World Health Organization

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**Prequalification Team Inspection Services**
**WHO PUBLIC INSPECTION REPORT**
**(WHOPIR)**
**Quality Control laboratory**

| **Part 1** | **General information** |
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| **Laboratory Details** | |
| Name of the Laboratory | TMDA Quality Control Laboratory |
| Address of inspected Laboratory | Off Mandela Road, Mabibo - External<br>P. O. Box 77150<br>Dar es Salaam<br>Tanzania |
| Address of corporate office | As above |
| | |
| Dates of inspection | 08 - 11 September 2025 |
| Type of inspection | Routine inspection |
| Inspection record number | INSP-QCL-2021-0933 |
| **Introduction** | |
| Brief description of testing activities | |

| **Type of analysis** | **Finished products** | **Active pharmaceutical ingredients** |
|---|---|---|
| Physical/ Chemical analysis | pH, melting point, optical rotation, conductivity, friability, tablet hardness, disintegration, dissolution, uniformity of dosage units | pH, melting point, optical rotation, conductivity |
| Identification | HPLC (UV-VIS, PDA detection), TLC, UV-VIS spectrophotometry | HPLC (UV-VIS, PDA detection), TLC, UV-VIS spectrophotometry |
| Assay, impurities and related substances | HPLC (UV-VIS, PDA detection), TLC, UV-VIS spectrophotometry, Polarimetry, Volumetric titration | HPLC (UV-VIS, PDA detection), TLC, UV-VIS spectrophotometry, Polarimetry, Volumetric titration |
| Microbiological tests | Microbial Limit Test, Bacterial Endotoxin Test (LAL), Bioassay | Microbial Limit Test, Bacterial Endotoxin Test (LAL), Bioassay |

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| General information | The TMDA Quality Control Laboratory, was established under section 14 (1) of the Tanzania Medicines and Medical Devices Act, Cap. 219 to carry out the analysis of regulated products. The laboratory forms the Directorate of Laboratory Services which is among the 4 directorates of the Tanzania Medicines and Medical Devices Authority (TMDA).<br><br>TMDA is under the Ministry of Health. It is responsible for controlling the quality, safety, and efficacy of medicines, medical devices, diagnostics, tobacco, and health related products.<br><br>TMDA operates 3 main laboratories located in Dodoma (performs chemical analysis of herbal medicines), Dar es Salaam (performs physico-chemical, microbiological analysis of medicines, medical devices, and diagnostics) and Mwanza (performs physico-chemical and microbiological analysis of medicines) within TMDA's Head Office, Sub-Head Office, and Zonal Office. These laboratories are supported by 27 Medicines Quality Assurance Centers, equipped with minilab kits. The centers are strategically stationed at ports of entry, zonal offices, and selected regional referral hospitals across the country. |
| History | The Quality Control Laboratory (Chemistry) attained prequalification status in January 2011.<br>The Quality Control Laboratory (Microbiology) attained prequalification status in November 2021.<br>No regulatory authority inspections have been conducted since prequalification routine inspection performed in 2021. |
| **Brief report of inspection activities undertaken - Scope and limitations** | |
| Areas inspected | Organization and management including:<br>- Structure<br>- QMS<br>- Documentation and records<br>- Computerized systems<br>Planning and strategic management including:<br>- Service providers and suppliers<br>- Performance management<br>- Quality risk management<br>Resources including:<br>- Personnel<br>- Premises<br>- Equipment qualification<br>- Reagents, Reference standards<br>Technical activities including:<br>- Handling of samples<br>- Validation, verification and transfer of analytical methods<br>- Testing, evaluation and reporting of results and OOS<br>Safety |

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| Restrictions | None |
| Out of Scope | The testing activities not in the above-mentioned list were excluded from the scope of this inspection. |
| **Abbreviations** | **Meaning** |
| ALCOA | Attributable, legible, contemporaneous, original and accurate |
| API | Active pharmaceutical ingredient |
| BCP | Business continuity plan |
| CoA | Certificate of analysis |
| CAPA | Corrective action & Preventive action |
| CNC | Controlled not classified |
| DG | Director General |
| DQ | Design qualification |
| DLS | Director Laboratory Services |
| 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 |
| IVD | In-vitro diagnostics |
| KF | Karl Fischer titration |
| LIMS | Laboratory information management system |
| LQO | Laboratory Quality Officer |
| 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-specifications 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 |
| PW | Purified water |
| QA | Quality assurance |

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| 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 |
| 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 |
| YTD | Year to date |

| **Part 2** | **Summary of findings and recommendations (where applicable)** |
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**1. Organization and management system**

1.1. Structural and general requirements

The TMDA Quality Control Laboratory located at the Sub-Head Office in Dar es Salaam was organized into 3 sections:

- Medicines Chemical Analysis
- Microbiological Analysis
- Medical Devices and In-Vitro Diagnostics (IVDs) Testing

The organizational structure of the laboratory, including responsibility, authority and interrelationship of the personnel, were indicated in the organizational chart.

1.2. Quality management system (QMS)

A documented QMS was established, implemented, and maintained with procedures covering key quality elements. The Laboratory Quality Manual included the following:

- Quality Policy Statement
- Mission Statement
- Vision Statement
- Quality Objectives

Proficiency Testing (PT)

The Quality Control laboratory participated in Proficiency Testing Schemes (PTS) to assess analytical procedures or reference substances (RS) following the SOP "Assuring the Quality of Test Results".

1.3. Control of documentation

The SOP "Control of Management System Documents and Records" detailed preparation, review, approval and control of documents. The QCL had established and maintained a system of SOPs to manage all documentation processes.

An electronic "Systems Procedures Documents Master List" was maintained, detailing the following:

- Document Name
- Document Number
- Revision Number
- Effective Date
- Review Date
- Location

The following was checked:

- "System Procedures Documents Master List"
- "Medicines Procedure Documents Master List"
- "Procedure Documents Master List Microbiology SOPs"

1.4. Change Control

Change management was performed in accordance with a documented SOP. Changes were classified as major or minor. All changes having an impact on quality systems, documents, facilities, equipment, computerized systems and customer product quality were managed by the change control system. They required impact assessment. The proposed change control required approval/rejection by the Section Manager. Change controls were retained for the specified years. The "Change Control Register" was maintained. An example of change control was reviewed and discussed.

1.5. Control of Records

A documented SOP "Control of Management System Documents and Records" outlined the procedures for establishing, identifying, storing, protecting, retrieving, retaining, and disposing of records.

All original documents and electronic copies were retained. Authorized hard copies for routine use were stored on designated laboratory shelves. When required, full active files were transferred to the Archive room.

1.6. Control of Data / Computerized Systems

Computer systems connected to laboratory instruments were installed with controlled access in an established network. These systems were restricted to authorized users only and were password protected.

An SOP on data integrity and backup described the personnel responsibilities as well as two types of computerized systems, namely LIMS and software-operated equipment. No external devices were allowed to be used. Audit trails for LIMS and software-operated equipment were regularly reviewed.

LIMS backup and data restoration checks were performed. Disaster recovery was addressed in the procedure.

The following SOPs were reviewed and discussed:
- SOP on the management of computerized systems applied to LIMS and software-operated equipment
- SOP on the validation of computerized systems

1.7. Deviations and Corrective and preventive actions

Deviations were managed in accordance with a documented SOP. Deviations were classified as planned or unplanned.

CAPAs were managed in accordance with a documented SOP. The register for tracking of deviation, non-conformity and CAPA was available.

1.8. Internal audits

The SOP for internal audits described the process for the planning and performing of internal audits which covered all relevant elements of the QMS. The procedure allowed additional audits to be conducted following recommendations resulting from:
- Customer complaint investigation reports
- External assessments
- Management reviews
- Director of Laboratory Services instructions
- Auditors' recommendations

An "Internal Audit Schedule" and a "List of Competent Internal Auditors" were available. The non-conformances observed during the internal audit were addressed through SOP "Control of Non-conformances and Corrective Action". The results of the audit were required to be reported to management and discussed at management review.

1.9. Complaints

An SOP on the handling of customer complaints was in place. Complaints were investigated and a "Complaint Form and Investigation Report" was required to be submitted within the specified number of days. For valid complaints, the root cause and corrective action were determined in accordance with SOP "Handling of Non-Conformance and Corrective Action". A response letter was required to be sent to the customer following the procedure. An example of a complaint was reviewed and discussed.

1.10. Management Review

An SOP described the process for management review.MR meeting shall be conducted annually. MR meetings were documented and checked.

1.11. Improvement

An SOP on management system improvement was reviewed. The laboratory identified opportunities for improvement and implemented necessary actions. Opportunities were obtained from reviews of policies, procedures, objectives, audit and inspection results, corrective and preventive actions, risk

assessments, management reviews, personnel suggestions, and analyses of data, trends, and proficiency testing results, as well as from customer feedback obtained through satisfaction surveys, communication records, and report reviews, using the information as a tool for improvement.

**2. Planning and strategic management**

2.1. Externally provided services and supplies

The laboratory documented its process for selecting and purchasing required products and services. including measurement materials (e.g., Reference and Certified Reference Materials, chemical and biological reference substances, equipment, reagents), and external services (e.g., calibration, qualification, sampling, testing, maintenance, proficiency testing, assessment, and auditing).

The following documents were reviewed:

- SOP on externally provided products and services which applied to all supplies and services required by TMDA QCL in line with the Tanzania Procurement Act and process.
- SOP on subcontracting of test work which covered subcontracting of test work in the TMDA QCL. A "Subcontract Testing Lab List" was available.

2.2. Review of tenders and contracts

The following documents were reviewed:

- The SOP "Review of test requests"
- Process map for handling of test samples
- Process map for review of request, tender and contracts

The requirements of reviewing requests, tenders, and contracts were clearly defined and documented ensuring that:

- The customer requirements were adequately defined and documented and the appropriate methods were selected to meet customer requirements.
- The laboratory possessed the capability and resources to meet the requirements.
  If testing could not be performed in-house, the testing could be subcontracted following SOP "Subcontracting of Test Work". If not, the customer would be notified that the testing could not be performed.
- A written contract defined the scope of work and responsibilities of each party, and any technical arrangements.

2.3. Performance management

The management review set objectives, performance indicators, and measurable targets for a specified period and monitored the performance against those objectives.

2.4. Quality risk management

SOP on management of risks and opportunities described the approach to risk management.

TMDA risks were categorized into strategic, operational, financial and systems as well as compliance. Risk scored at 3 levels. If the score was above the limit, mitigation action required to be taken. The "Risk Management Register" for 2024 was reviewed.

2.5. Crisis management

The laboratory maintained operational efficiency through proactive planning and budgeting to secure essential resources, including infrastructure maintenance etc. A documented Business Continuity Plan (BCP) was in place.

**3. Resources**

3.1. Personnel

The laboratory employed qualified personnel with documented education, training, and experience.

Chemistry testing was performed and supervised by qualified personnel with experience in pharmaceutical analysis or equivalent.

Microbiological testing was performed and supervised by qualified personnel with experience in microbiology or equivalent.

Job descriptions and records

Job descriptions were available for personnel involved in laboratory activities.

Training

An SOP on personnel training and competencies detailed the recruitment of personnel, identification of training needs, training, supervision of new recruits, personnel competence verification, and authorization. Personnel received initial and ongoing training in quality systems, methods, and safety.

Newly recruited personnel were required to perform laboratory activities under supervision of competent analyst until deemed competent. Competency was assessed, and authorization was granted upon successful completion. All training records were maintained indefinitely.

3.2. Premises

The laboratory building has 3 floors including:

- Sample Receiving area, Sample Storage room, Director's office
- Medicines Chemical Analysis laboratory
- Microbiology laboratory, IVDs Testing room, Storage of primary reference substances

In a separate building adjacent to the laboratory building:

- Dedicated store for the storage of flammable and hazardous materials, Glassware store
- Storage of chemicals/solvents awaiting disposal (locked cage), Archives room

The laboratory premises were constructed and maintained to support the operations. Access to laboratory facilities was restricted to designated personnel. Emergency exits were installed and accessible.

3.3. Equipment, instruments, and other devices

In general, laboratory equipment was appropriately installed, cleaned, and maintained. A "Master List of Equipment" was available.

The Chemistry laboratory was equipped with balances, pH meters, disintegration tester, dissolution tester, HPLC (Shimadzu, Agilent), UV-VIS-NIR spectrophotometer (Shimadzu), FT-IR spectrophotometer (Perkin Elmer), Karl Fisher titrator, and polarimeter etc.

The Microbiology laboratory was equipped with LAF hoods, Biosafety cabinets, incubators, autoclaves, refrigerators, freezer, hot air oven etc.

An SOP on handling of equipment and systems was available. It described 4 types of equipment namely computerised system, physical standards, general equipment, measuring/testing equipment other than computerised system.

A Validation Master Plan (VMP) was presented. The "Validation Schedule" for 2025 was in place. The implementation was monitored.

3.4. Reagents and materials

Chemistry laboratory

All materials were stored in a designated Chemical Reagents room with access control. All reagents and chemicals were required to be procured from approved suppliers. SOP on the handling of chemicals and reagents detailed the requirements.

Commercial reagents were procured from prequalified vendors who were subjected to annual performance review. This was performed according to an SOP on externally provided products and services.

Microbiology laboratory

A general procedure for preparation of culture media and reagents was in place. Media were prepared in-house and only when required (media not stored). Growth Promotion testing and Suitability of Counting Method was performed on every batch as per the requirements of the USP NF <61>.

Purified Water (PW)

PW used for testing purposes was generated using an EVOQUA Water Technique system. The feed water was sourced from the municipal city water supply and subjected to a pre-treatment process (Phase 1 and 2) and final treatment (Phase 3) to produce PW. The system, P&ID drawing, cleaning program, and water quality trend analysis were checked.

3.5. Reference substances and reference materials

Reference substances (RS) were managed according to the following procedures including purchasing, receiving, storage, usage, expiration, records of chemical/reagents and reference microorganism cultures:

- SOP on externally provided services and supplies

- SOP on ordering, handling and storage of reference standards
- SOP on handling of chemicals and reagents
- SOP on maintenance of reference microorganism cultures

Primary RS could be received from USP, BP, EP. The receipt of the RS was recorded in a logbook and stored in accordance with storage requirements. The Reference Standard Storage room was access controlled. RS were stored at the applicable storage temperatures, room temperature or 2 - 8 °C. The validity of RS was checked quarterly and documented electronically.

Microbiology laboratory sourced reference cultures from ATCC (American Type Culture Collection) and recorded the receipt of the cultures in the "Reference Microorganism Register". The reference stock cultures were stored at ⁻70°C and ⁻20°C depending on use while working cultures at 2 - 8 °C. Confirmation of the reference microorganism was performed using specific media and biochemical tests.

**4. Technical activities**

4.1. Sampling

The laboratory was not involved in physical sampling. In the case of internally submitted samples, sampling was performed by inspectors. Externally submitted samples were sampled by the customers.

Internally submitted samples were:
- Registration samples
- Port of Entry (PoE) samples
- Routine Surveillance (inspection) samples
- Post-Market Surveillance (PMS) program samples

Externally submitted samples were samples obtained from:
- International organizations e.g., WHO
- Foreign nations through MRA
- Government institutions in Tanzania and other domestic organizations and individual customers
- Research projects e.g., domestic universities

4.2. Incoming samples

An SOP on handling and testing of test samples described sample receipt, registration, storage, issuance, analysis, and disposal.

Sample test requests were reviewed and documented by the relevant Section Manager as per SOP on review of test requests. Samples were only accepted after the relevant Section Manager ensured the availability of:
- Test method
- Chemicals
- Calibrated equipment
- Competent analysts
- Adequate number of samples

Samples were then accepted in LIMS if the samples met the sample integrity criteria stipulated in the SOP:

- Physical appearance
- Proper sealing
- Frozen state for samples requiring freezing
- Absence of leakage/breakage
- Sample within shelf life
- Proper labelling
- Applicant has submitted the required number of samples as per the test procedure/pharmacopeia monograph

LIMS generated a unique laboratory code number (traceability of sample during the entire process until issuance of certificate of analysis). A unique identification code was either affixed or written using an indelible marker on both primary and secondary containers.

Samples awaiting testing were stored in the locked Sample Storage room with temperature and RH control.

4.3. Selection, validation, and verification of analytical procedures

An SOP on selection, verification, validation of method and measurement uncertainty was in place.

4.4. Technical records

All electronically generated technical records were archived in LIMS.
All supporting test records (e.g. chromatograms, spectra, reference material certificates, printouts) were attached to the corresponding "Sample Analysis Worksheet".

Completed "Laboratory Notebooks" were returned for archiving upon full utilization.

"Sample Analysis Worksheet" and associated "Certificates of Analysis" were filed sequentially in the "Sample Category File".

Once the "Sample Category File" reached capacity, records were transferred to the Archive room.

4.5. Testing

An SOP on handling and testing of test samples was in place.

Samples were assigned via LIMS using the "Sample Analysis Request Form" which specified the applicable test method. Upon receipt, the analyst quoted the unique laboratory code to the Sample Custodian and collected the samples. Testing was performed in accordance with the pharmacopeial monograph or specified method. All data were documented in the designated "Test Report" or "Laboratory Notebook".

4.6. Evaluation of test results

Reviewing and assuring the quality of test results was managed in accordance with an SOP on reporting of results.

All steps and activities related to the analytical/testing process were required to be documented.

Validated Excel spreadsheets were used in performing analytical calculations.

4.7. Measurement uncertainty
An SOP on selection, verification, validation of method and measurement of uncertainty was reviewed.

4.8. Validity of test results
An SOP on assuring the quality of test results was reviewed and discussed.

4.9. Out-of-specification results
OOS results were managed in accordance with the following procedures:
- SOP on handling of out of specification applicable to chemical analysis
- SOP on handling of out of specification applicable to microbiology testing
- SOP on control of non-conformance and corrective action procedure

The OOS registers were available.

4.10. Reporting of results
The "Test Report" was required to be reviewed and authorized prior to its release and communication to the customer, in accordance with the SOP on reporting of results. Analyst transferred final analytical work into an "Analysis Summary Report" provided in LIMS. The data was verified by another analyst through LIMS, then the "Laboratory Work Sheet" was submitted to the Laboratory Manager for review and approval.

4.11. Nonconforming work
An SOP on control of non-conformance and corrective action was available and addressed non-conformities related to:
- Internal audits
- Customer satisfaction survey
- PT results evaluation
- OOS results investigation etc.

A list of non-conformances was maintained, and CAPAs initiated and documented.

4.12. Retained samples
An SOP on handling and testing of samples described the process to be followed for the handling and disposal of retained samples.

Retained samples were stored in the Sample Storage room within a designated area. Samples were required to be held for 1 year post expiry. Samples subject to disputes or legal proceedings were required to be retained until conclusion of all related legal matters.

At the end of each calendar month, a review of retained samples was conducted to identify those samples requiring disposal. A "Disposal List" of retained samples was generated via LIMS and submitted to the respective Section Manager for approval. Disposal of retained samples was carried out by a contracted services provider approved by the National Environment Control Body and all disposal activities were performed in compliance with the existing national legislation.

**5. Safety rules**

SOP on laboratory safety was reviewed and discussed. Environmental health and safety policies were implemented to safeguard staff, the public, and the environment. A documented laboratory safety policy, outlining general and risk-based instructions, was made available to all staff and actively enforced. A designated staff member oversaw its implementation and monitored compliance.

General safety measures included:

- No smoking, eating, and drinking in laboratories
- Use of protective clothing (lab coats, eye protection, gloves as needed)
- Availability of an eye-wash station and emergency shower in the Chemistry laboratory
- Fire extinguishers and first-aid boxes with essential supplies

The waste management system was proceduralized complied with local legislation and ensured safe disposal of chemicals, solvents, and related materials.

| Part 3 | Conclusion - Inspection outcome |
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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, ***TMDA Quality Control Laboratory***, located at ***Off-Mandela Road, Mabibo-External, 16106 Dar es Salaam; Tanzania*** was considered to be operating at an acceptable level of compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories 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 |
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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-1033

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-annex2

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. Fifty-sixth Report, Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 2.

**Short name: WHO TRS No. 1044, Annex 2**
https://www.who.int/publications/m/item/trs1044-annex2

9. WHO guidelines on transfer of technology in pharmaceutical manufacturing. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-sixth Report, Geneva, World Health Organization, 2022 (WHO Technical Report Series, No. 1044), Annex 4.
**Short name: WHO TRS No. 1044, Annex 4**
https://www.who.int/publications/m/item/trs1044-annex4

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 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

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 TRS No. 1025, Annex 4**
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**
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