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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT (WHOPIR)
of the Quality Control laboratory

Part 1	**General information**
Laboratory Details	
Name	**National Drug Quality Control Laboratory**
Address	National Drug Quality Control Laboratory c/o National Drug Authority Uganda Plot 93, Buganda Road (NDA Tower) and Mulago Hill, Kampala, Uganda (Laboratory) P.O Box 23096, Kampala-Uganda. Website: www.nda.or.ug
Inspection details	
Date of inspection	19 – 21 May 2025
Type of inspection	Routine
Inspection record number	INSP-QCL-2019-0097
Introduction	

Brief description of testing activities

Type of Analysis	Finished Products	Active Pharmaceutical Ingredients
Physical/Chemical analysis	pH, Water content (Karl-Fisher), disintegration, loss on drying, dissolution, uniformity of dosage units, density, dimensions, extractable volume, conductivity, visible particulate matter.	pH, Water content (Karl-Fisher), loss on drying, melting point.
Identification tests	IR, (HP)TLC, (U)HPLC, GC, UPLC-q-tof (HRMS), ICP-MS, UPLC-MS/MS (MS^e) spectrophotometry and basic chemical tests, Capillary Electrophoresis, Raman Spectrometry.	IR, (HP)TLC, (U)HPLC, GC, UPLC-q-tof (HRMS), ICP-MS, UPLC-MS/MS (MS^e) spectrophotometry and basic chemical tests, Capillary Electrophoresis, Raman Spectrometry.
Assay, impurities and related substances	(U)HPLC (UV-VIS, ELSD, DAD, FLD detection, MS/MS, MS^e), GC, UV/Vis, (HP)TLC, ICP-MS, FTIR spectrophotometry, limit tests, volumetric titration. Determination of related substances and impurities by comparison with reference standards.	(U)HPLC (UV-VIS, ELSD, DAD, FLD detection, MS/MS, MS^e), GC, UV/Vis, (HP)TLC, ICP-MS, FTIR spectrophotometry, volumetric titration. Determination of related substances and impurities by comparison with reference standards.
Microbiological analysis	Subvisible particulate Matter, BET by MCS	Subvisible particulate Matter, BET by MCS

General information	The National Drug Quality Control Laboratory (NDQCL) operates under the Directorate of Laboratory Services of the National Drug Authority (NDA) in Uganda. The NDA, established in 1993, is a government regulatory agency. The Directorate of Laboratory Services is one of five directorates within the NDA, with all directors reporting to the Authority Secretary. NDQCL has been operational since 2000. It received pre-qualification from WHO for its Medicines Unit in 2015 and achieved ISO/IEC 17025:2005 accreditation for medical devices testing in December 2016. In January 2019, the scope of the ISO accreditation was expanded to include the Medicines Unit. The laboratory primarily tests medicines, medical devices, and public health products, such as insecticides found in long-lasting insecticide-treated mosquito nets (LLINs). While most test samples were finished products, the laboratory also had the capacity to test active pharmaceutical ingredients (APIs). The collection of samples of finished products was conducted by the Directorate, Inspectorate and Enforcement. Annually, about 1000 samples were tested. The use of Mini-Labs for field screening of samples was not included in the scope of this inspection. The laboratory had applied to expand its prequalification status to include additional physio-chemical tests following the purchase and commissioning of several additional equipment.
History	NDA Uganda's Medicine QC testing section was last inspected by WHO in June 2019. It also has annual ISO inspections and maintains ISO accreditation
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	The physical/chemical and microbiology laboratories related to pharmaceutical products
Restrictions	Medicines Unit (Herbal Medicine Laboratory) and Medical Device Unit of the NRA.
Out of Scope	N/A
Abbreviations	**Meaning**
ALCOA	Attributable, legible, contemporaneous, original and accurate
API	Active pharmaceutical ingredient
CoA	Certificate of analysis
FPP	Finished pharmaceutical product
FTIR	Fourier transform infrared spectrophotometry or spectrophotometer
GC	Gas chromatography or Gas chromatography equipment
GMP	Good manufacturing practices
HPLC	High-performance liquid chromatography (or high-performance liquid chromatography equipment)
KF	Karl Fisher titration
LIMS	Laboratory information management system
MB	Microbiology
MR	Management review
NC	Non-conformity

NCA	National control authority
NCL	National control laboratory
NRA	National regulatory agency
OOS	Out-of-specifications test result
PM	Preventive maintenance
PQ	Performance qualification
PQR	Product quality review
PQS	Pharmaceutical quality system
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure
URS	User requirements specifications
UV	Ultraviolet-visible spectrophotometry or spectrophotometer

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

Summary of the findings and comments

1. Organization and management

The laboratory, under the National Drug Authority of Uganda, employed multidisciplinary professionals to manage quality, conduct tests, validate processes, and take corrective actions. The Laboratory comprised of three sub-units:

- Quality Management System
- Medicines Unit
- Medical Device Unit

The inspected Medicines Unit was further subdivided in scope to include:

- Conventional Medicine Laboratory section (physical and chemical laboratory)
- Herbal Medicine Laboratory section
- Pharmaceutical Microbiology Laboratory section.

Each section was headed by a principal officer which reported into the Manager, Medicines.

Organization Structure

As per the NDA MACRO and Directorate of Laboratory Services structures, the Director of Laboratory Services oversaw three units:

- Laboratory Quality Management System
- Medicines
- Medical Devices

The Director reported to the Secretary of the Authority/Executive Director.

2. Quality management system

The laboratory had established, implemented, and maintained a quality management system that aligned with its activities. The quality system's elements had been thoroughly documented. The laboratory maintained a current master

list of standard operating procedures (SOPs) for both equipment and the quality management system. This list includes each SOP by number, version, effective date, and expiry date. The quality management system (QMS) endeavored to be compliant with ISO 17025: 2017 and WHO Good Practices for National Pharmaceutical Control Laboratories (GPCL) requirements.

Various SOPs were reviewed and found to be easily retrievable, with an appropriate version control in place. Since 2024, the laboratory had been updating its processes to comply with the latest WHO TRS 1052, 2024 Annex 4.

Quality manual (QM)
The NDQCL Quality Manual outlined the Quality Management System and was divided into the following sections:

- Organization and management
- Laboratory quality systems
- Document control
- Records
- Data-processing
- Personnel
- Premises
- Lab storage facilities
- Equipment, instruments, and other devices
- Contract, purchasing services and supplies
- Subcontracting of services and supplies
- Roles and responsibilities of key personnel
- Working procedure
- Safety

Job descriptions
The job descriptions were available for all staff members. Job descriptions had been authorized and accepted by the employees. Signed job descriptions defined roles and responsibilities. Analysts maintained confidentiality and declared no conflicts of interest.

A competency matrix, that outlined the tests an analyst or laboratory technician was permitted to conduct, was available. The test data was reviewed by qualified personnel and then forwarded to the Director for final review and authorization.

New staff were supervised to ensure that they were competent, and that their work complied with the laboratory quality management system.

Improvement in the Laboratory
The organization conducted a gap assessment analysis on WHO TRS 1052, Annex 4, identifying gaps that need to be addressed.

Change controls (CC)
The SOP on "Laboratory Change Control" and the corresponding CC register were available. The SOP was applicable to equipment, facilities, and documents, including changes to test methods. Changes were categorized as either minor or major.

Complaints
The Standard Operating Procedure (SOP) for “Handling of Laboratory Complaints” and an accompanying complaints register were in place. The Laboratory Quality Management System (LQMS) unit was responsible for managing

complaints. Investigations were conducted by a team comprising at least two members. The Director communicated the results of the investigation to the complainant through the Secretary to the Authority.

Management reviews (MR)

Performance Management

The laboratory was required to achieve annual targets established by government authorities, with progress monitored on a quarterly basis. The SOP on Laboratory Management Reviews stipulated that management reviews (MR) must be held at least annually following a standard agenda. The meetings were attended by the Director, Manager LQMS, analysts, managers, principal officers, and additional staff invited by the Director.

The performance of the Laboratory Quality Management System (LQMS) was assessed using quantifiable quality metrics, including:

- Number of invalidated Out-of-Specification (OOS) results
- Sample turnaround time
- Percentage of customer complaints successfully resolved
- Number of major observations identified during internal audits
- Percentage of successful proficiency tests

The Laboratory Management Meeting minutes were uploaded to the server, and a copy of the report was shared with the National Drug Authority Head of QA and the Secretary (CEO).

The Management Meeting reported the participation in proficiency testing and the corresponding outcomes. Work in the laboratory was organized using a Unit Performance Tracker. During weekly Unit Planning meetings, tasks were assigned to personnel based on staff competency. Various Unit leaders monitored staff output.

Internal audits

A SOP addressing Internal audit for the laboratory and the internal audit schedule were reviewed which were conducted annually. The SOP mandates an independent internal laboratory audit team, audit and CAPA response timelines. An audit encompassing all divisions of the Medicines Unit was planned for 4th quarter of 2025.

Proficiency testing

The SOP addressing “Proficiency Testing" for Medicines / Medical Devices was available which discussed inter-laboratory (external laboratory differences) and intra-laboratory (inhouse laboratory differences) comparisons.
The laboratory typically participated in the following proficiency testing schemes:

- WHO
- EAC (East African Community) - PTB
- NOMCol
- USP Ghana

In 2024, the laboratory took part in a WHO scheme proficiency test with satisfactory outcome.

Deviations and CAPA Management

The procedure, titled "Laboratory Incident and Nonconforming Work Management," outlined that incidents and nonconformities could originate from documentation reviews, customer surveys, performance evaluations, instrument calibrations, test report reviews, staff observations, and other sources. Additional triggers included Non-Conformity Reports, complaints, regulatory changes, Management Reviews, OOS (Out of Specification), deviations, trending, process monitoring, and both internal and external audits.

Out of Specifications (OOS) - Nonconformity testing results

The SOP on "Handling of out of specification results for the Medicines unit identified three stages of investigation which included:

- Preliminary investigation
- Phase I – Investigation by analyst 1 and principal officer to identify the root cause
- Phase II – Conducted when there is no clear evidence that a laboratory error has occurred. OOS results were analyzed at least annually and before management review meetings.

Trend Analysis
The SOP for handling OOS, OOT, borderline, and aberrant results stated that trends of confirmed suspect results should be analyzed quarterly and annually. The annual trend was discussed at management review meeting.

Selection of service providers and suppliers
The SOP on "Purchasing of Services and Suppliers for the Laboratory," required that the selection and evaluation of suppliers and service providers were conducted in accordance with the Public Procurement and Disposal Act (PPDA) and corresponding Regulations of 2003.

The Procurement and Disposal Unit (PDU), a division within the National Drug Authority (NDA), managed centralized procurement for all items required by the NDA. A pre-qualified list of service providers / catalog for each financial year, including reagents and other items, was available which allowed for direct procurement.

Quality Risk Management
In response to the publication of the WHO TRS 1052, 2024 Annexure 4 addressing Good Practices for Pharmaceutical Quality Control Laboratories, the laboratory had updated the SOP on Risk Assessment with key changes including:

- Replacing the first risk assessment step from risk identification to hazard identification.
- Adding impact on the quality/validity of analytical results in the guidance for severity of potential impacts.
- Introducing a risk management form
- Categorizing risk levels and including action implementation timelines.
- Introducing unit risk coordinators and incorporating detectability in risk analysis and rating criteria.
- Defining responsibilities for different staff categories.
- Including instructions to integrate risk management in all lab processes and systems.
- Introducing risk monitoring components and a risk assessment schedule.

Data integrity risk assessment
A data integrity policy and data integrity risk assessment document available.

Crisis management
A crisis management procedure focused on business continuity which included aspects of LIMS system failures etc.

3. Control of documentation

Procedures had unique IDs, version numbers, and implementation dates with a defined review period for general procedures and for equipment procedures. Documents could be extended if unchanged with an extended review stamp, allowed once per cycle. A change control system informed staff of updates. Obsolete documents were archived as per national regulations, accessible by written request to the LQMS Manager. Issue and retrieval were controlled. Standard Test procedures were reviewed yearly based on Pharmacopeia updates.

A "Laboratory document control" procedure was available which provided for:

- SOPs
- Lab test methods

- Equipment procedures
- Lab protocols
- Lab reports
- Forms
- Registers
- CoA

Certificates of Analysis and Analyst Reports were controlled by SOP in the Medicines Testing unit. Worksheets followed a specified format.

Documentation archive
A documentation archive section was available. Documents were well organized and stored in locked metal mobile racks.

4. Records
Original observations, calculations, derived data, calibration, validation, and verification records, as well as final results, were preserved. Records included data obtained and documented in analytical worksheets. A Data Integrity policy and Data Integrity Risk Assessment (DIRA) were available.

5. Data processing equipment
Equipment and devices were designed, constructed, located, and maintained as required for operations. SOPs documented equipment management, with technical staff overseeing qualification, calibration, and maintenance. Authorized personnel operated the equipment following established procedures. The IT Unit managed laboratory computer systems' qualification, validation, access, and data backup.

Computerized system/ Data processing
Various major equipment was inspected which included:

- HPLC and GC utilized Open Lab. The system was validated and was equipped with audit trail.
- User login was required to access the system. Different access levels provided different privileges. An audit trail was active, prompting password changes every number of days with restrictions on password recycling. The system automatically logged out when idle, synchronized time, and locks for changes.
- Files were stored locally on computers with automated daily backups to network storage, and twice-weekly synchronization to off-site storage. Backups were reviewed weekly, and data restoration was checked annually.
- Data processing was conducted using validated and locked Excel sheets stored in a shared folder. Staff open files, upload data, save, and print information. Raw data, audit trails, and Excel sheets were verified independently by the unit head and QA manager.

6. Personnel

The laboratory employed sufficient staff which included analysts, lab technicians, assistants, administrative staff, principal officers, managers, and a director. The personnel were trained and experienced for their roles. Staff training was supervised and assessed upon completion. Job descriptions were maintained.

Training
The SOP “Training of laboratory personnel” covered orientation, induction, competence assessment, and continuous training for new and existing employees, interns, and external trainees. Analysts and technicians qualify by analyzing an approved sample, with numeric values not varying by more than 1% from previous results and RSD not exceeding 1%. Yearly intra-proficiency tests and participation in proficiency schemes assess competency. A rotational development training plan was developed.

Training records were verified. The training records were well-documented, including GMP, QRM, Data integrity, Root cause analysis, CAPA, Endotoxin testing, etc. Competency tests followed six months of training, and analysts' competency matrix and signature specimens were available.

7. Premises

*The Conventional Medicine and Herbal Medicine Laboratory premises (*physical chemical laboratory)

The *Conventional Medicine and Herbal Medicine* laboratory premises were well-designed and spacious, tailored to support essential operations and functions. Separate rest and refreshment areas ensured clear distinctions from the laboratory spaces. Storage facilities for samples and reagents were conveniently located, and access to these areas was secured through fingerprint identification. The laboratory upheld safety standards, featuring proper safety equipment and maintaining good housekeeping practices. Additionally, it was equipped with ample instruments and infrastructure, such as work benches, stations, and fume hoods. Daily-use chemicals, reagents, and flammable materials were securely stored in designated cupboards within the laboratory.

Pharmaceutical Microbiology laboratory premises:

Bacterial endotoxin testing was conducted using a rapid test procedure (ELISA) enzyme-linked-immunosorbent assay.

The laboratory was equipped with LAF units. The LAF was commissioned insofar as particle count, velocity, HEPA integrity testing, air flow patterns. Testing of suboptimal particle matter conducted with readouts printed were conducted.

8. Equipment, instrument and other devices

The laboratory was furnished with advanced testing equipment, including HPLCs, GCs, auto-titrimeters, UV-Visible spectrophotometers, FTIR, and HPTLC. These instruments and devices were utilized for performing tests, calibrations, validations, and verifications, with calibration status labels affixed to each instrument. Additionally, laboratory instruments were accompanied by "instrument logbooks."

Several new pieces of equipment have been installed, notably UPLC-MS/MS, UPLC QTOF, and ICP-MS. However, these devices had only been employed for testing of herbal medicines. Logbooks were maintained for each piece of equipment, and the conventional medicines testing conducted up to the time of inspection was restricted to optimization processes and method validation. The labels on the equipment indicated that they were still within their calibration limits.

9. Contracts

Testing was subcontracted to a few laboratories only when the NQCL was unable to conduct the required test. An approved list of contract laboratories was available.

Technical Agreements were drafted according to SOP that stated that subcontracting was permissible to WHO Pre-qualified labs or ISO 17025 accredited labs, as well as recognized national (government) laboratories, without performing any on-site inspection.

10. Reagents

Reagents, chemicals, and flammable liquids were received and checked with receipt forms filled in manually. They were then moved to the identified storage area. Storage was in good order and inventory managed electronically. An AHU ensured proper conditions, with temperature and humidity recorded daily.

Labels included expiry date, date of receipt, and date of opening. Reagent solutions had varying expiry dates.

The SOP "Receipt, storage and handling of laboratory chemicals and reagents" required that consignments were inspected upon delivery for intactness, labeling, specifications, quantities delivered, manufacturer name, expiry date, and storage conditions. Items are issued following the FIFO system, prioritizing those with shorter expiry dates.

If a chemical does not have a specified expiry date, an expiration date was established based on historical data. For newly acquired reagents, the expiration date was adapted accordingly, with the maximum permissible period being five years.

Water
The equipment used to produce purified water was inspected. The primary components included filters, an RO membrane, an EDI unit, and a storage tank. The system appeared to be well maintained. Type II reagent grade water was produced using Millipore Elix 70 equipment. For the HPLC tests, water was filtered through a 0.22 µm filter to remove particulate matter. Conductivity measurements were taken both online and offline, with offline checks performed daily. The specifications for Type II reagent grade water were established and followed

Gases
Gases N_2 and H_2 used in chromatography were produced at the laboratory.

11. Reference substances and reference materials

The conventional and herbal medicine laboratory (physical chemical laboratory)
The laboratory primarily utilized reference substances from BP, USP, and EDQM. If primary reference substances were unavailable, materials were procured from Sigma Aldrich. Both primary and secondary reference substances were stored at either 2-8℃ or 21±1℃, with temperatures recorded twice daily. Refrigerators and deep freezers were equipped with sound alarm systems. Issuance and usage were documented.

Relevant SOPs verified:

- "Preparation and handling of secondary reference standards." Reference standards were prepared from substances with known potency and routinely checked for validity before use.
- "Receipt and handling of primary chemical reference standards." Upon receipt, primary reference standards were verified for name, standard/specification, quantity, Lot No/Control No, manufacturer name, expiry date, purity, CoA, storage conditions, and MSDS. The validity of these standards was monitored by lab technicians (stores), and their receipt was recorded in the central register.

The reference standard for some active substances was verified and deemed acceptable.

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

SOP on Equipment Management and Validation master plan were available for management of equipment. Calibration was conducted internally and externally. Annual Equipment Calibration Schedule (in house calibrations) listed equipment that would be calibrated during the year, including balance, dissolution tester, titrator, friability tester, GC, HPLC, leak tester, oven, disintegration tester, auto titrator, pH Meter, conductivity meter, UV-Vis spectrophotometer, and FTIR.

Daily verification of the balance was conducted, with records available. Calibration of one of the balances was reviewed. The calibration was conducted internally using standard weight. The standard weight was traceable to the National Metrology Institute of South Africa (with weight set certificated). Test conducted with all parameters found to meet the criteria. Test parameter includes:

- Repeatability
- Accuracy

- Eccentricity
- Linearity
- Measurement of Uncertainty
- Drift

Calibration/ Qualification of Gas Chromatograph was checked. Qualification was carried out annually in-house. The Calibration was conducted by adopting the manufacturer's protocol for the qualification. Records for each test were available. Based on the testing, the instrument was found to be compliant following the conduct of the following tests:

- Inlet pressure accuracy
- FID Flow Accuracy
- Oven Temperature Accuracy
- Oven Temperature stability
- FID Noise and Drift
- FID Signal to Noise Ration
- Injection Precision and Carryover
- FID Linearity

13. Traceability

Test results reported by the Conventional Medicine and Herbal Medicine Laboratory (physical and chemical laboratory), and Pharmaceutical Microbiology Laboratory were traceable to analysts, analytical instruments, equipment, reagents, reference substances, and test procedures.

14. Incoming samples

The National Drug Authority Uganda developed an annual sampling plan, which was coordinated by the inspection unit, laboratory unit, and other relevant units. Samples may originate from pre- and post-market surveillance programs, ports of entry, and proficiency testing. The inspection unit handled sampling for ports of entry and surveillance programs, documenting sample numbers, completing testing requests in the LIMS, and submitting samples to the sample receipt unit for verification. If samples are not sourced from the inspection unit, receipt staff complete the testing request in the LIMS while another verifies it. The procedure for receiving and managing samples is documented in Procedure.

Except for cold chain samples, receipt occurs at the National Drug Authority Head Quarters, (NDA Tower). Receipt staff verify the physical condition of the samples against LIMS information. Samples were stored in the sample receipt area. After coding, samples are transferred to the sample storage area.

The Laboratory unit prepared a weekly testing schedule. Samples were transported, received, and distributed to assigned analysts for testing.

15. Analytical worksheet

Analytical worksheets were used for analysis and was part of sample test file. It was validated/ verified and made into Standard Testing Procedure (STP). Method according to STP was inputted to the system. The method was verified by Unit Head and QA manager during review of the analytical worksheet. When samples from multiple products were tested in the same sequence, results from HPLC or GC were printed and copied so that each worksheet had a copy of the applicable raw data.

Analytical worksheets of random selected samples of HPLC testing and GC testing were reviewed. Overall testing was conducted in accordance with the STP.

17. Testing

Tests were conducted using Pharmacopoeia methods, specifically USP, International Pharmacopeia, BP, and EP. The choice of test was based on the general method across all Pharmacopoeia. If a test failed, the lab contacted the manufacturer for product specifications. Testing was done by an analyst or microbiologist. Raw data was entered into a validated Excel sheet by a data analyst and verified by a supervisor. QA reviewed the final results.

18. Evaluation of test results

The SOP "Review, release and reporting of test" applied to all test results generated internally and from sub-contracted laboratories. The Principal Officer was tasked with reviewing analytical worksheets, raw data, and analytical test reports. The Principal Officer's role was limited to review and did not include performing analytical tests. Print outs from HPLC and UV were compared with meta data. Final review and release of test results was done by Director DLS. The results were presented as part of the certificate of analysis.

19. Certificate of analysis

The SOP "Review, Release, and Reporting of Test" addressed the review and sign off of the Certificate of Analysis (CoA). The CoA was reviewed by the Manager of Medicines and approved by the Director of DLS. The release of the CoA was supported by the Laboratory Information Management System (LIMS).

20. Retained samples

Samples were retained for 1 year past shelf life.

21. Safety

Safety data sheets were provided. Smoking, eating, and drinking in the laboratory were not allowed. Staff wore laboratory coats, gloves, and used eye protection. Safety showers were accessible.

Part 3	Conclusion – Inspection outcome

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, the ***National Drug Quality Control Laboratory, located at Mulago Hill, Kampala Uganda, c/o National Drug Authority, P.O Box 23096, Kampala-Uganda*** was considered to be operating at an acceptable level of compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) Guidelines.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

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

Part 4	List of WHO Guidelines referenced in the inspection report

1. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Seventh Report. Geneva, World Health Organization, 2024 (WHO Technical Report Series, No. 957), Annex 1.
   Short name: WHO GPPQCL Guidelines or ***TRS No. 1052, Annex 4***
   http://www.who.int/medicines/publications/44threport/en/

2. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2.
   Short name: WHO TRS No. 961, Annex 2
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

3. WHO good manufacturing practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/
4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4.
   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5.
   Short name: WHO GDRMP guidance or ***WHO TRS No. 996, Annex 5***
   http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

6. 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***
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

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
   http://www.who.int/medicines/publications/44threport/en/

9. 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
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7.
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. 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. 961), Annex 9. ***Short name: WHO TRS No. 961, Annex 9***
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. ***Short name: WHO TRS No. 943, Annex 3***
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

13. 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**
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1010/en/

14. Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 2. **Short name: WHO TRS No. 1019, Annex 2**
https://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

15. 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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

16. Good manufacturing practices: guidelines on validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Third Report Geneva, World Health Organization, 2019 (WHO Technical Report Series, No. 1019), Annex 3. **Short name: WHO TRS No. 1019, Annex 3**
https://apps.who.int/iris/bitstream/handle/10665/312316/9789241210287-eng.pdf?ua=1

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***
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf