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RWANDA FDA Rwanda Food and Drugs Authority	Title: **SOP FOR GMP CERTIFICATION OF PHARMACEUTICAL MANUFACTURING FACILITY**	

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Date	16/07/2021	16/07/2021	16/07/2021	16/07/2021
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1.0 Purpose

This Standard Operating Procedure is to ensure that:

1.1 The procedures for issuing the GMP certificate to licensed Pharmaceutical Manufacturing Facilities are described

1.2 To ensure consistency in issuance of GMP certificates.

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to all pharmaceutical manufacturers of Finished Pharmaceutical Products and of Active Pharmaceutical Ingredients applied within the Rwanda FDA.

2.2 Applies to Pharmaceutical units applying for GMP certificate for export and import purposes

3.0 Policy

3.1 Law No. 003/2018 of 09/02/2018 establishing Rwanda FDA, determining its mission, organization, and functioning states in:

Article 8 (2) ...” regulate compliance with quality standards relating to the manufacture”; and Article 9 (2)…”grant or withdraw authorization relating to matters regulated under this law”.

3.1 Regulations No DIS/TRG/001 Rev. No 0 governing authorization to operate as a manufacturer or wholesaler or small scale manufacturing / compounding or retail seller of pharmaceutical products, 2019, Rwanda Food and Drugs Authority, Kigali, Rwanda.

3.2 GMP Guide – PE 009-13 (Part I), Pharmaceutical Inspection Cooperation Scheme, 1 January 2017, PIC/S Secretariat, Geneva.

4.0 Definitions and Abbreviations

4.1 “**Author**” The Author shall be the person(s) who created a document or any subsequent revision of the controlled document.

4.2 “**Approved by**” Endorsement providing authority for a document to become officially valid and to be put into formal use.

4.3 “**Checked by/ Authorised by**” Endorsement signifying that the internal document is ready for approval.

4.4 “**Controlled Copy**” A document which is distributed to pre-determined persons or staff and if any change or revision is made on the document, the Quality Management Systems Specialist shall submit the revised document and make sure that the previous (superseded) document is retrieved.

4.5 “**Document**”

a) “Document” means readable information and its supporting medium.

b) A “document” describes any policy, procedure, work instruction or form that is to be controlled.

c) A “document” can be a Law, Regulation, standard, policy statement, manual, guideline, protocol, process flow outlines, standard operating procedure, work instruction, drawing, specification, form, record, chart, report, certificate, checklist, aide memoir, register, worksheet, textbook, poster, notice, memorandum, software, photograph, drawing, or plan.

d) A “document” may be on various media e.g. paper, magnetic, electronic or optical computer disc, and may be digital, analog, photographic or written.

4.6 "**Effective Date**" A date after the concerned staff or persons have been formally trained or notified or oriented on the use of the document and records maintained, but shall not be later than 15 working days from the revision date.

4.7 "**External Document**"

a) A legal, regulatory or technical document which is not written or created (not internally generated), issued or revised by Rwanda FDA.

b) "External document" can be used as reference in writing internal documents or as a manual for operating equipment.

4.8 "**Internal Document**": A document which is issued and revised by Rwanda FDA.

4.9 "**Master Document**" Original of a controlled internal document that contains original signatures of the authorities that checked/authorized and approved the document.

4.10 "**Objective**" A brief statement(s) describing the purpose of the document.

4.11 "**Policy**" A short statements derived from the applicable law(s), regulation(s), standard(s), resolutions(s), decision(s) or concept(s) that govern the document or provide a mandate or basis for the document.

4.12 "**Procedure**"

When used as a title, e.g. in a Standard Operating Procedure (SOP), or Work instruction, a procedure shall be written as follows:

1) Write clear, concise, step-by-step instructions on how to perform the procedure.
2) Write the instructions chronologically for the user to follow, without a lot of theoretical background.
3) Indicate the preliminary steps that must be done before beginning the actual procedure.
4) Number each step so that repeat steps can be referred to rather than making the SOP very long.
5) Number each sentence so as to make reference to it easy under document revision history when it is revised.
6) Include explanations and an example of how to do any required calculations.
7) Create and indicate the Form(s) where the results, observations or data should be recorded.

4.13 "**Responsibility**" indicates the designations or titles of the Rwanda FDA staff or member and briefly describe their specific responsibilities in performing the procedure in a document and in ensuring that the document is implemented and performed correctly and consistently.

4.14 "**Review Due Date**"

A date three years from the effective date, to ensure continued adequacy and suitability of a document. A document may remain valid beyond its review due date if no major change had happened in the process, until the revised document is authorized.

4.15 "**Review**"

Assessment of the correctness, suitability and adequacy of a document including technical, legal, regulatory, health, safety, and environment compliance issues.

4.16 "**Reviewer**"

The Reviewer shall be the person(s) who assesses a document for technical, legal, regulatory, health, safety, and environment compliance issues as per Section 9.3 of the Document Control SOP number QMS/SOP/001.

4.17 "**Revision Date**" The date when the document is approved and thereby becoming officially valid.

4.18 "**Revision Number**" A numerical figure that changes serially; the first document shall have revision number "0" and its first revision number "1", second revision number "2" and so on.

4.19 "**Safety Precautions**" When used in a procedure e.g. SOP, indicate all safety precautions that must be taken before the procedure is performed. Includes special precautions and protective garments (containment facility clothing, masks, hoods, goggles, gloves, cleanup of spills, etc.) for working with physical, chemical, radioactive, biological or microbiological hazards.

4.20 "**Scope**" A brief statement of where the document applies, when it need to be applied and any limitations of the document.

4.21 "**Title**" A title shall be a short, precise statement representing the contents of the procedures

4.22 "**Uncontrolled Copy**"

A document which is issued to persons or staff who are not part of the distribution list for that document for information purposes only and if any change or revision is made on the document, the Quality Management Systems Specialist is not in control of retrieval of the previous (superseded) document.

5.0 Responsibility

5.1 The Director General is responsible for consideration and approval of issuance of GMP certificates

5.2 Head of Food and Drugs Inspection & Safety Monitoring Department is responsible for reviewing of the GMP certificate application after observing all the formalities as per this procedure

5.3 The Division manager, Food and Drugs Inspection & Compliance is responsible for coordinating the GMP certifications activities and submit to Head of Food and Drugs Inspection & Safety Monitoring Department.

5.4 Quality assurance analyst ensures the use of update version of the SOP, recalls obsolete documents and keeps document master list.

5.5 GMP Inspectors are responsible for conducting GMP desk assessment/conducting the inspection of the facility with reference to SOPs for conducting desk assessment /SOPs for conducting GMP Inspection and submitting the report within forty-five (45) days from the date GMP inspectors return to office.

6.0 Distribution

6.1 Director General

6.2 The Head of Food and Drugs Inspection and Safety Monitoring Department

6.3 Division Manager of Food and Drugs Inspection and Compliance

6.4 Quality assurance analyst

6.5 GMP Inspectors.

7.0 Safety Precautions

Not applicable to this SOP

8.0 Materials and Equipment

8.1 Laptop computers

8.2 Current Rwanda FDA GMP guidelines

8.3 Inspection reports

8.4 Inspection checklist used

8.5 Product dossier, if necessary

8.6 Compliance report following CAPA

9.0 Procedures

9.1 Upon conduction of successful GMP desk assessment/ GMP inspection of facility. The assessment/inspection report is scheduled for committee review and validation.

9.2 Once the application has been reviewed and validated, the GMP inspector will prepare a GMP certificate and submit it to the for Food and Drugs Inspection and Compliance Division Manager.

9.3 The Division Manager of Food and Drugs Inspection and Compliance will then review the dossier and submit it to the Head of Food and Drugs Inspection and compliance department.

9.4 The Head of Food and Drugs Inspection and compliance department shall forward the completed report and GMP certificate of compliance for endorsement by the Director General.

9.5 The endorsed report and GMP certificate shall be scanned and emailed to the contact person at the manufacturing site.

10.0 Validity of Certificate

10.1 GMP certificate issued as per this SOP will remain valid for a period of five years for export and import purposes from the date of issuance unless withdrawn earlier.

11.0 Withdrawal of certification

11.1 GMP certificate shall stand invalid if either the activities or categories certified change or if the facility is no longer rated to be in compliance with Good Manufacturing Practice.

12.0 Records

12.1 The quality manuals, master distribution list file, obsolete documents file and general list of documents shall be kept and maintained by QMS for a period specified in the respective document

12.2 Department list of documents shall be kept and maintained by the Head of Food and Drugs Inspection and Safety Monitoring Department.

13.0 References

13.1 EAC SOP for preparation and reviewing a GMP Inspection report, 2014

13.2 EMA Compilation of Community Procedures on Inspection and exchange of information, 16 July 2012, EMA/INS/GMP/321252/2012 Rev 15, Compliance and Inspection

13.3 Rwanda FDA guidelines on Good Manufacturing Practices on Pharmaceutical Products

13.4 PIC/S Inspection Report Format, PI 013
13.5 PIC/S SOP on Team Inspections, PI 031-1, 29 July 2009

14.0 Appendices

14.1 Certificate of compliance with Good Manufacturing Practice

15.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16 Jul 2021	0	Rwanda FDA Staff	First Issue

End of Document

Annex 1: CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE

Rwanda Food and Drugs Authority

Rue. KG 9 Avenue, Nyarutarama Plaza

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website: www.rwandafda.gov.rw

QMS N°: DIS/FMT/018

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Effective date:

Revision date: 16/04/2024

CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE

(Issued in accordance with Article 23 of the Regulations N° DIS/TRG/001 Rev. N° 0)

Certificate N°: Issue Date: Valid up to:

This is to certify that the pharmaceutical manufacturing facility with following details:

Name of facility:

Physical address:

License number:

Country:

E-mail:

Telephone:

Has been by the Rwanda Food and Drugs Authority for compliance with the Good Manufacturing Practice Guidelines.

On the basis of the carried out on it is certified that the pharmaceutical manufacturing facility indicated on this certificate complies with Good Manufacturing Practice for dosage forms listed in Table below:

Nº	Dosage form	Category	Activities

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate becomes invalid if the activities or the categories certified change or if the facility is no longer rated to be in compliance with Good Manufacturing Practice.

Dr Charles KARANGWA

Ag. Director General