

**Prequalification Team Inspection Services
WHO PUBLIC INSPECTION REPORT
of the Quality Control Laboratory
WHOPIR**

Part 1	General information		
Laboratory Details			
Name of the Laboratory	Egyptian Drug Authority - Central Administration for Drug Control		
Address of inspected Laboratory	Elmansourya Street, Haram Giza Arab republic of Egypt		
GPS Coordinates	29.96278° N 31.14830° E		
Address of corporate office, telephone number, and fax number	Same as above.		
Dates of inspection	27-29 April 2026		
Type of inspection	Initial		
Introduction			
Brief description of testing activities	<i>Type of analysis</i>	<i>Finished products</i>	<i>Active pharmaceutical ingredients</i>
	Physical/ Chemical analysis	pH, Water content (Karl Fischer), Friability, Hardness, Disintegration, Dissolution, Uniformity of dosage units, residual solvents.	pH, Water content (Karl Fischer), residual solvents
	Identification	HPLC (UV-Vis, DAD) detection, UV-Vis Spectroscopy	HPLC (UV-Vis, DAD) detection, UV-Vis Spectroscopy
	Assay, impurities, and related substances	HPLC (UV-Vis, DAD) detection, GC (FID), UV-Vis. spectrophotometer.	HPLC (UV-Vis, DAD) detection, GC (FID), UV-Vis. spectrophotometer.
	Bacterial Endotoxin Testing (BET)	Endotoxin Test (Gel Clot limit test)	Not applicable
General information	The Egyptian Drug Authority (EDA) is the national regulatory authority in Egypt responsible for regulating medical products and medical devices. It was		

EDA – CADC, Giza - QCL

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	established under Law No. 151 of 2019 and its Executive Regulation No. 777 of 2020 to ensure the quality, safety, efficacy, and availability of regulated products throughout their lifecycle. CADC (Central Administration of Drug Control) was responsible for performing laboratory testing of imported and locally manufactured pharmaceuticals, veterinary products, cosmetics, disinfectants, pesticides, raw materials, medical devices, and diagnostics within the scope of market authorization (registration), post-marketing, and complaints. CADC officially issued test reports of results in accordance with EDA Establishment Law No. 151 of 2019.
History	The Laboratory has undergone a WHO prequalification (PQ) peer audit of the former NODCAR (National Organization for Drug Control and Research) in 2016, accreditation of CADC laboratories in 2022 in accordance with ISO/IEC 17025:2017 requirements, following organizational restructuring, and achievement of WHO GBT Maturity Level 3 (ML3) for the medicines regulatory system scope in 2024. This inspection was the first WHO inspection of the Laboratory.
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 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	A limited number of documents were provided in Arabic. These were reviewed by the inspection team using either their language proficiency or translation tools.

Out of Scope	The microbiology laboratory II (MC2), except for bacterial endotoxin testing, was not included in the scope of the inspection. Among the premises, the Physicochemical Analysis Laboratory (III) / PC 3 lab was designated as being within the scope of WHO.
Abbreviations	Meaning
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
CAPA	Corrective action & Preventive action
CADC	Central Administration of Drug Control
DQ	Design qualification
FPP	Finished pharmaceutical product
GC	Gas chromatography or Gas chromatography equipment
GEC	General Administration of Evaluation and Control
GMP	Good manufacturing practices
GQC	General Administration of QC
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
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specifications test result
OQ	Operation qualification
Ph.Eur.	European Pharmacopoeia
PM	Preventive maintenance
PQ	Performance qualification
PT	Proficiency testing
PTS	Proficiency testing scheme
PW	Purified water
QA	Quality assurance
QC	Quality control
QP	Quality Procedure
QCL	Quality control laboratory

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QM	Quality manual
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure
SDS	Sample data sheet
USP	United States Pharmacopoeia
UV	Ultraviolet-visible spectrophotometry or spectrophotometer
VMP	Validation master plan
VS	Volumetric solution

Part 2	Summary of findings and recommendations
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1. Organization and management

A presentation detailing the Laboratory history and activities was provided during the opening meeting.

1.1. Structural and general requirements

The Laboratory was legally authorized by the Egyptian Drug Authority (EDA) to perform testing and issue certificates of analysis. It was responsible for the validity of all results and activities performed.

Senior management ensured the establishment, implementation, and maintenance of an effective quality management system, including a data governance system, by providing appropriate policies, training, and technical infrastructure.

Management ensured that personnel had the necessary authority and resources (financial, human, and infrastructure) to perform their assigned duties.

Procedures were established to safeguard impartiality and prevent undue influence. These included the declarations of conflicts of interest and the protection of the confidentiality of laboratory information. Declarations were updated following changes in roles or responsibilities.

The organizational chart describing the Laboratory's structure and management was updated on 2 February 2025. Quality management system activities were performed independently. It was demonstrated that the Human Pharmaceutical Products Unit consisted of seven labs, one of which was the Physico-Chemical III lab. Microbiology administration consisted of two laboratories, one of which is microbiology lab II (MC2). PC3 & and bacterial endotoxin testing in Microbiology Laboratory II (MC2) were identified to be within the scope of the PQ inspection.

The General Administration of Quality Control Laboratories comprised the following:

- Administration of Human and Veterinary Pharmaceutical Product Analysis
- Administration of Hazardous Pharmaceutical Products

- Administration of Cosmetics and Disinfectants Analysis
- Administration of In Vitro Diagnostics, Medical Devices, and Supplies
- Administration of Herbal Product Analysis
- Administration of Microbiological Analysis

The responsibilities, authorities, and interrelationships of all personnel who managed, performed, verified, reviewed, or approved activities affecting laboratory results were defined in job descriptions.

Trained substitutes or deputies were nominated for key management and specialized scientific personnel. A staff member was designated as Quality Assurance General Manager, responsible for QMS compliance and having direct access to the highest level of management. Effective communication and information flow were maintained across all staff levels, ensuring awareness of the relevance of activities, the mission, strategic direction, and operational priorities.

The observations were adequately addressed in the respective CAPA plan.

1.2. Quality management system

The Quality Assurance General Manager ensured the establishment, implementation, and maintenance of a QMS appropriate to the laboratory's activities. Prior to implementation, the QMS was communicated to and understood by relevant personnel. All elements of the system were documented, either electronically or in paper form.

The Quality Manual, dated 26 April 2026, included:

- A quality policy statement addressing service standards, commitment to QMS effectiveness, compliance with applicable guidelines, and access to management system documentation.
- The organizational structure.
- The documentation structure within the QMS.
- Internal quality management procedures and standard operating procedures (SOPs).
- Policies on personnel qualifications, experience, and training.
- Policies for audits, corrective and preventive actions, complaints, management review, analytical procedures, handling of atypical results, data governance, reference substances, proficiency testing, risk and opportunity management, and evaluation of service providers and suppliers.
- Standard operating procedures covering administrative and technical operations, including personnel management, document control, change control, corrective and preventive actions, internal audits, complaint handling, procurement, equipment qualification and maintenance, sampling, testing and validation procedures, ensuring validity of results, handling nonconforming work, cleaning, environmental and storage monitoring, and waste disposal.
- A Validation Master Plan that clearly defined and documented the laboratory's qualification and validation program.

The observations were adequately addressed in the respective CAPA plan.

1.3. Control of documentation

A master list, available electronically and in paper form, was established to identify the current versions and distribution of documents.

Procedures for document control and review ensured that:

- Each document had a unique identifier, version number, and effective date.
- Authorized standard operating procedures were readily accessible.
- Documents were periodically reviewed and updated as necessary.
- Obsolete documents were promptly replaced with authorized, revised versions.
- Revised documents referenced previous versions, which were retained in archives for traceability.
- Staff were trained in new and revised procedures.
- Documentation, including records, was retained in accordance with national legislation for at least five years.

Staff were informed of the new and revised procedures entering into force. The quality management system ensured that:

- Revised documents were prepared, reviewed, and approved at the same level as the original documents.
- Staff acknowledged awareness of changes and implementation dates through signatures or other approved mechanisms.

SOP for EDA staff training, current version last issued on 15 January 2025, was established to ensure that staff were trained in accordance with their respective training plans. A flowchart of the EDA staff training process was appended to the SOP to illustrate the training workflow, which was reviewed.

The observations were adequately addressed in the respective CAPA plan.

1.4. Change Control

SOP “Management of Change Quality Procedure” was established to define a system for managing all changes that could affect the EDA Quality Management System. It ensured that changes were adequately planned, controlled, assessed, documented, and approved prior to implementation and through to successful completion. Management of Change (MOC) was required and applied across all EDA divisions for any changes affecting the QMS.

The change originator should complete the MOC request form and define all risks associated with the change in accordance with the Risk Management Quality Procedure. Accordingly, the change originator evaluated whether a new risk assessment was required or whether an existing risk was relevant to the proposed change.

Randomly selected change control request documentation was reviewed.

The steps of the change control process included assessing impact, gaps, risks, and opportunities. Change requests were reviewed and implemented only after management approval, and appropriate records were maintained.

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

The laboratory authorized, documented, and validated changes prior to implementation, including configuration of laboratory software or modifications to commercial off-the-shelf systems. Validation reports were available, where applicable.

The Quality Assurance General Manager ensured that all changes were documented, assessed for impact, approved, planned, implemented, and reviewed.

Staff acknowledged awareness of changes and their effective dates through the Management of Change (MOC) staff notification form.

The observations were adequately addressed in the respective CAPA plan.

1.5. Control of Records

The applicable SOP, Coding and Formatting of EDA Quality Documents, described the identification, collection, indexing, retrieval, storage, backup, access, maintenance, and disposal of all quality, technical, and scientific records, whether in paper, electronic, or hybrid form. An electronic system, the Quality Management Program, was used for the management of SOPs. However, the master copy of each SOP, including templates and forms, was stamped, signed, and maintained by the QA General Administration. Additionally, the SOP for Control of Records Quality Procedure was in place.

Before issuing a document, a meeting was typically convened to share information and ensure appropriate issuance. A gap between the issuance and effective date of SOPs was maintained and recorded in the system.

A master list of SOPs could be generated through the Quality Management Program. This list was printed annually to support the review and revision of SOPs due for update.

All original observations, including calculations and derived data, as well as calibration, validation, verification records, and final results, were retained for at least five years.

The laboratory recorded analytical activities directly in data sheets generated by the Laboratory Information Management System (LIMS). Records for each test contained sufficient detail to allow repetition or recalculation, including the identification of personnel involved.

Records of samples related to legal proceedings were maintained in accordance with applicable legal requirements.

A data and information management system ensured the traceability of operations. Access to stored electronic data was restricted to authorized personnel. Traceability was further ensured by documenting the name and lot number of the reference substances used in product analysis. The sample data sheet also included the serial number of the HPLC column used for analysis. In addition, the certificate of analysis for the reference substance was included in the test report. Calibration reports documented the standards used for the calibration of analytical balances and other equipment.

Retained samples were stored under controlled environmental conditions for a defined period, after which they were disposed of in accordance with the procedure described in Sample Receipt, Handling, Distribution, Storage, and Retention under the General Administration of Evaluation and Control. Samples retained within the laboratories were also stored under controlled environmental conditions for a specified duration before being disposed of in accordance with the relevant procedure.

Original records were stored in cabinets in both PC III and the Microbiology (MC II) laboratories under confidential conditions, with access restricted to authorized personnel. Electronic storage and signatures were used in compliance with electronic record requirements.

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

The observations were adequately addressed in the respective CAPA plan.

1.6. Control of Data / Computerized Systems

A Master Validation Plan, current version last issued on 16 March 2026, was established to ensure that all systems, processes, equipment, analytical methods, computerized systems, and supporting utilities operated in a state of control. The VMP defined the principles, responsibilities, and documentation requirements necessary to maintain compliance with international guideline requirements for regulatory authority laboratories.

Commercial off-the-shelf software, when used within its intended application range, was considered sufficiently validated. The quality manual for LIMS was available.

The suitability and validation of the selected systems were evaluated.

Computerized systems were protected against unauthorized access, tampering, and data loss, and were operated in compliance with provider or laboratory specifications.

For test data in computerized systems:

- Electronic data were protected from unauthorized access, with audit trails enabled and periodically reviewed. An SOP, Audit Trail, and Audit Trail Review in the General Administration of Quality Control Laboratories was in place to define the review process for different software systems. Audit trail reviews for various systems were performed as scheduled.
- Computers and automated equipment were maintained and operated under appropriate environmental and operating conditions to ensure data integrity, including the implementation of audit trails within software systems.
- Electronic data were backed up at regular intervals in accordance with the SOP for Backup of EDA Electronic Data to ensure retrievability and secure storage to prevent data loss. Evidence of data restoration verification was available and reviewed.

SOP for Computerized Systems Lifecycle and Validation Quality Procedure was established to define the validation of computerized systems throughout their lifecycle. It was required to ensure confidence in the data captured, processed, reported, or stored by these systems, support accurate results, and reduce risks to data integrity.

An inventory list was available, including details on software applications, identification numbers, locations, validation status, next review dates, purpose, and responsible personnel:

- Computerized systems were periodically reviewed by the system owner to maintain their validated status, ensure regulatory compliance, and confirm fitness for intended use.
- The frequency of reviews was defined using a risk-based approach, as specified in the computerized systems inventory, and generally did not exceed three years.
- Reviews assessed the overall compliance status of each system and identified any required corrective actions.

The observations were adequately addressed in the respective CAPA plan.

1.7. Corrective and preventive actions

Any deviations or nonconformities reported by staff or otherwise identified were investigated through root cause analysis with the analyst to identify and correct the issue, in accordance with the SOP for Dealing with Nonconformity and Corrective Action Quality Procedure (current version last issued on 15 July 2025).

The laboratory:

- Identified responsible personnel for the required actions.
- Reviewed the effectiveness of corrective actions taken.
- Evaluated identified risks and opportunities.
- Prepared reports documenting deviations, their root causes, subsequent actions, and the outcomes of corrective actions; these were recorded and retained.
- Critically analysed deviations and nonconformities, their impact on the management system, and associated risks and opportunities.

Situations with the potential to lead to deviations or nonconformities were appropriately addressed and classified as low or high significance based on their criticality, leading to preventive actions. Depending on their potential impact, preventive actions were managed as risks or opportunities.

The CAPA registers for 2025 and 2026 were reviewed.

1.8. Internal audits

The Quality Assurance General Manager was responsible for organizing internal audits, including planning, establishing, implementing, and maintaining an audit program. This took into account the frequency, methods, responsibilities, significance of laboratory activities, changes affecting the laboratory, and the results of previous audits.

The laboratory established a system of planned and documented internal quality audits to verify compliance with planned arrangements and QMS requirements, and to assess the effectiveness of the quality system. An annual internal audit schedule was prepared and communicated to staff. The 2026 internal audit plan was available and reviewed.

The procedure for internal audits was established and reflected an independent and unbiased approach. Auditor independence was ensured, and internal auditors' competency was assessed and found satisfactory. The most recent internal audit resulted in zero nonconformities.

The procedures included:

- Planned and conducted audits periodically under the responsibility of the Quality Assurance General Manager to enable systematic assessment.
- Defined the scope of each audit using risk-based criteria, including critical activities and the implementation of corrective and preventive actions.
- Ensured that audits were performed by trained personnel independent of the activities being audited.
- Reported audit results to relevant management, discussed them during management reviews, and communicated them to staff.
- Implemented appropriate corrections and corrective actions promptly upon identification of nonconformities.
- Monitored the effectiveness of implemented corrective actions.
- Retained records as evidence of the audit program implementation and its results.

1.9. Complaints

The procedure for handling inquiries, complaints, and technical appeals, documented in the respective SOP and reviewed on 06 August 2023, specified that complaints were received via email by the General Administration of the Beneficiary Complaints, which reported directly to the Head of Central Administration of the EDA Chairman's Office. Complaints were then distributed to the relevant central Administrations, such as CADC, and assigned to a designated Complaint Officer. The Complaint Officer managed the case and forwarded it to the appropriate division, with acknowledgment confirming receipt.

The Laboratory Director was informed of all received complaints and ensured coordination of the complaint-handling process, including:

- A defined process, supported by a flowchart, for receiving, verifying, investigating, and tracking complaints, and for determining necessary actions.
- Assurance that appropriate actions were taken within predefined timelines to resolve complaints.
- Verification that the entire process was documented and fully traceable.
- Communication of the investigation outcome to the complainant, where possible and upon request.

The Complaint Follow-up Officer ensured the collection, verification, and recording of all necessary information and informed the complainant of the outcome of the process, where the complainant's identity was available.

1.10. Management Review

Management reviews were convened at planned intervals, in accordance with the respective SOP, at least annually, to monitor the effectiveness of the management system. Senior management, including the Head of CADC and the Quality Assurance General Manager, ensured that previous decisions had the intended impact on laboratory activities and resources. Planning for the subsequent period was also conducted to maintain the suitability, adequacy, and effectiveness of the laboratory QMS.

The outcomes of management reviews were recorded, documenting decisions and actions related to QMS effectiveness, improvement of laboratory activities, required resources, and identified areas for improvement.

Records of management reviews included the following information:

- Suitability of policies and procedures.
- Performance management.
- Status of actions from previous reviews.
- Changes in internal and external factors affecting the laboratory.
- Results of internal and external audits or inspections, including required follow-up actions.
- Changes in laboratory activities.
- Adequacy of resources.
- Training programmes.
- Feedback from customers and staff.
- Outcomes of received complaints.
- Corrective and preventive actions.
- Effectiveness of implemented improvements.
- Follow-up and monitoring of identified risks and opportunities.
- Results of external quality control.
- Trends and trend analysis results.
- Atypical and out-of-specification results.

1.11. Improvement

The laboratory identified and selected opportunities for improvement and implemented necessary actions in accordance with the applicable SOP. These opportunities were identified through:

- Review of policies, procedures, and objectives.
- Audit and inspection results.
- Corrective and preventive actions.
- Risk assessments.
- Management reviews.
- Staff suggestions.
- Analysis of data, trends, and proficiency testing results.

In addition, the laboratory obtained customer feedback through mechanisms such as customer satisfaction surveys issued together with reports, communication records, and review of reports. The feedback received was utilized as part of the laboratory's continuous improvement process.

A proficiency testing (PT) programme was conducted annually. Most PT tests were performed and analyzed by the Egyptian Drug Authority proficiency testing laboratory (EDA PT program accredited by the Egyptian Accrediting Body 'EGAC' in the Accreditation programs unit) provider: an independent unit from the general administration of quality control laboratories. For specialized tests, such as gas chromatography (GC), which were not available within the EDA PT laboratory, outsourcing was arranged through the AMQF Interlaboratory Comparison 2025 in Ethiopia. All tests included within the WHO prequalification scope were covered in the planned PT programme. The EDA laboratory was accredited by EGAC, demonstrating adherence to international quality standards.

The laboratory established a system to ensure that the technical competence of the NCL was periodically monitored to confirm the consistency and reliability of test results. CADC applied two quality procedures in this regard: Proficiency Testing and Inter-Laboratory Comparison Quality Procedure, which governed participation in proficiency testing and interlaboratory comparisons, and Ensuring the Validity of Results Quality Procedure. These procedures required participation in proficiency testing (PT) and interlaboratory comparisons (ILC), where applicable, based on laboratory needs (as defined in the PT plan), to ensure staff competence and to meet the requirements of ISO/IEC 17025:2017 and WHO standards.

The observations were adequately addressed in the respective CAPA plan.

2. Planning and strategic management

2.1. Externally provided services and supplies

The system used to define, review, and approve requirements for outsourced services or products required by the EDA, including criteria for selection, performance monitoring, evaluation, and re-evaluation of service providers to ensure compliance with requirements, was described in SOP Outsourcing and Technical Evaluation of EDA Provided Products/Services, current version last issued on 23 April 2025.

A governmental portal listed all pre-approved service providers that could be used by the laboratory for selection. The laboratory was responsible for reporting any out-of-specification (OOS) issues to the

relevant authority, where applicable. For services not listed on the portal, the laboratory evaluated the qualification of the service provider.

An internal master list of external suppliers for essential products and services was maintained by the laboratory. The following documentation was reviewed:

- Evaluation of outsourced product and service providers for the maintenance of spectrophotometers and atomic absorption equipment.(out of scope)
- Evaluation of outsourced product and service providers for calibration of safety cabinets, fume hoods, and CROM tools.
- Technical evaluation of outsourced products and services for the Company responsible for Water Unit 1 at the Agouza site.

2.2 Review of tenders and contracts

The procedure, current version, last issue date on 10 April 2025, established by the laboratory (customer) for reviewing requests, tenders, and contracts ensured that:

- Requirements were defined and documented.
- The contracted laboratory or organization had the capability and resources to meet the requirements, in accordance with the procedure for outsourcing and technical evaluation of EDA-provided products and services.
- Appropriate methods or procedures were selected to meet the laboratory's requirements and were suitable for the samples to be tested.
- The contracted laboratory informed the laboratory if the requested method was considered inappropriate or outdated, and clarified the customer's request.

A written contract should define the duties and responsibilities of each party, specify the scope of contracted work, and outline any technical arrangements, including the monitoring of the contract laboratory's performance. Any differences between the request or tender and the contract were resolved before the commencement of laboratory activities, ensuring mutual agreement without compromising the integrity or validity of the work. Records of relevant discussions with the customer regarding requirements were maintained.

In cases of subcontracting:

- Only approved organizations for the required activities were engaged.
- The contract allowed the laboratory to audit the facilities and competencies of the contracted organization and ensured access to relevant records and retained samples.
- The contracted organization did not subcontract any work to a third party without prior evaluation and approval by the laboratory.

The laboratory was responsible for periodically assessing the competence of any contracted organization and for maintaining a register of all subcontractors used, including records of competence assessments.

Although a comprehensive SOP for subcontracting was in place, the laboratory did not subcontract sample analysis outside the EDA.

2.2. Performance Management

During laboratory management reviews, objectives, performance indicators, and measurable targets were established for activities within defined timeframes. These were regularly monitored, and appropriate actions were taken where necessary.

There were three levels of performance indicators, namely: Strategic KPIs, Function KPIs and Division KPIs. Laboratory Testing KPIs included:

- The number of products tested compared with the planned number.
- The percentage of analytical test reports issued within a specified timeframe.
- Proficiency testing performance.

The laboratory was part of the National Medicines Regulatory Authority, and its objectives and targets were aligned with the organization's strategic goals. The resolution of complaints was also included as part of performance management and was monitored by the General Administration of Complaint Beneficiaries.

2.3. Quality Risk Management

The laboratory adopted a formal and well-established approach to risk management in accordance with the SOP for Risk Management Quality Procedure (current version last issued 19 March 2023). This approach 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 appropriate procedures and methodologies were defined to minimize, monitor, and control the likelihood and impact of adverse events and potential failures.

Two primary principles of quality risk management were followed:

- The evaluation of risks to quality was based on scientific knowledge and was ultimately linked to the protection of the patient/user.
- 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 Risk Coordinator and reporting to the Quality Assurance General Manager, was established and included experts from different areas to coordinate and facilitate science-based decision-making related to risks.

The initiation and planning of the quality risk management process included defining the risk, gathering relevant background information, and specifying timelines and decision-making levels.

Actions to address identified risks and opportunities were planned and tailored according to their potential impact on the validity of laboratory results and activities. These actions included avoiding risks, modifying their likelihood, adopting new practices, or implementing new technologies.

The process for identifying and managing risks and opportunities was documented, monitored, and regularly reviewed by senior management during management reviews.

2.4. Crisis Management

The correct and efficient functioning of the laboratory depended on appropriate planning and budgeting to ensure the availability of necessary resources, including infrastructure maintenance, energy supply, and continuity of activities, in accordance with the applicable SOP.

Business continuity planning enabled the implementation of effective measures to manage incidents and disruptions, ensuring the continuity of laboratory operations, particularly for critical public health functions, at an acceptable cost.

A system for prevention and recovery in the event of unplanned service disruptions was established and documented, ensuring staff safety and continuity of operations. This system was defined in advance to protect business processes, assets, and personnel, and enabled the rapid restoration of operational capability in the event of significant disruptions, such as natural disasters, cyberattacks, or pandemics.

The documented recovery plan included input from key stakeholders and personnel, defined critical activities, incorporated risk analysis, and outlined the implementation of mitigation measures, as well as the establishment of a continuity team. Recovery strategies for IT systems, including manual workflows and an IT disaster recovery plan, were also developed.

The laboratory tested the business continuity plan through simulations to confirm its suitability, and evidence of such testing was maintained. Relevant departments and stakeholders were informed of any situations posing a risk to public health, along with the remedial actions taken.

2.5. Communication management

Refer to previous sections.

3. **Resources**

3.1. Personnel

Personnel with the required education, training, technical knowledge, and experience for their assigned functions were employed, either permanently or on a contractual basis. Competence requirements for each function were documented, and procedures and criteria for selecting and assessing personnel competence were established in accordance with the QMS.

Staff undergoing training were supervised and assessed upon completion, with assessments fully documented. The Laboratory Director or designated staff member authorized personnel to perform specific laboratory activities, ensuring that only adequately qualified and trained personnel performed such tasks.

Procedures and criteria for the continuous assessment of personnel competence were documented, and training or requalification was provided as appropriate, in accordance with the SOP for Qualification, Requalification, and Evaluation of EDA Staff Competency. The SOP was reviewed, and no revisions had been made since the previous version.

A competency matrix for each staff member was maintained at the lab, and criteria for ongoing assessment of personnel competence were in place.

The General Administration of evaluation and control (GEC) in the Agouza site was responsible for consigning samples to specific administrations/units. Designated qualified personnel reviewed all analytical data to ensure the validity of test results and performed specific tests or analytical techniques requiring advanced technical expertise. Administration/unit managers were responsible for authorizing analytical test reports, and the General Manager of Quality Control Laboratories was responsible for authorization of certificates of analysis.

3.2. Premises

The laboratory was visited on the first day. The laboratory layout was documented and discussed, and the facility was of suitable size, construction, and location.

The premises adequately accommodated the requirements of a pharmaceutical testing laboratory and minimized risks to staff health and the quality of analytical results. Emergency exits were in place.

Rest and refreshment rooms and toilet facilities were located separately from laboratory areas. Changing areas were readily accessible and appropriate for the number of users.

Storage facilities were appropriately organized for the proper storage of samples, reagents, and equipment. Separate storage areas were maintained for secure custody of samples and products, with controlled temperature and humidity conditions, and were kept locked. Controlled substances were clearly labelled, stored separately, and access was restricted to designated personnel.

Safety procedures for handling toxic or flammable reagents were implemented.

The laboratory was equipped with adequate instruments and equipment, including workbenches, workstations, and fume hoods. Separate instrument rooms for different measurement techniques were available, as required. Appropriate safety equipment was in place, and measures were implemented to ensure good housekeeping and cleaning practices. The SOP Cleaning Glassware Instruction was reviewed and found to be adequate.

Weighing areas were located in environments with controlled temperature and humidity.

Preparation and analysis of cytotoxic and genotoxic substances were conducted in dedicated rooms equipped with appropriate measures to prevent staff exposure and cross-contamination.

Environmental conditions, including lighting, energy supply, temperature, humidity, and air pressure, were appropriate for the activities performed. Relevant conditions were monitored, controlled, and documented.

Procedures were in place for the safe disposal of waste, in compliance with local environmental requirements.

The server room was visited and found to be well organized.

An agreement for pest control with a governmental organization under the Ministry of Health was in place. Monthly visits were conducted for pest control monitoring across the facility. Supporting evidence, including invoices and records of visits, was available and reviewed.

Temperature mapping of refrigerators and sample storage areas was reviewed and discussed.

The UPS system was directly connected to analytical instruments, ensuring the power supply to the instruments was not interrupted in the event of a power outage. There are two automatically interchangeable main power lines feeding the premises, and in the unlikely event of both power lines failing, the emergency generator is activated within two seconds. The generator was capable of supplying continuous electricity to the site for up to 36 hours.

The observations were adequately addressed in the respective CAPA plan.

3.3. Equipment, instruments, and other devices

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

The laboratory had a dedicated department under the Administration of Maintenance and Calibration, responsible for the calibration and maintenance of equipment. This unit had undergone an accreditation process to perform in-house calibration and maintenance activities under its scope of accreditation since 2012. The unit held an accreditation certificate, valid until 24 May 2028, covering UV-Vis spectrophotometers and balances. Accreditation for HPLC calibration was in progress.

All equipment, modules, and accessories were uniquely identified, including identification numbers, location, and equipment specifications.

Documentation for the selected equipment was reviewed to verify that analytical equipment was adequately qualified, demonstrated fitness for its intended purpose, complied with pharmacopeial

requirements, and/or followed manufacturer recommendations, with the laboratory retaining overall responsibility for equipment qualification.

During the purchasing phase, an Equipment Qualification (EQ) plan was available for each item of equipment, ensuring supplier support for qualification activities, including testing, training, maintenance, and repair.

A preventive maintenance schedule and a division annual calibration plan were established for analytical equipment. These activities were performed either by the Laboratory or by a qualified external service provider.

All calibrations and equipment qualifications were traceable to appropriate reference standards, and any changes to analytical equipment were subject to change control. Requalification was required following specific changes.

Defective or out-of-specification equipment was taken out of service, repaired, requalified, and clearly labelled.

Documentation for preventive maintenance and calibration defined the responsible body or service provider, specified test procedures and acceptance criteria, detailed methods and materials, recorded test dates and results, specified actions in case of failure, and included signatures of the personnel involved.

Equipment logbooks were maintained to document the history of each item, including maintenance, calibration, and qualification records.

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. Commercial reagents were sourced from verified and approved qualified suppliers and were accompanied by certificates of analysis and the respective safety data sheets were available.

Reagent management covered the entire lifecycle, from purchasing and preparation to use and disposal, in accordance with standard operating procedures. The expiry date after opening of reagent containers was determined in accordance with the SOP for Handling of Reagents for Analytical Purposes Quality Procedure.

Labelling requirements included essential information such as the substance name, receipt and opening dates, expiry date, storage conditions, concentration, manufacturer details, batch number, and identification of the responsible personnel. In-house reagents prepared by the laboratory were also subject to specific labelling requirements.

The observations were adequately addressed in the respective CAPA plan.

3.5. Reference substances and reference materials

Reference substances were obtained from reputable commercial sources or supplied by the pharmaceutical product manufacturer.

Control of reference substances and materials was overseen by designated personnel. Reference standards were used once and discarded after completion of the analysis. Before use, the intended application and the expiry or retest date of reference substances were verified, and the relevant information was included in the test reports.

The observations were adequately addressed in the respective CAPA plan.

4. **Technical activities**

4.1. Sampling

The laboratory was not responsible for sampling.

Samples were collected by authority inspectors from pharmacies, distributors, or manufacturing sites and delivered to the Laboratory at the Agouza site. The Agouza laboratory registered the samples in LIMS as either marketing authorization or post-marketing samples, including relevant details such as specifications and required tests. A unique identification number was assigned to each sample.

4.2. Incoming samples

The SOP for Handling of Product Samples, File Assessment, and Issuing of Final Reports from the Central Administration of Drug Control described the procedures for implementing a structured and systematic workflow for the receipt, handling, storage, distribution, and retention of incoming samples. It also covered document review and assessment of the QC sections of product dossiers, review of analytical test reports and certificates of analysis, and issuance of final reports by CADC.

Following registration at the Agouza site, samples were transferred to the El-Mansourya site within CADC, accompanied by a data logger. Electronic records from the data logger were retained at the El-Mansourya site. Samples were transported with a sample distribution and transportation form, which was verified, signed, and dated upon receipt. A visual inspection was conducted before submission to the analytical laboratories (e.g., PC3 and MC2). The quantity of samples distributed to each laboratory was determined based on the required analyses.

The sample receipt and storage area was located on the third floor of a separate building from PC III, within the same premises. Two dedicated rooms were available: one for marketing authorization samples and one for post-marketing samples.

Sample registration in LIMS included:

- Name of the provider and date of receipt.
- Source of the material.

- Detailed sample description, and brand name.
- Packaging details.
- Dosage form, strength or concentration, manufacturer's name, and batch or lot number.
- Sample size.
- Reason for the analysis request.
- Sampling date.
- Consignment size, where applicable.
- Expiry date or retest date, if available.
- Reference documents and testing specifications.
- Additional comments or identified discrepancies.

Before commencing testing, the laboratory reviewed the test request to ensure that:

- The sample quantity was sufficient for the requested tests.
- The laboratory possessed the necessary capability and resources to perform the tests.
- Customer requirements could be met using available methods or procedures.
- Any issues were resolved with the request originator prior to testing, and records of the review were retained. If the laboratory determined which tests were to be performed, the test request form was updated accordingly.

Each sample container was labeled with a unique registration number without obscuring other markings or inscriptions.

Samples, both prior to testing and after completion of required analyses, were stored. The specific lab responsible for testing was determined by the unit/administration manager.

The observations were adequately addressed in the respective CAPA plan.

4.3. Selection and verification of analytical procedures

The laboratory selected the analytical procedures to be used for testing—either compliance testing or investigative testing—prior to the start of analysis.

Analytical procedures used for testing were confirmed to be suitable for their intended purpose in accordance with the SOP for Method Selection, Verification and Validation Quality Procedure. When analyzing non-pharmacopeial substances or products, preference was given to the manufacturer's approved methods.

Pharmacopeial procedures and methods approved by the licensing authority were considered validated for their intended use as described in the monograph. Where full validation was not required, method verification was performed. Verification applied to already validated methods and confirmed that they performed acceptably under the specific conditions of the laboratory (equipment, personnel, reagents, etc.). Verification ensured that a laboratory, other than the originator of a standard or previously validated

method, could obtain comparable results using its own equipment and personnel. It demonstrated that the method was suitable under the actual conditions of use within the laboratory.

Verification was completed prior to routine use, following a predefined protocol outlined in relevant quality documents. The characteristics assessed depended on the method and its intended purpose. For pharmacopeial methods, verification could replace full validation. All required performance criteria, including instrument and system suitability parameters, should be met. Overall, verification demonstrated that the laboratory could correctly perform the method and that it was appropriate for the sample being tested.

For method verification, the SOP for Elaboration of Validation/Verification Protocol was established to define the minimum requirements for validation of in-house methods and verification of transferred analytical procedures.

System suitability tests were performed prior to and during sample analysis to ensure that the entire analytical system—including the instrument, reagents, columns, and analyst—remained suitable for its intended use.

4.4. Technical records

An analytical data sheet generated by LIMS was used to record information related to the sample, including the test procedure, reagents, standards, materials, calculations, and test results. It incorporated all raw data obtained during the analysis. The analytical worksheet provided documented evidence to confirm compliance of the sample with specified requirements or to support any out-of-specification results. The records related to a selected sample were reviewed and discussed.

The laboratory was in the process of implementing an analyst notebook to serve as a source document for records that could not be directly captured in LIMS.

The analytical data sheet in LIMS included the following information:

- Registration number of the sample.
- Date of the test request.
- Dates on which the analysis was initiated and completed.
- Name and electronic signature of the analyst.
- Description of the sample received.
- References to specifications and a full description of the test methods used, including acceptance limits.
- Identification of the test equipment used.
- Details of reference substances used, including supplier, lot number, and potency or content.
- Results of system suitability tests, where applicable, along with analytical acceptance criteria.
- Identification of reagents, solvents, and columns used, where applicable.
- Results obtained.

- Interpretation of results and conclusions, including compliance with specifications, approved and signed by designated qualified personnel.

Calculations and data transfers were verified appropriately and systematically, either controlled through validated Excel sheets or using a calculator. These Excel sheets were uploaded into LIMS and used for calculations, where applicable. An SOP for the validation of Excel sheets was in place, and the files were stored in a secure folder.

Any changes made to original records, whether in paper or electronic form, were traceable, including details of what was changed, by whom, when, and why. Data deletion was not permitted. Records related to sample analysis were maintained within LIMS.

SOP for Ensuring the Validity of Results Quality Procedure (current version last issued 25 November 2025) was available and reviewed. It established procedures for implementing quality control programmes to ensure the validity of testing and calibration results, including proficiency testing.

The records of selected samples were reviewed.

The observations were adequately addressed in the respective CAPA plan.

4.5. Testing

According to the SOP for General Activities of Quality Control Laboratories, the workflow began with sample submission and administrative screening to confirm the scope. Accepted samples were logged and assessed by the Laboratory Manager to determine capability. If the laboratory was capable, testing was assigned; otherwise, the request was rejected or partially outsourced within EDA.

A Technical Supervisor verified the suitability of the sample prior to analysis, after which QC staff performed the testing. In cases of missing items, a formal request process was initiated before proceeding.

Results were reviewed, and any out-of-specification results were managed according to established procedures.

Finally, the results were approved by the Laboratory Manager, then authorized by the unit/administration Manager and the General Manager of Quality control laboratories authorized of certificates of analysis and submitted to GEC, completing the process.

Samples were appropriately stored in a dedicated storage facility under controlled environmental conditions until testing was conducted in accordance with the laboratory workplan.

Detailed guidance on pharmacopoeial requirements was provided in the general notices and specific monographs of the relevant pharmacopoeia. Test procedures were described and contained details to enable trained analysts to perform analyses. System suitability criteria were defined within the methods.

Endotoxin Testing (Gel Clot Method)

Endotoxin testing was performed using the gel clot method in accordance with the applicable SOP, based on USP Chapter <85>, Bacterial Endotoxins Test, and European pharmacopeia general chapter (2.6.14) Bacterial Endotoxins.

The respective Proficiency testing was conducted in two rounds (2023 and 2025) at a frequency of every two years, with successful participation in both rounds (Royal Quality System, Egypt, in 2023, and EDA in 2025).

The Limulus Amebocyte Lysate (LAL) reagent was sourced from a recognized supplier, and the associated certificates of analysis were reviewed and found to be acceptable. Storage conditions were appropriate (refrigerated), and reagent expiry dates were respected, with no extension beyond 28 days after opening. LAL reagent water was used as required.

The sensitivity of the lysate (λ) was verified using Positive Product Control (PPC), including appropriate negative controls (no clot formation) and positive controls (clot formation), under standard incubation conditions ($37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for approximately 60 minutes). All procedures were performed as specified.

Glassware and materials were adequately depyrogenated where required, and disposable glassware from Greiner Bio-One was used.

The observations were adequately addressed in the respective CAPA plan.

4.6. Evaluation of test results

Quantitative test results were recorded in a manner that allowed the detection of trends. Where appropriate, these results were reviewed and evaluated after completion of testing. The evaluation considered predefined action and rejection limits to determine whether the product met the acceptance criteria.

For compliance testing, the product was required to meet all acceptance criteria specified in the approved analytical specifications. Test results were compared against these specification limits to determine compliance, and a conclusion was drawn regarding conformity with the requirements.

All test results were traceable to primary reference substances, either from a pharmacopoeia or provided by the manufacturer, or, where applicable, to certified reference materials.

Test results were reviewed and approved or rejected by designated qualified personnel in accordance with the competency matrix or master list.

4.7. Measurement uncertainty

The uncertainty of measurement results was considered essential for the overall assessment and interpretation of analytical data. The management of measurement uncertainty was established to ensure the accuracy, reliability, and reproducibility of analytical results.

Requirements related to measurement uncertainty applied to all quantitative tests performed by NQCLs. The decision to estimate and consider measurement uncertainty in statements of conformity with specification limits was made by the laboratory on a case-by-case basis and was documented in advance.

Evaluation of measurement uncertainty was required in situations such as the use of methods with limited uncertainty data, confirmation of out-of-specification results, or establishment of limits for performance testing of equipment and critical method parameters. The laboratory demonstrated that critical factors influencing measurement uncertainty were adequately managed and controlled.

The assessment of measurement uncertainty was also applied, where appropriate, as an internal quality control measure at the discretion of the laboratory.

The pharmacopeial decision rule was applied to all specification limits defined in pharmacopeial monographs and marketing authorization documentation.

4.8. Reporting of results

The analytical test reports were generated electronically in LIMS and contained the test results for review by the technical supervisor and approval by the laboratory Manager, or a designated individual, and finally authorized by the unit/administration manager. The complete dossier, including all information related to the samples such as origin, chain of custody, and analytical data, was maintained within LIMS. The laboratory determined when to report measurement uncertainty and how conformity with specifications was to be evaluated.

The analytical test report included the following information:

- Title of the analytical test report.
- Laboratory registration number of the sample.
- Laboratory test report number.
- Name and address of the testing laboratory.
- Name and address of the originator of the analysis request.
- Name, description, and batch number of the sample, where applicable.
- Results of all tests performed, including numerical results and standard deviation, where applicable.
- Where applicable, the expanded measurement uncertainty of the reported result, with reference to its assessment and an explanation of how it was considered in the conformity decision.
- Discussion of the results obtained, where appropriate.
- A statement indicating that the results applied only to the items tested, calibrated, or sampled.
- Clear identification of any results generated by external service providers.
- Date of completion of the tests.

- Signature of the laboratory manager or other authorized individual responsible for review and approval of the report.
- Name of the original manufacturer and, where applicable, those of the re-packer or distributor.
- Date of sample receipt.
- Expiry date or retest date, where applicable.
- A statement indicating that the analytical test report, or any part thereof, could not be reproduced without authorization from the laboratory.

A certificate of analysis, containing the same information as the analytical test report, was prepared for each batch of a substance or product and approved by the general manager and the head of CADC in case of market authorization

The observations were adequately addressed in the respective CAPA plan.

4.9. Nonconforming work

The term “nonconforming work” referred to any instance in which analytical activities deviated from established procedures, internal requirements, or agreed analytical specifications with the customer. Such deviations included issues related to equipment, environmental conditions, internal quality-control criteria, and system-suitability criteria. All instances of nonconforming work were recorded, addressed, and managed in accordance with the SOP for Dealing with Non-conformity and Corrective actions QP.

Management of nonconforming work was reviewed through selected examples, and it was noted that such cases were addressed within the same system, ensuring that:

- Actions, including the suspension or repetition of work and withholding of reports, where necessary, were based on the risk level associated with the affected activity.
- The significance of the nonconforming work was evaluated, including its potential impact on previously generated results.
- Decisions were made regarding the acceptability of the nonconforming work.
- The customer was informed, where necessary, and work was recalled where applicable.
- Responsibility for authorizing the resumption of work was clearly defined.
- Records of nonconforming work were retained, including all actions taken.

Corrective actions were implemented when the evaluation indicated a potential for recurrence of the nonconforming work or when there was doubt regarding compliance with the QMS.

4.10. Retained samples

Retained samples were stored in the same receipt area in a dedicated cabinet with appropriate labeling in accordance with SOP Receipt, Handling, Distribution, Storage, and Retention of Samples in CADC. The laboratory retained only samples that remained after completion of analysis for a maximum period of three months for conformed samples and one year for OOS samples.

The observations were adequately addressed in the respective CAPA plan.

5. Safety rules

A tour of the facility was conducted on the first day.

A documented laboratory safety policy, including general and specific safety instructions reflecting identified risks, was available and applied by staff. A designated staff member was responsible for overseeing the policy and ensuring compliance.

A waste management system compliant with local legislation was in place to ensure the safe disposal of chemicals, solvents, and other relevant materials.

Training on safety-related topics was conducted at defined intervals, as specified in the QMS.

General safety rules were established and implemented in the laboratory. Safety data sheets were available prior to testing, and activities such as smoking, eating, or drinking were prohibited. Staff were trained in the use of firefighting equipment, first aid, and emergency procedures, and lab coats were used. Special precautions were applied when handling hazardous substances, with toxic materials managed in dedicated facilities. Chemicals were properly labeled, and safety measures for electrical equipment and compressed gas cylinders were followed.

Safety showers (for both eye wash and full body) were installed at appropriate locations. Rubber suction bulbs were used with manual pipettes and siphons. Staff were trained in the safe handling of corrosive reagents and solvents, including the use of safety containers or carriers to prevent spills.

Warnings, precautions, and instructions were incorporated, where appropriate, into standard operating procedures for handling hazardous reactions and materials, including violent or uncontrolled reactions (e.g., mixing water and acids, or acetone–chloroform with ammonia), flammable substances, and oxidizing or radioactive agents. Information on chemical neutralization was defined in the safety quality manual, and on-the-job training and related certifications were provided and reviewed.

SOP for controlled drugs was aligned with the procedure for returned samples, with additional provisions for the secure storage and handling of controlled substances. It required storage in a separate, secured cabinet.

The observations were adequately addressed in the respective CAPA plan.

Miscellaneous	
Assessment of the Laboratory Information File	The CADC Laboratory Information File, dated 28 January 2026, was implemented in accordance with WHO TRS No. 961 (2011), Annex 13.
Annexes attached	N/A

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 of ***Egyptian Drug Authority - Central Administration for Drug Control***, located at ***Elmansoureya Street, Haram, Giza; Egypt*** was considered to be operating at an acceptable level of compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories guidelines.

The deficiencies observed during the inspection, as listed in the full report, were addressed by the Laboratory to a satisfactory level before 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. 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>
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-eight 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>

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

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<https://www.who.int/publications/i/item/9789241209922>

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>

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>

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>

25. WHO Laboratory biosafety manual, 4th edition