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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	**Stabicon Life Sciences Pvt. Ltd.**		
Address of inspected laboratory site	Plot No. 28, Bommasandra Industrial Area (Sub-layout), 4th Phase, Jigani, Hobli, Anekal Taluk, Bangalore-560099 Tel: +9180-278392 59/60 GPS coordinates: Latitude – 12.8034579Longitude – 77.6607538 12°48'12.448" N, 77°39'38.713 E		
Inspection details			
Dates of inspection	12-15 March 2024		
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, loss on drying, friability, disintegration time, tablet hardness, dissolution testing, dimensions, Divisibility Test, Average weight/ fill volume, Viscosity, and uniformity of dosage unit.	pH, water content, loss on drying, Sulphated ash, Refractive Index, Melting point, and Specific Optical Rotation.
	Identification tests	TLC, HPLC, UPLC, GC, UV-Spectrophotometer, FTIR, and Chemical & physical tests.	TLC, HPLC, UPLC, GC, UV-Spectrophotometer, FTIR, and Chemical & physical tests.
	Assay, impurities and related substances	HPLC (UV-VIS, DAD & RI Detection), UPLC, Gas Chromatography (by headspace, Liq.	HPLC (UV-VIS, DAD & RI detection), UPLC, Gas Chromatography (by headspace, Liq.

		Injection technique.) UV-VIS Spectrophotometer, Volumetric titrations (by Potentiometric & manual titration), Determination of Related Substances by HPLC, GC (FID), TLC, and Impurities by comparison with a Reference Standard.	Injection technique.) UV-VIS Spectrophotometer, Volumetric titrations (by Potentiometric & manual titration), Determination of Related Substances by HPLC, GC (FID), TLC, and Impurities by comparison with a Reference Standard.
	Microbiological analysis	Validation, Verification, Microbial limit tests, preservative efficacy testing for sterile & Non-sterile Products, Pathogens, Microbiological Assay.	Microbial limit tests, Preservative efficacy testing for sterile & Non-sterile Products, Detection & Identification Pathogens, Microbiological Assay.
	Stability testing	Storage of samples at different conditions as per ICH and WHO Guidelines and testing of samples.	Storage of samples at different conditions as per ICH and WHO Guidelines and testing of samples.
General information about the laboratory	Stabicon Life Sciences Pvt Ltd was established in 2010 and mainly provides quality control testing and stability management services, including routine sample analysis, analytical method validation, verification, and microbiological testing. In addition, the company has a separate wing that provides services related to formulation development and analytical development for nutraceuticals, OTC, and ayurvedic preparations.		
History	The laboratory was first inspected by the WHO PQ inspection services in September 2013. The second PQ inspection occurred in June 2022. This is the third PQ inspection of the Stabicon laboratory.		
Brief report of inspection activities undertaken – Scope and limitations			
Areas inspected	The following areas were inspected: - Quality management system - Documentation and data integrity - Personnel and training - Premises, equipment and instruments - Calibration, verification and validation - Reagents and volumetric solutions - Traceability		

	- Sample and material management. - Supplier and contractors - Safety
Restrictions	None
Out of scope	Sterility and bacterial endotoxin tests were out of the scope of this inspection.
Abbreviations	**Meaning**
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
FMECA	Failure Modes, Effects, and Criticality 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

Stabicon Life Sciences Pvt. Ltd. (SLS) was established & registered in 2010 under the Companies Act (under section GLP 4.1) as per the rules governed thereunder. The laboratory was approved by the Regional Drug Controller, Karnataka. The laboratory had a Vice President of Operations responsible for the day-to-day operations of the laboratory. It was supported by the Director (Senior Consultant) and Chairman of the company. The quality assurance reported directly to the Director (Senior Consultant). The laboratory had arrangements to ensure that its management and personnel were free from any internal and external commercial, financial, and other pressure or conflicts of interest that might adversely affect the quality of their work.

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

2. Quality management system

Quality Manual was developed based on the requirements of National and International Standards such as Good Practices for Pharmaceutical Quality Control Laboratories (WHO GPPQCL) TRS 957, Annex-1, Schedule L1 of The Drugs and Cosmetics Act, 1940 and The Drugs Rule 1945 (India), ISO/IEC 17025: 2017, and various regulatory requirements like USFDA, ICH (Q1 to Q10), etc. The quality manual provided the laboratory's mission, vision, and objective. The quality policy was described in the quality manual.

Quality risk management procedure was reviewed. The procedure applied to different stages of the drug product life cycle, and it was based on the ICH Q9 requirements. The procedure also listed the tools used for the risk assessment (e.g. process flow diagram, failure mode effects analysis (FMEA), FMECA, cause and effect diagram, and fault tree analysis). The laboratory used a process flow diagram and FMEA, whereas a fishbone diagram was used. In 2024, one risk assessment related to the requalification frequency of equipment and instruments was performed. In 2023, a total of 24 risks were assessed.

The quality of the test results procedure was discussed. The procedure guided the performance of proficiency testing by all analysts. The lab participated in the PTS, inter-laboratory testing, and intra-laboratory testing, and the z-score was identified as the performance indicator. The PTS schedule for 2022, 2023 and 2024 was available. The schedule identified various tests for 2024 as part of the intra-laboratory testing (assay, melting point, specific optical rotation, related substances, pH, and loss on drying). Similarly, as part of the PTS, several tests (assay, dissolution, loss on drying, pH, specific optical rotation, melting point, Microbial limit test) were identified.

Management review (MR) meetings followed the principles described in the SOP. The management review meetings were conducted quarterly and chaired by the Managing Director / Management Representative/Designee. In addition, quality review meetings were held monthly and chaired by Head QA and QC. The agenda, attendance register, and the minutes of the last management meeting dated 25/01/2024 (covering the period October to December 2023) were reviewed. The minutes included information related to minutes of the previous meeting, changes, fulfillment, CAPA, complaints, Key performance indicators, pest control management, validation, human errors, OOS, and complaints.

Internal audits were conducted in accordance with the SOP. The Quality Assurance Manager was responsible for preparing the audit schedule and determining the audit details (objective, audit areas, auditors independent of activity being audited) twice a year. The audit team comprised of a lead auditor and at least one audit team member and they had to be appropriately qualified. A list of qualified internal auditors was presented. The internal audit schedule for 2024 (approved 20/01/2024) was reviewed. Two audits had been planned for March and September 2024. The records of the September 2023 internal audit were made available. They included the internal audit reports of the QC and QA departments and the corrective action requests for the observed deficiencies. The implementation and effectiveness of the CAPA plan were further assessed.

A procedure for the Management of Deviations was in place. Deviations could be categorized as critical, major, and minor. The team lead/designees were responsible for initiating the deviation. QA Head/designee was responsible for the final approval or disapproval of the investigation conclusion. The investigation should be initiated within 1 working day of the identification day. All deviations were trended annually to assess the repeatability of the deviations at the management review meeting of the last quarter of the year. The trend for 2023 was presented. A total of 22 deviations were reported. Each deviation was registered in Laboratory Deviation Form LDR-YYXXX, where YY was the year and XXX a serial number.

A procedure for Handling Laboratory errors was in place. The procedure was applicable to all laboratory activities. The analyst was responsible for reporting any errors identified during the analysis. The manager QC or his/her designee was responsible for investigating laboratory errors and CAPA. Errors were registered in the Laboratory Error Log Register. All lab errors were trended through annual management review meetings.

Corrective and Preventive Actions
Identification, investigation, correction, and management of quality events were carried out in accordance with the SOP. The Department Head or designee was responsible for preparing a CAPA plan. CAPA was registered in CAPA register: I or E-YYYY/XXX, where I stood for internal, E stood for external, YYYY was the year, and XXX was a serial number. The CAPA register was reviewed monthly.

A procedure for customer complaints was available. The QA Manager/Designee handled complaints. The complaint was initially registered on the Customer Complaint Investigation Form and then on the Complaint Log Register. Complaints were categorized into GxP and Non-GxP. All complaint investigations should be completed within 30 calendar days. Trending was carried out in management review meetings. In 2023, no complaints were received for pharmaceutical products.

A change control procedure was available describing the process for initiating, evaluating, reviewing, approving, or rejecting changes. The SOP provided a procedure for initiating temporary and permanent changes, which were classified as critical, major, or minor. The initiator / Assigned Person initiated the change control process by submitting the Change Control Request Form. Changes were registered in the Change Control Log register. The change control logs for 2022 – 2024 were presented.

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

3. Control of documentation

A separate room, "data archival," was provided to store the records' hard copies. The room was equipped with a split air conditioner. Pest control (Pest-24) was provided, and the room was equipped with a fire smoke detector and fireproof cabinet. The master documents were stored inside the fireproof cabinet, whereas validation data were stored perpetually, and other documents were stored for 5 years from the release date. A procedure was in place to prepare, review, approve, revise, distribute, and control SOPs. The review period was two years after the effective date. The SOPs were named SLS/SOP/XXX/YYY-ZZ, where SLS was Stabicon Life Sciences Pvt Ltd, XXX used the department code, YYY incremental serial numbers started from 001, and ZZ current version started from 00.

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

4. Records

Records of analytical testing were maintained, including raw data, calculations, method validations/ verifications, instrument use, calibrations, maintenance, and sample receipt. Appropriate templates or electronic systems were used to register the relevant data. In general, records were complete, signed, and dated. A procedure for Control of Quality records was in place. Electronic records and data files were backed up to the server regularly. Records were kept for 15 years, and analytical reports for 5 years. Logbooks for each equipment/instrument were available. The logbooks of balance E-008 and HPLC E-198 were reviewed. Media Preparation and Growth Promotion Records Logbook 021 MSDA -2211 and Culture Suspension Preparation Records Logbook 001 were reviewed.

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

5. Data processing equipment

Instruments such as HPLC, GC, and IR were linked to the computers operated by their respective software systems. Lab Solutions software was a chromatography database linked to the HPLC and one GC equipment, UPLC was supported by Empower-3 software, Open Lab software was linked to one GC, FTIR was connected to Micro Lab PC21CFR11 software, and stability chambers software/manufacturer was MDAQ / Pharma Meditech and ICDAS/Newtronics. Access to the instruments was done via unique usernames and passwords. The user privilege matrix for Lab Solutions was presented. Software system-generated audit trails were reviewed as part of the data review process. A separate room, the "server room," housed the server containing 5 hard discs, each of 2TB. The split air conditioner was used, and UPS was provided for the server and network systems. Restoration was performed by the IT personnel once every 3 months based on the request received from the QA department. The chromatograms were compared by the QC personnel and approved by the QA personnel.

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

6. Personnel

The laboratory had adequate personnel with the necessary education, experience, and training to carry out the laboratory work. Responsibilities and duties were appropriately defined in written job descriptions, as were the qualifications for each position according to the SOP on Management Organization. The procedure applied to all personnel and covered the preparation of the organization structure and the assignment of responsibilities.

The organizational chart reflecting administrative structure and departmental hierarchy was reviewed.

A procedure for personnel training and competency assessment was presented. New employees had to undergo induction training. Training requirements were identified and documented based on staff positions and assigned duties. Training could be on-the-job training, classroom training, or self-study. The training was evaluated by oral/practical assessment or written evaluation. The trainee was considered qualified if the test results were 80%. If the trainee was not qualified, re-training and re-evaluation were conducted till 80% results were obtained.

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

7. Premises

The inspectors visited the laboratory on day 2. The samples were received from the customers after an initial inquiry was made to the business development personnel. The samples were stored in the staging area at NMT 25ºC before being registered through the ERP system. The quantities of the samples required were stated in the protocol. However, it was noted that for certain customers, samples were received before the protocol was sent by the customers. The staging area was temperature-mapped for 7 days, covering one season only. The laboratory was divided into three floors:

- The ground floor was comprised of meeting rooms, registration of samples, a staging area, stability chambers, archives etc. The laboratory was equipped with several stability study chambers, both walk-in and standalone chambers with different conditions, such as 30ºC/75%, 25ºC /60%, 30ºC/65%, 5+/-3ºC, 40ºC/75%, and a photostability chamber. Some stability chambers were physically locked, whereas no system had a panel to access the chambers. The first floor had a sample room where samples were either under analysis or to be analyzed. The lab had made some changes from the last PQ inspection by providing hoods to the balances where hazardous materials were handled. The analytical balances were calibrated daily and monthly, and E2 class standard weights were used for the in-house calibration. The volumetric solutions were freshly prepared, used, and discarded, whereas a hold time study was established for several reagents. The chemicals received from the suppliers were labeled, providing information as to the date of the receipt, bottle opened, and used before. The lab confirmed that they use only Class A glassware. The Millipore water system was used, and water was tested for pH, TOC, and resistivity. Based on the requirements, the working and reference standards were stored in the

refrigerator and deep freezer. The lab does not prepare any working standards and uses the working standards and primary reference standards supplied by the customers. The temperature mapping of the refrigerator and deep freezer was performed once a year.

- The first floor comprised physical, chemical, and instrumentation sections. The lab was equipped with 13 HPLC (Agilent and Shimadzu) connected with UV-Vis, PDA, and RI detectors, 1 UPLC (Make Waters), 2 GC (Shimadzu and Agilent) with autosampler and headspace, and 4 dissolution apparatus besides other equipment and instruments. The HPLC and UPLC were connected to the server, whereas one GC was standalone. The HPLC and GC were calibrated in-house once every 6 months. The data were auto-backed up daily and monthly. The server was equipped with 5 hard discs. It was observed during the inspection that different PCs showed slightly different times though connected to the server. The audit trails were reviewed by the QA using a checklist primarily to confirm peak shape, integration type etc.
- The microbiology lab was housed on the third floor, and significant modifications were made during the last PQ inspection. Before entering the testing areas, the area had a new storeroom and a series of change rooms and airlocks. The airlock 2 was classified as Grade D (100,000). The media was prepared and transferred to the autoclave room using the dynamic pass box. The top-loading autoclave area was classified as Grade D (100,000). The dynamic pass box was used to transfer autoclaved media through the common personnel airlock to the BSC and LAF areas classified as Grade C (10,000). The incubators (20ºC-25ºC and 30ºC-35ºC) were available whereas a separate autoclave was used for the destruction of the used media and plates. The BSC chamber was negatively pressurized to the surrounding BSC room.

A procedure for Pest and rodent control was in place. Rentokil PCI provided monthly reports on the control.

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

8. Equipment, instruments and other devices

In general, laboratory equipment was appropriately installed and maintained. The laboratory had test equipment, instruments, and other devices for performing tests, calibrations, validations, and verifications. The instruments had calibration status labels attached. A list of equipment used in the laboratory was available in the LIF.

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

9. Contracts

There was a procedure describing the principles of engagement with external providers of laboratory services. Vendor/supplier evaluation was conducted annually to assess vendor performance. A list of approved vendors was presented. A procedure for the Management of public testing laboratories described the principles of subcontracting testing. In case of a breakdown in a facility or for rare services, a test could be subcontracted to an approved laboratory after the customer's approval. The Head QA/Designee was responsible for evaluating the laboratory, including reviewing the questionnaire and

approving the technical agreement. Re-evaluation was performed every 3 years. A list of approved external laboratories was available.

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

10. Reagents

Reagents were appropriately stored in different storage areas (e.g., solid reagents, liquid/solvents, toxic/hazardous material). The reagents used were labelled to display their content, receipt date of opening, and expiry date.

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

11. Reference substances and reference materials

A procedure for Handling and maintaining laboratory standards was in place. Official Pharmacopoeia standards (EP CRS, BP CRS, USP CRS) or standards supplied by the customer (WS) were mostly used for the analysis. Reference/Working standards were stored under the laboratory conditions required. Logbooks were maintained for the receipt/usage of RS/WS. The handling of the WS Ceftriaxone sodium was reviewed.

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

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

The Validation Master Plan (VMP) described the overall approach to facility qualification, equipment qualification, temperature mapping, chemicals/reagents shelf life, AHUs, water qualification, cleaning methods, CSV, pest control, training, waste management, data integrity risk assessment, SOPs review, change control, Proficiency testing, deviation, analytical method validation, preventive maintenance was reviewed. A risk assessment on validation/qualification strategy/extent of qualification process frequency established in VMP for defining the requalification frequency had been carried out. The internal yearly calibration schedule for 2024, the annual external calibration schedule for 2024, the external calibration schedule for 2024 for the Microbiology department, and the internal calibration schedule 2024 for the Microbiology department were presented.

A procedure for Computerized System Validation was in place. The procedure covered all CSVs, such as CaliberLIMS, Agile (standalone), and ERP. The CSV also included the Project Validation Plan, URS, Specification Phase, Detailed Design, Configuration Specification, Functional Risk Assessment, Activities at the Vendor Site, IQ, OQ, PQ, and Traceability matrix.

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

13. Traceability

The laboratory had an adequate process in place to ensure traceability. Upon reviewing various equipment and instruments' calibration and qualification records, adequate traceability was observed. Similarly, upon reviewing the analytical worksheets, details of the analysts, analytical instruments, equipment, reagents, working standards, and certified materials were referenced.

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

14. Incoming samples

The laboratory had a process in place for sample receipt and registration. The procedure described the principles for receipt, review of inquiry, verification, acknowledgment, and registration of all types of samples. The incoming samples were received from the customers after an initial inquiry was made to the business development personnel. Upon receipt of the samples, the samples were stored in a staging room under controlled conditions (NMT 25°C). The customer support department registered the incoming samples in the ERP system under the applicable category and assigned a unique number. Four categories were in place: routine samples, stability samples, validation samples, and development samples. The samples, along with the testing protocol, were transferred to the QA before testing was performed by the QC personnel. The type of test was registered in ERP. For the allotted specifications and analysis method, the master creation was created by QA in ERP. During the visit, it was observed that incoming samples were stored in the staging area awaiting testing protocol.

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

15. Analytical worksheet

The analysts recorded information about samples, performed testing procedures, calculations, and results in the analytical worksheet. The worksheets contained, among others, the following information:

- The test starting date
- Reference to specifications
- Identification of test equipment used
- Reference substances, reagents, and solvents employed
- Interpretation of the results and the conclusion whether the sample was found to comply with the specifications

Please refer to sections 17 and 18 for more detailed information.

16. Validation of analytical procedures

A procedure was established for analytical method validation, verification, and transfer. Analytical method validation was carried out as per ICH guidelines once the method had been fully developed by Stabicon or the customer. Analytical method verification was applicable for official methods in Pharmacopoeia prior to the implementation of changes and additions to Pharmacopoeia monographs.

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

17. Testing

Sample testing and analysis reporting results were performed according to the procedure. QAD issued the AWR (Analytical Work record) by ERP/LIMS. The sample was assigned to an analyst for the analytical work to commence. A competency matrix was maintained to ensure samples were assigned to qualified analysts. Test procedures were described in detail, allowing analysts to perform testing reliably.

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

18. Evaluation of test results

The test results were reviewed by the QC and then by the QA personnel. The out-of-specification and out-of-trend results were handled using the approved procedure.

Handling of OOS test results was reviewed, and it was noted that the procedure applied to all types of samples (such as APIs, starting materials, raw materials, intermediates, packaging components, process validation batches, stability studies, cleaning validation, environmental monitoring, and reference standards qualification studies). The procedure described how to perform the hypothesis before retesting was allowed. The OOS investigation was performed in the presence of QA. The investigation was performed in two phases i.e. Phase IA (obvious lab error) and 1B (extended lab investigation including hypothesis testing). In contrast, Phase II was divided into lab investigation and manufacturing investigation. Phase II will only be performed once approval from the customer. Retesting will be performed under Phase II.

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

19. Certificate of analysis

A procedure was established for evaluating the test records, checking the analytical worksheets, and drafting and issuing the Test Report-Form 39 and Certificates of Analysis (CoA). Quality Control /Microbiology Manager/Designee reviewed and updated the results in ERP software for Test Report-Form 39. A unique number was allotted to the Test Report - Form 39. The authorized person in QA was responsible for the release of Test Report-Form 39 sent to the customer. A certificate of Analysis was

issued by QA. A unique number was allotted to it. It was noted that a Test Report Form 39 was issued for routine analysis and was equivalent to CoA as per the Drugs Rule, 1945, India. A CoA was issued for stability studies, although this was clarified in the relevant SOP. Please refer to section 17 for more detailed information.

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

20. Retained samples

A procedure for the control sample was in place. The procedure defined the principles for collecting and storing control samples after the completion of the analysis. After completion of testing, QC personnel should hand over the residual/remnant samples and analytical data to the QC Manager/Designee. Control samples were stored for one year after issuing the certificate of analysis. The retention samples were stored in a separate room, "control samples." Pest control (Pest-25) was provided inside the room. The room was temperature-mapped for 7 days, covering one season. The room was equipped with a split air conditioner, and temperature (NMT 25°C) was recorded. A logbook was maintained for register control samples.

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

21. Safety

Adequate measures (e.g., eye and face washers, fuming hoods) were provided in the laboratory for safe operations. General safety rules were in place, including wearing appropriate protective clothing, gloves, and eye protection.

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, ***Stabicon Lifesciences Private Limited***, located at ***Bommasandra Industrial Estate,*** 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 quality control laboratory, 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 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-

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

4. Good manufacturing practices: guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Third Report. Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. ***Short name: WHO TRS 1019, Annex 3***
https://www.who.int/publications/m/item/trs1019-annex3

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

6. WHO guidelines on transfer of technology in pharmaceutical manufacturing. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Sixth Report Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4. ***Short name: WHO TRS No. 1044, Annex 4***
TRS 1044 - 56th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

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***
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs961-annex13-guidelines-preparing-laboratory-information-file.pdf?sfvrsn=54d1f397_2

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***
https://extranet.who.int/pqweb/sites/default/files/documents/TRS1010_Annex10.pdf
9. Good chromatography practice. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Forth 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