Format: QMS/FMT/001 Revision No: 0 Effective Date: 24 Aug 20	**Division**	**Quality Control Laboratory**

Document type: **Standard Operating Procedure**		Doc. Number : QCL / SOP /005
RWANDA FDA Rwanda Food and Drugs Authority	**Title: Selection, Verification and Validation of methods**	Revision Number : 0 Revision Date : 14 August 2020 Effective Date : 24 August 2020 Review Due Date : 24 August 2022

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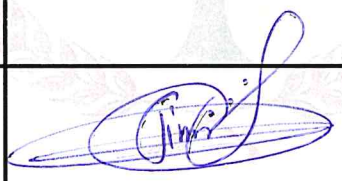
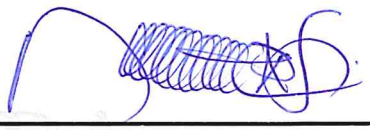
SIGNATURE			
DATE	24 August 2020	24/08/2020	24/08/2020

INSTRUCTIONS

1. Controlled issues of this SOP may **not** be copied
2. **All** amendments are written on the page provided
3. **Only** authorized, numbered, stamped copies of this SOP as described in the Procedure for Testing of equipment section above, are used
4. This SOP shall **not** be used outside the Rwanda FDA Quality Control Laboratory without the authority of the authorizing personnel.

1.0 Contents

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2.0 Purpose

This Standard Operating Procedure establishes the guidelines for method selection, verification and validation of method performance in Quality Control Laboratory.

3.0 Scope

This Standard Operating Procedure applies to all test methods used in Quality Control Laboratory.

4.0 Policy

ISO 17025 :2017 Clause 7.2 states that " *laboratory shall have procedure for selection,verification and validation of methods.*

5.0 Abbreviations and Definitions

In the context of this System Procedure, the terms defined in the Laboratory Quality Manual (QCL/MAN/001) shall apply in addition to the following :

5.1 Uncertainty of Measurement

Parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

5.2 Fitness for purpose

Degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose.

5.3 Method Validation

The process of establishing the performance characteristics of a method and the identification of the influences, which may change these characteristics, and to what extent.

5.4 Method Verification.

The internal process of examining and confirming by objective evidence that the specified requirements stated in validated test method are fulfilled.

5.5 Standard method.

This is a method that is traceable to a recognized, validated method.

5.6 Non-standard method

A method that is not taken from authoritative and validated sources. This includes methods from scientific journals and unpublished laboratory-developed methods.

6. Responsibilities

6.1. The laboratory Officer in collaboration with Laboratory Technicians are responsible for selection, verification and adoption of Quality Control Laboratory test methods.

6.2. The Human Medicine Analysis Laboratory Officer is responsible to ensure that all methods used in their respective units are validated or verified prior to being used;

6.3. The Human Medicine Analysis Laboratory Officer ensures that there is no deviation from use of approved Standards Operating Procedures;

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6.4. The Laboratory Officers and Technicians are responsible to ensure generation of data, and verification of selected method s is done.

7. Distribution

This Standard Operating procedure is issued on a control basis. Read access to all Quality Control Laboratory staff is provided through testing server.

8. Safety Precautions

NA

9. Procedure

9.1. General Approach

9.1.1. Quality Control Laboratory uses appropriate validated methods for all tests within its scope of operations, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data are performed.

9.1.2. Human Medicine Analysis Laboratory Officer ensures that Laboratory support document(LSD) for the evaluation of measurement uncertainty and validation / verification of all the selected methods to confirm that they fit for their intended use.

9.1.3. Each Laboratory records the results obtained during evaluation of measurement uncertainty and validation/ verification process and make a statement as whether the method is fit for the intended use.

9.1.4. Deviations from methods for all Laboratory activities occur only when the deviation is documented, technically justified, authorized and accepted by the customer.

9.2. Selection of the test method

9.2.1. Quality Control Laboratory selects appropriate test method basing on the following but not limited to available resources such as infrastructure, competent personnel, equipment.

9.2.2. Quality Control Laboratory uses the latest valid version of a method unless it is not appropriate or possible to do so.

9.2.3. Quality Control Laboratory uses the test method specified by the customer or any regulation covering the customer activities whenever possible.

9.2.4. When the customer specified method is not found suitable for the purpose, Quality Control Laboratory advices the customer on the appropriate method to be used and the requirements are respected.

9.2.5. If the customer/ regulation does not specify the test method to be used, Quality Control Laboratory selects appropriate test method basing on its verification / validation performance.

9.2.6. Test method Verification and validation process

9.2.7. Each test method is validated / verified based on the developed Laboratory Support Document in each Laboratory and evaluation of measurement uncertainty is done where applicable.

9.2.8. Method validation/ verification is done following the steps in method validation/ verification flow chart as seen in appendix A of this document.

9.3.Adoption of test method

9.3.1. Once a method is verified and found to fit for the purpose, the concerned Laboratory Officer or laboratory technician develop a standard operating procedure with additional details to ensure consistent application.

9.3.2. The Laboratory Officer reviews Standard Operating Procedures. During review, the latest current version of adopted method is considered.

9.3.3. Re-verification of Standard Operating Procedure is done when the main part of the adopted method such as principle and the scope has been revised.

9.4.Laboratory developed methods

9.4.1.The Quality Control Laboratory as a rule do not develop test methods.

9.4.2.Typical validation performance characteristics are:

9.4.2.1. accuracy,
9.4.2.2. precis ion,
9.4.2.3. selectivity/ specificity,
9.4.2.4. detection limit,
9.4.2.5. limit of quantitation,
9.4.2.6. linearity,
9.4.2.7. measuring range, and
9.4.2.8. ruggedness / robustness.

9.5.Verification and validation records

The Human Medicine Analysis Laboratory Officer retains the following records

9.5.1. The validation procedure used;

9.5.2. Specification of the requirements;

9.5.3. Determination of the performance characteristics of the method;

9.5.4. Results obtained;

9.5.5. A statement on the validity of the method detailing its fitness for the intended use;

9.5.6. The results from the test method validation/ verification are submitted to the Human Medicine Analysis Laboratory Officer for approval.

9.6.Estimation of uncertainties

9.6.1. Each Quality Control Laboratory has developed Laboratory Support Document with details on how estimation of uncertainties is done where applicable.

9.7. Control of data

9.7.1.Calculations and data transfers are subjected to systematic checks by the Designated laboratory officer to prevent the occurrence of mistakes during data processing and transfer.

9.7.2.Computers are protected from viruses through use of antivirus to avoid generated data loss, software used are calibrated by the manufacturers and care is taken to maintain their integrity.

9.7.3. The in-house development, configuration or modification of computer software for data collection (i.e. excel sheets) and statistical evaluation of test results has to be validated

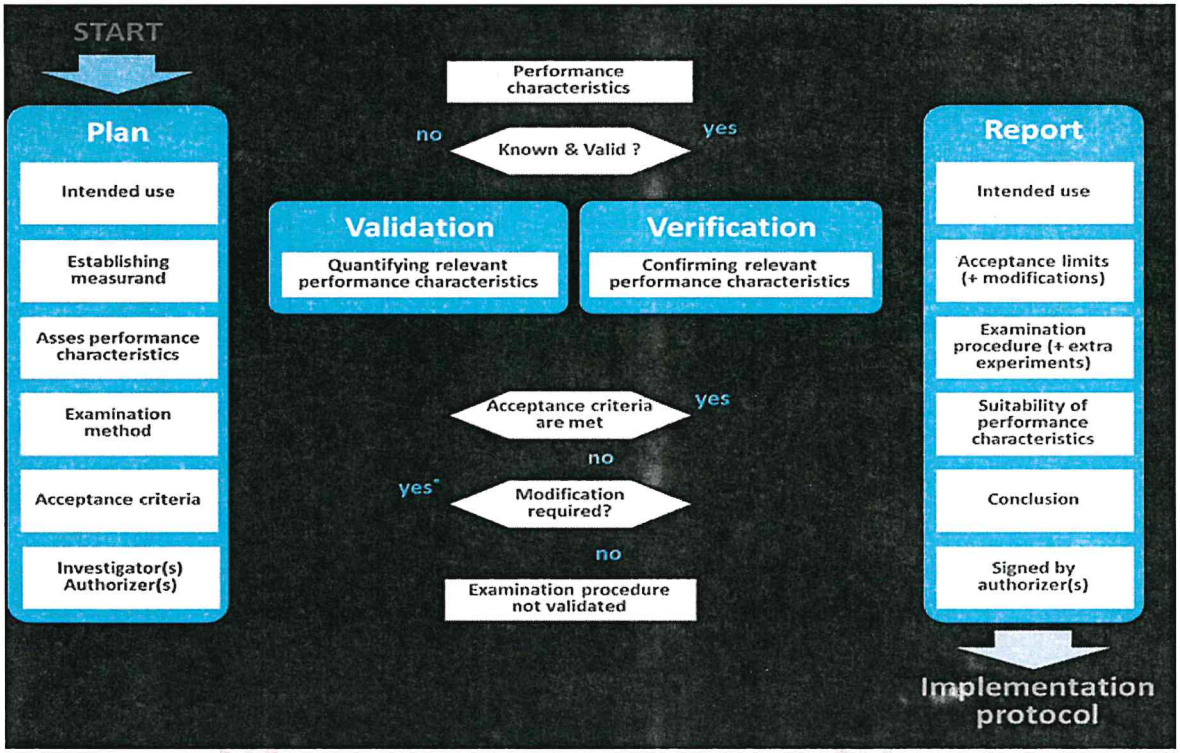
in sufficient detail to prove the adequacy for use. It is not needed to validate commercial off - the -shelf software as long as it is used in the appropriate condition and application range.

9.7.4. All data related to methods and samples are backed up to safeguard against the loss of information due to equipment malfunctions or human error.

10. Appendices

10.1. Appendix A: TEST METHOD VALIDATION / VERIFICATION FLOW CHART

Document type: **CHART**		Doc. Number: QCL/CHK/001 Revision number: Revision Date: 14 August 2020 Effective Date: 24 August 2020 Review Due Date : 24 August 2022
RWANDA FDA Rwanda Food and Drugs Authority	**Title: TEST METHOD VALIDATION / VERIFICATION FLOW CHART**	



10.2. Appendix B Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revisio
24 Aug 2020	0	TUYISHIME Felix	First Issue

11. References

11.1. ISO/ IEC 17025 : 2017 ; Clause 7.2
11.2. Laboratory Quality Manual (Q C L / M A N / 0 0 1)
11.3. U.S. Food and Drug Administration, Volume II, ORA Laboratory Procedures.

End of Document