RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR GOOD STORAGE AND DISTRIBUTION PRACTICES OF MEDICAL PRODUCTS

APRIL, 2024

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FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to the quality, safety and efficacy of distributed medical products in Rwanda. Considering the provisions of the technical regulations N° DD/PIL/TRG/006 governing Good Storage and Distribution Practices of Medical Products, the Authority issues these Guidelines N° DD/PIL/GDL/006 for Good Storage and Distribution Practices of Medical Products.

These guidelines provide guidance to the distributors and wholesalers of medical products about good storage and good distribution practices. Distributors of medical products are encouraged to familiarize themselves with these guidelines and follow them when storing and distributing medical products.

Adherence to these guidelines will ensure that relevant information is provided for storage and distribution of medical products. This will facilitate efficient and effective storage and distribution of medical products with assured quality, safety and efficacy. It will also help to avoid malpractices in the storage and distribution process of medical products.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Prof. Emile BIENVENU
Director General

Digitally signed by Rwanda FDA (Director General)
Date: 2024.04.23 16:55:58 +03'00'

DOCUMENT DEVELOPMENT HISTORY

First issue date	18/09/2020
Effective date of this revision	29/04/2024

Document Revision History

Revision number	Changes made and/or reasons for revision
1	1. The title of the Guidelines changed from "Guidelines for Good Distribution Practices of Medical Products" to Guidelines for Good Storage and Distribution Practices of Medical Products to reflect the related technical regulations. 2. Recommended storage conditions have been added 3. A section for transport and delivery validation has been added 4. Document was rearranged
2	1. Adoption of WHO GSDP guidelines 2. Types of GSDP inspections (routine inspection, concise inspection, follow up inspection, special inspection and any other types as the Authority may designate) were added 3. Inspection frequency has been added 4. Inspection preparation and execution have been added 5. Classification of deficiencies has been added 6. Decisions on compliance and guidance in responding to inspection findings have been added 7. The validity of the GSDP certificate has been revised from one (1) year to three (3) years 8. The format of GSDP certificate has been added

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ACRONYMES AND ABBREVIATIONS

CAPA	Corrective Actions and Preventive Actions
FEFO	First Expiry, First Out
GSDP	Good Storage and Distribution Practices
IRIMS	Integrated Regulatory Information Management System
SOP	Standard Operating Procedure
TRS	Technical Report Series
QRM	Quality Risk Management
WHO	World Health Organization

GLOSSARY / DEFINITIONS

The definitions provided below apply to the words and phrases used in these guidelines. Although an effort has been made to use standard definitions as far as possible, they may have different meanings in other contexts and documents.

"Authority" means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under article 2 of the Law Nº. 003/2018 of 09/02/2018.

"Authorization" means a legal document granted by Rwanda FDA to an applicant under the Law Nº 003/2018 of 09/02/2018, it includes licenses, permits, and certificates.

"Batch (or lot)" means a total quantity of goods produced at one time

"Corrective and preventative actions or its acronym (CAPA) means a system for implementing corrective and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings and trends from process performance and product quality monitoring.

"Critical deficiency" means a departure from current WHO Good Storage and Distribution Practices guidelines that may result in a medical product causing a significant risk to the patient and public health. This includes an activity increasing the risk of falsified medical products reaching the patients. This may also involve fraud, misrepresentation or falsification (of products, information). A combination of several major observations that indicates a serious systems failure may be also classified as a critical observation. Critical observations require immediate actions.

"Distribution" The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of medical products, with the exception of the dispensing or providing medical products directly to a client.

"Distributor" means an organization or an entity, such as a wholesaler that distributes manufacturer's products to market. They serve as an intermediary in the manufacturer's supply chain. promoting and selling the products to wholesalers or other entities, excluding the end consumer. Distributors are authorized to exclusively sell medical products for which they are the legal representatives to other wholesalers.

"First Expiry, First Out' (FEFO)" means a distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used.

"Good Distribution Practices (GDP)" That part of quality assurance that ensures that the quality of a medical product is maintained by means of adequate control of the numerous activities that occur during the trade and distribution process, as well as providing a tool to secure the distribution system from falsified, unapproved, illegally imported, stolen, substandard, adulterated and/or misbranded medical products

"Good Storage Practices (GSP)" is that part of quality assurance that ensures that the quality of medical products is maintained by means of adequate control throughout the storage thereof.

"GSDP inspector" is a person appointed by the Rwanda FDA who is qualified and experienced in the storage and distribution of medical products to conduct an inspection or assessment to verify

compliance with the minimum standards of storage and distribution of medical products to ensure that the quality and integrity of medical products are maintained throughout the supply chain.

"**Major deficiency"** means a non-critical deficiency which indicates a major deviation from current WHO Good Storage and Distribution Practices guidelines that may increase the risk to public health and safety. A combination of several observations classified as 'other', none of which on their own may be major, may together represent a major deficiency. Major observations require high priority actions.

"Medical products" includes human and veterinary drugs, human and animal vaccines and other biological products used in clinical as drug, herbal medicines, and human and veterinary medical devices.

"Minor deficiency" an observation classified as 'minor' may be defined as a deficiency which cannot be classified as either critical or major, but which indicates a departure from current WHO Good Storage and Distribution Practices guidelines. A deficiency may be other either because it is judged as minor or because there is insufficient information to classify it as major or critical.

"Premises" means any plot of land, buildings or boats, aircraft, vehicles, a part of a building, channels, yards, a place of storage, annexed to a building, or part of that building, carriage or receptacle of any kind, whether open or closed;

"Pharmaceutical product" means any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises in which food and drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses.

"Retailer" is an entity authorized to carry on the business of dispensing or providing medical products directly to a patient or his or her agent only. Retailers are not authorised to supply medical products to distributors or other retailers.

"Validation" means the action of proving, in accordance with the principles of Good storage and Distribution Practice, that any procedure, process, equipment, material, activity or system actually leads to the expected results

"Vehicles" means trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey regulated products.

"Wholesaler" is an entity that purchases large quantities of products and sells them in bulk to any entity other than the patient. Wholesalers can buy products from distributors but are not allowed to sell to the premises within the same category.

INTRODUCTION

The '*Guidelines for Good Storage and Distribution Practices of Medical Products'* are a Rwanda Food and Drugs Authority publication, which sets out procedures and requirements for the storage and distribution of medical products. They are issued in pursuance of Article 9 of Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning and in terms of Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products and regulations N° DD/PIL/TRG/006 governing Good Storage and Distribution Practices of Medical Products which were put in place to ensure quality within the medical products storage and distribution chain.

These Guidelines consist of links for World Health Organization (WHO) Technical Report Series (TRS) and other internationally recognized guidelines which details Good Storage and Distribution Practices (GSDP) requirements for various aspects applicable to the storage and distribution of medical products.

These guidelines are intended to provide guidance that should be followed by all companies involved in any aspect of storing, wholesaling and distribution of medical. It targets both public and private wholesalers and distributors of medical products.

Therefore, these guidelines shall form the basis of GSDP inspection by Rwanda Food and Drugs Authority (Rwanda FDA) as one of the requirements for the registration and licensing of premises involved in storing, wholesaling and distribution of medical products within Rwanda.

This document sets out appropriate steps to assist people in fulfilling the responsibilities involved in the different aspects of the storage and distribution processes within the health supply chain and to maintain the quality and safety and efficacy of medical products on the Rwandan market.

The relevant sections should be considered by various actors as applicable to the particular role that they play in the storage and distribution of medical products.

To maintain the original quality of medical products, every party active in the storage and distribution chain has to comply with the provisions of the Rwanda FDA laws regarding the handling of medical products. Every activity in the storage and distribution of medical products should be carried out according to the principles of GSDP.

SCOPE

These guidelines shall apply in all regulatory controls related to good storage and distribution practices for medical products and shall apply to all persons and companies involved in any aspect of the distribution and storage of medical products from the manufacturing site to the point of use.

These include but are not limited to governments at all levels, domestic, public and private health and storage facilities, manufacturers of medical products, importers, exporters, distributors, wholesalers, suppliers, retailers, freighters, forwarding agents, transporters, public and private customs bonded warehouses.

CHAPTER 1: GOOD STORAGE AND DISTRIBUTION PRACTICE INSPECTION

1.1 Types of inspections

1.1.1 There shall be four types of good storage and distribution practice inspections which should be divided into the following categories:

a. Routine inspection;
b. concise inspection;
c. follow-up inspection;
d. special inspection; and
e. any other types as the Authority may designate.

1.1.2 The inspection should be conducted as follows:

a. The routine inspection is a full inspection of all applicable components of GSDP and licensing provisions. It shall be conducted at any time when the premise has been licensed but before expiry of the premise license. It may be indicated when the premise is:

i. Requests for renewal of a premises license to operate
ii. Has a history of non-compliance with GSDP;
iii. Has introduced new products, or has made significant modifications to storage and distribution processes, or has made changes in key personnel, premises, equipment, etc.
iv. Has not been inspected during the last 3 to 5 years.

b. Concise GSDP inspections are the evaluation of limited aspects relating to GSDP compliance within a facility. The premises with a consistent record of compliance with GSDP through previous routine inspections are eligible for concise inspections. The focus of a concise inspection is on a limited number of GSDP requirements selected as indicators of overall GSDP performance, plus the identification of any significant changes that could have been introduced since the last inspection. Collectively, the information obtained will indicate the overall attitude of the firm towards GSDP. Evidence of unsatisfactory GSDP performance observed during a concise inspection should trigger a more comprehensive inspection.

c. Follow-up GSDP inspections (reassessment or re-inspection) are made to monitor the result of corrective measures. They are normally carried out from 6 weeks to 6 months after the initial inspection, depending on the nature of the defects and the work to be undertaken. They are limited to specific GSDP requirements that have not been observed or that have been inadequately implemented.

d. Special GSDP inspections may be necessary to undertake spot checks following complaints, recalls related to suspected quality defects in products or reports of adverse drug reactions. Such inspections may be focused on one product, a group of related products or a specific procedure such as storage. Special visits may be also made to establish how a specific product is manufactured as a prerequisite for marketing approval or issuance of an export certificate.

e. Any other types as the Authority may designate. This may include pre-approval inspection for newly established premises.

1.2 Application for GSDP

An applicant shall submit the application for premise licensing to the Authority through Integrated Regulatory Information Management System (IRIMS) available at Rwanda FDA website.

GSDP inspection shall be conducted in accordance to the GSDP annual inspection plan based on Quality risk management (QRM) principles. The GSDP certificate will be granted to new applicants concurrently with the premise license following a successful GSDP inspection. The Authority will then conduct a follow-up GSDP inspection after 12 months to ensure the implementation of standard operating procedures and related records.

The Application should be accompanied by prescribed fees as provided in the Regulations governing tariff/fees and charges on services rendered by Rwanda Food and Drugs Authority.

1.3 General requirements

The following are the requirements for all concerned premises that conduct storage and distribution of medical products:

a. The principles of GSDP are applicable both to medical products moving forward in the storage and distribution chain from the manufacturer to the entity responsible for dispensing or providing medical products to the patient and to the products that are moving backward in the supply chain, for example, as a result of the return or recall thereof.

b. All entities involved in the storage distribution processes should apply due diligence with adherence to the principles of GSDP, for example, in procedures relating to traceability and in recognition of security risks. These principles should also be adhered to in the case of medical products, which are donated.

c. Distributors should maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities. All distribution activities should be clearly defined and systematically reviewed. All critical steps of distribution processes and significant changes should be justified and where relevant validated. The quality system is the responsibility of the organisation's management and requires their leadership and active participation and should be supported by staff commitment.

d. There must be sufficient competent personnel to carry out all the tasks for which the distributor is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.

e. To have suitable and adequate premises, installations and equipment, so as to ensure proper storage conditions and distribution of medical products.

f. To have good written documentation to prevent errors from spoken communication and permit the tracking of relevant operations during the distribution of medical products.

g. To have a tracking system that ensures the safety, quality and efficacy of the medical product are not lost and that the distribution of medical products is performed according to the information on the outer packaging. The distributor should use all means available to minimise the risk of falsified medical products entering the legal supply chain.

h. To have records of all complaints, returns, suspected falsified medical products and recalls according to written procedures. Records should be made available to the competent authorities. An assessment of returned medical products should be performed before any approval for resale. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified medical products.

i. To provide a written Contract between the supplier and the distributor which clearly establishes the duties of each party. Any activity covered by the GSDP Guidelines that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product.

j. It is the responsibility of the distributor to ensure that the quality of the medical products is maintained from the manufacturer to the storage areas and then to the final consumer, the retailer or/and client. It is the responsibility of the supplying distributor to protect medical products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport. Regardless of the mode of transport, it should be possible to demonstrate that the medical products have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilized when planning transportation.

k. Self-inspection monitors the implementations and compliance with the principles of GSDP; self-inspections are conducted by a competent designated person; self-inspections should be conducted in order to monitor implementation and compliance with these principles and to propose necessary corrective measures. Self-inspections should be recorded; reports should contain observations and corrective actions taken and recorded.

l. To provide a Standard Operating Procedure (SOP) for transportation plans based on Quality Risk Management (QRM) principles to ensure that the medical products have not been exposed to conditions that may compromise their quality and integrity during transport.

1.4 Inspection Frequency

Wholesaler or distributor shall be inspected every 1 to 3 years according to Quality Risk Management (QRM) principles. However, a premise may be inspected at any time when necessary

1.5 Preparation for inspection

The Authority shall inform the premises of the proposed inspection date fifteen (15) calendar days before the inspection takes place. The inspector shall be responsible for communicating with the premise regarding the plan of inspection. The respective premise shall make the necessary preparations for inspection at the agreed time.

Under exceptional circumstances and with proper justification, a premise wishing to change the agreed inspection dates shall do so in writing proposing the most convenient date for both parties.

1.6 Execution of GSDP Inspection

During the inspection, inspectors shall observe, verify and review storage and distribution processes, procedures and records to establish compliance with the GSDP requirements stipulated in these guidelines. The inspector shall inspect using these guidelines.

At the end of an inspection, observations shall be documented in the Memorandum of Findings form which shall be signed by both parties along with the attendance list and a copy given to the person who has been inspected. Inspection of one premise shall take 1 to 2 days depending on the premise's size.

1.7 Reporting and communication of inspection findings

The inspection report shall be prepared and communicated to the person who has been inspected within thirty (30) working days from the last date of inspection.

The applicant should provide the CAPA within 15 working days after the receipt of the report. The CAPA assessment report should be shared with the applicant within 15 working days.

1.8 Classification of inspection findings

1.8.1 Critical deficiency

A deficiency which results in a medical product causing a significant risk to the patient and public health. This includes an activity increasing the risk of falsified medical products reaching the patients. This may also involve fraud, misrepresentation or falsification (of products, information). A combination of several major observations that indicates a serious systems failure may be also classified as a critical observation. Critical observations require immediate actions.

Examples of critical deficiencies

a. Lack of equipment for storage of cold chain products
b. Failure to monitor temperature and humidity for cold chain products within specified limits
c. Lack of procedure for receipt and dispatch of cold chain products
d. Failure to monitor transport storage conditions during receipt and transport of cold chain products.
e. Lack of appropriate controls and segregation for products requiring specific handling or storage conditions

1.8.2 Major deficiency

A non-critical deficiency:

a. which has produced or may produce a product, which does not comply with its marketing authorization; or,

b. which indicates a major deviation from Rwanda FDA Good Manufacturing Practice; or,
c. which indicates a major deviation from the terms of the manufacturing authorization; or,
d. which indicates a failure to carry out satisfactory procedures for release of batches or a failure of the authorized person to fulfil his/her required duties; or
e. a combination of several "other" deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such.

Examples of Major Deficiency:

a. Lack of qualification and validation for equipment and instruments, process and procedures
b. Failure to monitor temperature and humidity within specified limits
c. Lack of appropriate procedures and records for handling/management of temperature excursions outside of predefined temperature limit extremes.
d. Damage (holes, cracks, peeling paint) to walls/ceilings in the warehouse
e. Design of a warehouse that does not permit effective cleaning that could lead to mix-ups
f. Lack of designated and labelled storage area for expired, recalled/returned and/or substandard medical products
g. Inadequate initial and ongoing training and/or no training records
h. Cleaning procedures not documented and/or no cleaning records
i. Deviations from instructions not approved
j. No or inadequate internal inspection program
k. No proper release for supply procedure
l. No system/procedures for handling complaints or returned goods
m. Insufficient lighting in storage areas
n. The containers from which samples have been taken were not identified
o. Inadequate change control system
p. Inadequate deviation system
q. No investigation into alarms and temperature excursions for deviations from storage or transport requirements
r. Unpacking of finished products for individual unit's sales.
s. QA is not independent from the person responsible for operations
t. Lack restriction access measures to storage areas and/or computerized system.
u. The computerized system was not validated
v. Lack of procedures for software data back-up
w. Lack of cleaning procedures and records of implementation
x. Lack of pest control procedures and records of implementation

1.8.3 Minor deficiency:

A deficiency which cannot be classified as either critical or major, but which indicates a departure from good storage and distribution practice. A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as critical or major.

1.9 Decision on compliance

The status of compliance with these guidelines should be determined by the nature and number of deficiencies:

a. When there are minor deficiencies only:

i. the site is considered to be operating at an acceptable level of GSDP compliance,
ii. the wholesaler/ distributor is expected to provide CAPAs,
iii. CAPAs are evaluated and followed up during the next routine inspection

b. When there are minor and less than six (<6) major deficiencies observations from different 9 GSDP quality systems namely (1) Quality Management System; (2) Personnel, (3) Premises and equipment; (4) reception and storage of medical products; (5) Distribution; (6) activities and operations; (7) handling of complaints, returns, recalls and suspected falsified medical products; (8) Outsourced activities, (9) activities and operations:

i. The premise is compliant with GSDP after assessing the CAPAs,
ii. CAPAs for all deficiencies to include actions implemented and/or planned, timelines and documented evidence of completion, as appropriate,
iii. CAPAs are evaluated on paper and may or may not include an on-site, follow-up inspection.

c. When there are critical or six or more (≥6) major deficiencies observations from different quality systems:

i. The premise is considered to be operating at an unacceptable level of compliance with GSDP guidelines,
ii. another inspection will be required,
iii. administrative and/or legal enforcement actions are applied as necessary.

The next date for inspection of the site should be determined depending on the level of compliance and risk category as defined under national procedures. The report shall be signed by all inspection team members, but may be signed by the lead inspector after consultation with and on behalf of the inspection team, and reviewed in accordance with the quality system of the inspectorate.

1.10 Guidance on responding to inspection findings

The premises shall prepare and implement a CAPA plan where applicable upon receiving inspection findings. The CAPA plan and evidence for its implementation shall be prepared based on quality risk management principles and submitted to the Authority within 15 working days from the date of the inspection report cover letter. Upon receipt of the CAPA report, the inspectors review the CAPA plan and evidence of implementation and provide a CAPA assessment report within 15 working days.

If the company fails to submit a CAPA report within the prescribed period without any request for an extension, the premise shall be considered to be non-compliant and regulatory actions shall be applied accordingly.

The CAPA report shall indicate corrective actions and preventive actions, timelines and evidence for implementation for each deficiency observation and timelines as per the format provided in Appendix II of these guidelines.

1.11 Issuance of GSDP certificate

A certificate shall be issued upon compliance with GSDP requirements. The GSDP certificate shall be valid for three (3) years.

A GSDP certificate shall not be granted where the Authority finds the applicant not complying with the requirements prescribed in these guidelines and relevant regulatory documents.

1.12 Regulatory actions

Regulatory actions shall be applied in accordance to the Authority's regulations governing Good Storage and Distribution of medical products.

CHAPTER 2: GSDP INSPECTION REFERENCE GUIDELINES

The reference guideline documents listed below are the current WHO guidelines and may be updated from time to time. The latest versions of each guideline as revised by the WHO shall be applicable in each case. Other international Guidelines such as PIC/S, ICH, US FDA and EMA may be used as supplementary guidance documents while establishing compliance of facilities to GSDP requirements.

2.1 WHO Good Storage and Distribution Practices for medical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020: Annex 7 (WHO Technical Report Series, No. 1025).
https://www.who.int/publications/m/item/trs-1025-annex-7

2.2 Model Guidance for the storage and transport of time and temperature sensitive pharmaceutical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: Forty-fifth report. Geneva: World Health Organization; 2011: Annex 9 (WHO Technical Report Series, No. 961)
https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

2.3 Good trade and distribution practices for pharmaceutical starting materials. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016: Annex 6 (WHO Technical Report Series, No. 996)
https://www.who.int/publications/m/item/annex-6-trs-996

2.4 Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-fifth report. Geneva: World Health Organization; 2011: Annex 8 (WHO Technical Report Series, No. 961) https://www.who.int/publications/i/item/9789241209618

2.5 Guidelines on import procedures for medical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-third report. Geneva: World Health Organization; 2019: Annex 5 (WHO Technical Report Series, No.1019)
https://www.who.int/publications/i/item/WHO_TRS_1019

2.6 WHO guidelines on quality risk management. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-seventh report. Geneva: World Health Organization; 2013: Annex 2 (WHO Technical Report Series, No. 981)
https://www.who.int/publications/m/item/trs981-annex2

2.7 PIC/S Guide to Good Distribution Practice for medicinal products. Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-Operation Scheme. PE 011-1. 1 June 2014. https://picscheme.org/docview/3450

ENDORSEMENT OF THE GUIDELINES

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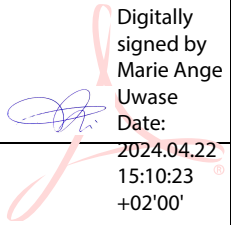
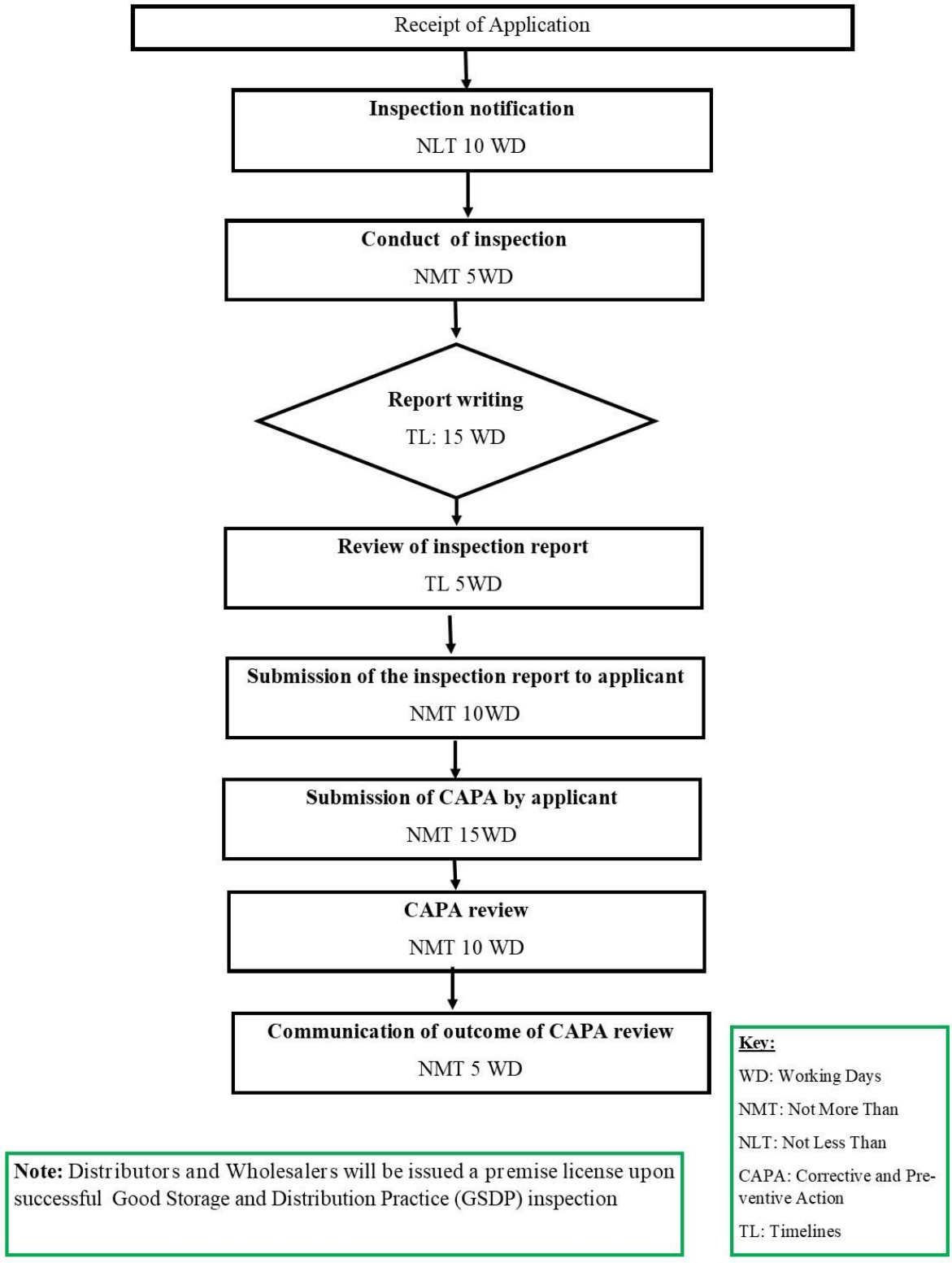
Signature		Digitally signed by Vedaste Habyalimana Date: 2024.04.22 12:36:29 +02'00'	 Digitally signed by Marie Ange Uwase Date: 2024.04.22 15:10:23 +02'00'	 Digitally signed by Rwanda FDA (Director General) Date: 2024.04.23 16:55:25 +03'00'
Date	22/04/2024			

APPENDICES

APPENDIX I: TIMELINES FOR GSDP INSPECTION



APPENDIX II: GSDP INSPECTION REPORT

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/PIL/FMT/023
Revision No:2
Effective Date: 29/04/2024

GSDP INSPECTION REPORT

Inspection dates:	**Report date:**
1.0 General Information	
1.1 Inspected establishment(s)	
a) Name: **b) Physical address:** **c) City:** **d) Country:** **e) Telephone**: **f) Email address**: **g) Website**:	
a) Premise registration certificate number: **b) Premise license number:**	
c) Contact person(s) of the inspected establishment:	
1.2 Activities carried out by the company at the inspected establishment:	
1.3 GSDP Inspectors	
Names of Rwanda FDA GSDP Inspectors that carried out the inspection.	
1.4 Name of expert if applicable:	
1.5 Foreign National Regulatory Authority Participation:	
1.6 Type of inspection:	
1.7 Purpose of Inspection:	
1.8 General information about the company **1.8.1 Regulatory status**	
1.9 Previous inspections conducted by the Authority:	
1.10 Major changes since the previous inspection	
1.11 Samples taken and results obtained (if applicable)	

2.0 Brief Report of the Inspection activities undertaken
2.1 Scope of Inspection
2.2 Observations and Findings
2.2.1 Personnel
2.2.2 Quality management system
1. Documentation system **2. SOP for SOPs** **3. Change Control** **4. Quality risk management** **5. Management of Deviations, Non-conformities and CAPA** **6. Management review** **7. Complaints management** **8. Self-inspection (Internal audit)**
2.2.3 Premises and equipment
1. Organization of the warehouse **2. Computerized system**
2.2.4 Reception and storage of products
1. Control at reception **2. Physical storage conditions** **3. Stock control and rotation**
2.2.5 Distribution
1. Dispatch **2. Transport**
2.2.6 Activities and operations
1. Qualification of suppliers **2. Qualification of customers** **3. Import and Export**
2.2.7 Handling of Specific products
1. Handling of regulated/controlled products (narcotics and psychotropic) **2. Handling of non-compliant products** **3. Management of returned products** **4. Management of product recalls**
2.2.8 Cold chain management
2.2.9 Management of outsourced activities
1. Outsourced activities related to storage

2. Outsourced activities related to distribution

3.0 Summary of Deficiencies to GSDP

3.1 Critical deficiencies

No.	Deficiencies	Reference
1		

3.2. Major Deficiencies

No.	Deficiencies	Reference
1.		

3.3 Other Deficiencies

No.	Deficiencies	Reference
1		

I.0 Recommendations and Conclusion

I.1 Recommendations

I.2 Conclusion – inspection outcome

Definition of Deficiencies

CAPA Plan format

Deficiencies	Corrective Action	Time line

NAMES OF THE INSPECTORS AND SIGNATURES

End of Report

APPENDIX III: FORMAT OF CERTIFICATE OF COMPLIANCE WITH GSDP

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/PIL/FMT/022
Revision No:2
Effective Date: 29/04/2024

CERTIFICATE OF COMPLIANCE WITH GOOD STORAGE AND DISTRIBUTION PRACTICE

Certificate N°: *Issue Date: DD/MM/YYYY* *Valid up to: DD/MM/YYYY*

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

Name of premise:
Physical address:
Premise registration certificate number:
License number:
E-mail: **Telephone:**

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

Based on the Physical Inspection carried out on DD/MM/YYYY, and DD/MM/YYYY, it certifies that the premise indicated on this certificate complies with Good Storage and Distribution Practice.

N°	**Scope**	**Activities**
1.	**Human Finished pharmaceutical Products, Human medical devices, In-vitro diagnostic, veterinary medical products**	Import/ Export, Storage, Distribution, wholesale,

The certificate provided indicates the compliance status of the premise as of the inspection date mentioned above. This certificate should not be relied upon to reflect the compliance status if more than three (3) years have elapsed since the date of that inspection.
This certificate becomes invalid if the activities or the scope certified change or if the premise is no longer rated to be in compliance with Good Storage and Distribution Practice.

Name of the Director General
Director General

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