RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department	
Document Type: **Standard Operating Procedure**		Doc. Number	: QMS/SOP/080
RWANDA FDA Rwanda Food and Drugs Authority	Title: **ISSUANCE OF GMP CERTIFICATION**	Revision Number	:15 May
		Revision Date:	:15 May
		Effective Date	:
		Review Due Date	:21 May 2023

STANDARD OPERATING PROCEDURE (SOP) FOR ISSUANCE OF GMP CERTIFICATION

	Author	Checked by			Authorized by	
Title				Quality Management Systems	Director General	Page 1 of 7
Signature & Date						

1.0 Purpose

This Standard Operating Procedure is to ensure that:

1.1 To describe the procedures for issuing the GMP certificate to licensed Pharmaceutical Manufacturing Facilities

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 NRA.

2.2 Applies to Pharmaceutical units applying for GMP certificate for export purpose

3.0 Responsibility

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

3.2 Head of Food and Drugs Inspection & Safety Monitoring Department is responsible for processing of the GMP certificate after observing all the codal formalities as per the procedure given at QMS/SOP/080

3.3 The Division manager, Food and Drugs Inspection & Compliance is responsible for coordinating the GMP certifications

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

3.5 GMP Inspectors are responsible for conducting the inspection of the facility with reference to SOPs for conducting GMP of Pharmaceutical Manufacturing Facilities and submitting the report within 7 days .

4.0 Distribution

4.1 Director General
4.2 The Head of Food and Drugs Inspection and Safety Monitoring Department
4.3 Division Manager of Food and Drugs Inspection and Compliance
4.4 Quality assurance analyst
4.5 GMP Inspectors.

5.0 Procedures

5.1 The application for GMP certificate can be made to the office of the Director General of Rwanda FDA, who will forward to the Head of Inspection &Safety Monitoring Department
5.2 Head of Inspection &Safety Monitoring Department will scrutinize the GMP inspection reports of the concerned Pharmaceutical Facility as per record available in the office
5.3 The GMP compliance of the Pharmaceutical Facility will be evaluated on the basis of GMP inspection report of the Pharmaceutical Facility as provided for by the GMP inspectors. This report should not be older than 180 days of the receipt of the application.
5.4 If GMP inspection of the pharmaceutical facility is not conducted within last 180 days of receipt of application, the GMP inspectors shall conduct the inspection of the firm to verify GMP compliance and submit the report as per the SOP for conducting GMP of Pharmaceutical Manufacturing Facilities within 7 days.
5.5 The applicant will provide the following documents for obtaining the GMP certificate for export purpose:
5.5.1 Request Letter addressed to Director General along with the following documents
5.5.2 Latest GMP inspection report as per GMP inspection conducted within last 180 days
5.5.3 Copy of Valid Drug Manufacturing License
5.5.4 Fee amounting to RWF …….as per article…
5.5.5 List of registered products (registration number should be mentioned)

5.5.6 If GMP certificate expired, cancelled/withdrawn or incase of first application for GMP certificate, two previous inspection reports within a year as per law…….

5.5.7 An undertaking on stamped paper which will be attested by Notary Public, that there are no case/litigation pending in any court/Board or Authority which relates to quality control or quality assurance of pharmaceutical products and also there is no sample declared substandard/adulterated at any laboratory during a period of the last 180 days.

5.6 After evaluating the GMP inspection report of the pharmaceutical facility, the Head of Inspection &Safety Monitoring Department will put up the case to the Director General with recommendation either for approval or disapproval as the case may be.

5.7 In case the application is approved by the Head of Inspection &Safety Monitoring Department, the Director General will issue the GMP certificate on approved format (Annex 1) for export purpose.

5.8 In case the application is not approved by Head of Inspection &Safety Monitoring Department, The Director general will inform the applicants accordingly along with reasons to this effect.

6.0 Validity of Certificate

6.1 GMP certificate issued as per this SOP will remain valid for a period of one year for export purpose from the date of inspection unless withdrawn earlier

6.2. In case of a requirement of an importing country otherwise, a certificate of such from the NRA of the importing country shall be produced

7.0 Withdrawal of certification

GMP certificate shall stand invalid if either the activities or categories certified therein are changed or not conforming to Law……and the regulations framed under.

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance
Document Type: **Standard Operating Procedure**		Doc. Number :DFC/SOP/00
RWANDA FDA Rwanda Food and Drugs Authority	Title: **STANDARD OPERATING PROCEDURE (SOP) FOR GMP DESK ASSESSMENT OF PHARMACEUTICAL MANUFACTURING FACILITIES**	Revision Number : Revision Date: : Effective Date : Review Due Date :

END OF DOCUMENT