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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	SGS India Pvt Ltd – Life Science		
Address of inspected laboratory site	Plot No A-772/773, MIDC, TTC Industrial Area, Koparkhairane, Navi Mumbai, Maharashtra, 400 701, India		
Inspection details			
Dates of inspection	25 to 27 June 2025		
Type of inspection	Routine		
Introduction			
Brief description of testing activities	**Type of Analysis**	**Finished Products**	**Active pharmaceutical ingredients**
	Physical/ Chemical analysis	pH, Density, Viscosity, Conductivity, Water content (Karl Fischer), Loss on drying, Refractive Index, Specific optical rotation, Limit tests, Residual solvents, Dimensions, Uniformity of dosage units (Mass, Content), Dissolution, Disintegration, Hardness, Friability, Nitrogen determination, Heavy metals, Osmolality, Particulate matter, Total organic carbon, Appearance, Extractable volume,	pH, Solubility, Water content, Melting point, Refractometry, Loss on drying, Limit tests, X- ray diffractometry, Thermal analysis (DSC, TGA), Optical rotation, Conductivity, Density, Specific gravity, Viscosity, Osmolarity, Heavy metals, Sulphated ash, Acid insoluble ash, Residual solvents, Nitrogen value, Osmolality, Particulate matter, Appearance, Clarity and Degree of opalescence of liquids, Degree of coloration of liquids,

		Particle size, Re-dispersibility (Reconstitution time) and Polarography.	Distilling range, Acid value, Ester value, Hydroxyl value, Iodine value, Peroxide value, Saponification value, Total organic carbon, Particle size, Freezing point, Drop point, Boiling point, Unsaponifiable matter, Organic volatile impurities, ICP-MS, AAS and Polarography.
	Identification	IR, HPLC (UV-Visible, PDA, RI detection, Electro chemical), TLC, AA Spectrophotometry, Basic tests, GC (FID, TCD), UV-Vis Spectrophotometry.	IR, HPLC (UV-Visible, PDA, RI detection, Electro chemical), TLC, AA Spectrophotometry, Basic tests, GC (FID, TCD), UV-Vis Spectrophotometry, Chemical reaction, FT-IR, GC/MS, LC/MS, CHNS and HRMS Analysis.
	Assay, impurities and related substances	HPLC (UV-VIS, PDA, RI detection), UV, AAS, GC MS, LC MS, HRMS Extractables & Leachable studies and Nitrosamine impurity testing, FTIR spectrophotometry, Volumetric titrations, Potentiometric titration, ICP-MS and dissolution.	HPLC (UV-VIS, RI detection), UV, AAS, GC MS, LC MS, HRMS Extractables & Leachable studies and Nitrosamine impurity testing, Volumetric titrations, ICP-MS and Potentiometric titration.
	Microbiological tests	Identification, Microbial limit tests, Microbial purity, and Bacterial	Identification, Microbial limit tests, Microbial purity,

		endotoxins test (LAL), Microbial assay, Preservative effectiveness test, Stability Study, ICH conditions.	Bacterial endotoxins test (LAL), Microbial assay, Preservative effectiveness test Stability Study, ICH conditions.

General information about the laboratory	SGS was originally founded in 1878 with its foundations in grain trading in Europe. The company was registered in Geneva, Switzerland as Société Générale de Surveillance (SGS) in 1919 and during the mid-20th century, SGS began to diversify into a variety of services across different sectors including industrial, minerals, oil, gas and chemicals. SGS laboratory is a contract laboratory that began operations in January 2012. This site is responsible for the testing of pharmaceutical samples (raw materials, Excipients, Active pharmaceutical ingredients, and finished products) according to the applicable pharmacopeial monographs or client test methods. SGS India carry out the following activities: • Physical-Chemical tests • Microbiological tests • Stability studies Validation of analytical methods of pharmaceutical
History	WHO inspection was performed in November 2022 for this site.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The inspection covered all sections of the WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL).
Restrictions	Nil
Out of scope	The laboratory did not perform any Sterility 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
GCMS	Gas chromatography-mass spectrometry
GMP	Good manufacturing practices
HPLC	High performance liquid chromatography (or high-performance liquid chromatography equipment)
HRMS	High resolution mass spectroscopy
KF	Karl Fisher titration
LCMS	Liquid chromatography-mass spectrometry
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**

1. Organization and management system

Structural and general requirements

The organization and management structure of the laboratory was clearly documented and defined within the organisational chart. Roles and responsibilities were available with the overall reporting structure available with clear delineation for release of product. Unit 1 housed the microbiological laboratory and the chemical laboratory where WHO samples would be tested.

The inspectors verified that the laboratory had established processes that met the requirements of WHO good practices for pharmaceutical quality control laboratories (Annex 1), and other applicable regulations.

There were no outsourcing processes occurring at the site.

The laboratory implemented policies and procedures in accordance with the Quality Manual to ensure the confidentiality of documentation/information received as well as generated. The procedures to ensure that staff were not subjected to commercial, political financial, and other pressures / conflicts was available.

Quality Manual (QM)

The Laboratory's Quality Manual adequately addressed and reflected the intended practices of the laboratory, with clear commitment from top management for the continual improvement and support of the QMS. Each business line was centralized from the SGS headquarters that were based in Geneva, Switzerland, with a high level, overarching QM for all sites. The manual was set out in accordance with the requirements of ISO 17025:2017 and WHO TRS 1052 Annex 4. It contained a description of the interaction between the processes of the QMS with a defined structure of the documentation system. The QMS consisted of organization structure, policies, procedures, processes, and resources needed.

Quality Policy

The Quality Policy and Quality Objectives were clearly defined within the QM and were endorsed by top management. There had been no significant changes since the last WHO inspection.

Control of documentation and records

There was an established process for the control of documents using the software programme Trackwise. Unique document numbers, effective date and next review date was all available. The control of documents was assigned to the QA team and staff were unable to print controlled documents. The system applied the name and date of the staff member printing the documents to the footer, ensuring full traceability of printed documents.

Change control:

The laboratory had a well-documented, high level change control process that addressed roles, responsibilities, and the approval process. Change notification would be performed and not limited to modification or introduction of new equipment, facilities, new customers or significant changes to key staffing personnel. All changes were to be tracked and controlled through TrackWise. Changes were reviewed and all supporting documents were available and easily accessible.

Proficiency Testing (PT)

A procedure and plan for participating in Proficiency Testing schemes was in place. The proficiency testing for Microbiology and was for Chemistry verified.

Control of Data / Computerized Systems

System information such as unique identification number of software systems or instruments, validation status, software version and system name were available. Computerized systems were validated. There was a procedure available for the backing up of electronic data. The daily backup was performed and verified by the inspection team, along with the daily verification of data by the IT personnel.

Data integrity and access to the data was controlled by user ID and protected by a password, also, chromatography data acquisition, processing, reporting, user account administration E-sign and system policy and audit trail verification for LIMs software was followed according to a documented procedure.

Management Review

A procedure for management review meetings was presented. These meetings were convened at planned intervals, to monitor the QMS's effectiveness.

Corrective and preventive actions

The corrective action and preventive action procedure was available. The procedure adequately described the steps for identifying and implementing corrective and preventive actions in relation to findings from internal or external audits, regulatory inspections, quality events such as complaints, deviations, or OOS. Any situation potentially leading to a deviation or nonconformity was addressed, leading to preventive action depending on their potential impact. Preventive actions were treated as risks or opportunities. Appropriate timelines were available within the document.

Internal audits

The laboratory continued to have a system of planned and documented internal Quality Audits to verify whether activities complied with planned arrangements, the requirements of the Quality Management System, and to determine the effectiveness of the Quality System. An annual schedule for internal audit was prepared and circulated for the staff members.

2. Planning and strategic management

Externally provided services and supplies

The process for selecting and purchasing products and services that the laboratory required was described in the Supplier/Vendor Evaluation procedure. The list was comprehensive, containing information on the supplier/vendor, category, date of assessment and date of reassessment. The re-qualification for all service providers and suppliers was performed every 2 years. There was a process for the discontinuation of suppliers who were not performing as required.

Review of tenders and contracts

At the time of inspection there were no tenders, subcontracting or other contracts in place.

Quality Risk Management

The laboratory had an adequate procedure for the management of risk. The laboratory used the FMEA model for risk assessment.

Incidents and deviations handling

The laboratory continued to have a documented procedure in place for the review of deviations. The deviations were classified into critical, major, and minor.

3. Resources

Personnel

The laboratory had sufficient personnel with the necessary education, training, technical knowledge, and experience for their assigned functions. Staff interviewed were open and forthcoming with information, there was a willingness to learn and were open to exploring new ideas. The competence requirements for personnel for each function were documented. The laboratory had procedures in place for the training of staff as well as a training plan.

The job description for the personnel responsible for the release of testing results was reviewed.

Procedures and criteria for the continuous assessment of personnel competence were documented, and training or requalification of personnel was provided.

Premises

The laboratory facilities were of suitable size and design to suit the functions and to perform the operations to be conducted in them. The laboratory was constructed with frame infrastructure with Reinforced Cement Concrete (RCC) roof. The facility was well maintained, clean and orderly and clearly sign posted. Access to the facility was controlled with the use of or electronic card access and a list of staff who were trained and had access to the area was available at the entrance of each secured facility.

All rooms were temperature and humidity monitored with recordings available at the start and end of the day. The laboratory was equipped with adequate instruments and equipment, including workbenches, workstations, and fume hoods. Separate instrument rooms for different measurement techniques were available as required. Where necessary, cold storage facilities, refrigeration (2-8°C), freezers (-20°C) and deep freezers (-70°C) were utilised. Adequate safety equipment was appropriately located, and measures were in place to ensure good housekeeping and cleaning routines.

Environmental conditions, including lighting, energy sources, temperature, humidity, and air pressure, were appropriate to the functions and operations performed, with relevant conditions monitored, controlled, and documented. There was one centralized AHU system for the chemistry laboratory to maintain the temperature between 15-25°C. The temperature monitoring was performed through a real time monitoring system with an alarm system.

The archive facilities were provided to ensure secure storage and retrieval of all documents, with records kept in secure rooms, locked by keys kept by the custodians of the documentation. The archive rooms were tidy and well organised.

The storage of samples, columns and reagents was only accessible to authorized personnel. The premises adequately accommodated the features required of a pharmaceutical testing laboratory and minimized the risk to staff health and the quality of analytical results. A separate microbiology laboratory was available on the same floor.

Procedures were in place for the safe removal of waste, conforming to local environmental standards and documented within the Waste disposal procedure.

Microbiology laboratory:

Access to the microbiology laboratory was controlled with the use of electronic card access and a list of staff who were trained and had access to the area was available at the entrance of each secured facility.

Equipment, instrument and other devices

The laboratory had the necessary apparatus, equipment, instruments, or instrument systems used in analyses (analytical equipment) for the correct performance of tests and related activities. All equipment, modules, and accessories were uniquely identified, including manufacturer details, identification numbers, location, and equipment specifications. Records/logbooks were kept for items of equipment with information to identify the device, current location, maintenance conducted, history of damage, malfunction, modification, or repair. Use of the instrument/column was also recorded.

Reference substances and reference materials

Reference substances from reputable commercial sources or those supplied by the pharmaceutical product manufacturer, or approved by the national medicines licensing authority, were available. The control of reference substances and materials was overseen by a designated staff member/custodian.

4. Technical activities

Incoming samples

The standard operating procedure for the test distribution, receiving, handling, storing, and transporting of samples was available and found appropriate. Samples to be subjected to stability studies were stored in qualified stability chambers (walk-in and reach-in chambers) and managed in accordance with established stability programs.

Dedicated staff from the laboratory were responsible for the transfer of samples from the storage area to the laboratory. Sample storage area contained a refrigerator and deep freezer. The temperature monitoring was monitored through an alarmed real-time monitoring system. Temperature sensitive materials which needed to be stored at 2-8°C were received with data loggers which were checked, and the temperature was recorded on the check list.

Selection, validation, and verification of analytical procedures

The laboratory had an analytical method validation procedure that was reviewed and found acceptable. A microbiological method validation and verification procedure was also available.

The analytical procedures available in the laboratory were either received from the client or a copy of the pharmacopoeia.

Evaluation of test results and OOS investigation

The laboratory had detailed procedures on the handling of suspected out-of-specification (OOS) results.

Retained samples

All samples received were divided upon receiving into three portions i.e., analysis portion, re-analysis portion and the retention portion. The samples were kept for six months after the expiry date and were kept in their original packaging. The retention samples room was locked, and access was restricted to authorized personnel only. The expiry dates were well managed. Samples were kept without any regular physical checking.

Subcontracting of testing

SGS Pharma Navi Mumbai laboratory did not subcontract testing to any external laboratory within or outside of India.

5. Safety rules

Environmental health and safety policies were followed to protect the staff, the public, and the environment.

Protective clothing, including eye protection, masks, and gloves, was available and fit for purpose. Safety showers (for eyes and full body) were installed at suitable locations and were fit for purpose. Staff were instructed in the safe handling of glassware, corrosive reagents, and solvents.

Presently, mobile elephant noses were present in the wet chemistry laboratory area, providing sufficient ventilation to remove fumes, odours and airborne contaminations. Spill kit equipped with liquid and dry powder spill control along with the safety manual was available.

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, ***SGS India Pvt Ltd – Life Science*** located at ***Plot No A-772/773, MIDC, TTC Industrial Area, Koparkhairane, Navi Mumbai, Maharashtra, 400 701, India*** 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 GPPQCL Guidelines or ***TRS No. 957, Annex 1***
   https://www.who.int/publications/m/item/who-good-practices-for-pharmaceutical-quality-control-laboratories---trs-957---annex-1

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 good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
Short name: WHO TRS No. 970, Annex 2
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs970-annex2-gmp-wate-pharmaceutical-use.pdf?sfvrsn=39eb16b8_0

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

5. Guideline on data integrity. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fifth Report Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 4.
Short name: WHO TRS No. 1033, Annex 4
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

6. 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 GMP guidelines or ***TRS No. 986, Annex 2***
https://apps.who.int/iris/bitstream/handle/10665/112733/WHO_TRS_986_eng.pdf?sequence=1

7. 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
http://apps.who.int/iris/bitstream/handle/10665/44291/WHO_TRS_957_eng.pdf?sequence=1

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 3.
Short name: WHO TRS No. 957, Annex 3
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/trs957-annex3-gmp-pharmaceutical-products-containing-hazardous-substances.pdf?sfvrsn=bd8e1374_5&download=true

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
   Short name: WHO TRS No. 961, Annex 6
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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

11. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9.
    Short name: WHO TRS No. 961, Annex 9
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

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
    http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

13. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8.
    Short name: WHO TRS No. 1010, Annex 8
    https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs1010-annex8-who-gmp-heating-ventilation-airconditioning.pdf?sfvrsn=c77698e2_0

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

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

16. WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. ***Short name: WHO TRS No. 961, Annex 14***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

17. WHO Guidelines on good manufacturing practices: validation, Appendix 7: non-sterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3. ***Short name: WHO TRS No. 992, Annex 3***
https://www.who.int/publications/i/item/9789241209922

18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. ***Short name: WHO TRS No. 992, Annex 4***
https://www.who.int/publications/i/item/9789241209922

19. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. ***Short name: WHO TRS No. 992, Annex 5***
https://www.who.int/publications/i/item/9789241209922

21. 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

22. 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://apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf?ua=1

23. Guidance for organizations performing in vivo bioequivalence studies. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 9.
Short name: WHO BE guidance or ***TRS996 Annex 9***
https://apps.who.int/iris/bitstream/handle/10665/255338/9789241209960-eng.pdf?sequence=1&isAllowed=y

24. Guidance for Good chromatography practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-fourth report, (WHO Technical Report Series, No. 1025, 2020), Annex 4.
Short name: WHO TRS No. 1025, Annex 4
https://cdn.who.int/media/docs/default-source/medicines/who-technical-report-series-who-expert-committee-on-specifications-for-pharmaceutical-preparations/trs1025-annex4.pdf?sfvrsn=53f56dbc_4&download=true

25. Good Manufacturing Practices, Annex 3; Guidelines on validation Appendix 5. Validation of computerized systems (adopted, subject to the changes discussed by the Expert Committee - WHO Technical Report Series, No. 1019, 2019)
Short name: WHO TRS No. 1019, Appendix 5
chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/production/who-good-manufacturing-practices-guidelines-on-validation.pdf?sfvrsn=9440a5c_0&download=true