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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	Auriga Research Private Limited		
Address of inspected laboratory site	Unit III, No. 136, 6th cross, 2nd stage Yeshwantpur Industrial suburb Bangalore 560022 India		
Inspection details			
Dates of inspection	8 to 11 November 2022		
Type of inspection	Initial		
Introduction			
Brief description of testing activities	**Type of Analysis**	**Finished Products**	**Active pharmaceutical ingredients**
	Physical/Chemical analysis	pH, Density, Refractometry, Water content (Karl Fischer), Limit tests, Disintegration time, Dissolution, Uniformity of dosage units (by mass or content), Friability	pH, Refractometry, Optical rotation, Loss on drying, Water content (Karl Fischer), Heavy metals, Acid Value, Iodine value, Limit tests, Nitrogen determination
	Identification tests	HPLC (UV-Vis, Refractive index detection), GC with headspace (FID), TLC, FT-IR, basic tests	HPLC (UV-Vis, Refractive index detection), GC with headspace (FID), TLC, FT-IR, basic tests.
	Assay, impurities and related substances	HPLC (UV-Vis, Fluorescence and Refractive index detection), GC with headspace (FID), ICP-OES, ICPMS, LCMS/MS, GCMS, TLC, UV- Vis	HPLC (UV-Vis, Fluorescence and Refractive index detection), GC with headspace (FID), ICP-OES, ICPMS, LCMS/MS, GCMS, TLC, UV- Vis

		spectrophotometry, FT-IR, Volumetric titrations.	spectrophotometry, FT-IR, Volumetric titrations.
	Microbiological analysis	Microbial Limit Test Bacterial Endotoxin Test. Sterility test. Antibiotic assays. Antimicrobial efficacy Test. Disinfectant efficacy Test, Preservative Efficacy Test.	Microbial Limit Test Bacterial Endotoxin Test. Sterility test. Antibiotic assays. Antimicrobial efficacy Test. Disinfectant efficacy Test, Preservative Efficacy Test.
	Stability studies	ICH conditions	ICH conditions

General information about the laboratory	The Arbro group was originally founded in 1985 and consists of the following Subsidiary companies: Pharmaceutical Manufacturing Unit • Arbro Pharmaceuticals (New Delhi) Commercial Testing Labs • Arbro Analytical Division (New Delhi) • Auriga Research Private Limited (Baddi H.P.) • Auriga Research Private Limited (Bangalore) • Auriga Research Private Limited (Manesar) • Auriga Research Private Limited (Ghaziabad) Auriga Research Private Limited (Bangalore) obtained Approval by Drug Control Department, Delhi (2014), NABL (2015), Food safety & standard authority of INDIA (FSSAI) (2016) and USFDA (2022). Since initial submission to WHO in 2018 the laboratory has increased in size from initial staffing numbers of 97 to currently employing 207 staff. Auriga Research Private Limited is a government approved commercial testing laboratory that provide analytical services to manufacturers, suppliers, consumers at national and international level, and the local regulatory authority. The scope of analytical services that are performed at Auriga Research Private Limited include: • Food and agricultural products • Water • Drugs and pharmaceuticals • Cosmetics and essential oils • Soap, detergents and toiletries • Wastewater Environment monitoring and testing of stack and ambient
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	Sampling was performed by the client (with the exception of water testing samples)
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	Nonconformity
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

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 207 FT with the facility growing rapidly over the past few years.

The laboratory was comprised of the following sections:

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

In general, the Laboratory had arrangements to ensure that its management and personnel were not subject to commercial, political, financial conflicts of interest, however the procedure was found to be lacking continuous monitoring of potential conflicts of interest.

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.

The facility was split over two floors with the lower floor dedicated to food and cosmetic analysis with the upper floor dedicated to the chemical laboratory and microbiological laboratory.

Tracking and inventory was currently handled within the YLIMs – laboratory information management system.

The laboratory established a two (2) year PTS plan which covered the participation of proficiency testing of some of the techniques / analytical activities executed within the facility.

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. It contained a description of the interaction between the processes of the Quality Management System (QMS) with a defined structure of the documentation system. The QMS consisted of organization structure, policies, procedures, processes, and resources needed.

The laboratory has been ISO 17025 accredited for several disciplines including: Biological – animal food & feed, Biological – cosmetics & essential oils, Biological – drugs & pharmaceuticals, Biological – food & agricultural products, Chemical – residues in food products, Biological – environment & pollution, Chemical – on pharmaceuticals: loss on drying, pH, specific optical rotation, disintegration and density. Method specific accreditation included: related substances testing of paracetamol using the Indian Pharmacopoeia.

Internal Audits:
The laboratory implemented an internal audit program including documented requirements with an internal audit schedule available. It was verified that the audits had been conducted by trained and qualified personnel who were independent of the activity that was audited. 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 biannually. Assigned tasks and responsibilities were available.

CAPA handling:
The laboratory had a documented procedure for the handling and disposition of non-conforming events. Investigation reports were available.

Incident and deviation handling:
The laboratory had in place a process for the review of incidents and deviations. Each incident was reviewed by the QA manager and appropriate action was determined.

The Deviation Control procedure was reviewed. Trending of deviations was available.

Complaints:
The laboratory had a customer complaint process available. Complaints were registered within a logbook; the severity of a complaint was determined and appropriate response timelines were available. Complaints were investigated to find out the root cause and appropriate corrective, preventive actions were proposed and implemented. No serious complaints had been received.

Change control:
The laboratory had a well-documented change control process that addressed roles, responsibilities, and the approval process. The laboratory renovated the facility in 2021 and the change for this was reviewed and found to be comprehensive. Requalification of equipment and impact of risk had been completed for the new area and for all the relocated equipment.

Disaster recovery:
The laboratory had a detailed and robust process for IT backup. The QA department provided IT with a monthly list of random equipment for review of backed up material. The IT department would open and print all files associated to that equipment that would then be verified by the QA department.

All hard disks were stored off site as well as stored on the cloud. 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

The laboratory had established and maintained a system of procedures to control all documents. Each controlled document had a unique identifier, issue number and date of implementation. The documents were released by the quality manager and available at the relevant location. Hard copy documents were stored onsite for 6 months, scanned, and then stored offsite at another organisation.

4. Records

Records were made 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. Records were signed, alterations were commented, and references were made to appendices containing the relevant recordings.

The specifications for the tests performed were consistent with that specified in the applicable methods of analysis. Records were kept in an archive.

5. Data processing equipment

An inventory of all computerised systems was available. Information such as unique identification number of software system, purpose, validation status, physical or storage location of the software system and responsible or contact person was available.

6. Personnel

The laboratory had sufficient personnel with the necessary education, training, technical knowledge, and experiences for their assigned functions. Staff undergoing training were supervised and assessed upon completion of training. Training records were available for staff with a process of retraining was to occur after deviation or if an incident had been recorded. The training records for internal auditors were available.

The laboratory made use of a skills matrix to summarize and track personal development of staff and was used to assign analytical tasks to staff – based on their individual skill level.

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 site had recently been renovated to increase the capacity with separation of tasks, with food and cosmetic analysis to occur on the lower floor and the chemical laboratory and the microbiology laboratory on the upper floor. Separate storage facilities were maintained for the secure storage of samples, control sample room for retained samples, reagents, laboratory accessories and reference substances. Electronic key was required to enter the facility and restricted access was assigned to high-risk areas, such as the IT server room.

All rooms were temperature and humidity monitored with recordings available at the start and end of the day. Pictorials were available at the entry of rooms where particular gowning requirements needed to be met. Cleaning procedures were available, with a general procedure available in local language. In practice the laboratory rotated the use of chemicals for cleaning. The mop head used in the microbiological facility was replaced weekly.

Microbiological testing was performed in a contained, access-controlled laboratory unit. Media preparation was performed in a separate area. All micropipettes were serviced by an external contractor.

Temperature control and mapping of facilities and critical instruments (i.e., refrigerators & stability chambers) were available for review.

8. Equipment, instruments, and other devices

Randomly selected equipment, instruments and other devices used for the performance of tests, calibrations, validations and verifications were inspected to verify whether they met the applicable requirements.

The information available with some of the reports provided by external contractors was limited and lacked crucial calibration information (e.g., reference equipment used, acceptance criteria).

The required test equipment and instruments for the performance of laboratory activities, including preparation of samples and the processing of and analysis of test and/or calibration of data were available.

9. Contracts

The laboratory had a procedure in place for the selection and purchasing of services and supplies. An approved list consisted of both contract manufacturers, providing the products and laboratories subcontracted to carry out sample testing, was presented.

The laboratory performed annual evaluation of suppliers.

10. 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.

Labels of reagent contained content, manufacturer, date received and date of opening of the container, concentration, if applicable, storage conditions and expiry date.

Culture media was stored in the room designated for the storage of media in the Microbiology laboratory. The media preparation process was recorded.

The quality of water was tested daily and monthly as per the procedure i.e., TOC, conductivity, silica, heavy metals, microbial counts, and pH to list only a few were regularly verified to ensure that the various grades of water met the appropriate specifications. Colour retention time (Oxiaizable Matter) was performed and used as an internal check and not reported outside of the facility. It was noted that the inhouse water was used for the blank.

The laboratory had a general storage tank and one unit in the chemical laboratory and another in the microbiological laboratory. All systems were tested monthly, and reports were available and were reviewed in detail.

Usage of columns was recorded on a logbook with an injection tally available. The laboratory had determined that 1500 injections and or deterioration of the peak was indication of column deterioration.

The laboratory had a procedure for the preparation and standardization of volumetric solutions, organic volumetric solutions had to be standardized prior to use. The laboratory performed a stability study on selected aqueous volumetric solutions in which they established documentary evidence for the stability of these volumetric solutions. The acceptable shelf-life and storage conditions were determined and documented as such.

11. Reference substances and reference materials

The laboratory made use of both primary and secondary (working) standards. Several secondary standards were sampled and traceability to suitable primary standards were confirmed. The laboratory had a procedure for the handling and usage of certified reference materials available. Reference substances were stored and periodically monitored in accordance with applicable procedures. Unique identification numbers were assigned to reference substances used. The reference standards were manged by a nominated person.

The calibration certificates and suitability of use of reference substances was reviewed.

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

The instrument and equipment observed all contained a unique identification label with the status of the calibration and the date when recalibration was due. The equipment reviewed underwent IQ, OQ and PQ.

Records and logbooks were kept at the place of use for items of equipment with information to identify the device, current location and maintenance carried out.

Procedures were available for the qualification, safe handling and maintenance of equipment used in the laboratory.

13. Traceability

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

14. Incoming samples

The laboratory was not responsible for sampling of materials or products. Samples were either collected by the laboratory or received at reception. Samples reception was logged in the YLIMs system as per the requirements. The Sample Handling procedure was reviewed.

The document titled Labelling Procedure was reviewed. The entering of sample information and labelling was observed. The operator entered the information into YLIMs using a request form from the supplier containing information on the tests required. YLIMs generated a unique barcode, and this was printed.

Prior to testing, chemical samples were stored in the Pharma sample storage room, taking into account the storage conditions for the sample.

Visual inspection of samples was carried out by the laboratory staff to ensure that labelling conformed to the information contained in the test request.

15. Analytical worksheet

Analysts were issued serialized raw data sheets which were used for the recording of analytical procedures and results. The analysts recorded information about samples, test procedures, calculations, and results on issued raw data sheets, which were completed by raw data. Analytical worksheets from different units related to the same test sample were assembled by the quality assurance department.

Where applicable, the raw data sheets were supplemented with system suitability check records and printer audit trails generated by the software.

All values obtained from each test, including blank results, were immediately entered on the analytical worksheet and all graphical data, whether obtained from recording instruments, were attached or were traceable to the instruments used in the generation of the data was available.

The completed raw data sheets were signed by the responsible analyst and verified, approved, and signed by the technical manager or designated member of staff. For corrections the old information was deleted by putting a single line through it; a reason for the deletion and was signed and dated by the person responsible for the correction.

Results were reviewed by an independent and qualified person in accordance with the procedure for review of analytical reports. A checklist had to be completed by the reviewer to approve the results generated. Two separate checklists were available: Chemical laboratory checklist & Microbiological checklist. Electronic data and audit trails were also reviewed on the source instrument.

16. Validation of analytical procedures

The procedure for analytical method validation and verification were available for review. The validation parameters included in the mentioned SOP were aligned with that specified in the ICH Validation guidelines. The validation expectations for dissolution methods lacked the inclusion of specificity requirements. Validation protocols were developed, reviewed and approved prior to the execution thereof, followed by the compilation of a validation report.

The glassware cleaning validation included acid residue and total organic carbon, the full range of glassware within the facility was considered.

17. Testing

Test procedures were described in detail and allowed analysts to perform the analysis in a reliable manner. The documented procedures were described in sufficient detail to allow the reconstruction and re-calculation of results based on the information presented.

18. Evaluation of test results

An SOP was in place describing the conduct of OOS investigations. When a doubtful result (suspected OOS result) was identified, a review of the procedures applied during the testing process was undertaken by the technical manager, analyst and QA manager.

A two phased approach was used for the investigation of doubtful results – including hypothesis testing if an assigned error could not be identified during phases 1(a) & 1(b). Clients were informed of OOS results within one (1) working day, the lab investigation had to be completed within seven (7) working days and in case of a confirmed OOS, the investigation had to be completed within thirty (30) working days.

If the investigation was inconclusive, the SOP gave clear guidance on the number of retests allowed (based on statistical principles). Once an error was identified, corrective and preventive measures were recorded and implemented. All individual results (all test data) with acceptance criteria were reported. The repeat of tests was done by a second analyst, as experienced (or more) and competent as the first one. The laboratory failed to consider inter- & intra-variance between quantitative results when evaluating similarity between re-test and initial-test values.

All OOS events were reviewed, and the root cause identified. Identified root causes were then subjected to trending and classified as either: analyst error, sampling error, no assignable cause or product related error. Based on the identified root cause a corrective- and/or preventive action was implemented.

19. Certificate of analysis

A certificate of analysis was prepared for each sample/batch of a substance or product and contained series of information, among others:
- the results of the tests performed with the prescribed limits and
- a conclusion as to whether the sample was found to be within the limits of the specification.
- The date on which the tests were completed.

20. Retained samples

The laboratory retained redundant samples (i.e., samples on which all analytical testing has been completed) in a separate storage area for one (1) year (which agrees with local legislation), after which the samples were destroyed.

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. First aid kits were available with contents within expiry dates. Staff received annual health checks.

There was a reliance on hand sanitizer as a method of disinfection without thorough investigation whether this was appropriate for the types of samples handled.

The laboratory included safety checks on some instruments such as leak detection tests on gas cylinders for GC instruments, and qualification of airflow on fume hoods (performed by external contractor).

22. Quality risk management

The laboratory had a Quality Risk Management (QRM) policy and this was made available. The QRM activities were performed in a systematic process which could facilitate and improve science-based decision making with respect to risk.

During the risk assessment process reasonable risk was identified and then a quantitative estimate of the risk was calculated and documented. The risk appetite of the laboratory had been clearly identified as well as the criteria for specified action levels. The outcome and output of QRM activities were communicated to all staff during training sessions and discussed with management during management review meetings.

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 for investigation tools. The risk register of the facility was reviewed and was found to be within developmental stages.

23. Data integrity

The laboratory had a written policy, procedure and data integrity declaration available. The laboratory reviewed all data generated (paper & e-records) for consistency with ALCOA+ principles.

Training records of staff were reviewed and indicated that staff has been trained on data integrity principles and the applicable laboratory procedure . Risk-reduction measures were implemented such as second-person oversight of data generated within the facility. Staff had been trained on good documentation practices.

The laboratory developed and implemented a procedure for the management of user accounts, roles and privileges in various application software. The implementation of the aforementioned SOP on HPLC, polarimeter and IR-spectrophotometer systems was evaluated and found to be in agreement with the rights specified in the SOP. IT staff (with no conflict of interest in data generation) had been appointed as system administrators. Individual user accounts had been created for staff on computer systems, and no shared or generic user accounts were detected. Date and time settings were adequately protected to avoid changes being made to it by unauthorised users. USB, CD and DVD drives have been deactivated for use by laboratory staff.

Audit trails had been activated on all computer systems and always remain enabled. Raw data and audit trails were reviewed as part of the data review procedure as discussed earlier. Electronic signatures were currently only being used on HPLC systems. All e-signatures were attributable to individuals, which were free from alteration and manipulation and was date and time stamped. All metadata associated with the e-signatures were retained on the systems.

The laboratory had established a password policy requiring the change of passwords every ninety (90) days and specified specific requirements for the composition of passwords.

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, ***Auriga Research Private Limited***, located at ***Unit III, No. 136, 6th cross, 2nd stage, Yeshwantpur Industrial suburb, Bangalore 560022, India 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 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***
   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