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RWANDA FDA Rwanda Food and Drugs Authority **Title: Prioritization of Testing Activities using risk based approach**	Revision Number : 0 Revision Date : 01 June 2021 Effective Date : 14 June 2021 Review Due Date : 14 June 2023

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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 document control, 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

2.0 Purpose

The purpose of this Standard Operating Procedure is to ensure efficient use of resources to address products of concern for public health such as substandard and falsified medical products.

3.0 Scope

This Standard Operating Procedure applies to all medical samples tested by Quality Control Laboratory.

4.0 Policy

The Quality Manual clause 7.4 paragraph 2 states that "Detailed procedure for prioritization of testing activities *using a risk based approach should be available".*

5.0 Definition and Abbreviations

The abbreviations provided in the Laboratory Quality Manual(QCL/MAN/001) shall apply in addition to the following:

5.1 **SCC:** Sample Control Center.

5.2 **Sample:** Any material brought to the laboratory for analysis.

5.3 **Customer:** A person, company, or other entity which requests / requires testing services from Quality Control Laboratory.

6.0 Responsibility

6.1 The Director of Unit ensure that all received samples are assigned to Laboratory officers and Laboratory Technicians.

6.2 The Director of Unit is responsible to give clarification to the customer, in the case of need, during contract review and authorize the disposal of samples in the respective laboratory.

6.3 The Laboratory Officers and Technician are responsible to test and report the assigned samples;

7.0 Distribution

7.1 Division Manager of Quality Control Laboratory

7.2 Designated Quality Management System Officer

7.3 Director of Unit

7.4 Laboratory Officers and Technicians

8.0 Safety Precautions

NA

9.0 Procedure

Before requesting analysis of a particular product, QCL interacts with its customers to assess the risk of poor quality.

9.1 Testing Prioritization

Testing focus on medicines most likely to pose a risk to patient

9.1.1 Sample from Post Market Surveillance

9.1.1.1 PMS sample tested at QCL has to meet the following criteria:

a) Produced by manufacturers for which poor evidence of compliance with the principles of good manufacturing practices (GMP) is available, or where the origin is uncertain
b) Suspected of being falsified;
c) Suspected of being substandard because of incorrect distribution or storage conditions, or their instability;
d) Suspected of causing adverse reactions due to a quality defect;
e) For which analytical testing results are needed as evidence in litigation (requires the implementation of a rigorous chain of custody)

9.1.1.2 Testing is not done for product where manufacturing site meet the following criteria:

a) The manufacturing site has been found to comply with GMP principles
b) The manufacturer is under regular supervision of an authority applying international standards
c) There is no quality complaint or a suspicion of quality deterioration during distribution or storage
d) The manufacturer's batch certificate indicates the quality of the product. Such a certificate should be issued in accordance with the criteria applicable to the WHO Model Certificate of good manufacturing practices or WHO Certification Scheme

9.1.2 Registration Samples

9.1.2.1 As the sample is selected and submitted by the manufacturer for registration, it may not provide a true picture of product quality.

9.1.2.2 QCL may provide testing services to assess functionality of analytical methods in local conditions when data reviewers have some doubts.

9.1.3 Testing Methodology

Testing methodology used at QCL are classified into three levels and each level would be used depending on sample to be tested.

9.1.3.1. Level 1: Visual inspection

a) After receiving the sample, the laboratory officer makes a visual inspection to detect any defect or indication of adulteration or non-compliance of good manufacturing practices.

b) Types of defect may include the following: Wrong labelling, particulates, crumbling tablets, under fill, glass particulates, mould contamination, discoloration, Wrong fill, Odor, poor storage condition.

c) If any of noncompliance listed in **9.1.3.1 a)** above was revealed, the laboratory officer makes a certificate of analysis without further testing.

d) If the product passes visual inspection, laboratory officer moves to the next levels

9.1.3.2 Level 2: Advanced screening

a) If the sample passes the level 1tests, the laboratory officer may use advanced screening techniques available at QCL and these include but not limited FTIR, TLC, UV-Vis and HPLC.

b) In case field based screening has to be conducted QCL uses advanced screening techniques like the use of Minilab™ or other screening technology available to the Rwanda FDA laboratory

c) Different steps to be followed at level 2 are shown in appendix A.

9.1.3.3 Level-3: Compendial testing

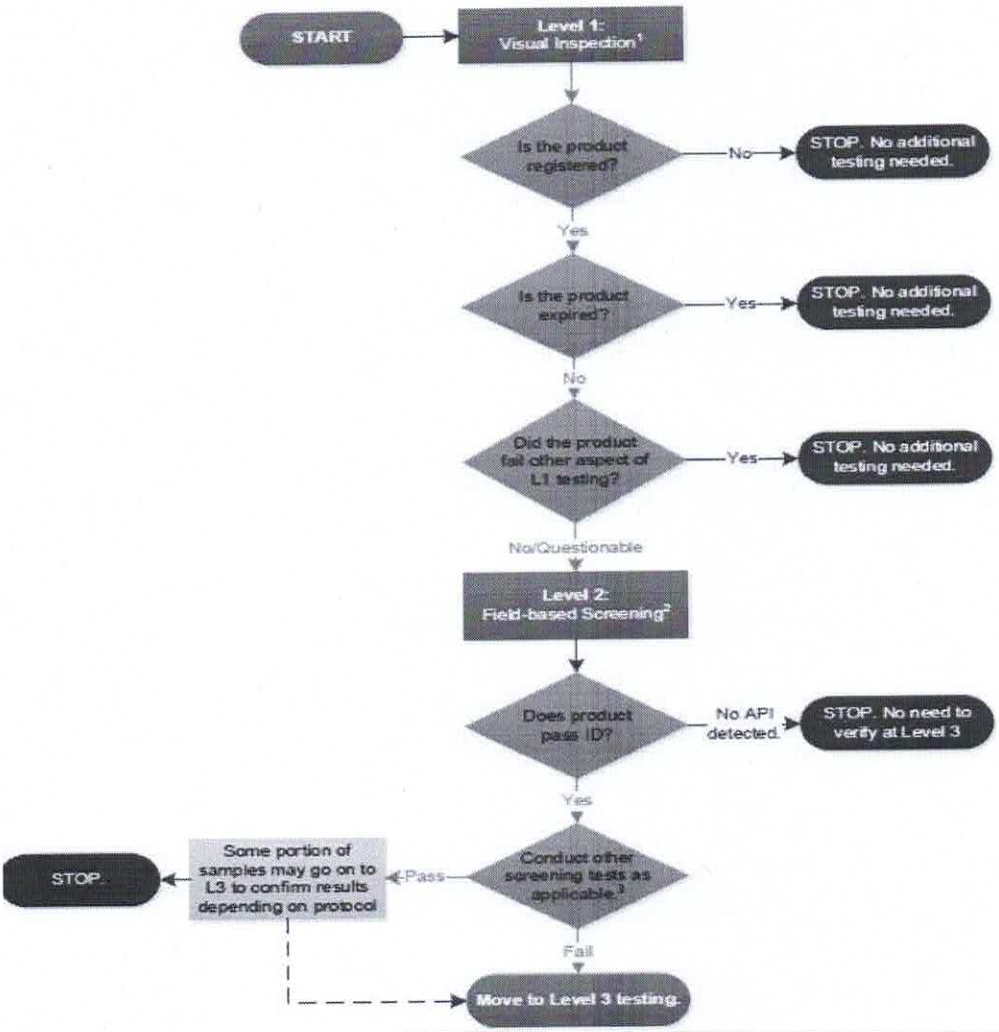
a) In case a product was deemed noncompliant, the laboratory officer will confirm the results following compendial methods and internal standard operating procedure(s).

b) Different steps to be followed at level 3 are shown in appendix B.

10. Appendices

10.1. Appendix A

Figure 2. Guidance for visual and field-based screening (Levels 1 and 2)



Footnotes:

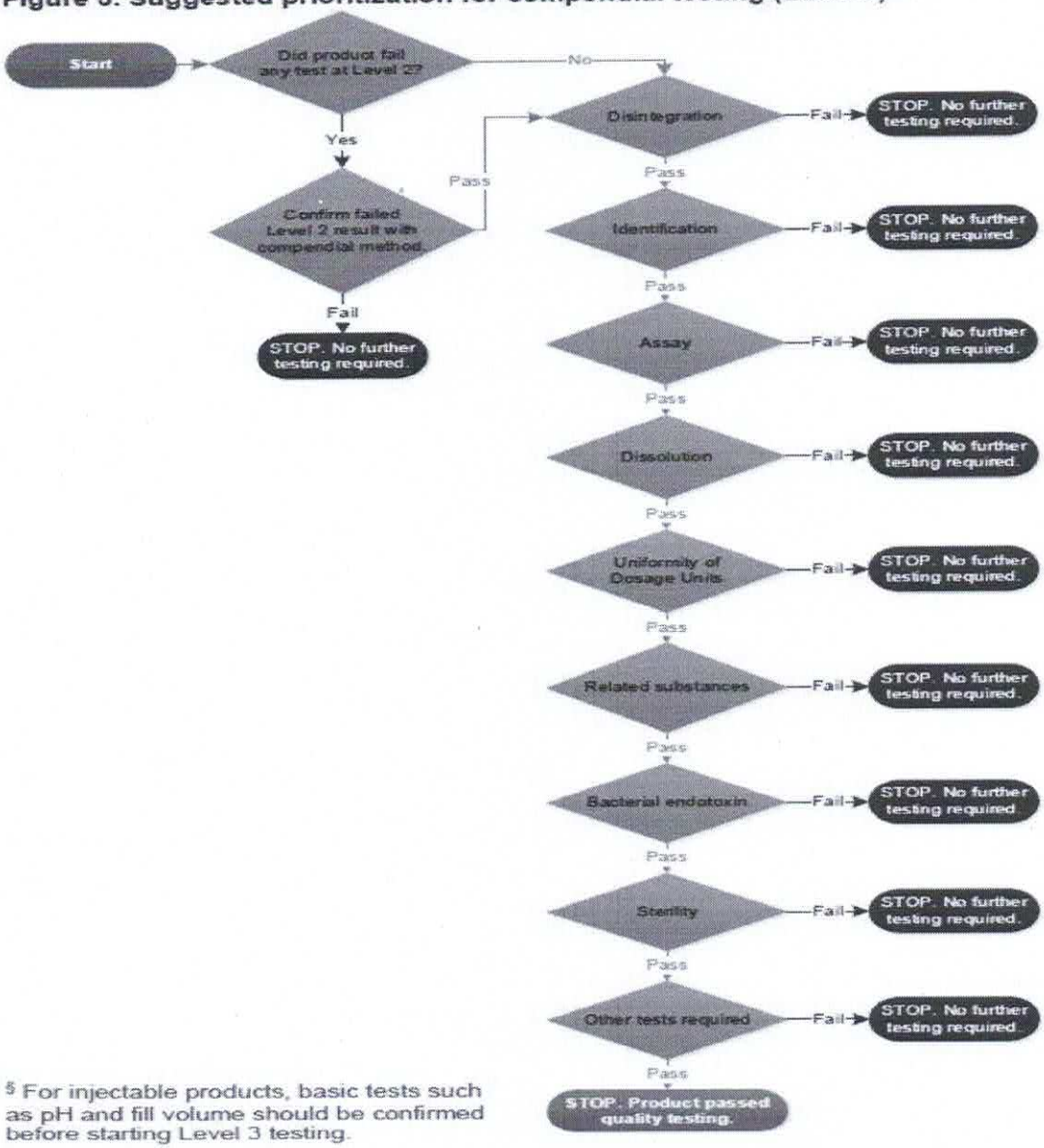
[1] Level 1: Visual inspection to include assessment of registration status, expiration date, labelling, batch number, scientific name, company logo, number of units per container, dosage form, strength, manufacturer's address, presence of a package insert, damage to packaging.

[2] Level 2: Field-based screening may include assessment of a product's identity (ID) and other screening tests as applicable.

[3] If a product passes identification, additional tests should be prioritized in the following order: content, disintegration, and impurities.

10.2. Appendix B

Figure 3. Suggested prioritization for compendial testing (Level 3)[§]



[§] For injectable products, basic tests such as pH and fill volume should be confirmed before starting Level 3 testing.

10.3.Appendix C: Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
01 June 2021	0	TUYISHIME Felix	First Issue

11.Reference

WHO Expert Committee on Specifications for Pharmaceutical Preparations