

**GUIDELINES FOR GOOD MANUFACTURING PRACTICES INSPECTIONS FOR PHARMACEUTICAL PRODUCTS MANUFACTURING FACILITIES**

**JANUARY, 2024**

# 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.

Considering the provisions of *the regulations No FDISM/FDIC/TRG/005, governing Good Manufacturing Practices for medical products.* The Authority issues the guidelines No FDISM/FDIC/GDL/012 on Guidelines on Good Manufacturing Practice Inspections for Pharmaceutical Products Manufacturing Facilities.

Badly manufactured Pharmaceutical products' effects are one of the public health concerns not only to our country but also all over the world. It is in this context that the Rwanda Food and Drugs Authority intends to put in place guidelines that provide for good manufacturing practices of Pharmaceutical 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 these guidelines will offer a clear understanding to manufacturers and other persons concerned by the guidelines during the evaluation process; they will protect consumers and pharmaceutical manufacturing industry, thus promoting health protection, business as well as the national economy as a whole.

**Dr. Emile BIENVENU**

**Director General**

# GUIDELINES DEVELOPMENT HISTORY

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# ABBREVIATIONS AND ACRONYMS

**CAPA:** Corrective and Preventive Actions

**GMP**→ Good Manufacturing Practices

**HVAC** →Heating, Ventilation and Air Conditioning

**ICH**→ International Council for Harmonization

**IAEA**→ International Atomic Energy Agency

**PIC/S**→ Pharmaceutical Inspection Cooperation Scheme

**Rwanda FDA**→ Rwanda Food and Drugs Authority

**TRS** → Technical Report Series

**WHO→** World Health Organization

**US FDA**→ United States Food and Drugs Authority

**DEFINITIONS**

**“Active pharmaceutical ingredient (API) or Drug substance”**any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body;

**“Batch or lot”** defines quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous. To complete certain stages of manufacture, it may be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. For the control of the finished product, a batch of a medicinal products comprises all the units of a pharmaceutical form which are made from the same initial mass of material and have undergone a single series of manufacturing operations or a single sterilization operation or, in the case of a continuous production process, all the units manufactured in a given period of time;

**“Cross-contamination”** contamination of a starting material, intermediate product, or finished product with another starting material or product;

**“Finished product”** A product that has undergone all stages of production, including packaging in its final container and labeling;

**“Herbal medicinal products”** Medicinal products containing, as active ingredients, exclusively plant material and/or vegetable drug preparations;

**“Manufacture”** All operations of purchase of materials and products, production, packaging, quality control, release, storage, shipment of finished products, and the related controls;

**“Manufacturer”** A company that carries out at least one step of manufacture;

**“Manufacturing process”** The transformation of starting materials into finished products (drug substances or pharmaceutical dosage forms) through a single operation or a sequence of operations involving installations, personnel, documentation and environment;

**“Marketing authorization”** a legal document issued by the competent Authority for the purposes of marketing or free distribution of a product which has been approved after evaluation for safety, efficacy and quality;

**“Pharmaceutical product”** 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 where food and drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses;

**“Production”** All operations involved in the preparation of a medicinal product, from receipt of materials, through processing and packaging, to its completion as a finished product;

**“Validation”** Action of proving, in accordance with the principles of Good Manufacturing Practice, that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also qualification);

# CHAPTER 1: INTRODUCTION

1. **Background**

Rwanda FDA is established by the law nº 003/2018 of 09/02/2018 determining its mission, organization and functioning. The mandate of the authority is to protect public health through regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco & tobacco products.

## 1.1 Purpose of these guidelines

These guidelines are consisted of links for World Health Organization (WHO) Technical Report Series (TRS) and other international recognized guidelines which details Good manufacturing practices (GMP) requirement for various aspects applicable to manufacturing facilities.

These guidelines are intended to provide guidance that should be followed by all companies involved in any aspect of manufacturing pharmaceutical products. It targets both domestic and foreign manufacturers who intend to obtain marketing authorization for their pharmaceutical products in Rwanda.

Therefore, these guidelines shall form the basis of GMP inspection by Rwanda Food and Drugs Authority (Rwanda FDA) as one of the requirements for registration of pharmaceutical products in Rwanda.

## 1.2 Legal Framework

Article No 9, paragraph 1 of the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning mandates states that Rwanda FDA has the power to formulate regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of regulated products.

One of the means of regulating manufacture of pharmaceutical products is through compliance with Good Manufacturing Practice (GMP) requirements as laid down in these guidelines.

These guidelines were also developed in accordance with Regulations No FDISM/FDIC/TRG/005 governing Good Manufacturing Practices for medical products.

## 1.3 Scope

These guidelines shall be used for GMP inspection of all manufacturers of pharmaceutical products within and outside Rwanda whose products are registered or subjected to registration in Rwanda; irrespective of their size, type of products, product range or location of the manufacturing facilities. Manufacturers that are GMP compliant shall be awarded certificates of compliance with GMP.

# CHAPTER 2: GOOD MANUFACTURING PRACTICE INSPECTION

## Types of inspections

1. There shall be four types of good manufacturing practice inspections which should be divided into the following categories:
2. Routine inspection;
3. concise inspection;
4. follow-up inspection;
5. special inspection; and
6. any other types as the Authority may designate.
7. The inspection should be conducted as follows:
8. The routine inspection is a full inspection of all applicable components of GMP and licensing provisions. It shall be conducted at any time when the product has been registered but before expiry of validity of registration of such product. It may be indicated when the manufacturer:
9. Requests for renewal of a manufacturing license to operate
10. Has a history on non-compliance with GMP;
11. Has introduced new product lines or new products, or has made significant modifications to manufacturing methods or processes, or has made changes in key personnel, premises, equipment, etc.
12. Has not been inspected during the last 3 to 5 years.
13. Concise GMP inspections are the evaluation of limited aspects relating to GMP compliance within a facility. The manufacturers with a consistent record of compliance with GMP through previous routine inspections are eligible for concise inspections. The focus of a concise inspection is on a limited number of GMP requirements selected as indicators of overall GMP 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 GMP. Evidence of unsatisfactory GMP performance observed during a concise inspection should trigger a more comprehensive inspection.
14. Follow-up GMP 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 GMP requirements that have not been observed or that have been inadequately implemented.
15. Special GMP 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 specific operations such as mixing, sterilization, or labeling. 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. A further reason for special visits to gather specific information on or to investigate specific operations and to advise the manufacturer of regulatory documents.
16. Any other types as the Authority may designate. This may include pre-approval inspection for newly established facility.

## 2.2 Application for GMP

The manufacturer or applicant who intends to apply for Good Manufacturing Practice inspection shall submit an application dossier to the Authority through Integrated Regulatory Information Management System (IRIMS) available at Rwanda FDA website.

The requirements for application for GMP inspection of finished pharmaceutical products and active pharmaceutical ingredients manufacturing facilities are detailed in the annexes 1 and 2 of these guidelines. Notwithstanding the provisions above, the inspection shall not be conducted to facility which has not submitted applications for product registration.

The Application should be accompanied by prescribed fees as provided in Regulations No. ODG/IMPO/TRG/001 governing tariff/fees and charges on services rendered by Rwanda Food and Drugs Authority.

**2.4 Inspection Frequency**

2.4.1 Manufacturing facility shall be inspected once after every 3 years. However, a

facility may be inspected at any time when necessary.

**2.5 Preparation for inspection**

2.5.1 The Authority shall inform the facility of the proposed inspection date before

the inspection takes place. The inspector shall be responsible for communicating with the facility regarding the modality and plan of inspection.

2.5.2 The respective facility shall make the necessary preparations for inspection at the agreed time.

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

2.6 **Execution of GMP Inspection**

2.6.1 During the inspection, inspectors shall observe, verify and review manufacturing processes, procedures and records to establish compliance with the GMP requirements stipulated in these guidelines.

2.6.2 The inspector shall inspect using these guidelines.

2.6.3 At the end of an inspection, observations shall be documented in the GMP inspection Memorandum Form which shall be signed by both parties and a copy given to the inspectee.

2.6.4 Inspection of one facility shall take 3 to 5 days depending on the number of production blocks or lines available at the facility.

**2.7 Reporting and communication of inspection findings**

2.7.1 Inspection report shall be prepared and communicated to the inspectee within 60 working days from the last date of inspection.

2.7.2 Compliant and non-compliant inspected facilities are published on the Rwanda FDA website.

**2.8 Classification of inspection findings**

Non compliances found during inspections are classified in the following three categories:

* + 1. **Critical non-compliance:** A non-compliance which has produced, or leads to a significant risk of producing either product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal.

**Examples of critical non-compliances**

* Lack of sterilization validation (relevant to all sterile products).
* Lack of adequate control measures resulting in an actual, or significant risk of, cross contamination above the level of the health based exposure limit in subsequent products.
* Evidence of gross pest infestation (relevant to all manufacturers).
* Falsification or misrepresentation of analytical results or records (relevant to all manufacturers).
* Failure to ensure the quality and/or identity of starting materials (relevant to all manufacturers).
* No master batch documents (relevant to all manufacturers).
* Absence, falsification or misrepresentation of manufacturing and packaging records (relevant to all manufacturers).
* Water system for sterile products not validated (for manufacturers of sterile products).
* HVAC system for sterile products not validated (for manufacturers of sterile products).
* Grossly unsuitable premises so that there is a high or likely risk of contamination (relevant to all manufacturers).
* No evidence that mandated recall processes have been complied with (relevant to all manufacturers).
	+ 1. **Major non-compliance**

A non-critical deficiency:

* + - 1. which has produced or may produce a product, which does not comply with its marketing authorization; or,
			2. which indicates a major deviation from Rwanda FDA Good Manufacturing Practice; or,
			3. which indicates a major deviation from the terms of the manufacturing authorization; or,
			4. 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
			5. 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:**

* Lack of validation of critical processes (applicable to all medicines, but could be “Critical” for low dose/high potency products; particularly sterilization processes for sterile products)
* No or grossly inadequate air filtration to minimise airborne
* contaminants (applicable to all medicines manufacturers - could be “Critical” if possible contaminants are a safety concern and “Critical “for sterile medicines)
* Missing or ineffective control measures to provide adequate confidence that cross contamination will be controlled within the health based exposure limit in subsequent products. (would be “Critical” if resulting cross contamination has or is likely to exceed the health based exposure limit)
* Damage (holes, cracks, peeling paint) to walls/ceilings in manufacturing areas where product is exposed in non-sterile areas
* Design of manufacturing area that does not permit effective cleaning Insufficient manufacturing space that could lead to mix-ups
* No raw material sampling area for medicine manufacturers (could be classed as “Other” if adequate precautions are taken)
* Sanitary fittings not used on liquid/cream manufacturing equipment
* Stored equipment not protected from contamination
* Individuals in charge of QC/production not qualified by education, competency training and experience
* Inadequate initial and ongoing training and/or no training records
* Cleaning procedures not documented and/or no cleaning records
* Production equipment cleaning procedures not validated
* Reduced QC testing of raw materials without data to certify suppliers
* Incomplete testing of raw materials
* Test methods not validated
* Complex production processes for non-critical products not validated
* Unapproved/undocumented changes to master batch or equivalent documents
* Deviations from instructions not approved
* No or inadequate internal inspection program
* No proper release for supply procedure
* Product reworked without proper approval
* No system/procedures for handling complaints or returned goods
* Inadequate testing of packaging materials
* No ongoing stability program and/or stability data for all products not available
* Insufficient lighting in production or inspection areas
* Containers from which samples have been taken not identified
* The temperature of critical temperature controlled storage areas not monitored and alarmed
* Inadequate change control system
* Inadequate deviation system
* No investigation into alarms and temperature excursions for deviations from storage or transport requirements
	+ 1. **Other non-compliance:**

A deficiency which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice. A non-conformance may be “other” either because it is judged as minor, or because there is insufficient information to classify it as critical or major.

The categorization of GMP inspection findings will be as described in PIC/S guidance on classification of GMP deficiencies, PI 040-1,3 Appendices,1 January 2019.

**2.9 Decision on compliance**

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

a) When there are other deficiencies only:

i. the site is considered to be operating at an acceptable level of GMP compliance,

ii. the manufacturer 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 non-compliance observations from different six quality systems namely, pharmaceutical quality; production; facilities and equipment; laboratory control; materials; and packaging and labelling systems:

i. the site is compliant with GMP 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 non-compliance observations from different quality systems:

i. the site is considered to be operating at an unacceptable level of compliance with GMP guidelines,

ii. another inspection will normally be required,

iii. administrative and/or legal enforcement actions are applied as necessary.

2.9.2 The next date for inspection of the site should be determined depending on the level of compliance and risk category as defined under national or regional procedures.

2.9.3 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.

**2.10 Guidance on responding to inspection findings**

2.10.1 The facility shall prepare and implement a CAPA plan where applicable upon

receiving inspection findings.

2.10.2 The CAPA plan and evidence for its implementation shall be prepared based on quality risk management principles and submitted to the Authority within 90 calendar days from the date of the inspection report cover letter.

2.10.3 If the company fails to submit a CAPA report within the prescribed period

without any request for an extension, the facility shall be considered to be non-

compliant.

2.10.4 The CAPA report shall indicate root cause analysis, corrections, corrective

actions and preventive actions, timelines and evidence for implementation for each non-compliance observation as per the format provided in Annex Ill of these guidelines.

# CHAPTER 3: GMP 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 PIC/S, ICH, US FDA and EMA may be used as supplementary guidance documents while establishing compliance of facilities to GMP requirements.

**GMP main principles**

WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2. Short name: WHO TRS No. 986, Annex 2

<https://www.who.int/publications/m/item/trs986-annex2>

**GMP for active pharmaceutical ingredients (bulk drug substances)**

WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2

[https://www.who.int/publications/m/item/annex-2-trs-957](https://www.who.int/publications/m/item/annex-2-trs-957/)

**Water for pharmaceutical use**

WHO good manufacturing practices: water for pharmaceutical use. WHO Technical Report Series, No.1033, 2021, Annex 3. Short name: WHO TRS No. 1033, Annex 3

<https://www.who.int/publications/m/item/annex-3-trs-1033>

**Water for injection by means other than distillation**

TRS 1025 - Annex 3: Production of water for injection by means other than distillation. WHO Technical Report Series, no. 1025,20 April 2020

<https://www.who.int/publications/m/item/trs-1025-annex-3-water-for-injection>

**Heating Ventilation and Air conditioning, HVAC**

-Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty Second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010), Annex 8. Short name: WHO TRS No. 1010, Annex 8

<https://www.who.int/publications/m/item/Annex-8-trs-1010>

-WHO good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (part 2): interpretation of guidelines. Annex 2, WHO Technical Report Series 1019, 2019

<https://www.who.int/publications/m/item/trs1019-annex2>

**Good manufacturing practices for sterile pharmaceutical products**

WHO good manufacturing practices for sterile pharmaceutical products

Annex 2, WHO Technical Report Series 1044, 2022.Short name: WHO TRS 1044 - Annex 2:

<https://www.who.int/publications/m/item/trs1044-annex2>

**Good manufacturing practices for medicinal gases**

TRS 1044 - Annex 5: WHO good manufacturing practices for medicinal gases

Annex 5, WHO Technical Report Series 1044, 2022

<https://www.who.int/publications/m/item/trs1044-annex5>

**Good manufacturing practices for biological products**

TRS 996 - Annex 3: WHO good manufacturing practices for biological products (jointly with the Expert Committee on Biological Standardization).

<https://www.who.int/publications/m/item/trs996-annex3>

**Blood products**

WHO guidelines on good manufacturing practices for blood establishments, Annex 4; World Health Organization.WHO Technical Report Series, No. 961, 2011.

<https://www.who.int/publications/m/item/trs961-annex4>

**Hold-time studies**

WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4. Short name**:** WHO TRS No. 992, annex 4.

<https://www.who.int/publications/m/item/trs992-annex4>

**Quality risk management**

WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2. Short name: WHO TRS No. 981, Annex 2

<https://www.who.int/publications/m/item/trs981-annex2>

**Validation**

WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-third report (WHO Technical Report Series, No. 1019). Short name: WHO TRS No. 1019, Annex 3 <https://www.who.int/publications/m/item/trs1019-annex3>

**Health-Based Exposure Limits (HBELs) in cleaning validation**

TRS 1033 - Annex 2: Points to consider when including Health-Based Exposure Limits (HBELs) in cleaning validation Annex 2, WHO Technical Report Series, No.1033, 2021

<https://www.who.int/publications/m/item/annex-2-trs-1033>

**Technology transfer**

TRS 1044 - Annex 4: WHO guidelines on technology transfer in pharmaceutical manufacturing

Annex 4, WHO Technical Report Series 1044, 2022

<https://www.who.int/publications/m/item/trs1044-annex4>

**Data integrity**

TRS 1033 - Annex 4: WHO Guideline on data integrity

Annex 4, WHO Technical Report Series, No.1033, 2021

<https://www.who.int/publications/m/item/annex-4-trs-1033>

**Sampling**

WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4. Short name: WHO TRS No. 929, Annex 4 <https://www.who.int/publications/m/item/trs-1025-annex-4>

**Investigational products**

- WHO good manufacturing practices for investigational products, WHO Technical Report Series 1044, 2022, Annex 7. Short name: WHO TRS 1044 - Annex 7:

<https://www.who.int/publications/m/item/trs1044-annex7>

-IAEA/WHO guideline on good manufacturing practices for investigational Annex 3, WHO Technical Report Series 1044, 2022.Short name: WHO TRS 1044 - Annex 3:

<https://www.who.int/publications/m/item/trs1044-annex3>

**Antimicrobial resistance**

Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance, WHO Technical Report Series, no. 1025, Annex 6. Short name: TRS 1025 - Annex 6:

<https://www.who.int/publications/m/item/trs-1025-annex-6>

**Herbal medicines**

-WHO good manufacturing practices for the manufacture of herbal medicines, WHO Technical Report Series 1010, 2018, Annex 1. Short name WHO TRS 1010 - Annex 1:

<https://www.who.int/publications/m/item/trs1010-annex1>

-WHO good manufacturing practices for the manufacture of herbal medicines

, WHO Technical Report Series 1010, 2018, Annex 2. Short name WHO TRS 1010 - Annex 2

<https://www.who.int/publications/m/item/trs1010-annex2>

**Hazardous Substances**

WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. Short name: WHO TRS No. 957, Annex 3

<https://www.who.int/publications/m/item/trs957-annex3>

**Site master file**

WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14. Short name: WHO TRS No. 961, Annex 14

<https://www.who.int/publications/m/item/trs961-annex14>

**Quality Control Laboratories**

WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1. Short name: WHO TRS No. 957, Annex 1

<https://www.who.int/publications/m/item/trs957-annex1>

**Good chromatography practices**

WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025, Annex 4. Short name: WHO TRS No. 1025, Annex 4

<https://www.who.int/publications/m/item/trs1025-annex4>

**Chemical reference standards**

General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3. Short name: WHO TRS No. 943, Annex 3

<https://www.who.int/publications/m/item/trs943-annex3>

**Good practices for pharmaceutical microbiology laboratories**

WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2. Short name: WHO TRS No. 961, Annex 2

<https://www.who.int/publications/m/item/trs961-annex2>

**Stability studies**

WHO guidelines on stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Technical Report Series 1010, 2018, Annex 10. Short name: WHO TRS 1010-Annex 10

<https://www.who.int/publications/m/item/trs1010-annex10>

**Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products**

Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. Short name: WHO TRS No. 961, Annex 9

<https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport>

**WHO Technical Supplements to Model Guidance for Storage and Transport of Time and temperature-sensitive pharmaceutical Products**

WHO Technical supplements to Model Guidance for storage and transport of time — and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5. Short name: WHO TRS No. 992, Annex 5

<https://www.who.int/publications/m/item/trs992-annex5>

**Non-Penicillin Beta-Lactam Drugs**

Guidance for Industry; Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross Contamination

<https://www.fda.gov/files/drugs/published/Non-Penicillin-Beta-Lactam-Drugs--A-CGMP-Framework-for-Preventing-Cross-Contamination.pdf>

**Veterinary Medicinal Products**

-PIC/S Guide to good manufacturing practice for medicinal products part II, PE 009-17 (Part II), 25 August 2023

<https://picscheme.org/docview/6607>

-PIC/S Guide to good manufacturing practice for medicinal products part I, PE 009-17 (Part I),25 August 2023

<https://picscheme.org/docview/6606>

-PIC/S Guide to good manufacturing practice for medicinal products annexes, PE 009-17 (Annexes),25 August 2023 <https://picscheme.org/docview/6608>

#  ENDORSEMENT OF THE GUIDELINES

|  |  |  |  |
| --- | --- | --- | --- |
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# ANNEXES

**ANNEX 1**: **Requirements for GMP Inspection Application for Finished Pharmaceutical Products & Active Pharmaceutical Ingredients Manufacturing Facilities**

1. Application letter addressed to DG of Rwanda FDA
2. Filled and signed application form
3. Proof of payment of prescribed fees
4. 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 colored printouts of water treatment, air-handling systems, including pipeline and instrumentation drawings (P&IDs) in A3 or A2 format
5. Current manufacturing license for foreign facilities and for domestic facilities to attach application form and proof of payment of manufacturing license.
6. Current GMP Certificate (GLP, ISO/IEC 17025 accreditation Certificate or WHO prequalification for outsourced laboratory)
7. List of all the products (medicinal or other) manufactured on site and List of products intended for supply in Rwanda. The lists should include proprietary names and international non-proprietary names (INN).

**The following additional documents may be required for GMP desk assessment, virtual inspection and temporary waiver:**

1. Copy of the recent GMP inspection report done by Local medicine regulatory authority and recent GMP inspection report from PIC/S SRA/WLAs or EAC NMRAs if available with a certified translated copy where this is not in English or French or Kinyarwanda.
2. 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.
3. Corrective and preventive action (CAPA) and proof of CAPA implementation related to the inspection report observations/deficiencies.
4. The most recent product quality review(s) (PQR)(s) of the concerned product(s)
5. 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
6. Quality Manual/Laboratory Manual or equivalent
7. The completed batch manufacturing/packaging record(s) including the analytical part for the most recently released batch of relevant product(s).
8. A list of any recalls or any Market complaints registered in the last three years.
9. Aseptic validation report (Required for products applied for that are not terminally sterilized).
10. Contract or agreement between the FPP or API manufacturer and the outsourced testing laboratory or sterilization institution (for Outsourced testing laboratory; and Outsourced sterilization).
11. Validation master plan.
12. Process validation for one of the products marketed or to be registered in the country of import.

NB: The documents submitted should be sent in searchable pdf format.

**ANNEX 2: Application form for GMP inspection for Finished Pharmaceutical Products Manufacturing Facilities**

|  |  |  |
| --- | --- | --- |
| Format: QMS/FMT/002Revision No: 1Effective Date: 20 June 2022 | Department/Division/Office/Unit |  Food and Drugs Inspection and Compliance Division |
| Document Type: **Form** | Doc. No | :FDISM/FDIC/FOM/001 |
|  | Title: **Application form for Good Manufacturing Practice Inspection for Finished Pharmaceutical Products Manufacturing Facilities** | Revision Number | : 1 |
| Revision Date:  | : 29/08/2022 |
| Effective Date | : 30/09/2023  |
| Review Due Date | : 29/09/2025 |
| Ref Doc.  | : FDISM/FDIC/GDL/001 |

**Applicant to fill the following sections**

1. **Particulars of the Applicant**

Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Telephone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Particulars of Manufacturing Site to be Inspected**

Name of site\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical Address (if different from 1. above)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Tel\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Note****: Separate application to be filled in for each individual site*

1. **Contact Person on Site**

Name of contact person\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Fax:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Authorized Representative/Agent in Rwanda**

Name of Local Technical Representative\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Type of Medicines/ Active Pharmaceutical Ingredients**

Type of medicines manufactured *(double click to check applicable box)*

Human ☐ Veterinary ☐ Human & Veterinary Herbal

1. **Registration of Products in Rwanda**

Have you registered any products in Rwanda YES ☐ NO ☐

Have you submitted product dossier for registration from the production line(s) applied for inspection? YES ☐ NO ☐ (If "YES", list of the products in the table below)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Trade Name (if any) | Generic Name | Dosage Form | Strength  | Primary Packaging |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Inspection Applied for** *(Double click to check applicable box*)

☐ First Inspection

☐ Routine Inspection (state previous inspection dates ………………*DD/MM/YYYY*)

☐ Re-inspection (after failure)

☐ Other *(please specify)* …………………………………………………………….

1. **Major Site Changes** **Since Last Inspection**

Provide summary of changes to personnel, equipment, buildings, specifications, computer systems, products (type, range or category), suppliers and contractors since last inspection, below or as an Attachment to this form.

………………………………………………………………………………………………………

………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………

**Production Lines to be Inspected** *(Please tick or fill in the applicable boxes)*

|  | Yes | No | Building Block name/ number | Number of production lines | Non β-lactam | β-lactam |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Penicillin | Cephalosporin | Cytotoxic | Hormones | Human | Veterinary |
| **1. MANUFACTURING OPERATIONS** |  |  |  |
| **1.1 Sterile products** |  |  |  |
| a | Aseptically prepared (list of dosage forms) |  |  |  |  |  |  |  |  |  |  |  |
|  | Large volume liquids |  |  |  |  |  |  |  |  |  |  |  |
|  | Lyophilisates |  |  |  |  |  |  |  |  |  |  |  |
|  | Semi-solids |  |  |  |  |  |  |  |  |  |  |  |
|  | Small volume liquids |  |  |  |  |  |  |  |  |  |  |  |
|  | Solids and implants |  |  |  |  |  |  |  |  |  |  |  |
|  | Other aseptically prepared products(e.g. eye drops, prefilled syringes) |  |  |  |  |  |  |  |  |  |  |  |
|  | Terminally sterilized (list of dosage forms) |  |  |  |  |  |  |  |  |  |  |  |
|  |  Large volume liquids  |  |  |  |  |  |  |  |  |  |  |  |
|  | Semi-solids |  |  |  |  |  |  |  |  |  |  |  |
|  | Small volume liquids |  |  |  |  |  |  |  |  |  |  |  |
|  | Solids and implants |  |  |  |  |  |  |  |  |  |  |  |
|  | Other terminally sterilised prepared products |  |  |  |  |  |  |  |  |  |  |  |
| **1.2 Non-sterile products (list of dosage forms)** |  |  |  |
| 1. a
 | Capsules, hard shell |  |  |  |  |  |  |  |  |  |  |  |
|  | Capsules, soft shell  |  |  |  |  |  |  |  |  |  |  |  |
|  | Impregnated matrices |  |  |  |  |  |  |  |  |  |  |  |
|  | Liquids for external use |  |  |  |  |  |  |  |  |  |  |  |
|  | Liquids for internal use |  |  |  |  |  |  |  |  |  |  |  |
|  | Dry powders for oral suspension |  |  |  |  |  |  |  |  |  |  |  |
|  | Medicated lozenges |  |  |  |  |  |  |  |  |  |  |  |
|  | Powders/granules in sachets |  |  |  |  |  |  |  |  |  |  |  |
|  | Medicinal gases |  |  |  |  |  |  |  |  |  |  |  |
|  | Other solid dosage forms (please specify) |  |  |  |  |  |  |  |  |  |  |  |
|  | Pressurised preparations |  |  |  |  |  |  |  |  |  |  |  |
|  | Radionuclide generators |  |  |  |  |  |  |  |  |  |  |  |
|  | Semi-solids |  |  |  |  |  |  |  |  |  |  |  |
|  | Suppositories |  |  |  |  |  |  |  |  |  |  |  |
|  | Tablets |  |  |  |  |  |  |  |  |  |  |  |
|  | Transdermal patches |  |  |  |  |  |  |  |  |  |  |  |
| 1. a
 | Intraruminal devices |  |  |  |  |  |  |  |  |  |  |  |
|  | Veterinary premixes |  |  |  |  |  |  |  |  |  |  |  |
|  | Other non-sterile medicinal products |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| **1.3** | **Biological medicinal products** |  |  |  |
|  |  Blood products |  |  |  |  |  |  |  |  |  |  |  |
|  | **Immunological products**  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Vaccines
 |  |  |  |  |  |  |  |  |  |  |  |
| 1. Sera
 |  |  |  |  |  |  |  |  |  |  |  |
| 1. Other immunological products
 |  |  |  |  |  |  |  |  |  |  |  |
|  | Cell therapy products |  |  |  |  |  |  |  |  |  |  |  |
|  | Gene therapy products |  |  |  |  |  |  |  |  |  |  |  |
|  | Biotechnology products |  |  |  |  |  |  |  |  |  |  |  |
|  | Human or animal extracted products |  |  |  |  |  |  |  |  |  |  |  |
|  | Biosimilar products |  |  |  |  |  |  |  |  |  |  |  |
|  | Other |  |  |  |  |  |  |  |  |  |  |  |
| **1.4 Other products or manufacturing activity** |  |  |  |  |  |  |  |  |
|  | **Manufacture of:** |  |  |  |  |  |  |  |  |  |  |  |
| 1. a
 | Herbal products |  |  |  |  |  |  |  |  |  |  |  |
|  | Homoeopathic products  |  |  |  |  |  |  |  |  |  |  |  |
|  | Biological active starting materials |  |  |  |  |  |  |  |  |  |  |  |
|  | Active pharmaceutical ingredients (chemical)  |  |  |  |  |  |  |  |  |  |  |  |
|  | Other |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **2.0**  **Sterilisation of active substance/excipients/finished product:** |  |  |  |
|  | Filtration |  |  |  |  |  |  |  |  |  |  |  |
|  | Dry heat |  |  |  |  |  |  |  |  |  |  |  |
|  | Moist heat (steam, superheated water) |  |  |  |  |  |  |  |  |  |  |  |
|  | Chemical (ethylene oxide, ozone |  |  |  |  |  |  |  |  |  |  |  |
|  | Gamma irradiation |  |  |  |  |  |  |  |  |  |  |  |
|  | Electric beam |  |  |  |  |  |  |  |  |  |  |  |
|  | Other |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **3.0 Quality control testing** |  |  |  |  |  |  |  |
|  | Microbiological: sterility |  |  |  |  |  |  |  |  |  |  |  |
|  | Microbiological: non-sterility |  |  |  |  |  |  |  |  |  |  |  |
|  | Chemical/Physical |  |  |  |  |  |  |  |  |  |  |  |
|  | Biological |  |  |  |  |  |  |  |  |  |  |  |
|  | Animal |  |  |  |  |  |  |  |  |  |  |  |
|  | Stability |  |  |  |  |  |  |  |  |  |  |  |

1. **Declaration**

*I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site(s).* *I also commit to welcome the Rwanda FDA GMP inspectors for the inspection.*

Signature of applicant……………………………. Date……………………………

Name……………………………………….. Designation..............................

***Notes****:*

*1. Please submit a copy of the current Site Master File together with this application (refer to Guideline on preparation of a Site Master File)*

*2. Submit the completed application together with proof of payment of the appropriate fees, to the Director General Rwanda Food and Drugs Authority.*

|  |
| --- |
| *This box is to be completed by Rwanda FDA official only* |
| **Inspection Reference Number**:  |
| *Assigned to:*  | *Lead GMP Inspector* | *Team GMP Inspector(s)* |
| *Name* |  |  |
| *Assigned by :**Name* |  *Title: signature: Date:*  |

**ANNEX 3: GMP Inspection Report**

 **Rwanda Food and Drugs Authority**

QMS No: FDISM/FDIC/FMT/019

Revision No: 1

Effective Date: 30/09/2022

 Nyarutarama Plaza, KG 9 Avenue

 P.O. Box: 1948 Kigali - Rwanda

 Email: info@rwandafda.gov.rw

 website: [www.](http://www.)rwandafda.gov.rw

|  |
| --- |
|  **GMP INSPECTION REPORT** |
| **Inspection dates:**  | **Report date:**  |
| **1.0 General Information**  |
| **1.1 Inspected Site(s)**  |
| 1. **Name:**
2. **Physical address:**
3. **City:**
4. **Country:**
 |
| 1. **Telephone:**
2. **Email address :**
 |
| 1. **Manufacturing license number:**
 |
| 1. **Contact person(s) of the inspected site or facility:**
 |
|  **1.2 Activities carried out by the company at the inspected site**  |
| **1.3 GMP Inspectors** |
| **Name of Rwanda FDA Lead Inspector:**  |
| **Names of Rwanda FDA GMP Inspectors that carried out the inspection:** |
| **1.5 Name of expert if applicable:**  |
| **1.6 Foreign National Regulatory Authority Participation:**  |
| **1.7 Type of inspection:**  |
| **1.8 Purpose of Inspection:**  |
| **1.9 Introduction**  |
| **1.10 Other manufacturing activities carried out on the site:** |
| **1.11 Use of outside scientiﬁc, analytical, or other technical assistance in manufacture and quality control** |
| **1.12 Previous inspections conducted by:** |
| **1.13 Other Regulatory Authorities** |
| **1.14 Major changes since the previous inspection** |
| **1.15 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 Pharmaceutical Quality System**  |
| * + 1. **Personnel**
 |
| * + 1. **Premises**
 |
| * + 1. **Utilities**
 |
| * + 1. **Equipment**
 |
| * + 1. **Documentation**
 |
| * + 1. **Good practices in production**
 |
| * + 1. **Good practices in quality control**
 |
| * + 1. **Outsourced Activities**
 |
| * + 1. **Complaints and Product Recalls**
 |
| * + 1. **Self-Inspection, Quality Audits, Supplier’s Audits**
 |
| 1. **Summary of non-conformances to GMP**
 |
| 1. **Recommendations and Conclusion**
 |
| **4.1 Recommendations** |
| **4.2 Conclusion – inspection outcome** |

Definition of Non-conformances

NAMES OF THE INSPECTORS AND SIGNATURES

**End of Report**

**ANNEX 4: FORMAT OF CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE**



 **Rwanda Food and Drugs Authority**

QMS No: FDISM/FDIC/FMT/001

Revision No: 2

Effective Date: 01/03/2023

 Nyarutarama Plaza, KG 9 Avenue

 P.O. Box: 1948 Kigali - Rwanda

 Email: info@rwandafda.gov.rw

 website: [www.](http://www.)rwandafda.gov.rw

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE**

|  |  |  |
| --- | --- | --- |
|  *Certificate No:*  | *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 facility:** **Physical address:** **License number:** **Country**: **E-mail:** **Telephone:** Has been **inspected/Assessed** by the Rwanda Food and Drugs Authority for compliance with the Good Manufacturing Practice Guidelines.Based on the **Physical Inspection/Virtual Inspection/Desk Assessment/Reliance Pathway** 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:

|  |  |  |  |
| --- | --- | --- | --- |
| **No** | **Dosage form** | **Category** | **Activities**  |
| 1. |  |  |  |

The responsibility for the quality of the individual batches of 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 of the Director General****Director General** |

End of document