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WHO Prequalification Unit (PQT) - Inspection Services Team (INS)
WHO INSPECTION REPORT
of the Quality Control laboratory

Part 1	**General information**
Laboratory Details	
Name of the Laboratory	Research Institute for Industrial Pharmacy (RIIP), incorporating CENQAM (RIIP®/CENQAM®)
Address of the inspected Laboratory	North-West University, Potchefstroom Campus Building G2 and G16 11 Hoffman Street Potchefstroom 2531 South Africa
Address of corporate office, telephone number, and fax number	As above
Dates of inspection	From 14 to 16 July 2025
Type of inspection	Routine inspection
Introduction	

Brief description of testing activities

Type of analysis	*Finished products*	*Active pharmaceutical ingredients*
Physical/ Chemical analysis	pH, water content (Karl Fischer), loss on drying, friability, disintegration, tablet hardness, uniformity of dosage units (mass, content), tablet dimensions, dissolution, density/specific gravity, re-dispersibility/ reconstitution time, re-suspendability, sedimentation rate, and turbidity.	pH, water content (Karl Fischer), loss on drying, X-ray diffractometry, Particle size analysis, Limit tests and Melting point (Capillary).
Identification	IR, TLC, HPLC, UV spectrophotometry, and basic tests.	IR, TLC, HPLC, UV spectrophotometry, and basic tests.
Assay, impurities, and related substances	HPLC (UV, UV-Vis, DAD, Fluorescence, and RI detection), GC, UV spectrophotometry, and volumetric titrations	HPLC (UV, UV-Vis, DAD, Fluorescence, and RI detection), GC, UV spectrophotometry, and volumetric titrations

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		Determination of related substances/impurities and degradation products.	Determination of related substances/impurities, degradation products, and residual solvents.
General information	The RIIP®/CENQAM® is part of the Centre for Pharmaceutical and Biomedical Services (CPBS) of the Faculty of Health Sciences at the North-West University, Potchefstroom Campus, South Africa. It is located on the Potchefstroom Campus of the North-West University. The laboratory provided a range of specialized services in support of pharmaceutical quality control, as outlined below: Final Product Release Control (FPRC): Although batch release analysis was generally conducted by the manufacturer, RIIP®/CENQAM® also participated in this activity, particularly in settings where the industry lacked advanced analytical infrastructure. Services included local batch release and post-importation testing. Drug Release Testing: RIIP®/CENQAM® possessed expertise in drug release testing and employed various techniques such as disintegration testing for solid dosage forms and dissolution studies. Solid-State Physico-Chemical Studies and Comparative API Analysis and Qualification: The laboratory specializes in identifying drug polymorphic forms (raw materials and solid dosage forms), compiling comparative synthesis route reports, conducting fingerprint or identity analysis, performing pre-formulation studies of API and IPI interactions, and executing monograph testing. Additional Services: Other activities included analytical method transfer, consultation, literature services and interpretation, training, and research.		
History	A desk-based assessment was conducted in November 2019, after an inspection carried out in 2014. The laboratory had been prequalified on 5 July 2005.		
Brief report of inspection activities undertaken – Scope and limitations			
Areas inspected	Organization and management, including: - Structure - QMS - Documentation and records - Computerized systems Planning and strategic management, including: - Service providers and suppliers - Performance management - Quality Risk management		

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	Resources, including: - Personnel - Premises - Equipment qualification - Reagents, RS Technical activities, including: - Handling of samples - Validation, verification and transfer of analytical methods - Testing, evaluation and reporting of results & OOS Safety
Restrictions	Not applicable
Out of Scope	Refer to the table of activities.
Abbreviations	**Meaning**
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
CAPA	Corrective action & Preventive action
DQ	Design qualification
FPP	Finished pharmaceutical product
FTIR	Fourier transform infrared spectrophotometry or spectrophotometer
GC	Gas chromatography or Gas chromatography equipment
GMP	Good manufacturing practices
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
IQ	Installation qualification
IR	Infrared spectrophotometry
KF	Karl Fischer titration
LIMS	Laboratory information management system
MB	Microbiology
MR	Management review
N	Normality
NC	Non-conformity
NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specification test result
OQ	Operation qualification
Ph.Eur.	European Pharmacopoeia
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PT	Proficiency testing
PTS	Proficiency testing scheme

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PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QM	Quality manual
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
RS	Reference Standard
SOP	Standard operating procedure
TLC	Thin layer chromatography
TOC	Total organic carbon
URS	User requirements specifications
USP	United Stated Pharmacopoeia
UV	Ultraviolet-visible spectrophotometry or spectrophotometer
VMP	Validation master plan
VS	Volumetric solution

Part 2	**Summary of findings and recommendations (where applicable)**

1. Organization and management system

1.1. Structural and general requirements

A detailed presentation of the Laboratory was provided during the opening meeting.

SAHPRA legally authorised the laboratory to operate and assume responsibility for the test results, certificates of analysis, and other activities performed.

Senior management was responsible for the establishment, implementation, and control of an effective quality system and data governance system by ensuring that appropriate policies, training, and technical systems were in place.

Management ensured that both managerial and technical staff were provided with the necessary authority and resources—financial, human, and infrastructural—to effectively perform their duties.

Procedures were established to prevent any influence that could compromise impartiality, including the declaration of conflicts of interest and the maintenance of confidentiality for all laboratory information, such as analytical methods and the transfer of results or reports.

Organizational charts defined the laboratory's organisational and management structure, its position within the parent organisation (Faculty of Health Sciences at NWU), and the relationships between management, technical operations, support services, and the QMS.

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The responsibility, authority, and interrelationships of all personnel who managed, performed, verified, reviewed, or approved work affecting the results of laboratory activities were specified in their respective job descriptions.

Substitutes or deputies were nominated for key management and specialised scientific personnel. A staff member was designated as the quality manager, responsible for ensuring compliance with the QMS and having direct access to the highest level of management.

Adequate information flow and communication were maintained across all staff levels to ensure awareness of the relevance of activities, the laboratory's mission, strategic direction, and operational priorities. This was achieved through information sessions, management meetings, assemblies led by the Director, managers' operational meetings, WhatsApp groups, and email communications.

1.2. Quality management system

The quality manager ensured the establishment, implementation, and ongoing maintenance of a QMS commensurate with the scope of the laboratory's activities. All elements of the system were documented, either in electronic or hard copy format.

The quality manual stated that the RIIP®/CENQAM® Quality Manual was modelled on cGMP and ISO/IEC 17025:2017 specifications and was deemed appropriate for all RIIP®/CENQAM® activities. It outlined the quality-related procedures to be followed to ensure the validity of analytical work, as well as the technical and administrative support provided by RIIP®/CENQAM® analysts. The quality assurance requirements and activities described in the manual addressed elements that could directly impact the quality and validity of the reported analytical results. The manual was scheduled for revision every three years.

The quality manual included:

- A quality policy statement addressing service standards, commitment to QMS effectiveness, and compliance with guidelines.
- Organizational structure.
- Operational and functional activities related to quality, with clear responsibilities.
- Documentation structure within the QMS.
- Internal quality management procedures and standard operating procedures.
- Personnel qualification, experience, and training policies.
- Reference to policies for audits, corrective/preventive actions, complaints, management reviews, analytical procedures, atypical results, data governance, reference substances, proficiency testing, risk/opportunity management, and service provider/supplier evaluation.
- Reference to SOPs for administrative and technical operations, including personnel matters, document control, change control, corrective/preventive actions, internal audits, complaints, procurement, equipment qualification/maintenance, sampling, testing/validation procedures, result validity, nonconforming work, cleaning, environmental/storage monitoring, and disposal.

Systematic and periodic internal and external audits were conducted to verify compliance with QMS requirements.

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SOP for Performing an Analytical Test Procedure and Ensuring the Integrity of the Data (Issue No. 13) applied to all activities related to the generation of analytical test results and quality data or records within the laboratory. The SOP was reviewed and discussed, and it was confirmed that all relevant personnel had been assessed in accordance with its provisions.

Observations related to the QMS were adequately addressed in the respective CAPA plan.

1.3. Control of documentation

A master list, available electronically, was established to identify the current versions and distribution status of all documents.

Procedures for controlling and reviewing documents ensured that:
- Each document had a unique identifier, version number, and implementation date.
- Authorized SOPs were readily accessible.
- Documents were regularly reviewed and updated as needed.
- Invalid documents were immediately replaced with authorized, revised versions.
- Revised documents referenced previous versions retained in archives for traceability.
- Staff were trained on new and revised procedures.
- Documentation, including records, was retained in accordance with national legislation for a minimum of six years for paper copies and ten years for electronic copies, unless associated with equipment having a lifespan exceeding ten years.

Staff were informed of new and revised procedures upon their entry into force. The QMS ensured that:
- Revised documents were prepared, reviewed, and approved at the same level as the original.
- Staff acknowledged awareness of changes and implementation dates through signatures or alternative mechanisms.

1.4. Change Control

The laboratory implemented SOP for the management of changes. The procedure included steps for assessing impact and risks. Change requests were reviewed and implemented only upon approval by management, and appropriate records were maintained. The change control process also applied to any modifications made to software systems.

When changes were required, such as improvements to existing procedures or the introduction of new methods, they were approved and monitored by senior management.

Change processes were also addressed during management reviews, thereby enabling their monitoring by senior management.

The laboratory authorised via the quality manager, documented, and validated all changes prior to implementation, including laboratory software configurations and modifications to commercial off-the-shelf software. Validation reports were available where applicable.

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Staff confirmed their awareness of the changes and their implementation date through signed acknowledgements.

1.5. Control of Records

All original observations, including calculations and derived data, calibration, validation, verification records, and final results, were retained for a minimum of ten years, in accordance with the applicable SOP.

Records included data entered in analytical worksheets composed of consecutively numbered pages, with references to relevant entries in appendices, maintained either in paper or electronic format.

Procedures, namely SOP for the generation and control of report books, administrative logbooks, and the control of templates, were in place to govern the issuance of blank paper templates for data recording. However, the SOP primarily addressed the control of logbooks and did not explicitly cover templates used in sample testing, such as plan sheets or analytical worksheets.

Records for each test contained sufficient information for repetition or recalculation, including the identity of personnel involved.

Traceability was ensured by documenting the name and lot number of the reference substance, including any impurities used in the product analysis. The test report also recorded the serial number of the HPLC column employed for the analysis. Additionally, a certificate of analysis for the reference substance was part of the test report.

Samples tested in the laboratory were retained for specific periods, depending on the product type and applicable regulations or contractual arrangements.

Quality and technical or scientific records were generally legible with some exceptions, readily retrievable, stored, and retained in a secure environment with access control.

Original records were stored under secure and confidential conditions, with access restricted to authorised personnel. Electronic storage systems and electronic signatures were used to ensure data integrity and controlled access.

Quality management records included reports from internal and external audits, inspections, management reviews, risk assessments, and records of complaints and their investigations, as well as documentation of corrective and preventive actions.

1.6. Control of Data / Computerized Systems

A list of computerized systems used for the laboratory activities was available.

The computerized systems were overseen by the Equipment Supervisor in collaboration with the system supplier, such as a chromatography software system. The installation and operational qualification of the system were conducted by the supplier, and a checklist was provided to ensure compliance with system requirements, data integrity, and data protection. Consequently, the

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commercial off-the-shelf software, when used within its intended application range, was generally considered validated.

The suitability and validation of the chromatography system were discussed. The system was challenged during the inspection. The audit trail of the system was selectively reviewed in collaboration with the system administrator to assess the functionality of the audit trail.

Computerized systems were protected against unauthorised access, tampering, and data loss. They operated in compliance with provider or laboratory specifications and were capable of recording system failures along with the corresponding corrective actions.

For test data in computerized systems:
- Electronic data was protected against unauthorised access, with an audit trail enabled and subject to periodic review. Audit trail reviews were conducted by the Compliance Officer, an assigned deputy, and/or the Section or Division Manager, in accordance with the applicable procedures.
- Computers and automated equipment were properly maintained and provided with necessary environmental and operating conditions for data integrity.
- Electronic data were backed up at regular intervals.

Observations related to the Computerized systems were addressed in the respective CAPA plan.

1.7. Corrective and preventive actions

Any deviation or nonconformity, whether reported by staff or otherwise identified, was investigated through root cause analysis involving the analyst in order to determine and rectify the issue in accordance with the respective SOP.

The laboratory:
- Identified responsible persons for necessary actions and established timelines for implementation.
- Reviewed the effectiveness of corrective actions taken.
- Evaluated risks and opportunities identified.
- Prepared a report documenting deviations, causes, subsequent actions, and results of corrective action, recorded and retained.
- Regularly analysed critically deviations and nonconformities, their impact on the management system, and identified risks and opportunities.

1.8. Internal audits

The quality manager was responsible for organising internal audits, including the planning, establishment, implementation, and maintenance of an audit programme. This programme took into account the frequency, methods, responsibilities, significance of laboratory activities, changes affecting the laboratory, and the outcomes of previous audits.

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SOP for Internal audits was established, which included the following provisions:

- Planning and conducting audits periodically by the quality division—annually, and every two years by an external contractor for GMP audits—to enable systematic assessments.
- Defining the scope of each audit using risk-based criteria, including critical activities and implementation of corrective and preventive actions.
- Ensuring audits were conducted by trained personnel independent of the activity being audited.
- Reporting audit results to relevant management, discussing them during management reviews, and communicating findings to staff.
- Implementing appropriate corrections and corrective actions promptly upon identifying nonconformities.
- Monitoring the effectiveness of implemented corrective actions.
- Retaining records as evidence of the audit program implementation and results.

Internal auditors were required to have experience in ISO/IEC 17025.

1.9. Complaints

The inspection team reviewed the applicable SOP, along with the list of complaints recorded since 2019.

The quality assurance manager was informed of received complaints and ensured coordination of the complaint handling process, including: defining the process for receiving, verifying, investigating, and tracking submitted complaints and determining necessary actions; ensuring that appropriate action was taken within predefined timelines to resolve complaints; verifying that the entire process was documented and fully traceable; and, where possible and upon request, informing the complainant of the outcome of the investigation.

Where possible, a staff member not directly involved in the subject of the complaint was assigned to participate in the handling process. The quality assurance manager ensured the collection, verification, and recording of all relevant information and, where the complainant's identity was known, communicated the outcome of the process to the complainant. However, in cases where the quality assurance manager was directly involved in the matter, the Director was responsible for communicating the outcome to the complainant.

1.10. Management Review

Laboratory management reviews, conducted in accordance with the respective SOP, were convened at planned intervals—at a minimum annually—to monitor and evaluate the effectiveness of the QMS.

Senior management, including the Laboratory Director (or equivalent) and the Quality Manager, ensured that decisions from previous management reviews had the intended impact on laboratory activities and resources. Planning for the forthcoming period was also undertaken to maintain the suitability, adequacy, and effectiveness of the laboratory's QMS.

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Outcomes of management reviews were documented, recording all decisions and actions related to the effectiveness of the QMS, improvement of laboratory activities, resource requirements, and necessary enhancements.

Records of management reviews included information on:
- Performance management.
- Status of actions from previous reviews.
- Results of internal and external audits or inspections and any required follow-up actions.
- Changes in laboratory activities.
- Adequacy of resources.
- Training programs.
- Feedback from customers and staff.
- Outcome of received complaints.
- Corrective and preventive actions.
- Effectiveness of implemented improvements.
- Follow-up and monitoring of identified risks and opportunities.
- Atypical and OOS results.

1.11. Improvement

The laboratory identified and selected opportunities for improvement and implemented the necessary actions. These opportunities were identified through:
- Review of policies, procedures.
- Audit and inspection results.
- Corrective and preventive actions.
- Risk assessment.
- Management review.
- Staff suggestions.
- Analysis of data and proficiency testing results.

Data trending (i.e., tracking of a measurand over time) was not evident at the time of the inspection. The topic was discussed with the laboratory in the context of its purpose and the types of data that could be considered for trending, as a potential area for enhancement.

Additionally, the laboratory sought feedback from customers through mechanisms such as customer satisfaction surveys. This feedback was utilised as a tool for continuous improvement.

Proficiency testing was conducted in accordance with the 2025–2030 plan.

2. Planning and strategic management

2.1. Externally-provided services and supplies

The process for selecting and purchasing the products (supplies) and services required by the laboratory was described in the applicable SOP. This included the procurement of measurement materials, chemical and biological reference substances, equipment, reagents, and services, including calibration, qualification, sampling, testing, maintenance, proficiency testing schemes, and assessment and auditing.

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A master list of approved external suppliers for products and services deemed essential was prepared and maintained by the laboratory. Randomly selected records of supplier qualification and evaluation were reviewed and discussed.

The laboratory documented the following: the review and approval of its requirements for externally-provided products and services; the definition of criteria for the evaluation, selection, performance monitoring, and re-evaluation of external providers; the evaluation of suppliers of critical products and services that impacted the quality of testing; the listing of approved suppliers that had demonstrated compliance with the laboratory's quality requirements; and any actions taken as a result of the evaluation, performance monitoring, and re-evaluation of external providers.

The laboratory communicated its requirements to external providers for:
- The products and services to be provided and their acceptance criteria.
- Competence (if applicable), including any required qualification of personnel.
- Activities that the laboratory or its customer intended to perform at the external provider's premises.

Observations related to the Suppliers were addressed in the respective CAPA plan.

2.2. Review of tenders and contracts

An SOP was established for the management of outsourced activities, particularly those involving contracted laboratories.

In cases of subcontracting:
- only organisations approved for the required activity were engaged;
- the contract granted the laboratory the right to audit the facilities and assess the competencies of the contracted organisation, including access to relevant records;
- the contracted laboratory was required to inform and obtain approval from the customer regarding the specific activities to be performed;
- the contracted organisation was prohibited from subcontracting any portion of the work to a third party without prior evaluation and approval by the laboratory.

Any deviations from the contractual agreement were to be communicated to and approved by the customer.

2.3. Quality Risk Management

The Laboratory adopted a formal approach to risk management in accordance with the respective SOP. This encompassed the identification, assessment, treatment, prioritization, continuous monitoring, and review of risks. All types of risks associated with processes, activities, stakeholders, products, and services were considered, and procedures and methodologies were defined to minimize, monitor, and control the probability or impact of adverse events and potential failures.

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Two primary principles of quality risk management were adhered to:

- Evaluation of the risk to quality was based on scientific knowledge and ultimately linked to the protection of the patient.
- The level of effort, formality, and documentation of the quality risk management process was commensurate with the level of risk.

An interdisciplinary team, led by the Quality Manager and including experts from various areas, was established to coordinate and facilitate science-based decision-making regarding risks. The procedure specified that additional staff members could be appointed depending on the nature of the identified risk. The laboratory had implemented a risk register that functioned primarily as a listing of identified risks rather than providing detailed descriptions. The supporting documentation for risk evaluation, including the rationale, was maintained separately in risk forms filed in designated folders.

Observations related to Quality risk management were addressed in the respective CAPA plan.

2.4. Crisis Management

The correct and efficient functioning of the laboratory at all times depended on appropriate planning and budgeting to secure the necessary resources, including infrastructure maintenance, energy supply, and continuity of activities. Business continuity planning had been developed in collaboration with NWU and enabled the implementation of effective measures during issues or incidents, ensuring their management and the continuation of operations—particularly for key public health functions—at acceptable costs. The laboratory was in active discussions with NWU to ensure that its unique needs were accommodated by the University under which it operated.

A system for prevention and recovery in the event of unplanned service disruptions was established and documented, ensuring employee safety and the continuation of work. This preventive system or plan was defined in advance to protect business processes, assets, and personnel, enabling the rapid restoration of functional competency in the event of significant disruptions such as natural disasters, cyberattacks, or pandemics.

The recovery plan included inputs from key stakeholders and personnel, the definition of critical activities, risk analysis, implementation of mitigation measures, and the formation of a continuity team. Recovery strategies for IT, including manual workflows and an IT disaster recovery plan, were developed.

3. Resources

3.1. Personnel

SOP for Training & Competency Evaluation was established to define any form of training within RIIP®/CENQAM® that may influence a test result or related activities within the laboratories. Of note, this procedure referenced an outdated version of the WHO Good Practices for Quality Control Laboratories guidance document. However, it was under revision at the time of inspection to more accurately reflect the roles and responsibilities of the various staff members involved in the training process.

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Job descriptions were used to identify training needs, which were recorded in a competency matrix maintained by the laboratory. This matrix, along with documented procedures and criteria for the continuous assessment of personnel competence, was regularly updated to reflect requalification requirements, typically every three years. A training matrix was also available. Job profiles were also used to inform the NWU Human Resources Department when recruiting suitable candidates for laboratory positions.

Personnel with the necessary education, training, technical knowledge, and experience for their assigned functions were employed, either permanently or under contract. Competence requirements for each function were documented. The laboratory had established procedures and criteria for the selection and competence assessment of personnel in accordance with the QMS. Job descriptions were used to identify training needs, which were recorded in a competency matrix that was regularly updated to reflect requalification requirements every three years.

Staff undergoing training were appropriately supervised, and their competence was assessed upon completion, with all assessments fully documented. The Laboratory Director or a designated individual authorised personnel to perform specific laboratory activities, ensuring that only adequately qualified and trained individuals were permitted to carry them out.

The laboratory management was responsible for consigning samples to specific units and approving analytical test reports and certificates of analysis. Designated qualified personnel were responsible for reviewing all analytical data to ensure the validity of test results and executing specific tests or analytical techniques requiring advanced technical training and knowledge.

The laboratory maintained an appropriate training schedule for staff. Evaluation results upon successful completion of training were recorded and made available, with the corresponding information incorporated into the competency matrix or master list.

Observations related to the Personnel were addressed in the respective CAPA plan.

3.2. Premises

The RIIP®/CENQAM® main facility was located in Building G2, occupying approximately 26 m² on the ground floor, 374 m² on the first floor, and 730 m² on the second floor.

The premises adequately accommodated the requirements of a pharmaceutical testing laboratory and were designed to minimise risks to staff health and the quality of analytical results. Emergency exits were available.

Appropriate entrance and sample reception areas were provided for staff, visitors, and incoming samples. Rest and refreshment rooms, as well as toilets, were located separately from laboratory areas. Changing areas were easily accessible and suitably equipped for the number of users.

Storage facilities were organised to ensure the correct storage of samples, reagents, and equipment. Separate, secure storage areas were maintained, with appropriate temperature control and locking mechanisms. Controlled substances were marked, stored separately, and access was restricted to

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designated personnel. Safety procedures were rigorously implemented for the handling and storage of toxic or flammable reagents. The alarm log for the storage of retained samples and the refrigerator for reference substances was reviewed.

The laboratory was equipped with adequate instruments and equipment, including workbenches, workstations, and fume hoods. Separate instrument rooms were available for different measurement techniques, as required. Appropriate safety equipment was strategically located, and measures were in place to ensure good housekeeping and the implementation of regular cleaning routines.

Weighing areas were located where environmental conditions of temperature were controlled.

pH adjustments for strong chemicals such as ammonia and strong acids were performed in an open space. It is recommended to place a pH meter inside a fume hood to ensure that hazardous fumes are adequately contained during such procedures.

Archive facilities were provided to generally ensure the secure storage and retrieval of all documents. Records were stored in secure rooms, while electronic records were retained with duplicate copies maintained at an external facility. The procedure was governed by SOP for Archiving of Records, which specified a retention period of ten years. This procedure applied to temporary document storage areas, as well as to the electronic archive of RIIP®/CENQAM®. The SOP outlined the process for archiving both paper-based and electronic records. Evidence of pest control services for June and July 2025 was available and reviewed. Pest prevention and control on the premises were carried out in accordance with the respective SOP. Potentially destructive or troublesome pests addressed included cockroaches, ants, rodents, paper lice, and moths.

Room temperatures were monitored using a device for manual daily readings of maximum and minimum temperatures, and an application for alarm notifications via email and SMS. At the time of inspection, the application system was still undergoing validation, and the corresponding SOP was in draft form. Temperature mapping of the room designated for retained samples, referred to as TSC Dispatch (Building G2, Room No. 125), was conducted in 2024 during the winter season, and the corresponding documentation was available.

Procedures were in place for the safe removal of waste, in conformity with local environmental standards.

Observations related to the Premises were addressed in the respective CAPA plan.

3.3. Equipment, instruments, and other devices

The laboratory was required to acquire the necessary apparatus, equipment, instruments, or instrument systems used in pharmacopeial analyses to ensure the correct performance of tests and related activities.

All equipment, modules, and accessories were uniquely identified, including details such as the manufacturer, identification numbers or names, location, and equipment specifications.

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The documentation of the selected equipment was reviewed to verify whether the analytical equipment had been adequately qualified, demonstrated fitness for its intended purpose, complied with pharmacopeial requirements, and/or followed the manufacturer's recommendations. The laboratory retained ultimate responsibility for equipment qualification, which was conducted under the supervision of the Equipment Supervisors.

A preventive maintenance schedule and equipment management plan were established for analytical equipment. Maintenance activities were carried out either by the laboratory or, when applicable, by a competent external service provider.

All calibrations and equipment qualifications were traceable to appropriate reference standards. A change control process was in place for any modifications to analytical equipment, and requalification was required following specific changes.

Defective equipment was required to be taken out of service, repaired, requalified, and clearly labelled before being returned to use.

Equipment logbooks were maintained to document the history of each instrument, including records of maintenance, calibration, and qualification. Columns were stored appropriately, and each column was assigned a unique log sheet containing details such as column specifications, dates of use, number of injections, and maintenance activities. A specific column was issued and used for each product, and the performance qualification of each column formed part of the system suitability evaluation.

Observations related to the Equipment were addressed in the respective CAPA plan.

3.4. Reagents and materials

Reagents and chemicals, including solvents and materials used in tests and assays, were required to meet appropriate quality standards and be suitable for their intended use, in accordance with SOP for the Administration of Chemicals and Laboratory Consumables, and SOP for Management and Control of Acute Toxic Substances. Once a chemical container was opened, the assigned shelf life, re-test date, or expiry date (whichever applied) remained unchanged, unless a specific manufacturer-defined expiry date upon opening was indicated. Additional in-house expiry requirements applied after opening, as outlined in the relevant SOPs. Commercial reagents were sourced from verified and approved qualified suppliers and were accompanied by certificates of analysis and material safety data sheets. Reagent management encompassed the entire life cycle, from procurement and preparation to use and disposal, in accordance with established SOPs.

Labelling requirements included essential information such as substance name, receipt and opening dates, expiry dates, storage conditions, concentration, manufacturer details, batch numbers, and personnel identifiers.

In-house reagents and water produced by the laboratory were subject to specific labelling requirements. Regular verification of water quality was performed, and appropriate storage conditions for reagents were maintained. Policies regarding expiry dates were documented and justified by the laboratory.

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3.5. Reference substances

Reference substances were obtained from reputable commercial sources or supplied by the client. The control of reference substances and materials was overseen by a designated staff member. Each reference substance and material was assigned a unique identification number, with a new number allocated to each batch. This identification number was marked on the individual vials. The certificate of analysis accompanied the reference substance to the laboratory, along with the corresponding worksheet.

A register was maintained for reference substances, containing detailed information including identification number, description, source, date of receipt, batch designation, intended use, storage location, expiry or retest date, certificates, and safety data sheets. The register also recorded the amount requested by each analyst and the remaining quantity on a hypothetical basis. It was recommended that the sample custodian weigh the container in order to record the exact amount of reference substance used for each test.

Before use, the intended use and the expiry or retest date of reference substances were verified, and the corresponding information was included in the test reports.

4. Technical activities

4.1. Sampling

The Laboratory was not responsible for any sampling.

4.2. Incoming samples

The laboratory received samples from clients via courier. Upon arrival and clearance through security, the samples were handed over to the sample custodian, unpacked, and checked against any accompanying client notification. All received parcels, whether test samples or reference substances, were logged in a register titled “Test Sample & RS Receipt Logbook”, which was issued by the QA unit. The logbook recorded details such as the sample name, client name, and storage requirements.

Following registration, a notification was sent to the relevant laboratory section to dispatch an analyst for the collection of the required sample quantity, as per the test method. The remaining sample portions were placed in designated cupboards and, every two weeks, transferred to the retained sample storage area, where they were stored for six months. If any required item for completing the analysis was missing, the samples remained in the reception area until the necessary item was provided by the client. A label containing information such as the date and time of delivery and the client's name was generated and affixed to the sample receipt form. The form was signed electronically using Adobe Acrobat Reader.

The shipping invoice also served as the test request and included relevant details. Testing was conducted in accordance with the quotation previously provided and accepted by the client:

- Name and date of receipt of the provider.
- Material source.
- Detailed sample description, including composition and brand names.
- Packaging details.

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- Dosage form, concentration or strength, manufacturer's name, and batch or lot number.
- Sample size.
- Reason for analysis request.
- Consignment size.
- Expiry date or re-test date (if known).
- Reference documents and testing specifications.
- Additional comments or discrepancies found.

Before commencing testing, the laboratory was required to review the test request to ensure:
- Adequate sample amount for requested tests.
- Possession of necessary capability and resources for conducting tests.
- Ability to meet customer requirements with available tests or methods.
- Any issues had to be resolved with the request originator before testing, and a record of the review had to be retained.

Each sample and its accompanying documentation were assigned a unique registration number using an Excel-based system. The numbering followed a chronological order and was categorized according to the type of product. Separate registration numbers were assigned for requests related to different medicines, dosage forms, batches, or sources.

A sample register was maintained, recording:
- Sample registration number.
- Receipt date.
- Upon receipt, the sample underwent visual inspection by laboratory staff to ensure conformity with the test request information. Any discrepancies or damages were promptly recorded on the test request form, and queries were directed back to the sample provider.

The specific unit responsible for testing was designated by the Laboratory Manager or an authorized delegate. Each numbered sample sent to the assigned unit was accompanied by a worklist that included the correct identification number, origin, purpose, and any additional information necessary for receipt and testing activities.

Observations related to the Incoming samples were addressed in the respective CAPA plan.

4.3. Selection, validation, and verification of analytical procedures

The laboratory selected the analytical procedures to be used for testing prior to the commencement of analysis. The suitability of the selected procedures for their intended use was ensured in accordance with SOP for the Verification of Analytical Methods, issued on 7 July 2025. This procedure applied to all validated analytical methods obtained from clients or other reliable sources and was intended for determining the analyte concentration in a sample. Method transfers were performed in accordance with client protocol requirements; however, the procedures for conducting method transfers were not addressed within this SOP.

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When analyzing a non-pharmacopeial substance or product, preference was given to the manufacturer's approved methods. In cases of investigative testing, a negotiation was conducted between the client and the laboratory to define the expectations to be met. The laboratory did not perform any method validation activities. Pharmacopeial procedures and those approved by the licensing authority were considered validated for the intended use as described in the respective monograph. In cases where validation was not required, method verification was performed in accordance with the applicable procedures.

At present, the laboratory conducts a limited number of tests of active pharmaceutical ingredients. When such testing was performed on an assignment from the manufacturer, it was limited to techniques such as IR, XPRD, or a combination thereof.

The laboratory confirmed, in particular, that:
- for finished pharmaceutical products, no interferences were observed from the excipients present.
- system suitability requirements were fulfilled in accordance with SOP for the Sequencing of Analyses, Issue No. 7. A verification of suitability under actual conditions of use was required in all cases. System suitability tests were conducted prior to and throughout the analysis of samples to ensure that the complete analytical system—including instruments, reagents, columns, and analysts—remained consistently suitable for the intended application. HPLC systems were allowed sufficient time to stabilize prior to use.
- the accuracy and precision of the procedure remained within predefined limits.

The performance of analytical procedures was monitored throughout their life cycle.

4.4. Technical records

The analytical worksheet, or a suitable alternative document such as a planning template (which included information on reagents and equipment), was an internal document used by the analyst to record information related to the sample, test procedure, reagents, standards, materials, calculations, and test results. It incorporated all raw data generated during the analysis.

The laboratory maintained a template, appended to each SOP, for every test type, such as HPLC, GC, dissolution, and others. For certain equipment, a dedicated logbook was used to record testing information. Upon completion of the analysis, all relevant templates, along with copies of the logbook entries, were compiled and archived as part of the documentation. In accordance with current practice, the completed worksheets were scanned and electronically stored in a cloud system.

The analytical worksheet provided the following information:
- registration number of the sample;
- page numbering, including the total number of pages (including annexes);
- date of the test request;
- name and signature of the analyst;
- a description of the sample received;

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- references to the specifications and a full description of test methods by which the sample was tested, including the limits, if applicable; as an alternative, a traceable reference to the test method was acceptable;
- identification of the test equipment used;
- reference substances used (including the provider, lot number, and in-house number) – the RS custodian would also provide the CoA of the RS together with the sample to the lab;
- results of the system suitability test, if applicable, as well as any analytical acceptance criteria;
- identification of reagents, solvents, and columns (if applicable) employed;
- conclusions, indicating whether or not the sample complied with the specifications, were recorded on the CoA that was approved and signed by designated qualified personnel;
- deviation record (or reference to it) for any deviation from a prescribed procedure;
- all values obtained from each test, including blank results, and all graphical data, whether obtained from recording instruments or plotted by hand, were attached or traceable to an electronic record file or document.

The completed analytical worksheet was signed by the responsible analyst and subsequently reviewed and approved by the relevant manager. The quality control unit transferred the results into the CoA, which was approved with the SANAS technical signature, indicating accreditation by the respective body, except in the case of GC results, which were signed by the GC Manager. This process confirmed that the laboratory was accredited for the specific technique under which the signature was provided. Calculations and data transfers were appropriately and systematically checked or controlled through a validated electronic system.

Any changes made to original records, whether in paper or electronic format, were fully traceable, indicating what was changed, by whom, when the change was made, and the reason for the modification. Deletion of data was not permitted. In cases where a mistake occurred in an analytical worksheet or data or text required amendment, all corrections were made in a traceable manner.

The analytical worksheet and all associated attachments, including calculations and instrument analysis records, were archived together with the relevant specification. For assay testing, the chromatography system was also capable of performing the necessary calculations to verify whether the sample met the defined acceptance criteria.

Observations related to the Technical records were addressed in the respective CAPA plan.

4.5. Testing

Testing methods were obtained from the medicine licensing authority or the monograph of the appropriate pharmacopoeia when testing for compliance with the specification. For the private sector, the testing methods registered in the dossiers were received from the client.

Detailed guidance on pharmacopeial requirements was typically provided in the general notices and specific monographs of the pharmacopoeia. Test procedures were described in sufficient detail to enable trained analysts to perform the analysis in a reliable and reproducible manner. System suitability criteria defined within the method were fulfilled.

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Samples were randomly selected for review of their respective documentation, encompassing the entire process from sample receipt to the issuance of the CoA, including sample retention. Where applicable, the investigation of any OOS results was also examined.

4.6. Evaluation of test results

For compliance testing, the product was required to fulfil all acceptance criteria outlined in the approved specification. Test results were compared against the specified limits to determine whether the sample met the defined requirements, and a conclusion was drawn regarding the conformity of the test result with the specification.

All test results were traceable to a suitable primary reference substance, either obtained from a pharmacopeia or a manufacturer, or, where appropriate, to a certified reference material. Test results were reviewed and either approved or rejected by designated qualified personnel, in accordance with the competency master list or matrix, which was available and verified during the inspection.

4.7. Validity of test results

The validity of results was ensured by the laboratory through a comprehensive procedure that encompassed the review of several key activities, including the use of appropriate reference substances or reference materials, verification of measuring and testing equipment, implementation of quality control checks, and the application of data analysis methodologies, such as control charts, trend analysis, and correlation of results for the tested sample. Additional measures included the performance of replicate tests, retesting of retained samples, and a thorough review of all raw data and reported results.

4.8. Out-of-specification results

When a suspected OOS result was identified, a review of the procedures applied during the testing process was conducted by the supervisor together with the analyst or technician, using a checklist. This review was carried out prior to any retesting and followed the provisions of SOP for the handling of OOS, OOE, and OOT results. The investigation ensured that:

- If stable, original sample preparations were not discarded until the investigation was complete.
- The appropriate procedures were applied and followed correctly, including requirements for validation and verification, and internal quality control tools.
- Examination of the raw data was undertaken to identify possible discrepancies.
- All calculations were checked.
- The equipment used was qualified and calibrated, and acceptable system suitability tests were performed.
- The appropriate reagents, solvents, and reference substances were used.
- The correct glassware was used.

The identification of an error that caused an aberrant result rendered the result invalid, and a retest of the sample was required to be performed by the same technician or analyst.

Suspected OOS results could only be invalidated if an error had been clearly identified. In cases where the investigation was inconclusive, a confirmatory test was required to be performed by another trained analyst. A similar result obtained during this confirmatory determination would

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indicate a confirmed OOS result. If comparable results were not obtained by the second analyst, the inconsistency was further investigated. Where available, confirmation using an alternative validated method was recommended and, if performed, was fully documented. If available, hypothesis testing was considered to better define the root cause.

All investigations and their conclusions were documented. In the event of an error, a root cause analysis was conducted, and all corrective actions were recorded, implemented, and recognized as opportunities for improvement and risk mitigation.

4.9. Retained samples

The retained sample was stored in its original packaging.

The observation related to the retained samples was addressed in the respective CAPA plan.

5. Safety rules

Environmental health and safety policies were adhered to in order to safeguard staff, the public, and the environment. A documented laboratory safety policy, encompassing both general and specific safety instructions based on identified risks, was made available to all staff and implemented accordingly. A designated staff member was assigned responsibility for overseeing the policy and ensuring compliance across all laboratory personnel.

General rules for safe working were outlined in the SOP for Safety Procedures, established in accordance with national regulations. These rules typically included the following requirements:

- Material safety data sheets were made available to staff before testing was carried out.
- Smoking, eating, and drinking in the laboratory were prohibited.
- Staff received training on firefighting and first aid equipment and techniques, evidenced by certificates.
- Staff wore laboratory coats or other suitable personal protective equipment, as required, including eye protection.
- All containers of chemicals were appropriately labeled and included prominent warnings whenever appropriate.
- Adequate insulation and spark-proofing were provided for electrical wiring and equipment, including refrigerators.
- Rules on the safe handling of cylinders of compressed gases were observed, and staff were familiar with the relevant color identification codes.
- Staff were not permitted to work alone in the laboratory.

Safety showers, both for eye and full-body use, were installed at appropriate locations and were fully functional. Rubber suction bulbs were used on manual pipettes and siphons to ensure safe liquid handling. Staff received instruction on the safe handling of glassware, corrosive reagents, and solvents, including the use of safety containers or baskets to prevent spillage. Warnings, precautions, and specific instructions were incorporated, where appropriate, into SOPs for handling violent, uncontrollable, or hazardous reactions, such as those involving the mixing of water with acids or combinations.

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SOPs governing the storage and handling of controlled substances were available and enforced. Poisonous or hazardous products were clearly identified, appropriately labelled, and stored separately from other materials to ensure safety and prevent cross-contamination.

Miscellaneous	
Assessment of the Laboratory Information File	The Laboratory Information File, effective 28 February 2025, was provided for review.
Annexes attached	N/A

Part 3 – Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, including the CAPA plan provided for the observations listed in the Inspection Report ***Research Institute for Industrial Pharmacy (RIIP), incorporating CENQAM (RIIP®/CENQAM®)***, located at ***North-West University, Potchefstroom Campus, Building G2 and G16, 11 Hoffman Street, Potchefstroom, 2531; South Africa,*** is 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 Laboratory to a satisfactory level prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4 List of WHO Guidelines referenced in the inspection report

1. 1. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-seventh Report, Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 1052), Annex 4.
   Short name: WHO GPPQCL Guidelines, TRS No 1052, Annex 4
   https://www.who.int/publications/i/item/9789240091030

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
   https://www.who.int/publications/m/item/trs961-annex2

3. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report, Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   https://www.who.int/publications/m/item/annex-4-trs-929

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4. 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/m/item/annex-4-trs-

5. 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://www.who.int/publications/m/item/trs986-

6. 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
https://www.who.int/publications/m/item/annex-2-trs-957

7. 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://www.who.int/publications/m/item/trs957-annex3

8. 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
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs961-annex6-gmp-sterile-pharmaceutical-products.pdf

9. 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
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs961-annex7-transfer-technology-pharmaceutical-manufacturing.pdf?sfvrsn=2e302838_0

10. 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. 96, Annex 9)
Short name: WHO TRS No. 961, Annex 9
https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

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11. 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
https://www.who.int/publications/m/item/trs943-annex3

12. 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/publications/m/item/Annex-8-trs-1010

13. 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/publications/m/item/trs981-annex2

14. 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://www.who.int/publications/m/item/annex-3-trs-981

15. WHO guidelines for preparing a laboratory information file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report, Geneva. WHO Technical Report Series, No. 961, 2011, Annex 13.
Short name: WHO TRS No. 961, Annex 13
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs961-annex13-guidelines-preparing-laboratory-information-file.pdf?sfvrsn=54d1f397_2

16. 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/m/item/trs992-annex4

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17. 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/m/item/trs992-annex5

18. 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://www.who.int/publications/m/item/trs1010-annex10

19. Good chromatography practices. 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 Good chromatography practices
https://www.who.int/publications/m/item/trs1025-annex4

20. Good manufacturing practices: guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-third report, Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1019), Annex 3.
Short name: WHO TRS No. 1019, Annex 3
https://www.who.int/publications/m/item/trs1019-annex3

21. WHO model certificate of analysis. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-second report, Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 4.
Short name: WHO TRS No. 1010, Annex 4
https://www.who.int/publications/m/item/trs1010-annex4

22. 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 No 1033, Annex 3
https://www.who.int/publications/m/item/annex-3-trs-1033

23. Guidelines on pre-approval inspections. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-sixth report, Geneva, World Health Organization, 2002 (WHO Technical Report Series, No. 902), Annex 7
Short name: WHO TRS No 902, Annex 7
https://www.who.int/publications/m/item/trs902-annex7

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24. Prequalification of quality control laboratories: procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-first report, Geneva, World Health Organization, 2017 (WHO Technical Report Series, No. 1003), Annex 3
Short name: WHO TRS No 1003, Annex 3
https://www.who.int/publications/m/item/annex-3-trs-1003

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