RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS FOR ANALYSIS OF PRODUCTS REGULATED BY RWANDA FDA

(Rwanda FDA Law N° 003/2018 of 09/02/2018, Article 9)

AUGUST, 2021

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO	20 June 2021
ADOPTION BY RWANDA FDA	20 June 2021
STAKEHOLDERS CONSULTATION	20 July 2021
ADOPTION OF STAKEHOLDES' COMMENTS	29 July 2021
DATE FOR COMING INTO EFFECT	09 August 2021

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning hereby ADOPTS and ISSUES these regulations No.: CBD/TRG/022 Rev_0 for Analysis of Products regulated by Rwanda FDA on this 09th August 2021.

Dr. Charles KARANGWA
Ag. Director General

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CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these regulations

The purpose of these Regulations is to provide a legal framework for the effective and efficient laboratory analysis of products regulated by Rwanda Food and Drugs Authority.

Article 2: Citation

These Regulations may be cited as "*Regulations for Analysis of Products regulated by Rwanda FDA*" and shall come into operation from the date of publication.

Article 3: Application and scope

These regulations shall apply to all regulated products that are analysed at Rwanda FDA Quality Control Laboratory.

Article 4: Definitions and acronyms

In these regulations, unless the context otherwise requires, the following terms have the assigned meanings:

1. **Authority** means the Rwanda Foods and Drugs Authority
2. **Customer** means a person who receives laboratory services offered by the Authority
3. **ISO/IEC**: International Standard Organization/ International Electrotechnical Commission
4. **OOS:** Out of Specifications
5. **PMS:** Post Market Surveillance
6. **Post marketing surveillance programme** means a programme for sampling and testing selected medical products to assess their quality after marketing authorization
7. **PT:** Proficiency Testing
8. **QCL**: Quality Control Laboratory
9. **Rwanda FDA:** Rwanda Foods and Drugs Authority
10. **Sample** means a portion of a material or product collected for testing according to a defined sampling procedure.
11. **Specifications** means a list of tests, references to analytical procedures and appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described
12. **Sub-contracting** means the process of entering a contractual agreement with a third party laboratory to perform analysis of products on behalf of the Authority
13. **Turnaround time:** is the time interval from sample submission to the time of release of test results.
14. **WHO**: World Health Organization

CHAPTER II: POWERS OF THE AUTHORITY IN LABORATORY ANALYSIS

Article 5: General Power

Subject to the provisions of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA, Quality Control Laboratory shall have powers to conduct laboratory analysis and issue test results of all regulated products.

Article 6: Power of authority to analyse regulated products

For the purposes of analysing regulated products, the Authority shall:

i) Take samples of regulated products as specified in the Article 3 of the law N° 003/2018 of 09/02/2018 establishing Rwanda FDA
ii) Sub-contract testing of regulated product samples when need arise
iii) Validate methods of analysis of products
iv) Offer training services on laboratory analytical techniques to industry experts, students, institutions and other stakeholders from within or outside Rwanda.
v) Issue certificate of Analysis

Article 7: Reliance

1. Subject to the article 8 paragraph 15 of the law establishing Rwanda FDA, the Quality Control Laboratory may rely or recognize analytical reports from laboratories which are WHO Pre-qualified or ISO/IEC 17025:2017 accredited.
2. The rationale shall be done to optimize innovative and more effective forms of collaboration in order to make the best use of available resources and expertise, avoid duplication in order to ensure the safety, quality and efficacy of locally used products.

Article 8: Testing Function of Quality Control Laboratory

The QCL Division has the following responsibilities:

i) To conduct analysis of regulated products and timely reporting of test results
ii) To maintain laboratory quality management system
iii) To elaborate the list of testing parameters and matrices for accreditation
iv) To plan and participate in PT and evaluate PT results
v) To maintain the equipment maintenance and calibration schedules
vi) To prepare procedures, test methods and standards operating procedures
vii) To perform test methods development, methods validation and estimation of uncertainty budget
viii) To ensure test data obtained from analytical work within the laboratory is secure and confidentiality is maintained

ix) To ensure proper storage of test samples, chemicals and reagents;
x) To ensure documentation of laboratory Standard Operating Procedures (SOPs) and submit them for approval

Article 9: Involvement and Contribution of QCL to other regulatory function

The laboratories shall interact with the different Divisions/Units and support the following key regulatory services of Rwanda FDA:

i) Registration of products (medicines; processed food for humans and animals, food supplements and fortified foods; medicated cosmetics; and medical devices);
ii) Inspection of premises for verification of Good Manufacturing Practices, Good Distribution Practices, Good Laboratory Practices, Good Hygiene Practices, Hazard Analysis Critical Control Point (medicines; processed food for humans and animals, food supplements and fortified foods; cosmetics; and medical devices),
iii) Control of import and export (medicines; processed food for humans and animals, food supplements and fortified foods; cosmetics; and medical devices, tobacco and tobacco products);
iv) Pharmacovigilance (medicines; cosmetics; and medical devices);
v) Safety monitoring for processed food, food supplements and fortified foods, tobacco and tobacco products;
vi) Post-marketing surveillance;
vii) Licensing of facilities (medicines; processed food, food supplements and fortified foods; cosmetics; and medical devices);
viii) Authorization of clinical trials and inspection of clinical trial sites; and
ix) Control of advertisements and promotion materials.

CHAPTER III: CATEGORIES OF SAMPLES

Article 10: Defining samples according to their source

There shall be the following sources of samples to be analyzed at Rwanda FDA laboratories:

i) Port of entry samples
ii) Registration samples
iii) Inspection samples
iv) Post marketing surveillance samples
v) Any other samples as it may be required.

Article 11: Port of entry samples

i) In case of suspicious batches of samples, the same shall be collected by inspectors at ports of entry for testing in the laboratories.
ii) All batches of samples which will fail laboratory testing shall be re-exported back to the country of origin or disposed at the expense of the importer as it may deem fit and as provided for in the Disposal Regulations in force.

Article 12: Registration samples

1. Samples submitted to support marketing authorization applications may be analyzed .
2. Both compendial and non-compendial methods, as appropriate, shall be used when testing samples for registration

Article 13: Inspection samples

In case of any suspicious products samples will be collected from the market during routine inspections including under-seal inspections, premise licensing inspections, awareness inspections, and shall be screened using minilab kits, scanners or any other instruments followed by confirmatory testing, where appropriate.

Article 14: PMS samples

Samples collected from the market through post marketing surveillance programme shall be screened using minilab kits, scanners or any other devices and tested in the laboratories to confirm their conformity to specifications.

Article 15: Controlled drugs samples

Samples of narcotic and psychotropic substances shall be recorded in a separate register and tested like other regulated products and each unit shall be reconciled at each stage of analysis including its final disposal.

CHAPTER IV: SAMPLE SUBMISSION AND TESTING

Article 16: Submission of Sample

1. Samples submitted for testing at Rwanda FDA laboratories shall be accompanied by the following:
   i) Dully filled test request form clearly indicating the parameters to be tested
   ii) Physical samples in their original containers
   iii) The minimum number of units to be submitted for testing depending on the nature of the medicinal product and medical devices or diagnostics is as prescribed in Appendix II and appendix III respectively
2. Samples submitted for testing shall have a remaining shelf life that is two times the turnaround time indicated on test request form.

Article 17: Receipt of samples

The Authority takes the following steps upon receiving the samples:

1. The Authority shall receive samples in their original containers and which have not been tampered with.
2. Upon receipt of samples the Authority shall verify the physical appearance and completeness of test request forms (appendix I)
3. Samples submitted shall be recorded in the sample receiving register.

Article 18: Handling of samples

1. Samples received shall be stored in accordance with the manufacturer's instructions as mentioned on the product sample.
2. In assigning samples for analysis measures shall be taken by the Authority to blind analysts to avoid testing bias.
3. In handling of samples during analysis, preservation and storage conditions of samples at all stages shall be maintained by the Authority.

Article 19: Testing of sample

1. Analysts shall ensure that assigned samples are tested as per agreed analytical methods.
2. When testing samples all measures must be taken to ensure that all methods including equipment have been calibrated, verified and validated as appropriate, for the intended purpose.

Article 20: Out of Specification/trend results

1. When a doubtful result (suspected OOS result) has been identified, QCL shall review different procedures applied during the testing before retesting is permitted.

2. The following steps should be followed:

   i) confirm with the analyst or technician that the appropriate procedure(s) was (were) applied and followed correctly
   ii) Examine the raw data to identify possible discrepancies;
   iii) Check all calculations
   iv) Check that the equipment used was qualified and calibrated, and that system suitability tests were performed and were acceptable
   v) Ensure that the appropriate reagents, solvents and reference substances were used
   vi) Confirm that the correct glassware was used
   vii) Ensure that original sample preparations are not discarded until the investigation is complete.

3. The identification of an error which caused an aberrant result will invalidate the result and a retest of the sample will be necessary.
4. QCL shall develop a detailed procedure for handling OOS results

Article 21: Issuance of certificate of analysis

1. The Quality Control Laboratory shall issue a certificate of analysis to the customer to authenticate that samples were tested and found to either comply or not comply with specifications.

2. The certificate of analysis or testing issued shall be in the format and content as prescribed in appendix VI

Article 22: Laboratory results disputes handling

1. Where there is any objection of laboratory results issued by the Authority, the customer shall submit the complaint to the Rwanda FDA
2. The complaint shall be submitted in a written notice within 14 days from the date of receipt of the results.
3. Upon receipt of objection from the customer, the QCL shall review the results and conduct a thorough investigation of the method used for analysis of the sample.
4. When the Authority is satisfied that the issued results were correct, it shall notify the customer within 14 days after completion of the review.
5. When the customer is aggrieved by the decision of the QCL may request to witness the testing of the samples.
6. In witnessing the testing of the samples, the QCL shall conduct the analysis of the samples together with the customer or his representative.
7. If the results are still disputed, an agreement shall be made between the customer and the QCL to send samples to an alternative laboratory for analysis.
8. The cost of analysis shall be borne by the Authority.

9. The QCL in agreement with the customer may re-sample products from the agreed source to avoid any testing bias.
10. In case of contradicting results between the QCL and the contracted laboratory, an alternative laboratory shall be sought for testing of the samples and the results shall be final.

CHAPTER V: SUB-CONTRACTING TESTING

Article 23: Identifying and selecting testing laboratories

1. The Authority may identify and select third party laboratories for testing of samples when need arise.
2. In selecting such laboratories, the following criteria shall be taken into account
   i) Accreditation status
   ii) Prequalification status
   iii) Laboratories which had complied with prior audit conducted by the Authority
   iv) Desk review of laboratories which complies with quality management system requirements
   v) The cost of analysis of the sub-contracted laboratories.

Article 24: Responsibilities of Rwanda FDA during sub contraction of testing service

1. The responsibilities of Rwanda FDA when subcontracting testing services are as follow:

i) The Authority shall obtain a written consent from the customer before sub-contracting samples for analysis, the subcontracting acceptance form (appendix IV) shall be used.

ii) The Authority shall enter into written agreement with the sub-contracting laboratories before sending samples for analysis in this case sample sub contraction form (Appendix V) shall be used

iii) The terms and conditions of the contract including the format to be used shall be specified by the Authority.

iv) When sending samples to the sub-contracting laboratories for analysis, the Authority shall take all measures to ensure that the samples remain intact and in acceptable integrity

v) The cost of sample transportation shall be borne by the Authority

vi) The Authority shall review results obtained from the sub-contracting laboratories for any discrepancies and if all parameters have been tested as agreed

vii) Upon satisfaction of the results, the Authority shall issue a certificate of analysis to the customer who submitted the product sample

viii) The Authority shall be accountable for results obtained from the sub-contacting laboratories.

ix) The Authority makes sure that the subcontracted laboratory signs the confidentiality and declaration of interest form before testing the subcontracted sample.

CHAPTER VI: DISPOSAL OF SAMPLES AND WASTE

Article 25: Disposal of samples analysed

1. All samples analysed in all Rwanda FDA laboratories shall be disposed in accordance with the procedure in place
2. Disposal of samples under these Regulations, shall comply with the Environmental Management law in force.

Article 26: Disposal of biological and chemical wastes

1. All hazardous substances and agents including biological and chemical wastes shall be identified, labelled as such and properly stored by the Authority before disposal
2. In handling such wastes, precautionary measures shall be taken by the laboratory staff to avoid any cross-contamination that might lead to health hazards.
3. The Authority may enter into agreement with companies approved by the institution responsible for environmental management to dispose wastes.

Article 27: Disposal of controlled drug samples

1. Disposal of controlled drug samples shall be reconciled by taking into account the following:
   i) Number of samples received
   ii) Number of units subjected into analysis
   iii) Number of units and empties remaining after analysis
   iv) Number of units disposed.

2. All records related to disposal of controlled drug samples shall be maintained to allow for audit by any relevant authorities.

CHAPTER VII: NATIONAL AND INTERNATIONAL COLLABORATIONS

Article 28: National Collaboration

1. Subject to the law N° 003/2018 of 09/02/2018 establishing Rwanda FDA article 8 paragraph 15 regarding building cooperation and partnership, Rwanda FDA Quality Control Laboratory, may as far as practicable, maintain a system of consultation and cooperation with other laboratory established by or under any other written laws.

Article 29: International Collaboration

1. The Authority may cooperate with regional and international laboratories on matters related to analysis of products regulated by Rwanda FDA.
2. The Authority may collect and share laboratory results for products that pose public health risks with other bodies at regional and international levels.

Article 30: Harmonization of laboratory requirements

The Rwanda FDA Quality Control Laboratory may participate in regional and international laboratory harmonization initiatives that aim at:

i) Harmonizing systems for analysis of products, quality management, information management and any other laboratory activities as may be appropriate;
ii) Providing for the recognition of regional, continental and other international technical laboratory guidelines;
iii) Participating in intra and inter laboratory proficiency testing schemes
iv) Participating in post-marketing surveillance activities
v) Establishing networks with other laboratories and collaborate in protecting public health.

CHAPTER VIII: CONFIDENTIALITY OF DATA AND RECORD KEEPING

Article 31: Confidentiality

1. All data generated in the laboratory including results of analysis shall be treated as confidential information.
2. All staff working in the laboratory shall sign a confidentiality agreement form issued by the Authority.
3. Disclosure of any confidential information by the Authority shall only be made upon order of the court or any other lawful directive.

Article 32: Electronic data management

1. The Authority shall maintain an electronic data management system to allow for safe custody of data generated in the laboratory.
2. Access to the electronic data management system shall be controlled through use of individual username and password.

Article 33: Archiving and record keeping

1. The Authority shall keep and maintain laboratory records to allow for traceability and reproducibility of results.
2. The records referred to in sub clause (1), shall include but not limited to the following:
   i) Test request forms
   ii) Analytical test report
   iii) Certificates of analysis
   iv) Sub-contracting customer request form
   v) Sub-contracting agreements
   vi) Procurement and supplies records
   vii) Equipment calibration and preventive maintenance records
   viii) Environmental monitoring records
   ix) Disposal records
   x) Training records
   xi) Out of specification records
   xii) Workbook/worksheet
   xiii) Any other records as it may deem necessary.
3. All electronic and paper based records except training records shall be retained for a period of 5 years before disposal

CHAPTER IX: FINAL PROVISION

Article 34: Commencement

This regulation shall enter into force on date of its signature and publication.

APPENDICES:

Appendix I: Test Request form

Document type: Form		Doc. Number :	QCL / FOM /051
RWANDA FDA Rwanda Food and Drugs Authority	**Title:** Sample Sub-contraction Form	Revision Number	: 1
		Revision Date	: 14 June 2021
		Effective Date	: 14 June 2021

1. Name of the product: .....
2. Size of the submitted sample: .....
3. File reference number: .....
4. Labelling/identification:
   Description: .....
   .....
   .....
   Lot No: .....
   Man. Date: .....
   Expiry date: .....
5. Physical condition of the sample upon arrival:
   State: Frozen, chilled, Room temperature
   Packaging: Sealed, Unsealed, Damaged, Un-damaged
   General appearance: Good, Poor
6. Ref. standard specification:
   .....
7. Parameters to be tested:
   .....
   .....
   .....
   .....
   .....
   .....
   .....
8. Recommended storage temperature:
   .....
9. Details of sample:
   Place/Country of origin:
   .....
   Exact point source: .....
10. Customs entry number: .....
11. Customer release order number:
    .....
12. State of the source:
    Frozen, chilled, room temperature
13. Subcontracted by:
    .....
    Sent by: .....
    Signature: .....
    Date &time of submission: .....
14. Rwanda FDA Number: .....
15. Subcontractor
    Name: .....
    Address: .....
16. Sender details
    Name: .....
    Company: .....
    Designation: .....
    Address: .....
17. Courier: .....
    .....
    Address: .....
    Date and time of sample receipt:
    .....
    Courier track No:
    .....

    Signature: .....
18. Remarks:

Appendix II: Minimum number of units required for chemical and microbiological testing

No.	Formulation	Pack Size	Minimum Sample Submission
1.	Injectables	≤ 10 mL 10 - 100mL 100 - 2000ml	30 vials/ampoules 12 vials/ampoules 6 bottles
2.	Powders for oral suspension	1-50g ≥ 50g	30 Sachets 15 Sachets
3.	Eye or ear drops	< 10 mL > 10 mL	100 bottles 50 bottles
4.	Tablets or capsules	All	100 tablets/capsules
5.	Suspensions or syrups	≤ 10 mL 10 – 500 mL 500 – 2000 mL	20 bottles 15 bottles 4 bottles
6.	Transdermal patches	5 – 100 g > 100 g	100 sachets 50 sachets
7.	Sprays or inhalers	All	10 Packs
8.	Creams, emulsions or gels	< 5 g 5 – 50 g > 50 g	20 tubes 10 tubes 5 tubes
9.	Disinfectants or antiseptics	< 50 mL 50 – 250 mL 500-1000 mL 5000 mL	8 bottles 4 bottles 2 bottles 1 bottle
10.	Active Pharmaceutical Ingredient (s)	Solids Liquids	5 g 1000 mL

Appendix III: **Minimum number of units required for medical devices and diagnostics testing**

No.	Product	Pack Size	Minimum Sample Submission
11.	MRDT Test Kit	20 – 25 tests	4 kits
12.	HIV Test Kit	20 – 25 tests	4 kits
13.	Urine Pregnancy Test (UPT) Kit	25 tests	4 kits
		50 tests	2 kits
14.	Absorbable surgical sutures	All	20 units
15.	Male condoms	All	144 units
16.	Female condoms	All	144 units
17.	Surgical sutures	10 – 20	13 units
18.	Surgical blades	All	9 units
19.	Cotton wool	Rolls	2 rolls
20.	Surgical gloves	100/box	213 units
21.	Examination gloves	100/box	213 units
22.	Baby diapers and pads	All	20 units
23.	Absorbent gauze	All	1 roll
24.	Absorbent cotton	All	9 units
25.	Absorbent viscose wadding (bandage)	All	9 units
26.	Needles & syringes	50 pcs	1 box
27.	Plaster of Paris and zinc oxide	All	6 units
28.	Face mask	All	5 units

Appendix IV: Subcontracting Acceptance form

Document type: Form		Doc. Number : QCL / FOM /048
RWANDA FDA Rwanda Food and Drugs Authority	**Title:** Subcontracting Acceptance Form	Revision Number : 1 Revision Date : 01 June 2021 Effective Date : 14 June 2021

I ……....., on behalf of ……
……...

For which I am employed as ……
……

Hereby authorize Rwanda FDA/QCL to sub-contract my sample(s);

Sample description:

Rwanda FDA number:

To (Name of subcontracted laboratory)……..

Signature ……..… Date ……

Rwanda FDA/QCL use only

Reasons for subcontracting ……
……..
……..
Any action(s) to limit subcontracting ……

Appendix V: Sample sub-contraction Form

Document type: Form		Doc. Number :	QCL / FOM /051
RWANDA FDA Rwanda Food and Drugs Authority	**Title:** Sample Sub-contraction Form	Revision Number	: 1
		Revision Date	: 14 June 2021
		Effective Date	: 14 June 2021

1. Name of the product: .....
2. Size of the submitted sample: .....
3. File reference number: .....
4. Labelling/identification:
   Description: .....
   .....
   .....
   Lot No: .....
   Man. Date: .....
   Expiry date: .....
5. Physical condition of the sample upon arrival:
   State: Frozen, chilled, Room temperature
   Packaging: Sealed, Unsealed, Damaged, Un-damaged
   General appearance: Good, Poor
6. Ref. standard specification:
   .....
7. Parameters to be tested:
   .....
   .....
   .....
   .....
   .....
   .....
   .....
8. Recommended storage temperature:
   .....
9. Details of sample:
   Place/Country of origin:
   .....
   Exact point source: .....
10. Customs entry number: .....
11. Customer release order number:
    .....
12. State of the source:
    Frozen, chilled, room temperature
13. Subcontracted by:
    .....
    Sent by: .....
    Signature: .....
    Date &time of submission: .....
14. Rwanda FDA Number: .....
15. Subcontractor
    Name: .....
    Address: .....
16. Sender details
    Name: .....
    Company: .....
    Designation: .....
    Address: .....
17. Courier: .....
    .....
    Address: .....
    Date and time of sample receipt:
    .....
    Courier track No:
    .....

    Signature: .....
18. Remarks:

Appendix VI: Certificate of Analysis

CERTIFICATEN°: FDA/xxx/yyyy
DOC N°: QCL/FOM/003

RWANDA FDA
Rwanda Food and Drugs Authority

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/NNNN/MM/YYY	**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:	**Verified by**	**Approved by**
……..	……..	……
Laboratory Officer	Director of Unit	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

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