



GUIDANCE ON GOOD PRACTICES FOR DESK ASSESSMENT FOR COMPLIANCE WITH GMP AND GLP FOR MARKETING AUTHORISATION OF PHARMACEUTICAL PRODUCTS

SEPTEMBER, 2022

Doc. No.: FDISM/FDIC/GDC/002	Revision Date: 23/09/2022	Review Due Date: 29/09/2025
Revision No.: 1	Approval date: 27/09/2022	Effective Date: 30/09/2022


FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law No 003/2018 of 09/02/2018 determining its mission, organization and functioning. One of its main powers is to formulate regulations and guidelines for regulating the manufacture of Pharmaceutical products to ensure that they comply with quality standards required for Good Manufacturing Practices (GMP).

Considering the provisions of the regulations N° FDISM/FDIC/TRG/001, Regulations Governing Licensing of public and private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products and the regulations N° FDISM/FDIC/TRG/005, governing Good Manufacturing Practices for medical products. The Authority Issues Guidance N° FDISM/FDIC/GDL/007 on good practices for desk assessment for compliance with GMP and Good Laboratory Practices (GLP) for marketing authorisation of medical products.

Poor quality of Pharmaceutical products is one of the public health concerns worldwide. It is in this context that the Rwanda FDA intends to put in place guidelines that provide guidance on good practices for desk assessment for compliance with GMP and GLP for marketing authorisation of medical products to ensure that manufactured medicines do not constitute harmful effects to people's health that leads to losses of life.

It is expected that this guidance will offer a clear understanding to manufacturers and other persons concerned by the guidance during the evaluation process, they will protect consumers and Pharmaceutical manufacturing industry, thus promoting health protection.


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Director General



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GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	10/08/2020
ADOPTION BY RWANDA FDA	18/08/2020
STAKEHOLDERS CONSULTATION	25/08/2020
ADOPTION OF STAKEHOLDERS' COMMENTS	28/08/2020
DATE FOR COMING INTO EFFECT	30/09/2022

DOCUMENT REVISION HISTORY

Date of revision	Revision number	Changes made and/or reasons for revision
03/09/2021	0	First Issue
23/09/2022	1	<ol style="list-style-type: none"> 1. Section on the criteria of desk assessment by adding new criteria 2. General principles of GMP/GLP desk assessment 3. General requirements for GMP/GLP desk assessment audit 4. List of triggers and factors leading to conducting onsite inspection. 5. Application submission and processing became part of chapter II 6. A section on processing of applications for desk assessment 7. Replaced appendix A: Annex a: replaced the desk assessment format with the correct format of GMP Desk review report format; 8. Included new annexes, which include annex b: Model format of Certificate of Desk Assessment for Good Manufacturing Practices (GMP) Compliance

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ACRONYMS AND ABBREVIATIONS

APIs:	Active Pharmaceutical Ingredients
CA:	Cooperation Agreements
CAPA:	Corrective and preventive action
EAC:	East Africa Community
EMA:	European Medicines Agency
FPP:	Finished Pharmaceutical Product
GLP:	Good Laboratory Practices
GMP:	Good manufacturing practice
GxP:	Good practice
ICH:	International Conference on Harmonisation
INN:	International non-proprietary names
LTR:	Local Technical Representative
MoU:	Memorandum of understanding.
MRA:	Mutual Recognition Agreements
NMRAs:	National Medicines Regulatory Authorities
NRA:	National Regulatory Authorities
PQR:	Product quality review
QCLs:	Quality Control laboratories
SRA:	Stringent Regulatory Authority
TGA:	Therapeutic Goods Administration
WHO PQT:	WHO Prequalification Team
WHO:	World Health Organization
WLAs:	WHO Listed Authorities

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GLOSSARY / DEFINITIONS

The definitions given below apply to the terms used in this guidance. They may have different meanings in other contexts:

1. **“Agent or Local Technical Representative”**: Any applicant who is not resident in Rwanda shall appoint a local technical representative who must be a company incorporated in Rwanda and authorized by Rwanda FDA to deal in medicinal products and must hold a wholesale operating license. The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney duly notarised in country of origin.
2. **“Applicant”**: An applicant is a person who applies for registration of a human medicinal product to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured. The applicant shall therefore be responsible for signing the registration application form. In the event that the applicant wants another person to register the medicinal product on his/her behalf, then Powers of Attorney, duly notarised in the country of origin, and registered with the Registrar of Companies in Rwanda shall be provided. After the product is registered, the applicant shall be the Marketing Authorisation Holder.
3. **“Cooperation Agreement”**: is a formal business document outlining the basic terms of your agreement with another individual, group or entity. Also called a Memorandum of Understanding or cooperation contract, it's one of the first steps toward a more detailed contract.
4. **“Information sharing”**: is defined as exchange of data between individuals or entities outside the traditional organisational boundaries, to achieve a common goal in terms of better policies and deliver better services that otherwise would not be possible without the exchange of data. This may mean that one party is disclosing information while the other is collecting the information or both parties are mutually disclosing and collecting information.
5. **“Manufacture”**: All operations that involve preparation, processing, filling, transforming, packaging, and repackaging and labelling of medicinal products.
6. **“Manufacturer”**: A manufacturer is a person or a firm that is engaged in the manufacture of medicinal products. It involves operations such as production, packaging, repackaging, labelling and relabelling of pharmaceuticals.
7. **“Marketing authorization holder”**: *a person granted with a marketing* Authorization of a product by an NRA.
8. **“Marketing authorization”** Approval from the authority necessary to market and sell a product in Rwanda. This is a legal document that establishes the detailed composition and formulation of the product and the pharmacopoeia or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, labelling and shelf-life.

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9. **“Memorandum of Understanding”**: is a formal agreement between two or more parties. Companies and organizations can use MOUs to establish official partnerships. MOUs are not legally binding but they carry a degree of seriousness and mutual respect, stronger than a gentlemen's agreement.
10. **“Mutual Recognition Agreement”**: is defined as the reciprocal adoption or acceptance of regulatory decisions or outcomes in other Partner States as valid in the form of a legal basis – law or regulations or agreements.
11. **“Stringent Regulatory Authority(SRA)/ WHO Listed Authorities (WLAs)”** A regulatory Authority which is a member of the International Conference on Harmonisation (ICH) or an ICH observer, or is associated with an ICH member through a legally-binding, mutual recognition agreement.
12. **“Quality System”**: The sum of all that is necessary to implement an organization’s quality policy and meet quality objectives. It includes organizational structure, responsibilities, procedures, systems, processes and resources. Typically,

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CHAPTER 1: INTRODUCTION

Rwanda Food and Drugs Authority (Rwanda FDA) is established by the Law N° 003/2018 of 09/02/2018 and considering the provisions of the technical regulations N° FDISM/FDIC/TRG/005, governing Good Manufacturing Practices for medical products.

National Regulatory Authorities (NRA) worldwide use systems for the authorization and post-marketing surveillance of medical products that depend upon the assessment of submitted dossiers, variations files and the inspection of Finished Pharmaceutical Products (FPP) and Active Pharmaceutical Products (APIs) manufacturers, and Quality Control Laboratories (QCLs) in the development, manufacture and distribution of the product. These inspections are performed for dossier data verification and to provide evidence that the FPP and APIs manufacturers, QCLs are in compliance with the relevant good practice (GxP) guidelines and requirements.

The performance of on-site inspection of manufacturing, testing and clinical trials as well as the supply and distribution chain outside the NRA's domestic territory is a resource-intensive activity and one that often lies on the critical path to regulatory decision-making. Furthermore, the hosting of multiple regulatory inspections and audits is also a significant overhead for the sites inspected that adds to the cost of producing the products. Even the best resourced NRAs face resource limitations and therefore it is regulatory best practice to use quality risk management in prioritizing inspection activities. In order to best use the limited inspection resources and minimize multiple and repeated inspections, it is therefore good practice for national authorities to leverage available and reliable evidence of compliance and noncompliance with good practice requirements as part of their risk-based inspection planning process, such that there is no on-site inspection without a well-founded cause.

Verification and confirmation of GMP Compliance of a manufacturer of a FPP or API in a foreign country may be based on the assessment of evidence of GMP compliance that includes a recent inspection of the manufacturer by a competent regulatory agency from country of origin and other internationally recognized institutions.

The use of a desk assessment process for Good Manufacturing Practice verification and confirmation has been an element of assessment by some organizations and agencies like WHO Prequalification Team (WHO PQT), European Medicines Agency (EMA) and the Australian Therapeutic Goods Administration (TGA) for some years. One element of this risk-based approach is the desk assessment of inspection information from reliable and trusted sources in coming to a national or regional decision as to whether to perform a further inspection before coming to a final decision on marketing authorization or renewal of marketing authorization or other regulatory action.

Agencies have relied on regulatory decisions made by other agencies basing on bilateral or multilateral agreements as binding. A range of international and regional agreements may be utilized to facilitate the effective management of the regulatory decision in order to increase access to good quality, safe and effective products on the market. These include Mutual Recognition Agreements (MRA), Cooperation Agreements (CA) and Memorandum of Understanding (MoU).

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Mutual recognition works well if there are common technical standards that are used, clear procedural legislation in form of agreement, tracking tools to support the process, and trust (good regulatory practice, good science and no political interference in technical decisions). On the other hand, cooperation agreements or Memorandum of understanding should be pursued where there is minimal legal obligation. Furthermore, facilities located in countries with Stringent National Medicines Regulatory Authorities (NMRAs), WHO listed authorities (WLAs) and East Africa Community National Medicines Regulatory Authorities (EAC NMRAs) may be assessed using desk assessment review unless otherwise required.

The desk assessment process involves submission of documentary evidence by the applicant, usually a manufacturer or Local Technical Representative (LTR) in order to demonstrate the conformity of the FPP or API manufacturer, outsourced QCL, or to GMP or GLP. The evidence provided is assessed to determine the level of compliance based on the accepted standard and the scope of the application. The outcome of the assessment process is used to make a regulatory decision. The option to undertake the desk assessment process does not preclude an on-site inspection in cases where the outcome of the assessment shows non-compliance to the stipulated practices.

1.1 Scope

This guidance applies to FPP and API manufacturers, and outsourced quality control laboratories that are subjected to GxP inspections.

The guidance covers the information and evidence required to undertake a desk assessment process and excludes the process of on-site inspection.

1.2 Aim and objectives of the guidance

This guidance aims at providing an approach for use by Rwanda FDA in order to assess GMP/GLP confirmation using the desk assessment pathway thus reduce the necessity for duplication of inspections while relying on authentic and reliable documentary evidence from other regulatory authorities and /or manufacturers

The objectives of this document is to:

- a) Ensure that a standardized procedure is followed for desk assessment of inspection reports issued by Stringent Regulatory Authority (SRA)/WHO Listed Authorities (WLAs), countries which are standing PIC/s members, and EAC member states operating at WHO GBT maturity level 3 (ML3).
- b) Facilitate a convergent approach and model for exchange and use of inspection information in national decision-making concerning the necessity to perform pre approval and surveillance inspections.

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1.3 Criteria for desk assessment

Pharmaceutical products manufacturing facilities to be considered for desk assessment should meet any or all of the following criteria:

- a) Facilities located in countries and/or issued a GMP certificate from a Stringent National Medicines Regulatory Agencies/WHO listed authorities;
- b) Facilities located in countries which are standing PIC/s members;
- c) Facilities inspected and approved under the framework of World Health Organization (WHO) prequalification program.
- d) Facilities inspected and hold a valid GMP certificate from the EAC member states operating at maturity level 3(ML3) or maturity level 4 (ML4)

1.4 Criteria for recognition

Pharmaceutical products manufacturing facilities to be considered for recognition should meet any or all of the following criteria:

- a) The manufacturing facilities that have been inspected by NMRA which have recognition agreement with Rwanda FDA
- b) Facilities inspected under the EAC Joint GMP inspection procedure within the last 3 years without participation of Rwanda FDA.

1.5. Criteria for Work-sharing

- a) Facilities inspected under the EAC Joint GMP inspection procedure within the last 3 years with participation of Rwanda FDA.
- b) Facilities inspected under WHO Joint GMP inspection procedure with inspectors from WHO's Prequalification Inspection Services Team

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CHAPTER 2: PROCESSING AN APPLICATION FOR DESK ASSESSMENT

The principles of quality risk management shall be employed to perform desk assessment considering the management of resources in terms of time, funding and personnel. The aim of the assessment process shall be to provide quality products in a timely manner without putting the public at risk.

Based on the fact that other competent and trusted National Regulatory Authorities (NRAs) and organizations have inspected the site of manufacture and in some cases several products manufactured on site, the assessment shall take into consideration and focus on the critical products and critical processes in the manufacture of a specified product in relation to public health risk.

2.1 Application submission

The application including proof of GMP fees payment, shall be submitted to the following address:

The Director General
Rwanda Food and Drugs Authority
Email: info@rwandafda.gov.rw
Kigali, Rwanda

2.2. Information Required for GMP Desk Assessment

A list of the documents in English or French or Kinyarwanda language that should be provided for desk assessment is given in Table 2. The documents below are required for the manufacturing sites desk assessment. For QCL desk assessment, the inspector should choose the documents that are relevant QCLs desk assessment as indicated in Table 2.

Where a mutual recognition agreement (MRA) has been established, a copy of the GMP certificate granted by local authorities together with a certified translation where this is not in English or French or Kinyarwanda may suffice.

Where a cooperation agreement (CA) or other bilateral or multilateral arrangements has been established, the document in the above stated table should be provided in addition to:

- a) Site master file (*Annex 14, WHO Technical Report Series, No. 961*) that is not older than one year from its approval date and any forecasted modifications, including legible coloured printouts of water treatment, air-handling systems, including pipeline and instrumentation drawings (P&IDs) in A3 or A2 format);
- b) List of all the products (medicinal or other) manufactured on site and List of products intended to be supplied in Rwanda. The list should include proprietary names and international non-proprietary names (INN).

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- c) Copy of the last inspection report with a certified translated copy where this is not in English or French or Kinyarwanda and if relevant GMP certificates coming from these inspections with a certified translated copy where this is not in English or French or Kinyarwanda.
- d) Local authority full report(s) and/or PIC/S, SRA/WLAs and EAC NMRA's full report(s) of those inspections performed in the last two years.
- e) A copy of any warning letter or equivalent regulatory action issued by any authority to which the site provides or has applied to provide the product.
- f) Corrective and preventive action (CAPA) and proof of CAPA implementation related to the last inspection report observations/deficiencies or any warning letter or equivalent regulatory action.
- g) The most recent product quality review(s) (PQR)(s) of the concerned product(s):
- h) PQR(s) (WHO Technical Report Series, No. 986), Annex 2). or equivalent documentation covering all required subsections and trend results should be presented.
- i) A confirmation by the senior quality assurance representative that a full self-inspection or external audit dedicated to the product(s) has been performed and all matters dealt with.
- j) Master batch manufacturing/packaging record(s) of the product(s) of interest.
- k) The completed batch manufacturing/packaging record(s) record including the analytical part for the most recently released batch of relevant product(s).
- l) A list of any recalls in the last three years.

The evidence documents required for desk assessment of each type of facility are mentioned in Table 1.

2.3 GMP Certificate issued under a Mutual Recognition Agreements

In accordance with Mutual Recognition agreements with certain countries and institutions, Rwanda FDA should accept compliance with the GMP requirements based on a current GMP certificate issued by the regulatory agency of the other party to the MRA.

Recognition of the GMP certificate issued by the other party should be accepted by Rwanda FDA within the scope of a MRA.

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2.4 Requirements for documents to be submitted for desk assessment

The desk assessment process involves submission to the Authority of documentary evidence by the applicant, usually a manufacturer or Local Technical Representative (LTR) in order to demonstrate the conformity of the FPP manufacturing site to GMP standards. The evidence provided is assessed to determine the level of compliance based on the accepted standard and the scope of the application. The outcome of the assessment process is used to make a regulatory decision that serves as a prerequisite in determining the marketing authorization of a pharmaceutical product.

Before the desk assessment process is initiated for a particular manufacturing site, application for market authorization of finished pharmaceutical medicinal products must be lodged by an applicant to the Authority.

Application for GMP desk assessment should be made to the Authority by submitting the following:

Table 1: Type of facility and evidence documents required for desk assessment

Type of Facility	Where Mutual Recognition Agreement (MRA) exists	Where CA/MoU exist; or member of PIC/S; or SRA regulator; or WHO Prequalification Scheme, EAC NMRA	Where no MRA, CA, MoU; or member of PIC/S; or SRA regulator; or WHO Prequalification Scheme exists, EAC NMRA
Non-sterile products facilities a) FPP b) API	Evidence List A	Evidence List B	On-site GMP assessment
Sterile products facilities a) FPP b) API c) biotech	Evidence List A and certification to relevant ISO Standards for sterilization facility).	Evidence Lists B and C	On-site GMP assessment

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Outsourced (contract) testing laboratory; and Outsourced sterilization	Evidence List A	Evidence List D	On-site laboratory assessment
			On-site GMP assessment
Contract Research Organization a) Clinical Facility b) Clinical Laboratory c) Bio-analytical laboratory d) Company performing pharmacokinetics statistical analysis.	Evidence List E	Evidence List E and F	On-site GLP/GCP assessment

TYPE OF DOCUMENTATION REQUIRED FOR DESK ASSESSMENTS

The type of documentation required for these assessments is listed in Evidence List A, B, and C, D, E et F in Table 2 below.

Table 2: Documentary Evidence Requirements

	Required Evidence	Comments/Exclusions
Evidence List A	Current GMP Certificate. (GLP or ISO/IEC 17025 certification for outsourced laboratory)	Certificates must be sufficient to cover the scope of the GMP compliance application.
Evidence List B	Current GMP Certificate	GMP agreements may be requested if the foreign manufacturer performs the release for supply function.
	Current manufacturing license	The manufacturing license should show the scope of products and activities approved by the local NRA.
	Regulatory inspections conducted within the past 3 years	Provide a list of all inspection reports applicable to the scope of the application.

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	Required Evidence	Comments/Exclusions
	and a copy of the most recent inspection report amongst those stated under Table 1 above.	<p>These may be sent to the NRA directly from the manufacturer.</p> <p>Processing can be expedited if reports for two or more of the above inspections are provided.</p> <p>Corrective action and preventive action evaluation report for the recent inspection report should be provided</p>
	Market complaints register	<p>for the previous three years, including one investigation report for one of the complaints classified as high risk to public health.</p> <p>The complaint register should be applicable to the products applied for.</p>
	Details of any regulatory actions in the past 3 years.	For example, product alerts, warning letters, import alerts, recalls due to defects.
	Site Master File, Quality Manual or equivalent.	<p>Site Master File (<i>refer to WHO Technical Report Series, No. 961, Annex 14 for guidelines for writing site master file</i>).</p> <p>Site master file not required if the scope of the application is only for the step of release for supply.</p>
	List of products intended for supply in Rwanda.	
	<p>a) Product Quality Assessment (PQR) report;</p> <p>b) Process validation report; and</p> <p>c) Batch records (batch manufacturing, packaging</p>	<p>The PQR reports should be provided for each product. In case of multiple products provide one PQR report from each FPP dosage form applied for.</p> <p>The batch records of a product for each FPP dosage form manufactured in the last 6 to 12 months; and the corresponding</p>

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	Required Evidence	Comments/Exclusions
	and testing) for each product applied for.	process validation reports and annual product quality assessment reports
Evidence List C	Validation Master Plan	Not required if the scope of the application is only for the step of release for supply.
	Aseptic validation report	Required for products applied for that are not terminally sterilized.
Evidence List D	Current GMP Certificate or ISO/IEC accreditation Certificate or WHO prequalification	For outsourced testing laboratories, a Good Laboratory Practice (GLP) certificate issued by a recognized Regulatory Authority or a current ISO/IEC 17025 accreditation certificate or prequalification of the laboratory by WHO may be used in lieu of a GMP Certificate For outsourced sterilization facilities certification to applicable ISO sterilization standards (e.g. ISO 11137, ISO 11135) may be used in lieu of a GMP Certificate.
	Quality Manual/Laboratory Manual or equivalent.	The quality manual/laboratory manual should be written as per the WHO good practices for pharmaceutical quality control laboratories, or as per the ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.
	Contract or agreement between the FPP or API manufacturer and the outsourced testing laboratory or sterilization institution	A copy of the contract or agreement clearly describing the roles and responsibilities of the manufacturer and the testing laboratory or sterilization institution should be submitted.

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	Required Evidence	Comments/Exclusions
	A list of tests a laboratory is authorized to perform as per the scope of its accreditation to the ISO/IEC 17025 or WHO prequalification. For botanical ingredients, evidence that authenticated standard reference materials are used.	The scope of activities of the outsourced laboratory should include the type, range and volume of testing and/or calibration, validation and verification activities it undertakes.
Evidence List E	Current GCP/GLP Certificate	Issued by national regulatory authority
Evidence List F	Clinical trial approval by the national regulatory authority	Provide a list summarizing the approved trials and their outcome. Provide a complete study report if no application has been submitted for marketing authorization of a product.
	Copy of IRB/IEC clinical trial approval	Provide approved protocol and consent form. Provide list of committee members of the IRB/IEC
	Quality Manual or equivalent	Quality Manual (<i>refer to guidelines for writing Quality Manual</i>). Responsibilities of the sponsor and clinical investigator should be provided. Management and assessment of subcontracted vendors should be provided. Deviation management and procedures for handling the investigational product.
	Regulatory inspections conducted within the past 3 years and a copy of the most recent inspection report amongst those stated under Table 1 above.	Provide a list of all inspection reports applicable to the scope of the application. These may be sent to the NRA directly from the manufacturer

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	Required Evidence	Comments/Exclusions
		<p>Processing can be expedited if reports for two or more of the above inspections are provided.</p> <p>Provide the following inspection reports:</p> <p>a) by national regulatory authority, and</p> <p>b) study monitoring report by the sponsor, except where the sponsor are the same.</p>
	Concerns/alerts raised by the NRA and any other responsible authority	Provide details of investigation of any non-compliances and how they were addressed.

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Documentary evidence should adhere to the following requirements:

- a) All certificates and other supporting documents should be in English or French or Kinyarwanda.
- b) Where the document is not in English or French or Kinyarwanda, it should be submitted with a certified translation.
- c) translated documents must be accompanied by a signed and dated statement, by the certified translator, stating that it is a true and accurate translation of the original document;
- d) documents must be the most recent and reflect current activities and practices and dated (expired/superseded documentation cannot be used);
- e) documents must provide sufficient information to cover the scope of activities for which GxP compliance is sought; and
- f) All documents are to be submitted electronically and are not required to be certified as original copies unless requested by Rwanda FDA. Certification of documents may be requested if for example, there was concern over the validity of the supplied documents.

Rwanda FDA can request certified copies of original documents at any time. Certified copies must be legible and authenticated as true copies by any one of the following:

- 1. The competent national regulatory authority of the country of origin.
- 2. A Public Notary (include details of the relevant practice certificate or license number).

The following is an example of a declaration that should appear on the front page of the document being certified:

<i>Declaration of Authenticity</i>		
<i>I, the undersigned, as afor the state/city of, country</i>		
<i>declare that the attached copy of the document issued byand certified by me,</i>		
<i>is a true and accurate copy of an original document presented to me for certification.</i>		
_____	_____	<i>Date:/...../.....</i>
<i>Full Names</i>	<i>[Signature]</i>	<i>Day/Month/Year</i>

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2.5 Application Processing

The Authority shall process the application within 120 days upon the receipt of a complete dossier. The Authority issues a GMP certificate valid for 3 years upon successful desk assessment completion. Appropriate responses on missing information or issues that require clarification by the applicant shall be received within 30 calendar days of the query letter receipt and where appropriate responses are not received within 30 calendar days an onsite inspection is scheduled. Furthermore, the Authority may revoke or suspend the issued desk assessment GMP certificate upon being satisfied that the facility is no longer considered to be in compliance with GMP requirements and Rwanda FDA shall plan for on-site inspection.

2.5 Triggers and factors leading to conducting onsite inspection

- a) If it is known that the facility or site has not been inspected and approved by the SRA/WLA, WHO-PQ or regional harmonization initiatives (EAC).
- b) The site or facility or production line was not relevant to the specific SRA, WLA or WHO-PQ product.
- c) Failure to submit documentary evidences or any requested information during desk assessment
- d) Facilities that have been subjected to successful desk review for two consecutive times.
- e) Any other risk factors that may be identified by the Authority

2.6 Responsibilities of the Applicant

The main responsibilities of an applicant for GMP desk assessment are listed below:

- a) Ensuring that all required evidence documents are submitted with applications for GMP desk assessment. Incomplete applications may be rejected.
- b) Remitting all application fees at the time of lodging an application for GMP Desk Assessment
- c) Submitting a signed statement confirming the authenticity and uniformity of the documents with those submitted to the NMRA Rwanda FDA relied on.
- d) Submitting applications for renewal of a GMP Certificate at least six months prior to the expiry of the current Certificate.
- e) Promptly submitting any additional information that may be requested by Rwanda FDA during an assessment to complement the requested documents or information. Failure to

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provide required documents within the specified time, depending on additional information requested, may result in the application being rejected.

2.7. Actions taken by the Authority in response GMP non-compliance requirements



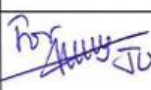

The impact of the non-compliance should be assessed by Rwanda FDA to ascertain the potential risk to public health, supply and availability of affected medicines. This assessment should take into consideration the risk of exposure of national shortages and divergent actions.

The following are some of the actions taken by Rwanda FDA in response to reported serious non-compliance:

- a) Issuance of a rapid public alert to collaborating partners
- b) Issuance of non-compliance letter
- c) Suspension of Marketing Authorization
- d) Withdrawal/cancellation of the GMP certificate
- e) Institution of a recall
- f) Suspension of supply or importation

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ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	Division manager	Head of Department	Quality Assurance Analyst	Director General
Names	Dr. MURINDAHABI. M. MARILYN	Dr. Eric NYIRIMIGABO	Théogène NDAYAMBAJE	Dr. Emile BIENVENU
Signature				
Date	26/09/2022	27/09/2022	26/09/2022	27/09/2022



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APPENDICES

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Appendix A: GMP Desk Review Report Format



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QMS N°: FDISM/FDIC/FMT/018
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GMP DESK REVIEW REPORT FORMAT FOR FINISHED PHARMACEUTICAL PRODUCTS AND ACTIVE PHARMACEUTICAL INGREDIENT MANUFACTURERS

Part 1. General information	
a) Particulars of the applicant	<i>Name of applicant, physical address, postal, address of applicant (if different from physical address), 24-hour telephone numbers, fax, email address</i>
b) Particulars of the manufacturer	<i>Name of manufacturer, physical address of manufacturer including the block and/or unit number, postal address of manufacturer (if different from physical address), 24-hour telephone number(s), fax, email address, contact person</i>
c) Activities performed on the site	<i>For example, manufacture of APIs, manufacture of FPPs, intermediates or bulk packaging, laboratory testing, batch release, warehousing, primary and secondary packaging</i>
d) Date of last Inspection by NRA	<i>Date when the last inspection was carried out, name of the national medicines regulatory authority that carried out the inspection</i>
e) Production and packaging lines applied for	<i>For FPP: dosage form line, category: beta lactam, non-beta lactam, biologicals, vaccines, hormones, cytotoxic products For API: name of API</i>

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f) Authorized representative of marketing authorization holder in the recipient country	<i>For example, representative, agent</i>
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Part 2. Documentary evidence (comment on adequacy of information provided)	
a) Current site master file	<i>Comment on date, completeness and adequacy in accordance with Rwanda FDA guidelines on FPP</i>
b) List of all regulatory inspections carried out in the past three years	<i>Name of all the regulatory authorities that carried out the inspection, dates when the inspection was carried out, inspection outcomes.</i>
c) Copy of valid manufacturing license granted by the NRA together with a certified translation, if not in English	<i>Number of manufacturing license, name of regulatory authority that granted the licence, validity of the manufacturing licence and scope</i>
d) Copy of valid GMP certificate granted by the national medicines regulatory authority together with a certified translation, if not in English	<i>Number of GMP certificate, name of NRA that granted the certificate, validity of the GMP certificate and scope</i>
e) List of products manufactured at the site and those to be exported to the country of import	<i>List of products, dosage form (where applicable), list of registered products and those to be registered</i>
f) Notarized copy of inspection report(s) from the national medicines regulatory authority and/or that from WHO prequalification (whichever is applicable) carried out within the past three to five years	<i>Name of the regulatory authority that carried out the inspection, dates of the inspection, scope of inspection, findings and recommendations, list of findings of noncompliance, conclusion CAPA reports submitted and found satisfactory for the most recent inspection (adequacy of CAPA, timelines)</i>

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g) Performance of the company's products on the market over the past three years	Any product alerts, warning letters, market complaints, product failure, product recall or any unacceptable findings for the product(s) in scope Any product alerts, warning letters, market complaints, product failure, product recall, or any unacceptable findings for the product(s) in scope
h) Reports of product quality review	For products for which marketing authorization is being sought or renewed: assess the consistency of the processes, trends, specifications, process changes, recalls, returns, market complaints, deviations from critical parameters, in-process controls, quality control tests, stability study data (select product of interest)
i) Validation master plan	Validation policy, utilities qualification, equipment qualification, procedures, protocols, reports, cleaning, personnel qualification, process validation, analytical method validation, computer validation, revalidation, requalification, validation matrix
j) Process validation for one of the products marketed or to be registered in the country of import	Comment on adequacy
k) One batch manufacturing record (BMR) for each product together with the master batch record including the packing and analytical part (with a certified translation of the original BMR where applicable); BMR should refer to a product marketed or to be registered in the country of import	Comment on adequacy
l) Out-of-specification (OOS) procedure: records of three OOS including at	

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least one assigned to a laboratory error.	
m) List of reprocessed or reworked product batches in the past two years	

Part 3. Recommendation
<p>1. Recommended for a GMP compliance approval? <i>(Provide recommendation based on the results of the assessment done in Parts 1 and 2)</i></p>
<p>2. If Yes, list production lines, product, pharmaceutical active ingredient recommended:</p>
<p>3. If No, state reasons and the relevant sections of the guideline(s) below:</p>

Part 4. Evaluation team
<p>First assessor Signed: _____ Date: _____ Name: _____ Position: _____ (BLOCK CAPITALS)</p>
<p>Second assessor Signed: _____ Date: _____ Name: _____ Position: _____ (BLOCK CAPITALS)</p>

Reference:

1. WHO Technical Report Series, No. 1010, 2018; Annex 1 “Model report format for desk assessment for finished pharmaceutical products and active pharmaceutical ingredient manufacturers”

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Appendix B: Model format of Certificate of Desk Assessment for Good Manufacturing Practices (GMP) Compliance



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QMS N°: FDISM/FDIC/FMT/027
Revision No: 0
Effective Date: 30/09/2022

CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE

(Issued in accordance with Article 9, paragraph 2 of Law N° 003/2018 of 09/02/2018)

Certificate N°:	Issue Date: DD/MM/YYYY	Valid up to: DD/MM/YYYY
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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 inspected by the Rwanda Food and Drugs Authority for compliance with the Good Manufacturing Practice Guidelines.

Based on the **Desk Assessment** carried out on DD/MM/YYYY, DD/MM/YYYY, and DD/MM/YYYY it certifies that the pharmaceutical manufacturing facility indicated on this certificate complies with Good Manufacturing Practice for dosage forms, categories and activities listed in Table below:

N°	Dosage form	Category	Activities
1.			

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.

Name and signature of Director General

Director General

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