TMDA/DMC/MCIE/G/014
REV.#. 01

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR RELIANCE ON GOOD MANUFACTURING PRACTICES INSPECTIONS

MAY 2026

TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma - Tanzania, Tel: +255 (26) 2961989/2061990/ +255(22) 2450512/2450751/2452108,
Email: info@tmda.go.tz, Website: www.tmda.go.tz, Toll free: 08001100834

Table of Contents

Abbreviations ii
Acknowledgements iii
Foreword iv
Definition of Terms v
PART I: CONSIDERATION FOR DESK ASSESSMENT FOR GMP INSPECTION RELIANCE 1
1.1 Introduction 1
1.2 Criteria for Desk Assessment 2
1.3 Decision Tree for Desk Assessment 3
1.4 Application Procedure for Desk Assessment 4
1.5 Processing Applications for Desk Assessment 5
1.6 Documentary Evidence Requirements 6
1.7 Triggers and Factors leading to Conducting an Onsite Inspection 7
1.8 Publication of GMP Desk Assessment Reports 7
PART II: CONSIDERATION FOR GMP INSPECTION DURING EMERGENCIES 8
2.1 Introduction 8
2.2 Reliance on Other Institutions 8
2.3 Virtual GMP Inspection 8
2.4 Application Procedure 9
2.5 Issuance of GMP Certificates during Emergencies 9
3. Annexes 11
4. Bibliography 22

Abbreviations

AMA	African Medicines Agency
CAPA	Corrective Actions and Preventive Actions
COVID-19	Coronavirus Disease of 2019
CSC	Client Service Charter
EAC	East African Community
EU	European Union
FPP	Finished Pharmaceutical Products
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
ICH	International Council on Harmonization
IEC	International Electrotechnical Commission
ISO	International Organization for Standards
LTR	Local Technical Representative
MCAZ	Medicines Control Authority of Zimbabwe
NCA	National Competent Authority
NRA	National Regulatory Authority
PQR	Product Quality Review
SADC	Southern African Development Community
SMF	Site Master File
TMDA	Tanzania Medicines and Medical Devices Authority
WHO	World Health Organization
WHO-PQ	WHO- Prequalification
WLA	WHO Listed Authority

Acknowledgements

The formulation of these guidelines was made possible through the technical expertise and invaluable contributions of the following experts: -

Prof. Raphael Sangeda	Consultant
Mr. Emmanuel Alphonce	Manager. Medicines Inspection and Enforcement Section
Mr. Adonis Bitegeko	Manager, TMDA Eastern Zone Office
Ms. Grace Shimwela	Manager, Quality and Risk Management Section
Mr. Mwemezi Ngemera	Consultant, US Pharmacopoeia
Mr. Joel Kibona	Consultant
Mr. Magembe Ugassa	Consultant
Mr. Maganga Bundala	Medicines Inspection and Enforcement Section
Mr. Paul Sonda	Medicines Inspection and Enforcement Section
Ms. Joyce Komba	Directorate, Human and Veterinary Medicines

I wish to express my sincere gratitude to all of them for their tireless efforts and determination in ensuring the timely completion of these guidelines. Sincere appreciation is also extended to the Gates Foundation for financing the development of these guidelines.

Finally, the TMDA Management is highly acknowledged for providing strategic guidance and valuable comments throughout the deliberations leading to the final approval of this document.

Dr. Yonah H. Mwalwisi

DIRECTOR FOR HUMAN AND VETERINARY MEDICINES

Foreword

The Tanzania Medicines and Medical Devices Authority (TMDA) was established under the Tanzania Medicines and Medical Devices Act, Cap 219, operating as an Executive Agency under the Executive Agencies Act, Cap 245. The Authority is mandated to protect and promote public health by ensuring the quality, safety, and effectiveness of medicines, medical devices, diagnostics, and other health-related products.

Good Manufacturing Practices (GMP) inspection of manufacturing facilities seeking to market finished pharmaceutical products in Tanzania is a core function in fulfilling this mandate. While TMDA has historically verified compliance through on-site inspections, a high volume of applications has often delayed the process by up to 12 months from receipt.

The COVID-19 pandemic further underscored these challenges, as travel restrictions severely hindered timely on-site assessments. Because Section 51(c) of Cap 219 strictly mandates that all registered products originate from GMP-compliant facilities, these combined operational delays have impacted service delivery, increased customer complaints, and limited patient access to essential medicines.

To address these challenges, optimize resource utilization, and accelerate access, TMDA has developed these guidelines to facilitate timely GMP verification through a desk assessment of submitted documentation. This streamlined approach aligns with WHO-recommended practices and aims to: -

a. Reduce duplication of GMP inspections conducted under WHO Prequalification, WHO Listed Authorities, and TMDA-recognized regional harmonization initiatives;
b. Improve efficiency and speed up service delivery by decreasing reliance on frequent on-site inspections; and
c. Ensure ongoing adherence to GMP requirements by permitting onsite inspections if documentary evidence indicates non-compliance.

By implementing this desk assessment mechanism, TMDA will enhance transparency, maintain business continuity during emergencies, and minimize supply chain bottlenecks. Applicants are strongly encouraged to submit comprehensive and accurate documentation as outlined herein to facilitate prompt marketing authorization decisions.

Dr. Adam M. Fimbo
DIRECTOR GENERAL

Definition of Terms

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

Act
Means the Tanzania Medicines and Medical Devices Act, Cap 219;

Authority
Means the Tanzania Medicines and Medical Devices Authority, or the acronym "TMDA", established under section 4(1) of the Act;

Agent or Local Technical Representative
Means a person residing in the country authorized by the applicant or manufacturer to deal in medical products to be an agent (local technical representative);

Applicant
Means an applicant is a person who applies for marketing authorization of a medical product to TMDA, who must be the owner of the product;

Competent Regulatory Authority
Means any organization that has legal authority or power to perform a designated regulatory function for the authorization of a medical product;

Desk Assessment
Means an evaluation of prior documentary evidence by a competent regulatory authority recognized by the national regulatory authority for compliance with the required good practices (good manufacturing practices) in support of marketing authorization;

Emergency Situation or State
Means unexpected factors, including pandemics, that make it impossible for the Authority to conduct on-site inspections either in a particular country or all countries. Late planning for inspection, limited resources or war in a country where the facility is located shall not be considered an emergency.

Good Manufacturing Practice
Means the quality assurance part, which ensures that products are consistently produced and controlled to the quality standards appropriate for the intended use and as required by the marketing authorization. GMP standards are primarily aimed at diminishing the list of inherent risks in any pharmaceutical production that cannot be prevented completely through the testing of the final product;

Manufacture
Means all operations of purchase of materials and products, production, quality control, release, storage, distribution of medicinal products and the related controls;

Manufacturer
Means a company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of pharmaceuticals;

Marketing Authorization
Means a legal document issued by the competent regulatory authority 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;

Orphan Medicines
Means a medicine designated as such under the terms and conditions set out under Regulation 9 of the Tanzania Medicines and Medical Devices (Orphan Medicines) Regulations, 2018.

Pharmaceutical Product
Means any material or product intended for human or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form that is subject to control by pharmaceutical legislation in the exporting state and/or the importing state;

Regional Harmonization Initiative
Means programs aimed at complementing regulatory activities within the regions, i.e. EAC, SADC and AMA, for the purpose of making efficient use of resources. Under these arrangements, inspections are conducted jointly, and the outcomes are recognized by the member states.

Reliance
The act whereby a regulatory authority considers and gives significant weight to assessments or authoritative information from another trusted jurisdiction or institution to reach its own decision. The relying authority remains fully independent, responsible, and accountable for the final decision taken.

Site Master File
Means a document containing specific information about the activities undertaken in the pharmaceutical manufacturing site and is usually prepared by the manufacturer.

PART I: CONSIDERATION FOR DESK ASSESSMENT FOR GMP INSPECTION RELIANCE

1.1 Introduction

With the complexity of global supply chains, the demand for inspecting pharmaceutical manufacturing facilities far exceeds what any national competent authority can accomplish. Over the years, TMDA has experienced an increased number of applications, which has overwhelmed its capacity to conduct onsite Good Manufacturing Practice (GMP) inspections promptly.

An informed decision on the GMP compliance of a manufacturing facility can be made in certain circumstances, based on the outcome of work by another National Medicines Regulatory Authority (NMRA). Consequently, it is possible (outside the established framework of a mutual recognition agreement, or equivalent and where legal requirements allow) for inspectorates to identify specific instances based on risk management principles where an onsite inspection of a manufacturing facility in an overseas territory is not required because an acceptable level of GMP compliance has been confirmed and assured by another authority or authorities.

Confirming GMP compliance through remote (desk assessment), where appropriate, without undertaking an on-site inspection, helps to speed up the processing of applications for marketing authorisation. In addition, it also helps to avoid duplication of work between regulatory authorities, reduces regulatory burden on manufacturing sites and enhances efficient use of resources.

The desk assessment process involves the submission of current, accurate, and authentic documentary evidence by the applicant/manufacturer to the authority to demonstrate the conformity of all processes involved in the manufacturing of pharmaceutical products. The evidence provided is assessed to determine the level of GMP compliance based on the accepted standards and the scope of application.

These guidelines focus on overseas manufacturers who intend to obtain marketing authorisation of human and veterinary medicines in Tanzania through submission of documentary evidence to assess GMP conformity without an on-site inspection. The guidelines are developed based on Section 6 of the Tanzania Medicines and Medical Devices (Good Manufacturing Practices Enforcement) Regulations, 2018.

The guidelines are divided into six (6) major sections. The sections delineate the principles and general requirements for desk assessment, the application procedure for desk assessment, processing applications, documentary evidence requirements, triggers and factors leading to

conducting onsite inspections, and the publication of GMP desk assessment reports on the TMDA website.

1.2 Criteria for Desk Assessment

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

a. Located in countries with WHO Listed Authorities (WLA) or inspected and approved by WLA (see List of WLA), and as may be updated by WHO from time to time.

b. Inspected and approved by the World Health Organization (WHO) under the Medicines Prequalification Program.

c. Jointly inspected and approved by Regional Harmonisation Initiatives, namely, East African Community (EAC), Southern African Development Community (SADC) and African Medicine Agency (AMA).

For facilities falling in category 1.2 (c) above, there will be no formal desk assessment, but rather the approval letter or GMP certificates and GMP reports issued under this arrangement shall be adopted by the Authority in issuing GMP certificates.

Where a facility is deemed to be inspected or located in a country with a Stringent Regulatory Authority, which is not yet included in the WLA list, the Authority may decide to conduct a Desk Assessment for its GMP inspection applications.

1.3 Decision Tree for Desk Assessment

TMDA has the final mandate to decide on whether to conduct a desk assessment or an on-site inspection. The following decision tree shall guide whether a facility qualifies for a desk assessment.

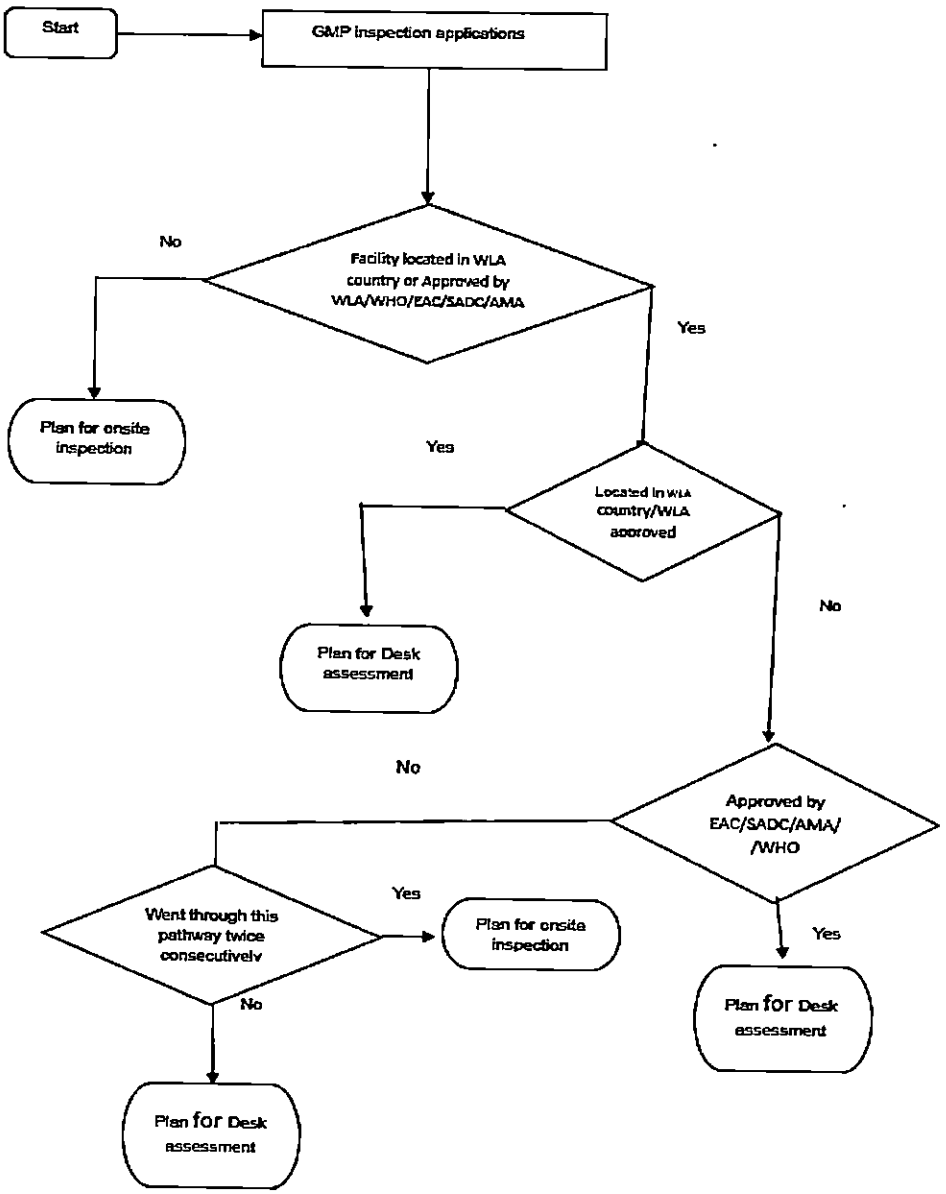


Figure 1: Decision tree for GMP Inspection through desk review

1.4 Application Procedure for Desk Assessment

Principle

The desk assessment process involves submission of documentary evidence by the applicant, usually a manufacturer or Local Technical Representative (LTR), to the Authority to demonstrate the conformity of the manufacturing facility 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 medicinal product.

General

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

1.4.2 Application for GMP desk assessment shall be made to the Authority by submitting the following: -

a. A duly filled-in GMP desk assessment application form whose template is attached as Annexe I to these guidelines, submitted online or a soft copy in *PDF* format using an external storage device.

b. A non-refundable GMP inspection fee as prescribed in the fees Regulations in force. The Desk assessment fee is the same as the physical inspection fee.

c. Documentary evidence(s) and information as indicated in Annexe II to these guidelines; and

d. Updated electronic *PDF* version of the Site Master File (SMF) containing minimum information as provided in Annexe III to these guidelines.

1.4.3 The Authority may request some other additional documentation for clarification during assessment.

1.4.4 The applicant shall ensure that the documentary evidence(s) provided, upon which GMP approval is granted, are current, accurate and authentic. Any document submitted must adhere to the following general requirements: -

a. All certificates and other supporting documents should be in either English or the Swahili language.

b. Where the document is not in English or the Swahili language, 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, valid, with the effective version, reflect current activities and practices and be dated; and

e. Documents must provide sufficient information to cover the scope of activities for which GMP compliance is sought.

1.4.5 The Authority may request certified copies of original documents at any time. Certified copies must be legible and authenticated as true copies.

1.4.6 The information in an application shall be deemed confidential and not shared with any other party outside TMDA.

1.5 Processing Applications for Desk Assessment

Principle

The principles of quality risk management shall be employed to perform a desk assessment considering the management of resources in terms of time, funding and personnel. The assessment process aims to ensure timely decision-making on approval of products that meet quality, safety and efficacy standards without putting the public at risk.

Based on the fact that other competent and trusted NMRAs and organizations have inspected the manufacturing facility and, in some cases, multiple products manufactured at the site, the assessment shall take into consideration and focus on the critical products such as sterile or biological products and critical processes such as aseptic filling and terminal sterilization in the manufacture of a specified product in relation to public health risk.

General

1.5.1 Once an application has been received and GMP inspection fees paid as prescribed in the fees regulations enforced, the Authority shall process the application as per the time frame set out in the current TMDA Client Service Charter (CSC).

1.5.2 In case of missing information or issues that require clarification by the applicant, these shall be communicated to the applicant via a letter of query. If no responses or appropriate responses are received within 30 calendar days, an on-site inspection shall be scheduled.

1.5.3 In case of outright rejection of submitted documentary evidence, TMDA shall inform the applicant and plan for an on-site inspection.

1.5.4 If the evidence provided demonstrates the GMP compliance of a facility, the Authority shall issue a desk assessment GMP certificate in a format whose template is attached as Annex IV to these guidelines and update the application status in the database to 'compliant'.

1.5.5 The validity of the desk assessment GMP Certificate shall be three (3) years from the date of issuance.

1.5.6 The Authority shall suspend/revoke the issued desk assessment GMP certificate if satisfied that the facility is no longer considered to comply with GMP requirements, and TMDA shall plan for on-site inspection.

1.6 Documentary Evidence Requirements

Principle

Documents submitted by manufacturers establish the basis for determining GMP compliance of the manufacturing facilities; hence, they should contain information that is accurate and reflects the current status of the facility. Submission of inaccurate or false information may result in the declaration of the manufacturer as GMP non-compliant.

General

1.6.1 Facilities shall be required to submit documents for desk assessment as mentioned in **Table 1** below.

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

Type of facility	Where inspected by EAC or SADC, or AMA joint harmonization initiatives	Where inspected by the WLA or the WHO Prequalification Scheme
Non-sterile products facilities	Evidence List A and the current joint EAC or SADC, or AMA GMP inspection report.	Evidence List A and B

Sterile products, biological and immunological facilities	Evidence List A: current joint EAC or SADC, or AMA GMP inspection report or GMP Certificate issued by the WLA country.	Evidence Lists B, C and D
Outsourced (contract)testing laboratory, and outsourced sterilization	Evidence List A, current joint EAC, SADC, or AMA GMP inspection report and certification from relevant ISO Standards for the sterilization facility (if applicable to the manufacturing facility or contracted activity)	Evidence List D

1.6.2 A list of the documents that shall be used for desk assessment is provided in Annexe II and categorized as evidence lists A, B, C and D.

1.7 Triggers and Factors leading to Conducting an Onsite Inspection

1.7.1 If it is known that the facility has not been inspected and approved by WLA, WHO-PQ or regional harmonisation initiatives (EAC, SADC or AMA).

1.7.2 The facility or production line was not in the scope of WLA or WHO- PQ approval.

1.7.3 Failure to submit documentary evidence or any requested information during the desk assessment.

1.7.4 Facilities that have been subjected to successful desk review for two consecutive times (For facilities not located in WLA countries).

1.7.5 Facilities that have recurring reports of manufacturing substandard products.

1.7.6 Any other risk factors that may be identified by the Authority.

1.8 Publication of GMP Desk Assessment Reports

Summarized desk assessment reports for facilities found to be GMP compliant shall be published on the TMDA website: www.tmda.go.tz

PART II: CONSIDERATION FOR GMP INSPECTION DURING EMERGENCIES

2.1 Introduction

A decision on GMP compliance for manufacturing facilities during emergency states may be made through either reliance or virtual GMP inspection. During declared emergencies which restrict travel to manufacturing facilities for more than six (6) months, reliance on desk assessment could be the best option for establishing GMP compliance. However, not all facilities meet the criteria stipulated in section (2) of Part I of these guidelines.

The criteria stipulated in section (2) of Part I shall be waived for facilities manufacturing the following categories of products: -

a. Low-risk pharmaceutical dosage forms such as those administered orally or topically;

b. Products of public health importance such as anti-retroviral (ARVs), vaccines, anti-tuberculosis (Anti-TBs), Anti-malaria, anti-cancer, some antibiotics, and orphan medicines;

c. Products intended to be used for emergencies; and

d. Products undergoing license renewal applications.

In addition, facilities that manufacture products that do not fall under a) to d) above shall be subjected to virtual Inspection.

2.2 Reliance on Other Institutions

Reliance for GMP inspection during inspections can be made on inspections conducted by other institutions other than WLA, EAC, SADC, AMA and WHO as indicated below;

a. Desk assessment shall be based on an inspection conducted by local and other NMRAs to determine qualification for a one (1) year GMP inspection waiver.

b. For the desk assessment to be conducted, the facilities shall have in advance submitted application dossiers and their information assessed and accepted.

2.3 Virtual GMP Inspection

New applications for GMP inspection for manufacturing facilities that manufacture high-risk medicines, such as parenteral formulations and paediatric oral solutions that have no

registered therapeutic equivalent, shall qualify for virtual inspection during declared emergencies. Other new applications for GMP inspection of high-risk product manufacturing facilities shall wait until the emergency state is over.

For the conduct of virtual inspection, the following shall be considered: -

a. Use of applicable procedures that already exist for planning, coordinating, preparing and conducting GMP inspections;

b. Taking into account the limitations of time-zone differences between the manufacturing site and the inspectors, and the health and well-being of personnel involved in the inspection;

c. Criticality of the continuity or commencement of supply of the pharmaceutical product; and

d. Security and integrity of the supply chain of the pharmaceutical product.

2.4 Application Procedure

There shall be no applications made for virtual GMP inspection or reliance on institutions other than WLA, EAC, SADC, AMA and WHO during the state of emergency; instead, already submitted applications shall be used to make informed decisions.

2.5 Issuance of GMP Certificates during Emergencies

a. There will be no GMP certificates issued through reliance on GMP inspection during emergencies or virtual GMP inspection. Instead, one (1) one-year waiver for onsite GMP inspection shall be issued.

b. Validity of GMP inspection waiver issued during emergencies

c. The validity of one (1) year shall be issued and may be extended. On-site GMP inspection shall be conducted immediately after the emergency is over, and subject to the inspection plan prepared by the Authority.

d. The Authority shall officially inform an applicant about the granted one (1) year waiver for GMP inspection.

Revision History

Revision No:	Date	Author	Description of change	Section(s) Modified	Approvals
1	06/03/2025	DMC	Replacing EAC GMP Guidelines with TMDA GMP Guidelines	Part 1: Section 1.0	DG
			Includes a statement that excludes payment of GMP inspection fees for facilities inspected under the ZAZIBONA initiative	Part 1; Section 3.2.2	
			Removing definitions related to medical devices	Definition of Terms	
			Adding the wording "for facilities not located in WLA countries"	Part I; 6.4	
			Removing texts related to medical device quality audit, as this is currently under a separate directorate.	Cover page and Parts II and III	
			Merging Parts II and III to form Part II and including a requirement to rely on inspection reports of other NMRAs other than WLA, WHO, EAC, SADC or AMA joint inspections	Part II and III	

3. Annexes

Annexe I: GMP Desk Assessment Application Form

TMDA Tanzania Medicines & Medical Devices Authority	GMP DESK ASSESSMENT APPLICATION FORM	TMDA/DMC/MCIE/R/014 Rev #:02

Please read this section carefully before completing the form

1. Please check the corresponding box in the "Encl." column if any document is enclosed and indicate the respective indexes in the submission folder
2. Please check the boxes as appropriate

A. PARTICULARS OF THE APPLICANT AND MANUFACTURING SITE

Note	Particulars of Applicant		
A.1	Applicant's name		
	Physical address of Head Office		
	Post Code:	Country:	
	Contact Person:	Telephone and mobile number:	
	Fax:	E-mail:	
	Website:		
Note	**Particulars of the Manufacturing Site(s)**		
A.2	Name		
	Unit		
	Block		
	Physical address of the site		
	Post Code:	Province/State:	
	Country:	Contact Person:	

	Telephone and Mobile Number:	Fax:	
	E-mail:	Website:	

B: AUTHORIZED REPRESENTATIVE/AGENT IN THE COUNTRY

	Name of Local Technical Representative (LTR):		
	Physical address:		
	Post Code:	Country:	
	Contact Person:	Telephone and Mobile Number:	
	E-mail:	Fax:	

C: PRODUCTION LINES TO BE ASSESSED

DOSAGE FORM	Tick where applicable	*CATEGORY	**ACTIVITIES
Tablets			
Capsules			
Injections (SVP)			
Injections (LVP)			
Oral liquids			
Creams/Ointments/lotions			
Others (specify)			

*Category means any of the following: -
Beta lactam, non-beta lactam, Biologicals, Vaccines, Hormones, Cytotoxic products.

**Activity means any of the following: -

- Formulation (dispensing, mixing, blending)
- Processing (compression, emulsification, etc.)
- Packing
- Quality Control
- Warehousing (raw material, finished products)

D: DOCUMENTARY EVIDENCE REQUIRED

D.1	Evidence List A	Encl
	Current GMP Certificate (must be with at least 1-year remaining validity)	☐
D. 2	**Evidence List B**	**Encl**
	a. Current GMP Certificate (must be with at least 1year remaining validity)	☐
	b. Current manufacturing license	☐
	c. List and GMP status of regulatory inspections conducted within the past three years	☐
	d. Copy of the most recent (not older than 2 years) inspection reports issued by Authorities (i.e. EAC, SADC, AMA, WLA and WHO-PQ Program)	☐
	e. Market complaints register (for the previous three years), including one investigation report of one of the complaints classified as high risk to public health	☐
	f. Details of any regulatory actionundertaken by the regulatory agencies in the past three years (e.g. product alerts, warning letters, import alerts, recalls)	☐
	g. Updated electronic PDF version of the Site Master File	☐
	h. List of products intended for supply in Tanzania including;	☐
	i. PQR report for each product	☐
	ii. Process validation report	☐
	iii. Batch manufacturing records for products manufactured in the last 6 to 12 months	☐
D3	**Evidence List C (Additional documents for sterile products)**	**Encl**
	a. Validation Master Plan	☐
	b. Aseptic processing and filling validation reports(this is for a non-terminal sterilization process)	☐
D4	**Evidence List D**	**Encl**

	a. Current Certificates (GMP, ISO/IEC 17025 Certification or WHO-PQ)	☐
	b. Quality manual /laboratory manual or equivalent	☐
	c. Contract or agreement between the facility and outsourced testing or sterilization institution	☐
	d. A list of test parameters a laboratory is authorized	☐
	e. For botanical ingredients, enclose evidence to authenticate standards references that are used	☐

E. DECLARATION BY APPLICANT

I, the undersigned, certify that all the information in this form and accompanying documentation is current, accurate and authentic to the best of my knowledge.

Name: ....Position: .....

Signature:.....Official stamp:

Date: .....

Annexe II: List and description of documentary evidence

TMDA Tanzania Medicines & Medical Devices Authority	LIST AND DESCRIPTION OF DOCUMENTARY EVIDENCE	TMDA/DMC/MCIE/R/014 Rev #:02
	Required evidence	**Comments and Exceptions**
Evidence List A	Current GMP certificate.	Certificates must have at least one year of remaining validity to cover the scope of the GMP compliance application.
Evidence List B	Current GMP certificate	Certificates must have at least one year of remaining validity to cover the scope of the GMP compliance application.
	Current manufacturing license	The manufacturing license shall be valid and show the scope of products and activities approved by the local NRA.
	Regulatory inspections conducted within the past three years, and a copy of the most recent inspection report issued by WLA, WHO-PQ and Regional Harmonisation Initiatives	Provide a list and GMP status of all inspections conducted applicable to the scope of the application. A copy of the most recent inspection report conducted within the last two (2) years must be sent to TMDA directly from the manufacturer. Corrective action and preventive action (CAPA) evaluation report for the recent inspection report shall be provided
	Market complaints register	For the previous three years, including an investigation report for one of the complaints classified as high risk to public health The complaint register shall apply to the products applied for.
	Details of any regulatory actions in the past three (3) years	For example, product alerts, warning letters, import alerts, recalls due to defects
	Site Master File	Site Master File (refer to Annex III to these guidelines for writing the Site Master

		File) Site Master File shall not be required if the scope of the application is only for the step of release for supply.

	List of products intended for supply in the country a. PQR report; b. Process validation report; and c. Batch records (batch manufacturing, packaging and testing) for each product applied for marketing authorisation	The PQR reports shall be provided for each product. In case of multiple products, provide one PQR report from each FPP dosage form applied for registration. The batch records of a product for each FPP dosage form manufactured in the last 6 to 12 months, and the corresponding process validation reports and annual product quality review reports
Evidence List C	Validation Master Plan	The Validation Master Plan shall be valid at the time of submission of the application. Not required if the scope of the application is only for the step of release for supply
	Aseptic processing and filling validation reports	Required for products applied that are not terminally sterilized.

Evidence List D	Current GMP certificate or ISO/IEC accreditation certificate, or WHO prequalification	For outsourced testing laboratories, a GLP certificate issued by a recognized regulatory authority or a current ISO/IEC 17025 accreditation certificate or prequalification of the laboratory by the WHO For outsourced sterilization facilities, certification to applicable ISO sterilizations standards (e.g. ISO 11137, ISO 11135)
	Quality manual/laboratory manual or equivalent	The quality manual/ laboratory manual shall 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 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. The institution shall be submitted.
	A list of test parameters a laboratory is authorized to perform as per the scope of its accreditation to the ISO/IEC 17025 or the WHO prequalification For botanical ingredients, evidence that authenticated standard reference materials are used.	The scope of activities of the outsourced laboratory shall include the type, range and volume of testing and/or calibration, validation and verification activities it undertakes.

Annexe III: Model format of Site Master File for FPP manufacturing facility

TMDA Tanzania Medicines & Medical Devices Authority	MODEL FORMAT OF SITE MASTER FILE FOR FPP MANUFACTURING FACILITY	TMDA/DMC/MCIE/R/014 Rev #:02

1. COVER PAGE WITH NAME AND COMPLETE ADDRESS OF THE SITE

2. TABLE OF CONTENTS

3. GENERAL INFORMATION

a. Contact information on the manufacturer
b. Scope of production and authorized pharmaceutical manufacturing activities of the site.
c. Any other manufacturing activities carried out on the site.

4. QUALITY MANAGEMENT

a. Brief descriptions of the quality management system and quality risk management run by the company, and reference to the Standards used;
b. Responsibilities related to the maintenance of the quality system, including senior management;
c. Information on activities for which the site is accredited and certified, including dates and contents of accreditations, and names of accrediting bodies; and
d. Release procedure of finished products.

5. MANAGEMENT OF SUPPLIERS AND CONTRACTORS

6. PRODUCT QUALITY REVIEWS

Brief description of methodologies used.

7. PERSONNEL

a. Organization chart, qualifications, experience and responsibilities of technical personnel
b. Outline of arrangements for basic and in-service training and how records are maintained.
c. Personnel hygiene requirements, including clothing.

8. PREMISES AND EQUIPMENT

a. Layout of manufacturing facilities, including three-dimensional drawings of the premises, air handling systems and water purification systems
b. Nature of construction and finishes
c. Brief description of planned preventive maintenance programmes for premises and of the recording system.
d. Brief description of other relevant utilities, such as steam, compressed air, and nitrogen.
e. Availability of written specifications and procedures for cleaning manufacturing areas
f. List of production and quality control equipment
g. Brief description of the procedures used for cleaning major equipment.
h. Brief description of planned preventive maintenance programmes for equipment and of the recording system.
i. Brief description of the company's Qualification and Calibration policy, including the recording system. Reference should be made to the Validation master plan.

9. DOCUMENTATION

a. Arrangements for the preparation, revision, distribution and achieving necessary documentation for manufacture should be stated.
b. Brief description of the validation master plan
c. Brief description of the change control and deviation procedures
d. Any other documentation related to product quality that is not mentioned, such as microbiological controls on air and water.

10. PRODUCTION

a. Type of products
b. Process validation: Material management and warehousing. Arrangements for the handling of rejected materials and products.

11. QUALITY CONTROL

12. DISTRIBUTION, COMPLAINTS, PRODUCT DEFECTS AND RECALL

13. SELF-INSPECTION

14. SHELF LIFE / STABILITY DETERMINATION PROGRAM

General policy for the determination of the shelf-life and stability of products manufactured at the site.

15. REFERENCES

16. REVISION HISTORY

Annexe IV: Model format of Certificate of Desk Assessment for Good Manufacturing Practices Compliance

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

CERTIFICATE OF COMPLIANCE TO GOOD MANUFACTURING PRACTICES (GMP) THROUGH DESK ASSESSMENT

Made under regulation 6 of the Tanzania Medicines and Medical Devices (Good Manufacturing Practice Enforcement) Regulations, 2018

GMP Certificate No.....

Based on the desk assessment carried out on..... I certify that..... located at.....has been found to comply with Good Manufacturing Practices requirements for dosage forms and categories of medicines listed below:-

S/ N	Dosage Forms	Categories of Medicines	Manufacturing Operations

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured lies with the manufacturer and /or marketing authorization holder.

This certificate shall remain valid until it becomes invalid if the dosage forms, operations and /or categories certified herewith are changed or if the site is no longer considered to comply with current GMP.

_____ _____

Date **DIRECTOR GENERAL**

Note:

a. This Certificate certifies the status of the site described above
b. This Certificate shall remain valid for a period of 3 years from the date of issue.

4. Bibliography

a. EAC (2014). Compendium of Good Manufacturing Practices (GMP) Technical Documents for Harmonization of Medicines Regulation in the East African Community, September 2014, East African Community, Arusha, Tanzania.

b. WHO (2018). Guidance on Good Practices for Desk Assessment of Compliance with Good Manufacturing Practices, Good Laboratory Practices and Good Chemical Practices for Medicinal Products, TRS 961, Annex 9, World Health Organization, Geneva, Switzerland.

c. PIC/S, (2018)., *Guidance GMP Compliance Reliance,* PI048-1, Pharmaceutical inspection Cooperation Scheme, Geneva, Switzerland.

d. TMDA (2003). *Tanzania Medicines and Medical Devices Act, Cap 219*. Tanzania Medicines and Medical Devices Authority. Government Printer, Dar es Salaam, Tanzania.

e. TMDA (2018). *Tanzania Medicines and Medical Devices (Good Manufacturing Practices Enforcement) Regulations GN No. 295*. Tanzania Medicines and Medical Devices Authority. Government Printer, Dar es Salaam, Tanzania.

f. TMDA (2015). *Guidelines on submission of documentation for Registration of Human Pharmaceutical Products*, 1st Ed, Tanzania Medicines and Medical Devices Authority, Dar es Salaam, Tanzania

g. USFDA (2020). Manufacturing, Supply Chain, and Drug and Biological Products Inspections During COVID-19 Public Health Emergency Questions and Answers, Guidance for Industry.

h. TGA (2020). *GMP Approach to Overseas Manufacturers of Medicines and Biologicals During the COVID-19 Pandemic* <available on https://www.tga.gov.au/nod/906141> dated 25th September, 2020.

i. Swissmedic, (2020)., *Updates on Inspections in Switzerland During the COVID-19 Pandemic*< available on https://www.swissmedic.ch>news>coronavirus-covid-19> dated 25th September 2020.

j. EU (2020)., A Guide to Quality and Regulatory Compliance During COVID-19

k. MCAZ (2020). Guidance on Good Practice (GxP) Inspections During Emergencies/Disasters, including the COVID-19 Pandemic.

l. TMDA (2003). Tanzania Medicines and Medical Devices Act, Cap 219, Tanzania Medicines and Medical Devices Authority, Government Printers, Dar es Salaam, Tanzania.

m. TMDA (2020). Guidelines on Submission of Documentation for the establishment of Compliance to Good Manufacturing Practices Through Desk Assessment, Tanzania Medicines and Medical Devices Authority.

n. IFPMA. Best Practices for Virtual Inspection-23 July 2020. www.ifpma.org-content/uploads/2020/07 retrieved on 24th December,2020.

All rights reserved:
This is a controlled document. It must not be copied without authorisation from the Manager, Quality and Risk Management or Director General. Only originals or authorized copies shall be used as working documents.