RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department	
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RWANDA FDA Rwanda Food and Drugs Authority	Title: **GMP DESK ASSESSMENT OF PHARMACEUTICAL MANUFACTURING FACILITIES**	Revision Number	:0
		Revision Date:	:15May 2021
		Effective Date	:21 May 2021
		Review Due Date	:21May 2023

STANDARD OPERATING PROCEDURE (SOP) FOR GMP DESK ASSESSMENT OF PHARMACEUTICAL MANUFACTURING FACILITIES

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

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance	
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1.0 Purpose

1.1 To ensure that desk assessment of applications for Good Manufacturing Practice compliance for pharmaceutical manufacturing facilities is consistently done prior to issuance of a GMP certificate

1.2 To outline a process for desk assessment of GMP compliance of overseas facilities to identify instances where an acceptable level of GMP compliance can be confirmed and assured from the activities of another regulatory authority or authorities without the need for an onsite inspection.

1.3 To help Rwanda FDA to make optimal use of inspection resources.

2.0 Scope

2.1 This SOP applies to all pharmaceutical manufacturing facilities which are located in countries with Stringent Drug Regulatory Authorities (SRA) and sites approved by World Health Organization or EAC NMRAs

3.0 Responsibility

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

3.2 Head of Food and Drugs Inspection & Safety Monitoring Department is responsible for ensuring that the review and assessment of GMP applications is done as per this procedure.

3.3 The Division manager, Food and Drugs Inspection & Compliance is responsible for coordinating the assessment activities.

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 adherence to this procedure and maintaining records arising out of this procedure.

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.

6.0 PROCEDURES

6.1 Receiving GMP Applications

6.1.1 Applicants submit their applications with relevant attachments as per guidelines on good manufacturing practices for finished pharmaceutical products No DIS/GDL/002in duplicate at Rwanda FDA head office central secretariat and a copy of such application is stamped "Received" and returned to the applicant as a reference.

6.1.2 The received application is recorded with a reference number and a copy is filed at the central secretariat and sent to the Head Food and Drugs and safety monitoring department within prescribed time**.**

6.1.3 For online applications, the dossier is submitted via Rwanda FDA email: info@rwandafda.gov.rw and the application is acknowledged by the central secretariat

6.1.4 The central secretariat downloads and creates the file on Rwanda FDA server for reference purpose before the application file is submitted to Head of Food and Drugs and Safety Monitoring Department

6.1.5 Upon receipt of the applicant's file, the Head of Food and Drugs inspection and Safety Monitoring Department assigns it to the Food and Drugs Inspection and Compliance Division Manager who records the application in the relevant Food and Drugs Inspection and Compliance incoming dossier database and further assign it to the GMP Inspectors for assessment.

6.1.6 Screening of the application:

a) GMP Inspectors verify the completeness of the relevant attachments as mentioned in guidelines on good manufacturing practices for finished pharmaceutical products

b) The GMP Inspector prepares and submit a feedback to the Division Manager based on screening findings in case the application is not complete.

c) The Division Manager reviews the feedback and submit it to the Head of Food and Drugs Inspection and Compliance Department for approval and submission to the applicant.

6.1.7 Assessment of the Application:

a) In case the application is complete the dossier undergoes the first assessment

b) After the first assessment, the Division Manager assigns the second assessor.

c) The Second assessor submits the assessment report to the Division Manager

d) The Division Manager schedules the assessment report for committee review and validation.
e) The Head of food and drugs inspection and safety monitoring department shall forward the completed report together with GMP certificate of compliance (only for manufacturing sites rated as GMP compliant) for endorsement by Director General.
f) The endorsed report, GMP Certificate shall be scanned and emailed to the contact person at the manufacturing site.
g) Where queries are made and/or additional information is required, the assessment shall be deferred and communication formerly made to the manufacturing site to provide responses to queries and/or the required information.
h) Responses to queries and/or additional information submitted by the applicant shall be received and evaluated.
i) After evaluation, the completed desk assessment report with a recommendation to either approve or reject shall be submitted to the Division Manager for checking.
j) Any Desk review assessment with critical or major deficiencies, on-site inspection is scheduled.

6.2 Materials and equipment

6.2.1 Rwanda FDA GMP database

6.2.2 GMP Desk Assessment Checklist
6.2.3 WHO prequalified sites
6.2.4 Updated list of countries considered as Stringent Regulatory Authorities (SRA)
6.2.5 EAC NMRAs

7.0 Records

GMP Desk Assessment Checklist, GMP Desk Assessment report and GMP Certificate

8.0 ANNEXE

Annexure 1: Content of GMP Desk Assessment Report

Site information	• Name and address of the manufacturing site under assessment • Further details, if available/applicable such as building number/GPS location/UFI. • Name and contact details of site contact
Regulatory authority performing the assessment	• Name of the regulatory authority performing the assessment • Name and job title of the person performing/responsible for the assessment • Date of the assessment • Name and Signature of the person responsible for/endorsing the assessment
Scope of assessment	• A statement that the assessment of GMP compliance is being performed under the Rwanda FDA Scheme • Specific products/dosage forms that are within the scope of the assessment • Activities that are within the scope of the assessment (e.g. manufacture of API/non-sterile finished product/sterile finished

	product/biological finished product; packaging; importation etc.).
Basis for the assessment (Review of documentation)	•A list of documents reviewed as part of the assessment including versions/dates • Date, scope and outcome of the last inspection by PIC/S, SRA/WLAs or EAC NMRAs • Confirmation that the GMP certificate (where available) or inspection report covers the products and activities that are of interest to the regulatory authority performing the assessment
Assessment outcome and rationale	For example: • "Based upon the collected information, along with the oversight of the operations by the Participating Authority in the country in which the site is based, no onsite inspection by Rwanda FDA is considered to be required at this time. A new GMP certificate can be issued." • Due to the following "summary of risk factors" , an onsite inspection is considered to be required.

9.0 Document Revision History

Date of revision	Revision number	Document Number	Author(s)	Summary of Changes	Reasons for revision
				NA	New

	Author	Checked by			Authorized by	Page 7 of 7
Title	Senior Licensing Officers, Drug and Food Inspectorate	Head, Drug Inspectorate Services	Head, Drug Assessment & Registration	Head, Quality Management	Executive Secretary /Registrar	
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