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/024
RWANDA FDA Rwanda Food and Drugs Authority	**Title: Preventive Maintenance and Verification of Instruments and Equipment's**	Revision Number : 0 Revision Date : 14 August 2020 Effective Date : 24 August 2020 Review Due Date : 24 August 2022

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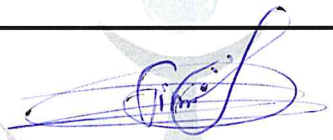
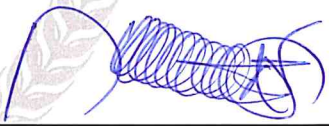
SIGNATURE			
DATE	24 August 2020	24/08/2020	24/08/2020

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. Table of contents

2. Purpose

This Standard Operating Procedure is to lay down the procedure for the preventive maintenance of all quality control instruments and equipment used at Rwanda FDA Quality Control Laboratory Division

3. Scope

This Standard Operating Procedure:

3.1 Applies to all instruments and equipment used by the Quality Control Laboratory at Rwanda FDA Quality Control Laboratory Division.

4. Policy

4.1The Law N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning states in:

Article 8 (3) … *"establish the quality assurance and quality control…through designated quality control laboratories"*

4.2 WHO Good Practices for Pharmaceutical Quality Control laboratories WHO Technical Report Series No. 957, 2010, Annex 1; sections 3 *"Equipment, instruments and other devices should be .....qualified..."*.

5. Definitions and abbreviations

5.1. QCL: Quality Control Laboratory

5.2. QMS: Quality Management System

5.3. SOP: Standard Operating Support Procedure

5.4. FTL: Food Testing Lab

5.5. Q: quarterly

5.6. Y: Annually (Per Year)

6. Responsibility

6.1 The Quality Control Laboratory Division Manager is responsible for checking and ensuring that the preventive maintenance and verification schedules are adhered to

6.2 Laboratory Officers and Analysts are responsible for checking the status of equipment regularly and prior to use to ensure that only instruments and equipment fit for use are used to carry out any work in the quality control laboratory.

7. Distribution

7.1 Division Manager, Quality Control Laboratory Division

7.2 A QMS shared folder on Rwanda FDA head office server

7.3 Hard copies to staff that have no access to the Rwanda FDA server.

8. Safety precautions

Not applicable to this procedure.

9. Procedure

9.1 The calibration frequency shall be established basing on historical data, frequency of use and/or manufacturer's recommendation. Each piece of equipment will be uniquely identified by a code assigned by the laboratory officer.

9.2 Rwanda FDA shall notify external calibrating agencies at least one month prior to the calibration date. Rwanda FDA shall ensure that a valid contract with each external service provider is in place

9.3 Rwanda FDA shall have a list of equipment which requires calibration and maintenance and a schedule for calibration and maintenance.

9.4 For equipment which is maintained and calibrated off-site, the maintenance and calibrating agencies will pick up and return the equipment after providing the agreed service. The condition of the equipment will be evaluated upon return to Rwanda FDA.

9.5All equipment shall have the following;

9.5.1. Calibration sticker affixed to the equipment.
9.5.2. Verification sticker affixed to the equipment.
9.5.3. A calibration certificate containing information
9.5.4. Preventive maintenance sticker affixed to the equipment

9.6. Calibration Certificates shall contain the following information;

9.6.1. Equipment ID Number
9.6.2. Date Calibrated
9.6.4. Next Calibration due date
9.6.5. Calibrated by
9.6.6. Measurement uncertainty statement
9.6.7. National Bureau of Standards Traceability
9.6.8. Statement of condition of equipment
9.6.9. Reference to Accreditation status or logo

9.7 If any equipment is found to be defective,

9.7.1. Conduct an investigation (if warranted)
9.7.2. Affixed with an "Out of Order" sticker

9.7.3. After repair it shall be shown by calibration/verification to perform satisfactorily.
9.7.4. If the equipment cannot be repaired it shall be permanently removed from the division.

9.8 An instrument history report is maintained for all test equipment.
The report shall include the following:
9.8.1. Current status
9.8.2. Calibration procedure used
9.8.3. Date of calibration
9.8.4. Results of calibration
9.8.5. Person performing calibration

9.9 Repaired equipment will be calibrated first before use.

9.10 New test equipment is calibrated on receipt and incorporated into the annual calibration schedule.

9.11 Infrequently used test equipment is verified each time before use. In-house calibration and or verification of test equipment is performed according to the appropriate calibration schedule.

9.13 When equipment is maintained or repaired, it is then calibrated and verified

9.14 After calibration, if calibration process give rise to a set of correction factors, these factors shall be recorded and communicated to users who can then factor them in data calculations.

9.15 All calibration factors or correction factors shall be recorded on calibration certificates and written on equipment labels for the relevant period under calibration.

9.16 Calibration factors or correction factors that have a bearing on software shall also be updated along with hard copies as way of full change control procedure.

9.17 All calibration records shall be filed and stored securely for easy retrieval whenever they are needed to be used.

10. Appendices

10.1 Appendix A: Preventive Maintenance Schedule Template

Sr No	Equip details	Equip I.D. No	Location	Preventive Maintenance Date	Jan		Feb		Mar		Apr		May		Jun		July		Aug		Sept		Oct		Nov		Dec	
					Q	Y	Q	Y	Q	Y	Q	Y	Q	Y	Q	Y	Q	Y	Q	Y	Q	Y	Q	Y	Q	Y	Q	Y
				Remove the top cover to inspect the spindle drive belt for wear fraying, and tension																								
				Actual date																								

10.2. Appendix B: Instrument and equipment verification logbook template.

EQUIPMENT		(EQUIPMENT NAME)		
#		Check points	Status	Comments
1.				
2.				
3.				
	P.M. carried out by:		P.M. verified by	

All necessary checks have been done on this equipment and is according to the checklist. The equipment is approved for operation.

Laboratory Officer: ..... **Datee:** .....
/Technician: .....

Designated Laboratory officer: ..... **Date**: .....

10.3. Appendix C: Document revision history

Date of revision	Revision number	Author(s)	Summary of reasons for revision Changes
24 August 2020	0	Felix TUYISHIME	First Issue

11. Reference

11.1Rwanda FDA Regulations and Guidelines on Good Laboratory Practices.

11.2WHO Website (Information and the full text of the relevant WHO documents on Good Laboratory Practices)