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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	14 to 17 November 2022		
Type of inspection	Initial		
Introduction			
Brief description of testing activities	**Type of Analysis**	**Finished Products**	**Active pharmaceutical ingredients**
	Physical/Chemical analysis	pH, water content, Loss on drying, limit tests, tablet hardness, friability, disintegration, dissolution, uniformity of dosage units (mass, content), Optical rotation, AAS, ICPMS, LCMS/MS, GC-MS/MS Residual solvents.	pH, melting point, loss on drying, heavy metals, water content, limit tests, Specific Optical rotation, AAS, ICPMS LC-MS/MS, GC-MS/MS Residual solvents.
	Identification tests	HPLC, GC, TLC, UV-Vis spectrophotometry, FTIR, Chemical Identification Tests.	HPLC, GC, TLC, UV-Vis spectrophotometry, FTIR, Chemical Identification tests.
	Assay, impurities and related substances	HPLC, GC, UV-VIS spectrophotometry, ICP-MS/MS volumetric titrations	HPLC, GC, UV-VIS spectrophotometry, ICP-MS/MS volumetric titrations
	Microbiological analysis	Microbial limit tests, bacterial endotoxins	Microbial limit tests, bacterial endotoxins

		test, preservative efficacy test, microbial assay of antibiotics, Particulate matter test, Bioburden, Purity check	test, preservative efficacy test, microbial assay of antibiotics, Particulate matter test, Bioburden, Purity check
	Stability studies	ICH conditions	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 operates across a wide variety of industry sectors with more than 96,000 employees across 2,700 offices and laboratories and are active in nearly every country in the world.		
History	This was the initial inspection of this site.		
Brief report of inspection activities undertaken – Scope and limitations			
Areas inspected	Quality Management System Personnel Training and Safety Documentation and Records Premises and Equipment Validation – Qualification –Calibration Laboratory Practices Reference standards – Reagents – Water		
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		
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 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. At the time of inspection, the total number of staff was 125 in Unit 1 and 52 in Unit 2. Unit 1 housed the microbiological laboratory and the chemical laboratory where WHO samples would be tested if this site were found compliant.

The laboratory was comprised of the following sections:

- Chemical
- Microbiology
- QA
- Management
- Support staff and others

Top management had an established Quality Policy. The inspectors verified that the laboratory had established processes that mostly met the requirements of WHO good practices for pharmaceutical quality control laboratories (Annex 1), the standard (ISO 17025:2017), and other applicable regulations (notwithstanding the nonconformities identified during this inspection).

The laboratory has obtained ISO 17025:2017 method-specific accreditation for selected chemical- and biological tests.

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.

2. Quality management system

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 according to the requirements of various standards including but not limited to ISO 9001, ISO 17025 and ISO 22003 (food safety). 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.

Job descriptions for the business director, quality manager and technical manager were available within the manual.

Internal Audits:
The laboratory implemented an internal audit program including documented requirements. This high-level corporate document described the requirements for independent auditors. Training records were reviewed and found appropriate. All nonconformities identified were captured as corrective actions and were followed using the laboratory's CAPA process.

Management Review (MR):
Documented requirements for management review were implemented and the review meetings were held annually. The global quality policy was discussed and implemented at this site, there was no site-specific quality policy. Target completion dates were available within the minutes as well as major changes to equipment. Supplier audits were limited due to COVID-19. Trending was available.

CAPA handling:
Handling and disposition of non-conformity events, as well as related a CAPA plan took place in accordance with the procedure. An appropriate timeline was available within the document with minor or major CAPAs being actioned within ten (10) days and all critical in nature within one (1) day. CAPAs raised for 2021 and 2022 were reviewed. CAPAs were to be initiated from findings from internal or external audits, regulatory inspections, quality events such as complaints, deviations or OOS. The majority of CAPAs raised were the result of OOS or deviations. Effectiveness checks were performed before closure of the CAPA.

Incident and deviation handling:
The laboratory had a documented procedure in place for the review of deviations. A 30-day timeline for the closure of deviations was documented.

All supporting documents were linked and readily accessible in the system, including email communications etc.

Complaints:
The laboratory had a customer complaint process available. Complaints were registered and monitored within TrackWise. The procedure clearly defined timelines for when complaints were to be dealt with and assigned to the appropriate team to action.

Depending on the nature of the complaint and investigation findings, a CAPA would be raised. All related documents were readily available and linked within TrackWise. Complaints were reviewed during MR as per the procedure. During investigation, root cause analysis was performed along with 5 WHY technique with all documents available.

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.

Purchasing:
The laboratory relied upon software for supply inventory and the system would alert personnel when stocks were low.

Disaster recovery:
The laboratory had a detailed and robust process for IT. Backup of data was to occur daily, weekly, monthly, and yearly. A random review of files was performed.

All laboratory-based PCs were not connected to the internet and were all password protected with users changing passwords every 90 days.

3. Control of documentation

There were well defined documented procedures for document and record control which met the requirements of the standard.

TrackWise (a Salesforce product) was implemented in late 2019 and used for this purpose with three levels of access and permission control available. QA were the only ones provided with printing permission. The review period was 3 years with validation protocols every 5 years, with a retention period of 5 or 10 years depending on the document type. Each controlled document had a unique identifier, version number and effective date. All staff had access to a computer and instrument SOPs were available at the point of use. An audit log was available within the TrackWise system. All Certificates of Analysis (CoA) were released through LIMs.

4. Records

Records were available of analytical tests, including calculation and derived data, instrument use, calibrations and maintenance, and sample receipt in logbooks containing consecutively numbered pages. Overall records were found to be complete.

5. Data processing equipment

An inventory of all computerised systems was available. Information such as unique identification number of software system or instrument, validation status, software version and system name were available. The laboratory implemented procedures to protect the integrity- and confidentiality of data and records generated.

6. Personnel

The laboratory was staffed with personnel who had the necessary education, training, technical knowledge, and experiences for their assigned functions. Staff questioned were open and forthcoming with information, there was a willingness to learn and were open to exploring new ideas.

Staff training was structured on three levels: (i) New employee orientation, (ii) Technical training and (iii) Retraining of current staff. A training plan was available which identified the training coordinators responsible for the development of training courses and quizzes on the e-training management system. The laboratory classified training courses into three categories: instructor led courses, virtual classrooms, and self-paced online courses. On-the-job (OTJ) training of staff was also performed and manually documented by dedicated trainers. Basic training needs and criteria for evaluation have been identified and documented in the work instruction for training management system. A training matrix was maintained and available for review during the inspection. All training activities were trended and training activities for continuous improvement have been identified and discussed during the annual management review meetings.

Training files for staff were maintained and available for review during the inspection. Training files contained the following for each staff member: CV, orientation check list, job description, self-declaration on data integrity, declaration on e-signatures, technical training needs, basic technical training forms, technical training proficiency forms. Re-training of staff was performed as part of the CAPA / deviation management process in the laboratory.

The training records for internal auditors, QA manager and selected chemical- and microbiological analysts were available upon request.

7. 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 facility was well maintained, clean and orderly and clearly sign posted. The Pest control management procedure was available.

Access to the facility was controlled with the use of either fingerprint recognition or electronic card access with access restriction assigned to high-risk areas. A list of staff who were trained and had access to the area was available at the entrance of each secured facility. The IT server room was temperature monitored. All contractors were provided a copy of the Laboratory safety policy and procedures that was read and signed. For high-risk areas such as the microbiological facility, contractors would be always accompanied by a staff member.

All rooms were temperature and humidity monitored with recordings available at the start and end of the day. A real time temperature monitoring system was in the process of being implemented (vendor was currently performing IQ) but was not fully functional at the time of inspection.

There was a separate specimen reception area, with separate area for the storage of samples.

Separate storage facilities were maintained for retained samples and archived documents.

There was a cleaning procedure available for the microbiological facility with a rotation of disinfectants used.

The laboratory performed regular environmental monitoring of the microbiological facility. The trend analysis between July 2022 and September 2022 was reviewed. Acceptance criteria was available within the report.

The facility installed and used a dedicated hepahood that was equipped with an analytical balance, for the weighing of toxic and/or high-risk chemical materials.

8. Equipment, instruments and other devices

The laboratory had a well-documented system for the calibration, maintenance and use of equipment with individual procedures available for all equipment.

The facility had a designated lockable storage area for columns. All columns were supplied by the client and were assigned a SGS LIMs unique identifier for ease of identification. Injection numbers were tracked via LIMs and upon completion of the project the column was returned to the client.

The laboratory made use of automated and manual glassware cleaning procedures. Validation records for the cleaning procedures applied within the laboratory were available and considered acceptable during the inspection. Validation records for the cleaning of dissolution apparatus and auto-sampling equipment used were available for review.

All equipment selected had the maintenance and calibration logbooks readily available. All maintenance reviewed was within the calibration period assigned by the laboratory.

All temperature mapping was conducted by an external company.

The laboratory performed a functional risk assessment on the polarimeter to aid in the establishment of user requirement specifications and qualification requirements for the mentioned instrument

9. Contracts

The laboratory had a process in place for the review and evaluation of suppliers in the Supplier/Vendor procedure. Suppliers were classified into three (3) levels according to risk and criticality. Suppliers that were classified as either level 1 or 2 were re-evaluated every three years.

10. Reagents

Reagents used within the laboratory were managed in accordance with the procedure for the management of reagents. The laboratory had a process in place for the labelling of chemicals and reagents upon receipt and again once opened that included using a sticker that contained the required information as per the standard.

The laboratory had a procedure for the evaluation and approval of suppliers / which required the approval of chemical- / reagent suppliers prior to using them.

11. Reference substances and reference materials

The laboratory had a documented procedure for the use and control of reference substances and reference materials, which classified reference substances into three classes. The terminology used and defined in the mentioned SOP was found was aligned with that recommended by the WHO.

The facility maintained a register for all reference substances and was managed by nominated members of staff. Certificates of analysis and material safety data sheets were maintained for reference substances. The laboratory makes use of primary- and working reference standards in the testing of pharmaceutical samples.

The use of reference substances was documented on reference substance dedicated usage logs. The expiry of reference substances was checked monthly, and expired substances removed from the storage facilities.

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

The list of all equipment, instruments and computerized systems was maintained by the laboratory. Unique identification numbers were assigned to all equipment and instruments used.

The validation master plan described the overall approach to the calibration, verification and performance qualification of equipment, instruments, facility, computerized systems, personnel, cleaning and vendor qualification. The frequency for preventive maintenance, calibration, verification and performance qualification as well as the procedures and relevant acceptance criteria have been documented in instrument / equipment specific standard operating procedures.

Specific procedures were available for each instrument / equipment being used within the facility. Staff were suitably trained and authorised to operate instrument / equipment. Records for the use, maintenance and calibration/verification thereof were maintained and available for review during the inspection.

13. Traceability

The laboratory had an adequate process in place to ensure traceability.

14. Incoming samples

The laboratory had a process in place for sample management.

The laboratory was not responsible for sampling of materials or products, all samples were provided by clients for testing.

Sample information was maintained on the Laboratory Information Management System (LIMs). Quantity was entered and the number of labels printed was determined by this quantity. If an error occurred during printing the operator was required to contact support to enable additional labels to be printed.

Samples to be subjected to stability studies were stored in qualified stability chambers (walk-in and reach-in chambers) and managed in accordance to established stability programs.

Once samples were released from specimen reception, they were retained in appropriate secure locations within the appropriate testing areas.

15. Analytical worksheet

The laboratory made use of analytical worksheets which were complimented by raw data. Worksheets were issued and controlled by the quality assurance department using Trackwise Separate analytical worksheets were used for different analytical activities and all worksheets relating to the specific product were assembled and maintained by the quality assurance department upon completion of the testing activities.

Completed analytical worksheets were signed by the responsible analyst, verified by a second qualified analyst, then verified and approved by the applicable supervisor. In general, the documentation practices implemented by the laboratory was found to be acceptable.

16. Validation of analytical procedures

The cleaning validation for the microbiological facility was reviewed. The microbiological facility was using the disinfectants as per the findings in the validation report.

The laboratory had a well-documented protocol and report for the validation of the glassware cleaning procedure used in the facility. The HPLC method used for the detection of impurity residues during the cleaning validation studies was suitably validated for its intended use.

The laboratory made use of pharmacopoeial methods, in-house developed methods and client supplied methods for the chemical analysis of APIs and FPPs. The analytical method validation procedure was available and required that when the validation of a method of analysis was requested by a client, the validation protocol should be developed by the laboratory, reviewed by the QC and QA departments as well as the client prior to the execution of the validation study. In the event where the client provided a validation protocol, the proposed protocol should be reviewed and approved by SGS prior to initiating the study. The validation parameters considered in the development of the validation report were aligned with that specified in the WHO and ICH validation guidelines. The SOP provided general guidance for the establishment of acceptance criteria to be included in the validation protocol for all analytical techniques performed at the facility.

The laboratory also performed verification of compendial methods in accordance with a documented procedure. As for method validation, the laboratory also developed individual method verification protocols and verification reports.

17. Testing

Test procedures were described in detail and allowed analysts to perform the analysis in a reliable manner.

18. Evaluation of test results

Analytical reports and data were reviewed before the analyst enters the test results on the LIMS. Test results and analytical reports were then reviewed and approved by the quality assurance department. The

procedure for the review and evaluation of test results had been described the relevant procedure. The procedure specifies the responsibilities of the analyst and reviewers with regards to the evaluation of suitability of analytical method of analysis used, experimental setup, suitability of reagents, chemicals, consumables and reference materials, equipment setup, data integrity checks and good documentation practices, audit trail reviews and traceability of all data generated. The evaluation process was facilitated by means of check lists that were to be completed to document the outcome of the review process.

Out of specification, out of expectation and out of trend results were managed in accordance with the TrackWise out of specification procedure. Investigation of OOS results were performed by an investigation team consisting of laboratory head, QA manager, analyst, data reviewer, senior scientist, equipment engineers and project manager. The client was informed of the OOS result identified within 1 working day of identification of the result, and the analytical investigation was required to be completed within 30 days. The laboratory used a 2-phased approach in the OOS investigation. Deficiencies identified in this procedure have been identified and reported. The OOS reports and all related data (including equipment qualification, staff training records, method verification / validation reports, analytical worksheets and certificates of analysis) of the following samples were reviewed during the inspection:

19. Certificate of analysis

The laboratory issued a certificate of analysis for samples tested where method validation or method verification / transfer had been performed by the laboratory. In instances where the client did not request method validation or method verification/transfer, a report of analysis (without any compliance statement) was issued by the laboratory.

20. Retained samples

The laboratory had a separate facility for the retained samples that was well maintained.

21. Safety

At the time of inspection staff were observed wearing laboratory coats, appropriate footwear, and suitable eye protection. Special care was taken in handling highly potent, infectious, or volatile substances. The facility was clean and orderly. Eye wash and shower stations were available that were regularly flushed.

The microbiological facility had in place a process of fumigating the microbiological facility every 15 days.

First aid kits were available with contents within expiry dates.

22. Quality risk management

The laboratory had a Quality Risk Management (QRM) procedure available. The QRM activities were performed in a systematic process which could facilitate and improve science-based decision making with respect to risk. TrackWise was used to track, monitor, and assign responsibilities for risks identified. During the risk assessment process the laboratory performed reasonable risk identification and then a quantitative estimate of the risk was calculated and documented.

The QRM tools (5W's, gap analysis, brainstorming, fish bone analysis & 5-why's analysis) utilized by the laboratory have been described in the procedure.

23. Data integrity

The laboratory had a documented data integrity policy which focussed on the responsibilities, data integrity principles, user access, good documentation practices, principles for data acquisition and processing, e-data backup & audit trails and archival of data and records. The SOP on data integrity provided guidance to staff to support ALCOA+ principles.

Data integrated risk assessments (DIRA) were carried out to identify and assess areas of risk for specific processes / procedures / instruments.

Computerized systems performing GXP functions were validated in accordance with the procedure for computer system validation. Computer system validation checks were performed on computerized systems based on the GAMP category assigned to the specific software installed and used. A list of all installed applications controlled and regulated on GXP and non-GXP systems were provided for review during the inspection.

User profiles and access rights were created and maintained by the IT department (with no conflict of interest in data) of the laboratory in accordance to the data backup – disaster recovery security policy and equipment software management. Different user profiles and access rights have been documented for all computerized systems in the applicable SOP. No modification, copy of deletion rights were assigned to staff of the facility. The maintenance and validity of assigned user profiles were periodically verified by the IT department.

The laboratory made use of GPS wireless clocks and implemented a procedure for the date and time synchronization.

The IT department of the laboratory was responsible for all electronic backups that had to be performed in accordance with the data backup – disaster recovery security policy and equipment software management.

All GXP relevant audit trails were enabled and periodic verification that it remained enabled throughout the data life cycle was performed by the IT team. Electronic signatures were being used on HPLC software systems. Each e-signature was appropriately controlled in that it was attributable to an individual, free from manipulation and date and time stamped. All metadata associated with the e-signatures were retained.

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 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