MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

LABORATORY SERVICES DIRECTORATE

QUALITY MANUAL

OCTOBER 2023

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Acronyms and Abbreviations

CAPA:	Corrective Action Preventive Action
CEO:	Chief Executive Officer
EDQM:	European Directorate for the Quality of Medicines and Healthcare
HPTs:	Health Product and Technologies
HRM&D:	Human Resource Management and Development
IEC:	International Electrotechnical Commission
ISO:	International Organization for Standardization
MAN:	Manual
OOS:	Out of Specification
PCL:	Physical Chemical Laboratory
PPB:	Pharmacy and Poisons Board
QC:	Quality Control
QCL:	Quality Control Laboratory
QMS:	Quality Management Systems
RIR:	Receipt Inspection Report
SOP:	Standard Operating Procedure

Glossary of terms

In this Manual:

'*Board'* means the Pharmacy and Poisons Board

'*Conformity*' means compliance with standards or specifications.

'*Interested Party*' means a person or organization that is involved in or perceives itself to be affected by activities and actions taken by the Board. It can be customers, suppliers, contractors, government, etc.

'*Nonconformity*' is the failure to meet a requirement

'***Procedure***' means documented instructions to execute an activity or a process.

'***Pharmacopoeia***' refers to an official publication containing a list of medicinal drugs with their molecular structure, respective test methods and specifications.

'***Reference standard'*** refers to highly characterized material suitable to test the identity, strength, quality and purity of substances for pharmaceutical use and medicinal products.

'***Sampling protocols'*** refer to the procedures used to select HPTs from the market that are considered representative of the study market.

'*Specifications*' refers to criteria to which a health product should conform for it to be considered acceptable.

'*System suitability tests'* refer to a set of tests performed for a method to ensure that the complete analytical system is suitable for the intended application.

'*Validation of test method'* refers to the documented process of ensuring a pharmaceutical test method is suitable for its intended use.

'***Verification of test method'*** is a confirmation of whether a test method fulfils the specified requirements by inspecting the given parameters in the test method and preparing the related documentation.

Acknowledgements

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Quality Policy

The Pharmacy and Poisons Board (PPB) aims to be a global leader in promoting and protecting public health by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious, and affordable health products and technologies. The Board's strategic direction is to improve access through leveraging research and technological innovation which translate into real-world solutions for diagnostics, treatments, and cures.

Our commitment is to maintain and continually improve a quality management system and ensure customer satisfaction based on ISO 9001:2015 and ISO 17025: 2017, customer, statutory and regulatory requirements, and emerging trends in the pharmaceutical sector.

Quality objectives have been established at corporate and functional levels in line with the strategic plan and international best practices. This quality manual shall act as a guide for conducting laboratory testing at the PPB Quality Control laboratory and shall be communicated to all other staff, made available to relevant interested parties, and reviewed periodically for continuing stability.

Dr. F. M. SIYOI

CHIEF EXECUTIVE OFFICER

1.0 Scope of the manual

The Pharmacy and Poisons Board is committed to a policy of providing exemplary service with respect to performing accurate testing and analysis of Health Products and technologies. This manual describes the quality management system being implemented at the Pharmacy and Poisons Board Quality Control laboratory (PPB QC). The PPB QC laboratory shall be concerned with the sampling and testing of HPTs, and with the documentation that ensures that the necessary and relevant tests are actually carried out and that HPTs registered in Kenya are of acceptable quality, and compliant with the Marketing Authorization requirements. The laboratory will not be confined to laboratory operations only but will be involved in many decisions regarding the quality of HTPs supplied to Kenya. Further to note is that this document makes its reference to the mother document, the PPB Quality manual (CEO/PQR/QMS/MAN/002) which details the Quality policy (PPB/REG/QMS/POL/002), the management's commitment to good professional practice that includes quality of testing, calibration, validation and verification, the outline of the structure of the documentation used in the organization and a policy for internal and external audits.

2.0 Purpose of the Manual

The purpose of this manual is to describe the quality management system employed at the PPB QC laboratory which includes documented procedures established by the laboratory as well as the overarching PPB Quality management system that meets the ISO/IEC 9001:2015 and ISO 17025:2017 requirements.

3.0 General Resources

3.1 Impartiality

Procedure for Declaration of conflict of interest and confidentiality (CEO/PQR/QMS/SOP/003)

The PPB QC laboratory is dedicated to undertaking testing activities impartially and eliminating risks to impartiality that arise from its activities and the activities of its personnel. PPB QC has policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity. Conflicts of interest cast doubt on the accuracy and validity of results and cannot be allowed to influence testing activities.

The Board ensures its senior executives and staff are free from any commercial, financial, and other pressures that might influence the results of the testing process. The Board of Directors as well as top management are free from any commercial, financial, or other pressures that might influence decisions and regularly sign Conflict of Interest agreements stating as such.

The Board is responsible for the impartiality of its activities and ensures its personnel are free from any undue internal and external commercial, financial, and other pressures and influences that may adversely affect the quality of their work. Employee salaries and promotions are not dependent upon the outcome of testing or any related commercial activity.

The PPB QC routinely identifies risks to impartiality that arise from its activities and relationships, and the activities and relationships of its personnel. Risks are identified and evaluated through the following means:

1. Personnel conflict of interest forms are filled at the time of hiring and annually for continuous checks. (Conflict of Interest Form Addendum 2 FOM021/QMS/SOP/003)

2. Annual management reviews are conducted in accordance with the procedure for conducting management review meetings CEO/PQR/QMS/SOP/008
3. When risks to impartiality are identified, PPB QC takes steps to eliminate or minimize those risks as per the Board's Risk Management Policy CEO/LAR/POL/009

3.2 Confidentiality

Procedure for Declaration of conflict of interest and confidentiality (CEO/PQR/QMS/SOP/003)

The PPB QC lab and its personnel are legally obligated to keep confidential all information supplied to it by the client as well as all data, records, and information obtained during testing activities except for information required or considered to be publicly available unless authorized by the client. Confidentiality is maintained by the use of computer passwords, individual software user accounts, locks on doors and filing cabinets, padlocked covers on equipment under test as well as observation by PPB QC personnel.

Where the law or contractual agreements require information to be made public or disclosed to any other party, the client shall be informed in advance of what information was provided unless the law prohibits such notification.

Any information about the client which was obtained from any outside source shall be treated as confidential. The source of such information shall also be considered confidential. All PPB QC personnel and subcontractors involved in testing activities sign a Confidentiality and Disclosure Agreement (SOP for outsourcing tests, SOP for confidentiality).

3.3 PPB Organizational Structure, grading, and staff establishment manual.

The PPB QC laboratory is a directorate of the Pharmacy and Poisons Board which is a legal entity on the basis of a national regulatory body. The QC Lab Director has overall responsibility for the technical operations, quality

assurance, and the provision of the resources needed for laboratory operations. The functions of the laboratory are detailed in the PPB Organization structure, grading, and staff establishment manual (PPB/BSA/HRM/GUD/005).

The PPB QC lab scope of testing includes all required testing for HPTs performed in its permanent facilities, including the headquarters and regional/satellite laboratories as well as field activities. The lab shall claim conformity with the requirements of ISO 17025:2017 and ISO 9001:2015; however, this excludes externally provided laboratory activities. The laboratory carries out its testing activities according to the requirements of ISO/IEC Standard 17025, ISO 9001 and to satisfy the client's needs.

The PPB QC's organization and management structure, as well as the relationship between the management, technical operations and support services, is defined in the PPB Organization structure, grading and staff establishment manual (PPB/BSA/HRM/GUD/005). The responsibilities of laboratory personnel are defined in the Job description manual (PPB/BSA/HRM&D/GUD/006). The laboratory's current procedures are accessible to all PPB personnel through the document management system (ALFRESCO).
http://qms.pharmacyboardkenya.org/share/page/context/shared/sharedfiles#filter=path%7C%2FPPB

The PPB QC regulatory officers are accorded the necessary authority and resources needed to carry out their duties, including:

a) Implementation, maintenance and improvement of the quality management system through regular review of its QMS.
b) Identification of deviations from the laboratory procedures.
c) Initiation of actions to prevent or minimize such deviations
d) Reporting to laboratory management on the performance of the management system and any need for improvement;
e) Ensuring the effectiveness of laboratory activities.

f) Development, modification, verification, and validation of analytical methods.
g) Analysis of results, including statements of conformity and interpretations
h) Report, review, and authorization of results

The PPBQC Laboratory management ensures that:

a) Communication flows regarding the effectiveness of the management system by actively participating in the PPB's management review meetings.
b) The integrity of the management system is maintained when changes to the management system are planned and implemented.

4.0 Laboratory Resources

4.1 Personnel

As guided in the Human resources policies and procedures manual (PPB/BSA/HRM/POL/005), the Board shall:

a) Determine the necessary competence for personnel performing laboratory testing
b) Identify the training needs of the laboratory personnel
c) Develop a training plan, which is reviewed and updated annually
d) Document a procedure for training all employees: Procedure for training and development (CSD/HRM/SOP/015).
e) Develop key performance indicators to evaluate the effectiveness of trainings

The PPB QC lab is equipped and staffed with adequate resources necessary to perform its laboratory activities. The laboratory personnel sign confidentiality and conflict of interest agreements at the time of hiring and subsequently every financial year. The Laboratory analysts are competent as they are qualified through the analyst qualification procedure

(LAB/QCL/PCL/SOP/005) as well as participation in proficiency test schemes and/or interlaboratory test schemes. The Board has documented the competence requirements for the laboratory function in the Board's Competence matrix (PPB/BSA/HRM/POL/014). Regular competence mapping is carried out to identify the current knowledge and skills gaps. The responsibilities of the different strata of the laboratory personnel are defined in the Job description manual PPB/BSA/HRM&D/GUD/006. The Individual job descriptions signed at the time of hiring or in case of assigning different and/or additional roles, spell out the personnel's duties, responsibilities, and authorities.

PPB has the procedures and retains records for:

a) Determining the competence requirements
b) Selection of personnel
c) Training of personnel
d) Supervision of personnel
e) Authorization of personnel
f) Monitoring the competence of personnel

4.2 Facilities

The environmental conditions that interfere with accurate analysis are documented in the lab standard operating procedure for environmental monitoring. Daily records are kept for the laboratory areas as well as the sample storage areas. The standard operating procedure (SOP) for conducting and reporting analysis (LAB/QCL/PCL/SOP/007) as well as individual equipment SOPs instruct the analyst to monitor and perform testing in the correct environmental conditions for the applicable analyses.

The procedures also specify measures necessary to prevent cross-contamination where and if applicable. All personnel are responsible for housekeeping. The requirements for the accommodation of environmental conditions and cross-contamination are met regardless of the location. This

includes testing conducted at the PPB QC laboratory and any field activities.

4.3 Equipment

The PPB QC lab is furnished with supplies, reference materials, and equipment required for the correct performance of tests as per Procedure for acquisition and maintenance of equipment (LAB/QCL/PCL/SOP/006) and records maintained in the Laboratory Equipment Inventory (FOM 013/QCL/SOP/006). The laboratory also has minilab kits in regional sites and ensures the equipment contained in the kits is regularly calibrated and well maintained in line with the requirements of ISO/IEC 17025:2017 standards.

The laboratory has procedures for the correct handling, storage, calibration, and preventive maintenance of test equipment contained in the individual equipment SOPs. Personnel qualified and authorized to operate equipment are responsible for its accurate operation. All measuring equipment is verified to conform to the manufacturer's specifications prior to commissioning for use. Equipment is calibrated per the individual equipment calibration protocols that include the manufacturer's recommendations as well as the EDQM guidelines on the calibration of various equipment.

All measuring equipment is calibrated against a traceable reference material according to the specified annual calibration schedule as provided in the procedure for the acquisition and maintenance of equipment. In accordance with the procedures, all calibrated equipment, those due for calibration and the faulty equipment are accorded status labels.

Test equipment is safeguarded from adjustments that would invalidate the test results as defined in LAB/QCL/PCL/SOP/006. Records are maintained for each piece of equipment which include identification of the equipment, operator manuals, calibrations, maintenance, and repairs. Up-to-date instructions on the use and maintenance of equipment are readily available

for use by the designated personnel as physical copies in the lab as well as electronic copies in the document management system ALFRESCO. Calibration and maintenance records are kept on file in the lab office.

5.0 Laboratory Processes

5.1 Measurement Traceability

Equipment Calibration Procedure

The procedure for the calibration of equipment is designed and followed to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI). When calibrations cannot be made in SI units, the lab uses certified reference materials provided by a competent supplier to give a reliable characterization of a material. The lab only uses calibration labs meeting the requirements of ISO/IEC 17025. The lab uses only certified reference materials provided by an approved supplier. Lot numbers of reagents and chemicals are recorded in the Chemical/Reagent Log.

When traceability to the (SI) system is not possible, traceability is made to certified reference materials provided by an approved and certified provider.

5.2 External Provided products and services

For laboratory activities that are beyond the capability of PPB QC, subcontractors shall be chosen that meet the requirements of the following Standards:

1. Testing and calibration - ISO/IEC 17025 /WHO Prequalification
2. Auditing of quality systems - ISO/IEC 17021
3. Certified reference materials - ISO/IEC Guide 34
4. Proficiency testing - ISO/IEC 17043

PPB Procurement department has a procedure for procurement of goods, works, and services (CEO/SCM/SOP/003) that provides for the approval of subcontractors and the selection and purchasing of services and supplies as

well as a procedure for outsourcing test services (LAB/QCL/PCL/SOP/014). On receipt of purchased materials, they are verified against the specifications provided by the use of the Receipt inspection report (RIR) (FOM 051/QCL/SOP/006).

The SOP for outsourcing test services (LAB/QCL/PCL/SOP/014) provides for the qualification and requalification of the subcontracted laboratories. The Board follows the procedures for outsourcing test services as well as the procedure for procurement of goods, works, and services to ensure that sub-contractors and suppliers are qualified and evaluated to perform their work assignments and that their activities are monitored. The Board's Procurement department maintains a list of qualified subcontractors and suppliers for all services and goods including laboratory supplies and services.

The procedure for outsourcing test services LAB/QCL/PCL/SOP/014 requires PPB and subcontracted laboratories to sign legally binding contractual agreements for the scope of outsourced tests. The PPB QC Laboratory shall decline to undertake the testing if there is a lack of competence or capability for any of the required activities.

Any amendments to the contracts may require additional review including revision to the evaluation plan, re-assignment of personnel or resources, and distribution of additional documents and information.

The Board's procedure for procurement of goods works and services (CEO/SCM/SOP/003) has a procedure for the review of requests, tenders, and contracts, and records of pertinent discussions, reviews, requests, tenders, and contracts are retained as per the Control of records procedure (CEO/PQR/QMS/SOP/002).

5.3 Selection, Verification, and Validation of Methods

The PPB QC laboratory employs approved manufacturer's test methods, pharmacopeial methods as well as appropriate methods for all tests within

its scope. Methods selected by the lab shall be verified before adoption in accordance with the procedure for analytical method validation (LAB/QCL/PCL/SOP/012). The approved validated manufacturer's methods selected for testing shall be subjected to system suitability tests before use while pharmacopeial methods are verified before use. The PPB QC lab does not develop methods. Any deviations from verified methods shall be documented and reported by the laboratory analysts and authorized by the Laboratory Quality assurance officer.

5.4 Sampling

The PPB QC laboratory has sampling procedures (LAB/QCL/PCL/SOP/001) for all off-site and on-site sampling activities. Field sampling protocols shall be developed for a sampling conducted by PPB QC personnel at locations off-site. Any deviations from the sampling procedures or protocols are documented. Reports in line with the protocols are prepared after all sampling and testing activities are completed for a particular field survey.

5.5 Management of test samples

The laboratory has a procedure in place for the management of test samples (LAB/QCL/PCL/SOP/002) that provides for unique laboratory identification of the test samples upon receipt. It also has acceptable quality and quantity criteria for submission of all HPTs. Samples are rejected upon deviation from this criteria and reasons for rejection are documented and communicated to the client. The submitted samples for analysis shall be stored in the sample storage areas adhering to the manufacturer's recommended storage conditions.

5.6 Technical Records

The Board has a procedure for the conducting and reporting of analysis (LAB/QCL/PCL/SOP/007) that ensures that laboratory technical records that ensure records are complete, attributable, and contemporaneous as well as the reproducibility of laboratory results. Any amendments to

technical records are tracked to the previous versions or to original observations. Both the original and amended versions are retained in accordance with the procedures for the control of documents (CEO/PQR/QMS/SOP/001).

5.7 Measurement Uncertainty

The Calibrations of PPB QC equipment are evaluated for measurement uncertainty at the time of calibration and documented in the calibration reports. The laboratory employs standard methods of analysis; this includes pharmacopeial methods and authorized manufacturer's methods. These methods specify the limits to the values of the major sources of measurement uncertainty and specify the form of presentation of the calculated results which is implemented in the reporting of PPBQC test results.

5.8 Assuring the Validity of Results

The PPBQC laboratory shall employ various approaches to assuring the validity of test results:

a) The use of reference materials that are calibrated according to the procedures for calibration of reference standards (LAB/QCL/PCL/SOP/003)
b) The use of calibrated equipment to provide traceable results (LAB/QCL/PCL/SOP/006)
c) Regular functional checks of measuring and testing equipment before use in accordance with the various equipment SOPs.
d) Use of working standards with control charts (LAB/QCL/PCL/SOP/003)
e) Review of reported results (LAB/QCL/PCL/SOP/007)
f) Participation in Interlaboratory comparisons/proficiency test schemes (LAB/QCL/PCL/SOP/005)

5.9 Data Reporting

All test data generated by the PPB QC laboratory is reviewed and laboratory analysis reports are authorized and signed by the Director or Deputy Director; this is in accordance with the procedure for conducting and reporting of analysis (LAB/QCL/PCL/SOP/007). The laboratory analysis reports can be issued electronically or as hard copies.

The laboratory analysis reports are clear, complete, and include certain basic information:

a) The name and address of the lab and the location of testing
b) The name and contact information of the client.
c) Unique identification by use of the unique laboratory sample identification number
d) Identification of the method used.
e) Identification of the persons performing the tests and authorizing the report
f) A title, page numbers, and a unique test report number on every page.
g) Dates for collection, receipt, analysis, and the report.
h) The results, units of measurement, and any deviations.
i) Clear identification when results are from subcontracted laboratories.
j) Statement of conformity with the specifications

The laboratory is also responsible for sampling HPTs from the field in accordance with the procedures for sampling (LAB/QCL/PCL/SOP/001). This provides for a sample collection form (FOM 001/QCL/SOP/001) that contains the following information:

a) The date of sampling,
b) Unique identification of the HPT being sampled
c) The location of the sampling
d) Reference to the sampling plan detailed in the sampling protocols
e) The environmental conditions during sampling.

The PPB QC lab is responsible for sampling conducted by the lab and data produced by the lab and its qualified subcontracted laboratories. The lab is not responsible for data and sampling conducted by the client. The lab does not generate calibration certificates and only reports test results against the specification and a subsequent statement of conformity. It does not report opinions and interpretations.

Amended test reports shall include the identification of which information was changed and the reason for the change. Amended reports shall meet all of the ISO 17025 requirements for amended test reports. When it is necessary to issue a completely new test report, it is uniquely identified and contains a reference to the original.

5.10 Complaints

The Board has a procedure for the receipt, investigation, and resolution of complaints received from clients or other external parties (**Procedure for handling customer complaints and appeals CEO/PQR/QMS/SOP/004).**

Records are maintained of all complaints, investigations, and corrective actions taken by the laboratory. All Complaints are logged and tracked for closure as per the procedure. The outcome of complaint investigations is communicated to the complainant.

5.11 Non-Conformances and Corrective and Preventive Actions Procedure

PPB has a procedure for handling non-conformances, and corrective and preventive actions (CEO/PQR/QMS/SOP/007) following an audit. The lab also has an additional internal procedure for handling deviations from the normal procedures while conducting analysis (LAB/QCL/PCL/SOP/007). All deviations and non-conformances are thoroughly investigated and Corrective Actions and /or preventive actions shall be initiated following root cause analysis. Records are maintained of all non-conformances, investigations, root causes, and corrective actions taken by the laboratory. The effectiveness of the CAPA is monitored through the CAPA register.

6.0 Control of Data

The PPB QC shall have in place a laboratory information management system (computerized and /or non-computerized) that shall be used for the collection, processing, recording, reporting, storage, or retrieval of data. This system shall:

a) Be protected from unauthorized access, tampering, and loss through the use of individual user accounts, passwords, and lockable files.
b) Be maintained in a manner that ensures the integrity of the data and information by use of audit trails and reviews.
c) Include recording system failures and the appropriate immediate and corrective actions. All procedures, manuals, and reference data are readily available to the laboratory personnel as hard copies at the laboratory as well as electronic copies through the document management system ALFRESCO.

7.0 Quality Management System

The Board has established a quality management system that supports and demonstrates the consistent achievement of the requirements of both ISO/IEC 17025: 2017 and ISO 9001: 2015. This is well documented in the PPB Quality Manual (CEO/PQR/QMS/MAN/002). The PPB QC laboratory, being a directorate of the Board follows all the provisions of the management system as spelled out in the referred overarching manual.

8.0 References;

1. International Organization for Standardization. General requirements for the competence of testing and calibration laboratories. ISO/IEC 17025:2017.
2. International Organization for Standardization. Quality management systems requirements. ISO/IEC 9001:2015.
3. Official Medicines Control Laboratories Network of the Council of Europe, Quality Assurance Documents: PA/PH/OMCL (08) 73 — Qualification of equipment (http://www.edqm.eu/ medias/fichiers/NEW_Qualification_of_equipment_core_document.pdf
4. The Republic of Kenya, Ministry of Health, Pharmacy and Poisons Board, Quality Manual, CEO/PQR/QMS/MAN/002.
5. WHO Good practices for pharmaceutical quality control laboratories TRS No. 957, 2010 Annex 1
6. WHO guidelines for sampling of pharmaceutical products and related materials. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth report. Geneva, World Health Organization, 2005, Annex 4 (WHO Technical Report Series, No. 929).

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