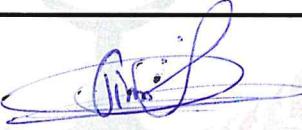
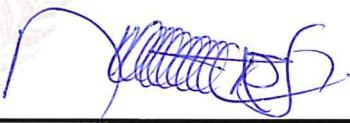


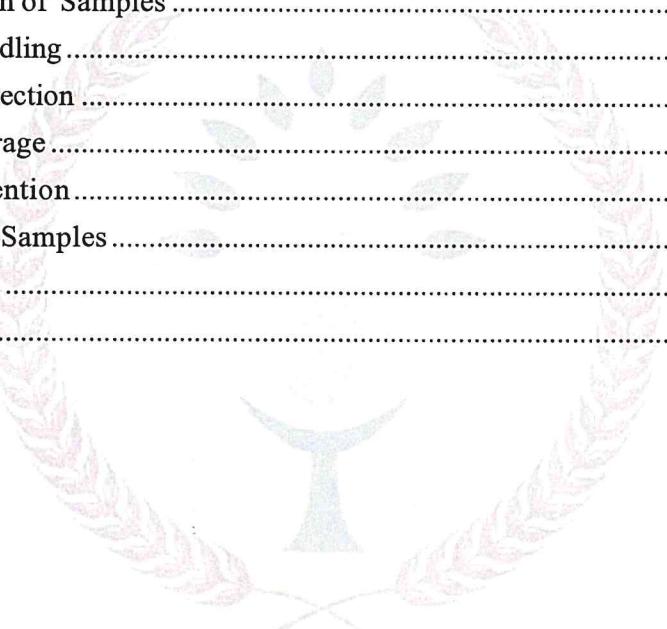
| | | | |
|--|---|--|---|
| Format: QMS/FMT/001 Revision No: 0 Effective Date: 24 Aug 20 | Division | Quality Control Laboratory | |
| Document type: STANDARD OPERATING PROCEDURE | | Doc. Number : QCL / SOP /004 Revision Number : 0 Revision Date : 14 August 2020 Effective Date : 24 August 2020 Review Due Date : 24 August 2022 | |
|  RWANDA FDA <small>Rwanda Food and Drugs Authority</small> | | Title: Handling of Test Items | |
| TITLE | Author Designated QMS Officer | Authorised by Human Medicine Laboratory Officer | Approved by Division Manager |
| NAME | TUYISHIME Felix | UWAMBAJINEZA Tite | MUKUNZI Antoine |
| SIGNATURE |  |  |  |
| DATE | 24 August 2020 | 24/08/2020 | 24/08/2020 |
| INSTRUCTIONS <p style="font-size: small; margin-left: 20px;"> 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. </p> | | | |

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2.0 Purpose

This Standard Operating Procedure describes receipt, handling, protection, storage, retention and disposal or return of test items in Quality Control Laboratory to ensure the accountability, preservation and integrity.

3.0 Scope

This Standard Operating Procedure applies to all samples received in Quality Control Laboratory.

4.0 Policy

4.1 ISO/IEC 17025:2017 Clause 7.4 states that "*The laboratory shall have a procedure for handling test item*".

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 **TRF:** Test Request Form

5.2 **SCC:** Sample Control Center.

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

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

6.0 Responsibility

6.1 Laboratory Officers and laboratory technicians can make rotation for the task of sample reception to implement responsibilities of designated Sample Control Officer; hence there is a sample reception timetable validated by Division Manager;

6.2 Human medicine Laboratory Officer prepare sample reception timetable;

6.3 Responsibilities of designated sample control officer are: reception of incoming samples, registration, distribution, storage of samples and disposal or return of samples;

6.4 Designated Laboratory Officer of Medicine Cosmetics and poison Laboratory and the other from Food Testing Laboratory are responsible to assign Medicated Products and Food samples to analyst.

6.5 The Human Medicine Laboratory officer is responsible to ensure that all received samples are assigned to Laboratory officers and Laboratory Technicians.

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

6.7 The sample assigned analyst is responsible to make follow up of his/her sample turn round time;

6.8 The Human Medicine Laboratory officer 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.

7.0 Distribution

7.1 Division Manager of Quality Control Laboratory

7.2 Designated Quality Management System Officer

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7.3 Laboratory Officers and Technicians

8.0 Safety Precautions

NA

9.0 Procedure

9.1 Receipt of Samples

- 9.1.1 The customer submits a sample to the designated Sample Control Officer with the information of the parameters to be tested.
- 9.1.2 The designated Sample Control Officer checks the physical conditions of the sample as indicated in the Test Request Form (*see Appendix A*).
- 9.1.3 When there is doubt about the suitability of sample, or when sample does not conform to the description provided, the designated Sample Control Officer and the designated Laboratory Officer consults the customer for further instructions before proceeding and record the results of this consultation and the identified deviation on test request form.
- 9.1.4 When the customer requires the sample to be tested as it is, the customer acknowledges the deviation from specified conditions, the designated Sample Control Officer receives the sample and the responsible officer who tested the sample indicates in test report the condition in which the sample was tested and disclaimer that the sample was tested as brought to facilitate the interpreter on possible compromise on the results.
- 9.1.5 The designated Sample Control Officer indicates on the Test Request form the condition of the sample during reception while submitting the sample in relevant Laboratory.
- 9.1.6 The designated Sample Control Officer only accepts the samples of sufficient size for both Laboratory samples and reference samples, in case where the designated Sample Control Officer is not certain on the size of the sample to be submitted for specific test the designated Laboratory Officer is consulted.

9.2 Identification of Samples

- 9.2.1 The designated Sample Control Officer records details of the sample information in the Sample Distribution Register, see Appendix C and in Sample Register **QCL/REG/003 when applicable** (*see Appendix B*)
- 9.2.2 All samples received at Sample Control Center are assigned a unique identification number and labeled as follows: **FDA>NNNN/MM/YYYY**, where: **NNNN** is the serialized number of samples received in the year in four digits; **MM** stands for the month and **YYYY** is the year e.g. FDA/0001/ 01/ 2020.
- 9.2.3 The sample is appropriately labeled or a label affixed on item or tagged with the number generated above or marked by using a permanent marker pen.
- 9.2.4 Only one identification number is assigned to both Laboratory sample and the Reference Sample.

9.3 Sample handling

9.3.1 Sample delivery to the Laboratory

- 9.3.1.1 Depending on the parameters requested designated Sample Control Officer determines

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the routing of the samples in the Laboratory.

- 9.3.1.2 The designated Sample Control Officer submits samples and their corresponding properly filled test request forms to the designated Laboratory Officer.
- 9.3.1.3 To avoid microbiological contamination, if the same submitted samples requires tests of microbiological parameters in addition to physico-chemical parameters, the sample is first submitted into microbiology Laboratory and then transferred to other respective Laboratories after obtaining the appropriate test portion. In this case, designated Sample Control Officer notifies next Lab with sample submission form to prepare for incoming sample.
- 9.3.1.4 The transfer of the sample from one section to another is documented in part 20 of the Test Request form, transfer of the sample is done within two hours after obtaining the test portion.
- 9.3.1.5 The designated Laboratory Officer cross checks the Sample Test request form and the delivered samples to sort out possible discrepancies and acknowledge sample receipt by signing in the sample register (*see Appendix B*).

9.3.2 Samples while in the Laboratory

- 9.3.2.1 The Human Medicine Laboratory Officer ensures that all received samples are assigned to analysts of respective Laboratories.
- 9.3.2.2 The assigned analyst handles and store samples according to pre-determined conditions so as to maintain their integrity.
- 9.3.3 If the submitted sample is in large size Laboratory officer homogenizes and obtains representative reference sample and test portion as per relevant test method.
- 9.3.4 The remaining sample is returned by the assigned Laboratory Officer to the Sample Control Center with the filled sample return form (*Appendix D*).
- 9.3.5 Depending on the nature of the sample, the remaining stable sample may be returned to the owner on request or kept by the designated Sample Control Officer in appropriate condition until the due time for disposal.

9.4 Sample protection

- 9.4.1 The designated Sample Control Officer, and assigned analyst ensures that the sample is kept in conditions as declared by the customer on the sample container as stated in test method or specific product standard.
- 9.4.2 The designated Sample Control Officer, and analyst ensures that samples are stored in a separate area away from any contaminant.
- 9.4.3 Integrity of samples received is secured through but not limited to
 - 9.4.3.1 Camera to track any unauthorized personnel to sample access,
 - 9.4.3.2 Limiting access to the Laboratories and sample storage area.
 - 9.4.3.3 Fingerprint system to restrict unauthorized entrance in the laboratory.

9.5 Sample storage

- 9.5.1 The designated Sample Control Officer ensures that Samples stored in Sample

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Control Center are placed in the designated storage areas. The storage area is identified as “*reference samples*”; “*Sample retained for Quality control purpose*” and “*sample waiting for disposal*”.

- 9.5.2 When in the laboratory, Designated Laboratory Officer ensures that the sample is placed in the designated storage areas. The storage areas are identified as “*untested sample*”; “*samples in progress*”, “*Finished samples*”, **Reference sample, and sample waiting for disposal**.
- 9.5.3 The designated Laboratory Officer ensures that for the samples that need to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored and recorded as per customer or as per standard requirements.

9.6 Sample retention

- 9.6.1 The designated Sample Control Officer (one of lab technicians) delivers the Laboratory sample to the Laboratory within 2 hours of sample submission.
- 9.6.2 The Laboratory Officer stores the Reference Sample in the required storage conditions up to **four** weeks after the results of food and cosmetics samples have been released; however, medicine samples are stored in the whole **one year** counted from expiry date.
- 9.6.3 The Laboratory Officer ensures that tested samples are either disposed of or returned to the Sample Control Center.
- 9.6.4 Medicine samples will be retained for a period spanning from date of expiry plus one year; Food and cosmetic samples will be retained for one month after release of certificate of analysis.

9.7 Disposal of Samples

- 9.7.1 For samples which do not require specific disposal measures, Laboratory Officer ensures that, finished samples are disposed off, **four** weeks after release of Certificate of Analysis, this is the case of food and cosmetics samples;
- 9.7.2 Depending on the nature of the Samples, samples which cannot be disposed off within the Laboratory may be returned to the Sample Control Center for disposal arrangement. (Human Medicine Laboratory collaborates with the Laboratory Division Manager and arrange disposal with contracting company)
- 9.7.3 The designated Sample Laboratory Officer of the specific unit collaborates with the Laboratory Division Manager for the disposal of such samples and methods to be used, disposal methods include but not limited to burying and incinerating or any other appropriate way depending on the nature of the sample.
- 9.7.4 The Laboratory technician periodically lists the sample to be disposed in each unit basing on the “first in first out” (*see Disposal form in Appendix E*) and forward to the Human Medicine Laboratory Officer.
- 9.7.5 The Laboratory Officer checks the list of samples to be disposed and determines the samples with negative impact on health, safety and environment and provides the appropriate way of disposal within or outside Laboratory.
- 9.7.6 The Laboratory Officer may give instructions of disposal or assign the staff to perform or

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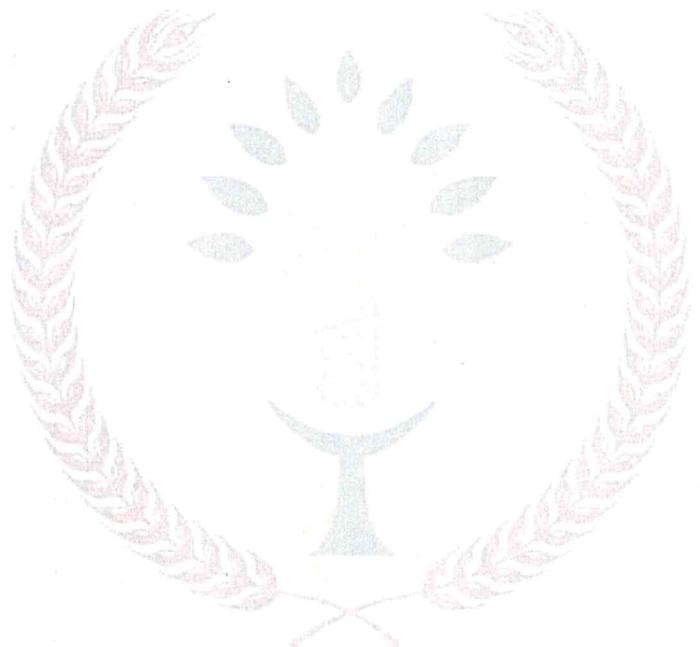
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supervise the disposal.

- 9.7.7 The Laboratory Officer authorizes the disposal of samples from their respective units.
- 9.7.8 The lab technician maintains the records of the disposed samples.



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10. Appendices

10.1 Appendix A: Test Request Form

| | | |
|--|--|--|
| RWANDA FDA Rwanda Food and Drugs Authority | Division : Quality Control Laboratory | Doc. N°: QCL/FOM/001 Revision N°: 0 Effective Date: 13 Mar 2019 Ref. Doc: QMS/SOP/001 |
| | Doc Title : Test Request Form | |

| | |
|---|--|
| 1. Full Description (<i>Generic name / Trade name if any ,other names</i>) Composition: | 10. Would you like QCL to choose the Appropriate test method(s) to be used in above tests? Yes / No if no suggest : |
| 2. Manufacturer Names and Address: Batch No: MFG Date: EXP Date: Retest date (APIs and Pharmaceutical excipient) : | 11. Source of the sample : Institution / Company: Country: Address / Tel : |
| 3. Size of submitted sample: | 12. Marketing Authorization number : |
| 4. Size of the consignment/package: | 13. Date sample collected: |
| 5. Required storage condition: | 14. Sample Submitted by : Institution: Position: Address / Tel : |
| 6. Physical condition of the sample upon arrival: State: Frozen, Chilled, Room temp Packaging: Sealed, Unsealed, Damaged. Un-damaged General appearance : Good, Poor Discrepancies: | 15. Receiver's name & signature : Date and time of submission: |
| 7. Reason for analysis request: | 16. Laboratory Sample registration number: |
| 8. Specification to be used for testing: | 17. Turnaround time: |
| 9. Parameters to be tested : | 18. Note If any: |

19. For Laboratory use only....

| | | |
|------------------|--|------------------|
| Received by | | Date & signature |
| Assigned Analyst | | Date & signature |

20. Sample transfer

| Quantity (mg, ml...) | Transferred by | Received by | Time and date | Signature |
|----------------------|----------------|-------------|---------------|-----------|
| | | | | |

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10.2. Appendix B: Sample register

| | |
|---|----------------------------------|
| Document type: Form | Doc. Number: QCL/REG/003 |
|  The logo of the Rwanda Food and Drugs Authority (FDA) features a stylized tree with a yellow fruit at its top, set against a background of two golden wheat stalks. Below the tree, the word "RWANDA" is written in a bold, sans-serif font, followed by "FDA" in a slightly smaller font. At the bottom, the full name "Rwanda Food and Drugs Authority" is written in a smaller, italicized font. RWANDA FDA Rwanda Food and Drugs Authority | Revision number: 0 |
| | Revision Date: 14 August 2020 |
| | Effective Date: 24 August 2020 |
| | Review Due Date : 24 August 2022 |

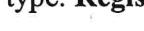
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10.3.Appendix C: Sample Distribution Register

| | |
|---|----------------------------------|
| Document type: Register | Doc. Number: QCL/REG/001 |
|  RWANDA FDA Rwanda Food and Drugs Authority | Revision number: 0 |
|  | Revision Date: 14 August 2020 |
|  | Effective Date: 24 August 2020 |
|  | Review Due Date : 24 August 2022 |

| | |
|---|--|
| Test report | |
| FDA Number | |
| Sample description | |
| Date sample received | |
| Assigned Laboratory Officer | |
| Signature | |
| Date analysis started | |
| Date analysis completed | |
| Test report verified by DM (sign& Date) | |
| Test report received by assigned SCO (Sign& date) | |
| Comment | |

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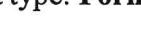
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10.4.Appendix D: Sample return form

| | |
|---|----------------------------------|
| Document type: Form | Doc. Number: QCL/FOM/032 |
|  RWANDA FDA Rwanda Food and Drugs Authority | Revision number: 0 |
| | Revision Date: 14 August 2020 |
| | Effective Date: 24 August 2020 |
| | Review Due Date : 24 August 2022 |

Prepared by Laboratory
Officer.....Signature.....Date.....

Authorized by Human Medicine
Laboratory Officer **RWANDA FDA**Signature.....Date.....

Disposed
(name)..... Signature..... Date..... by

| | | |
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10.5.Appendix E: Sample disposal form

| | | |
|--|-----------------------------|---|
| Document type: Form | | Doc. Number: QCL/FOM/033 |
|  RWANDA FDA Rwanda Food and Drugs Authority | Title: SAMPLE DISPOSAL FORM | Revision number: 0 Revision Date: 14 August 2020 Effective Date: 24 August 2020 Review Due Date : 24 August 2022 |

| Subject | SAMPLE DISPOSAL FORM | | | |
|---|----------------------|-------------------------|----------------------|------------------|
| Rwanda FDA No | Sample description | Date results dispatched | Certificate No. | Mode of disposal |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Prepared Officer..... | by Signature..... | Laboratory Date..... | | |
| Authorized by Human Medicine Laboratory Officer | Signature..... | Date..... | | |
| Disposed (name)..... | Signature..... | Date..... | by Signature..... | Date..... |

| | | |
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10.6 Appendix F: Document Revision History

| Date of revision | Revision number | Document Number | Author(s) | Summary of Changes | reasons for revision |
|------------------|-----------------|-----------------|--------------------|--------------------|----------------------|
| 14 August 2020 | 0 | QCL/SOP/004 | Felix TUYISHIME | | |
| | | | | | |



| | | |
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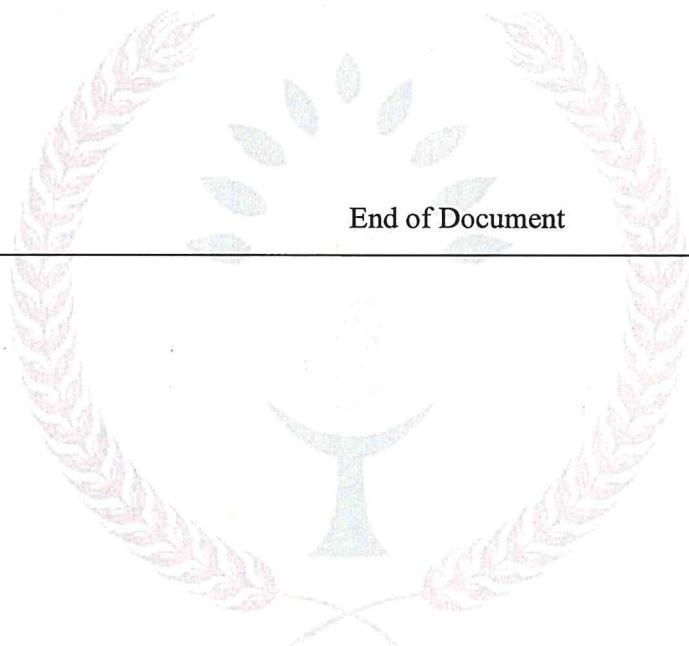


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11. References

- 11.1.ISO/ IEC 17025: 2017 Clause 7.4
- 11.2.Laboratory Quality Manual(QCL/MAN/001)

End of Document



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