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Prequalification Unit Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Quality Control Laboratory

Part 1	**General information**		
Inspected laboratory details			
Name of Laboratory	**TUV SUD PSB Pte Ltd**		
Address of inspected laboratory site	15 International Business Park TUV SUD @ IBP Singapore 609937		
Inspection details			
Dates of inspection	16-19 January 2023		
Type of inspection	Routine inspection		
Introduction			
Brief description of testing activities	**Type of Analysis**	**Finished Products**	**Active pharmaceutical ingredients**
	Physical/Chemical analysis	pH, water content (KF), Loss on Drying, Dissolution, Uniformity of Dosage (or mass content)	pH, water content (KF), Loss on Drying, Dissolution, Uniformity of Dosage (or mass content)
	Identification tests	HPLC, Spectrophotometry Basic test (TLC, coloring reaction, precipitation reaction)	HPLC, Spectrophotometry Basic test (TLC, coloring reaction, precipitation reaction)
	Assay, impurities and related substances	HPLC (UV, PDA, Fluorescence, Electrochemical detectors); GC; Spectrophotometry (UV – Vis and FTIR), Volumetric and Potentiometry Titrations, Gravimetry.	HPLC (UV, PDA, Fluorescence, Electrochemical detectors); GC; Spectrophotometry (UV – Vis and FTIR), Volumetric and Potentiometry Titrations, Gravimetry.
	Microbiological analysis	Microbial limit test, endotoxin test, sterility test	Microbial limit test, endotoxin test, sterility test

	Miscellaneous	None	None
General information about the laboratory	The TUV SUD PSB was relocated from 1 Science Park Drive to 15 International Business Park in 2020-2021. The Chemical and Materials (CHM) Center has a total of eight (8) laboratories (industrial chemicals, micro-contamination, coating, surface analysis, elemental analysis, environmental monitoring, food & pharmaceutical and microbiology). Dr Li Sihai is responsible for six laboratories, whereas Mr Randy Chin is responsible for food & medicine and microbiology. In addition, Dr Li is the quality representative for all eight laboratories. The TÜV SÜD PSB Pte Ltd headquarter is located in Singapore. The company is a private laboratory that provides product testing, certification, inspection and auditing services. The company employs more than 820 employees in the Asian region, including Singapore, Malaysia, the Philippines, Thailand and Vietnam. Of these, more than 500 staff work in the headquarter in Singapore. The laboratory performs pharmaceutical testing including chemical, physical, microbiology and biological testing. Some examples of chemical tests include identification, assay, uniformity of content, particular matter test, dissolution and disintegration tests. The microbiology laboratory conducts microbial limit tests for oral and topical applications as well as sterility tests.		
History	The PQ inspection services have regularly inspected the laboratory. The last on-site PQ inspection was performed in October 2016. In addition, a desk assessment was completed in April 2020. The laboratory has been accredited with ISO 9001:2015, ISO/IEC 17025:2017, ISO 45001:2018 and ISO/IEC 27001:2013.		
Brief report of inspection activities undertaken – Scope and limitations			
Areas inspected	1. Organization and management 2. Quality management system 3. Control of documentation 4. Records 5. Data-processing equipment 6. Personnel 7. Premises 8. Equipment, instruments and other devices 9. Contracts 10. Reagents 11. Reference substances and reference materials 12. Calibration, verification of performance and qualification of equipment, instruments and other devices 13. Traceability 14. Incoming samples 15. Analytical worksheet 16. Validation of analytical procedures 17. Testing		

	18. Evaluation of test results 19. Certificate of analysis 20. Retained samples 21. Safety
Restrictions	None
Out of scope	The WHO PQ inspection scope included pharmaceutical testing covering physical, chemical, instrumentation and microbiology. The scope did not include non-pharmaceutical testing.
Abbreviations	**Meaning**
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
FPP	Finished pharmaceutical product
FTIR	Fourier transform infrared spectrophotometry or spectrophotometer
GMP	Good manufacturing practices
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
KF	Karl Fisher titration
LIMS	Laboratory information management system
MB	Microbiology
MR	Management review
NC	Non-conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specifications test result
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
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometry or spectrophotometer

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

1. Organization and Management

The organization and management structure of the laboratory, including responsibility, authority and interrelationship of the personnel, was specified in several organizational charts depicted in the Quality Management Manual. The Chemicals & Materials Centre (CHM) was headed by Vice President Dr Lin Jianhua and Mr Randy Chin Kok Fei were overseeing operations for Food and Pharmaceutical, and Microbiology and Dr Li Sihai were responsible for the Quality Management of the Chemical Centre. The Quality Management Committee organizational chart depicted that the Quality Manager and the Deputy Quality Manager reported to the Chief Financial Officer (CFO). The total number of staff accounted for 11 for Food and Pharmaceutical Testing, including 2 Laboratory Managers / Supervisors, 7 Chemists / Analysts and 2 Quality Assurance staff. For Microbiological Testing there was 1 (one) Lab Manager / Supervisor and 12 Microbiologists. The TUV SUD PSB operates several laboratories under the same roof with the same management.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

2. Quality management system

Testing Services Quality Management System (defined as the quality management system adopted by the test laboratories of TÜV SÜD PSB Pte Ltd. The TSQMS was designed to meet ISO/IEC 17025:2017, ISO/IEC 17065:2012 (Product Certification), ISO 9001:2015 and ISO45001:2018 requirements. The quality management system of TÜV SÜD PSB Pte Ltd was documented in 5 level documents as follows:

- Level 1 was the Testing Services Quality Manual and Certification Department Quality Manual,
- Level 2: Testing Services Procedures, CRT Procedure Manual - Product Certification and Operation Manual,
- Level 3: Test Laboratories Procedures,
- Level 4: Test Methods, Work Instructions and Test Specifications and Test Standards that need to be controlled and
- Level 5 was Work Sheets, Records and other Reference Manuals.

Quality Manual clearly describes management's responsibility of ensuring adequate resources in terms of qualified and experienced personnel. The reference was made to the quality policy and quality objectives. Annual Management review was used for opportunities for improvement on quality policies and objectives, customer complaints, internal and external audits, as well as corrective and preventative actions (CAPA). Other aspects of the quality system discussed in the document included feedback and service to clients, risk assessments etc. Changes were incorporated in each section, e.g., documentation changes, method changes etc.

The quality policy of the laboratory was approved by the CEO.

Internal Quality Audit was discussed. The laboratory activities were audited annually using a comprehensive checklist which provided additional comments and observations. The selection and qualification of auditors were specified. The selection was based on the following:

- Educational qualification,
- Experience in GMP of more than ten years
- External Audit training

The internal audit was performed annually according to timelines. Responsibilities of the lead auditor and co-auditor were listed as well as other aspects such as procedures to follow during the opening meeting, audit, and report writing. The inspector was informed that the lead auditor would provide timelines for report completion and CAPA to be completed after the audit. This process should have been mentioned in the SOP.

Change Control was discussed. The procedure was recently changed to include oversight by QA, as previously, it was only signed off by technical personnel. Changes could be major or minor, whereby major changes could affect the quality of the results, which would be critical for the clients to meet specifications, and minor changes did not affect the accuracy of results. Any changes were to be communicated to and approved by clients.

The deviation control Procedure was reviewed and discussed. Deviations could be planned or unplanned and further classified into major and minor, whereby major could affect the accuracy of results and minor not. The method of issuing numbers for deviations was not described in the operating procedure, and although identifying numbers were allocated by chemistry and microbiology laboratories for deviations, different methods of numbering were used.

Corrective and preventative action (CAPA)
CAPA Doc was discussed. It was found that CAPA was recorded and only then an investigation and root cause identification was started. The ETQ Reliance Electronic system was used to record CAPA. The QA recorded the CAPA record in the system and allocated it to be investigated. Action steps and root cause identification were covered within the system.

Antimicrobial resistance (to treat viral, parasitic, and fungal diseases)
The procedure for the testing process was discussed to understand how antimicrobial waste was handled in the laboratory. The laboratory outsources waste by a third party approved by the National Environment Agency (NEA), Singapore which is quarterly disposed of.

Complaint management
Customer feedback and compliments process and channels were discussed. There was no specific procedure or policy available dealing with complaints. The customer feedback procedure was found ambiguous as it did not describe the terms such as feedback and compliments.

Quality risk management (QRM)
The risks and opportunities procedure were discussed. The procedure was established to identify and evaluate actions taken to address risks and opportunities that would have a potential impact on the conformity of products and services or impact customer satisfaction using business risk assessment techniques. A business risk assessment form was used for the risks and opportunities. Element 11 – risk and opportunity assessment procedure described systematic processes for identification, evaluation, and control of hazards in the workplace using risk assessment techniques. The procedure stated that risk

assessment should be performed for all routine and non-routine work activities. The risk assessment was performed using the risk priority number (severity and occurrence without using detectability.

The business continuity manual stated that in the event of a disaster which interferes with TUV SUD PSB's ability to conduct business, the manual has identified responsible individuals to coordinate the management of incidents and its business recovery. Localized disasters were identified such as fires, floods, landslides, epidemics, and explosions.

Quality management review procedure guided conducting management reviews at the laboratory levels. The scope provided the areas that will be covered and will be carried out at least once every fiscal year.

Proficiency testing schemes (PTS)
The procedure of handling proficiency tests guided the development of a proficiency test plan to cover chemical tests and microbiology tests for pharmaceutical QC testing. The maximum cycle time is 3 years and at least two PT tests for chemical tests and microbiology tests shall be signed per year. The PT test may be either from a commercial provider, developed internally, or completed through a cooperative effort from the external laboratory.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

3. Control of documentation

The following procedures were applied to Document Control and related activities:

- Operating Procedure Document Control detailing the control of documents.
- Organization Chart and Document Structure.

Level 1 and 2 documents were in the custody of the Quality Manager who was responsible for updating and control of the documents. Level 3 documents were controlled by the Quality Management Representative (QMR) and Level 4 documents were controlled by the technical manager. Level 5 documents were governed by a procedure in the respective testing laboratories. All quality or procedure documents prepared had to be reviewed and approved by authorized personnel and each document was given a unique number with a version number. The frequency of reviewing the quality manual and standard operating procedures was indicated to be every six years as per the Laboratory Information File. Operating procedures were prepared and controlled on ROXTRA and if printed would be considered uncontrolled documents. Obsolete documents were removed and archived in the company's share drive.

Guidance on good documentation practices was reviewed. The procedure described the guidance on good documentation practices and gave reference to ALCOA+ principles. The procedure was referenced to WHO TRS 996, annexe-5 which has been replaced with WHO TRS 1033, Annex-4.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

4. Records

Logbooks for instrument usage and other records were filled manually at the time of use. For instruments, user logins were recorded in logbooks because of the limitation in terms of electronic systems for data-generating instruments. Testing Records were generated by analysts on test reports and reviewed for completeness and accuracy by the verifier. Electronic spreadsheets were used for calculation during testing.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

5. Data processing equipment

The laboratory has been using standalone computer systems for chromatography and non-chromatography analysis of pharmaceutical samples. The laboratory informed that LIMS will be implemented effectively in the year 2023. A communication email in this regard was presented by the laboratory. All instruments were stand-alone and although logbooks were available to specify the date logged on and by whom. Mostly date and time functions were locked and could not be changed.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

6. Personnel

TÜV SÜD PSB Pte Ltd has more than 500 staff members working in the regional headquarters within Singapore. More than 70 staff members were involved in the chemical and microbiological testing and out of the 70 staff, approximately 24 were involved in Food and Pharmaceutical Testing. It appeared from the review of various documents that sufficient personnel were not employed to ensure procedures and work instructions were timely reviewed. Also, there was an inadequate review of the records.

A staff competency matrix for analysts was maintained. The matrix provided a high-level overview of the test standards, test parameters and the names of analysts competent to carry out testing of different pharmaceutical products for tests such as assay, dissolution, related substance, identification, specific optical rotation, uniformity of content, uniformity of dosage, and other tests. A staff competency matrix for microbiologists was maintained. The matrix provided a high-level overview of the test standards, test parameters and the names of microbiologists competent to carry out testing such as microbial limit test, antimicrobial effectiveness test, detection of mycoplasmas, cleanroom monitoring, water testing, biological assay, sterility testing etc. The laboratory managers of both laboratories confirmed that supporting training and competency records are available for each analyst and microbiologist.

Training

Staff qualification and training defined minimum qualification requirements for various levels of staff to upgrade their skills and for recognition of skills acquired. The staff competence was documented based

on the participation in proficiency testing, organization of intra-laboratory comparisons or evaluation using a reference material or mock sample. All personnel involved in activities related to the quality and accuracy of testing were required to complete on-board training and on-the-job training emanated from the person's job description. The training folder and training plan were kept for each employee and included training evidence and evaluation of effectiveness records. Three methods of assessments were applied namely testing controlled samples, analysis under close supervision and classroom training test paper. Training plans for 2023 were reviewed and found acceptable.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

7. Premises

The facility consisted of seven floors. The chemical laboratory was located at level 4 whereas the microbiology laboratory was located at level 5. The total floor area occupied by the Food, Pharmaceutical, and Microbiology laboratories was 830 m^2 of which the Microbiology Laboratory occupied 522,69 m^2. The laboratory facility was of a suitable size, construction and location and was generally designed to suit the function and operations to be conducted in them. It was however noted that the laboratory had not introduced a logical flow of the personnel before entering the laboratory. The gowning was changed inside the laboratory instead of before entering the laboratory. The temperature was monitored through Data loggers and maintained at room temperature in testing areas. Flammable solvents and hazardous chemicals were stored in safety cabinets following Singapore Fire and Safety requirements.

Balances were placed inside the chemical laboratory surrounded by chemicals, reagents and solutions and were constantly affected by the inflow of air from the air handling units.

Microbiology laboratory

A change room facility was provided before entering the microbiology laboratory. The entire microbiology laboratory was divided into different sections such as media preparation, incubators, endotoxin, cytotoxicity test, microbial limit test (MLT), sterility test and biochemistry lab. Biosafety cabinet (BSC) Class II was used for endotoxin, cytotoxicity test, water testing and MLT. A sterility test was performed using an isolator. The gloves used for the isolator were not suitable for the intended purpose. The integrity testing on gloves and sleeves was not justified for monthly and biennially respectively. The incubators were temperature mapped as informed. The dehydrated media was used for testing purposes and was subjected to a growth promotion test (GPT). The GPT report provided traceability about the name, date, autoclave ID and lot number of the media. The media was autoclaved in an autoclave equipped with a printer facility and plates were prepared under laminar airflow. A separate autoclave was used for the decontamination and destruction of the media plates. Sterility testing was observed for water for injection. 6.0% H_2O_2 was used as a disinfectant and ready-to-use wipes (ethylene oxide sterilization) were used. The positive controls were handled separately.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

8. Equipment, instruments and other devices

The equipment and instruments used in TÜV SÜD PSB were shared for Food and Pharmaceuticals. It was noted that some instruments were dedicated to food. Instruments used for food and pharmaceuticals included but were not limited to HPLC (High-performance liquid chromatography), GC (Gas chromatography), FTIR Fourier-transform infrared spectroscopy) and UV VIS (Ultraviolet-visible spectroscopy) etc.

HPLC Column Management

Maintenance Procedures of the HPLC Column was reviewed. It was stated that all Columns should be recorded in the column list to monitor performance. The number of injections had to be recorded in addition to the column number, lot number date of purchase and supplier name.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

9. Contracts

Purchase of Test Equipment and Supplies indicated that critical suppliers of critical valuables and services which affect the quality of testing should be evaluated and that records of these evaluations and lists must be kept. Approved supplier Evaluation and Records were reviewed. The evaluation score was 1-5 with 1 indicating poor and 5 excellent, however, the scoring method was not defined and there was no documented evidence available to justify the score given. The laboratory made use of a subcontracting laboratory if certain tests could not be performed. It was confirmed through documentation that permission would be requested from the customer before any subcontracting was allowed.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

10. Reagents

The SOP for Incoming Materials, Chemicals and Reagent Management, Doc. was reviewed. The operating procedure was outdated. The SOP indicated that reagents and chemicals must be purchased against the approved supplier list.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

11. Reference substances and reference materials

Handling and Storage of Chemical Reference Substances was discussed. Receipt of reference standards was performed electronically in a spreadsheet indicating the name, purity, location, category number, source, quantity, date received, expiry date and checked date. The procedures stated that the assay shall be recorded as 100 % if not claimed on the vial or CoA of a chemical reference substance suggesting that CoA might not be required. Reference standards could be received from USP, IP, BP, EP or Sigma Aldrich as per the inventory list. It was confirmed that all reference substances were received either from

USP, Sigma, EDQM, BP or EP. No working standards were prepared but secondary standards could be purchased. The SOP further stated that the current lot and a previous lot of pharmacopoeias should be checked every three months. It was further noted that during each test the analyst should check whether the specific lot number was still valid. This practice was confirmed through the documentation on the Stock Control Card.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

12. Calibration, verification of performance and qualification of equipment, instruments and other devices

During the tour of the laboratory, it was confirmed that all instruments were uniquely identified except for one instance as observed on the UPLC. Labels indicating the calibration date and next calibration date were generally attached to instruments and equipment. The calibration/qualification/verification instrumentation master list for the Laboratory was reviewed. The calibration was performed by the calibration unit of the TUV SUD PSB (Electrical Department) and by several external parties as specified in the approved vendor/supplier list. The Singapore Accreditation Council (Accreditation scheme for laboratories) provided types of calibration/verification per type of instrument and frequency.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

13. Traceability

Data generated on the pH meter software was backed up on the shared drive once a month. Records of the backup data were reviewed and were in the form of an Excel spreadsheet. It was noted that the test solution was recorded as buffer preparation and the traceability method by date and time.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

14. Incoming samples

The samples were received at level 1 named as “central collection and dispatch centre”. The incoming samples were manned by Singapore Post and stored under air condition for a short period though the area was not temperature monitored. The incoming samples were transferred to level 4 and recorded in the spreadsheet. Incoming Samples and Test Job Management was managed through as well as through the Chemical Centre Food and Pharmaceutical Procedure of Testing Process. Both procedures were applied when receiving samples.

Samples for routine testing, ad-hoc testing or for investigative purposes could be received. For customers other than the UN samples would be routine samples, or for investigative purposes as well as stability testing. Stability testing samples were not applicable for UN purposes and were not included in the scope of this inspection. The laboratory receives samples from the IDA Foundation, UNICEF and UNRWA (United Nations Relief and Works Age). The staff on Level 1 would inform the laboratory personnel of

incoming samples, specifically those that were temperature sensitive. Samples with cold storage conditions would be picked up immediately and taken to Level 4 where all samples would be stored, and testing is conducted. Samples were logged in the Sample Log Form on a computer system in the laboratory. Each sample would be assigned a unique identification number. There was a discrepancy between the two operating procedures used on how the sample number should be allocated.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

15. Analytical worksheet

The analytical worksheet of Artesunate, NaCl and $NaHCO_3$ for injection 60 mg was reviewed. The samples were requested by UNICEF for complete testing. The tests such as endotoxin (by Gel clot method as per International Pharmacopoeia), sterility test by membrane filtration method, particulate matter, uniformity of mass, pH, assay, related substances etc were performed by the laboratory.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

16. Validation of analytical procedures

Verification of compendial procedures and manufacturer's in-house methods for pharmaceutical products was discussed.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

17. Testing

Significant samples were tested by the laboratory since the last WHO PQ inspection. A competency matrix was available confirming the names of the analysts and test parameters for which analysts had been qualified. The specification and test methods were provided by the laboratory manager along with the record form to analysts.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

18. Evaluation of test results

The SOP for out-of-investigation (OOS) guided the handling of OOS investigation in different phases. Also, the procedure stated that hypothesis testing should be performed to find out potential obvious errors.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

19. Certificate of analysis

The certificate of analysis for Oxytocin solution for injection and some other products was reviewed. The CoA was prepared following the recommendations given in the WHO GPPQCL.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

20. Retained samples

Retained samples were mostly kept for one month before being discarded as per Handling of Incoming Pharmaceutical Samples. Adequate samples for two re-analyses were not retained. The temperature was maintained below 25 °C.

The deficiencies noted in this section were addressed satisfactorily and the same will be verified during future PQ inspections.

21. Safety

Personnel were provided with laboratory coats, safety glasses and gloves. The equipment was equipped with safety hoods.

The deficiencies noted in this section were addressed satisfactorily and the same 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, ***TUV SUD PSB Pte Ltd***, located at ***15, International Business Park, Singapore*** was considered to be operating at an acceptable level of compliance with WHO GPPQCL 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 5	**List of WHO Guidelines referenced in the inspection report**

1. 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***
http://www.who.int/medicines/publications/44threport/en/

2. 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

3. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
Short name: WHO TRS No. 929, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

4. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4. ***Short name: WHO TRS No. 937, Annex 4***
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

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

6. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7. ***Short name: WHO TRS No. 961, Annex 7***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

7. WHO Guidelines for preparing a laboratory information file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 2011), Annex 13. ***Short name: WHO TRS 961, Annex 13***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/GuidelinesPreparingLaboratoryInformationFileTRS961Annex13.pdf?ua=1TRS%20961:%20Annex%2013:%20WHO%20guidelines%20for%20preparing%20a%20laboratory%20information%20file

8. 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

9. 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

10. 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

11. 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