RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR LOT RELEASE OF VACCINES AND OTHER BIOLOGICAL PRODUCTS

OCTOBER, 2022

Doc. No.: QCL/GDL/001	Revision Date: 12/10/2022	Review Due Date: 14/10/2025
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FOREWORD

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 this guideline N° QCL/GDL/001 Rev.0 for lot release of vaccines and other biological products, made on this 14/10/2022.

Considering the provisions of the technical regulations No QCL/TRG/002 Rev_0 governing lot release of vaccines and other biological products, and other relevant regulations the authority shall develop guidelines for lot release of vaccine and other biological products.

In accordance with WHO guidelines for independent lot release of vaccines by regulatory authorities, each batch of human vaccines and other biological products, and each batch of medicinal product derived from human blood or human plasma shall be examined by a national control laboratory prior to placing it on the market. The national control laboratory must declare that the batch in question is in compliance with the approved specifications laid down in the Marketing Authorization.

Dr Emile BIENVENU
Director General

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GUIDELINES DEVELOPMENT HISTORY

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DOCUMENT REVISION HISTORY

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14/10/2022	0	First issue

TABLE OF CONTENTS

ACCRONYMES AND ABBREVIATIONS

Rwanda FDA	Rwanda Food and Drugs Authority
GMP	Good Manufacturing Practices
HCR	Holder of the Certificate of Registration
ISO	International Organization for Standardization
QCL	Quality Control Laboratory
NRA	National Regulatory Authority
OOS	Out of specification
PMS	Post-marketing surveillance
NCL	National Control Laboratory
MAH	Marketing Authorization Holder
EDQM	European Directorate for the Quality of Medicines
OCABR	Official Control Authority Batch Release
VAR	Vaccine arrival report
WHO	World Health Organization
WHO- NNB	WHO National Control Laboratory Network for Biologicals

GLOSSARY / DEFINITIONS

First release: the first lot release issued for a final labelled lot.

Further release: the case where additional consignments of a vaccine previously released by Rwanda FDA are imported for lot release, and the final primary container lot number and expiry date are identical to that previously released by Rwanda FDA.

Local manufacture: a process that includes the formulation of the drug product and/or filling of a primary container.

Lot: a defined quantity of starting material, packaging material or product, processed in a single process or series of processes so that the quantity is expected to be homogeneous. The lot size can be defined either as a fixed quantity or as the amount produced in a fixed time period.

Lot release: the process of NRA/NCL evaluation of an individual lot of a licensed vaccine before giving approval for its release to the market.

Marketing Authorization Holder (MAH): a person or legal entity in whose name a registration certificate has been granted and who is responsible for all aspects of the vaccine/medicines, including quality, safety and compliance with conditions of registrations.

Out of specification (OOS): an OOS result is generated when a vaccine is tested and fails to meet a predefined registered specification.

Product Labelling Information: Printed materials that accompany a prescription medicine and refers to all labelling items such as medicines and related substances.

Application for registration: A formal application to Rwanda FDA for approval to register and market a new medicine/vaccine. The purpose of the application is to determine whether the medicine/vaccine meets the statutory standards for safety, effectiveness, product labelling information, chemistry, manufacturing and control.

Responsible NRA/NCL: the NRA/NCL taking responsibility for regulatory oversight of a product with regard to the critical regulatory functions defined by WHO, including independent lot release. The responsible NRA/NCL is usually that of the country of manufacture unless specific agreements exist within defined territories, such as in the European Union, where the "country" of manufacture is the European Union and the activity of the responsible NRA/NCL is designated among member states.

Specification: A list of tests, references to analytical procedures, and appropriate acceptance criteria, which are numerical limits, ranges or other criteria for the tests described in the marketing authorisation dossier. Specifications are critical quality standards proposed and justified by the manufacturer and approved by the regulatory authorities.

Summary protocol: also called "lot summary protocol", is a document summarising all manufacturing steps and test results for a lot of vaccines, which is certified and signed by the responsible person of the manufacturing company.

Vaccine: Preparations containing antigens capable of specific and active immunity in humans against an infectious agent or toxin.

1. INTRODUCTION

The lot release of human vaccines is performed in compliance with the WHO guidelines for independent lot release of vaccines by regulatory authorities.

Vaccines are biological products used in healthy populations, and the impact of using substandard lots may not be known for a very long time (years). Similarly, safety issues with a particular lot may not be known immediately (within a few hours) after administration, and there could be a drastic impact if a large number of healthy persons receive unsafe vaccines to prevent infection or minimize disease severity. For these reasons, a careful independent review of manufacturing and quality control data on every lot is necessary before it is marketed.

The lot release of vaccines by regulatory authorities is part of the regulation of vaccines and involves the independent assessment of each lot of a licensed vaccine before it is released onto the market. This assessment is based, as a minimum, on the review of manufacturers' summary protocols. It may be supplemented by other documents such as the release certificate from the responsible national regulatory authority (NRA) or national control laboratory (NCL) and, in some circumstances, by testing that is independent of the manufacturers' quality-control testing.

2. SCOPE

This guideline focuses on vaccines registered for human use and vaccines supplied. The guideline is intended to provide guidance to the holder of the certificate of registration (HCR) and vaccine suppliers on the requirements and administrative procedures to be followed for lot release. It may also be relevant to public health authorities, such as a national immunisation programme.

3. LOT RELEASE

3.1. LOT RELEASE PATHWAYS

Rwanda FDA currently makes provision for two lot release pathways which can include expedited release and the parallel testing procedure:

3.2. First release

In the case where a vaccine lot is submitted to Rwanda FDA for the first time, a full lot release is performed consisting of a review of the manufacturers lot summary protocol, review of the cold chain data for the shipment/s, review of the product labelling information and possible selected independent retesting. A first lot release certificate is issued for a final labelled lot. The first lot release is subject to payment of a lot release fee to Rwanda FDA.

3.3. Further release

If additional consignments of a vaccine previously released by Rwanda FDA are imported and where the final labelled primary container lot number and expiry date is identical to that previously released, a further lot release is issued. The further lot release process is limited to

reviewing the cold chain data for the shipment/s and a review of the product secondary packaging labelling information (if different from the first release). A further lot release certificate is issued for a final labelled primary container lot with the same lot number and expiry date.

3.4. Summary protocol review

Manufacturers' summary protocols summarise information taken from the production and test records, according to GMP requirements, to ensure that the lot meets the specifications in the product registration dossier. In addition, summary protocols submitted to the quality control laboratory should be approved by the person designated as responsible for quality assurance or quality control of the manufacturer. In general, the format and content of the protocol are finalised and approved by the NRA/NCL during the review of the license application. The format of the protocol should be amended in response to changes in the approved production process and should be approved by the NRA/NCL.

The lot summary protocol submitted by the MAH for review should therefore reflect all appropriate production steps and controls as outlined in the registration dossier for the product. Rwanda FDA will accept manufacturer summary protocols compiled to comply with an EDQM OCABR model protocol format (https://www.edqm.eu/en/human-ocabr-guidelines) or a WHO-recommended format. The MAH must notify the quality control laboratory of any approved amendments relevant to the lot under review at the time of submission.

An independent review of critical data from each lot of vaccine and other biological products is essential to:

a. assure the consistency of quality of each manufactured lot;
b. obtain confidence in the claimed strength of active components;
c. assess the validity and accuracy of the tests performed.

This review encompasses the traceability of critical source materials, active and critical components used in the manufacture of the product, and the results from tests performed by the manufacturer at various stages of production, including tests performed on critical components, intermediates, final bulk and final product.

3.5. Independent testing

Rwanda FDA applies a risk-based testing policy to reduce redundant testing and promote reliance between releasing authorities. However, the risk-based approach must still guarantee that Rwanda FDA meets its obligation, which is to ensure the safety and quality of all released vaccine and other biological products lots, i.e., imported and locally manufactured. As far as practically possible, the same methods, equipment, reagents, and reference standards used by the manufacturer are used in the tests to ensure comparability of test results.

It is the responsibility of the MAH to facilitate technology transfer to the Rwanda FDA quality control laboratory if required for lot release testing or post-marketing surveillance (PMS). It is recommended that the proposed MAH engages with the Rwanda quality control laboratory during the registration application process to determine the need to transfer analytical methods.

Rwanda FDA strives to align itself with the current best international practice for lot release and, as such, adopted the testing scope for final containers as detailed in the EDQM OCABR product- specific guidelines (https://www.edqm.eu/en/human-ocabr-guidelines).

3.6. Parallel testing procedure

The MAH of a locally manufactured vaccine can request lot release testing through the Parallel Testing Procedure. In this case, the QCL will start independent testing before the manufacturer's Quality Control has completed the analytical testing on the finished product. The request for parallel testing must be indicated on the application form for lot release. Labelled samples must be submitted to the Rwanda FDA Quality Control Laboratory, and the approved lot summary protocol is then sent to the Quality Control Laboratory at the completion of the tests by the Quality Control Laboratory from the manufacturer.

Rwanda FDA will only issue a lot release certificate after testing the samples and reviewing the lot summary protocol completed by the Rwanda FDA Quality Control Laboratory.

Should the MA want to withdraw the lot during the parallel testing procedure due to non-compliance with the specifications during the analytical testing or any other reason, Rwanda FDA Quality Control Laboratory must be notified, and the procedure is stopped.

3.7. Reliance

The requirement for routine independent lot release testing will be based on a risk assessment and whether reliance can be applied. The risk assessment considers the post-marketing experience related to the safety and quality of the product. Reliance on some or all tests or reduced independent testing may be considered subject to the availability of a lot release certificate issued by a releasing NCL that is a full member of the WHO National Control Laboratory Network for Biologicals (WHO- NNB) or a National Regulatory Authority (NRA) with which Rwanda FDA is aligned, and the outcome of the risk assessment.

3.8. Cold chain review

The Rwanda FDA Quality Control Laboratory reviews the integrity of the cold chain for all vaccine shipments to Rwanda. A vaccine arrival report (VAR) must be submitted to the Rwanda FDA Quality Control Laboratory for each lot and shipment to be released, and must comply with the format requirements. The MAH should provide the Rwanda FDA Quality Control Laboratory with validated transport stability data that would support transport temperature guidelines. Note: Containers in which the temperature monitoring

devices have malfunctioned or have been omitted must be separated from the rest of the consignment. Rwanda FDA Quality Control Laboratory will not release the vaccines in these containers unless proof can be provided that all the shippers were transported as a unit until unpacking by the recipient (e.g., cling-wrapped on a pallet), as consignment homogeneity cannot be guaranteed.

3.9. Product labelling information review

The Rwanda FDA Quality Control Laboratory also reviews the printed materials that accompany the vaccine batch to ensure that all labelling items comply with the relevant regulations. In the case where Rwanda FDA granted an exemption from these conditions, the approval letter must be submitted to the Rwanda FDA Quality Control Laboratory.

3.10. Evaluation of the lot and the decision-making process

If a vaccine lot conforms with the release requirements, the Rwanda FDA will notify the MAH by email and provide an electronic copy of the lot release certificate.

If a vaccine lot does not conform to the release requirements due to an out of specification (OOS) test result, and after investigation, a quality defect is confirmed, a rejection note is issued to the MA with the instruction to destroy the lot and to provide a copy of the destruction certificate to the Rwanda FDA.

Prior to issuing a destruction note, however, the Rwanda FDA will engage with the MA and the manufacturers Quality Control Laboratory to investigate the cause of the out of specification (OOS) test result. If the quality defect is confirmed after the investigation, a report will be compiled and submitted to Rwanda FDA with a recommendation for rejection of the lot.

In the case where there is evidence that the cold chain of a shipment or part of a shipment was not adequately maintained or controlled, and the temperature deviation impacted the quality of the product, the affected doses will not be released. The MAH will be instructed with the instruction to destroy the affected doses and provide a copy of the destruction certificate to the Rwanda FDA.

3.11. Expedited release process

Under exceptional circumstances, e.g., an emergency situation or a critical vaccine or other biological product stock shortage, the lot release for a particular lot can be prioritised and expedited, but will at a minimum still include a review of the manufactures lot summary protocol, review of the cold chain data for the shipment/s, and review of the product labelling information. However, an expedited release is subject to the availability of a lot release certificate issued by the responsible NCL. A request for expedited release must be submitted to Rwanda FDA. The applicant will therefore submit a request for expedited review to Rwanda FDA with adequate motivation and communication subject expedited

release request in case the expedited review is approved by Rwanda FDA to expedite the review process.

3.12. Lot release fees

Rwanda FDA requires payment of a lot release fees for the first release of each vaccine final lot. The release fees must be paid directly to the Rwanda FDA account, and proof of payment must be sent to Rwanda FDA. It is important that the MAH use the appropriate reference (i.e., product name, registration number and the final lot number) which reflects the payment advice. This is a requirement to ensure traceability for audit purposes. Please consult the regulation related to regulatory services tariff fees and fines to Rwanda FDA.

4. REQUIREMENTS AND ADMINISTRATIVE PROCEDURE FOR LOT RELEASE SUBMISSION

4.1. Application for lot release

A completed application form for lot release based on Rwanda FDA requirements must be signed, dated and submitted to Rwanda FDA Quality Control Laboratory and the notification of proof of payment submitted to info@rwandafda.gov.rw.

4.2. Submission of lot release applications

Naming the folders that will contains the lot release application files should follow the below naming conversion, or naming format:

MAH _LOTRL- App No- BatchNo

Example of how the file might look like using the above format **Biopharma_ LOTRL_2043-01**

Where:

MAH_LOTRL _: Marketing authorization holder name Lots Release

AppNo – Application number

BatchNo – Batch Number

Should there be corrections or follow-up documents on the same QCL LOTS RELEASE APPLICATION, the following format must be followed in the previous folder name please add -1 when you resubmit for the first time, and -2, for the second time, and so forth.

The folder should look like below example, for the first resubmission LOTRL-2043-01-1

4.3. Samples

The following amount of samples must be supplied to the Rwanda FDA Quality Control Laboratory for each lot to be released:

a. For imported vaccines, thirty (30) vials/syringes of the single or multi-dose final container;
b. For locally manufactured vaccines forty (40) vials/syringes of the single or multi-dose final container per sampling point;

c. For BCG culture, four (4) vials of the final container;
d. If more than the required containers are sent to the Rwanda FDA Quality Control Laboratory, the excess containers cannot be returned;
e. Samples should be sent at the correct transport temperatures to the Rwanda FDA Quality Control Laboratory. Appropriate cold chain monitor(s) must accompany each consignment of vaccine samples to the Rwanda FDA Quality Control Laboratory. Samples received without monitor(s) or with alarmed monitors will not be accepted and will be destroyed. Replacement samples will need to be provided;
f. Rwanda FDA Quality Control Laboratory will receive samples from Monday to Friday during office hours (08:00 to 17:00);
g. Final labelled and packaged containers are preferred for testing;
h. For the parallel testing procedure and under exceptional circumstances and with good motivation, final labelled containers without packaging are also accepted;
i. Provisionally labelled containers will be accepted, provided that this is pre-arranged with the Division Manager of the Rwanda FDA Quality Control Laboratory;
j. A lot release certificate will only be issued once proof of final packaging and labelling has been provided.

4.3.1. Sampling shall be performed as follows:

a. Quarantined shippers, i.e., where a temperature excursion has occurred, must not be sampled;
b. The samples taken must represent the commercial consignment as far as practically possible, i.e., sampled from different shippers at different locations. The Rwanda FDA Quality Control Laboratory acknowledges that the sampling procedure could be constrained due to different shipping configurations;
c. Clearly indicate on the receiving documents from which shipper(s) sampling was performed;
d. If resampling is required for retesting, the Rwanda FDA Quality Control Laboratory will provide guidance on which shippers must be sampled;
e. For locally manufactured lots, samples must be taken from three sampling points, i.e., from the beginning, middle, and end of the filling run. Containers should be clearly labelled to distinguish from which part of the filling run the samples originate. The MAH will be informed by Rwanda FDA Quality Control Laboratory, of any change/reduction of the number of samples and sampling points subject to sufficient data confirming the consistency of production.

4.3.2. Documentation submission

All lot release documentation must be uploaded to the Rwanda FDA information system. Document names should include the type of vaccine, the corresponding batch no. and a short description without special characters.

4.3.3. Lot summary release protocol submission

4.3.3.1. Lot summary protocols (not certificates of analysis) must accompany each lot. Electronic copies must be sent before or at the time of sample submission;

4.3.3.2. The lot release certificate from the releasing NRA must be included. Where possible, it should be accompanied by the respective test report;

4.3.3.3. File names must contain the vaccine name and lot number (e.g., vaccine_ABC_123_protocol.pdf). Spaces or special characters in file names should be avoided;

4.3.3.4. Testing will not commence until both the samples and protocols have been received, except for the case of the parallel testing procedure.

4.3.4. Proof of cold chain integrity

A vaccine arrival report (VAR) must be submitted to the Rwanda FDA Quality Control Laboratory for each lot to be released. In those instances, where a lot is imported in multiple shipments, each shipment's documentation must be clearly distinguished. This report must include the following:

a. The product name and lot number must be clearly visible on all documents;
b. The date, time and location of dispatch and receipt of shipment;
c. A copy of the air waybill;
d. The quantity per shipment;
e. A packing list indicating the number of containers/shippers per shipment and the number of doses per container/shipper;
f. A temperature monitor check sheet indicating the number of temperature devices per container/shipper, serial number, location [e.g., inside (top or bottom) or outside the container], and status of each temperature monitor, i.e., a temperature excursion noted or whether it malfunctioned or not. Freeze tag information should be provided in instances where vaccines are not allowed to freeze;
g. The vaccine lot number and the number of the container/shipper must be clearly indicated on the document displaying the temperature monitor data. Alternatively, supporting documentation must be attached showing the serial numbers of electronic monitors used in each shipper/container of the shipment;
h. Raw data from electronic temperature monitoring devices (including QTag WHO Type 1 monitors) is required, except for devices where a summary is automatically generated. In these cases, the summary is preferred;
i. File names must contain the vaccine name and lot number (e.g., vaccine_ABC123_VAR.pdf, Vaccine_ABC123_AWB.pdf, etc.);
j. Collate all the documents for a shipment and verify that it is complete before uploading to the Rwanda FDA information system.

4.3.5. Proof of payment of the lot release

4.3.5.1. Proof of payment must be sent to the- Rwanda FDA Quality Control Laboratory.

4.3.5.2. No release certificate will be issued without proof of payment.

4.3.6. Acknowledgement of the receipt

4.3.6.1. The Rwanda FDA Quality Control Laboratory will acknowledge receipt of samples and or documentation confirming that they are for a first or further release;

4.3.6.2. It is the responsibility of the MAH to inform the Rwanda FDA Quality Control Laboratory who should be on the mailing list and receive the acknowledgement of receipt for samples and documentation;

4.3.6.3. The MAH is advised to follow up with the Rwanda FDA Quality Control Laboratory if an acknowledgement of receipt has not been received within two (2) working days.

4.3.7. Further lot release

4.3.7.1. If consignments with the identical final labelled primary container lot (including identical expiration dates) are imported after the release of the first consignment/s, it is regarded as a further lot release;

4.3.7.2. A vaccine arrival report (VAR) and proof of secondary packaging is required;

4.3.7.3. A copy of the lot summary protocol as detailed in section 4.4 is required;

4.3.7.4. Clearly indicate in the application form for lot release to Rwanda FDA Quality Control Laboratory if it is a further lot release and provide the first lot release certificate number (if already available);

4.3.7.5. A lot release performed through the further release process will be processed within five (5) working days.

4.3.8. Lead times

4.3.8.1. Rwanda FDA Quality Control Laboratory must maintain impartiality at all times. The vaccine lot release process will be performed on a "first in, first out" basis with strict adherence to lead times. In the case of an unexpected delay due to retesting or delays in the availability of reference materials, delays will be communicated to the MAH.

4.3.8.2. The lead time is determined by the nature and scope of independent testing required. The lead time will be communicated to the MAH at the time of product licensing. The lead time countdown will start once the lot release application form, samples and a complete summary protocol have been received by the Rwanda FDA Quality Control Laboratory;

4.3.8.3. For the parallel testing procedure, the lead time is five (5) working days after receipt of the approved lot summary protocol;

4.3.8.4. It remains the MAH's responsibility to keep a record of all samples and information submitted to the Rwanda FDA Quality Control Laboratory. The vaccine arrival report

and/or final proof of packaging/labelling can be submitted later, but this will result in the lead time extension of five (5) working days after receipt;

4.3.8.5. Lead times have been approved by Rwanda FDA Quality Control Laboratory and will be shortened only under exceptional circumstances.

ENDORSEMENT OF THE GUIDELINES

	Author	**Checked by**	**Approved by**
Title	**Division manager**	**Quality Assurance Analyst**	**Director General**
Names	**Ass. Prof. MUGANGA Raymond**	**NDAYAMBAJE Theogene**	**Dr. Emile BIENVENU**
Signature			
Date	13/10/2022	14/10/2022	14/10/2022

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APPENDICES

Appendix 1: Lot release request form

Format: QMS/FMT/002 Revision No: 1	Department/Division/Office/Unit	Quality Control Laboratory
Document Type: **Form**		Doc. No : QCL/FOM/059 Revision Number : 0 Revision Date : 10/10/2022 Effective Date : 15/10/2022 Review Due Date : 15/10/2023
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Lot Release Request Form**	

To: Rwanda FDA Quality Control Laboratory
Rwanda Food and Drugs Authority
Nyarutarama Plaza, KG 9 Avenue
KIGALI

Reference No. _____
Date: _____

Please issue the lot release certificate in respect of vaccines and other biological products as detailed below. All the required documents are enclosed along with.

1. Importer/ manufacturer details	
Name and address of the importer/manufacturer	
Commercial invoice No.	
Invoice date	
Shipment reception date	
Date of endorsement of invoice	
Shipment mod	
Port of shipment reception	
Name and address of the indent holder (if applicable)	
2. Product details	
Product bland name	
Product generic name	
Registration No.	
Lot No.	
Manufacturing date (dd/mm/yyyy)	
Expiry date (dd/mm/yyyy)	
Storage temp	
Transportation temp.	

Name and address of the manufacturer	
Pharmaceutical dosage form	
Type of container	
Number of doses per container	
Strength quantity per container	
Transportation/storage data evidence	
Quantity applied for lot release	

3. Solvent / diluent details (in case of freeze dried product)

Solvent/ diluent name	
Lot No.	
Type of container	
Volume per container	
Registration No.	
Mfg. Date	
Exp. Date	
Name & address of the manufacturer	

4. Lot Release requested by authorized person

Name	
Designation	
Signature	
Date	
Telephone No.	
Cell No.	
Name of the firm / pharmaceutical company	
Complete address	
Official stamp	

5. Required documentation

a. Importing packing list (not applicable to domestic products).
b. Lot Release certificate issued by the health authority/NRA-NCL of country of origin. (Not applicable to domestic products).
c. Drug approval license or a copy of the approval document from the central competent health authority.
d. Documents of the manufacturing processes, testing methods, specifications, and standards of the biologics and related literature.
e. If the documents from the original manufacturer are identical to those being recognized during the previous process of applying for drug approval license, item (4) can be waived.
f. Standard operating procedures (SOP) of source management on animal–derived materials and proof of source of derived materials.
g. Poof of application fees.

6. Applicant confirmation

I hereby declare that I have inspected all batch documents and that the products and its packaging have been manufactured and inspected in accordance with marketing authorization and meet the requirements.

Date	
Name and signature of applicant:	

For Official Use only:

1.	Summary protocol received	□ Yes	□ No
2.	Lot release certificate from NRA of exporting country received (in case of imported products)	□ Yes	□No Exemption Certificate
3.	Batch production record received (for locally manufactured products).	□ Yes	□ No
4.	Copy of the registration letter received.	□ Yes	□ No
5.	Copy of the endorsed paid bank receipt received.	□ Yes	□ No
6.	Copy of endorsed invoice received	□ Yes	□ No

Reception date		Received by (sign)	
Application accepted	□ Yes	Name	
If rejected (reason)		Designation	

Assessment required	□ Summary protocol review	□ Laboratory Access
Assigned reviewer		
Deadline for assessment		

Appendix 2: Lot release certificate format

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Rwanda Food and Drugs Authority

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Revision No: 0
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LOT RELEASE CERTIFICATE

No. RWA-FDA-LRC-XXX

DD, MM., YYYY

The lot referenced below meets the national requirements for lot release and conforms to the approved specifications. The lot has been tested on the basis of critical evaluation of the manufacture's production and control protocols and on the basis of the evaluation of samples at the Rwanda Food and Drug Authority.

1. Product trade name:
2. Product Common name:
3. Lot number appearing on package:
4. Lot manufacturing date:
5. Lot number Expiry date:
6. Number of containers:
7. Number of doses per container:
8. Type of container:
9. Dosage form:
10. Strength of the product:
11. Storage condition:
12. Name and address of manufacturer:

Signed by

Division Manager of Quality Control Laboratory

Under the delegated authority of Director-General

Rwanda Food and Drug Authority
Nyarutarama Plaza, KG 9 Avenue

End of Document