The Revolutionary Goverment of Zanzibar

Ministry of Health and Social Welfare

GUIDELINES FOR PHARMACEUTICAL INSPECTION

JANUARY, 2008

Ministry of Health and Social Welfare in Collaboration with:

World Health Organization

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FOREWORD

The Guidelines for Pharmaceutical Inspection is a first document in Zanzibar developed to assist drug inspectors to perform their activities according to existing drug laws.

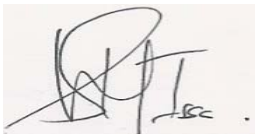
These Guidelines provide valuable guidance to all health workers as well as trained personnel for inspection as an administrative framework for regulatory system intended to assure the quality, safety and efficacy of registered and authorized products in Zanzibar. They can also be applied to withdraw unsafe or illicit medicinal products which are already in circulation within the country.

Safe and effective use of a medicinal product depends not only upon innate biological activity, but upon the judgment, knowledge and qualification of the person responsible for supplying, selling, prescribing or administering it. Therefore, the need to safeguard patients is an important aspect by ensuring rational use of drugs.

This document was completed after combination of different ideas and comments of specialists.

My sincere thanks to all those who tirelessly worked hard to finalize this document.

I hope these guidelines will be much useful to all drug inspectors in Zanzibar.



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Minister for Health & Social Welfare
ZANZIBAR.

ACKNOWLEDGEMENT

This work has been developed with the input of pharmaceutical experts in the country whose contribution is greatly appreciated for enabling the production of this document of guidelines for inspection of medicines in Zanzibar.

We gratefully acknowledge them for sharing their ideas and experiences in this area which helped much to accomplish this work. Sincere thanks are especially given to the following:

1. Mr. Burhani Othman Simai -Chief Drug Inspector
2. Mr. Habib Ali Shariff -Chief Pharmacist
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Finally yet importantly, we thank the editorial team lead by Ms. Mgeni Hamad Bashiru for their valuable input in finalizing the document ready for publication.

ABBREVIATIONS

DCs	-District Commissioners
FEFO	-First expired first out
FOB	-Free on Board
GMP	-Good Manufacturing Practices
NGOs	-Non Governmental Organizations
OTCs	-Over the counter Medicines
PBQL Laboratory	-Pharmacy Board Quality Control
PoE	-Port of entries
RCs	-Regional Commissioners
SOPs	-Standard Operating Procedures
TRA/C&E	-Tanzania Revenue Authority/Customs and Excise Department
WHO	- World Health Organization
ZFDB	-Zanzibar Food and Drugs Board

GLOSSARY

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

Batch
A defined quantity of any drug product processed in a single process or series of processes such that it can reasonably be expected to be uniform in character and quality.

Batch number
A distinctive combination of numbers and /or letters which specifically identifies a batch on the labels, the batch records, the certificate of analysis, etc.

Chain of custody

is the record of individuals who have accessed sample material from the time of collection by an inspector to its ultimate destruction. The sample and the record, from its time of collection to the time of its destruction, must be kept safely (under key and lock) and under systematic control.

Certificate of Analysis

This is a document supplied by the manufacturer summarizing the physical and analytical data for a particular lot or batch of drug product that formed the basis for the product batch or lot being released for sale

Confiscate
This is to officially take away from a vendor or importer, to assume custody of a drug consignment stocked in the premises or at the port of entry. The intention is to stop the drugs' distribution to the public. Usually done for drugs shown to be counterfeit or of substandard quality or associated with unexpected illness or death.

Controlled drugs
Narcotic drugs and psychotropic substances and chemical precursors regulated by provisions of national drug laws.

Counterfeit pharmaceutical product
A pharmaceutical product which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and may include products

with the correct ingredients, with the wrong ingredients, without active ingredients, with an insufficient quality of active ingredient or with fake packaging.

Detain
is a word calling for the following actions—
1. Write "DETAIN" in the space provided in the port of entry Screening and Testing Form.
2. Stop the inspection, complete the Rejection or Detention Form, and inform the Tanzania Revenue Authority/Customs and Excise Department of the rejection or detention.
3. Give a copy of the form to the Tanzania Revenue Authority and the customer.
4. Refer the importer/consignee to the ZFDB.
5. Upon resolution of detention issues, by written instructions from the ZFDB, continue the inspection from where it stopped.

Detention
is the retention of a consignment pending resolution of outstanding issues by the Pharmacy Board. However, if the issues are not resolved to the satisfaction of the Pharmacy Board, Detention status, upon written instruction from the Pharmacy Board, is converted to Rejection.

Drug (pharmaceutical product)
Any substance or mixture of substance that is manufactured for sale or distribution, sold, supplied, offered for sale or presented for use in:

(i) the treatment, mitigation cure, prevention or diagnosis of disease, an abnormal physical state or the symptoms thereof and abnormal physiological conditions in human or animal; or
(ii) the restoration, correction or modification of organic functions in human or animal.

Finished pharmaceutical product
A pharmaceutical product that has undergone all stages of production and quality control, including being packaged in its final container and labeled.

Free on board
is the cost of a consignment at the port of export. It does not include the freight charges from the port of export to the destination of import.

Good Manufacturing Practice
Good Manufacturing Practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality

standards appropriate to their intended use and as required by the marketing authorization.

Good pharmacy practice
The practice of pharmacy aimed at providing and promoting the best use of drugs and other health care services and products, by patients and members of the public. It requires that the welfare of the patient is the pharmacist's prime concern at all times.

GPHF Minilab
stands for German Pharma Health Fund Minilab, a pharmaceutical product testing kit that has materials for color reaction, thin-layer chromatography, and disintegration testing of essential drugs

Immediate container
is a packing material such as a tin or a bottle that is in direct contact with the medicine; an immediate container is also often referred to as the "primary container"

Import Certificate
is a document issued by the Pharmacy Board authorizing the importation of approved drugs into the country

Over the counter drugs
There are drugs that can be sold from licensed dealers without prescriptions. These drugs are suitable for self-medications, for minor disease and symptoms.

Percent (%) of remaining shelf life
This value is equal to—

$$\frac{\text{(Expiry Date – Date on Receipt at Port of Entry)}}{\text{(Expiry Date – Manufacturing Date)}} \times 100$$

Or—

$$\frac{\text{(Remaining Shelf Life on Arrival)}}{\text{(Shelf Life of the Product)}} \times 100$$

Pharmacist
The holder of degree in Pharmacy with a certificate of completion of an internship course from a recognized institution by the ZFDB.

Pharmacy-only drugs
These are drugs authorized to be sold only in licensed pharmacies under the supervision of a licensed and registered pharmacist; they may be sold without a prescription.

Poison
A substance specified in the poisons list prescribed under section 78 of the Zanzibar Food, Drug and Cosmetic Act No. 2 of 2006, such as agrochemicals and other related substances which are harmful to human being.

Port of entry name

This is the name of an authorized place of entry for drug consignment; this name must be filled in the port of entry Screening and Inspection Form.

Prescription – only drugs
These are drugs supplied only in licensed pharmacies on the presentation of signed prescriptions issued by a licensed and registered medical practitioner, licensed and/or registered dentist (for dental treatment only) and/or licensed registered veterinarian (for animal treatment only), and the supply and dispensing of these drugs must be carried out by a pharmacist or under the supervision of a drugs (narcotic drugs and psychotropic substances) and non-controlled drugs.

Product recall
Product recall is a process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.

Pro forma invoice (PI)
This is a document presented by the importer showing quantities and cost of medicines to be entered in the country. It is presented to the ZFDB for approval before a shipment can enter Tanzania. A properly endorsed PI has two signatures from ZFDB officials and the ZFDB stamp. The signatures and the stamp indicate that the exporter and consignee are both properly licensed and that the drug manufacturer, product, and dosage forms are in compliance with regulations.

Prohibited drugs
There are drugs with toxicity or side effects that outweigh their therapeutic usefulness, so that public health and welfare are protected by prohibiting their production, manufacture, export, import, trade, distribution, supply, possession or use, export in amounts required for medical and scientific research. Prohibited drug are normally determined by the national or regional registration/licensing authority.

Quality assurance

Quality assurance is a wide-range concept covering all matters that individually or collectively influence the quality of a product. It is the totality of arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

Quality control
Quality control covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that raw materials, intermediates, packaging materials and finished pharmaceuticals products conform with established specifications for identity, strength, purity and other characteristics.

Quarantine
This is the retention of a consignment until further tests are performed to ascertain its quality

Secondary container
is a packing material that encloses a number of immediate or primary containers

Sample Receipt Form
is a document drug inspectors must complete for every sample of a batch of drug product collected

Unauthorized market
The unauthorized markets consist of wholesale establishments and retail outlets distributing or selling drugs without authorization from a competent authority.

1. INTRODUCTION

One objective of the Zanzibar drug policy is the assurance of the quality, safety, and efficacy of the drugs circulating on the Zanzibar market. Zanzibar receives pharmaceutical products from different channels of supply. These Pharmaceutical products are further distributed to health facilities, private pharmacies, shops (for OTCs) and Non-Governmental Organizations (NGOs) to reach the patients. A quality assurance programme is therefore necessary to ensure that all drugs are rigorously inspected so that only drugs of good quality reach the patients.

Although Zanzibar lacked specific guidelines which could assist drug inspectors to conduct inspection in accordance to the principles of Zanzibar Food and Drug Board (ZFDB), inspection has been regularly conducted. These activities were carried out using specific inspection forms in accordance to the type of inspection to be conducted such as:

- Pre- approval inspection
- Routine inspection
- Special/investigative inspection
- Concise inspection
- Follow – up inspection

Drug Inspection is performed for monitoring of quality throughout the distribution chain to utilization. Quality assurance of drugs at the level of manufacturer is outlined in the Good Manufacturing Practices (GMP) of pharmaceutical products published by WHO. Compliance with these guidelines will ensure that products released for distribution are of good quality.

For inspection at all levels however, only the holder of marketing authorization for a pharmaceutical product, or alternatively the (legal) person responsible for the initial marketing of a product, who ideally should be a Pharmacist, or a pharmaceutical company authorized to practice in Zanzibar; must ensure that products are only released for distribution after they have conformed with the product specification of the ZFDB.

The level of quality should be maintained throughout the pharmaceutical supply system or distribution network to the last distribution point.

Basic principles of GMP are applicable to wholesale operations and (to same extent) to retail outlets. These principles may be summarized as follows:

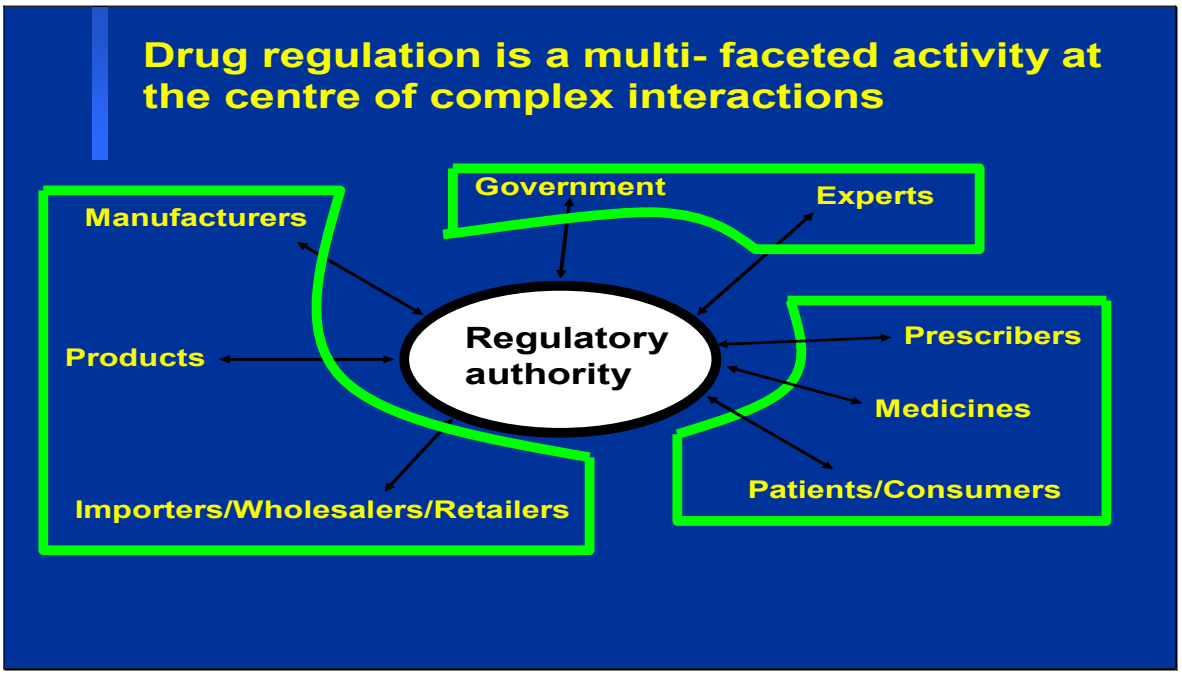
- Only registered or authorized products are distributed.
- A quality system is in place which includes quality policy, quality management, appropriate analytical controls, and self-inspection.

- Personnel are quality conscious, adequately trained and motivated.
- Premises and equipment are suitable for their intended use, and kept in good sanitary condition.
- All products are received, stored and handled appropriately (protected against contamination, cross-contamination, and mix-ups, environmental factors such as heat, moisture and lights).
- All medicine related operations are performed in accordance with written procedures, are properly supervised and adequately documented. Documentation ensures complete traceability of receipt of all materials, quality testing processes and shipping.
- An adequate provision exists to handle complaints, recalls and returned goods.

2. GENERAL CONSIDERATIONS

The health system in the country counts on the Drug Regulatory Authority for good, safe, and effective medicines and for fair rules and control on drug trade, information, and use.

Drug regulation is a multi- faceted activity at the centre of complex interactions between various stakeholders as shown in figure below.



A comprehensive system to assure the safety, efficacy and quality of pharmaceutical products at a national level is therefore necessary and this must have the following basic functions:

- Licensing of manufacturers, importers, distributors, wholesale and retail outlets (premises, persons and practices)
- Marketing authorization for drug products
- Quality control laboratory testing
- Provision of drug information and monitoring of drug promotion and advertising
- Inspection of manufacturing and distribution channel premises
- Adverse drug reaction monitoring
- Authorization of clinical trials
- Monitoring of drug dispensing and prescribing practices

- Monitoring of drug utilization and promotion of rational drug use
- Application of sanctions

Drug regulation comprises of all the legal, administrative & technical arrangements which are meant to ensure that:

- all premises, persons & practices engaged in the development, manufacture, importation, exportation, wholesale, supply, dispensing & promotion of drugs comply with approved standards, norms, procedures and requirements
- drug products are safe, effective and of acceptable quality
- product information is unbiased, accurate and appropriate
- drugs are available
- drugs are used rationally

These key elements are:

Legal:
- Drug legislation

Administrative:

- drug regulatory authority with functions of product registration, licensing of manufactures, importers and distributors (wholesales, retail and for institutions), inspection and independent testing of samples
- Enforcement
- Health Policy
- National drug Policy

- **Technical:**
  - regulations
  - standards and norms
  - guidelines
  - independent quality control laboratory(ies)

3. THE NEED FOR THE PHARMACEUTICAL INSPECTION GUIDELINES

The usefulness of drug in the treatment of ailments disease and disorders is well recognized and appreciated. It is also recognized that the inappropriate use of drugs can produce adverse effects, some of which may be fatal.

Drugs may be classified into four types as follows:

- over the counter drugs
- pharmacy only drugs,
- prescription only drugs
- Prohibited drugs.

A drug inspector must be well accustomed with these drug classifications in order to be able to conduct inspection at different areas to ensure the circulation of good quality, safety and efficacious pharmaceutical products in Zanzibar.

These guidelines are needed for the enforcement of the drug laws, using a system of inspections organized through the ZFDB inspectorate unit. They are intended for use by pharmaceutical inspectors and other trained personnel according to the Zanzibar legal requirements and available resources.

General objectives

To ensure the provision of safe, efficacy and good quality medicine circulating in Zanzibar

Specific objectives:

- To protect patients and members of the public from malpractice by distributors and suppliers of drugs.
- To adhere to the drug laws and regulations governing compounding, distribution, importation, export and storage of drugs.
- To maintain high ethical and professional standards of pharmaceutical practice.

4. PHARMACEUTICAL INSPECTION

An essential part of any medicine control system is the provision of an inspection body with the responsibility and authority to inspect some or all of the activities involved in research, development, manufacture, control, distribution, and supply of medicines. Qualified and experienced drug inspectors constitute an indispensable component of the inspection system.

What Is Inspection?

To "inspect" is "to look closely at something, especially to check that everything is in good order." "Inspection" is, therefore, the act of looking closely at something to ensure that it meets certain prescribed or known standards and specifications.

Drug inspection is therefore, the act of examining or looking closely at all the drug attributes and the condition of all the facilities that deal with drugs.

The overall objectives of drug inspection are to ensure that drugs and related supplies, either locally manufactured or imported from outside the country, meet set standards of quality.

Why do we want to achieve this objective?
Drug Inspection is performed for monitoring of quality throughout the distribution chain to the utilization point. The aim is to ensure the safety of the patients and members of the public. The safety of drugs can be assured by enforcing drug laws and regulations governing compounding, distributions, importation, exportation, storage, and use of drugs.

What Needs to Be Inspected?

To ensure the quality of drugs entering or circulating in the market, the following establishments associated with drug supply and the distribution chain should be inspected regularly—

- Ports of entry (POEs)
- Pharmacies and Part 2 pharmacy shops (both established and new ones, before they are licensed)
- Wholesalers (both established and new ones, before they are licensed)
- Manufacturing facilities (both established and new ones, before they are licensed)

Types of inspection

The Inspectors use different types to check compliance with the Zanzibar drugs laws and regulations, Regional or International conventions.

The types used are:-

1. Pre-approval Inspection.

This is an inspection generally intended for a new establishment which has applied for permit to operate a pharmacy practice or has changed premises or wants to extend scope of operation.

The inspection should be announced

2. Routine inspection:

This type of inspection is generally carried out for already approved and an operating pharmaceutical establishment

It may be indicated when the establishment:-

a) has not been inspected for a long time (1-2) years
b) has made important changes in its key personnel
c) has a history of non - compliance with GMP or GDP

The inspection may be unannounced

3. Special/Investigative Inspection

This type of inspection is undertaken to deal with specific complaints received about lapses or non compliance with standards of professional practice or performance of new establishment whose scope of operation was previously unknown.

Such inspection may be focused on one product, a group of related products or specific operations such as mixing, sterilization or labelling etc.

The inspection should be unannounced

4. Concise inspection.

This is reserved for establishments that have previously been inspected with a view to assessing standards of good pharmacy practice. The outcome of the inspection will help in the proper assessment of the establishment.

Evidence of unsatisfactory pharmacy practice performance observed during concise inspection should trigger a more comprehensive inspection.

The inspection will be done at least twice a year and should preferably be unannounced

5. Follow –up inspection.

This is normally carried out to ensure that corrective measures have been undertaken following advice and notice given during a previous inspection. The inspection should be unannounced.

Specific inspection applicable to individual establishments

Inspectors when going for inspection should make sure that they do a fully comprehensive inspection. This should include the following:

1. Importer

(a) All drugs accompanied by import documents such as bill of lading, export authorization, product licence and batch certificate
(b) Controlled drugs also accompanied by export authorization certificate or export declaration, whichever is applicable
(c) Imported drugs are in original packs, except for drugs imported in bulk for repackaging and/or manufacturing drug formulations.

2. Retail and hospital pharmacy

(a) Compounding of drugs carried out by or under the supervision of a pharmacist
(b) Quality of raw materials used in compounding complies with pharmacopoeial specifications
(c) Dispensing of prescription drugs carried out by or under the supervision of a pharmacist
(d) Entries of dispensed prescription drugs made in prescription book and for controlled drugs in controlled drugs book
(e) Prescriptions for prescription drugs retained on premises for periods provided in the drug laws
(f) dispensed drugs labelled appropriately with name of drug, name of patient, name and address of pharmacy, clinic or hospital, instructions for using the drugs and, where appropriate, warning labels
(g) Counselling of patients on use of dispensed drugs
(h) Adequacy of containers for dispensed drugs
(i) Personnel observe high standard of personal hygiene and wear clean protective clothing
(j) Dispensing area clean, adequate and has necessary equipment
(k) Walls in dispensing area easily cleaned
(l) Quality of extemporaneous preparations
(m) Sources of drugs sold and supplied from the pharmacy
(n) Suitable cabinets for storage of controlled drugs and poisons.

3. Clinics, nursing and maternity homes

(a) Sources of drugs used, supplied and administered
(b) records of controlled drugs used, supplied and administered
(c) storage facilities and security for controlled drugs.

4. Unauthorized markets

(a) Investigate sources of drugs in the unauthorized market
(b) sample drugs for quality assessment
(c) seize drugs in the unauthorized market

Guidance on handling collected samples

As it is very important for the collected samples to have legal standing, sample handling and transferring to the quality control laboratory of the ZFDB or other laboratories for analysis must be done according to special procedures outlined in the SOP and form for dispensing outlets (appendix 2a and 2b). For suspicious samples, the inspector should follow the SOP for suspicious samples. All collected samples should follow the SOP for Chain of Custody.

The chain of custody

Introduction

The chain of custody is the list of individuals who have had access to the collected sample materials. The chain begins with the first person to assume custody of the materials. Individuals who handle the secured materials but who do not compromise the seals or closures are not part of the chain. (Common Carrier employees who ship the secured materials are not part of the chain)

Types of Collections

1. Adverse action samples—generally compromised samples—have seals that have been broken; these materials include products associated with unexpected illnesses or deaths.
2. Products that are reported to be ineffective—generally a group of findings, not a single incident.
3. Suspicious samples—generally unopened containers.
4. Labeling or containers that seem incorrect.
5. Routine surveillance samples—generally unopened containers.

Purpose of Maintaining the Chain

1. The collected materials may be used as evidence in a legal proceeding and must be protected to have status in court.

2. The collected materials are not a tourist site—only individuals with a need to access the material should do so.

Breaks in the Chain

- Any actual or potential unrecorded access to the material breaks the chain. Materials must be either under seal or strict control at all times.
- Any unauthorized person who accesses the secured material (i.e., breaks security) ends the chain.
- The chain is maintained to document the access to the evidence.

The End of the Chain

- The chain status ends after it is determined the evidence will not be used in a legal proceeding.
- The collected materials are property of the government and should be destroyed at the conclusion of the findings.
- Apart from documenting handling fraud, the chain has no status after the sample is destroyed or taken off active inventory.

Law Enforcement

- The food and drug laws are commerce laws and not criminal laws.
- If possible criminal violations of the law are uncovered, abandon your investigation and turn the matter over to criminal investigators.
- An inspector should never put their lives in danger!

5. Drug inspectors

Qualifications

Inspectors should normally be pharmacists who have work experience in community and/or hospital pharmacy. Where persons other than pharmacists are employed as drug inspectors, they should be adequately experienced in drug control affairs and suitably trained in inspection functions. The possibility of having part-time inspectors with special knowledge as part of inspection teams may also be considered if deemed necessary.

The inspector should:

1. Advise on whether applicants and premises should be issued license to engage in drug related activities.
2. Ensure that all licensed premises and authorized persons adhere to existing laws and regulations.
3. Ensure that counterfeit and substandard pharmaceutical products are not found in Zanzibar

Inspection should be held regularly. Premises should be inspected at least once every 6 months. Where problems are frequently noticed, the inspection should be carried out more frequently (e.g. every three months). For premises with a good record, less frequent inspection may be needed.

Inspections

When inspecting establishments, the inspector will use the appropriate references. The method of inspection will be laid down in a SOP which also contains the requirements for a specific type of establishment. The inspection SOP will be in the format of a checklist.
When sampling is part of the inspection procedure, the SOP will contain guidance for the inspector

Special Categories of drugs

When special categories of drugs are present the inspector will require a modified SOP. This situation is likely to occur with controlled drugs, pharmaceutical products moving in international commerce, or with counterfeit or substandard pharmaceutical products. For this last category an example of extra guidance is needed.

Attributes of an inspector

An inspector should possess the following attributes:

- Good knowledge of pharmacy, laws and regulations to be enforced.
- Good command of technical terms and excellent communication skills.
- Awareness of the probable methods of using forged or false documents for transactions in pharmaceutical preparations and skills in determining the genuineness of documents presented for examination.
- Maturity, honest and integrity.
- Responsible conduct which commands respect.
- Willingness to accept challenges.
- Ability to organize their own work with minimum supervision.
- Ability to assess facts quickly and take rational and sound decisions without delay.
- Ability to assess character and honesty of persons being interviewed.
- Good public relations image with key personnel/pharmacists in charge of premises while remaining firm, fair and resolute.
- Ability to hold discussion with company management at the completion of inspection.
- Ability to motivate other inspectors.
- Commitment to hard work and long hours.
- Ethical approach to any potential conflict of interest.
- Have good eye sight.
- Always be presentable and have a pleasant character.
- Ability to adopt new work and assignment.
- Be punctual.

Do's & Don'ts for Inspectors during inspection

- Exercise confidentiality: do not reveal to a third party findings/observations regarding your work.
- Make accurate reports of the facts observed.
- Be courteous and demonstrate poise and competence in your work.
- Refrain from expressing personal views; such remarks or opinions may be interpreted as official.
- Do not lose temper when abused or accused.
- Do not miss a single object, correspondence, record, accounts book, chit, rough book, or other relevant papers, which may prove to be material evidence in establishing conduct, transactions, circumstances, and so on of the establishment being inspected.
- Do not fail to mention or record all items seized. Full details and descriptions of the incriminating articles or circumstances for which a charge will be opened (in case of intention to institute legal charges) should be recorded with witnesses present and signatures of responsible persons should be on the seizure document.

Procedures for Drug Inspection

(a). During inspection of facilities, remember the following—

1. Contact the person in charge of the establishment by approaching him or her in a dignified, authoritative, and cordial manner. Avoid being arrogant.
2. Present credentials (e.g., your identity card) and explain the purpose of your visit.
3. Use diplomacy, tact, and persuasiveness to acquire the necessary information and all necessary inspection details. Use the standard operating procedures (SOPs)/Inspection Checklist to achieve this.
4. In case of refusal to undergo inspection, explain that refusing is a criminal offense and courteously discuss the matter with the owner or responsible person on the premises.
5. Upon completion of inspection, meet the owner or person in charge to discuss the findings. Adopt a courteous attitude in calling attention to the practices or conditions observed at the time of inspection; make suggestions for minor corrections to be made as you perform the inspection.
6. If any samples have been taken for testing, furnish a receipt for these samples to the person from whom samples are taken.

(b) During inspection at the port of entry, follow SOPs for—

- Port of entry inspection
- Physical examination
- Testing

(c) During post-marketing surveillance, follow SOPs for—

- Dispensing outlets inspection
- Physical examination
- Suspicious drugs and chain of custody

Organisational aspects

All inspectors should be employed or nominated by the ZFDB, which ensures the following aspects:

- A job description which describes the duties of the inspector.
- Proper reporting procedures; inspectors should report to the drug inspectorate unit.
- Uniformity of approach;
    (a) Regular meetings of inspectors, in which experiences on the job are exchanged, will help promote a uniform approach

to inspection as well as enhance the performance of the inspectors.

(b) Inspectors should work according to a work plan and to SOPs.

(c) Inspection report should be in four parts:
   (i) date of inspection and general information on the establishment inspected,
   (ii) description of the inspection activities undertaken, including analytical data of sample taken,
   (iii) observations and recommendations,
   (iv) Conclusions.

(d) Inspectors should submit weekly reports of work to ZFDB.

Note: The existence of unauthorized markets for the distribution of drugs possesses considerable health hazards. The inspectors should, with the assistance of task forces if necessary, investigate the extent of the unauthorized markets, the types of drugs distributed and supplied, and the sources of the drugs. All unauthorized markets for drugs should be prohibited through effective inspection activities.

The inspector should also investigate the sources of supply of suspect counterfeit or substandard pharmaceutical products.

Cooperation with other agencies:

The inspector will be expected to interact and cooperate with other interested parties such as:

a) industrial, community and hospital pharmacists,
b) management and supervisory staffs of pharmaceutical establishment and hospitals, medical practitioners , dentists, veterinarians, nurses, midwives and other health workers,
c) public analysts,
d) drug law enforcement officers including the police and customs,
e) officers of port authorities, clearing agents at the ports importers and exporters,
f) members of the public(RCs, DCs, Shehas and so on)
g) staff of department of pharmacy in the collage of health science,
h) foreign drug regulators authorities

Independence.

Inspectors should never depend on the hospitality of the facility to be inspected for example for inspection costs, transport etc.

Special Categories of drugs

When special categories of drugs are present the inspector will require a modified SOP. This situation is likely to occur with controlled drugs,

pharmaceutical products moving in international commerce, or with counterfeit or substandard pharmaceutical products. For this last category for example, extra guidance is needed.

Reference/information sources

When inspecting establishments, the inspector will use the appropriate references. The method of inspection will be laid down in a SOP which also contains the requirements for a specific type of establishment. The inspection SOPs will be in the format of a checklist.
When sampling is part of the inspection procedure, the SOPs will contain guidance for the inspector

The reference/ information sources to be used by inspectors should include:

- Existing Zanzibar drug laws and regulations and international convention covering such aspects as:
    - licensing
    - GMP
    - good distribution practice
    - good pharmacy practice
    - promotion of pharmaceutical products
    - controlled drugs
    - counterfeit or substandard pharmaceutical products

- Codes of inspection
- Codes of professional ethics
- Available data on imports/exports/prohibited drugs
- Inspection checklists.

6. THE USE OF THE GERMAN PHARMA HEALTH FUND MINILAB FOR QUALITY CONTROL OF DRUGS

Quality assurance of pharmaceutical products, whether locally manufactured or imported, is of prime importance in any health-care system; lack of quality assurance endangers the lives of citizens of a given country.

The Zanzibar Food and Drug Board currently does not have a quality control laboratory for analysis of drugs. Thus, affordable but reliable methods for quality assurance were urgently required to ensure that both locally manufactured and imported products meet the prescribed standards and thus are safe for human use.

Since 2002, the MOHSW through WHO support acquired GPHF Minilab kits for screening of quality at the point of entries in both Zanzibar and Pemba. Confirmatory tests when required are done at the Quality control laboratories of the Tanzania Food and Drug Authority in Dar es salaam.

One of the most reliable, simple, and relatively easy and cheap techniques for quality assurance is thin-layer chromatography (TLC). The German Pharma Health Fund (GPHF), which is a not-for-profit organization, developed a kit that can be used for quality screening of pharmaceutical products being imported and those already on the market. The GPHF Minilab kit is equipped with all the materials needed for carrying out disintegration tests, TLC, and color reactions for most essential drugs.

The GPHF Minilab has been developed in such a way that it can be easily used to monitor the quality of drugs in various places, without the need for complicated methods and complex pieces of equipment. The kit contains all necessary requirements for testing several samples of the essential drugs included in the materials provided. Details of TLC analysis have also been provided under each drug monograph, and the general details are as described below.

Verification of Identity and Drug Content via TLC

Principle

Drug is extracted from tablets and capsules with an appropriate solvent, as specified in the monograph and determined by TLC with reference to an authentic secondary standard.

Equipment and Reagents

a) Pestle
b) Aluminum foil
c) Laboratory glass bottles with a filling capacity of 25 to 100 mL
d) Funnel
e) Set of straight pipettes (1 to 25 mL)
f) 10-mL vials
g) Label tape
h) Marker pen
i) Pencil
j) Ruler
k) Merck TLC aluminum plates pre-coated with silica gel 60 F 254, size 5 × 10 cm
l) Glass micro-capillaries of 2-µL filling capacity
m) Hot plate
n) TLC developing chamber (jar)
o) Filter paper
p) Pair of scissors
q) UV light of 254 nm
r) Safety pipette filler
s) Solvents for extraction
t) Solvents for mobile phase
u) Reference and sample tablets

Preparation of the Standard Stock Solution

The preparation of a stock standard solution requires a whole reference tablet containing a stated amount of drug, which is crushed prior to extraction, the precise procedure being as follows. Wrap a tablet in aluminum foil and crush it to a fine powder using a pestle. Empty contents of the aluminum foil over a laboratory glass bottle of appropriate capacity and wash down all residual solid with an appropriate volume of solvent using a straight pipette. Close the bottle and shake for about three minutes until most of the solids are dissolved. Allow the solution to stand for another five minutes until the undissolved residue settles below the clear supernatant liquid. This solution should be labelled as "Drug Stock Standard Solution"; it contains a known concentration of the drug per milliliter. Freshly prepare the standard solution for each test.

Preparation of the Working Standard Solution 100 Percent (Upper Working Limit)

Using a pipette, add a stated volume of the clear stock standard solution into an appropriate vial and add a stated volume of diluting solvent. Close and

shake the vial. The solution obtained should be labeled as "Drug Working Standard Solution 100 Percent" and contain a known amount of the drug per milliliter.
This higher working standard solution represents a drug product of good quality containing 100 percent of the drug.

Preparation of the Working Standard Solution 80 Percent (Lower Working Limit)

Pipette a given volume of the stock standard solution into an appropriate and add a stated volume of a specified solvent. Close and shake the vial. The solution obtained should be labeled as "Drug Working Standard Solution 80 Percent" and contain a known amount of drug per milliliter. This is more dilute than the 100 percent working standard solution and thus represents a drug product of poor quality containing just 80 percent of the amount of drug stated on the product's label. In the current investigation, this drug level represents the lower acceptable limit for a given product.

Preparation of the Stock Sample Solution from a Drug Product Claiming a Stated Potency per Unit

The preparation of a stock sample solution requires a whole tablet or capsule from an appropriate drug product sampled in the field. The drug is extracted completely from the sample using the same procedure as for the authentic reference standard: tablets are wrapped into aluminium foil and crushed to a fine powder prior to transfer into a laboratory glass bottle of a specified capacity. Powder obtained from a capsule should be transferred directly into the laboratory glass bottle, finally putting the empty cap and body shells into the bottle as well. Add a specified volume of appropriate solvent using a straight pipette, close the bottle, and shake for about three minutes until most of the solids are dissolved. Allow the solution to stand for another five minutes until the undissolved residue settles below the clear supernatant liquid. This solution should be labeled as "Drug Stock Sample Solution"; it contains a known amount of total drug per milliliter. Freshly prepare the sample solution for each test.

Preparation of the Working Sample Solution

Pipette a specified volume of the stock sample solution into a specified vial and add a given volume of solvent. Close and shake the vial. The solution obtained should be labelled as "Drug Working Sample Solution." The expected concentrations of both drug compounds in the working sample solution should match the concentration of drug of the higher working standard solution produced previously.

Spotting

Mark an origin line parallel to and about 1.5 cm from the bottom edge of the chromatoplate and apply 2 µL of each test and standard solution as shown in the picture opposite using the microcapillary pipettes supplied.

Up to five spots can be placed on a plate. Check the uniformity of all spots using UV light of 254 nm. All spots should be circular in shape and equally spaced across the origin line. Although their intensity might differ, their diameter never should. Different intensities are due to residual amounts of tablet and capsule excipients or different drug concentrations in the sample solutions. A difference in spot size, however, relates to poor spotting. Repeat this step if homogeneous spotting is not achieved the first time.

Development

Using a pipette, add a given volume of mobile phase into the jar being used as the TLC developing chamber. Close the chamber and mix thoroughly. Line the chamber's wall with filter paper and wait for about 15 minutes, thus ensuring saturation of the chamber with solvent vapor. Carefully place the loaded TLC plate into the jar. Close the jar and develop the chromatoplate until the solvent front has moved about three-quarters of the length of the plate, the developing time being about 15 minutes. Remove the plate from the chamber, mark the solvent front, and allow any excess solvent to evaporate, using a hot plate if necessary.

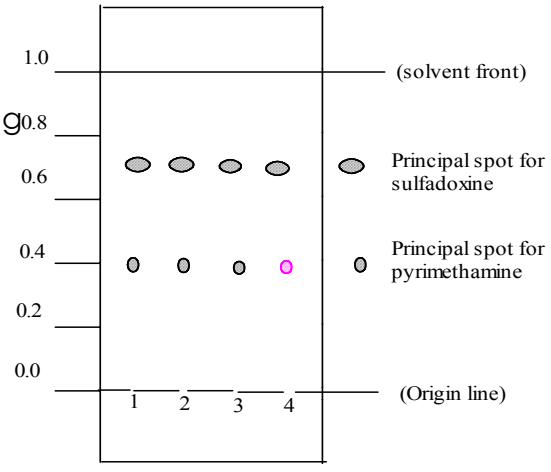
Detection

Dry off all residual solvent, and where necessary, use the supplied hot plate. Observe the chromatoplate obtained with UV light of 254 nm using the battery-driven fluorescent lamp supplied. Also observe the plate in daylight after iodine staining or application of any other specified reagent.

Figure 1. CHROMATOPLATE OBSERVED AT 254 NM
EXAMPLE: SULFADOXINE/PYRIMETHAMINE

Run No. 1:
Standard drug's upper working limit representing 100% of total drug

Run No. 2:
A drug product of good quality
Run No. 3:
A drug product of poor quality
Run No. 4:
Standard drug's lower working limit



representing 80% of total drug

Observations Made at 254 nm

The presence of a drug is indicated by a principal spot representing individual drug components at different travel distances. Do not release the batch unless all expected spots are visible. Additional strong spots generated by the test solution indicate drug degradation, especially when associated with a smaller principal spot. Some fainter spots emerging near or on the origin line of the chromatoplate are normally caused by auxiliary agents incorporated in the different tablet or capsule formulations.

Observations Made in Daylight after Staining with Iodine or Any Other Specified Reagent

Only the spots reacting with iodine or any other specified reagent become visible for further evaluation of quantities present.

Results and Actions to Be Taken

The principal spots in the chromatogram obtained with the test solution must correspond in terms of color, size, shape, and travel distance to those in the chromatograms obtained with the lower and higher standard solutions. This result must be obtained for each method of detection. If this is not achieved, repeat the run with a second sample from scratch. Reject the batch if the drug content cannot be verified by a third run. For a second opinion, refer additional samples to a fully equipped drug control laboratory. Retain samples and put the batch on quarantine until a final decision on rejection or release has been made.

EXAMPLES OF ANALYSIS FOR SOME MEDICINES

Analysis of Artesunate Tablets

Extraction Medium

- Methanol

Stock Standard Solution

ARTESUNATE STOCK STANDARD SOLUTION (5 mg/mL)
▪ Grind a 50-mg reference tablet and wash down the powder completely with 10 mL of methanol into a 25-mL glass bottle ▪ Close the bottle

▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles ▪ Label the bottle as "Artesunate Stock Standard Solution"

Working Standard Solution

ARTESUNATE WORKING STANDARD SOLUTION 100% = 5.0 mg/mL	**ARTESUNATE WORKING STANDARD SOLUTION 80% = 4.0 mg/mL**
▪ Artesunate working standard solution does not need any further dilution	▪ Pipette into a 10-mL vial ▪ 4 mL of stock standard solution ▪ Add 1 mL of methanol ▪ Close, shake, and label it as "Artesunate Working Standard Solution 80%"

Stock Sample Solution

ARTESUNATE STOCK SAMPLE SOLUTION (5 mg/mL) Produced from a 50-mg tablet or capsule	ARTESUNATE STOCK SAMPLE SOLUTION (5 mg/mL) Produced from a 100-mg tablet or capsule	ARTESUNATE STOCK SAMPLE SOLUTION (5 mg/mL) Produced from a 200-mg tablet or capsule
▪ Grind a 50-mg tablet and wash down the powder completely with 10 mL of methanol into a 25-mL glass bottle ▪ For capsules: open and transfer powder plus cap and body shells into a 25-mL glass bottle and add 10 mL of methanol	▪ Grind a 100-mg tablet and wash down the powder completely with 20 mL of methanol into a 25-mL glass bottle ▪ For capsules: open and transfer powder plus cap and body shells into a 25-mL glass bottle and add 20 mL of methanol	▪ Grind a 200-mg tablet and wash down the powder completely with 40 mL of methanol into a 50-mL glass bottle ▪ For capsules: open and transfer powder plus cap and body shells into a 50-mL glass bottle and add 40 mL of methanol
▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles ▪ Label the bottle as "Artesunate Stock Sample Solution"	▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles ▪ Label the bottle as "Artesunate Stock Sample Solution"	▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles ▪ Label the bottle as "Artesunate Stock Sample Solution"

Working Sample Solution

ARTESUNATE WORKING SAMPLE SOLUTION 100% = 5.0 mg/mL
▪ **Artesunate stock sample solution prepared from either unit dosage form requires no further dilution**

Preparation of Developing Chamber

PROCEDURE	SOLVENT	AMOUNT
▪ Pipette into the developing chamber (jar) ▪ Add ▪ Add	Ethylacetate Acetone Glacial acetic acid	18 mL 4 mL 0.1 mL (precisely)
▪ Close the jar (developing chamber) and mix thoroughly ▪ Line the chamber's wall with filter paper ▪ Wait for about 15 minutes for chamber saturation; use this time for spotting (next step)		

Spotting

LOADING THE TLC PLATE WITH SAMPLE SOLUTION
▪ Mark an origin line about 1.5 cm from the bottom edge (with pencil) ▪ Apply 2 µL of each working standard solution ▪ Apply 2 µL of each working sample solution (up to five samples will fit on the plate) ▪ Wait till all spots are dried off ▪ Check the uniformity of all spots with UV light of 254 nm

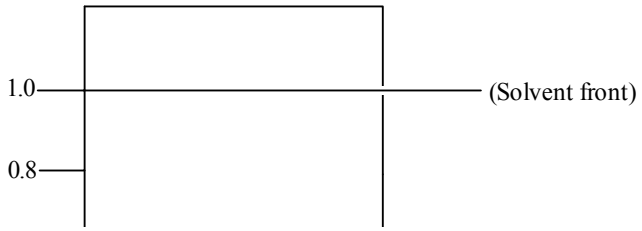
Development

- Carefully place the loaded plate into the developing chamber and close the jar
- Wait until the solvent front has moved three-fourths of the length of the plate (developing time, about 15 minutes)
- Remove the plate
- Mark the solvent front
- Air dry the plate or use hot plate if necessary

Detection

- Observe the chromatoplate in daylight after staining with sulfuric acid
- Observe the plate in daylight after iodine staining
- Compare the result with the description in the manual

Final Chromatoplate



- Run no. 1 = 2.0 µL of artesunate 100% standard solution
- Run no. 2 = 2.0 µL of sample solution of a high-quality product
- Run no. 3 = 2.0 µL of sample solution of a poor-quality product
- Run no. 4 = 2.0 µL of artesunate 80% standard

Analysis of Quinine Preparations

Extraction Medium

- Aqueous methanol

Stock Standard Solution

QUININE STOCK STANDARD SOLUTION (10 mg/mL)
▪ Grind a 300-mg reference tablet and wash down the powder completely with 3 mL of water into a 50-mL glass bottle ▪ Close the bottle ▪ Shake the bottle for one minute ▪ Add 27 mL of methanol ▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles ▪ Label the bottle as "Quinine Stock Standard Solution"

Working Standard Solution

QUININE WORKING STANDARD SOLUTION 100% = 1.25 mg/mL	**QUININE WORKING STANDARD SOLUTION 80% = 1.0 mg/mL**
Pipette into a 10-mL vial ▪ 1 mL of stock standard solution ▪ Add 7 mL of methanol ▪ Close, shake, and label it as "Quinine Working Standard	Pipette into a 10-mL vial ▪ 1 mL of hazy stock standard solution ▪ Add 9 mL of methanol ▪ Close, shake, and label it as "Quinine Working Standard Solution 80%"

Solution 100%"	

Stock Sample Solution

QUININE STOCK SAMPLE SOLUTION (10 mg/mL) produced from a product with 100 mg/mL or unit	**QUININE STOCK SAMPLE SOLUTION (10 mg/mL) produced from a product with 200 mg/mL or unit**	**QUININE STOCK SAMPLE SOLUTION (10 mg/mL) produced from a product with 250 mg/mL or unit**
Oral preparations ▪ Grind a 100-mg tablet and wash down the powder completely with 1 mL of water into a 25-mL glass bottle, shake for one minute, then add 9 mL of methanol ▪ For capsules: open and transfer powder plus cap and body shells into a 25-mL glass bottle and add 1 mL of water, shake for one minute, then add 9 mL of methanol ▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles ▪ Label the bottle as "Quinine Stock Sample Solution" For parenterals: ▪ Pipette 1 mL of injection fluid into 25-mL bottle	Oral preparations ▪ Grind a 200-mg tablet and wash down the powder completely with 2 mL of water into a 25-mL glass bottle, shake for one minute, then add 18 mL of methanol ▪ For capsules: open and transfer powder plus cap and body shells into a 25-mL glass bottle and add 2 mL of water, shake for one minute, then add 18 mL of methanol ▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles ▪ Label the bottle as "Quinine Stock Sample Solution" For parenterals: ▪ Pipette 1 mL of	Oral preparations ▪ Grind a 250-mg tablet and wash down the powder completely with 2 mL of water into a 25-mL glass bottle, shake for one minute, then add 23 mL of methanol ▪ For capsules: open and transfer powder plus cap and body shells into a 25-mL glass bottle and add 2 mL of water, shake for one minute, then add 23 mL of methanol ▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all

▪ Add 9 mL of methanol and shake	injection fluid into 50-mL bottle ▪ Add 19 mL of methanol and shake	insoluble material settles ▪ Label the bottle as "Quinine Stock Sample Solution" For parenterals: ▪ Pipette 1 mL of injection fluid into 50-mL bottle ▪ Add 24 mL of methanol and shake

QUININE STOCK SAMPLE SOLUTION (10 mg/mL) produced from a product with 300 mg/mL or unit	**QUININE STOCK SAMPLE SOLUTION (10 mg/mL) produced from a product with 500 mg/mL or unit**
Oral preparations ▪ Grind a 300-mg tablet and wash down the powder completely with 3 mL of water into a 50-mL glass bottle, shake for one minute, then add 27 mL of methanol ▪ For capsules: open and transfer powder plus cap and body shells into a 50-mL glass bottle and add 3 mL of water, shake for one minute, then add 27 mL of methanol ▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles ▪ Label the bottle as "Quinine Stock Sample Solution" Parenterals: ▪ Pipette 1 mL of injection fluid into 50-mL bottle	Oral preparations ▪ Grind a 500-mg tablet and wash down the powder completely with 3 mL of water into a 100-mL glass bottle, shake for one minute, then add 47 mL of methanol ▪ For capsules: open and transfer powder plus cap and body shells into a 100-mL glass bottle and add 3 mL of water, shake for one minute, then add 47 mL of methanol ▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles ▪ Label the bottle as "Quinine Stock Sample Solution" Parenterals: ▪ Pipette 1 mL of injection fluid into 100-mL bottle

▪ Add 29 mL of methanol and shake	▪ Add 49 mL of methanol and shake

Working Sample Solution

QUININE WORKING SAMPLE SOLUTION 100% = 1.25 mg/mL
▪ Pipette into a 10-mL vial ▪ 1 mL of hazy stock sample solution ▪ Add 7 mL of methanol ▪ Close, shake, and label it as "Quinine Working Sample Solution"

Preparation of Developing Chamber

PROCEDURE	**SOLVENT**	**AMOUNT**
▪ Pipette into the developing chamber jar ▪ Add	Methanol Conc. ammonia solution	20 mL 0.5 mL
▪ Close the jar (developing chamber) and mix thoroughly ▪ Line the chamber's wall with filter paper ▪ Wait for about 15 minutes for chamber saturation: use this time for spotting (next step)		

Spotting

LOADING THE TLC PLATE WITH SAMPLE SOLUTION
▪ Mark an origin line about 1.5 cm from the bottom edge (with pencil) ▪ Apply 2 µL of each working standard solution ▪ Apply 2 µL of each working sample solution (up to five samples will fit on the plate) ▪ Wait till all spots are dried off ▪ Check the uniformity of all spots with UV light of 254 nm

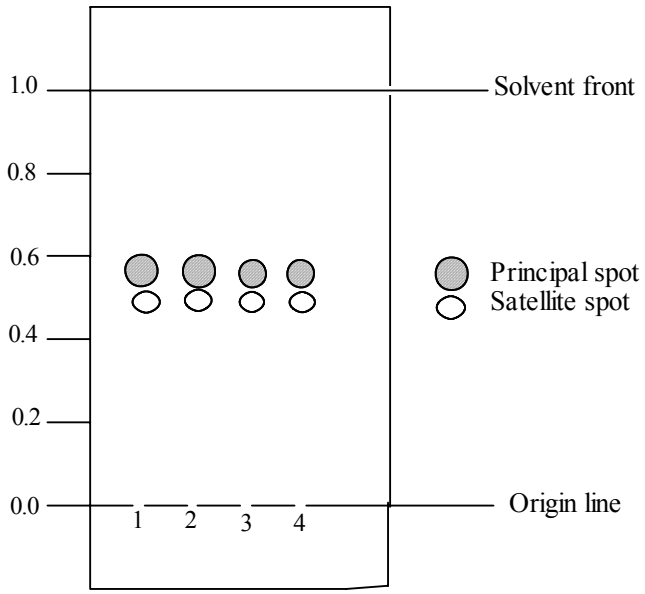
Development

▪ Carefully place the loaded plate into the developing chamber and close the jar ▪ Wait until the solvent front has moved three-fourths of the length of the plate (developing time, about 20 minutes) ▪ Remove the plate ▪ Mark the solvent front ▪ Air dry the plate or use hot plate if necessary

Detection

- Observe the chromatoplate with UV light of 254 nm
- Observe the plate at 365 nm
- Observe the plate in daylight after iodine staining
- Compare the result with the description in the manual

Final Chromatoplate Observed at 254 nm



- Run no. 1 = 2.0 µL of quinine 100% standard solution
- Run no. 2 = 2.0 µL of sample solution of a high-quality product
- Run no. 3 = 2.0 µL of sample solution of a poor-quality product
- Run no. 4 = 2.0 µL of quinine 80% standard

Analysis of Sulfadoxine/Pyrimethamine Tablets

Extraction Medium

- Methanol

Stock Standard Solution

SULFADOXINE/PYRIMETHAMINE STOCK STANDARD SOLUTION (25.0/1.25 mg/mL)
▪ Grind a 500/25 mg reference tablet and wash down the powder completely with 20 mL of methanol into a 25-mL glass bottle ▪ Close the bottle ▪ Shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles below the supernatant liquid ▪ Label the bottle as "Sulfadoxine/Pyrimethamine Stock Standard Solution"

Working Standard Solution

SULFADOXINE/PYRIMETHAMINE WORKING STANDARD SOLUTION 100% (6.25/0.3125 mg/mL)	SULFADOXINE/PYRIMETHAMINE WORKING STANDARD SOLUTION 80% (5.00/0.25 mg/mL)
▪ Pipette into a 10-mL vial ▪ 1 mL of stock standard solution ▪ Add 3 mL of methanol ▪ Close, shake, and label it as "Sulfadoxine/Pyrimethamine Working Standard Solution 100%"	▪ Pipette into a 10-mL vial ▪ 1 mL of stock standard solution ▪ Add 4 mL of methanol ▪ Close, shake, and label it as "Sulfadoxine/Pyrimethamine Working Standard Solution 80%"

Stock Sample Solution

SULFADOXINE/PYRIMETHAMINE STOCK SAMPLE SOLUTION (25.0/1.25 mg/mL) produced a drug claiming a potency of 500 + 25 mg of total compounds
▪ Tablets: Grind one and wash down the powder completely with 20 mL of methanol into a 25-mL glass bottle ▪ Capsules: Open one and transfer powder plus cap and body shells into a 25-mL glass bottle and add 20 mL of methanol
▪ Close and shake the bottle for three minutes ▪ Let the bottle stand for five minutes until all insoluble material settles below the supernatant ▪ Label the bottle as "Sulfadoxine/Pyrimethamine Stock Sample Solution"

Working Sample Solution

SULFADOXINE/PYRIMETHAMINE WORKING SAMPLE SOLUTION 100% (6.25/0.3125 mg/mL)
▪ Pipette into a 10-mL vial ▪ 1 mL of stock sample solution

▪ Add 3 mL of water ▪ Close, shake, and label it as "Sulfadoxine/Pyrimethamine Working Sample Solution"

Preparation of Developing Chamber

PROCEDURE	SOLVENT	AMOUNT
▪ Pipette into the developing chamber ▪ Add	 Ethylacetate Methanol	 15 mL 5 mL
▪ Close the jar (developing chamber) and mix thoroughly ▪ Line the chamber's wall with filter paper ▪ Wait for about 15 minutes for chamber saturation: use this time for spotting (next step)		

Spotting

LOADING THE TLC PLATE WITH WORKING STANDARD AND SAMPLE SOLUTIONS
▪ Mark an origin line about 1.5 cm from the bottom edge using a pencil ▪ Apply 2 µL of each working standard solution ▪ Apply 2 µL of each working sample solution between the lower and higher reference standard (up to three samples will fit on the plate) ▪ Wait till all spots are dried off ▪ Check the uniformity of all spots with UV light of 254 nm

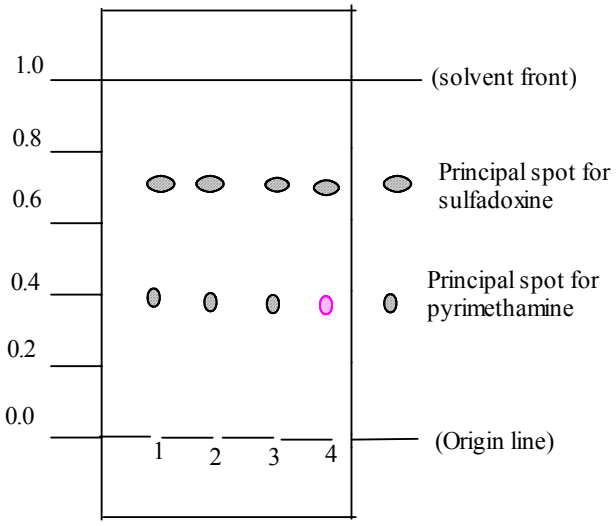
Development

▪ Carefully place the loaded plate into the developing chamber and close the jar ▪ Wait until the solvent front has moved three-fourths of the length of the plate (developing time, about 15 minutes) ▪ Remove the plate ▪ Mark the solvent front using a pencil ▪ Air dry the plate or use hot plate if necessary

Detection

▪ Observe the chromatoplate with UV light of 254 nm ▪ Expose the plate to iodine vapor for about one minute ▪ Observe the plate in daylight during and after iodine staining ▪ Compare the result with the description in the manual

Final Chromatoplate



- Run no. 1 = 2.0 µL of sulfadoxine/pyrimethamine 100% standard solution
- Run no. 2 = 2.0 µL of sample solution of a high-quality product
- Run no. 3 = 2.0 µL of sample solution of a poor-quality product
- Run no. 4 = 2.0 µL of sulfadoxine/pyrimethamine 80% standard

Visual Inspection

Beginner's Summary

For documentation purposes, write down all product particulars using the reporting form as a guide during the visual inspection of pharmaceutical products.

General Screening

Drug products from particularly cheap sources: drug products with missing or incorrect accompanying documents; and drug products with defective dosage forms or packaging or with incomplete, damaged, or missing labels or with labels written in a foreign language should be subjected to disintegration and identity tests and, if they pass, further scrutinized by TLC for the determination of drug content and gross degradation. Repeat the examination with two other samples to eliminate anomalous results. Should a product not pass all tests, ask for a second opinion and refer an additional sample to a fully equipped drug control laboratory. Keep some retained samples in a safe place for future investigations.

Inspection of Packaging Material

Tablets and capsules can be presented in single-unit or multi-unit dose containers such as blister packs or bottles. Patient packs may contain just 10 or 20 tablets, whereas bulk packs may contain 1,000 or more tablets. On reception, the container should be properly sealed and labeled and be without defects and damage. Seals should not have been violated. On opening of the container, a strong smell often indicates drug degradation. Exceptions are allowed for products containing flavors or drug substances with a characteristic odor, such as penicillins. Excessive powder or pieces of tablets at the bottom of the container indicates the presence of abraded and broken tablets or crushed and opened capsules.

Other deleterious effects might be caused by excessive moisture uptake and are indicated by fused tablets and capsules or are shown by recrystallized drug substance on the solid formulation itself or on the container.

Inspection of Labels

Both the immediate container and the carton should have a durable label fixed on them. Labels can be replaced by print. The print on the label or packaging must be legible and indelible. The label should provide at least (1) the name of the drug, (2) the drug's strength, (3) the number of unit doses in the container, (4) the manufacturer's or distributor's name and full address, (5) the batch or lot number, (6) the expiry date, and (7) the storage conditions.

Inspection of Dosage Forms

Solid oral dosage forms are normally presented as uncoated tablets and capsules. Sometimes they are specially coated and should then be labeled as such—for example, as enteric-coated capsules. Tablets might be designed as dispersible or effervescent tablets for dissolving in water before swallowing.
Tablets and capsules should show no signs of blemishes such as dirty marks or spots, abrasion or erosion, cracks or chips, or any other defects such as fusion or swelling. In addition, hard gelatin capsules should show no signs of softening, and the capsule shells should be properly sealed and free of cracks and dents. The color of a broken tablet or the content of an opened capsule must be white with no signs of any mottling or discoloration. Allowances must be made for products where the drug substance or any excipient itself consists of colored powder or crystals.

Disintegration Test

Tablets should be sufficiently hard to withstand handling without crumbling or breaking, but they should also be sufficiently soft for easy disintegration in the stomach or intestine in order to make the drug available to the body. Due to poor drug processing or wrong storage, tablets and capsules may harden and fail the disintegration test. The test determines whether tablets or capsules disintegrate in water within 30 minutes.

All uncoated tablets and capsules and all soluble, dispersible, effervescent, and film-coated tablets—hence, all quick-release formulations—have to comply with this time of complete disintegration. Sugar-coated tablets may meet this specification, but it is not a requirement. Only modified-release and enteric-coated tablets and capsules are allowed to deviate from this time of complete disintegration. These tablets and capsules should be labeled as such and not be subjected to this test. These products require a more sophisticated disintegration test.

Simple counterfeit preparations such as capsules containing just sand or ground ceramics, or tablets made only of meat flour, are easily spotted by their disintegration behavior. Ground ceramics or sand settles straight to the bottom of the flask, whereas the supernatant liquid stays clear or almost clear. Tablets and capsules containing only meat flour never really disintegrate. They just soak up water and form a sticky mass or disintegrate into a couple of sticky lumps that slowly settle at the bottom of a beaker. State-of-the-art tablets and capsules containing modern disintegrants behave completely differently. For example, uncoated tablets of good quality will normally completely disintegrate in water at 37˚C within 15 minutes.

Disintegration is defined as that state in which no residue of the tablets and capsules, except fragments of undissolved coating, remains in the test solution. It is a major defect if a drug product doesn't pass this test. The product can be rejected at this stage already. No further TLC assay or any other tests are required. This will save organic solvent and reference samples.

Beginner's Summary

Place one tablet or capsule into a 100-mL wide-neck bottle containing 100 mL of water. The temperature of the water should be close to body temperature (37˚C). Stir or shake the liquid from time to time, continuing for 30 minutes. You may stop earlier if the tablet or capsule disintegrates much faster. The tablet or capsule passes the test if no residue remains in the liquid, or if any remaining residue consists of fragments of coating or is a soft mass with no palpable core.
Repeat the test on five more tablets or capsules. The batch passes the test if all six tablets or capsules disintegrate. Repeat the entire test cycle if one tablet or capsule fails to disintegrate. Repeat the batch if another tablet or capsule fails again in the second run.

Color Reactions

Introduction

We have already covered a general overview of the Minilab concept, visual inspection of labels, packaging materials, multi-unit dose containers, single-unit dose containers, folding cartons, tablets, and description aids for visual inspection of capsules.

We have also described a simplified disintegration test. Both tests will allow the identification of rough counterfeits for timely rejection prior to employing color reactions for further examination. Therefore, color reaction will be our third weapon to use if all the above tests appear to be positive. We have discussed a number of color reactions in the previous sections. If you have done color reactions by using the monographs described above, you will know that most of the color reactions involved are not only tedious but also time consuming, and you need some special training to be able to do them precisely. In contrast, the color reactions discussed next are not only cheap but also require little training.

The Minilab color reaction is easy to use and is the perfect tool for primary screening of spurious drug products on the spot. Many national and international pharmacopeias have been screened for the selection of color reactions on pharmaceutical preparations.

All methods selected have been tested and are sufficiently rugged, accurate, and sensitive to verify the identity of drug product on routine basis. A time-consuming extraction of the drug will not be necessarily required. All the tests are well described in the manual that is provided with our Minilab kits. The tests described in the manual are only intended to verify the identity of pharmaceutical preparations. They should not be used to replace pharmacopeial monographs.

All samples, which are potentially counterfeit, should be subjected to a TLC assay as described in the second volume of the manual or referred to a full-equipped laboratory for further investigations prior to taking legal action. For good and reliable analytical results, only reagents and solvents of high purity should be used. The concentrations, which are commonly expressed in normalities or molarities, have been converted into percentages for easier understanding.

Reagents and test solutions are dispensed via volume. Tablets or capsules containing a fixed amount of drug substance are dispensed by just dividing

them into equal parts as directed in the individual monograph. A balance will not be required.

Deionized or distilled water is the most common solvent to be used. In places where this grade of quality is not easily accessible, clear tap or rainwater might be used. (There are provisions made that are indicated on the individual monograph concerned.)

Heath and Safety

It is recommended to use protective clothing—for example, an apron and safety spectacles—before starting work on a color reaction. Spectacles must be worn at all times to avoid accidental contact with potentially hazardous test solutions and subsequent eye injuries.

Preparation of Test Solutions

A measuring cylinder, a funnel, graduated transfer pipettes, and wide-neck bottles are supplied for the preparation of test solutions.

1. The measuring cylinder should have a 5 to 50 mL capacity.
2. The transfer pipettes should have a volume of 0.5 to 3 mL. These and the graduated test tubes are the only dosing aids supplied.
3. A funnel is used for transferring liquid and solid reagents into the dropping bottles for mixing and finally for dispensing.
4. The wide-neck bottles are designed for the preparation and mixing of test solutions requiring frequent shaking—for example, dissolution of NaOH pellets in water. They come with a Teflon-lined closure.
5. More information on how to prepare your reagent and test solutions can be found on pages 70–72 of the color reaction manual.

A label tape and marker pen should be used for the permanent identification of test solutions either on polyethylene dispensing bottles or the brown glass bottles with an attached transfer pipette.

Note the following—

- Remember to write down the date the test solution was prepared.
- All test solutions have shown to be stable for at least three months under tropical climate conditions.
- Protective clothes and safety spectacles must be worn to avoid accidental contact with strong acids and alkaline solutions or any other potentially hazardous chemicals.

Sample Preparations

A pestle and circular filter paper instead of a mortar is needed for grinding tablets or granules to fine powder. Using a filter paper avoids the risk of cross

contamination between different batches during routine work because each sample will need a fresh filter paper.
Note the following—

- If no filter paper is available, it may be replaced by any other sort of paper, such as newsprint.
- Grinding should be done away from strong fans, as it will blow the sample off the bench top. This may be of potential hazard to you if inhaled or if it comes in contact with eyes or skin and may trigger an allergic reaction to penicillin or other related compounds.

For sachets, hard gelatin capsules are just opened and their contents poured straight onto the filter paper supplied. Division of the powder should be done to reflect instruction given on individual monograph using a spatula supplied. Soft gelatin capsules are opened by cutting them into an appropriate number of pieces using a pair of scissors, a blade, or a scalpel. Then transfer the appropriate amount of powdered sample or the appropriate number of pieces into a graduated test tube using either the spatula or a micro-spoon as directed in the individual monographs.

Test Performance

The test tube should be held using a wooden clamp. Add the required volume of the test sample and then shake the tube: a characteristic color for identification purposes is produced.
Polyethylene dropping bottles or brown glass bottles with an attached transfer pipette are used to accommodate the test solutions for easy dispensing. The graduated test tube will indicate how much of that solution has been applied already. Dispense the required volume as directed in the individual monograph.

Note the following—

- Vigorous shaking of the test tube is often required in order to achieve the necessary color reaction.
- Shake, do not swing, the test tube; swinging may lead to anomalous test results.

Last, you might want to place the test tube into the tube rack provided for a moment. Sometimes, a hot water bath is required to get the color reaction started. This can be achieved by using a 100-mL wide-neck bottle with about 50 mL of water and heat on a hot plate. Then insert the test tube containing the test sample into water, making sure that the reaction mix in the test tube is just below the water surface. A color, which didn't appear in the cold, will now be gradually produced in the heat.

Note the following—

- A Philips world travel iron can serve as a hot plate when placed upside down.

- Avoid direct contact with the hot plate.

Sometimes even a hot water bath doesn't produce enough heat to get a color reaction started; then an alcohol lamp including methylated spirits is supplied in order to produce naked flames sufficiently hot to cause the color reaction. Just hold the test tube containing the test sample into the flame using a clamp and frequently shake the tube. Gradually, a colour is produced that would not emerge in the cold.

Cleaning

- The test tube should be thoroughly cleaned after use.
- Dispose of all test mixtures and rinse the empty tube with water.
- Use the test tube brush supplied for test tube cleaning.
- If there are persistent stains, soak the tubes in a mixture of water and detergent overnight.
- Do not use a spatula or anything similar to scrape off resistant stains. This will destroy the test tube.
- Finally, rinse all test tubes with deionized water if available before drying, thus avoiding scum and stains. Return the tubes upside down to the test tube rack.
- Disposal of used reagents and test solutions should be done in a special dedicated waste liquid container preferably made of polypropylene.
- For further disposal, follow rules of your local area.

Restoring the Minilab to its Former Condition

All items should be put back into the protective case after being properly cleaned and dried

Screening Certificate

After screening of a product, a screening certificate should be filled out.

SCREENING CERTIFICATE			
Station			
Sample Number		**Date**	
Collected By		**Signature**	
Approved By		**Signature**	

CLIENT NAME	
ADDRESS	

PRODUCT	

Active Ingredients(s)	
Dosage Form	
Batch No.	
Manufacturer	
Expiration Date	
Label Claim	
Date Received	
Date of Analysis	

TEST(S)	**METHOD**	**RESULTS**
COMMENTS:		
ACTION TAKEN:		

Screening done by ……..
Signature ……
Date ……

7. POST MARKETING SURVEILLANCE

Post-marketing surveillance or as now known as a comprehensive science named pharmacovigilance, is the practice of monitoring a pharmaceutical drug or device after it has been released on the market. Since drugs are approved on the basis of clinical trials which involve relatively small numbers of people who have been "controlled", post-marketing surveillance can confirm or deny the safety of a drug after it is used in the general population by large numbers of people who have a wide variety of medical conditions.

The aims of pharmacovigilance or post marketing surveillance are to enhance patient care and patient safety in relation to the use of medicines, especially with regard to the prevention of unintended harm from the use of drugs; to improve public health and safety in relation to the use of medicines by the provision of reliable, balanced information resulting in more rational use of drugs; and to contribute to the assessment of the risk-benefit profile of medicines, thus encouraging safer and more effective use of medicines and a resolution of the sometimes apparently conflicting interests of public health and individual patient welfare.

In the Zanzibar, post-marketing surveillance is overseen by the MOHSW in collaboration with the ZFDB to which health workers can voluntarily report adverse reactions to drugs to the pharmacovigilance centre.

While spontaneous reporting remains a cornerstone of pharmacovigilance in the regulatory environment, and is indispensable for signal detection, the need for more active surveillance has also become increasingly clear. The ZFDB therefore has a role to play to ensure that medicines in the market of Zanzibar are not only of good quality but also are safe especially as many other issues are also of relevance to the science of pharmacovigilance. eg:

- Substandard medicines
- Medication errors
- Lack of efficacy reports
- Use of medicines for indications that are not approved and for which there is
- inadequate scientific basis
- Case reports of acute and chronic poisoning
- Assessment of drug-related mortality
- Abuse and misuse of medicines
- Adverse interactions of medicines with chemicals, other medicines, and food.

In conclusion, sound drug regulatory arrangements provide the foundation for a national ethos of drug safety, and for public confidence in medicines.

8 REFERENCES

- WHO; Expert Committee on specifications for Pharmaceutical Preparations, Thirty-Fifth Report (1999)
- Zanzibar Food, Drugs and Cosmetic Act, No. 2 of 2006
- WHO; Quality Assurance of Pharmaceuticals - A Compendium of Guidelines and Related Materials - Volume 2: Good Manufacturing Practices and Inspection (WHO, 1999)
- Inspectors Hand book, MOHSW Tanzania mainland
- GPHF Minilab Manuals

9 APPENDICES

ZFDB FORM NO. 1

REVOLUTIONARY GOVERNMENT OF ZANZIBAR

ZANZIBAR FOOD AND DRUGS BOARD

Application for permit to sell, **WHOLE SALE/RETAIL** over the counter medicines **(OTC) under Section 18(b) of Act 02/06.**

I/We …….. of ……..

Postal Address:
……

Do hereby apply for permit to sell by **WHOLESALE/RETAIL** the following over the counter medicines

……

……

……

My shop is located at:
……

Health Personnel (s) who will be dispenser(s) of my OTC is (are):

1. …… (Attach Certificate)
2. ……(Attach Certificate)

Date ……

…… ……

NAME OF APPLICANT SIGNATURE

ZFDB FORM NO. 2

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
ZANZIBAR FOOD AND DRUGS BOARD

APPLICANT FOR RENEWAL OF WHOLESALE/RETAIL DEALER'S LICENCE UNDER SECTION 18 OF THE ACT 2/06

The Registrar,
Zanzibar Food and Drugs Boards,
Ministry of Health and Social Welfare
P.O.BOX 236,
Zanzibar.

I/WE
……

Of…….....

Wishing to carry on a business of a Wholesale/retail dealer in Poison at ……

……

……

Hereby apply for the issue of Wholesale/retail dealer's license.
The registered pharmacist in control of the distribution of Poisons is

……

Resident at ……..…….....

Other Pharmaceutical Staff are:

1 ……}

2 ……} Attach Certificate

…….. ……
Date Signature of applicant

ZFDB FORM NO.3

REVOLUTIONARY GOVERNMENT OF ZANZIBAR
ZANZIBAR FOOD AND DRUGS BOARD

APPLICATIONS FOR REGISTRATIONS OF PREMISES
(SECTION NO 16 OF THE ACT)

The Registrar,
Zanzibar Food and Drugs Board
Ministry of Health and Social Welfare
P.O. Box 236
Zanzibar.

In accordance with the provisions of sections 16 of the Food, Drug and Cosmetics Act 2006.

I/We
……

……

Wishing to carry on a business of a Cosmetics do hereby apply for registration of

Premises situated at ……

……

The retail sale of cosmetics will be under the control of ……

……

…… ……
Date Signature of applicant

ZFDB FORM NO.4

REVOLUTIONARY GOVERNMENT OF ZANZIBAR
ZANZIBAR FOOD AND DRUGS BOARD

APPLICATIONS FOR REGISTRATIONS OF PREMISES
(SECTION NO 16 OF THE ACT)

The Registrar,
Zanzibar Food and Drugs Board
Ministry of Health and Social Welfare
P.O. Box 236
Zanzibar.

In accordance with the provisions of sections 16 of the Food, Drug and Cosmetics Act 2006.

I/We
……

……

Wishing to carry on a business of a Pharmacy do hereby apply for registration of

Premises situated at ……

……

The retail sale of drugs will be under the control of ……

……

Who is registered as Pharmacist. (His registration certificate will be available when required).

…… ……
Date Signature of applicant

ZFDB FORM NO. 9

MINISTRY OF HEALTH AND SOCIAL WELFARE
ZFDB FORM NO.9 UNDER SECTION 61 OF THE ACT 02/06
REJECTION/RETENTION OF PHARMACEUTICAL CONSIGNMENT(S)

Exporter/Manufacturer ……..
Importer/Consignee ……
The inspected consignment (s) as per Proforma Invoice no…… Airway Bill/Import
Declaration Form Number …… dated …….. and the single Bill of Entry
Number ……dated …….. has been
Rejected/retained for the following reasons:- (Tick whichever applicable)

1. Proforma invoice is not approved by the Pharmacy Board ☐
2. 2% FOB is not paid to the Pharmacy Board ☐
3. The product(s) is/are not registered by the Pharmacy Board ☐
4. Consignee is unauthorized dealer of pharmaceuticals ☐
5. Manufacturer of the products is not indicated ☐
6. Description of the item is not clear ☐
7. Manufacturing and or expiring date of products not indicated. ☐
8. The products shelf life is too short/expired ☐
9. Physical quality of the products/ packaging material is poor ☐
10. Storage conditions is poor ☐

……	……	……
Name of Drug Inspector	**Signature**	**Date**

……..	……	……
Full name of consignee /clearing agent	**Signature**	**Date**

ZFDB FORM NO. 10

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
ZANZIBAR FOOD AND DRUGS BOARD FORM NO.10 UNDER SECTION 74 OF ACT 02/06

1.1 PORTS OF ENTRY (POE) INSPECTION, SCREENING AND TESTING FORM

(A rejoinder to SOP for Inspection and testing of Drug at Ports of Entry (POE)

Particulars in this checklist must be scored for every consignment imported into the country:

POE Name ..... POE# ..... Name of Consignee .....

Product particulars

S/N	Product names	S/N	Product names

(A) Summary

1	2	3	4	5
Consignment OR "R" Number	Date &Time inspection started	Date & Time inspection completed	Status; Release/Rejected (indicate as appropriate upon conclusion of the inspection and testing)	Initials or Signature of Inspector

(B) Documentation

1	Instructions	Result /Decision (Tick Y for yes or N for no. Unless otherwise specified. If no write "DETAINED)		
(a)	Does the consignee have Proforma Invoice (P1) and endorsement by the (IC) with the original endorsement by the Pharmacy Board(PB)? If yes proceed to (c) below	Y	N	
(b)	Are the specified product imported from sources indicated in the PI/IC? If yes , proceed to (c) below	Y	N	
(c)	Is the consignment being imported through the declared POE?	Y	N	
	If yes enter the PI and IC numbers and proceed to #2 below:	IP/IC no: Date:		
2.	Is the Clean Report of Findings CRF/Final Classification and Valuation Report (FCRV0/IDF? receipt date within the expiry date of the PI/C? If yes , record the date of receipt and proceed to #3 below.	Y	N	
3.	Are the exporter and importer named in the CRF/Final Classification and Valuation Report (FCVR) the same as those listed in the PI? If yes, proceed to item # below.	Y	N	

! Proforma with be valid for 6 months from date of endorsement by the ZFDB

"[2] DETAINED" Means: (1) stop inspection, (2) complete Rejection /Detention From, (3_ Inform the TRA/C&E of the rejection/detention, (4) give a copy of the TRA, Rejection/Detention from to TRA

"If detention issues are resolved by written instructions from the ZFDB, proceed from where the inspection stopped"

4.	Does the FOB value of the CRF/FCV/IDF MATCH the PI? If yes proceed to item #5 below.	Y	N	
(a)	Do the items description and the quantities for each of the products indicate in the CRF/FCVR MATCH the quantities authorized in the PI? If yes, proceed to item #5 below.	Y	N	If no see 4b and 4c below
(b)	Are the item description and quantities indicated in the CRF GREEATER THAN authorized in the PI? If yes, detain consignment.	Y	N	If no see 4c below
(c)	Are the item description and quantities indicated in the CFR LESS THAN authorized I the PI? If yes, mark the quantities of short landed items on the PI and the word "and proceed to tem # 5 below.	Y	N	
5. Review the Certificate of Analysis (COA) to determine:				
	Is the COA signed and stamped by authorized person(s) If yes, proceed to (b) below:	Y	N	
	Ate the reported test results within specification limits? If yes, proceed to (b) below:	Y	N	
	For products with more than 24 months shelf life do they have 60% of their shelf life remaining? If yes or not applicable, proceed to (d) below.	Y	N	
	For the products with less tan 24 months shelf life, do they have 80% of their shelf life remaining/ If yes, proceed to Section C below for further verification of the consignment.	Y	N	

(C) Physical Examination and Testing

	Is there Certificates Analysis for each batch? If yes, proceed to item#2.	Y	N	
	Does the label show any evidence of tampering/ if not, proceed to #3	Y	N	
	Is the language written on the label and package insert ia Swahili and of English? If the language is correct and package insert is available, proceed to #4.	Y	N	
	Do the expiration dates on the unit samples and the COAs match? If yes, proceed to #5	Y	N	
	Do the batch numbers on the unit examples and the COAs match? If yes , proceed to #6	Y	N	
	Do unit samples collected from each batch, have tamper-proof seals? Are the seals intact? If both are yes, proceed to 7	Y	N	
	Are the samples required for testing? If yes, proceed to Section C items #10-14 of SOP#?	Y	N	If no proceed to section D below to conclude the inspection.

SECTION D: Conclusion

The consignment and tested as required is hereby:		Status (tick as appropriate)	**Remarks (if any)**
1.	Released:		
2.	Rejected:		Reasons for rejection must clearly indicated:

Name of Inspector: …….. ……	Signature ……	Date

ZFDB FORM NO. 11

MINISTRY OF HEALTH AND SOCIAL WELFARE
ZANZIBAR FOOD AND DRUGS BOARD.

CONFISCATED DRUGS FOUND AT THE PREMISE CONTRARY TO THE LAW TAKEN AS EXHIBIT/SAMPLE AS PER SECTION 61 OF FOOD,DRUG AND COSMETIC ACT NO.2 OF 2006)
DATE _____
TIME .....

NAME OF THE PREMISES _____

LIST OF DRUGS CONFISCATED/TAKEN BY INSPECTORS

No.	NAME	UNIT	QUANTITY	No.	NAME	UNIT	QUANTIYT
1.				16			
2.				17			
3.				18			
4.				19			
5.				20			
6.				21			
7.				22			
8.				23			
9.				24			
10.				25			
11.				26			
12.				27			
13.				28			
14.				29			
15.				30			

PARTICULARS

I _____ Owner/In charge of the Premises of the above named premise/dispensary, confirm that the drugs listed have been confiscated/taken by Inspectors
Signature of the Owner/In charge

INSPECTORS NAME **SIGNATURE**

…… ……..
…… ……
…… ……..

ZFDB FORM NO. 12

THE REVULOTIONARY GOVERNMENT OF ZANZIBAR
ZANZIBAR FOOD AND DRUG BOARD FORM NO 12 UNDER SECTION 16 OF THE ACT 2/06

PRE-APPROVAL INSPECTION FORM
INSPECTION OF NEW PREMISES (RETAIL AND WHOLESALE) CHECKLIST

Date ……

REQUIREMENTS

1. Name and Address of Pharmacy:
……
……
……

2. Name of proprietor
……
……
Reg. No. ……..

3. Location:
i) Plot No, House No, street and Town:
……
……
……

ii) The distance from the nearest Pharmacy
……
……
……
……
……

4. Size and number of rooms:
A: For Retail Pharmacy:
i) At least three room (i.e Display and Store)
a) Display room …… Present/Not present
b) Dispensing room …….. Present/Not Present
c) Store room ……Present/Not Present

ii) Utilities ……

B: For Wholesale Pharmacy:

i) Storage area …….. Present/Not Present
ii) Sales Area …….. …..Present/Not Present
iii) Dispatch Area…….. Present/Not Present
iv) Utility Room…….. …..Present/Not Present

5. General condition of Premises:
i) Cleanness ……
ii) Lighting ……
iii) Cooling System……
iv) Floor an Walls……

6. Security of Premises:

a) External:
i) Provision of adequate barriers
ii) Conducive surroundings

b) Barriers to prevent unauthorized access:

C) Internal:
i) Provision of suitable lockable storage of poison

……..……..

ii) Special cupboard for Dangerous Drugs (I\if kept in the premises
……
……..

iii) Shelves……
……

iv) Pallets (Wholesale)
……

7. Equipment: (for retail business)
i) Water supply and hand wash basin/sink
……

ii) Hot plate or any other source of heat
……..

iii) Weight balance and weights
……..

iv) Dispensing measure (measuring cylinders, beakers etc.)
……

v) Source of clean and safe (water filter)
……

vi) Pestle and mortar, spatula and dispensing tray
……..……

vii) Fridge (refrigerator)
……

8. Reference books:

- Extra Pharmacopoeia (Martindale) current Edition Yes/No
- Veterinary Drug Handbook Yes/No
- British National Formulary (BNF) Yes/No
- Tanzania Pharmaceuticals Hand book (THB) Yes/No
- Zanzibar Essential Medicine List and Standard Treatment Guidelines (NEDLIT and STG) Yes/No

- Zanzibar Food and Drug Act and its regulations Yes/No
- Good Dispensing Manual (English /Swahili) Yes/No
- Tanzania National Formulary Yes/No

9. Record Books :
i) Prescription Book (Retail only) …… Present / Absent
ii) Poison book (Wholesale and retail) ……. …….. Present / Absent
iii) Dangerous Drug Book (Whole sale and Retail) ……..…… . Present / Absent

10. Any other observations

……

……

……

11. Recommendations

……

……

Name of Inspectors Signature

…… ……

…… ……

ZFDB FORM NO. 13

REVOLUTIONARY GOVERNMENT OF ZANZIBAR
ZANZIBAR FOOD AND DRUGS BOARD FORM NO.13 UNDER SECTION 16 OF ACT 2/06

Drug Premises Inspection Form

1. General

1.1	Name of Outlet ……						
1.2	Type : (Tick as appropriate):						
	1.2.1	1.2.2	1.2.3	1.2.4	1.2.5	1.2.6	1.2.7
	Warehouse	wholesale	Retail Part I	Retail Part II	Hospital	Health centre	Dispensary
1.3	Mailing Address: …… …… …… ……				1.4	Physical Address/Location:	
1.5	Telephone No. 1.6				Fax No. ……		
1.7	E- mail ……						
1.8	Date of inspection …… ……				1.9	date of last Inspection:	
		1.10.1			1.10.2		
1.10	Ownership	Government/Private/NGO (delete what is not applicable)			(Specify type) …… (In case of private indicate name of owner or		

			proprietor (s)
1.11	Y/N If the owner is not a pharmacist, does he/she have a valid contract with a Registered Pharmacist?		
1.12	Premises Licence No ……	1.13 valid Y/N	1.14 Is the original Licence displayed? Y/N
1.12	If not explain:		

2. . Type of Inspection (Tick as appropriate)

2.1	Routine:		2.2	Concise:		2.3	Follow up:	
2.4	Investigative:		2.5	Announced/Unannounced: (delete what is not applicable)				

3. Personnel

3.1 Responsible Staff

3.1.1	Name:	……
	Qualification:	……
	Position/Title:	……

3.2. 1Sales Person(s):

	3.2.1 Name	3.2.2 Qualifications
1.		
2.		
3.		
4.		

4. General condition of premises

4.1	Is the premise appropriate for the intended purpose in respect to:					
		Ware house	wholesale	Retail PI	Retail II	Hosp/Disp
1	Layout					
2.	Size/Number of rooms					
3.	Hygiene					
4.	State of repair					
5.	Ventilation & Cooling system					

6.	Lighting					
7.	Display of drugs					
8.	Utilities: water, hand wash basins, WC					
4.2	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

5. **Security of premises**

S/N	Is the premises secure in respect to:					
		Ware house	wholesale	Retail PI	Retail II	Hosp/Disp
1.	External Perimeter security e.g fencing, gates, walls, window etc					
2.	Special secure cupboards for restricted drugs e.g. controlled drugs					
3.	Accessibility to unauthorized person(s)					
4.	Documents/records keeping					
5.2	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

6. Storage Conditions

S/N	Is the premises secure in respect to:					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/Disp
1.	Durability of floor and ease of cleaning					
2.	Prevention of infestation by vermin and pests					
3.	Adequate shelving					
4.	Pallets					
5.	Execution of stock rotation/FEFO					
6.	Storage of returned/recalled/expired/quarantined					
7.	Cold rooms/refrigerator for the storage of vaccines and/or biological					
6.2	In case of non-conformity, explain:					

		(If space provided is not enough, please use continuation page(s)

7. Ancillary items

7.1	Are suitable ancillary available for the intended purpose in respect to the follow items:					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/Disp
1.	Hotplate or any other source of heat					
2	Weighing balance(s) and weights					
3.	Dispensing measuring cylinders, beakers etc					
4.	Source of clean and safe water					
5.	Mortar and Pestle, spatula and dispensing tray					
7.2	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

8. Record – keeping and documentation

8.1	Are record keeping and documentation suitable for intended use in respect to:					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/HC/Disp
1.	Prescription Book					
2	Poison Book					
3.	Controlled Drugs Book					
4.	Written procedures for maintenance of cold chain product					
5.	Import Permit					
6.	Ledger Book or an appropriate inventory Control System					
7.	ZFDB endorsed Proforma invoices					
8.	Receipts/Invoices					
9.	Copies of delivery notes					
10.	Accuracy					
11.	Endorsement of					

	entries by authorized person(s)					
12.	Legality of the source(s) of supplies					
13.	Written procedures for handling returned, recalled and/or expired drugs					
14.	Written procedures for dealing with complaints and/or adverse reaction reports					
8.2	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

9. Label examination

9.1	Is the product suitable for intended use in respect to					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/Disp
1.	Language of labels and package inserts					
2	Any signs of tempering					
3.	Labeling requirements					
9.2	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

10. Sample for examination

11 Reference materials

11.1	Are record keeping and documentation suitable for intended use in respect to:					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/HC/Disp
1.	Zanzibar National Formulary (Current Edition)					
2.	Tanzania Pharmaceutical Hand Book					

3.	Standard Treatment Guidelines					
4.	Zanzibar Essential Medicine List					
5.	Current List of Registered Drugs					
6.	Zanzibar Food and Drug Act and its corresponding Regulations & Guidelines					
7.	Good dispensing Manual (Swahili/English Versions)					
8.	British National Formulary					
9.	British Veterinary Codex					
11.2	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

12. Any other Observations

(If space provided is not enough, please use continuation page(s)

13. Recommendations:

(If space provided is not enough, please use continuation page(s)

14. Owner's /In – charge Declaration

1/We ..... in charge/owner of the said premise, certify that, the information and observations made on this sheet during the inspection of the premises to be true and correct.

Signature ……

Date……

15. Names of inspectors: Signature

- ……
- ……
- ……

Date: ……

ZFDB FORM NO. 14

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
ZANZIBAR FOOD AND
DRUGS BOARD FORM 14 UNDER SECTION 102 OF ACT 2/06

SAMPLE RECEIPT FORM

1. Name of Institution/Company (under inspection)

2. Address ……

3. Date of inspection /collecting sample ……..

4. Reason for collection (Indicate analysis needed where possible)……

……

5. Product name and description/Identification(e.g. colour, dosage form etc)
……

6. Size of Lot from which sampled……..

7. Name and address of Manufacturer ……

……..

8. Batch no. ……Manufacturing Date ..……Expiring Date ……..
Place sampled (Port of entry, Manufacturing plant, Wholesale/Retail Pharmacy, Part II
Shop, etc.) ……

9. No. of samples taken (tins, packets, etc.) ……....

……

10. Collectors Identification on Seal ……

11. Name of Representative (s) of the Inspected Establishment.	Signature	Date.
(1). ……	……..	…….
12. Name of Drug Inspector(s)	Signature	Date

(Sampling Officer)

(1) ……	……	…….
(2) ……	……	……

MINISTRY OF HEALTH AND SOCIAL WELFARE
ZANZIBAR FOOD AND DRUG BOARD UNDER SECTION 102 OF ACT 2/06

PHYSICAL EXAMINATION RESULTS FORM **ZFDB NO.15**

This form is a rejoinder to SOP # PBQCL 10 for Physical Examination of Samples of Pharmaceutica Dosage Forms)

Name of Consignee/Facility
……

Consignment # (incase of PoE)
……..

A.Product particulars.

SN	NAME OF PRODUCTS	BATCH NO	SN	NAME OF PRODUCT	BATCH NO

B. Test Results and Observations: Tablets/ Capsules

	Parameter	Specification(s)	Status		Results/ Other observations
			Pass	Fail	
1.	Odour (on immediately on opening the outer and immediate container:	No odour, except for flavored tablets and those with active ingredients normally having characteristic odour.			
2.	Odour (after exposing the tablets according to recommended plan of exposure):	No odour, except for flavored tablets and those with active ingredients normally having characteristic odour.			
3.	Uniformity of size(visual inspection)	Uniform in:size.			
4.	Uniformity of shape:	Uniform in shape.			
5.	Uniformity colour:	Uniform in colour.			
6.	Colour of tablets/capsules in bottle(in case of glass container)	Uniform in colour.			
7.	Uniformity of coating (can be film coated, sugar coated, or enteric coated);	Uniform			
8.	Tablet core fully covered:	Uniform coating with core fully covered.			
9.	Polishing	Uniform polished and free of adhering fine powders			
10.	Markings (scoring, letters etc)	Uniform and identical			

11.	Breaks	Free of breaks			
12.	Cracks	Free of cracks			
13.	Splitting	Free of splitting			
14.	Capping or cavitations	Free of capping or cavitations			
15.	Embedded surface sports or contamination	Free of embedded surface sports and contamination			
16.	Foreign particulate contamination	free from foreign particulate contamination			
17.	Evidence of embedded or adherent foreign matters	Free of any evidence of embedded or adherent foreign matters			

18.	Pinholes	Free of pinholes in capsules			
19.	Presence of empty capsule	Free of empty capsules			
20.	Presence of open or broken capsules	Free of open or broken capsules			
21.	Presence of weak points in body of capsules	Free of weak points			
22.	Capsule not intact; cap separate from body	Capsule intact			
23.	Stickiness	Non-stick			
24.	Container /bottle free of extraneous material	Container /bottle free of extraneous material			
25.	Other (specify)				

C. Test Results and Observations: Solution and Suspension Dosage Forms

1	Parameter	Specification(s)	Status		Results/ Other observations
			Pass	Fail	
2	(a) Particulate matter:	Liquid (syrups and solutions) should be entirely free from foreign particles.			
	(b) clarity	The liquid/solution should be clear and free from turbidity			
	Liquid solutions and pareteral dosage forms				
3		Easily dispersed to obtain a homogenous suspension upon moderate shaking for 20 seconds.			
4		Remain homogenous for at least 3 minutes.			
5		Injected aqueous suspension should flow freely without binding when the contents of vial/ampoule are aspirated through a 22-gauge. 1 inch hypodermic needle, using a suitable volume hypodermic syringe			
6		Non-aqueous injectable suspensions should flow freely without binding when the contents of the vial/ ampoule are aspirated through 18- gauge, 1-11/2 inch hypodermic needle using a suitable volume hypodermic syringe.			
7	State of primary container	Should not show any evidence of cracks, break, tears and leakage.			

D.Conclusion/decision

The sample as visually inspected:	Status	**Remarks (if any)**

		(tick as appropriate)	
1.	Passes:		
2.	Fails:		
Name of Inspector		Signature	Date .....

ZFDB FORM NO. 16

REVOLUTIONARY GOVERNMENT OF ZANZIBAR
ZANZIBAR FOOD AND DRUGS BOARD UNDER SECTION 16 OF ACT 2/06

OTC DRUG INSPECTION FORM

1. General

1.1 Name of Outlet ……

1.2 Type (Tick as appropriate)

Wholesale	retail

1.3 physical Address/Location

……

……

……

1.4 Telephone No. …… Fax No. ……..

1.5 Date of Inspection …… Date of Last Inspection ……

1.6 owner Name …….. E-mail ……..

1.7 Premises License No. ……

2. Type of Inspection

Routine		**Concise**		**Follow- up**	
Special		investigative		Announced/unannounced	

3. Personnel

	Name	**Qualifications**
1.		
2.		
3.		

4. General Condition of Premise

(G =Good; S= Satisfactory= Poor)

	Wholesale	Retail
Hygiene		
Ventilation		
External Environment		
Lighting		
Display of Drugs		
Durability of Floor and ease of cleaning		
Adequate shelving		
Pallets		
Execution of stock ration/FEFO		
Prevention of infestation by vermin and pests		

5. Label Examination

Language of label ((English/Kiswahili)	
Any sign of tempering?	
Labeling requirements	
Is the product suitable for intended use in respect to the above?	

6. Recommendations

7. Owner's/In charge Declaration

I/We …….. in charge/owner of the said premise, certify that, the information and observations made on this sheet during the inspection of the premise to be true and correct.

8. Name of Drug Inspectors **Signature**

- …… ……
- …… ……
- …… ……

Date ……

ZFDB FORM NO. 17

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

THE ZANZIBAR FOOD, DRUGS AND COSMETICS ACT 2/06 (TREATMENT AND DISPOSAL OF UNFIT FOOD) UNDER SECTION 102

SAMPLING NOTIFICATION AND RECEIPT

To ……

Name and address of owner or agent

……..……

……

I …… have this ……..
(Name of Inspector)

day of …… taken/procured/purchased sample of the hereunder detailed product(s) from the premises situated at

…… under powers
Vested in me under Section 102 of the Zanzibar Food, Drugs and Cosmetics Act, 2006 for further examination. If I consider it necessary, will have the same analysed by an Analyst.

Details of the food product(s) sampled

S/N	Brand name	Common Name	Qty or Number	Batch/lot number	Date of manufacture	Expiry date

Date …… Size of sample (quantity or No.)…… Place:……...

…… …… ……
Name of Inspector Signature of Inspector Title of Inspector

…… ……..
……
Address of Inspector Address of Manufacture

……..……
Name and Signature of Owner or Agent

ZFDB FORM NO. 18

REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

To.
Registrar
Zanzibar Food and Drugs Board,
Zanzibar.

RE: APPLICATION FOR IMPORTATION OF PHARMACEUTICALS. UNDER SECTION 74

We …… Situated at

……

Wishing to import pharmaceuticals as per attached Profoma Invoice(s)
No:…….. Date……

Thank you

…… ……
OWNER …….. PHARMACIST INCHARGE

ZFDB FORM NO. 19

MINISTRY OF HEALTH AND SOCIAL WELFARE
THE REVOLUTION GOVERNMENT OF ZANZIBAR

ZANZIBAR FOOD AND DRUG BOARD

CERTIFICATE OF REGISTRATION
(Zanzibar Food and Drug Act .2/2006)
UNDER SECTION 46

Full name:
.....

- I hereby certify that the following is a true extract from the entry in the register relating to the fully registered Pharmacist the details in respect of who are set out below!

REGISTRATION		**DATE OF BIRTH**	**NATIONALITY**	**ADRESS**	**QUALIFICATION**	**PLACE AND DATE OF QUALIFICATION**
NO.	**DATE**					

Date..... .....
REGISTRAR

NOTES (1)This Certificate affords immediate evidence of registration in due course the name of the pharmacist will be published in the list of registered pharmacist published annually by the Board ; and reference should thereafter be made to the current published list for evidence as to continue registration
(2) This certificate is not evidence of the identity of its holder or the named above

ZFDB FORM NO. 20

REVOLUTION GOVERNMENT OF ZANZIBAR
ZANZIBAR FOOD AND DRUG BOARD

APPLICATION FOR REGISTRATION AS PHARMACIST/
PHARM. TECHNICIAN/PHARM ASSIST
(Zanzibar Food and Drug Act .2/2006)
Under Section 46

The registrar,
Zanzibar Food and Drug Board.

Dear Sir.

I.....

Hereby apply for provisional/Full/Temporary as Pharmacist/Pharmaceutical Technician/Assist

My qualifications are:

.....

.....

Place and Date of qualifications.....

.....

Date of Birth.....

Nationality.....

Adress.....

I am enclosing the following certificates/ Diploma/Degree.

Documents:
.....

.....

.....

.....

I hereby declare that documents enclosed are genuine and best of my knowledge, belief and information, there no circumstances that would disqualify for registration.

Date..... .....
Signature

ZFDB FORM NO. 21

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

Application for registration as food importer

Section 36(1) of the Zanzibar Food, Drugs and Cosmetics Act 2/06 and Regulations 123(e)

(To be filled in Quadruplicate)

To: The Registrar
Zanzibar Food and Drugs , Board,
P.O.Box 236,
Zanzibar.

Name of applicant ……

Postal address ……Tel. No. ……..

Physical address ……Street/Village

Plot No. ……..

I /We Hereby apply for registration as food importer for the

year ……

Fees paid Tshs …… Receipt No……..

Date of receipt ……....

…… **……**
Date **Signature of applicant**

Registration of (name) ……..

As food importer for the year ……..is hereby granted.

…….. **……** **……**
Date **Registration No.** **Signature of Registrar and stamp**

ZFDB FORM NO. 22

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE
ZANZIBAR FOOD AND DRUGS BOARD

APPLICATION FOR PERMIT

Section 18(1) of the Zanzibar Food, Drugs and Cosmetics Act, 2006 and

Registrar
Zanzibar Food and Drugs , Board,
P.O.Box 236,
Zanzibar.

PART 1
I/We hereby apply for renewal/a new licence to manufacture, sell, pack, store or distribute the following:
……

1. Name of applicant ……
2. Postal address ……
3. Full names of Partners and/ Director ……..

   ……..

   ……
4. Premises situated at ……..Street/Village

   Plot No. ……
5. Premises registered for a business of ……..
6. Premises Registration No. …….. …… Date: ……
7. Existing Licence No..…… Dated …… Expiring on ……..
8. My/our financial resources committed for this business amount to ……

   and my/our annual projected turnover is Tshs ……..

PART II: APPLICBLE FOR MANUFACTURERS ONLY

PRODUCT REGISTRATION STATUS
I wish to manufacture the following item whose registration status is shown below:

S/N	Common/Generic Name	Trade Name	Registration No.	For official use only

PART III: APPLICANT DECLARATIONS

1. If my /our business is licenced I /We shall keep the premises in hygienic condition and good state of repair as required under the mentioned Act and Regulations made thereunder.

2. I/We have not been convicted of any offence relating to provision of the Zanzibar Food, Drugs and Cosmetics Act, 2006 and Regulations made thereunder within 12 months immediately proceeding this application and have not been disqualified from holding a license/ certificate and my/our license is/is not suspended.

N.B . False declaration constitutes an offence

Date …… **…….**
Signature of applicant and stamp

Fees Tshs……..….. **receipt No. ……. Of ……**

FOR OFFICIAL USE ONLY

License granted/not granted because ……..

……..

License No. ……..

Approved by Management meeting No. ……of ……

……. **…….**
Date **Signature of Registrar and stamp**

ZFDB FORM NO.23

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE
ZANZIBAR FOOD AND DRUGS BOARD

APPLICATION FOR REGISTRATION OF PREMISES

Section 16(2) of the Zanzibar Food, Drugs and Cosmetics Act, 2006 and

Registrar
Zanzibar Food and Drugs , Board,
P.O.Box 236,
Zanzibar.

I /We hereby apply for registration of my/our existing/new premises in accordance with the Zanzibar Food, Drugs and Cosmetics Act, 2006.

1. Name of applicant ……
2. Postal address ……
3. Full name of partners and/Director ……

   ……

   ……
4. Situated at …….. Street/Village Plot No…….
5. Premises to be registered for a business of ……..
6. The business will be under the direct supervision of ……
7. My/ our financial resources committed for this business amount to ……..
   and my/our annual projected turnover is Tshs ……
8. If my/our premise is registered and licenced I/We shall keep it in hygienic condition and good state of repair under the above mentioned Act and Regulations made there under.
9. I /We have not been convicted of any offence relating to provision of the Zanzibar Food, Drugs and Cosmetics Act 2006 and Regulations made thereunder within 12 months immediately proceeding this application and have not been disqualified from holding a licence/certificate and my /our licence is/is not suspended.

N.B. False declaration constitutes an offence
Date …… signed ……

Fees Tshs …… Receipt No …… of ……..

FOR OFFICIAL USE ONLY

Registration granted/not granted because ……

……...

Registration No. …… Approved by Management meeting No. ……

Of ……..
…… ……
Date Signature of Registrar and stamp

ZFDB FORM NO.24

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

THE ZANZIBAR FOOD, DRUGS AND COSMETICS (TRANSPORT OF MEAT) REGULATIONS, 2006.

MEAT MOVEMENT PERMIT

(Regulations 123(d))

Permission is hereby granted to transport meat described below:-

Type ……

Quantity/No. ……

……

From …… to ……

Meat Transport Permit No. ……

Name of Driver ……

Name(s) of Attendant(s)

……

Date and time of departure ……

……

Date of Issue ……

……
Name of Inspector

……
Signature and stamp

……
Date

ZFDB FORM NO. 25

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

THE ZANZIBAR FOOD, DRUGS AND COSMETICS (TRANSPORT OF MEAT) REGULATIONS, 2006.

MEAT TRANSPORT PERMIT

(Regulations 123 (d))

Meat Transport Permit No. ……

Name and address of the owner ……

……

This permit is issued in respect of ……..……...

Description and registration marks of the carrier and container

……

Date of issue ……..

Fees paid ……Receipt No. …… date ……20 …….

This permit expires on the 31st Dec ……

……
Signature of and stamp the Registrar

ZFDB FORM NO. 26

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD
THE ZANZIBAR FOOD, DRUGS AND COSMETICS (TRANSPORT OF MEAT) REGULATIONS, 2006.

APPLICATION FORM FOR LICENCE TO TRANSPORT MEAT
(Regulations 123 (d))

TO: The Registrar
Zanzibar Food and Drugs Board,
P.O.Box 236,
Zanzibar.

I hereby apply for a Licence to Transport Meat under the Zanzibar Food, Drugs and Cosmetics (Transport of Meat) Regulations, 2006.

Name of applicant ……(Name of Person, Firm, Company, etc. to be inserted)

Full names of partners, Directors or Office of Company responsible

for transport of meat ……

Description (Type and Capacity) of carrier ……

Registration No. of carrier ……

Postal Address of applicant ……..

Date …….. Application fees paid ……....

Receipt no …….. Date of Receipt ……

FOR OFFICIAL USE ONLY

Permit is granted/Not granted because ……

……

Permit No. ……..... Approved by Management meeting

No. …… Of ……

…… **……**
Date **Signature and stamp of the Registrar**

ZFDB FORM NO. 27

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

APLICATION FOR PERMISSION TO IMPORT NON-REGISTRABLE FOOD

Section (35) of the Tanzania Food, Drugs and Cosmetics Act, 2006 and Regulation 123 (e)
(To be filled in Quadruplicate)

Name of applicant …..…… Postal address ……

Physical address …….. Street/Village, Plot No. ……..

Tel. No. ……Invoice No. ……..Date ……

I /We hereby apply for permission to import the following non-registrable food item and/or substances used in the preparation/manufacture of food in accordance with the above mentioned Act and Regulations made thereunder:-

Sn	Food item		Quality parameters	Proportion/ percent /level	For official use Only
	Brand name	Common name			

Fees paid Tshs ……..... Receipt No. …… Dated ……

…… ……..……
Date Signature of Applicant

PART B:

Permission is hereby granted/not granted to import items marked approved in the last column above. The importer has to call in the Port ZFDB inspector to examine the approved product(s) for fitness for the intended use before being allowed entry into Zanzibar

…….. ……..
Date Signature of Registrar and stamp

PART C:
I ……being ZFDB inspector at ……ZFDB port office has examined the above listed product(s) and have found them fit/not for the intended use hence allowed/not allowed entry into Tanzania.

……. **……**

Date

Signature of ZFDB port officer and stamp
(The Inspector has to return immediately a Completed copy of this permit together with a copy of a release certificate to the Registrar)

N.B: **This form is for single consignment only.** * **Delete whichever is not applicable**

ZFDB FORM NO. 28

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

APPLICATION FOR PERMISSION TO IMPORT REGISTRABLE PRODUCT(S)

Section 19(3) of the Zanzibar Food, Drugs and Cosmetics Act, 2006 and Regulation 123 (e)
(To be filled in Quadruplicate)

TO: The Registrar
Zanzibar Food and Drugs Board,
P.O.Box 236,
Zanzibar.

PART A:

Name of registered importer ……Registration

No. …… Postal Address ……Tel. No. ……

Exporting Country ……Invoice No. …….. Date ……

Exporting/Sender …….. Postal address ……Arrival expected by

Ship/air/motor vehicle, Via……port of entry

I /we hereby apply for permission to import the following product(s) in accordance with the above mentioned Act and Regulations made thereunder:

s/n.	Product		Registration No.	Quantity Ordered (Litre/kg/no.)	Quantity Delivered(litre/ kg/no.	For official Use only
	Brand name	Common name				

Fees Tshs …… Receipt No. …….. Dated ……

…… ……
Date Signature of applicant and stamp

PART B:
Permission is hereby granted/not granted to import items marked approved/not approved in the last column above. The importer has to call in the Port ZFDB Inspector to examine the approved product(s) for fitness for the intended use before being allowed entry into Zanzibar.

…… ……
Date Signature of Registrar and stamp

PART C:

I…….. …… being ZFDB inspector at…… ……..ZFDB port office has

examined the above listened product(s) and have found them fit/not for the intended use hence allowed/not allowed entry into Tanzania.

.....	.....
Date	Signature of ZFDB port officer and stamp (The Inspector has to return Immediately a completed copy of this Permit together with a copy of a release Certificate to the Registrar

N.B This form is for single consignment only. *Delete whichever is not applicable

ZFDB FORM NO. 29

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

THE ZANZIBAR FOOD, DRUGS AND COSMETICS ACT 2/06 (TREATMENT AND DISPOSAL FOR UNFIT FOOD) UNDER SECTION 33

CERTIFICATE OF COMPULSORY CONDEMNATION OF FOOD STUFF.

(Regulation 123 (V))

PART "A"

S/N	Food article (s)		Qty or No.	Batch NO.	Expiry date	Estimated monetary value	Reasons for unfitness
	Brand name	Common name					

PART "B"

I certify that I have examined the above named food article(s) and am of the opinion that it is/they are unsound and unfit for human consumption due to the reasons started above and hereby recommend that the said food(s) be condemned and destroyed or otherwise disposed of by order of court.

…… ……

Date **signature of Name of Inspector**

PART "C"

I certify that the above named food article(s) has/have being of the opinion that it is/they are unfit for human consumption, hereby condemn it/them and orderit/them to be destroyed/disposed of by:-

……

……

…… …… ……..

Name of Magistrate or Judge **Signature and Stamp** **Date**

PART "D"

I certify that the above named food article(s) has/have been destroyed/disposed of as ordered, under my supervision.

……

……

…… …… ……

Name of Inspector **Signature and stamp** **Date**
Zanzibar

ZFDB FORM NO.30

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

THE ZANZIBAR FOOD, DRUGS AND COSMETICS ACT 2/06 (TREATMENT AND DISPOSAL FOR UNFIT FOOD) UNDER SECTION 33.

SEIZURE CERTIFICATE – B

(Regulation 123 (V))

(To be used where the food article(s) has/have to be left under care of owner or his agent)

To ……
(Name and Address of owner or agent)

……

Whereas I …… have reason to believe that the
(Name of Inspector)

Stock of food article(s) detailed below which is in your possession at the premises situated at ……
Contravenes the provisions of the Zanzibar Food, Drugs and Cosmetics Act, 2006 or Regulations made thereunder. Now, therefore, I hereby seize the Said food article(s) under the provision of section …… Of the said Act, and direct you to keep the said sealed stock in safe custody subject to such orders as may be issued subsequently in relation thereto. Be it known to you that removal or alteration or interference in any way with the said food article(s) without my authority is an offence under section …… of the said.

S/N	Brand name	Common name	Qty or number	Batch Number	Date of manufacture	Expiry date	Reasons for seizure

I hereby further order you to sign your name on this seizure certificate as a declaration of your acknowledgement of receipt of this certificate with the said food article(s) intact as mentioned above.

Date …….. ……
Signature of inspector

Date …….. ……

Signature of owner or agent

ZFDB FORM NO.31

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

THE ZANZIBAR FOOD, DRUGS AND COSMETICS ACT 2/06 (TEATMENT AND DISPOSAL FOR UNFIT FOOD) UNDER SECTION 33.

SEIZURE CERTIFICATE - A

(Regulation 123 (V))

(To be used in case of seizure of food article(s) where the food article(s) are to be removed from the Premises)

To ……
(Name and Address of owner or agent)

……

Whereas I …… have reason to believe that
(Name of Inspector)

The Stock of food article(s) detailed below which is in your possession at the

Premises situated at …….. contravenes the provisions of the Zanzibar Food, drugs and Cosmetics Act, 2006 or the Regulations made thereunder. Now, therefore, I hereby seize the said food article(s) under the

Provisions of section …….. of the said Act.

Details of food article(s) seizes

S/N	Brand name	Common name	Qty or number	Batch Number	Date of manufacture	Expiry date	Reasons for seizure

If you consent to the destruction or disposal of the food articles seized as mentioned above as I direct, you should sign your name to the following voluntary declaration and return the original of this certificate to me.

Date …… **……**

……
Signed Name, Designation and address of Inspector in block letters

I consent to the destruction or disposal of the food article(s) seized and mentioned above

Date …….. **……**
Signature of owner or his agent in possession

ZFDB FORM NO. 32

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

FOOD IMPORTER REGISTRATION CERTIFICATE

Section 19(3) of the Zanzibar Food, Drugs and Cosmetics Act, 2006 and Regulations 123 (e)

M/S. **Of**

Postal address **.....** having

Premises at **.....** Street/Village,

Plot No**. .....** is hereby granted registration

No. **.....** as importer of food or substances to be used in manufacture of food as entered in the importers register under his/her name.

This Certificate expires on **.....**

Issued on **.....**

..... **.....**
Date **Signature of Registrar and stamp**

ZFDB FORM NO. 34

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

REGISTRATION CERTIFICATE OF PREMISES

Section 19(3) of the Zanzibar Food, Drugs and Cosmetics Act, 2006

This is to certify that the premises owned by M/S **……** of ……which is located on Block/Vessel/Truck ……..

……..situated/plying within **……**

……..street, in **……**

Village/Township/Municipality/city, have been registered to be used as ……..

……

…….for preparation/selling /packing/carrying/advertising/storing/manufacturing

of……

……

Subject to the following conditions:-

1. the premises and the manner in which the business is to be conducted must conform with the requirements of the Zanzibar Food, Drugs and Cosmetics Act, 2006 related to premises registration at all times failing of which this certificate shall be suspended or revoked.

2. Any change in the ownership of the registered premises shall automatically invalidate this certificate.

3. this certificate is not transferable to other premises or to any other person.

4. this certificate shall be displayed conspicuously in the registered premises.

……
Date **Signature of Registrar and stamp**

*** N.B: Delete whichever is not applicable**

ZFDB FORM NO. 33

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

PERMIT

ZANZIBAR FOOD AND DRUGS BOARD

(Made under Section 18(3) of the Zanzibar Food, Drugs and Cosmetics Act, 2006)

Licence is hereby granted to M/S. **…….. Of**

P. O. Box **……..** to manufacture/prepare /pack /sell/store/carry/advertise

……

……

At the premises situated at **…….** Street/Village

Plot No. **……** And with Registration **……..**
This licence shall have and continue to have effect from and including the day when it is issued until it ceases

to have effect on **……**

Issue on **……..** Dated **……**

Receipt No. …… Fees paid Tshs
……..

…… **…….**
Date **Signature of Registrar and stamp**

CONDITIONS

1. This licence shall cease to have effect if the prescribed annual fees is not paid on or immediately after the due date.

2. It does mot authorize the holder to operate business in an unregistered premises or during the period of suspension, revocation or cancellation of registration of the premises I n respect of which it was issued.
3. It is not transferable without a written approval of Board.

ZFDB FORM NO. 35

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

COSMETICS IMPORTER REGISTRATION CERTIFICATE

Section 19(3) of the Zanzibar Food, Drugs and Cosmetics Act, 2006 and Regulations 123(e)

M/S. **.....** of

Postal address ..... having

premises at ..... Street/Village,

Plot No.....is hereby granted registration

No. **.....** as importer of Cosmetics or substances to be used in manufacture of Cosmetics as entered in the importers register under his/her name.

This Certificate expires on **.....**

Issued on.....

.....
Date

.....
Signature of Registrar and stamp

FDB FORM NO. 36

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

PERMIT

ZANZIBAR FOOD AND DRUGS BOARD

(Made under Section 18(3) of the Zanzibar Food, Drugs and Cosmetics Act, 2006)

Licence is hereby granted to M/S **……**

Of …….. to manufacture/prepare /pack /sell/store/carry/advertise

……

……

At the premises situated at…….. Street/Village

Plot No…….. And with Registration No. ……...
This licence shall have and continue to have effect from and including the day when it is issued until it ceases

To have effect on **……..**

Issue on **……** Dated……

Receipt No. …… Fees paid Tshs ……..

…….. **…….**
Date **Signature of Registrar and stamp**

CONDITIONS

4. This licence shall cease to have effect if the prescribed annual fees is not paid on or immediately after the due date.

5. It does mot authorize the holder to operate business in an unregistered premises or during the period of suspension, revocation or cancellation of registration of the premises in respect of which it was issued.
6. It is not transferable without a written approval of Board.

ZFDB FORM NO. 37

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

Application for registration as Cosmetics importer

Section 36(1) of the Zanzibar Food, Drugs and Cosmetics Act, 2006 and Regulations 123(e)

(To be filled in Quadruplicate)

To: The Registrar
Zanzibar Food and Drugs , Board,
P.O.Box 236,
Zanzibar.

Name of applicant …….

Postal address ……Tel. No. ……..

Physical address …….Street/Village

Plot No. ……..

I /We Hereby apply for registration as food importer for the

year ……

Fees paid Tshs …… Receipt No……..

Date of receipt ……....

…… **……**
Date **Signature of applicant**

Registration of (name) ……..

As food importer for the year ……..is hereby granted.

…….... **……** **……**
Date **Registration No.** **Signature of Registrar and stamp**

ZFDB FORM NO:38

THE UNITED REPUBLIC OF ZANZIBAR
MINISTRY OF HEALTH
ZANZIBAR FOOD AND DRUGS BOARD
APPLICATION FORM FOR REGISTRATION OF PREPACKAGED FOOD UNDER SECTION 26 OF ACT 2/06

Date: ..... Application Number (for official use only)
.....

1.0 Particulars of product:

1.1 Brand Name: .....
1.2 Common Name: .....
1.3. Product form (Solid, Liquid, etc.,) .....
.....

1.4 Intended use: .....

.....

1.5 Type of packaging material and seals:
.....

1.6 Packaging unit: .....

.....

1.7 Shelf life: .....

.....

1.8 Shelf life (after first opening of container) .....

.....

1.9 Shelf life (after reconstitution, where applicable) .....

.....

1.10 Recommended storage conditions: .....

.....

2.0 Particulars of Applicant

Name: ……

Physical Address: ……..

……

Postal Address: ……..

Telephone:……

Fax No:……

Email:……..

3.0 Particulars of a resident responsible person (for foods to be imported only)

Name: ……..

……..

Physical Address: ……

……..

Postal address ……

Phone: …… Fax: …… Email: ……..

4.0 Manufacturer and qualified person for manufacture of the product

(a) Manufacturer

Name: ……..

Physical Address: ……

……

Postal Address: ……

…. ……

Phone: …….. Fax: …….. E-mail: ……..

(b) Qualified person:

Name: ……

Qualification: ……

……

Address: ……..……..

Phone…….. Fax…… Email……

5. Status of registration of the product in the country of origin, authorization/registration number and date (where applicable and for foods to be imported only).

……..

……..

6. Nutritional information of the product.

…… ……

……..

7. Ingredients used

A. Typical food ingredients

SN	Name	Proportion (% or Ratio)	Purpose

ZFDB FORM NO. 39

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE
ZANZIBAR FOOD AND DRUGS BOARD

FOOD INSPECTION

- Name of establishment
- Location

G/Y/N/B

- Date of inspection
- Starting time of inspection

  - Identify your self and your team
  - State objectives of the Inspection
  - Outline the Inspection procedure
  - Assure management confidentiality
  - Request management collaboration
  - Inspection to be accompanied by Manager or Supervisor
  - Question flow personnel
  - Concentrate on addressing food borne illness risk factors

- Items to look at
  - Premises (General) and cleanliness
  - Equipments
  - Ventilation
  - Water
  - Maintenance
  - Sanitation
  - Pest control

- Personnel Facilities and Hygiene
  - Monitoring and Record keeping
  - Packaging and labeling, No tampering or fraud
  - Product storage – moisture, pests, FEFO
  - Corrective Actions
  - Closing Meeting
- Discuss Findings, especially non-compliances and violations
  - Establish a time line for correction
  - Discuss possible improvement
  - File Report

- Schedule follow up inspection if needed

❖ Observations

❖ Recommendations

Owner's /In – charge Declaration

1/We …… in charge/owner of the said premise, certify that, the information and observations made on this sheet during the inspection of the premises to be true and correct.

Signature …… Date ……

Names of inspectors: Signature

- …… ……
- …… ……..
- …… ……..

Date: ……

…… **……**
Signature of Inspector(s) **Signature of Owner**

ZFDB FORM NO.41

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

FOOD EXPORTER REGISTRATION CERTIFICATE

Section 19(3) of the Zanzibar Food, Drugs and Cosmetics Act, 2006 and Regulations 123 (e)

M/S. **.....** of

Postal address **.....** having

Premises at …….. Street/Village,

Plot No. **.....** is hereby granted registration

No. **.....** as exporter of food or substances to be used in manufacture of food as entered in the exporters register under his/her name.

This Certificate expires on……

Issued on ……

.....
Date

.....
Signature of Registrar and stamp

ZFDB FORM NO. 42

THE REVOLUTIONARY GOVERNMENT OF ZANZIBAR
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD AND DRUGS BOARD

Application for registration as food exporter

Section 36(1) of the Zanzibar Food, Drugs and Cosmetics Act 2/06 and Regulations 123(e)

(To be filled in Quadruplicate)

To: The Registrar
Zanzibar Food and Drugs , Board,
P.O.Box 236,
Zanzibar.

Name of applicant ……

Postal address ……Tel. No. ……..

Physical address ……Street/Village

Plot No. ……..

I /We Hereby apply for registration as food exporter for the

year …….

Fees paid Tshs …… Receipt No……..

Date of receipt ……....

…… **……**
Date **Signature of applicant**

Registration of (name) ……..

As food exporter for the year ……..is hereby granted.

…….... **……** **……**
Date **Registration No.** **Signature of Registrar and stamp**

STANDARD OPERATING PROCEDURES

SOP FOR INSPECTION AT POE

ZANZIBAR FOOD AND DRUG BOARD STANDARD OPERATING PROCEDURE				
TITLE: INSPECTION AND TESTING OF DRUGS AT PORTS OF ENTRY				
SOP NO: ZFDBSOP 01	**SUPERCEDES:**	**DATE OF ISSUE: JAN. 2007**	**EFFECTIVE DATE: JAN. 2007**	**NEXT REVIEW DATE:**

Purpose

The objective of this SOP is to outline the procedure that drug inspectors must follow at ports of entry to conduct inspection and testing of drugs entering the country. The instructions outlined in this SOP refer to the POE Inspection, Screening, and Testing Form.

Scope

This SOP details the procedure for inspection, screening, and testing of drugs at ports of entry before either release for marketing or denial of entry to the country.

Responsibility

The Zanzibar Chief Drug Inspector, drug inspectors, and drug laboratory analysts shall ensure implementation of this SOP.

Accountability

The Zanzibar Chief Drug Inspector is ultimately accountable for drug inspections at POEs.

Distribution of Forms

The Registrar, the Chief Drug Inspector, the drug inspectors, and drug analysts should get copies of the POE Inspection, Screening, and Testing Form. In addition, one copy should be kept in a master file.

References

1. Zanzibar Food and Drug and Cosmetics Act
2. Ministry of Health and Social Welfare, Zanzibar, *Guidelines for Donations* and safe disposal of medicines, medical supplies and equipments (2006)
3. List of Registered Products

Special Instructions

The following forms, which form part and parcel of this SOP, are annexed—

1. POE Inspection, Screening, and Testing Form
2. Rejection/Detention Form
3. Sample Receipt Form

Prepared by:	**Checked by:**	**Approved by:**
Date:	**Date:**	**Date:**

Procedure

The procedure described in this SOP consists of four sections. The sections relate to the POE Inspection, Screening, and Testing Form, which must be used to record results of inspection, screening, and testing of consignment samples at POE. Each section clearly indicates the decision(s) that are to be taken by the drug inspector when consignment(s) fail or pass inspection and testing.

The procedure described in this SOP entails that the drug inspector, at POE, must—

1. Request for and obtain the consignment to be inspected and tested (if necessary) from Tanzania Revenue Authority, Customs and Excise Department (TRA/C&E).

2. Record all the particulars of the consignment on the POE Inspection, Screening, and Testing Form according to the procedures outlined in this SOP.

Section A: Summary

This section summarizes operational details of the inspection, physical screening, and/or testing activities that the drug inspector must record. The following particulars must be recorded—

1. **Consignment or Reference (R) Number**
   The consignment number is a number assigned by TRA/C&E for every consignment entering the country. In TRA/C&E terminology, the number is often referred to as the "R" number. The number can be found in the Customs Control Advise document issued by TRA/C&E. The full declaration number should be recorded, including the date (e.g., R 28569 of 14/06/07). The date is important because the same number

can be used in different years. In case of doubts, the drug inspector should ask the responsible TRA/C&E official for the "R" or consignment number (item #1).

2. **Date and Time Inspection Started**
   In the space provided, the inspector should record the actual date and time the inspection started (item #2).

3. **Date and Time Inspection Completed**
   In the space provided, the inspector should record the date and time the inspection was completed (item #3).

4. **Status of Inspection: Released or Rejected/Detained**
   In the space provided (item # 4), the inspector should record the status of the inspection. This portion of the form is completed after the inspection is concluded. The status of the consignment (in respect to rejection/detention or acceptance of the consignment) can be found in Section D of the form.

5. **Initials or Signature of Inspector**
   The initials or signature of the inspector(s) who performed the inspection must be written in the space provided (item #5).

Section B: Documentation

The objective of Section B of the form is to enable the inspector to verify the particulars of the consignment and make appropriate decisions before proceeding any further with the inspection.

Item # 1: Examination of the Pro Forma Invoice and Import Certificate

Confirm that the consignee has a PI and an IC with the original endorsement by the ZFDB. If the consignee does not have a PI or an IC with the original endorsement by the ZFDB:

1. Stop the inspection
2. Complete the Rejection/Detention Form
3. Inform the TRA/C&E of the detention and give a copy of the form to TRA
4. Give a copy of the form to the consignee

Upon resolution of detention issues and on written instructions from the ZFDB, the inspector will continue with inspection from where she/he had stopped.

If the consignee has a PI or an IC with the original endorsement by the ZFDB , record in the space provided the endorsement date and the number of the PI and proceed to item #2.

Item # 2: Examination of the CRF/FCVR

Obtain from TRA/C&E the original of the Clean Report of Findings/Final Classification Valuation Report. Confirm that the CRF receipt date is within the expiry date of the IC.

If not—

1. Write "No" in the space provided
2. Stop the inspection
3. Complete the Rejection/Detention Form
4. Inform TRA/C&E of the rejection/detention

If the CRF receipt date is within the expiry date of the IC, proceed to item #3.

Item # 3: Verification of Exporter and Consignee

Confirm that the name(s) and address(es) of the exporter and importer named in the CRF and the PI are the same. If not—

1. Stop the inspection
2. Complete the Rejection/Detention Form
3. Inform TRA/C&E of the rejection/detention

If the name(s) and address(es) of the exporter and importer named in the CRF and the PI are the same, proceed to item #4.

Item # 4: Verification of Drug Names and Quantities

Confirm that the quantities for each of the products indicated in the CRF match the quantities in the endorsed PI.

If the quantities indicated in the CRF are greater than amounts authorized in the PI:

1. Complete the Rejection/Detention Form
2. Inform TRA/C&E of the rejection/detention and give a copy of the form to TRA

If the quantities indicated in the CRF are less than the amounts authorized in the PI, mark the quantities of short-landed products on the endorsed PI and add the words "partial shipment" and proceed to item #5.

Item # 5: Determination of Acceptable Shelf Life

Review the Certificate of Analysis (COA) to determine—

1. If the COA has been signed and stamped by the authorized person(s)
2. If the reported test results are within specification limits
3. If products with more than 24 months of shelf life have 60 percent of their shelf life remaining
4. If products with less than 24 months of shelf life have 80 percent of their shelf life remaining

If the answer to any of the above is "No"—

1. Stop inspection
2. Complete the Rejection/Detention Form
3. Inform the TRA/C&E of the rejection/detention and give the TRA a copy of the form

If the answer to all of the above is yes, proceed to Section C.

Section C: Physical Examination and Testing

Sort products in the consignment by product type. For example, the consignment may consist of five products: Paracetamol tablets, artesunate tablets, quinine sulfate tablets, quinine hydrochloride tablets, and Sulfadoxine/pyrimethamine (SP).

Sort the products by batch numbers.

Verify the presence of Certificates of Analysis for each batch.

If any of the batch(es) does not have a COA—

1. Stop the inspection
2. Complete the Rejection/Detention Form
3. Inform TRA/C&E of the rejection/detention and give the TRA a copy of the form

If COA is available for all the batches, proceed to item #4.

Take a sample from each batch.

Carefully examine the labelling to ensure it complies with legal requirements. Check if—

1. Entire label or parts thereof have been cut off
2. New labels have been pasted over old ones
3. Label details were erased or painted over and replaced with new details
4. No labels on primary container (a primary container is a packing material such as a tin or a bottle that is in direct contact with the medicine)
5. No labels on secondary containers (a secondary container is a packing material that encloses a number of primary containers)
6. The label does not bear the name and address of the manufacturer

If the label shows any evidence of tampering—

1. Stop the inspection
2. Complete the Rejection/Detention Form
3. Inform the TRA/C&E of the rejection/detention and give the TRA a copy of the form

If the labels meet the requirements, proceed to item #6.

Verify that the language written on labels and package inserts is Swahili and/or English.

If the language is not correct or package inserts are not available—

1. Stop the inspection
2. Complete the Rejection/Detention Form
3. Inform the TRA/C&E of the rejection/detention and give the TRA a copy of the form

If the language is correct and the package inserts are available, proceed to item #7.

Verify that batch numbers on the COAs match the batch numbers on the unit samples.

If any of the batch numbers on the COAs do not match the batch numbers on the unit samples:

1. Stop the inspection
2. Complete the Rejection/Detention Form
3. Inform the TRA/C&E of the rejection/detention and give the TRA a copy of the form

If the batch numbers do match, proceed to item #8.

Verify the expiration date on the unit samples and the corresponding COAs.

If any of the unit samples' expiration dates do not match with those on the COAs—

1. Stop the inspection
2. Complete the Rejection/Detention Form
3. Inform the TRA/C&E of the rejection/detention and give the TRA a copy of the form

If the dates match, proceed to item #9.

From the sample collected from each batch, verify if the samples have intact tamper-proof seals. If not:

1. Stop the inspection

2. Complete the Rejection/Detention Form
3. Inform the TRA/C&E of the rejection/detention and give the TRA a copy of the form

If yes, proceed to item #10.

Perform physical examination of the sample(s) in accordance with SOP #?

If the samples are satisfactory and testing is required, proceed to item #11. If samples are not required for testing, proceed to Section D to conclude the inspection.

For each sample required for testing, collect the minimum sample quantities indicated in Table 1. To determine the number of unopened unit pack(s) for testing, see Table 2.

Table 1. Sampling Plan

Dosage Form	**Minimum Sample Size to Be Taken from Each Batch for Testing**
Tablets/capsules	100 tablets/capsules
Suppositories/ovules	20 suppositories/ovules
Powders/sachets	20 packets/sachets
Injectables (ampules)	20 ampules
Injectables (vials)	20 vials
Eyedrops	6 bottles
Syrups	6 bottles
IV fluids	6 bottles

Table 2. An Example of Sample Size Determination (Based on Table 1: Sampling Plan)

1	2	3	4	5	6
	Description	**Batch No.**	**Unit Pack**	**Quantity**	**Number of Units to Be Collected**
1	Quinine sulfate tablets	020717F	T/1,000	10,000	1 × 1,000
2	Artenusate tablets	BF86	P/12	3,000	9 × 12
3	SP	U7MW3	P/2 × 20	10,000	3 P/2 × 20

Complete a Sample Receipt Form (SRF) for each sample collected.

Assign and mark each sample collected with a number from the respective Sample Receipt Form. The following sample numbering system is recommended—date, month, year, region abbreviation, number of

inspection. Example sample number: 150507PBA1 = Inspection number 1 conducted in the PEMBA Region on 15 May 2007.

Inspection Site Abbreviation	Inspection Site

Test the samples according to the surveillance program's SOPs (see SOPs SPD #02-00). If the sample must be sent to the TFDA at the DQCL, pack and ship it according to the packing and shipping SOP (see SOP #?).

Section D: Conclusion

This section of the form requires the inspector to reject or accept the consignment. Mark, as appropriate, the rejection or acceptance decision in the space provided on the inspection form and include remarks (if any).

If the consignment is accepted, all supporting documents relating to the released shipment must be stamped "APPROVED FOR RELEASE."

If the consignment is rejected, it must be detained in the safe custody of TRA/C&E and disposed of in the manner and conditions specified in the *Guidelines for donations and disposal of unwanted Pharmaceuticals,*

> To conclude the inspection and testing, the inspector must sign and date the inspection form as appropriate. Then the inspector must fill in the summary in Section A, indicating the date and time the inspection was concluded, the status of the inspection, and the initials or signature of the inspector.

To keep a record of the actions and decisions taken and compliance to the SOP during inspection, the SOP has been translated into a form that the inspector must fill out appropriately.

SOP for Physical Examination of Pharmaceutical Products

ZANZIBAR FOOD AND DRUG BOARD STANDARD OPERATING PROCEDURE				
TITLE: PHYSICAL EXAMINATION PROCEDURES FOR PHARMACEUTICAL PRODUCTS				
SOP NO: ZFDB QCL 10	**SUPERSEDES: None**	**DATE OF ISSUE:**	**EFFECTIVE DATE:**	**NEXT REVIEW DATE:**

Objective

The objective of this standard operating procedure (SOP) is to outline the procedure and instructions that drug inspectors have to follow when examining physical attributes of sample(s) of pharmaceutical products.

Scope

This SOP details the procedure for physical examination of pharmaceutical products during inspection at port of entry and post-marketing surveillance.

Responsibility

The Registrar, the Chief Drug Inspector, the drug inspectors, and the drug laboratory analysts shall ensure implementation of this SOP.

Accountability

The Chief Drug Inspector is accountable for the final results.

Distribution

The Registrar, the Chief Drug Inspector, the Drug Inspectors, and the Drug Analysts. Copies of forms must also be kept in a master file.

References

1. Physical Examination Glossary
2. *GPHF Minilab Manual*
3. *WHO Screening Manual*
4. List of Registered Products
5. *Drug Defect Reference Manual*

Special Instructions

The following forms, which form part and parcel of this SOP, are annexed—

1. Physical Examination Results Form
2. POE Inspection, Screening, and Testing Form
3. Rejection/Detention Form
4. Sample Receipt Form
5. Confiscation/Quarantine Form

Procedure

The procedure and instructions given in this SOP relate to Physical Examination Results Form which must be used to record results of physical examination of the samples so examined. A pass or fail result has to be captured in this form and accordingly the overall result transferred to Section D of the POE Inspection, Screening and Testing Form. For postmarketing surveillance, the overall assessment should be recorded under Section C, Conclusion/Decision.

Section A: Provides instructions for physical examination of tablets and capsules.

Section B: Outlines the procedure and instructions for physical examination of liquid and semisolid dosage forms and injectable/parenteral dosage forms.

Section C: Captures the conclusion or the final decision after the physical examination of the sample.

Section A: Physical Examination of Tablet/Capsule Sample

The drug inspector should make sure that the particulars of the tablet/capsule sample have been recorded on the SRF.

Tests to Be Conducted

The following tests should be conducted and their results and/or observations recorded on the Physical Examination Results Form.

Odor of the Tablet/Capsule Sample

Determine the odor of the tablet/capsule samples in the following way—

1. Remove/open the container seal (at room temperature and in a room that is free from drafts) and smell the odor of the opened container.
2. Remove any cotton wool or fillers (if present) before tearing open (if any) the immediate container[1] before smelling the odor again.
3. Expose the tablets/capsules according to the following chart.
4. After exposure to the air at room temperature (in a room that is free from drafts for the duration indicated in the above chart), the contents of a freshly opened container should be odorless.
5. Record the results of this test appropriately in the Test Result Record Form.

Other Physical Characteristics of the Tablet/Capsule Sample

To determine other characteristics of the tablet/capsule samples, the inspector should—

1. Take a sample of the tablets/capsules for visual inspection. Wear surgical gloves to avoid handling the sample with bare hands.
2. Use a spatula, spoon, or a tablet/capsule counter to obtain a sample of the tablets/capsules from the original container.
3. Draw 5 to 25 tablets and place the tablets on a piece of white paper.
4. Examine one side of the tablet/capsule in ordinary room daylight.
5. With the help of the spatula, turn the tablet/capsule and examine the other side.
6. Record observations of this test appropriately on the Test Physical Examination Results Form.

Note the following—

1. **Uniformity of Size:** the tablets/capsules should be uniform in size
2. **Uniformity of Shape:** the tablets/capsules should be uniform in shape
3. **Uniformity of Colour:** the tablets/capsules should be uniform in colour.

[1] Some containers have plastic bags as their immediate containers, which have to be torn to smell the odor.

4. **Colour of tablets/capsules in the container/bottle** (in case of glass container/bottle): should be uniform in colour.

5. **Coating** (tablets only: can be film-coated, sugar-coated, or enteric-coated): the coating should be uniform.
6. **Markings** (scoring, letters, etc): markings should be uniform and identical

7. **Breaks:** the tablets/capsules should be free of breaks

8. **Cracks:** the tablets/capsules should be free of cracks

9. **Embedded surface spots** or contamination: the tablets/capsules should be free of embedded surface spots and contamination

10. **Contamination with foreign particles:** the tablets/capsules should be free from foreign particulate contamination

11. **Splitting:** the tablets/capsules should be free of splits

12. **Pinholes:** the tablets/capsules should be free of pinholes

13. **Presence of empty capsules** in the case of a sample of capsules: the sample examined should be free of empty capsules

14. **Presence of open or broken capsules:** the sample examined should be free of open or broken capsules

15. **Presence of weak point in body of capsule:** the sample capsules should not show any evidence of weak points in the body

16. **Are the capsule's cap and body separated?:** the capsules in the sample should be intact

17. **Capping or cavitations of tablets/capsules:** the tablets/capsules should be free of capping or cavitations

18. **Coating** (sugar-coated or film-coated tablets): the tablets should have a uniform coating, with the base of the tablets fully covered

19. **Polishing:** the tablets/capsules should be uniformly polished and free of powders

20. **Stickiness:** the tablets/capsules should be nonsticking

21. **Evidence of embedded or adherent foreign matters:** the tablets/capsules should be free of embedded or adherent foreign matters

Section B: Physical Examination of Solution and Suspension Dosage Forms

This section outlines the procedure and instructions for examining physical characteristics of liquid, parenteral, and injectable suspension dosage forms. The section is divided into the following subsections—

1. Liquid and parenteral dosage forms
    a) Particulate matter
    b) Clarity of liquid/solution (including parenterals/injectables)

2. Suspension dosage forms
    a) Flowability
    b) Uniformity/homogeneity/redisperseability of suspensions

3. State of primary containers

Liquid and Parenteral Dosage Forms

Particulate Matter

Method
Invert the container several times or swirl gently. Do not agitate, as agitation will incorporate air into the liquid/solution.

Inference
Liquids (syrups and solutions) should be entirely free from visible foreign particles. Foreign matter (solid particles) is usually irregular in shape and will tend to settle to the bottom of the container, whereas lint or threadlike particles may float in the liquid. In contrast, fine air bubbles, which may be seen moving on the surface of the solution, may be spherical or oval.

Clarity of Liquid/Solution (Including Parenterals/Injectables)

Method
Without disturbing the container, examine the container (preferably against a black background) under ordinary light.

Inference
The liquid/solution should be clear and free from turbidity.

Suspension Dosage Forms

Uniformity/Homogeneity/Redisperseability of Suspensions

Method
For dry powders for reconstitution, reconstitute as directed by the manufacturer. Gently shake the container to obtain a uniform suspension.

Inference
The suspension is easily dispersed. A homogeneous suspension that remains homogeneous for at least three minutes should be obtained.

For injectable suspensions:

- Suspensions in aqueous vehicles, after shaking as above, should flow freely without binding when the contents of the vial are aspirated through a 22-gauge, 1-inch hypodermic needle, using a hypodermic syringe with a suitable volume.

- Suspensions in non aqueous vehicles, after shaking as above, should flow freely without binding when the contents of the final containers are aspirated through an 18-gauge, 1.5-inch hypodermic needle using a hypodermic syringe with a suitable volume.

State of Primary Containers

Method
Physically examine each of the sample primary containers for evidence of damage such as cracks, breaks, tears, or leakage.

Inference
Primary container should not show any evidence of cracks, breaks, tears, or leakage.

Section C: Conclusion/Decision

Fill in the results of the tests described above in the space provided in this section.

1. If the sample passes the physical tests:

    a. In case of POE, continue to SOP #?

    b. In case of antimalarials, for which a sample must be taken for further testing, refer to SOP #?

2. If the sample fails the physical tests:

    a. In case of POE, reject the consignment and fill in Section D of the POE Inspection, Screening, and Testing Form.

b. In case of postmarketing surveillance:

- Collect samples for further testing according to SOP # and quarantine the remaining part of the batch(es) by filling in the Confiscation/Quarantine Form.
- The quarantined products should be detained until the DQCL completes the evaluation.

To keep a record of the actions and decisions taken and compliance to the SOP during inspection, the SOP above has been translated into a form, which the inspector must fill in appropriately.

SOP FOR DISPENSING OUTLETS INSPECTION

ZANZIBAR FOOD AND DRUG BOARD- INSPECTION DEPARTMENT STANDARD OPERATING PROCEDURE				
TITLE: DISPENSING OUTLETS INSPECTION				
SOP NO: ZFDBINS 03	**SUPERSEDES:**	**DATE OF ISSUE:**	**EFFECTIVE DATE:**	**NEXT REVIEW DATE:**

Objective

The purpose of this standard operating procedure (SOP) is to outline the procedures drug inspectors must follow when undertaking inspection of dispensing outlets. Dispensing outlets in this context include, but are not limited to, pharmaceutical warehouses, wholesalers (including the Central Medical Stores), pharmacy (part I drug) shops, part II drug shops, referral and cottage hospitals, Primacy health care centres, and Primary health care units.

Scope

This SOP details the procedures for conducting inspection of the above-cited outlets. The SOP covers the following areas: general particulars of the premises, type of inspection being conducted, personnel, general condition of the premises, security of premises, storage conditions, availability of ancillary items, record-keeping and documentation, product labeling examination, sample collection for further testing, reference materials available at the premises, any other relevant observations made by the inspectors, recommendations made by the inspectors, owners/officer in charge of premises, declaration/acceptance of findings, and observations of inspectors and the name(s) and signature(s) of inspector(s) who conducted the inspection. Inspection findings and observations must be recorded in the Drug Premises Inspection Form.

Responsibility

The Registrar, the Chief Drug Inspector, Department, the drug inspectors, and the drug laboratory analysts shall ensure implementation of this SOP.

Accountability

The Chief Drug Inspector is accountable for the implementation of this SOP.

Distribution

The Registrar, the Chief Drug Inspector, the Head of the Drug Registration Department, the Head of the Drug Quality Control Laboratory, the drug inspectors, and the drug laboratory analysts.

References

1. WHO Inspection Guidelines
2. Recognizing Counterfeit Drugs, WHO
3. Physical Examination Glossary
4. *GPHF Minilab Manuals*
5. List of Registered Products
6. *Drug Defect Reference Manual*

Special Instructions

The following forms, which form part and parcel of this SOP, are annexed—

1. Drug Inspection Premises Form
2. Sample Receipt Form
3. Confiscation/Quarantine Form

Procedure

Section A: Preparation

Inspectors must prepare themselves for the inspection by collecting all the necessary tools needed to conduct the inspection judiciously and thoroughly. Preparation for inspection of the premises should include an introduction to the person in charge.

Section B: Introduction to Person in Charge of Premises

Upon reaching the premises where the inspection is to take place, the inspection must begin with the introduction of the inspector(s) to the person in charge of or responsible for the premises. Inspector(s) must present their credentials and a notice describing the purpose of the inspection to the individual in charge.

Section C: Conducting the Inspection

Inspectors should conduct the inspection systematically using the Drug Inspection Form (PB Form 03) as a checklist and accordingly record their findings and observations.

General Particulars of the Outlet

1.1 This subsection requires the inspector to write the name of the outlet in the space provided.

1.2 This subsection requires the inspector to mark as appropriate the type of outlet being inspected. The following types of outlets are listed on the form:

1.2.1 Warehouse
1.2.2 Wholesale
1.2.3 Retail part I
1.2.4 Retail part II
1.2.5 Hospital
1.2.6 Cottage
1.2.7 Primary Health Care Centre
1.2.8 Primary Health Care Unit

1.3 This subsection requires writing the mailing address of the outlet in the space provided.

1.4 This subsection requires the inspector to write the physical location/address of the outlet in the space provided.

1.5 This subsection requires the inspector to write the telephone number of the outlet in the space provided.

1.6 This subsection requires the inspector to write the fax number of the outlet in the space provided.

1.7 This subsection requires the inspector to write the e-mail address of the outlet in the space provided.

1.8 This subsection requires the inspector to write the date of inspection of the outlet in the space provided.

1.9 This subsection requires the inspector to write the date of the last inspection of the outlet in the space provided.

1.10 This subsection requires the inspector to write the ownership of the outlet in the space provided. The following are ownership categories to choose from:

1.10.1 Government/private/NGO (delete what is not applicable)
1.10.2 Other (specify): Inspectors should specify any other type in the space provided and, for private outlets, indicate the name of the owner.

1.11 This subsection requires the inspector to ascertain and accordingly indicate Y (for Yes) or N (for No), depending on whether the owner is a pharmacist or has a valid contract with a registered pharmacist.

1.12 This subsection requires the inspector to record the license number of the premise in the space provided.

1.13 This subsection requires the inspector to ascertain the validity of the license and accordingly mark Y (for Yes if the certificate is valid) or N (for No if not valid).

1.14 This subsection requires the inspector to mark Y (for Yes if the original license if displayed on the premises) or N (for No if it is not displayed).

1.15 This subsection requires the inspector to explain briefly in the space provided the reasons for the original license not being displayed on the premises.

Types of Inspection

This section requires the inspector to mark, alongside the appropriate box, the type of inspection being conducted. The following types of inspection are listed:

2.1. Routine
2.2 Concise
2.3 Follow-up
2.4 Special
2.5 Investigative
2.6 Announced or Unannounced

Definitions of these categories/types of inspection are given in the glossary list.

Personnel

This section requires the inspector to ascertain and collect information on the status and quality of personnel at the facility being inspected. The inspector should ascertain and record the following particulars:

2.1 For the person responsible/in-charge of the premises

2.1.1 Name
2.1.2 Qualification
2.1.3 Position or title
2.1.4 Registration number (if he/she is a pharmacist)
2.1.5 Status of his/her Certificate of Registration. The inspector is required to indicate the validity of the Certificate of Registration by marking Y (for Yes) or N (for No) in the space provided on the form.
2.1.6 Display of his/her Certificate of Registration. The inspector is required to marking Y (for Yes) if the certificate is conspicuously

displayed or N (for No) if the certificate is not conspicuously displayed.

2.2 For sales staff

2.2.1 Name
2.2.2 Qualification(s)

General Condition of the Premises

Inspectors should be familiar with the requirements/standards set out by the Pharmacy Board in respect to:

- Warehouses for the storage of pharmaceuticals
- Wholesale outlets
- Retail outlets (Part I)
- Retail outlets (Part II)
- Hospitals/Health centers/Dispensaries

3.1 This section requires the inspector to ascertain and record the appropriateness of the premises for the intended purpose in respect to:

3.1.1. Layout
3.1.2. Size/number of rooms
3.1.3. Hygiene
3.1.4. State of repair
3.1.5. Ventilation and cooling system
3.1.6. Lighting
3.1.7. Display of drugs
3.1.8. Utilities: water, handwash basins, WC

3.2 In case of nonconformity to any of the above, explain in the space provided on the form. If the space provided on this form is not enough, use the separate continuation pages that are attached to the form.

Security of Premises

4.1 This section requires the inspector to ascertain and record the security of the premises in respect to:

4.1.1 External perimeter security structures (e.g., fencing, gates, walls, windows, etc.)
4.1.2 Special secure cupboards for restricted drugs (i.e., controlled drugs)
4.1.3 Accessibility to unauthorized person(s)
4.1.4 Documents/record-keeping
4.1.5 In case of nonconformity to any of the above, to explain in the space provided on the form. If the space provided on this form is

not enough, use the separate continuation pages that are attached to the form.

Storage Conditions

5.1 This section requires the inspector to ascertain and record the suitability of the storage conditions for the intended purpose in respect to:

1. Durability of floor and ease of cleaning
2. Prevention of infestation by vermin and pests
3. Adequate shelving
4. Pallets
5. Execution of stock rotation on the basis of first expiry, first out (FEFO)
6. Storage of returned/recalled/expired/quarantined goods
7. Availability and appropriateness of cold rooms or refrigerators for the storage of vaccines and/or biologicals

5.2 In case of nonconformity to any of the above, explain in the space provided on the form. If the space provided in this form is not enough, use the separate continuation pages that are attached to the form.

Ancillary Items

3.1 This section requires the inspector to ascertain and record the availability and suitability of ancillary items for the intended purpose in respect to the following items:

6.1.1. Hot plate(s) or any other sources of heat
6.1.2. Weighing balance(s) and weights
6.1.3. Dispensing measures (e.g., measuring cylinders, beakers)
6.1.4. Source of clean and safe water
6.1.5. Mortar and pestle, spatula and dispensing tray

3.2 In case of nonconformity to any of the above, explain in the space provided on the form. If the space provided on this form is not enough, use the separate continuation pages that are attached to the form.

Record-Keeping and Documentation

3.1 This section requires the inspector to ascertain and record the suitability of record-keeping and documentation for intended use in respect to:

7.1.1. Prescription book
7.1.2. Poison book
7.1.3. Controlled drugs book
7.1.4. Written procedures for maintenance of cold-chain product
7.1.5. Import permit(s)
7.1.6. Ledger book or an appropriate inventory control system
7.1.7. PB-endorsed Pro Forma Invoices
7.1.8. Receipts/invoices

7.1.9. Copies of delivery notes
7.1.10. Accuracy
7.1.11. Endorsement of entries by authorized person(s)
7.1.12. Legality of the source(s) of supplies
7.1.13. Written procedures for handling returned, recalled, and/or expired drugs
7.1.14. Written procedures for dealing with complaints and/or adverse reaction reports

3.2 In case of nonconformity to any of the above, explain in the space provided on the form. If the space provided in this form is not enough, use the separate continuation pages that are attached to the form.

Label Examination

8.1 This section requires the inspector to ascertain and record the suitability of the products stored in the facility for intended use in respect to:

8.1.1. Language of labels and package inserts
8.1.2. Any signs of tampering
8.1.3 Labeling requirements

8.2 In case of nonconformity to any of the above, explain in the space provided on the form. If the space provided in this form is not enough, use the separate continuation pages that are attached to the form.

Sample for Examination

This section requires the inspector, to take samples of suspicious drugs for screening and testing in accordance with PMSP 02-00 or PMSP 02-01.

Reference Materials

This section requires the inspector to record any other observations in the space provided in the form. If the space provided in this form is not enough, use the separate continuation pages that are attached to the form.

11.1 This section requires the inspector to ascertain and record the availability and appropriate reference material(s) kept at the facility in respect to the following basic required material(s):

1. Zanzibar or *Tanzania National Formulary* (current edition)
2. *Tanzania Pharmaceutical Handbook*
3. Standard treatment guidelines
4. Zanzibar essential medicines list
5. Current list of registered drugs
6. Zanzibar Food and Drug Act and its corresponding regulations and guidelines

7. *Good Dispensing Manual* (Swahili/English versions)
8. *British National Formulary*
9. *British Veterinary Codex*

And any other relevant documents as required by the ZFDB

11.2 In case of nonconformity to any of the above, explain in the space provided on the form. If the space provided in this form is not enough, use the separate continuation pages that are attached to the form.

Recommendations

This section requires the inspector to make recommendations based on the findings of the inspection. The recommendation should be written in the space provided on the form. If the space provided in this form is not enough, use the separate continuation pages that are attached to the form.

Owners/Person in Charge Declaration

This section requires the inspector to give a copy of his/her declaration of acceptance of findings and other observations to the owner or person in-charge. The owner or the person in-charge of the premises should write his/her name in the space provided and sign and date the declaration.

Name and Signature of Inspector(s)

This section requires the inspector to testify that the findings and other observations they made are correct by writing his/her name in the space provided and sign and date the inspection form to conclude the inspection.

Post-inspection Procedures

This section requires the inspector to write and submit an inspection report to the Zanzibar Chief Inspector and the Registrar of the ZFDB after inspection of premises.

SOP FOR SUSPICIOUS SAMPLE SURVEILLANCE PROGRAM

ZANZIBAR FOOD AND DRUG BOARD STANDARD OPERATING PROCEDURE				
TITLE: SUSPICIOUS SAMPLE SURVEILLANCE PROGRAM				
Surveillance Program No.: 02-00	**SUPERSEDES:**	**DATE OF ISSUE:**	**EFFECTIVE DATE:**	**NEXT REVIEW DATE:**

Objective
The objective of this standard operating procedure is to outline the procedure drug inspectors must follow to collect samples that appear suspicious.

Scope
This SOP details the procedures for inspectors to collect suspicious samples at any point in the distribution system. If possible, collected samples should be in unopened containers and within their expiry date.

Responsibility
The Registrar, the Chief Drug Inspector, the drug inspectors, and the drug laboratory analysts shall ensure implementation of this SOP.

Accountability
The Chief Drug Inspector is accountable for the implementation of this SOP.

Distribution
The Registrar, the Chief Drug Inspector, the drug inspectors, and the drug laboratory analysts.

References

1. Recognizing Counterfeit Drugs, WHO
2. Physical Examination Glossary
3. *GPHF Minilab Manuals*
5. *WHO Screening Manual*
6. List of Registered Products
7. *Drug Defect Reference Manual*

Special Instructions

The following forms, which form part and parcel of this SOP, are annexed—

1. Physical Examination Results Form
2. Sample Screening Tests Form
3. Sample Receipt Form
4. Confiscation/Quarantine Form

Procedure

The procedure described in this SOP entails that the drug inspector should collect and screen by GPHF minilab procedures (if possible) all suspicious samples. Samples that require further testing should be sent to the QCL in the Mainland. For each suspicious sample to be sent for further testing, collect sample(s) as indicated in Table 4 below. If these amounts are not available, collect what is available.

Table 4: Preferred Sample Size from Each Batch

Dosage Form	Preferred Sample Size from Each Batch
Tablets/capsules	100 tablets/capsules
Suppositories/ovules	20 suppositories/ovules
Powders/sachets	20 packets/sachets
Injectables (ampoules)	20 ampoules
Injectable (vials)	20 vials
Eye drops	6 bottles
Syrups	6 bottles
IV Fluids	6 bottles

To determine the number of unopened unit pack(s) for testing, see Table 5 below.

Table 5: Sample Size Determination (Based on Sampling Plan Shown in Table 1)

Description	Batch No.	Unit Pack	Number of Units to Be Collected
Aspirin Tablets	020717F	T/1,000	1 × 1,000s
Clotrimazole Pess	BF86	P/6	4 × P/6
Dextrose IV Solution	U7MW3	B/24 × 500 mL	6 × 500 mL

1. Complete a Sample Receipt Form (SRF) for each sample collected.

2. Explain details of the sample on the continuation page of the SRF.

3. Assign and mark each sample with a number from their respective SRF. The following sample numbering system is recommended: Date, month, year, region abbreviation, inspection number (REG sequence number); for example, 150507ZIA1 = Inspection number 1 conducted at the Zanzibar Airport on May 15, 2007.

Inspection Site Abbreviation	**Inspection Site**
ZNZN	Zanzibar North Region
ZNZS	Zanzibar South
ZIA	Zanzibar Airport
ZNZH	Zanzibar Harbour

Samples that require further testing should be sent to the DQCL in accordance with the SOP Chain of Custody, packaging, and shipping.

SOP FOR CHAIN OF CUSTODY, PACKING AND SHIPPING PROCEDURES

ZANZIBAR FOOD AND DRUG BOARD STANDARD OPERATING PROCEDURE				
TITLE: CHAIN OF CUSTODY, PACKING AND SHIPPING PROCEDURES				
SOP NO.: **TBD**	**SUPERSEDES:**	**DATE OF ISSUE:**	**EFFECTIVE DATE:**	**NEXT REVIEW DATE:**

Objective

The objective of this standard operating procedure (SOP) is to describe the procedures drug inspectors must follow to establish Chain of Custody and to package and ship samples to official examination points.

Scope

This SOP details the procedures for inspectors on how to maintain a Chain of Custody system and how to package and ship all types of samples to the DQCL or other examination points.

Responsibility

The Registrar, the Chief Drug Inspector, the drug inspectors, and the drug laboratory analysts shall ensure implementation of this SOP.

Distribution

The Registrar, the Chief Drug Inspector, the drug inspectors, and the drug laboratory analysts

Accountability

The Chief Drug Inspector is accountable for the implementation of this SOP.

Distribution

The Registrar, the Chief Drug Inspector, the drug inspectors, and the drug laboratory analysts should receive copies of the form; a copy should also be kept in a master file.

Special Instructions

The following forms, which form part and parcel of this SOP, are annexed above

1. Chain-of-Custody Form
3. POE Inspection, Screening, and Testing Form
1. Rejection/Detention Form
2. Sample Receipt Form
3. Post marketing Surveillance Suspicious Products Form

This SOP is divided into four sections. Section A covers the Chain of Custody control mechanism and form. Instructions for packaging samples are given in Section B. Instructions for sealing the samples is given in Section C. Maintenance of Chain of Custody records is covered in Section D.

Procedure

The procedures in this SOP describe how the drug inspector establishes chain of custody and packages and ships samples for examination. Samples are collected through surveillance programs, and samples that require examination must be shipped under strict Chain of Custody procedures in order to protect the legal integrity of the sample. This SOP also describes how other official staff members are to maintain the Chain of Custody through to the final destruction of the sample. The collecting inspector must maintain the collected samples under control at all times until the sealing operation is complete.

Section A: Chain of Custody Control Form

1. Sample collections: For routine surveillance programs, only unopened containers with intact safety seals should be collected. Products associated with adverse patient events may be collected "as is," with a description of the collection circumstances noted on the Chain of Custody continuation page(s).

2. Complete the Chain of Custody Control Form for each batch of samples collected. The collecting inspector should keep unsealed samples under complete control at all times (e.g., in a secure locked area) when not in the inspector's immediate possession. The completed Chain of Custody Control Form and any continuation pages should be folded and placed in a business-size envelope.

Section B: Packaging

1. The bottom of the sample bag should be completed and the collecting inspector should complete the seal number.

The bottom of the paper sample bag should be labeled with either a ballpoint pen or other indelible ink marker.

Sample Number:
Trade/Generic Name:
Manufacturer Name:
Lot Number:
Consignee:
Inspector Name (printed):

2. The sample(s) should be placed in the labelled sample bag and the top of the bag should be folded over two or three times with about half-inch folds.

3. The completed seal should be glued over the folded centre of the bag so that opening the bag breaks the seal.

4. The envelope containing the Chain of Custody Control Form should be stapled through the fold, thereby closing the bag and attaching the envelope.

5. For samples that are too large to fit in the sample bag:
    a. Complete the required information on the bottom of the bag.
    b. Wrap the container on two axes with the completed paper tape seal. Opening the container should break the seal.
    c. Attach the completed sample bag and Chain of Custody envelope to the sample container. Larger samples may be packaged in other containers using the same labelling as that on the bottom of the sample bag. That container should also have glued paper tape seals over any possible opening sites so that the seal is broken if the container is opened.

Section C. Sealed Sample Shipment

The sealed samples should be appropriately placed in shipping containers for forwarding to their examination point. The shipping containers should be filled with crumpled paper or other packing material to prevent damage to the samples.

Section D. Chain of Custody Record Maintenance

1. The individual who breaks the seal and opens the bag should complete the Chain of Custody Control Form and keep the samples secure during the examination period.
2. Any transfers of the sample(s) to other individuals should be documented either through resealing before forwarding or by documentation on the continuation page.
3. The sample should then be returned under seal to the sample custodian for retention until it is destroyed.
4. After the examination has been concluded and all legal actions have been completed, the sample custodian should complete the destruction portion of the form and forward the form to his/her supervisor for approval of the destruction of the remaining portion of the sample(s). The destruction should be in accordance with ZFDB regulations.