TMDA/DMC/CIE/G/000
Rev. #:00

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR GOOD STORAGE AND DISTRIBUTION PRACTICES OF PHARMACEUTICAL PRODUCTS

May, 2024

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ABBREVIATIONS AND ACRONYMS

ADDO	Accredited Drug Dispensing Outlets
CAPA	Corrective and Preventive Actions
FEFO	First Expiry First out
FIFO	First in First out
GMP	Good Manufacturing Practices
GPS	Global Positioning System
GSDP	Good Storage and Distribution Practices
HVAC	Heating, Ventilation and Air Conditioning Systems
INN	International Non-proprietary Name
MSH	Management Sciences for Health
MTaPS	Medicines, Technologies and Pharmaceutical Services
QMS	Quality Management Systems
SF	Substandard and Falsified
SOP	Standard Operating Procedures
TMDA	Tanzania Medicines and Medical Devices Authority
WHO	World Health Organization

ACKNOWLEDGEMENTS

I wish to thank everyone who participated in the preparation of these Guidelines. I am especially indebted to the following staff from Tanzania Medicines and Medical Devices Authority (TMDA) whose technical experiences and valuable contributions enabled the preparation and finalization of this document.

Mr. Emmanuel Alphonce	-	Medicines Control Inspection and Enforcement Section
Mr. Damas Matiko	-	Clinical Trials Control and Pharmacovigilance Section
Mr. John Bugalama	-	Medical Devices Premises Licensing and Compliance Section
Dr. Itikija Mwanga	-	Medicines Control Inspection and Enforcement Section
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Ms. Doreen Nyaki	-	Medicines Control Inspection and Enforcement Section
Ms. Aziza Sengo	-	Medicines Control Inspection and Enforcement Section
Ms. Siya Ringo	-	Medicines Control Inspection and Enforcement Section
Mr. Elia Nyeura	-	Medicines Control Inspection and Enforcement Section
Ms. Elizabeth Mollel	-	Medicines Control Inspection and Enforcement Section
Ms. Gloria Matemu	-	Eastern Zone Office

The Authority appreciates the efforts, determination, support and contributions of several individuals and organizations that made the development of these Guidelines possible.

Special gratitude is extended to USAID-funded Medicines, Technologies and Pharmaceutical Services (MTaPS) program being implemented by Management Sciences for Health (MSH) for its financial and technical support which enabled the drafting and finalization of these Guidelines. TMDA is also indebted to all stakeholders who despite their busy schedules provided constructive inputs which refined these Guidelines.

Last but not least, the TMDA Management is acknowledged for positive comments and guidance during deliberations and endorsement of these Guidelines.

Dr. Yonah H. Mwalwisi
Director, Human and Veterinary Medicines

FOREWORD

Tanzania Medicines and Medical Devices Authority (TMDA) was established under the Tanzania Medicines and Medical Devices Act, Cap, 219 with the Mission of protecting and promoting public health by ensuring the quality, safety and effectiveness of medicines, medical devices, diagnostics and other health-related products.

In view of expounding and enforcing the Act, Cap, 219; TMDA developed the Tanzania Medicines and Medical Devices (Good Storage and Distribution Practices) Regulations, 2021. The scope of the Regulations, 2021 is to provide regulatory oversight and controls related to good storage and distribution practices of pharmaceutical products in mainland Tanzania.

Due to TMDA vital role in providing guidance for self - compliance on the legal requirements to its stakeholders such as manufacturers, importers, distributors, wholesalers, retailers and end users or patients both in public and private sectors; the Authority has found the importance of developing this first Good Storage and Distribution Practices (GSDP) Guidelines so as to translate and simplify the implementation of the legal requirements stipulated in the GSDP Regulations, 2021.

These Guidelines are intended to be used by persons and entities involved in any aspect of the storage and distribution of pharmaceutical products from the manufacturing site to the point of sale or use. Other beneficiaries of these Guidelines are TMDA pharmaceutical inspectors who shall use them while enforcing the Act, Cap, 219 and its corresponding Regulations, 2021. The Guidelines can also be used as a training tool for personnel working in facilities undertaking the storage and distribution of pharmaceutical products.

This document is arranged into different sections covering general GSDP principles, organization and personnel, quality management systems (QMS), premises, warehousing and storage facilities, vehicles and equipment, operational management, donated pharmaceutical products and self-inspection. Forms and checklists have also been appended for easy of referencing during use of these Guidelines.

Pharmaceutical dealers throughout the supply chain are urged to familiarize themselves with these Guidelines to ensure that pharmaceutical products in their custody comply with the legal requirements.

Any comments or inputs that will improve these Guidelines in the future are highly welcomed and can be submitted through info@tmda.go.tz

Dr. Adam M. Fimbo
DIRECTOR GENERAL

DEFINITION OF TERMS

For the purpose of these guidelines, the following terms or phrases are defined as follows;

Audit	An independent and objective activity designed to add value and improve an organization's operations by helping the organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes.
Batch	A defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogenous.
Batch number	A distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.
Calibration	The set of operations which establishes, under specific conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure and the corresponding known values of a reference standard.
Change control	The processes and procedures to manage system changes.
Computerized system	A system including the input of data, electronic processing and the output of information to be used either for reporting or automatic control
Consignment	The quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include pharmaceutical products belonging to more than one batch.
Container	The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they intend to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.

Contamination	The undesired introduction of impurities of a chemical or microbiological nature, or foreign matter, onto or onto a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transportation.
Contract	Service agreement for the supply of goods or performance of work at a specified price
Controlled pharmaceutical products	Any narcotics, psychotropic products or precursors as described under section 77 (2) of TMDA Act, Cap 219
Cross-contamination	Contamination of a starting material, intermediate product or finished pharmaceutical product with another starting material or product during production, storage and transportation.
Deviation	Departure from an approved instruction or an established standard.
Distribution	The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of pharmaceutical products.
Distributor/ pharmaceutical dealer	A person or organization who receives, stores, warehouses, handles, holds, offers, market or displays pharmaceutical products. It shall be an entity that is appropriately authorized to perform the intended function as provided in the GSDP Regulations, and which can be held accountable for its activities. These include but not limited to government institutions at all levels, bilateral and multilateral agencies, non-governmental organizations, public and private health and storage facilities, manufacturers of finished products, importers, exporters, wholesalers, suppliers and retailers.
Expiry date	The date given on the individual container (usually on the label) of a pharmaceutical product up to and including the date on which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.
Falsified pharmaceutical product	Any pharmaceutical product with a false representation of (a) Its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; (b) Its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorization holder; or its history including the records and

documents relating to the distribution channels used.

First expiry/first out (FEFO)	A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with the later expiry date is distributed and/or used.
Good Distribution Practices (GDP)	That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from unapproved, illegally imported, stolen, falsified, substandard, adulterated, and/or misbranded pharmaceutical products.
Good Manufacturing Practices (GMP)	That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization
Hazardous pharmaceutical products	A product or substance that may present a substantial risk of injury to health or the environment
Importation	The act of bringing or causing any pharmaceutical products to be brought into a customs territory (national territory, excluding any free zone)
Labelling	Process of identifying a pharmaceutical product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier
Marketing Authorization	An official authorization or registration of a product by Authority for t marketing or free distribution in Tanzania after evaluation for quality, safety and efficacy
Pests	Includes birds, bats, rodents and insects whose uncontrolled presence affects hygiene and cleanliness.

Pharmaceutical product	Any product intended for human use or veterinary product intended for administration to food-producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines.
Procuring	Obtaining, acquiring, purchasing or buying pharmaceutical products from manufacturers, importers or other wholesale distributors.
Recall	A process for withdrawing or removing a pharmaceutical product from the distribution chain because of defects in the product, complaints of serious adverse reactions to the products and/or concerns that the product is or maybe

1.0 INTRODUCTION

The distribution of pharmaceutical products is an important activity in the supply chain and involves several players such as manufacturers, importers, wholesalers, distributors, retailers and other persons authorized by TMDA to supply pharmaceutical products in the public and private sectors. Distribution activities consist of procuring, storage, supplying, sale, importing and exporting of pharmaceutical products.

These Good Storage and Distribution Practice (GSDP) Guidelines are intended to help key players in the supply chain of pharmaceutical products to comply with the TMDA Good Storage and Distribution Practice Regulations, 2021. The GSDP regulations prescribe the minimum requirements for good storage and distribution of pharmaceutical products in the entire supply chain.

Further, the Guidelines provide appropriate tools to assist all categories of pharmaceutical dealers in conducting their activities in orderly manner and hence contribute to ensure the quality of pharmaceutical products including prevention, detection and timely respond to presence of substandard and falsified (SF) medical products in legal supply chain. Equally, the Guidelines are intended to help in minimizing the inherent risks in distribution such as mix-ups, adulteration, contamination, cross-contamination and diversions.

Generally, the Guidelines apply to persons and entities involved in any aspect of the storage and distribution of pharmaceutical products from the manufacturing site to the point of sale or use. The Guidelines apply to all government institutions, non-governmental organizations, public and private health and storage facilities, manufacturers of finished pharmaceutical products, importers, exporters, wholesalers, distributors, suppliers, and retailers as regulated by the Act, Cap 219 and the Pharmacy Act, Cap 311.

Some sections of these Guidelines also apply to other entities involved in the storage and distribution of pharmaceutical products such as clearing and forwarding agents, freighters and transporters. The Guidelines also apply to dealers that are established or operating in Customs areas, such as free zones, bonded warehouses or free warehouses.

The Guidelines shall be used in conjunction with other relevant pharmaceutical products laws in the country. Implementation of these guidelines will depend on the complexity of the design and operations of premises. For example, the complexity of operations in ADDOs is not the same as that of importers or wholesalers, similarly the design of premises is not the same for all categories of pharmaceutical operations. This can also impact on the premises requirements of the different outlets. Although the guidelines have generic requirements there could be a need to tailor them based on the category of premises during implementation of these guidelines.

2.0 GENERAL PRINCIPLES

2.1 All parties involved in the storage and distribution of pharmaceutical products have a responsibility to ensure that the quality of pharmaceutical products and

the integrity of the distribution chain are maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient.

2.2 Good storage and distribution practices shall apply both to pharmaceutical products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing the product to the end user; and to products which are moving backwards in the chain such as those returned and recalled from the distribution chain.

2.3 Good storage and distribution practices shall also apply to donated pharmaceutical products.

2.4 All pharmaceutical dealers should apply due diligence with adherence to the principles of GSDP, for example, in procedures relating to traceability and in recognition of security risks.

2.5 All dealers should comply with the existing national legislation on pharmaceutical products.

2.6 All dealers should be authorized and shall be accountable for all the activities that relate to the distribution of pharmaceutical products.

2.7 Only entities which have marketing authorization for pharmaceutical products or their agents or as may be authorized by Authority are entitled to import or export pharmaceutical products.

2.8 Pharmaceutical products may be distributed within or to a country or territory if a marketing authorization or similar authorization has been granted, which allows the use of that pharmaceutical product in that country or territory.

2.9 Holders of an authorization to distribute pharmaceutical products should obtain their supplies only from persons or entities which have the applicable authorization to sell or supply such products

2.10 Distributors or their agents should supply pharmaceutical products only to persons or entities which are themselves authorized to acquire such products either in terms of an authorization to act as a distributor or to sell or supply products directly to a patient.

2.11 Responsible person(s) may delegate or contract out duties and responsibilities to suitably designated persons or entities as authorized and as necessary. However, there should be no gaps or unexplained overlaps about the delegated duties and responsibilities in application of the GSDP. The delegated and contracted out activities should be documented in agreements or contracts such that there should be a periodic audit of such activities about the application of GSDP.

2.12 Pharmaceutical dealers should put in place a system to monitor transactions and investigate any irregularity in the sales patterns of narcotics, psychotropic substances, hazardous products or other controlled substances. Unusual sales patterns that may constitute diversion or misuse of pharmaceutical products should be investigated and reported to the Authority timely.

3.0 ORGANIZATION AND PERSONNEL

3.1 General Overview

3.1.1 Key personnel involved in the distribution of the pharmaceutical products should have the ability and experience appropriate to their responsibilities for ensuring that pharmaceutical products are distributed properly.

3.1.2 Personnel involved in the distribution of pharmaceutical products should wear garments suitable for the activities that they perform. Personnel dealing with hazardous pharmaceutical products, including products containing materials that are highly active, toxic, and infectious or sensitizing, should wear Personal Protective Equipment (PPE) as necessary.

3.1.3 Dealers should ensure that there are procedures and conditions of employment for permanent employees, temporary staff and other personnel. The procedures must be designed and administered to assist in minimizing the possibility of products coming into the possession of unauthorized persons or entities.

3.1.4 Codes of practices and punitive procedures as provided by the Pharmacy Council from time to time shall be in place and used to prevent and address situations where persons involved in the distribution of pharmaceutical products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or falsification of any product.

3.1.5 Dealers should develop appropriate procedures relating to personnel health, hygiene and clothing relevant to the activities being carried out.

3.2 Responsible Person

3.2.1 All pharmaceutical dealers must designate a person as responsible person who is the superintendent pharmacist as required by the Pharmacy Act Cap. 311 and Regulations in force. The responsible person should have appropriate competence and experience as well as knowledge of and training in good storage and distribution practices regulations and Guidelines in force.

3.2.2 The responsible persons shall fulfil their responsibilities personally and

should be continuously contactable. The responsible person may delegate duties but not responsibilities.

3.2.3 The written job descriptions of the responsible persons should define their authority to make decisions about their responsibilities. The dealers should give the responsible person the defined authority, resources and responsibility needed to fulfil their duties.

3.2.4 The responsible person should carry out his/her duties in such a way as to ensure that the dealers can demonstrate GSDP compliance and that obligations to the public are met. The responsibilities of the responsible person include:-

a. ensuring that a quality management system is implemented and maintained;
b. focusing on the management of authorized activities, the accuracy and quality of records;
c. ensuring that initial and continuous training programs are implemented and maintained;
d. coordinating and promptly performing any recall operations for pharmaceutical products;
e. ensuring that relevant customer complaints are investigated and dealt with effectively;
f. ensuring that suppliers and customers in the distribution chain are approved;
g. approving any subcontracted activities which may impact on GSDP;
h. ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place;
i. keeping appropriate records of all activities related to GSDP;
j. executing disposition of returned, rejected, recalled or falsified products;
k. approving any returns to saleable/useable stock;
l. ensuring that any additional regulatory requirements imposed on certain products are adhered to; and
m. performing any other functions as stipulated in these Guidelines.

3.3 **Training**

3.3.1 All personnel involved in distribution activities should have the appropriate competence and experience before commencing their tasks.

3.3.2 All personnel involved in distribution activities should be trained on the requirements of GSDP as per written standard operating procedures (SOPs).

3.3.3 Personnel should receive initial and continuing training relevant to their roles, based on written procedures and in accordance with a written training program. The responsible person should also maintain their competence in GSDP through regular training.

3.3.4 Notwithstanding the Guidelines above, training should include aspects of product security, as well as aspects of product identification, the detection of falsified products and the avoidance of falsified pharmaceutical products entering the supply chain.

3.3.5 Personnel dealing with any products that require more stringent handling conditions such as hazardous products, radioactive materials, products presenting special risks of abuse (including narcotics and psychotropic substances), as well as time, humidity and temperature-sensitive products should receive specific training.

3.3.6 Training records should be kept and evaluation should be periodically conducted and documented.

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General

4.1.1 Entities involved in the storage and distribution of pharmaceutical products should have a comprehensively designed, documented, and properly implemented quality system that incorporates GSDP, principles of quality risk management, and management review.

4.1.2 Top management shall have the ultimate responsibility to ensure that an effective quality system is established, resourced, implemented, and maintained.

4.1.3 The quality management system should ensure that:

a. GSDP is adopted and implemented to ensure that the quality of pharmaceutical products is maintained throughout their shelf life in the supply chain;
b. pharmaceutical products are appropriately procured, stored, distributed, and delivered (in compliance with the legislation) to the appropriate recipients;
c. operations are clearly specified in written procedures;
d. responsibilities are clearly stated in job descriptions;
e. all risks are identified and effective controls are implemented;
f. procedures are in place for the management of outsourced activities;
g. procedures for self-inspection are developed and implemented;
h. there are written procedures for managing returns, complaints and recalls; and
i. there are written procedures to manage changes, deviations

and corrective and preventive actions (CAPAs).

4.1.4 There should be an approved quality manual which incorporate quality policy describing the overall intentions and requirements regarding quality of pharmaceutical products dealt with.

4.1.5 The quality policy should be conspicuously displayed within the premises.

4.1.6 Each premises should have an approved organizational structure. The responsibility, authority, and interrelationships of personnel provided in the organizational structure should be clearly indicated.

4.1.7 Roles and responsibilities provided in the organizational structure should be clearly defined, communicated, and understood by the individuals concerned, and recorded as written in job descriptions.

4.2 **Documentation**

Good documentation constitutes an essential part of the quality management system.

4.2.1 Written procedures should be developed for the preparation, review, approval, use of and control of all documents.

4.2.2 Documents, and in particular instructions and procedures relating to any activity should be designed, completed, reviewed, and distributed with care.

4.2.3 Written documentation should be available to permit the tracing and tracking of relevant operations during the distribution of pharmaceutical products. Records should be made at the time each operation is undertaken.

4.2.4 Documentation shall comprise all written procedures, instructions, contracts, records, and data, in paper or electronic forms, reports from internal (and external if performed) audits and management reviews, as well as records of all complaints and their investigations, including records of possible corrective and preventive actions.

4.2.5 Documentation should be readily available and retrievable.

4.2.6 Documentation should be comprehensive with respect to the scope of the activities and in a language understood by personnel. It should be written in clear, unambiguous language and be free from errors.

4.2.7 Documentation should be approved, signed, and dated by appropriate authorized persons. No document should be changed without authorization and approval.

4.2.8 Documents should not be hand-written; although, where it is necessary, sufficient space should be provided for such entries.

4.2.9 Any alteration made in the documentation should be signed and dated; the alteration should be done in a way to permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.

4.2.10 Documents should be retained for at least five (5) years or as required in specific sections of these Guidelines.

4.2.11 Documents should have unambiguous content; title, type, and purpose should be clearly stated and laid out in an orderly format for easy implementation.

4.2.12 Documents should be reviewed regularly and kept up-to-date. Version control should be applied to procedures. After the revision of a document, a system should exist to prevent inadvertent use of the outdated version.

4.2.13 Outdated procedures should be removed from workstations and archived.

4.2.14 Written procedures and records for all activities relating to the distribution of pharmaceutical products, including all applicable receipts and invoices should be available.

4.2.15 Dealers should keep records of all pharmaceutical products received. Records should contain at least the following information:

a. Receiving or Issue date;
b. Brand name, Generic name;
c. Strength of the pharmaceutical product;
d. Dosage form of the products;
e. Pack size (stock keeping unit);
f. Quantity received, or supplied;
g. Name and address of the supplier/customer;
h. Batch number and corresponding date markings; and
i. Manufacturing and expiry dates.

4.2.16 The nature, content, and retention of documentation relating to the distribution of pharmaceutical products and any investigations conducted and action taken, should be retained for at least one year after the expiry date of the product of concern.

4.2.17 Dealers must establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

4.2.18 All quality records should be readable and readily retrievable. They should be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration, and/or loss of documentation.

4.2.19 Mechanisms should exist to allow for the transfer of information, including quality or regulatory information, between a distributor, a customer, and the Regulatory Authority.

4.2.20 Permanent records, written or electronic, should exist for each stored product indicating recommended storage conditions and any precautions to be observed.

4.2.21 Where records are generated and kept in electronic form, backups should be maintained within and outside the facility to prevent any accidental data loss.

4.2.22 The conditions under which all original records are stored should be such to ensure their security and confidentiality and access to them should be restricted to authorized personnel.

4.2.23 Electronic storage and signatures may also be employed but with

restricted access and in conformance with requirements for electronic records.

4.3 Control of Documentation

Documentation is an essential part of the quality management system. The organization should establish and maintain procedures to control and review all documents (both internally generated and from external sources) that form part of the quality documentation.

4.3.1 A master list identifying the document number and current version.

4.3.2 Distribution list of documents should be established and readily available.

4.3.3 The document control procedures should ensure that:

a. each quality document, has a unique identifier, version number, and date of implementation;
b. appropriate and authorized SOPs are available;
c. documents are kept up to date and reviewed as required;
d. any obsolete document is removed and replaced with the authorized, revised document with immediate effect;
e. a revised document includes references to the previous document;
f. obsolete documents are retained in the archives to ensure traceability of the evolution of the procedures; any copies are destroyed;
g. all relevant staff are trained for the new and revised SOPs; and
h. quality documentation, including records, is retained for a minimum of five (5) years.

4.3.4 Procedures should be in place to inform staff of new and revised document(s).

4.4 Deviations, Investigations, and Corrective and Preventive Actions

The handling of deviations is important in assuring the quality of pharmaceutical products and contributing to continuous improvement. The deviation system should identify non-conformances and potential non-conformances and define when and how corrective and preventive actions (CAPA) should be undertaken. Once a deviation is detected, it needs to be contained with immediate actions, the root causes identified as necessary, and systemic actions implemented to prevent the same or similar non-conformances in the future.

4.4.1 A procedure should be in place outlining the process for identifying, documenting, investigating, and closing deviations and the timelines involved.

4.4.2 The responsible person should be notified of deviations and an assessment should be performed to determine product quality implications and/or impact on the quality system.

4.4.3 Immediately a potential deviation or incident is identified, the documentation of investigations should be commenced. Should the outcome of an investigation conclude that no deviation has occurred then the documentation of the investigation should still be maintained and available to an inspector.

4.4.4 Deviation investigations should aim to identify the root cause of the

deviation.

4.4.5 Corrective and preventive actions (CAPAs) may arise as a result of deviations, self-inspections, observations or from other incidents.

4.4.6 A list of deviations and suspected deviations should be maintained and all investigations, root cause identifications and resulting CAPAs should be documented.

4.4.7 CAPAs should be subjected to regular review to ensure their full implementation and effectiveness as per documented procedures.

4.4.8 The principles of quality risk management should be built into the deviation process. Each deviation should be considered and a decision taken as to whether a risk assessment is required. The requirement for a risk assessment to be considered should be documented on the deviation form.

4.5 Quality Risk Management

4.5.1 There should be a system to assess, control, communicate, and review risks identified at all stages in the supply chain.

4.5.2 The evaluation of risk should be based on scientific knowledge and experience and ultimately be linked to the protection of the patient.

4.5.3 Appropriate controls should be developed and implemented to address all risks. The effectiveness of the controls implemented should be evaluated at periodic intervals.

4.6 Quality Management Review

There should be a system for periodic quality management review for manufacturers, importers, wholesalers, health facilities and retails pharmacies. The review should include at least:

a. top management;
b. review of the quality system and its effectiveness by using quality metrics and key performance indicators;
c. identification of opportunities for continual improvement; and
d. follow-up on recommendations from previous management review meetings.

4.7 Traceability of Pharmaceutical Products

Traceability ensures that the distribution of pharmaceutical products including transportation and storage conditions from the point of supply to the end-user can be tracked. This is essential to demonstrate that pharmaceutical products have been correctly distributed to facilitate product recalls and to detect theft and fraud.

4.7.1 All distributors of pharmaceutical products should foster a safe, transparent and secure distribution system that includes product traceability throughout the supply chain.

4.7.2 All parties involved in the supply chain should be identifiable.

4.7.3 Measures should be in place to ensure that pharmaceutical products have documentation that can be used to permit traceability and recall of the

products throughout distribution channels from the manufacturer /importer to the entity responsible for selling or supplying the product to the patient or client. Records including expiry dates and batch numbers may be part of a secure distribution documentation enabling traceability.

4.7.4 Where electronic commerce (e-commerce) is used for any of the distribution steps, defined procedures and adequate systems should be in place to ensure traceability and confidence in the quality of the pharmaceutical products concerned.

5.0 PREMISES, WAREHOUSING AND STORAGE FACILITIES

5.1 General

5.1.1 Premises should be suitably located, designed, constructed or adapted and maintained to ensure appropriate operations such as receiving, storage, picking, packing and dispatch of pharmaceutical products.

5.1.2 Premises should have sufficient space, lighting, ventilation and security to ensure required segregation, appropriate storage conditions, cleanliness and allow access only to authorized personnel.

5.1.3 Premises should protect products from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight.

5.1.4 Premises should be protected from the entry of birds, rodents, insects and other animals. A rodent and pest control procedure should be in place.

5.2 Receiving

5.2.1 Each incoming consignment should be checked on arrival against the relevant documentation to ensure that the correct product is delivered from the correct supplier. This may include, but is not limited to purchase order, containers, label description, batch number, expiry date, product and quantity.

5.2.2 Receiving and dispatch bays shall protect pharmaceutical products from unfavourable weather. Receiving areas shall be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage. This is not applicable to retail pharmacies and ADDOs.

5.2.3 Physical or other equivalent validated segregation shall be provided for the storage of useable, rejected, expired, recalled or returned products and suspected substandard and falsified (SF) products.

5.2.4 The products and the areas concerned shall be suitably marked and access restricted to authorized personnel until a decision as to their future has been made.

5.3 Storage Areas

5.3.1 Storage areas should be of sufficient capacity to allow the orderly storage

of the various categories of pharmaceutical products namely commercial and non-commercial products, quarantined, quarantined and released, rejected, returned or recalled products as well as those suspected to be falsified; and precautions should be taken to prevent unauthorized persons from entering storage areas.

5.3.2 Storage areas should be kept clean and there should be sufficient space and lighting maintained within acceptable and specified temperature limits. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these should be provided, controlled, monitored and recorded.

5.3.3 All pharmaceutical products should be stored off the floor and suitably spaced to permit ventilation, cleaning and inspection. Suitable pallets and/or shelves as applicable should be used and kept in a good state of cleanliness and repair.

5.3.4 There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination and a written sanitation procedures should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.

5.3.5 Storage areas should be clean and free from accumulated waste and vermin. Dealers must ensure that premises and storage areas are cleaned regularly. There should also be a written procedures for pest control. The pest control agents used should be safe and there should be no risk of contamination of pharmaceutical products.

5.3.6 Hazardous and/or sensitive products such as highly active and radioactive materials, presenting risks of fire/explosion or use (e.g. Combustible liquids, solids and pressurized gases) should be stored in a dedicated area(s) that is subject to appropriate additional safety and security measures.

5.3.7 Narcotic medicines should be stored in compliance with international conventions, the Tanzania Medicines and Medical Devices Act Cap 219, Guidelines for dealing in Controlled Drugs in force.

5.4 **Storage Conditions**

5.4.1 Storage conditions for pharmaceutical products should comply with the recommendations of the manufacturer as indicated on the product labelling.

5.5 **Temperature and Relative humidity Monitoring for Warehouses**

5.5.1 Temperature and relative humidity, as appropriate, should be controlled

and monitored at regular intervals. Data should be recorded, and the records should be reviewed. The equipment used for monitoring of storage conditions should be calibrated regularly and be suitable for their intended use. All records about mapping and monitoring should be kept for a suitable period of time and as required by GSDP Regulations, 2021.

5.5.2 Mapping studies for temperature and relative humidity, as appropriate, should be done, this applies to rooms, refrigerators and freezers.

5.5.3 Temperature mapping should show uniformity of the temperature across the storage facility and during different seasons (cold and hot). It is recommended that temperature monitors (wall thermohygrometers) be located in areas that are most likely to show fluctuations.

5.5.4 Records of temperature and humidity monitoring data shall be available for review, the equipment used for monitoring shall be checked at suitable predetermined intervals and the results of such checks shall be recorded and retained.

5.5.5 Where, heating, ventilation and air conditioning systems (HVAC) are installed, they should be appropriately designed, installed, qualified and maintained to ensure that the required storage conditions are maintained.

5.5.6 All monitoring records shall be kept for at least the shelf-life of the stored pharmaceutical product plus one year.

5.6 **Defined Storage Instructions**

Pharmaceutical products that must be stored under defined conditions require appropriate storage instructions. Unless otherwise specifically stated (e.g. continuous maintenance of cold storage) deviation may be tolerated only during short-term interruptions, for example, during local transportation.

The use of the following labelling instructions are recommended;

Freezer	The temperature is thermostatically controlled between -15°C and 0°C
Refrigerator	The temperature is thermostatically controlled between 2°C and 8°C
Cool Place	The temperature is between 8°C and 15°C
Ambient temperature	The required storage temperature of non-refrigerated pharmaceutical product; usually stated on the product as 'between 15°C to 25°C'
Room Temperature	The temperature is between 20°C and 30°C
Warm	The temperature is between 30°C and 40°C
Excessive heat	The temperature is above 40°C
Do not store over	from +2°C to +30°C

30°C	
Do not store over 25°C	from +2°C to +25°C
Do not store over 15°C	from +2°C to +15°C
Do not store over 8°C	from +2°C to +8°C
Do not store below 8°C	from +8°C to +25°C
Protect from moisture	no more than 60% relative humidity in normal storage conditions; to be provided to the patient in a moisture resistant container.
Protect from light	to be provided to the patient in a light-resistant container.

6.0 INVENTORY CONTROL

6.1 There should be procedures and plan for stock taking, reconciliation, tracking, tracing and monitoring of saleable, expired, rejected, returned, recalled and damaged pharmaceutical products to ensure adequate stock is available to cater demand.

6.2 Records of stock levels for products in store should be maintained in either paper or electronic format and such records shall be updated after each transaction including entries, issues, losses, and adjustments.

6.3 Equally, records generated from these processes should be well kept for at least 5 years.

7.0 VEHICLES AND EQUIPMENT

7.1 Vehicles

7.1.1 There should be procedures in place to ensure that the integrity of the products is not compromised during transportation.

7.1.2 Vehicles used for the distribution, storage, and handling of pharmaceutical products should be suitable for their intended purpose and should not compromise product integrity such as affecting their stability and packaging integrity.

7.1.3 The design of vehicles used in the transportation of pharmaceutical products should aim to minimize the risk of errors and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or dirt, and/or any adverse effect on the quality of the pharmaceutical products being distributed.

7.1.4 Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of pharmaceutical products during transportation.

7.1.5 Dedicated vehicles and equipment should be used, where possible when handling pharmaceutical products.

7.1.6 Where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the pharmaceutical product

will not be compromised.

7.1.7 Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned pharmaceutical products as well as those suspected of being substandard or falsified. Such pharmaceutical products should be securely packaged, clearly labelled, and accompanied by appropriate supporting documentation.

7.1.8 To ensure that temperature-sensitive pharmaceutical products are safely transported within the transport temperature profile defined for each product and that compliance can be demonstrated to the Authority and other interested parties. Vehicles used for the distribution of such products should be: -

a. capable of maintaining the temperature range defined by the system set points over the full annual ambient temperature range experienced over known distribution routes and when the vehicle is in motion, or parked with the main engine stopped;
b. equipped with calibrated temperature monitoring devices with sensors located at points representing temperature extremes;
c. equipped with alarms to alert the driver in the event of temperature excursions and/or refrigeration unit failure;
d. fitted with doors with security seals and/or security that protect against unauthorized access during transit;
e. qualified and regularly calibrated and maintained and records kept to demonstrate compliance.

7.1.9 Where feasible, consideration should be given to adding technology, such as global positioning system (GPS), electronic tracking devices and engine-kill buttons to vehicles, which would enhance the security of pharmaceutical products while in the vehicle.

7.1.10 Where third-party carriers are used, all distributors of pharmaceutical products should have contractual agreement for the same, including maintaining appropriate documentation and records. Such agreements should be in line with the requirements of the Authority.

7.1.11 Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination. Agents used for the cleaning of vehicles should not affect the quality of the pharmaceutical product.

7.1.12 Defective vehicles and equipment should not be used and should either be labelled as such or removed from service

7.1.13 Vehicles and containers should be kept free from rodents, vermin, birds, and other pests. There should be written procedures and records for such pest control. The cleaning and fumigation agents used should not have any adverse effect on product quality.

7.1.14 There should be procedures in place for the operation and maintenance of all vehicles involved in the distribution process, including cleaning and safety precautions.

7.2 Equipment

7.2.1 All equipment impacting on storage and distribution of pharmaceutical products should be designed, located, and maintained to suit its intended purpose and minimizes any risk of errors or contaminations.

7.2.2 All equipment should be of suitable materials for their intended purposes, kept clean and dry and free from accumulated waste.

7.2.3 Equipment/instruments used to control or monitor the environmental conditions (e.g. temperature and humidity) within vehicles, containers and storage areas should be calibrated as per calibration schedule.

7.2.4 There should be systems or devices/instruments for temperature and relative humidity monitoring for all storage areas, vehicles and containers used for transportation.

7.2.5 Temperature monitoring systems and devices should be provided for all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers while humidity monitoring devices and systems should also be provided in rooms where pharmaceutical products which are adversely affected by high relative humidity are stored.

7.2.6 Appropriate temperature and humidity alarm systems should be in place to provide alerts where there are excursions from predefined storage conditions. Alarm levels should be appropriately set and alarms should be regularly tested to ensure adequate functionality at least once in 6 months. An automatic telephone dial-up or SMS text warning system should be installed to alert on-call personnel when an alarm is triggered outside working hours.

7.2.7 A preventive and emergency maintenance schedule and procedure should be in place and should be implemented for temperature-controlled rooms, cold rooms, freezer rooms, refrigerators, freezers, and all other equipment vital to the maintenance of the quality of pharmaceutical products in storage or in transit.

7.2.8 All calibration of equipment should be traceable to international measurement standard.

7.2.9 Equipment repair, maintenance and calibration operations should be carried out in such a way that the integrity of the pharmaceutical products is not compromised. Records for the same should be retained.

7.2.10 Where special storage conditions (e.g. temperature and/or relative humidity), different from, or limiting, the expected environmental

conditions, are required during transportation, these should be provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of five (5) years and should be made available for inspection by the Authority.

7.2.11 Special attention should be paid to the design, use, cleaning and maintenance of all equipment used for the handling of pharmaceutical products which are not in a protective shipping carton or case.

7.3 Computerized Systems (Where applicable)

7.3.1 Before any computerized system is used in pharmaceutical product distribution operations (e.g. inventory management, environmental monitoring) it should be demonstrated, through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.

7.3.2 A written, detailed description of the system should be available (including diagrams where appropriate). This should be kept up-to-date. The document should describe principles, objectives, security measures, system scope and main features, how the computerized system is used and the way it interacts with other systems.

7.3.3 Data should only be entered into the computerized system or amended by persons authorized to do so.

7.3.4 Data should be secured by physical or electronic means and protected against accidental or unauthorized modifications. Stored data should be checked periodically for accessibility. Data should be protected by backing up at regular intervals. Backup data should be retained for at least ten years at a separate and secure location.

7.3.5 Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data.

7.4 Equipment Qualification and Process Validation (For Manufacturers, Wholesalers, Health facilities, Retail Pharmacies)

7.4.1 All key equipment should be qualified and key process should be validated.

7.4.2 The scope and extent of such qualification and validation activities (such as storage, pick and pack processes) should be determined using a documented risk assessment approach.

7.4.3 Equipment and processes should be respectively qualified or validated before commencing use and after any significant changes, e.g. repair or maintenance, change in transportation method for products requiring cold conditions.

7.4.4 Validation and qualification reports should be prepared summarizing the results obtained and commenting on any observed deviations. Deviations from established procedures should be documented and further actions should be taken to correct deviations and avoid their reoccurrence. The

principles of CAPA should be applied where necessary. Evidence of satisfactory validation and acceptance of a process or piece of equipment should be produced and approved by the responsible person.

8.0 OPERATIONS MANAGEMENT

8.1 General

8.1.1 All actions taken by pharmaceutical dealers should ensure that the identity of the pharmaceutical product is not lost and that the distribution of pharmaceutical products is performed according to the information on the outer packaging.

8.1.2 All pharmaceutical dealers should use all means available to minimize the risk of falsified pharmaceutical products entering the legal supply chain.

8.1.3 All pharmaceutical products distributed must be appropriately authorized. All key operations described below should be fully described in the quality system in appropriate documentation.

8.2 Qualification of Suppliers and Customers

8.2.1 There must be a procedure to ensure that suppliers and customers are registered/authorized to supply or receive pharmaceutical products and comply with the requirements of these Guidelines.

8.2.2 Appropriate qualification and approval of suppliers, should be performed before any procurement of pharmaceutical products. This should be controlled by a procedure and the results documented and periodically reassessed.

8.2.3 Repacking or re-labelling of the products must not be performed throughout the distribution supply chain, unless it is instructed by the manufacturer or is part of a corrective action and approved through written instruction from the Authority.

8.2.4 When entering into a new contract with new suppliers, the pharmaceutical dealers should carry out ‘due diligence’ checks to assess the suitability, competence and reliability of the supplier. Attention should be paid to:

a. the reputation and reliability of the supplier;
b. pharmaceutical products more likely to be falsified;
c. large offers of pharmaceutical products which are generally only available in limited quantities; and
d. out-of-range prices

8.2.5 Pharmaceutical dealers should monitor their transactions and investigate

any irregularity in the sales patterns of narcotics, psychotropic substances or other controlled substances. Unusual sales patterns that may constitute diversion or misuse of pharmaceutical products should be investigated and reported to the Authority as per approved procedures.

8.3 Dispatch and Receipt

8.3.1 Pharmaceutical products should only be sold and/or distributed to persons or entities that are authorized to acquire such products by the GSDP Regulations, 2021 and these Guidelines. Written proof of such authority may be obtained before the distribution of products to such persons or entities.

8.3.2 There should be a procedure in place to ensure that pharmaceutical products which are intended for supply to the Tanzania market are authorized for sale/use. This may be by checking for the presence and validity of TMDA authorization and keeping the record.

8.3.3 Before the dispatch of the pharmaceutical products, the supplier should ensure that the person or entity, e.g. the contract acceptor for transportation of the pharmaceutical products, is aware of the products to be distributed and complies with the appropriate storage and transport conditions.

8.3.4 The dispatch and transportation of pharmaceutical products should be undertaken only after the receipt of a valid delivery order or material replenishment plan, which should be documented.

8.3.5 Written procedures for the dispatch of pharmaceutical products should be established. Such procedures should take into account the nature of the product as well as any special precautions to be observed.

8.3.6 Pharmaceutical products under quarantine will require a release for dispatch by the person responsible.

8.3.7 Records for the dispatch of pharmaceutical products should be prepared and should include at least the following information:

a. date of dispatch;
b. complete business name and address (no acronyms), the entity responsible for the transportation, telephone number and names of contact persons;
c. complete business name, address (no acronyms), and status of the addressee (e.g. retail pharmacy, hospital or clinic);
d. a description of the products including, e.g. name, dosage form and strength (if applicable);
e. quantity of the products, i.e. number of containers and quantity per container (if applicable);
f. applicable transport and storage conditions;

g. a unique number to allow identification of the delivery order;
h. assigned a batch number and expiry date.

8.3.8 All records should be readily available and accessible on request.

8.3.9 Records of dispatch should contain enough information to enable traceability of the pharmaceutical product. Such records should facilitate the recall of a batch of a product, if necessary, as well as the investigation of falsified or potentially falsified pharmaceutical products.

8.3.10 In addition, the assigned batch number and expiry date of pharmaceutical products should be recorded at the point of receipt to facilitate traceability.

8.3.11 Vehicles and containers should be loaded carefully and systematically, where applicable on a first-out/last-in basis, to save time when unloading, prevent physical damage and reduce security risks. Extra care should be taken during loading and unloading of cartons to avoid damage.

8.3.12 Pharmaceutical products requiring special storage or security measures should be prioritized and once appropriate checks have been conducted, they should be immediately transferred to appropriate storage facilities.

8.3.13 Pharmaceutical products should not be supplied or received after their expiry date, or so close to the expiry date that this date is likely to be reached before the products are used by the consumer.

8.3.14 Incoming shipments should be examined to verify the integrity of the container/ closure system, to ensure that tamper-evident packaging features and labelling are intact.

8.4 Transportation and Products in Transit

8.4.1 It is the responsibility of the pharmaceutical dealers to protect pharmaceutical 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 pharmaceutical products have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilized when planning transportation.

8.4.2 Methods of transportation, including vehicles to be used, should be selected with care, and local conditions should be considered, including the climate and any seasonal variations experienced. Delivery of products requiring controlled temperatures should follow the applicable storage and transport conditions.

8.4.3 Delivery schedules should be established and routes planned, taking local needs and conditions into account. Such schedules and plans should be

realistic and systematic. Security risks should also be taken into account when planning the schedules and routes of the delivery.

8.4.4 Pharmaceutical products should be stored and transported in accordance with procedures such that:

a. the identity of the product is not lost.
b. the product does not contaminate and is not contaminated by other products.
c. adequate precautions are taken against spillage, breakage, misappropriation and theft.
d. appropriate environmental conditions are maintained, e.g. using cold chain for thermo labile products.

8.4.5 If a deviation such as temperature excursion or product damage has occurred during transportation, this should be reported to the distributor and recipient of the affected pharmaceutical products. A procedure should also be in place for investigating and handling temperature excursions.

8.4.6 In cases where the recipient notices the deviation, it should be reported to the distributor. Where necessary, the distributor should contact the manufacturer of the pharmaceutical product for information about appropriate steps to be taken.

8.4.7 Written procedures should be in place for investigating and dealing with any non-compliance with storage requirements, e.g. temperature deviations.

8.4.8 Where applicable, drivers of vehicles should identify themselves and present appropriate documentation to demonstrate that they are authorized to transport pharmaceutical products. This is to ensure that they have received appropriate training and briefing on the peculiarities of pharmaceutical product transportation.

8.4.9 Products containing narcotics and other dependence-producing substances should be transported in safe and secure containers and vehicles and be stored in safe and secure areas.

8.4.10 Deliveries should be made to the address stated on the delivery note and into the care of the consignee. Pharmaceutical products should not be left on alternative premises.

8.4.11 For emergency deliveries outside normal business hours, persons should be designated and written procedures should be available.

8.4.12 Where transportation is performed by a third party, there should be a procedure in place encompassing necessary requirements for maintaining the quality of products.

8.4.13 The transporter should be made aware by the pharmaceutical dealers of

the relevant transport conditions applicable to the consignment. Where the transportation route includes unloading and reloading or transit storage at a transportation hub, particular attention should be paid to temperature monitoring, cleanliness and the security of any intermediate storage facilities. Provision should be made to minimize the duration of temporary storage while awaiting the next stage of the transportation route.

8.4.14 Spillages should be cleaned up as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of spillages.

8.4.15 Vehicles and operators should be provided with additional security, as appropriate, to prevent theft and other misappropriation of products during transportation.

8.4.16 Physical or other equivalent (e.g. electronic) segregation should be provided for the storage and distribution during transit of rejected, expired, recalled or returned pharmaceutical products and suspected falsified. The products should be appropriately identified, securely packaged, clearly labelled and be accompanied by appropriate supporting documentation.

8.4.17 The interiors of vehicles and containers should remain clean and dry while pharmaceutical products are in transit.

8.5 Shipment Containers and Container Labelling

8.5.1 Pharmaceutical products should be stored and distributed in shipment containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.

8.5.2 Products and shipment containers should be secured to prevent or provide evidence of unauthorized access.

8.5.3 Packaging materials and shipment containers should be of suitable design to prevent damage to pharmaceutical products during transport. Where applicable seal control procedures should be in place and managed properly.

8.5.4 Selection of a container and packaging should be based on the storage and transportation requirements of the pharmaceutical products; the quantity of medicines; the anticipated external temperature extremes; and the estimated time for transportation.

8.5.5 Shipping containers should bear labels providing sufficient information on:

a. identification of the product by TMDA labeling requirements relevant to the container content, source, route, and modes of transport.
b. identification of hazardous products under relevant international labelling conventions.
c. handling and storage conditions and precautions to ensure that the products are properly handled and secure at all times.

8.5.6 Internationally accepted abbreviations, safety symbols, names or codes should be used in the labelling of shipment containers.

8.5.7 Special care should be taken when using dry ice in shipment containers. In addition to safety issues, it must be ensured that the pharmaceutical product does not come into contact with the dry ice, as it may hurt the

quality of the product.

8.5.8 Written procedures should be available for the handling of damaged and/or broken shipment containers. Particular attention should be paid to those containing potentially toxic and hazardous products.

8.6 Products Requiring Special Conditions

8.6.1 Where special conditions are required during transportation that are different from or limit the given environmental conditions (e.g. temperature and humidity) these should be provided by the manufacturer on the labels, monitored and recorded.

8.6.2 Measures should be in place to prevent theft and misappropriation as well as ensure the security and safety of drivers of vehicles transporting controlled pharmaceutical products (such as narcotics and psychotropic substances).

8.6.3 Vehicles should be equipped with lockable doors and where deemed necessary with an intruder alarm.

8.6.4 Vehicles should use unique seal lock indicating devices such as cable seal locks with unique identifiers that are tamper-resistant to protect against unauthorized access during transit. Other means include

a. Employ security-cleared delivery drivers.
b. All deliveries are documented and tracked.
c. Signed dispatch and arrival records are kept.
d. Shipments are fitted with security equipment appropriate to the product being transported and the assessed security risk, such as global positioning system (GPS) devices located in the vehicle and/or hidden in the product.

8.6.5 Pharmaceutical products containing hazardous substances, such as toxic, radioactive material, and other controlled pharmaceutical products presenting special risks of abuse (e.g. narcotics and psychotropic substances), fire or explosion (e.g. combustible or flammable liquids, solids and pressurized gases) should be transported in safe, suitably designed, secured containers and vehicles. In addition, the requirements of the Authority and applicable international agreements should be met. There should be additional control systems in place for the delivery of these products and procedures to address the occurrence of any theft.

8.6.6 For temperature-sensitive products, qualified equipment (e.g. thermal packaging, temperature-controlled containers or temperature-controlled vehicles) should be used to ensure correct transport conditions are maintained between the manufacturer, distributor and customer.

8.6.7 Damage to containers and any other event or problem that occurs during transit must be recorded and timely reported to the relevant department, entity or authority, and investigated.

8.7 Storage of Pharmaceutical Products

8.7.1 Pharmaceutical products should be stored separately from other products likely to alter them and should be protected from the harmful effects of

light, temperature, moisture and other external factors. Particular attention should be paid to products requiring specific storage conditions.

8.7.2 Incoming containers of pharmaceutical products should be cleaned, if necessary, before storage.

8.7.3 Broken or damaged items should be withdrawn from usable stock and stored separately.

8.7.4 If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination. Adequate cleaning procedures should be in place for the sampling areas.

8.7.5 A system should be in place to ensure that the pharmaceutical products due to expire first are distributed first (first expiry/first out (FEFO)and first in/first out (FIFO)). Exceptions may be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.

8.7.6 Pharmaceutical products should be handled and stored in such a manner as to prevent spillage, breakage, contamination and mix-ups. Pharmaceutical products should not be stored directly on the floor unless the package is designed to allow such storage (such as for some pharmaceutical gas cylinders).

8.7.7 Pharmaceutical products that are nearing their expiry date/shelf life should be withdrawn immediately from saleable/useable stock either physically or through other equivalent electronic segregation.

8.7.8 Periodic stock reconciliation should be performed by comparing the actual and recorded stocks. This should be done at defined intervals. Stock irregularities should be investigated and documented.

8.7.9 Stock discrepancies should be investigated by a specified procedure to check that there have been no inadvertent mix- ups, incorrect issues and receipts, thefts and/or misappropriations of pharmaceutical products.

8.8 Repackaging and Relabeling

8.8.1 Repackaging and relabeling of pharmaceutical products is not allowed by TMDA unless or otherwise, exceptional cases may be considered on a written approval from the Authority.

8.8.2 Where they do occur, they should only be performed by entities appropriately authorized to do so and in compliance with TMDA Good Manufacturing Practice for Pharmaceutical Products Regulations.

8.8.3 In the event of repackaging by companies other than the original manufacturer, these operations should result in at least equivalent means of identification and authentication of the products; such activities should be carried out under the supervision of the Regulatory Authority.

8.8.4 Procedures should be in place for the secure disposal of original packaging.

8.9 Complaints

8.9.1 There should be a written procedure in place for the handling of complaints. A distinction should be made between complaints related to

the quality of the product or its packaging and those related to distribution. In the case of a complaint about the quality of a product or its packaging, the original manufacturer and/or marketing authorization holder should be informed as soon as possible while the complaints on distribution should be managed by the distributor and records kept.

8.9.2 All complaints and other information concerning potentially defective and potentially substandard and falsified pharmaceutical products should be reviewed carefully according to written procedures describing the action to be taken, including the need to consider a recall where appropriate.

8.9.3 Any product complaint should be recorded and thoroughly investigated to identify the root cause of the complaint (e.g. repackaging procedure or original manufacturing process). The remedial actions taken should also be recorded and trends in the complaint records analyzed and monitored.

8.9.4 If a defect relating to a pharmaceutical product is discovered or suspected, consideration should be given to whether other batches of the product should also be checked.

8.9.5 Where necessary, appropriate follow-up action (including CAPA) should be taken after the investigation and evaluation of the complaint. There should be a system in place to ensure that the complaint, the response received from the original product manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties including the Authority.

8.9.6 Product quality issues or suspected cases of substandard or falsified pharmaceutical products identified should be handled according to relevant authorized procedures and documented. The information should be immediately shared with the regulatory authority and a recall initiated where appropriate.

8.9.7 Dedicated personnel should be appointed to handle complaints and allocated sufficient support.

8.10 **Recalls**

8.10.1 There should be a system, which includes a written procedure in compliance with TMDA requirements, to effectively and promptly recall pharmaceutical products known or suspected to be defective or falsified. This procedure should be checked regularly and updated as necessary.

8.10.2 Recall may be initiated by the Authority, Marketing Authorization Holder (MAH), Local Technical Representatives (LTR), Manufacturers or any other authorized importers.

8.10.3 The original manufacturer and/or marketing authorization holder should be informed in the event of a recall. Where a recall is instituted by an entity other than the manufacturer and/or marketing authorization holder, consultation with the manufacturer and/or marketing authorization holder should, where possible, take place before the recall is instituted.

8.10.4 The TMDA must be notified in the event of any recall. If a recall of the

genuine product is necessary because of a substandard and falsified product which is not easily distinguishable from the genuine product, the manufacturer of the original product should also be informed.

8.10.5 The recall procedure should be regularly challenged (at least once per year) to ensure that the process is effective and capable of tracing all customers and products in the event of a recall promptly. This challenge may involve identifying a particular batch of a product and reconciling quantities received with those in stock and distributed to customers. A mock recall need not be carried out where the company has participated in an actual recall during the previous year which has utilized the same traceability system.

8.10.6 All recalled pharmaceutical products should be stored in a secure, segregated area pending appropriate action.

8.10.7 Recalled pharmaceutical products should be segregated during transit and clearly labelled as recalled products. Where segregation in transit is not possible, such pharmaceutical products must be securely packaged, clearly labelled, and be accompanied by appropriate documentation.

8.10.8 The particular storage conditions applicable to a pharmaceutical product which is subject to recall should be maintained during storage and transit until such time as a decision has been made regarding the fate of the product in question.

8.10.9 All customers and regulatory authorities of all countries to which a given pharmaceutical product may have been distributed (including promotional samples by sales representatives) should be informed promptly of any intention to recall the product because it is, or is suspected to be, defective or falsified.

8.10.10 Any recall operation should be recorded at the time it is carried out. Records should be made readily available to the regulatory Authority. The distribution records should be readily accessible to the person(s) responsible for the recall, and should contain sufficient information on distribution entities (name, addresses, contact details i.e phone and/or fax numbers, batch numbers, and quantities delivered), including those for exported products and promotional samples.

8.10.11 The progress of a recall process should be recorded, which includes reconciliation between distributed and recalled quantities of products.

8.10.12 The final recall progress report and investigation report (CAPA) should be submitted to TMDA based on the type of recall.

8.11 **Returned Products**

8.11.1 Pharmaceutical dealers should receive pharmaceutical product returns or exchanges under the terms and conditions of the agreement between the supplier and the recipient. Both distributors and customers should be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of substandard and falsified products.

8.11.2 Pharmaceutical products that have left the premises of the distributor should only be returned to saleable/useable stock if all of the following are confirmed:

a. the pharmaceutical products are in their unopened and undamaged secondary packaging and are in good condition; have not expired and have not been recalled;
b. it has been demonstrated by the customer that the pharmaceutical products have been transported, stored and handled in compliance with their specific storage requirements;
c. they have been examined and assessed by a sufficiently trained and competent person authorized to do so;
d. the distributor has reasonable evidence that the product was supplied to that customer (via copies of the original delivery note or by referencing invoice numbers, etc.) and the batch number for products bearing the safety features is known, and that there is no reason to believe that the product has been falsified.

8.11.3 Pharmaceutical products requiring specific temperature storage conditions such as low temperature can only be returned to saleable/useable stock if there is documented evidence that the product has been stored under the authorized storage conditions throughout the entire time. If any deviation has occurred, a risk assessment has to be performed, on which basis the integrity of the product can be demonstrated. The evidence should cover:

a. Delivery to the customer;
b. Examination of the product;
c. Opening of the transport packaging;
d. Return of the product to the packaging;
e. Collection and return to the distributor;
f. Return to the distribution site refrigerator.
g. Products returned to saleable/useable stock should be placed such that the 'first expired first out' (FEFO) system operates effectively.

8.11.4 Provision should be made for the appropriate and safe transport of returned products by the relevant storage and other requirements.

8.11.5 Rejected and returned pharmaceutical products should be appropriately identified and handled by the requirements of these Guidelines.

8.11.6 Destruction of pharmaceutical products should be done by the requirements of the Regulatory Authority and other requirements regarding the disposal of such products, and with due consideration to the protection of the environment.

8.11.7 Records of all returned, rejected and/or destroyed pharmaceutical products should be kept for at least 5 years.

8.12 Substandard and Falsified Pharmaceutical Products

8.12.1 Provision should be made for a visual and/or analytical identification of potential substandard and falsified products. The procedure to be followed when a suspected product is identified should include provisions for notification, as appropriate, of the holder of the marketing authorization, the entity identified on the label (if different from the manufacturer) and the Authority.

8.12.2 Substandard and Falsified pharmaceutical products found in the distribution chain should be physically segregated and stored in a dedicated area away from all other pharmaceutical products to avoid any confusion. They should be clearly labelled as not for sale.

8.12.3 The sale and distribution of a suspected substandard and falsified pharmaceutical product should be suspended and the source of the incident thoroughly investigated. The Authority and the marketing authorization holder must be notified without delay.

8.12.4 Upon confirmation of the product being substandard or falsified a formal regulatory decision should be taken on its fate and its ultimate disposal, ensuring that it does not re-enter the market, and the decision recorded.

8.12.5 All relevant activities related to such products should be documented and records retained.

8.13 Disposal

Pharmaceutical dealers should notify the Authority of all unfit pharmaceutical products requiring disposal such as substandard, expired, and damaged products. Submit an online application for disposal through RIMS in line with the Recall, Handling and Disposal of Unfit Pharmaceutical Products Guidelines in force.

8.14 Contract for Distribution and Storage Activities by Manufacturers and MAH

8.14.1 General

a. Any activity relating to the distribution of a pharmaceutical product that is outsourced should be correctly defined, agreed and controlled to avoid misunderstandings which could affect the integrity of the product.

b. Any activity relating to the distribution of a pharmaceutical product which is outsourced to another person or entity should be performed by parties appropriately authorized for that function and by the terms of a written contract where applicable.

c. There must be a written contract between the contract giver and the contract acceptor which clearly defines the responsibilities of each party and the communication processes including observance of the principles of GSDP and relevant warranty clauses. The contract

agreement must state that the contract giver and the regulatory authority have the right to audit the premises of the contract acceptor.

d. It should also include the responsibilities of the contractor for measures to avoid the entry of substandard and falsified pharmaceutical products into the distribution chain, such as through suitable training programs.

8.14.2 **Contract Giver**

a. The contract giver is responsible for the activities contracted out.
b. The contract giver is responsible for assessing the competence of the contract acceptor to successfully carry out the work required and for ensuring using the contract and through audits that the principles of GSDP are followed.
c. An audit of the contract acceptor should be performed before the commencement of, and whenever there has been a change to, the outsourced activities.
d. The frequency of audits should be defined based on risk depending on the nature of the outsourced activities. Audits should be permitted at any time.
e. The contract giver should provide the contract acceptor with all the information necessary to carry out the contracted operations by the specific product requirements and any other relevant requirements.

8.14.3 **Contract Acceptor**

a. The contract acceptor should have adequate premises and equipment, procedures, knowledge and experience, and competent personnel to carry out the work ordered by the contract giver.
b. The contract acceptor should refrain from any activity that may adversely affect the quality of the product(s) handled for the contract giver.
c. The contract acceptor must forward any information that can influence the quality of the product(s) to the contract giver by the requirements of the contract.
d. All contract acceptors should comply with the requirements in these Guidelines.
e. Contract acceptors should be audited periodically.
f. The contract acceptor should not pass to a third party any of the work entrusted to him under the contract without the contract giver's prior evaluation and approval of the arrangements and an audit of the third party by the contract giver or the contract acceptor.
g. The third party or subcontractor should be authorized by respective Authorities for the function.
h. Arrangements made between the contract acceptor and any third party should ensure that the distribution information is made available in the same way as between the original contract giver and the contract acceptor.

9.0 DONATED PHARMACEUTICAL PRODUCTS

9.1.1 In the case of donations, importers must have a donation certificate and adhere to the Guidelines for Donations issued by the Ministry responsible for Health.

9.1.2 Storage and distribution shall be in accordance with the GSDP Guidelines.

10.0 SELF INSPECTION

10.1.1 The quality system should include self-inspections. These should be conducted to monitor implementation and compliance with the principles of GSDP and, if necessary, to trigger corrective and preventive measures.

10.1.2 Self-inspection should be conducted periodically according to the schedule.

10.1.3 Self-inspections should be conducted by a designated, competent person/team with appropriate knowledge and experience.

10.1.4 The results of all self-inspections should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures.

10.1.5 The inspection report and the proposed corrective action (where applicable) should be submitted to the Management for review and then shared with the respective department.

10.1.6 There should be an effective follow-up program for review of the corrective action and preventive action implementation

11.0 MONITORING OF IMPLEMENTATION OF THE GUIDELINES

The Authority in collaboration with stakeholders shall have the duty to monitor implementation of these Guidelines through routine inspections. Routine inspections shall be performed by use of checklist(s) covering the different aspects related to Good Storage and Distribution Practices. The checklist forms Annex 1 of this document.

However, inspection of compliance to GSDP for manufacturers shall be performed during GMP inspection as warehouse inspection is part of the inspection. Decisions on whether a facility other than the manufacturer is regarded as GSDP compliant will be made based on the percentage score. The criteria for compliance will be ≥ 70%.

The formular for calculating the percentage score for a facility is as indicated below;

Percentage score

$$\frac{Total\ score}{100 - ((NA\ x\ 1) - (NA\ x\ 2))}\ x100$$

Note:

- NA = Not applicable requirement,
- The numbers 1 and 2 are scores based on the type of not applicable requirements.

12.0 BIBLIOGRAPHY

1. TRS 1025 - Annex 7: Good storage and distribution practices for medical products, Annex 7, WHO Technical Report Series, no. 1025
2. NAFDAC (2021) Good Distribution Practice Guidelines for Pharmaceutical Products
3. Ghana FDA Guidelines for Good Distribution Practice. Revision 00
4. TMDA (Good Storage and Distribution Practices) Regulations, 2021
5. The Pharmacy Act, Cap. 311
6. The Tanzania Medicines and Medical Devices Act, Cap. 219
7. TMDA Guidelines for Premises Licensing and Good Distribution and Storage Practices (Medical Devices), 2023

13.0 ANNEXES

Annex 1: GSDP Inspection Checklist

1. General Information

1.1	The region where the facility is situated ……					
1.2	Name of Facility ……..……..					
`	Type of Inspection (Routine/Concise, / Follow-up/ Investigative/ special					
1.4	Business Type: (Tick as appropriate):					
	Manufacturer	Warehouse	Health facilities	Wholesalers	Retail Pharmacy	ADDO
1.5	Postal Address: ……..…….. ……..……..	1.6	Physical Address/Location: Street/Ward……..... District……			
1.7	Telephone No: ……..	1.8	Email……			
1.9	Premises Business Permit No…….....	1.10 Valid	Y/N/NA	1.11 Is the Business Permit Displayed	Y/N/NA	
1.12	Premises Registration Certificate No ……					
1.13	Name of the Superintendent & Registration No.: …….....			1.14 Is the Certificate of Registration of premises displayed?	Y/N/NA	
1.15	Date of inspection: ……..	1.16	Date of last inspection: ……			
1.16	Ownership: (Private/Government)	Name of Proprietor(s) i……..... ii.....				
1.17	If the owner is not a pharmacist, does he/she has a valid contract with a Registered Pharmacist?				Y/N/NA	

Specific Requirements		
SN	**Requirement**	**(Score/NA)**
2.0 Organisation and Personnel (Score-2 if in place and 0 if not)		
2.1	Is there an Organogram?	
2.2	Are there contracts for personnel?	
2.3	Are there Job Description for the Responsible Personnel (Superintendent/ADDO Dispenser)?	
3.0 Training (Score-2 if in place and 0 if not)		
3.1	Is there a standard operating procedure for training?	
3.2	Did the Responsible personnel receive induction training on GSDP? (check availability of training records)	
3.3	Are personnel receiving refresher trainings on GSDP? (check availability of training records)	
4.0 Quality Management System (For Manufacturers, Wholesalers and Hospitals, Polyclinics) (Score-1 if in place and 0 if not)		
4.1	Is there an approved Quality Manual?	
4.2	Is there a quality policy?	
4.3	Is the quality policy conspicuously displayed?	
4.11 Control of Documentation (Score-2 if in place and 0 if not)		
4.111	Are there written procedures developed for the preparation, review, approval, use of and control of all documents.	
4.12 Deviations, Non-conformances, Investigations and Corrective and Preventive Actions (For Manufacturers, Wholesalers and Hospitals, and Polyclinics) (Score-1 if in place and 0 if not)		
4.12.1	Is there an SOP for Deviation Management?	
4.12.2	Is there a list of deviations?	
4.12.3	Are all planned deviations approved?	
4.12.4	Are all non-conformances investigated?	
4.12.5	Are proposed CAPA for the non-conformances implemented?	
4.13 Quality Risk Management (For Manufacturers, Wholesalers and Hospitals) (Score-1 if in place and 0 if not)		
4.13.1	Is there an SOP for risk management?	
4.13.2	Have the risks associated with storage and distribution of pharmaceuticals been identified? (Check risk register)	
4.13.3	Is there a risk treatment plan?	
4.13.4	Is there an implementation report for the risk treatment plan?	
4.14 Quality Management Review (For Manufacturers, Wholesalers and Hospitals) (Score-1 if in place and 0 if not)		
4.14.1	Is there an SOP for Quality management Review Meetings?	
4.14.2	Are management review meetings being conducted as per the frequency indicated in the procedure? (Verify meeting minutes)	
4.15 Traceability of Products		
4.15.1	Does the facility keep records of purchased products (invoice, delivery note, receipts) indicating the following? (**Score-2 if in place and 0 if not or incomplete**)	
	a) Product name,	

	b) Manufacturing and Expiry dates	
	c) Batch number	
	d) Quantity	
	e) TMDA import permits (For importers)	
4.15.2	Are the records of all customers to whom pharmaceutical products were supplied (sample some product and verify presence of such records) indicate the following? (**Score-2 if in place and 0 if not or incomplete**)	
	a) Name of premises to where products were distributed	
	b) Batch number of products	
	c) Quantity distributed	
	d) Manufacturing and Expiry dates	
4.15.3	Is there a procedure to guide electronic commerce to ensure product quality? (**Score-1 if in place and 0 if not**)	
5.0 Premises, Warehousing and Storage Facilities (Score-2 if in place and 0 if not)		
5.1	Is there a designated area for receiving of incoming pharmaceutical products (where applicable)?	
5.2	Are there areas reserved for segregation of saleable/usable, rejected, expired, recalled, returned and SF products?	
5.3	Is the premises clean?	
5.4	Are there adequate shelves/pallets for storage of pharmaceutical products? (Check absence of products stored directly on the floor)	
5.5	Are there lock and key facilities for storage of controlled drugs?	
5.6	Have temperature mapping studies been conducted? (Check records)	
5.7	If yes, for 5.6 above, have RH and Temperature monitoring devices being placed at hot and cold points?	
5.8	Are there daily RH and Temperature monitoring records?	
6.0 Inventory Control (Score-3 if in place and 0 if not)		
6.1	Are there procedures and plan for stock taking, reconciliation, tracking, tracing and monitoring of saleable, expired, rejected, returned, recalled and damaged pharmaceutical products.	
6.2	Are there records of stock management for products in either paper or electronic format?	
6.3	Are there only registered products stocked in the premises?	
6.4	Are there only authorized products on stock (No government products, No prohibited products & No SF products?)	
6.5	Is there a procedure that requires products under quarantine to be authorised only by the responsible person?	
7.0 Vehicles and Equipment (Manufacturers and Wholesalers) (Score-1 if in place and 0 if not)		
7.1	Are transportation vehicles easy to clean?	
7.2	Are transportation vehicles having adequate space?	

7.3	For temperature sensitive products, are there vehicles or other means specifically designed for transport of such pharmaceutical products?	
7.4	Are thermohygrometers and sensors calibrated? (Check calibration records)	
7.5	For manufacturers using computerised systems (e.g. those used for inventory management and environmental monitoring), are they validated or verified? (Check reports)	
7.6	Is there use of passwords for computerised system?	
7.7	Is there data back-up for the electronic records? (check if there is use of for example external drives, google drive, icloud).	
8.0 Operations Management (Manufacturer, Wholesalers, Hospitals)(Score-1 if in place and 0 if not)		
8.1	In case of repacking or relabelling activities at the site, are they authorised by TMDA?	
8.2	Is there a procedure for Handling of complaints?	
8.3	Is there a register for all received complaints?	
8.4	Are all complaints investigated as per procedure?	
8.5	Is there a procedure for recall?	
8.6	Are all recalls notified to the Authority?	
8.7	Are there recall reports and register?	
9.0 Self-Inspection (Manufacturers, Wholesalers) (Score-2 if in place and 0 if not)		
9.1	Is there a procedure for Self -inspection?	
9.2	Is the self-inspection conducted as per frequency indicated in the self-inspection SOP? (Check records -schedule and reports)	

10. Visual Inspection of Products and Label examination (Score-3 if in place and 0 if not)

Closely examine the products on stock and evaluate the labels in respect to:				
		Comply	Not comply	Remarks if any
1.	Language of labels and package inserts is in English/ Swahili or both (Check randomly)			
2.	No signs of tampering			
3.	Minimum labelling requirements are met, i.e. Product name, Manufacturing & expiry dates, name and address of the manufacturer, Pack Size, Batch number and storage conditions			
4.	Appearance (colour, clarity, shape)			
5.	State of the package (No cracks, breaks, tears, leakage)			

6.	In case of non-conformity, explain:
7.	The Total Score is: **……**
8.	Percentage score $$\frac{Total\ score}{100 - ((NA\ x\ 1) - (NA\ x\ 2))}\ x100$$ Note: • NA = Not applicable requirement, • The numbers 1 and 2 are scores based on the type of not applicable requirements.
9.	The percentage score is……The facility is deemed compliant/non-compliant with GSDP requirements. (delete whichever is not applicable) **Note**: Criteria for compliance is ≥ 70%.

Inspectors

S/N	Name	Signature	Date
1.			
2.			
3.			
Inspectees			
S/N	**Name**	**Signature**	**Date**
1.			
2.			

14.0 Revision History

Revision No:	Date	Author	Description of change	Section modified	Approval

Annex 2: **observation form**

Name of Premises…….....

Address of the Premises:
……..

Purpose of inspection:
……..
(Special/Routine/Registration/Licensing/Complaint/Follow Up/Others)

Date: .....

……

……

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……

I, ……..…….. In charge/Owner of the said premises, certified that, the information provided above is correct.

In charge/Owner's Signature …… Date ……..……..

Name of Inspector(s)	Signature(s)
1. ……..	……..
2. ……..	……..
3. ……..	……..
4. ……..	……..

Annex 3: Confiscation form

MEDICINES/COMPLIMENTARY PRODUCTS FOUND AT THE PREMISES CONTRARY TO THE LAW AND SEIZED/CONFISCATED AS PER TANZANIA MEDICINES AND MEDICAL DEVICES ACT, CAP 219 SECTION 106

DATE: _____

NAME OF THE PREMISES: _____

LIST OF MEDICINES/COMPLIMENTARY PRODUCTS SEIZED/CONFISCATED

……..

……...

…….

……..

……

PARTICULARS

I _____ Owner/In charge of the above named premise, confirm that the medicines/medical devices/diagnostics listed above have been seized/confiscated by Inspectors after being found at the premise illegally.

Signature of the Owner/Incharge_____

Name of Inspector_____ Signature of Inspector _____

Name of Inspector_____ Signature of Inspector _____

Name of Inspector_____ Signature of Inspector _____

Name of Inspector_____ Signature of Inspector _____

Annex 4: Sample collection form

(Made under Section 101 (1) of Tanzania Medicines and Medical Devices Act, CAP 219)

Name of Institution/ Company/PoE ……..……

Address:
……

Date of collecting sample:
…….....

Reasons for collection (Indicate analysis needed where possible)

Sample ref. number	Product Name and	Product Description eg. Color,	Batch No.	Manufacturing date	Expiry Date	Name and Address of Manufacturer	Quantity sampled

	strength	Dosage, etc					

Name of Representative(s) of the Company/ consignment.	**Signature**	**Date**
1. …….....	……	……
2. …….	……	……

Name of TMDA Inspector (s) (Sampling Officer)	**Signature**	**Date**
1. ……...	……	……...
2. ……...	……	……