. (Fukang Pharm.) was established in 1993. The company has 17 workshops for API and FPP manufacturing. The site manufactured a range of APIs, but no beta-lactams, steroids or hormones. A limited range of formulations (tablets and pellets) were also manufactured at this site. Industrial grade chemicals were also manufactured on the site in dedicated facilities including segregated storage area.
History	This was the second on-site inspection conducted by WHO PQP. The initial on-site inspection was held in 2015 followed by a desk assessment in 2019.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	***Document reviewed were related to the following topics:*** • Quality management • Personnel • Buildings and facilities • Process equipment • Documentation and records • Material management • Production and in-process controls • Packaging and identification labelling of APIs and intermediates. • Storage and distribution • Laboratory controls • Validation

	• Change control • Rejects and reuse of materials • Complaints and recalls • Contract manufacturers (including laboratories) ***Site area visited:*** • Production Blocks: Workshops101, Workshops102 • Warehouses for starting materials and finished APIs • QC laboratories • Water system
Restrictions	The scope of the inspection was restricted to the API in the WHO PQ programme.
Out of scope	Other products and/or processes outside the scope of WHO pre-qualification were not inspected.
WHO APIs covered by the inspection	• Sulfamethoxazole API (hereinafter referred to as SMZ) used for FPPs • Trimethoprim API (hereinafter referred to as TMP) used for FPPs
Abbreviations	**Meaning**
AHU	Air handling unit
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
APR	Annual product review
BMR	Batch manufacturing record
BPR	Batch production record
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
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

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

1. Quality management

Principles, quality manual (QM) and quality policy (QP)

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 the production department. Persons authorized to release APIs were specified. Quality-related activities were recorded at the time they were performed. Deviations from established procedures were documented and explained. Regular internal audits were performed in accordance with an approved schedule.

Product quality review (PQR)

The product periodic review was performed following the SOP for API product quality review.
The following PQRs were reviewed.

- SMZ APQR 2022
- SMZ APQR 2023
- TMP APQR 2023

Management review (MR)
The SOP for management review was reviewed. The SOP defined the frequency, attendance, input, and documentation of the MR meetings. A planner was established annually for MR meetings. The MR meetings conducted in May 2024 and May 2023 were checked. Attendance was documented in the form of attendance sheet. Top management and chief officers attended both meetings. The MR meeting minutes were available and were signed by the management representative.

Quality risk management (QRM)
The SOP for QRM was in place. The SOP provided for risk management flow including initiation, identification, assessment, analysis and evaluation as well as risk controls and risk review. Risk tools were also referenced in the SOP. The risk register for the assessments conducted in 2023 and 2024 was reviewed and few risk assessments were spot-checked.

Deviations
The SMP "Deviation management procedure" was checked. According to the risk assessment, deviations were classified as critical, major and minor. Deviation register for 2024 was checked. A deviation in respect of related substance OOS of TMP and CAPAs were reviewed.

Internal audit (self-inspection)
The SOP for self-inspection was in place. The SOP provided for self-inspection organization including team, plan (at least once per year for all GMP relevant activities), preparation, references and guidelines, scope, deficiencies classification, CAPA, records and reports. The 2024 and 2023 self-inspection protocols were reviewed.

CAPA management
The SOP for CAPA management was in place. The SOP provided for source of CAPA, root cause investigation, CAPA preparation, implementation, evaluation and review including annual trend. A register of CAPA was maintained on annual basis. The 2024 and 2023 lists of CAPA were reviewed and several CAPAs were spot-checked.

Product release
The SMP "Product and material release procedure" was checked. Upon analysis request, the sample was prepared and delivered to QC for analysis. After analysis, analytical raw data (BAR), BMR, BPR and internal CoA were reviewed by QA. Final release was done by the QP or the delegated QA staffs. The product release record of a TMP batch was checked.

The SOP "Warehouse computerised system operation procedure" were checked. The batch release and dispatch operation in the computerised system was checked during the inspection.

2. Personnel

Approximately 957 staff were employed at the site at the time of the inspection. The site did not employ any temporary staff.

An organogram was well-established at Shouguang Fukang Pharmaceuticals Co., Ltd. The organogram provided for separation between production/operations and quality related activities. The quality assurance and quality control activities at the site were undertaken by a quality unit under the responsibility of the Head of quality. Quality unit comprised two different subunits namely QA and QC under the responsibility of two different staff.

Personnel qualification

Personnel met during the inspection were adequately qualified based on education, experience and training. The responsibilities of all personnel engaged in the manufacture including production and control were specified in writing in the form of job descriptions. The job descriptions of General Manager, Head of quality, Head of production, the Quality manager and Qualified Person including delegated QP, department production responsible, material control department were reviewed.

The qualification including education and experience of major personnel engaged in production and control activities were indicated in the SOP for personnel evaluation and recruitment management.

Training

Training activities were managed as per the SOP for personnel training. Training needs were identified by the Heads-QA or designee in consultation with functional departments. The SOP provided for initial induction training, periodic on the job training, re-training. Training was also necessary in case of prolonged shutdown of the manufacturing for longer than three months. All new employees were given initial induction training prior to their actual involvement in manufacturing activities.

Efficacy of training was performed in the form of written questionnaire and oral Q&A for cGMP related training activities. Some training efficacy required evaluation through actual operation. The 2024 training plan was reviewed and few training activities were spot-checked. The training records of a couple of production and QA personnel were spot-checked. In addition, an example, of QC analyst initial qualification was reviewed and found satisfactory.

Personal hygiene

The SOP for personal hygiene was in place. The SOP provided good hygiene practices at the clean and chemical areas. Eating, drinking and smoking were not allowed at the production area. Another SOP was established for medical check-up. The SOP established a frequency of medical check-up on regular basis for all staff. New staff were also mandated to go through medical check-up before employment. A couple of medical records of production and QA personnel were spot-checked.

Personnel accessing cleanrooms were requested to gown properly before entering. The gowns and gowning process was apparently appropriately used. The cleanroom gowns issuance logbook was checked where gowns were traced for issuance and due replacement date through unique identification numbers which were also displayed on the gowns. Gowns were regularly replaced on annual basis.

3. Buildings and facilities

Design and construction

Buildings and facilities used in the manufacture of intermediates and APIs were located, designed, and constructed to facilitate cleaning, maintenance and operations as appropriate to the type and stage of manufacture. Facilities were designed to minimize potential contamination.

The site was divided into east and west parts by a road. Buildings and facilities had adequate space for the orderly placement of equipment and materials to prevent mix-ups and contamination. Buildings used in the manufacture of intermediates and APIs were properly maintained, repaired and kept in a clean condition.

Production

The API facilities included blocks of Workshop 101 and Workshop 102 were visited. They were dedicated for synthesis, purification, drying, final processing and packaging of SMZ and TMP APIs. The flow of materials and personnel through the building or facilities was designed to prevent mix-ups and contamination.

Air Handling Units (AHUs)

The utilities were briefly inspected noting that Air Handling Units (AHUs) were installed. Cleanrooms were served with two AHUs. Air supplied to the clean zone areas was filtered through pre-filters, fine filters and HEPA filters to arrest the airborne contaminants. These filters are periodically cleaned/replaced. The pressure difference across the filters was checked on daily basis and recorded in the respective logbooks. The frequency for periodic validation of HVAC/cleanroom was defined within the SOP for equipment and utilities qualification. The procedure for clean area management described the testing frequency for air volume, and number of air changes etc.

The OQ/PQ protocol and report of workshop 102 HVAC system along with the record of cleanroom air volume and number of changes in 2024 were reviewed.

The environmental monitoring (EM) of the cleanrooms were performed according to a number of SOPs including SOP for particle counts, SOP for settle plates, SOP for active air monitoring and SOP for contact plates. The EM trend analysis of workshop 102 for 2022, 2023 as well as the ongoing 2024 data were reviewed, and no adverse trend was identified.

Compressed air

The compressed air system was visited and found well maintained, clean and tidy order. Related measuring equipment was regularly calibrated with attached tags indicating calibration status and the due date for calibration. The compressed air was monitored according to a well-established SOP. The 2023 trend analysis and the ongoing 2024 data of the compressed air was reviewed and not adverse trend was identified.

Water

The P &ID of water system was available. There were two purified water systems on the site used for TMP and SMZ production respectively. The 101 Purified Water System was visited. City water was used as the feed water, and it was processed through a series of filters including carbon columns followed by two RO membranes treatment. PW was continuously circulated at ambient temperature. The

sanitization was regularly performed by heating circulating water at the temperature 80-85^{0}C. Sampling points were identified throughout the system.

The PW produced was in compliance with EP and USP specifications. PW monitoring program and PW quality trends for 2023 were checked and showed that microbiology action limit and alert limit were established. Records of monitoring indicated that the system was under acceptable control.

4. Process equipment

Design and construction

Equipment used in the manufacture of the APIs within the scope of the inspection was generally of a good standard and suitable for intended use. The equipment used for manufacturing TMP and SMZ were dedicated. Permanently installed equipment and processing lines were appropriately identified.

Equipment maintenance and cleaning

Equipment was maintained by the engineering department following the SMP "Equipment use, maintenance and repair procedure" and SOP "Equipment numbering procedure". Equipment was classified into three levels depending on maintenance requirements and risk. The equipment maintenance schedule of Workshop101in 2024 was checked.

Written procedures were established for cleaning of equipment and its subsequent release for use in the manufacture of intermediates and APIs. Equipment and utensils were cleaned, stored and sanitized to prevent contamination or carry-over of a material that would alter the quality of the intermediate or API.

Calibration

The procedure for calibration management was checked. Equipment/instrument was classified into three types depending on calibration requirements. A schedule was available for different types of instruments and their calibration schedule. Measuring equipment was labelled with a calibration tag. All of those reviewed indicated that the calibration was within date.

Computerized systems

The SOP for computerized systems and SOP for computerized systems validation (CSV) were in place. The latter SOP guided different aspects of CSV including classification (following GAMP), validation process including URS, risk assessment, supplier selection and evaluation, DQ, FAT, SAT, IQ, OQ and PQ, change management, deviations, documentation as well as periodic review, revalidation and retirement. A list of computerized systems used at the site was available. A number of CS were used in the QC and warehouse but not for production.

The 2024 validation report of chromatographic network system version upgrade was reviewed. The protocol and report of the QC computerized systems annual review was checked. The annual review was comprehensive and covered verification of the SOP, version update, changes, events, issues, and others.

The automatic logistic management software revalidation protocol and report were reviewed. Another SOP entitled warehouse computerized system management procedure which addressed data backup and recovery of the system. The 2023 annual review report for the system was also spot-checked. The system was used as part of the batch release process as the status change of the finished API was managed by the computerized system.

5. Documentation and records

Documents related to the manufacture of intermediates or APIs were prepared, reviewed, approved and distributed according to written procedures. The issuance, revision, superseding and withdrawal of all documents was controlled with maintenance of revision histories. The sample of documents reviewed during the inspection indicated that the documentation system was working effectively.

Master production and control records

Master production batch records for each API were available. The approved master formula of the inspected API's was checked and compared to the ones used in practice.

Batch numbering system and batch production records

The procedure for bath numbering system and BMR issuance were checked. The in-process BMRs and the completed BMRs reviewed were found acceptable.

The procedure for record management required documents to be kept up to date and periodic review was required to be performed if there are no changes.

Equipment cleaning and use records

The SOPs for cleaning each type of equipment were available and the records were maintained. There was a usage logbook for each major piece of equipment and the sample reviewed was up to date and satisfactory.

Laboratory control records

The SOP for the QC electronic data review (including audit trail) was in place. The SOP mandated for audit trail of each tested batch (raw materials, finished APIs, etc.). A template for the audit trail was provided in the SOP and the same was spot-checked for some actual testing activities at the QC laboratory.

6. Materials management

General controls

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

Receipt and quarantine

The SOP for materials receipt and checking was in place. The SOP provided for incoming materials verification, unloading and check in, QC test request, sampling and release.

Sampling and testing of incoming production materials

The SOP for incoming raw materials sampling was checked. Similarly, the SOP for finished API sampling was in place. Both SOPs provided for sampling preparation, actual sampling including sampling location, sampling plan, sampling person, sampling tools, sample handling and forwarding to QC for analysis.

Storage

Raw materials and APIs were stored at different warehouses. The warehouses for starting materials, packaging materials, finished API, and rejected materials etc. were briefly inspected. Materials were issued from the warehouse to the production according to an established SOP.

Finished API products warehouse was visited. The product status control was managed by a computerised system. A TMP batch's status control, release and dispatch were checked in the system.

Supplier evaluation
The SOP for vendor qualification was available. The SOP provided for materials classification (critical and non-critical), vendor selection and qualification including sampling and testing and onsite audit as well as quality agreement. The qualification packages of a couple of KSM suppliers were checked including supplier questionnaire, vendor audit, quality agreement, specifications, method of analysis, TSE/BSE statement, and other related documents.

7. Production and in-process controls

Production of TMP and SMZ took place in dedicated facilities. Both APIs in the inspection scope was in operation at the time of inspection.

Workshops 101 and 102 were visited and production operations were checked and generally found acceptable. Most of reactors and material tanks were labelled with the batch in progress in general and the associated batch documentation was up to date.

Time limits
Time limits were specified in the BMR where necessary. The holding time study for crude API and intermediates in-process stage were established.

In-process sampling and controls
In-process sampling and testing was spot checked during visit of Workshop 101, and found it was conducted as specified in the relevant BMR.

8. Packaging and identification labelling of APIs and intermediates

Packaging materials
Packaging materials were purchased from approved suppliers and placed in quarantine before sampling, testing and release by QC. The storage and labelling of these materials were acceptable.

Packaging and labeling operations
Packaging and labelling were performed in areas dedicated for this purpose. These areas were appropriately designed and classified as Grade D, with condition of temperature10-26^{0}C and RH 45-65%. The SOP "TMP packaging operation procedure" was checked. The line clearance check before packaging and labelling operations starts, was required to be performed and recorded.

9. Storage and distribution

API products were stored in the finished product warehouse and held until released by the Authorized Person. The environmental requirements for finished APIs storage were monitored but not controlled areas.

APIs were released for distribution to third parties after they have been released by the quality unit and transported in a manner that did not adversely affect their quality.

10. Laboratory controls

The physical and chemical laboratory was visited. The company had an organized and suitably equipped QC laboratory equipped included HPLC, GC and other testing instruments. The procedures that were reviewed and discussed during the inspection were generally of an acceptable standard.

There was no microbiology laboratory at this site. The microbiology laboratory previously at the site had been relocated at Site 2 in 2024. All the microbiological testing for API product, environment and PW of this site were performed at Site 2 microbiology laboratory.

Receiving samples

Receipt, testing, approval, and rejection of samples as well as the issuance of analysis reports were managed through a number of SOPs.

Management of reference standards

The SOP for standard management was in place. According to the SOP for working standard qualification of SMZ, the suitability of each batch of secondary reference were determined prior to the first use by comparing against a compendial/primary reference standard. Each batch of secondary reference standard was also periodically requalified.

Testing of intermediates and APIs

QC testing was conducted as specified in the relevant specification and according to documented test methods. Samples for testing were kept in a designated area. The sample receiving, and distribution logbook was checked.

Primary pharmacopoeia reference standards were available and secondary reference standards were prepared against the primary reference standards.

The computer access control, authorization of the functions and testing data backup of IR were checked during the inspection.

Stability studies

A range of stability chambers including a backup stability chamber were available at the QC lab. Stability studies were performed according to written protocol. The sample register was maintained, and spot checked and found generally satisfactory. The studies of the WHO PQ products reported and reviewed in the PQRs were discussed.

Retention samples.

The procedure for API retention sample management procedure was checked.

A designated temperature-controlled area for storage of retention samples was visited. Access to this area was restricted. The retention sample was kept under conditions of temperature 10-25^{0}C and RH ≤75%.

OOS management

The OOS/OOT management procedure and the OOS register were reviewed. Several OOS/OOT were checked.

11. Validation

Validation policy

Validation master plan (VMP) was available and defined the validation and qualification policy, including process validation, cleaning validation, analytical method validation etc. The VMP for 2024 was checked.

Qualification

Guidance on equipment qualification was provided in the VMP as well as the equipment and utilities qualification SOP. In general, production and control equipment were kept at a satisfactory status of qualification. The mentioned SOP specified time interval of requalification of equipment if no major or critical change.

An equipment master list including qualification status and due date for requalification was established and spot-checked. The 2024 annual validation plan was also established with list of equipment due to requalification in 2024. Equipment qualification reports were reviewed.

Process Validation

The SOP for process validation was in place. Prospective approach with at least three consecutive batches was taken by the company, and revalidation was performed on regular basis if no changes.

The process validation protocol and report of SMZ and process revalidation of TMP were reviewed.

Cleaning Validation (CV)

The SOP for cleaning validation was in place. The SOP guided, among others, calculation of limits which were based on 0.1% of minimum batch size, 10 ppm, maximum therapeutic daily dose (MTDD), LD50 or PDE values. The minimum calculated limit was selected among the aforementioned methods. PDE were obtained from qualified toxicologists.

The CV protocol/program and report for final purification stage of SMZ dated November 2019 and June 2020 were spot-checked. Similarly, the CV protocol and report for TMP dated were spot-checked. The dirty equipment hold time (DHT) and clean equipment hold time (CHT) were established based on the aforementioned CV studies. Equipment batch to batch cleaning and cleaning after campaign production were also available.

Analytical method validation

Considering the antimicrobial properties of SMZ and TMP, the manufacturer performed a study for suitability of the microbial limit test. The protocol and report were reviewed. The study revealed and confirmed the appropriateness of the test method.

The analytical method for TMP and SMZ in PQ followed EP pharmacopeia method. The analytical method validation protocol for TMP related substance, approved in September 2023 and the validation report of TMP testing approved in September 2024 were checked. No objection comments were made.

12. Change control

The procedure for change control management and change control register for 2024 were available and spot checked. Changes were classified into significant, major and minor. Several CCs were reviewed and discussed.

13. Rejection and re-use of materials

Reprocessing and reworking

The product reprocessing management procedure was checked. The reprocessed TMP batch caused by OOT of single and total impurity limit was reviewed and discussed.

The rejected product management procedure was checked. The procedure specified that reworking was not allowed. The rejected product register for 2024 was checked.

Recovery and re-use of materials

The SOP for solvents recovery and mother liquor reuse was available. The SOP provided for conditions for recovery and reuse, disposal, and storage. The SOP stated that the recovered solvents can be used within the same stage or earlier stage of production of same product. For SMZ and TMP, only solvent recovery was considered. Mother liquor reuse was not applicable.

14. Complaints and recalls

The SOP for API user's complaints handling was in place. The SOP provided for receipt, initial classification, handling, root cause investigation, final classification, CAPA, follow up, response and closing. The SOP also provided for numbering of complaint cases, archiving requirement and annual review. Once complaint was received, complaint record along with relevant evidence were filed to QA with feedback to clients within specified working days. Complaints were classified based on the impact to product quality. The latest version of this SOP included additional guidance on user complaint record, guidance on complaint information summary report and management of repeat complaints.

The complaints logbook of 2024 and 2023 were checked. Complaint annual review for 2023 involved comparison to data from 2022 for better complaint management was available.

The SOP for product recall management was implemented. The SOP involved recall decision/approval, recall preparation and initiation, notification, evaluation, handling of recalled products, summary report, CAPA and recall closing. Recalls were classified into three levels: level 1 recall to be triggered within 1 working day from notice of the requirement for recall; level 2 to be triggered within 3 working days; and level 3 to be triggered within 7 working days. The SOP indicated that recall decision was to be made by the responsible person based on advice from a team of experts from the site. The SOP provided for conduct of mock recall if no actual recall was conducted. The frequency of mock recall was specified. API mock recalls in 2022 and 2021 were spot-checked.

15. Contract manufacturers (including laboratories)

There was no contract manufacturing of APIs in the inspection scope. However, external contract laboratory was used for LDPE bag testing for permissibility of moisture and oxygen, abnormal toxicity. Contract testing was performed in accordance with written procedure. A quality agreement was required to be established.

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, ***Shouguang Fukang Pharmaceutical Co., Ltd.*** located at ***Northeast of Dongwaihuan road, Dongcheng Industrial area, Shouguang city, Shandong Province, P.R. of 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 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of GMP guidelines referenced in the inspection report

1. WHO good manufacturing practices for 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 guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report. Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 9.
   Short name: WHO TRS 1010, Annex 9
   https://www.who.int/publications/m/item/trs1010-annex9

4. 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
   https://www.who.int/publications/m/item/annex-3-trs-1033

5. 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/annex-4-trs-929

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. 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/publications/m/item/Annex-8-trs-1010

9. Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1019), Annex 2.
   Short name: WHO TRS No. 1019, Annex 2
   https://www.who.int/publications/m/item/trs1019-annex2

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
    Short name: WHO TRS No. 1044, Annex 4
    https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1044-annex4-technology-transfer-in-pharmaceutical-manufacturing.pdf

11. WHO good manufacturing practices for sterile pharmaceutical products. Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
    Short name: WHO TRS No. 1044, Annex 2
    https://www.who.int/publications/m/item/trs1044-annex2

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://www.who.int/publications/m/item/trs943-annex3

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://www.who.int/publications/m/item/trs961-annex2

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://www.who.int/publications/m/item/trs981-annex2

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://www.who.int/publications/m/item/annex-3-trs-981

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
https://www.who.int/publications/m/item/tr961-annex14

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://www.who.int/publications/m/item/trs1019-annex3

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.
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