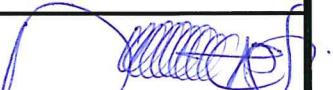


Format: QMS/FMT/001 Revision No: 0 Effective Date: 24 Aug 20	Division	Quality Control Laboratory	
Document type: Standard Operating Procedure		Doc. Number : QCL / SOP /003	
 RWANDA FDA Rwanda Food and Drugs Authority	Title: Reporting of Results	Revision Number : 0 Revision Date : 14 August 2020 Effective Date : 24 August 2020 Review Due Date : 24 August 2022	
	Author	Authorized by	Approved by
TITLE	Designated QMS Officer	Human Medicine Laboratory Officer	Division Manager
NAME	TUYISHIME Felix	UWAMBAJINEZA Tite	MUKUNZI Antoine
SIGNATURE			
DATE	24 August 2020	24/08/2020	24/08/2020
INSTRUCTIONS			
<ol style="list-style-type: none"> Controlled issues of this Test method may not be copied All amendments are written on the page provided Only authorized, numbered, stamped copies of Test method as described in the document control method above, are used This SOP shall not be used outside the Rwanda FDA Quality Control Laboratory without the authority of the authorizing personnel. 			

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2. PURPOSE

This procedure determines how laboratory tests results are reported accurately, clearly, unambiguously reviewed within Quality Control Laboratory and authorized prior to release.

3. SCOPE

This procedure applies to all samples received in Quality Control Laboratory

4. POLICY

NA

5. DEFINITION AND ABBREVIATION

The definition and abbreviations provided in the Quality Control Laboratory shall apply.

6. RESPONSIBILITIES

- 6.1 The Quality Control Laboratory personnel directly involved in the Quality Control Laboratory analysis process are responsible for the implementation of this system procedure.
- 6.2 The Laboratory officer and Laboratory Technician are responsible for testing of samples, recording of findings and preparation of test reports manually or through Laboratory Information Management System.
- 6.3 The Laboratory officer is responsible for cross- checking the test results.
- 6.4 The Laboratory Officer is responsible for counter checking the results, and signing off the test report.
- 6.5 Division Manager is also responsible to sign the Certificate of Analysis.

7. DISTRIBUTION

This System procedure is issued on a control basis. Read reports access to all Quality control Laboratory staffs is provided through testing server.

8. SAFETY PRECAUTION

All test results are recorded in the form hard and softcopy in Quality control laboratory system (server).

9. PROCEDURE

9.1 Preparation and review of Certificate of Analysis.

The reporting process in Quality Control Laboratory is performed manually or through Laboratory Information Management System software. The reporting method using Laboratory Information Management System software is preferred; however, the manually reporting method is used when Laboratory Information Management System software is faulty or not applicable.

- 9.1.1 The designated Quality Management Systems officer prepares the Certificate of Analysis by filling the obtained data in a Certificate of Analysis.
- 9.1.2 The designated Quality Management Systems officer forwards the prepared Certificate of Analysis submission form and Work Book/Worksheet to the Division Manager for checking.

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- 9.1.3 After checking, the Division Manager submits the checked Certificate of Analysis submission form and Work Book/Worksheet to The Designated Quality Management Systems officer for cross checking the results.
- 9.1.4 In case the Division Manager is not around or in case the test is done by the designated Quality Management Systems officer. Laboratory Officer or any competent the designated Quality Management Systems officer can countercheck the results.
- 9.1.5 After correction of Results (if any) the reports are submitted to the Division Manager for approval.
- 9.1.6 The Laboratory Officer submits the signed reports to the Division Manager for final checks and authorization on behalf of Director General.
- 9.1.7 After authorization, the Division Manager returns the report to the Laboratory Officer who then forwards the report to designated Quality Management Systems officer
- 9.1.8 The Laboratory designated management system Officer takes the report to administrative assistant in the Director General's office for the official stamp.
- 9.1.9 The designated Quality Management Systems officer submits the reports to the Inspectorate or Enforcement division.
- 9.1.10 The designated Quality management system Officer acknowledges the reception of reports through registering the received reports in the sample reception registers.
- 9.1.11 The Laboratory Officer and designated Quality management system Officer keep the copy of the test report for record purpose.

9.2 Common Requirement of Test Report: Format of Certificate of Analysis

9.2.1 The Certificate of Analysis format (*see Appendix A*) includes at least the following information:

- 9.2.1.1 A title: "Certificate of Analysis"
- 9.2.1.2 Name of Laboratory "Quality Control Laboratory."
- 9.2.1.3 Identification of Certificate Number: CERTIFICATE No: FDA/xxx/yyy (xxx denotes serialized no and yyy denotes year)
- 9.2.1.4 Identification of Document Number: DOC No: QCL/FOM/xxx
- 9.2.1.5 The name and address of the customer
- 9.2.1.6 Rwanda FDA Identification Number
- 9.2.1.7 A description of the condition of the item tested
 - Product Name
 - Manufactured by
 - Batch No
 - Condition of the sample
 - Manufacture Date
 - Expired Date
- 9.2.1.8 Indication of Date of Sample reception
- 9.2.1.9 Indication of Reference Standard used
- 9.2.1.10 Date analysis Started
- 9.2.1.11 Date Analysis Completed
- 9.2.1.12 Laboratory results
 - 9.2.1.12.1 Indication of Laboratory of parameter tested

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- 9.2.1.12.2 Identification of the test method used
9.2.1.12.3 Indication of Limit specification
9.2.3 The Certificate of Analysis includes a page number of the total page numbers.
9.2.4 Indication of Conclusion to interpret the test results
9.2.5 Indication of Document code, revision number, Revision date, effective date, Review due date and the one page number in each page of the Certificate of analysis in footer of report template
9.2.6 Indication of Unit measurements;
9.2.7 Indication of the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the Certificate of Analysis
9.2.8 "This Certificate of Analysis cannot be reproduced other than in full; except with the approval of the Director General".
9.2.9 "The results contained herein apply only to the particular sample(s) tested as submitted by the client whose Rwanda Food and Drugs Authority Number is herein quoted".
9.2.10 "This Certificate of Analysis cannot be used to advertise a product without a written consent of the Director General".
9.2.11 When the test report has more than one page each page of the test report shall bear all the general information and authorizing signatures.
9.2.12 When no product standard specification is stated by the customer in the sample submission form, the word "No standard quoted" is written in the space for the standard used and the column for the requirement is removed.
9.2.13 Where some parameters requested are not covered by the standard quoted, the word "Not covered by the standard" (NCS) is written in the column for requirement.
9.2.14 Laboratory results
9.2.15 Sub contracted Results
9.2.16 For sub contracted samples, the sub-contracting laboratory forwards the test report to the Laboratory Director Manager
9.2.17 Results from the subcontractors are received by the Laboratory officer and shared with the Division Manager relevant to the subcontracted parameters for verification.
9.2.18 If there is anything not clear on the Certificate of Analysis, it should be clarified before the Certificate of Analysis is released to the customer.
9.2.19 The reviewed subcontracted the Certificate of Analysis t is stamped with the Quality control Laboratory stamp before being released to the client.
9.2.20 The Laboratory Director Manager forwards the Certificate of Analysis to the Laboratory designated management system Officer
9.2.21 The Laboratory designated management system Officer registers the Certificate of Analysis in the sample reception register
9.2.22 Copy of the sub contracted Certificate of Analysis is kept for record traceability purpose.

9.3 Submission of Results to the Customer

- 9.3.1 Following receipt of the Certificate of Analysis, the Laboratory designated management system Officer informs the customer about the availability of the Certificate of Analysis through signed hard copy or email.

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9.3.2 Quality Control Laboratory does not allow electronic transmission of test results but scanned hard copy can be provided following customer request; and when electronic feedback of receipt of the scanned copy is done the same email is filed as hard copy.

9.3.3 The Laboratory designated management system Officer provides the references to the laboratory procedures to the customer to sign as acknowledgement of receipt of the Certificate of Analysis.

9.4 Results opinions and interpretations

9.4.1 When a customer requires opinions and interpretation of test results, the customer makes a request by writing to the Laboratory Officer through Laboratory designated management system Officer

9.4.2 Division Manager approves the request and assigns the relevant the Laboratory designated management system Officer to address the request.

9.4.3 The advice, opinions and interpretations provided by the Laboratory designated management system Officer to the customer are documented in the Opinions and Interpretations form of Certificate of Analysis.

9.4.4 When the customer requests a statement of conformity to a specification or standard for the test (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision is clearly defined communicated to, and agreed with, the customer. This case is reported as opinion and interpretation upon customer request.

9.4.5 The Laboratory designated management system Officer keeps a copy of the opinion and interpretation provided.

9.5 Amendment of Certificate of Analysis

9.5.1 In case a mistake in the Certificate of Analysis is identified when the customer has already received the Certificate of analysis, a new Certificate of analysis shall be issued.

9.5.2 The corrected Certificate of Analysis bears the same identity as the original it replaces but the word “ORIGINAL” in the top left corner is changed to “: AMENDED TEST REPORT”, both returned original Certificate of analysis and a copy of amended one shall be kept in the Laboratory designated management system Officer.

9.5.3 In case the Certificate of analysis is misplaced the customer requests the duplicate in writing to Laboratory designated management system Officer and the Division Manager authorizes the relevant the designated Quality

9.5.4 In cases where mistake is done on identification of the Certificate of Analysis and when the results have completely changed, the new complete Certificate of Analysis with unique identification shall be given with reference to original that it replaces.

9.6 Information of Certificate of Analysis (see Appendix A)

The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a Certificate of analysis), and shall include the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. The issued Certificate of analysis shall be retained as technical records (see ISO/IEC 17025: 2017 clause 7.8.1.2).

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NOTE 2: Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

- 9.6.1 Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse: (see ISO/IEC 17025: 2017 clause 7.8.2.1)
- 9.6.2 A title (e.g. "Certificate of Analysis",
- 9.6.3 The name and address of the laboratory;
- 9.6.4 The location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
- 9.6.5 Unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
- 9.6.6 The name and contact information of the customer;
- 9.6.7 Identification of the method used;
- 9.6.8 A description, unambiguous identification, and, when necessary, the condition of the item;
- 9.6.9 The date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
- 9.6.10 The date(s) of performance of the laboratory activity;
- 9.6.11 The date of issue of the report;
- 9.6.12 Reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;
- 9.6.13 A statement to the effect that the results relate only to the items tested, calibrated or sampled;
- 9.6.14 The results with, where appropriate, the units of measurement;
- 9.6.15 Additions to, deviations, or exclusions from the method;
- 9.6.16 Identification of the person(s) authorizing the report;
- 9.6.17 Clear identification when results are from external providers.

NOTE: Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.

- 9.6.18 The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

9.7 Information of Worksheet (Control of Record), See Appendix B

- 9.7.1 Rwanda FDA laboratories retain on record original observations, calculations, staff records, quality records (e.g. audit and review records) The records for each test contain sufficient information to enable the test to be repeated under conditions as close as possible to the original. However, the Quality Control laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting

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the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original.

- 9.7.2 The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results.
- 9.7.3 Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task (see ISO/IEC 17025: 2017 clause 7.5.1).
- 9.7.4 The Quality Control laboratory shall establish and retain legible records to demonstrate fulfillment of the requirements in this document.
- 9.7.5 The Quality Control laboratory shall implement the controls needed for the identification of its records. The Quality Control laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available (see ISO/IEC 17025: 2017 clause 8.4).

9.8 Information of Test Report (See Appendix C)

In addition to the requirements listed in 10.5, the Quality Control laboratory provides test reports with the following details where necessary; Information on specific test conditions, statement of conformity with requirements or specifications, measurement uncertainty presented in the same unit as that of the measurand or as a relative to the measurand, opinions and interpretations, and additional information that may be required by specific methods, authorities, customers or group of customers(ISO/IEC 17025:2017, clause 7.8.3).

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10. Appendices

10.1. Appendix A: Certificate of Analysis Format



RWANDA FDA
Rwanda Food and Drugs Authority

CERTIFICATE N°: FDA/xxx/yyy
DOC N°: QCL/FOM/003

Rwanda FDA
QUALITY CONTROL LABORATORY
CERTIFICATE OF ANALYSIS

1. Customer Address:(NAME and tel.)/ position/Institution	6. Condition of the sample:
2. Rwanda FDA identification No: FDA/NNN/MMM/YYYY	7. Mfd Date:
3. Product Name:	8. Exp Date:
4. Manufactured by:(full address)	9. Date of Sample reception:
5. Batch No:	10. Standard used:
	11. Date analysis Started:
	12. Date Analysis Completed:

13. LAB RESULTS

Test	Methods	Results	Specifications

Note:

Conclusion:

Prepared by:

.....
Laboratory Technician/Officer

Verified by

.....
Laboratory Officer

Approved by

.....
Division Manager of
Quality Control Lab

The results contained herein apply only to the particular sample(s) tested as submitted by the client, whose
Rwanda FDA number is herein quoted

Rwanda Food and Drugs Authority
P.O. Box 84 Kigali, info@rwandafda.gov.rw
www.rwandafda.gov.rw

ORIGINAL

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10.2. Appendix B: Form of Analytical Worksheet (Control of Record)

Document type: QUALITY CONTROL LABORATORY	Doc. Number : QCL/ FOM /004
 RWANDA FDA Rwanda Food and Drugs Authority	Revision Number: TITLE: Analytical worksheet
	Revision Date :14 August 2020
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A. Sample details

1. Name of product: (Generic name & Trade name if any)		
2. FDA registration No:	3. Sender:	
4. Condition of the sample:		5. Quantity received :
6. Batch No:	7. Manufacture date:	8. Expiration date:
9. Submitted on:	10. Received on:	
11. Analysis started on :		12. Analysis completed on:
13. Reference standard:		
14. Address of manufacturer:		
15. Name& amount of APIs on label claim:		
16. Parameters requested:a) Identification, b) Assay, c) uniformity of weight, d) Dissolution e) Friability f) Disintegration, g) Heavy metals(Pb, Cd, As, Hg), h) Other(specify)		

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B. Description and uniformity of weight

1. Sample Description (appearance, color, shape)						
S/N	Weight of whole tab/caps (mg)	Weight of empty container for caps (mg)	S/N	Weight of whole tab/caps (mg)	Weight of empty container for caps (mg)	Average weight of 20 tabs/Caps
1			11			
2			12			
3			13			
4			14			
5			15			
6			16			
7			17			
8			18			
9			19			
10			20			
Name of analytical balance used:			Lab ID/Serial number of analytical balance:		Date for next calibration:	

C. Weighing of sample & preparation of identification and assay solution 1&2

1. Equipment used for	i) Identification	HPLC	UV spec	FTIR	TLC	Other (specify)
	ii) Assay	HPLC	UV spec	Titration	GC/FID	Other (specify)

2. Calculation of actual weight(g) to be taken for assay test = $\frac{\text{Theoretical Wt} * \text{Average Wt per tab(Caps)}}{\text{Label Claim}}$

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3. Theoretical weight to be taken (mg)		6. Name of analytical balance used:
4. Actual weight taken for assay 1 (mg)		7. Lab ID/Serial number of analytical balance :
5. Actual weight taken for assay 2 (mg)		8. Date for next calibration:

9. Volumetric flasks used(<i>Amber/Clear</i>)	10.Pipettes used
Volume.....ml Next calibration date:	Volume.....ml Next calibration date:
Volume.....ml Next calibration date:	Volume.....ml Next calibration date:

11.Incubation i) Temperature(°C): ii) Start time: iii) stop time:	12. Dissolution a)Vortex mixing i) Speed: ii) Time: b)Sonication i) Temperature(°C): ii) Duration:	13. Dilutions applied DF=	14.Filtration i) Method: ii)Type & size of filter :	15. Centrifuge i) Speed : , ii) Time :
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Composition of diluent:

Note and observation (if any):

D. Weighing & preparation of certified reference standard for identification and assay.

1.Certified reference standard(s) (CRS) used: Primary (USPRS ,Eur. PRS, other (specify))					
2.Name(s)of CRS(s) prepared	3. Lot/ID No	4. Validity Exp date	Note	5. Date first opened	6. Purity

7.Calculation of weight (g) to be taken for standard preparation = $\frac{\text{Wt of CRS to be taken}*100}{\text{Purity(in \%)} }$		
8. Weight of CRS to be taken		11. Name of analytical balance used:
9. Actual weight of CRS taken for Standard 1(mg)		12. Lab ID/Serial number of analytical balance:
10. Actual weight of CRS taken for standard 2 (mg)		13. Date for next calibration:

14. Volumetric flasks used(Amber/Clear)	15.Pipettes used
Volume.....ml Next calibration date:	Volume.....ml Next calibration date:
Volume.....ml Next calibration date:	Volume.....ml Next calibration date:

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16.Incubation	17. Dissolution	18. Dilutions applied	19.Filtration	20. Centrifuge
i) Temperature(°C):	a)Vortex mixing i) Speed:		i) Method: ii)Type & size of filter:	i) Speed: ii) Time:
ii) Start time:	ii) Time: b)Sonication: i)Temperature(°C):	DF:		
iii) stop time:	ii)Duration:			

Composition of diluent:

Note and observation (if any):

E. HPLC Set- up and sample measurement

1.Method File name:	2.Sequence File name:	3.Test to be done: (identification/assay/dissolution)
4.Name of HPLC:	5.Lab Id/Serial number:	6.Detector type: Next calibration date
7. Name of column used:	8.Type of stationary phase:	9.Length x internal diameter (mm)
10. Particle size (μm):	11.Serial number:	12.Column Temperature $^{\circ}\text{C}$:
13.Composition of mobile phase:	14.Date prepared:	15.Flow rate:

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16.Run time:	17.Injection volume:	18.Detector wavelength:
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19.System suitability	STD1	STD2	Average (%RSD)
Relative standard deviation of area for 5 replicate injections of standard (% RSD)			
Relative standard deviation of Retention Time, RT for 5 replicate injections (% RSD)			

%RSD limit for area should be NMT 2%	Fail or Pass	%RSD limits for RT should be NMT 2.5%	Fail or Pass
---	--------------	--	--------------

Similarity factor for the standards	$\frac{W1 * R2}{W2 * R1} =$	Should be within:[0.98 - 1.02]
Theoretical plates:	Limits specified in monograph:	Fail or Pass
Resolution (where applicable):	Limits specified in monograph:	Fail or Pass
Tailing factor:	Limits NMT 2. Fail or Pass	Attach the obtained printouts

Note and observation (if any):

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F. UV- Visible Spectrophotometer Set - up and absorbance/concentrations

1.Method File name:	2.Data file name:	3.Test to be done: (identification/assay/dissolution)
4.Name of UV Spectrophotometer:	5.Lab Id/Serial number:	6. Date for next performance test:
7. Scan range:	8.Scan speed:	9. λ maxima:
10.Specific absorbance(1%,1cm) :	11.Cell path length:	12.Diluent composition:
13. Blank solution used:	14. Dilution Factor:	15. Equipment reading sample1: Sample2: Average: %RSD: Criteria : NMT 2%

16. Q.C on retained sample or PT

Sample ID:	Date of analysis:	Previous Reading (P)/Assigned value (for PT):	Current reading(C):

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%RSD for P& C should be NMT 2%	Fail or Pass	Attach the obtained printouts
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N.B:In case of specific absorbance is not specified, prepare standards according to point D

Note and observation(if any):

G. Dissolution Apparatus set-up, sampling & preparation of dissolution solutions

i) Dissolution Apparatus set-up

1.Name of dissolution tester:	2.Lab ID/Serial number:	3.Configuration name:	4.Method file name:
5.Data file name:	6.Date for next calibration:	7. Apparatus used: Basket (type1) Paddle (type 2)	8.Rotation speed:
9. Medium Used:	10.Volume of medium:	11.Temperature of medium:	12.Cell path length:
13. Duration for dissolution:	14. Equipment used for reading after dissolution:	15. Attach the obtained printouts	

ii) Weighing & preparation of certified reference standard for dissolution

1.Certified reference standard(s) (CRS) used: Primary (USPRS, Eur. PRS, other (specify))					
2.Name(s)of CRS(s) prepared:	3. Lot/ID No	4. Validity Exp date:	5. Date first opened:	6. Purity:	

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7. Weight of CRS to be taken(mg) <i>(include calculations)</i> :	8. Actual weight of CRS taken (mg):	9. Volume (ml) used to prepare standard <i>(include dilution factor if any)</i> :
10. Name of analytical balance used:	11. Lab ID/Serial number of analytical balance:	12. Date for next calibration:
13. Cuvette reading/ vessel reading:		

ii) Sample handling

1. Dilution applied (if any):	2. Filtration type and filtersize:	3. Theoretical final concentration:
4. Measuring cylinder used:	5. Pipette used	6. Date for next calibration: a) Measuring cylinder: b) Pipette:
7. Equipment used for reading after dissolution:		

Note and observation if any:

H. Friability

1. Name of Friability tester used:	2. Lab ID/Serial number of Friability tester:	3. Date for next calibration:
4. Number of revolutions:	5. Initial weight of tablets (mg):	6. Final weight of tablets(mg):
7. Name of analytical balance used:	8. Lab ID/Serial number of analytical balance:	9. Date for next calibration:

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10.%Friability:	11. Acceptance criteria NMT 1 %:	12.Pass or Fail
-----------------	-------------------------------------	-----------------

Note and observation, if any:

I. Disintegration

1.Name of disintegration tester used:	2. Lab ID/Serial number of disintegration tester:	3.Date for next calibration:
4. Dosage form:	5. Medium used:	6. Disintegration temperature(°C):
6. Disintegration time (min):	7. Acceptance criteria NMT:	8. Pass or Fail

Note and observation, if any:

J. Heavy metals analysis by AAS or ICP MS

J.1. Equipment used

1.Name of equipment used:	2. Lab ID/Serial number:	3. Method/Result file name:
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J.2. Standard preparation

1.Certified reference standard(s) used: NIST, Sigma-Aldrich; (if other, specify)	3. Lot/ID No	4. Validity		
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2. Name(s) of CRS(s) prepared		Exp date	Note	5. Date first opened	6. Concentration of stock solution:
7. Bulk concentration prepared(GFAAS):	8. Volumetric Flask used:	9. Micropipette used:		10. Date for next calibration i) Volumetric flask: ii) Micropipette:	

J.3. Sample preparation

1. Weight of sample taken (in mg)	2. Name of analytical balance used:	3. Lab ID/Serial number of analytical balance:
Sample1: Sample 2:		
4. Date for next calibration:	5. Dilution (applied if any) DF:	6. Purity of reagent used(HNO ₃ and H ₂ O ₂):
7. Blank used	8. Digestion Temperature:	9. Attach the print out including calibration curves

Composition of diluent:

Note and observation, if any:

K. Other test (specify)

Done by :	Signature:	Date:
Checked by:	Signature:	Date:
Approved by:	Signature:	Date:

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10.3. Appendix C: Information of Test Report

Document type: FORM		Doc. Number :	QCL/ FOM /005
 RWANDA FDA Rwanda Food and Drugs Authority	TITLE: Information of Test Report	Revision Number:	: 0
		Effective Date	: 14 August 2020
		Review Due Date	: 14 August 2022
		Ref doc	QCL/SOP/001

Quality Control Laboratory

Rwanda FDA Reg. No:	FDA..../.../20...			
Generic Name:	Trade Name:			
Lebel claim, mg	Batch No:			
1. Identification & Similarity Factor(S.F):				
Equipment used				
Test method used				
1.1 Identification				
1.1.1 Preparation of sample				
Number of tablets required for sampling				
Average Weight of tablets (mg)				
Actual Wt of sample1 (Mf1) in mg				
Actual Wt of sample2 (Mf2)				
Volume of Volumetric flask(Vol) in mL				
D.F				
Wt std, mg				
V std, mL				
D.F std				
% conversion factor				
Std purity				
1.1.2. Results for Identification				
Parameters:	Peak area		Retention time	
Stds:	Std1	Std2	Std1	Std2

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Replicates				
MEAN				
STDev				
RSD				

	RT and Peak Area of Sample	
	RT	
	Spl- 1A	Spl- 1B
1		
2		
3		
Mean		
STD		
RSD		

1.1.3 Acceptance criteria

The RT of the major peak of the Sample solution corresponds to that of the Standard solution

1.1.4. Conclusion:	Pass			
1.2.Similarity Factor(S.F)	N.A			
Weight of std1(Wt1)			Peak Area for std2 (Area2)	
Weight of std2(Wt2)			Peak Area for std1(Area1)	
1.2.1. Calculations of S.F				
$S.F = \frac{(Wt1)}{(Wt2)} * \frac{(Area2)}{(Area1)}$		S.F=		

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1.2.2. Acceptance criteria	NLT 0.98 and NMT 1.02			
1.2.3. Conclusion				
2. Assay				
Test method used				
2.1 Preparation of sample				
We use the solution as prepared for identification test				
2.2 Results				
Peak area of sample obtained on HPLC	Sample 1	Sample 2		
	Spl- 1A	Spl- 1B		
	Average			
	STD			
	RSD(%)			

2.3 Calculation of assay result

$$\% \text{ Assay of Paracetamol} = \frac{Ru * Wt std * Avg Wt * V spl * DF spl * P * 100}{Rs * Wt Spl * V std * DF std * Lc}$$

Ru: Peak response of sample solution

Wt std: weight of RS

Avg Wt: Average of tablets

Vspl: Volume of volumetric flask used to dissolve sample powder

DF Spl: Dilution factor for the sample

RS: Peak response of std solution

Wt spl: weight of the powder of tablets taken

V std: Volume of volumetric flask used to dissolve Paracetamol RS

DF stdl: Dilution factor of the standard solution

P: std purity

LC: Label claim of sample

N.A: Not Applicable

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NLT: Not less than

NMT: Not more than

% Assay for sample 1, %L.C	
% Assay for sample 2, %L.C	
Reported average	

2.4.Acceptance criteria:

2.5 Conclusion:

3.0 Uniformity of weight

Method QCL/STP-070

3.1 Calculation of results

$$\% \text{ Deviation} = \frac{(X_i - X) * 100}{X}$$

where:

Xi: Weight of tablet

X: Average weight

No	Xi: Weight,tablet	X	% Deviation
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			

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17			
18			
19			
20			

Average

3.2 Number of tablets

No of tablets meeting the criteria	range	Average weight of tablets	Deviation %	Number of tablets
20	Min 18
0	Max 2

3.4 Conclusion:

4. DISINTEGRATION

4.1. Method used:

Dosage form

Disintegration time, min

Acceptance Criteria

4.2. Conclusion:

5. Dissolution

5.1. Standard preparation

Weight of standard(mg)

Volume used to prepare standard(ml)

Concentration of standard (mg/ml)

Media volume(ml)

Purity of Std

Dilution factor

lebel claim

5.2 Formula used to calculate % dissolved

$$\% \text{ dissolution} = \frac{(\text{Sample Abs} \times \text{Std weight} \times \text{Purity of std} \times \text{Media volume}) \times 100}{(\text{Std abs} \times \text{Std Volume} \times \text{Dilution factor of Std} \times \text{Lebel Claim})}$$

Absorbance of standard solution, Abs U			

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Absorbance of the sample solution, Abs U			
	Vessel 1	Vessel 2	Vessel 3
	Vessel 4	Vessel 5	Vessel 6
5.3 Results			
	% Vessel 1	% Vessel 2	% Vessel 3
	% Vessel 4	% Vessel 5	% Vessel 6
Average			
SD			
RSD			
Acceptance criteria			

5.4. Conclusion: Pass

6. Friability Test

Method Used:	QCL/STP/070		
Initial weight of tablets(mg)			
Final weight of tablets(mg)			
6.1 calculation of % friability			
	$\% \text{ Friability} = \frac{(W_o - W_f) \times 100}{W_o}$		
Where:	Wo: initial weight		
6.2 Result			
6.3. Acceptance criteria	NMT 1%		
6.4 Conclusion:			

7.0 General Conclusion:

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Tested by:	Signature & Date
Report generated by:	Signature & Date
Reviewed by:	Signature & Date
Approved by:	Signature & Date

10.4. Appendix D: Document Review History

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

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11.0 References

11.1 ISO/IEC 17025:2017 Clause 7.8

11.2 Quality Manual Clause 8.8

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