ETHIOPIAN FOOD, MEDICINE AND HEALTHCARE ADMINISTRATION AND CONTROL AUTHORITY

STANDARD OPERATING PROCEDURES FOR PHARMACEUTICALS GOOD DISTRIBUTION AND STORAGE PRACTICES

April 2018

Addis Ababa, Ethiopia

Introduction

Distribution of pharmaceutical products is an important activity in the integrated supply-chain management. Feeble points in the distribution processes of pharmaceutical products provide viable ground for counterfeit, illegally imported, stolen and substandard medicines to enter the supply chain. To maintain the original quality of pharmaceutical products, every party involved in the distribution chain should comply with the applicable practices, legislation and regulations. Each activity in the distribution of pharmaceutical products should be carried out according to the principles of Good Manufacturing Practice (GMP), good storage practices (GSP) and good distribution practices (GDP).

The Ethiopian Food, Medicine and Healthcare Administration and Control Authority is mandated to ensure the availability of quality assured pharmaceutical products to the public. In addition, to ensure the integrity, quality and responsiveness of the supply chain, the authority is required to implement and enforce internal quality management systems in all importers and wholesalers of pharmaceutical products. As part of this effort, the authority has developed model standard operating procedures (SOPs) for pharmaceuticals good distribution practice, good storage practices and other related activities with a view to integrate and standardize internal quality assurance systems of pharmaceutical importers and wholesalers in Ethiopia.

Therefore, these model SOPs are prepared to guide pharmaceutical importers and wholesalers to adapt them for their contexts. The pharmaceutical importers and wholesalers are expected to implement the adapted SOPs and display the SOPs in the respective areas at all times. These SOPs define and describe the functional relationships, the work processes, the roles and internal controls that promote efficiency, transparency and accountability.

The following Model Standard Operating procedures are included in the document

1. Standard Operating Procedure for Pharmaceutical Storage Practice
2. Standard Operation Procedure for Receiving of Pharmaceutical products
3. Standard Operating Procedure for Dispatch and Transport
4. Standard Operating Procedure for Inventory
5. Standard Operating Procedure for Cleaning
6. Standard Operating Procedure for Self-inspection
7. Standard operating procedure for Corrective and Preventive Action
8. Standard Operating Procedure for Complaints Handling
9. Standard Operating Procedure for Return Products Handling
10. Standard Operating Procedure for Recall Handling
11. Standard Operating Procedure for Medicine Waste Handling and Disposal
12. Standard Operating Procedure for Security

Title: Standard Operating Procedure for Pharmaceutical Storage Practice			Logo
Status:			SOP Nº.
Prepared by	Approved by	Revised by	Version N$^{o.}$
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

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1. Purpose

The purpose of this SOP is to describe the storage requirements of medicines and medical products at warehouse and during transportation in the distribution channel.

2. Scope

This SOP is applicable to institutions involved in storage and distribution of stores pharmaceutical products. These include but not limited to manufacturers, importers, distributors and medicine retail outlets.

3. Responsibilities

3.1. Warehouse manager

- Receive and store medicines according to their storage conditions
- Daily Monitoring of temperature and relative humidity of the store
- Store products at their appropriate place.

3.2. Technical Director

- Ensure that medicines are stored according to their storage condition
- Document periodic monitoring record
- Ensure that this SOP is followed
- Update this SOP when required

4. Definitions

The definitions given below should be used in the context of this SOP only.

4.1. **Expiry date:** The date given on the individual container (usually on the label) of a pharmaceutical product up to and including the date on which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.

4.2. **Packaging material:** Any material, including printed material, employed in the packaging of a pharmaceutical product, but excluding any outer packaging used for

transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

4.3. **Pharmaceutical product:** Any product intended for human use, presented in its finished dosage form, which is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products that may be sold to patients without a prescription, biologicals and vaccines.

4.4. **Storage:** The storing of pharmaceutical products and materials up to their point of use.

4.5. **Supplier:** A person or entity providing pharmaceutical products and materials upon request. Suppliers may be agents, brokers, distributors, manufacturers or traders. Where applicable, suppliers should be authorized by a competent authority.

5. Materials and Equipment's

- Calibrated Digital thermo-hygrometers
- Logbooks
- protective or working garments
- Temperature and humidity recording log sheet

6. Procedures

6.1. Warehouse manager

- Receive pharmaceutical shipments in clean receiving bay as per receiving SOP (SOP No…..) and check label such as Name, strength, batch number, expiry date according to supplier dispatch document (packing list, sales invoice etc).
- Store products on clean, undamaged pallets and according to product specification.
- Maintain adequate space between the rows of stored products for cleaning, monitoring and inspection.
- Ensure safe and appropriate storage of pharmaceutical products.
- Properly handle and store NPS drugs in compliance with international conventions, and national laws and regulations.

- Store separately highly toxic and radioactive materials, and other hazardous, sensitive and/or dangerous materials and pharmaceutical products in dedicated area that is subject to appropriate additional safety and security measures.
- Follow appropriate stock rotation to ensure that the oldest stock sold first within its shelf life and moved to the front of the picking face and the new stock put to the back.
- Store recalled and return products according in a dedicated area under key and lock and clearly labelled.
- Periodically segregate and records damaged and expired products.
- Ensure cleanliness of warehouse, monitor as per cleaning schedule and records are maintained as per Annex 3.
- Control and monitor room temperature and relative humidity using calibrated thermo-hygrometer and records are maintained as per the temperature and RH log sheet.
- Check the condition of newly arrived cold box that contain the product.
- Ensure safe and appropriate storage of cold chain pharmaceutical products.
- check and ensure cold chain products are not placed directly against the refrigerator side or back wall or near the cooling plate.
- Maintained sufficient space around the cold chain products for air to circulate.
- Check the expiry date of the cold-chain products on a regular basis.

6.2. Technical manager

- Ensure medicines are stored according to their storage condition.
- Ensure daily monitoring of temperature and relative humidity is carried out.
- Ensure handling of NPS according to national legislation.
- Ensure proper handling of recall, returned, expired products.
- keep all monitoring records for at least the shelf-life of the stored pharmaceutical products pluses one year.
- Ensure cold-chain medicines are stored and managed properly.
- Ensure this SOP is followed and updated when required.

- Monitor proper transfer of the products to the cold room.

7. Distribution

This SOP distributed to:

- Quality assurance department/general managing/ technical manager offices
- Warehouse manger

8. Records

8.1. After the completion of each activity, all documents and correspondence should be recorded and filed in folder.

8.2. File numbers should be kept electronically and/or in hard copy for easy of tracing folders.

8.3. The change histories of this SOP should be kept and filed properly including all versions

8.4. The different versions should be kept for _____years in traceable manner.

9. Revision History

Revision number	Summary of change	Effective date
R0	New SOP	To be assigned
R1		
R2		
R3		

Reference

1. http://www.fmhaca.gov.et/documents/GDP,%20GSP%20and%20Recale%20Guideline%202015.pdf
2. WHO, guide to good storage practices for pharmaceuticals, series No 908.2003.

Annexes

Annex 1: Defined storage Instructions and Meanings

Storage condition on the label	**Interpretation**
Freeze/Freezer	The temperature is -20°C to -10°C
Refrigerator	The temperature is 2°C to 8°C
Cold place	The temperature is ≤ 8°C
Cool place	The temperature is 8°C to 15°C
Room temperature	The temperature is 15°C to 30°C
Do not store over 30°C	From +2°C to +30°C
Do not store over 25°C	From +2°C to +25°C
Do not store over 15°C	From +2°C to +15°C
Do not store over 8°C	From +2°C to +8°C
Do not store below 8°C	From +8°C to +25°C
Protect from moisture	≤ 60% relative humidity
"Protect from light"	To be provided to the patient in a light-resistant container
Do not store over 30°C	From +2°C to +30°C
Do not store over 25°C	From +2°C to +25°C
Do not store over 15°C	From +2°C to +15°C

Annex 2: Rejected products log

Rejected by and date	**Product name**	**Product strength**	**Batch no.**	**Quantity**	**Reason**	**Removed by and date**	**Disposition by RP (R / D)***

R (Returned to supplier), D (Destroyed)

Annex 3: Cleaning log sheet

Type of cleaning: ☐ Daily ☐ Monthly ☐ Annual

Date	Cleaning carried out	Area cleaned	Cleaning agent used	Performed by	Checked by

Reviewed by:_____Date:_____

Title: Standard Operating Procedure for Monitoring Temperature and Relative humidity			Logo
Status:			SOP Nº.
Prepared by	Approved by	Revised by	Version Nº.
Name:	Name	Name	Effective date:
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Date:	Date:	Date:	Supersedes:

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1. Introduction

Temperature and/or relative humidity monitoring is essential in warehouses and storage facilities housing sensitive medical equipment and pharmaceuticals product. Failure to store such items within the specified temperature range may affect their quality and effectiveness. Failure to monitor and record temperatures and relative humidity accurately can mean that health professionals may be unaware of these potential effects on medical product. This may well include the monitoring and control of room temperature storage required by the manufacturer. This Temperature and relative humidity monitoring SOP directs how to monitor temperature and/or relative humidity of medical product during storage, transportation and distribution.

2. Purpose

This Standard Operating Procedure (SOP) describes the procedure when monitoring and recording of temperatures and/or relative humidity of medical products.

3. Scope

This SOP applies to the monitoring of temperature and relative humidity for medical product during the storage, distribution and transportation

4. Responsibility

4.1 Store keeper

- Monitor the room temperature and refrigerator temperature regularly
- Record the reading of temperature and/or relative humidity
- Report any discrepancy occurred

4.2 Technical manager

- Ensures the room and refrigerator temperature monitored regularly
- Ensures records are kept

5. Materials and equipment

- Temperature and humidity recording log sheet
- Stationeries
- Calibrated thermometer
- Calibrated hygrometer

6. Procedure

6.1 Monitoring and recording of room temperature

6.1.1 Ensures calibrated temperature monitoring device positioned according to the result of mapping exercise.

6.1.2 Control and monitor temperatures using calibrated monitoring device.

6.1.3 Conduct monitoring at points representing the extremes of the temperature range (hot spots or cold spots)

6.1.4 Record twice daily and it contains date, time, minimum and maximum temperatures and name and sign of person recording. (Annex1)

6.1.5 Check the thermometer used for monitoring at suitable predetermined intervals.

6.1.6 Record the results of such checks and retain the record.

6.1.7 Calibrate thermometer at least [put period re-calibration date]

6.1.8 Report any deviation to technical manager

6.1.9 Keep all monitoring records for a period of [put document retain period]

6.1.10 Investigate any deviation and take appropriate corrective and preventive action.

6.1.11 Record the action taken.

6.2 Monitoring and Recording of Refrigerators and Freezer Temperature

6.2.1 Calibrated control sensors/thermometer positioned at the hot and cold spots determined by temperature mapping,

6.2.2 Ensures control sensors independent of the temperature monitoring system

6.2.3 Check the maximum, actual and minimum fridge temperature between intervals.

6.2.4 Record the Maximum, Current/Actual, and Minimum temperature twice daily. (Annex1)

6.2.5 Keep temperature logs close to the refrigerator/freezer (but not inside)

6.2.6 Use a separate temperature record for each refrigerator/freezer. (Annex1)

6.2.7 Calibrate the thermometer at least [put re-calibration date]

6.2.8 Record any activity which may affect the temperatures recorded e.g. tidying, re-stocking, cleaning, defrosting at the time it takes place.

6.2.9 The temperature log signed and date by individuals checks.

6.2.10 Investigate out of specification reading and take corrective action and preventive action.

6.2.11 Record action taken.

6.2.12 Out of specification reading exists for several time for an unknown reason, take advice from the manufacturer regarding the stability of product/Excursion time/.

6.2.13 Keep all monitoring records for [put document retain period].

6.3 Humidity control and monitoring

6.3.1 Ensures calibrated relative humidity monitoring device placed at the storage area.

6.3.2 Monitor the reading of the relative humidity between intervals.

6.3.3 Record the reading of the relative humidity measuring device twice daily (Annex 2)

6.3.4 Keep all monitoring records for [put document retain period].

6.3.5 Investigate out of specification reading and take corrective and preventive action

6.3.6 Record the action taken.

7. Distribution

This SOP will be distributed to:

- Technical manager office
- Store keeper/warehouse manager

8. Records

1. After the completion of each activity, all documents and correspondence should be recorded and filed in folder.
2. File numbers should be kept electronically and/or in hard copy for easy of tracing folders.
3. The change histories of this SOP should be kept and filed properly including all versions.
4. The different versions should be kept for _____years in traceable manner.

9. Revision History

Revision number	Summary of change	Effective date
R0		
R1		
R2		
R3		

10. Reference

- GSP, GDP and pharmaceuticals recall guideline, 2015.
- WHO Annex9, model Good Cold Chain Management for Temperature- Time-Sensitive Pharmaceutical Products
- Good Cold Chain Management for Temperature-Sensitive Pharmaceutical Products, Edition 2, 2017. Republic of Lebanon Ministry of public health, Quality assurance and pharmaceuticals product program.

Annexes

Annexure 1: Room and refrigerator temperature recording format

Max and Min temperature /acceptance limit/_____
Month_____
Id.no_____

Date	Time	Actual Temperature reading	Taken by		Action/comment or outcomes when temperature excursion/
			Name	Sign	

Annexure 2: Relative humidity recording format

Max and Min relative /acceptance limit/_____
Month_____
ID.no_____

Date	Time	Actual relative humidity	Acceptance limit	Taken by	Action/comment or outcomes

			Min. Temp	Max. Temp.	Name	Sign	

Title: Standard Operating Procedure for Dispatch and Transport			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
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Date:	Date:	Date:	Supersedes:

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1. Background

[Company name] has prepared this SOP to ensure quality and integrity of pharmaceutical products and materials that can be affected by lack of control during storage and poor compliance to good distribution practices. Distribution is an important activity in the integrated supply-chain management of pharmaceutical products. [Company name] are generally responsible for the handling, storage and distribution of such products. In some cases, however, a person or entity is only involved in and responsible for certain elements of the distribution process.

This document sets out appropriate steps to assist in fulfilling the responsibilities involved in the different aspects of the distribution process within the supply chain and to avoid the introduction of counterfeits into the marketplace via the distribution chain. The involvement of unauthorized entities in the distribution and sale of pharmaceutical products is a particular concern.

2. Purpose

The purpose of this procedure is to describe the dispatching and transportation activities of pharmaceutical products.

3. Scope

This procedure is applicable to the entire process during dispatch and transportation of pharmaceuticals products.

4. Acronyms and Abbreviations

SIV	Store Issue Voucher
SOP	Standard Operating Procedure
GDP	Good Distribution Practice
GSP	Good Storage Practice

5. Responsibility

Title	**Responsibility**
Warehouse manager	• Counting and verification of items during dispatching. • Handover of items to driver/receiver. • Verification of items against the issue order and SIV.
Deliverer	• Transfer the items to the receiving storekeeper by availing himself when all items are unloaded, counted and verified with documents. • Counting and verification with the documents before transport the product. • Monitoring temperature and humidity during transit • Informing any discrepancy during transit • Bring proof of delivery from the health facility.
Warehouse operatives	• Arrange product during handover • Picking and dispatching of pharmaceuticals
Storage and distribution officer	• Confirm the delivery and discrepancies if any.
Technical manager	• Approves (sign and stamp) the sales and requisition form. • Check customer qualification procedure

6. Materials and equipment

- Dispatch product Report format/log book
- Store Issue Voucher (SIV)
- Discrepancy record format
- Deliverer log book

7. Procedures

1.1. Prepare requisition form when receiving a request by telephone or formal letter or any other means of communication from the qualified customer (including their transportation mechanisms) and hand over to the warehouse operatives.

1.2. Warehouse operatives pick and collect items from the storage area or warehouse as exactly mentioned on the requisition form/issue order (check the expiry date and batch number).

1.3. Selected products are placed on dispatch area (care must be given for cold chain items) and arranged by category convenient for count.

1.4. Count and verify the dispatch products against requisition form/issue order by the warehouse manager.

1.5. Technical manager confirms the correctness of the dispatch count and approves the requisition/dispatching process by checking all necessary information presented on the requisition form.

1.6. Requisition form/issue order is then sent to store clerk for the preparation of store issue voucher.

1.7. After preparation of the store issue voucher the finance officer prepares invoice based on the requisition form/SIV.

1.8. Prior to calling driver or the authorized receiver into dispatch area and given the invoices for the items to be delivered. Records for dispatch product must be retained, stating at least:

- Date of dispatch; complete receiver organization name and address (no acronyms),
- Type of entity responsible for the transportation, telephone number and names of contact persons;
- Complete receiver organization name, address (no acronyms), and level of the receiver (e.g., retail pharmacy, hospital);

- Product description, e.g., product name, dosage form and strength (if applicable); quantity of the products, i.e., number of containers and quantity per container (if applicable); batch number and expiry date (where not possible at dispatch, this information should at least be kept at receipt to facilitate traceability).
- Applicable transport and storage conditions; and
- Unique number to allow identification of the delivery order;

1.9. The receiver counts the dispatched items and verify against the invoices.

1.10. Pack the delivery and make ready for delivery. Delivery documentation is ready (check all partially filled cartons are packed and sealed properly, after count, in front of the driver/receiver or the qualified customer).

1.11. Both the receiver and storekeeper sign the invoices.

1.12. One original and one copy of the invoices are given to the deliverer to be submitted to the receiver, one copy of the invoice will be given to the technical manager of the customer and sign on both invoice of the original and copy.

1.13. Items are loaded on the vehicle. Loading on vehicle should be arranged in such a way that items for the nearest receiver are loaded last and for the remotest first.

1.14. Distribution of invoices and SIV: Storekeeper, finance, documentation follow up and two copies of invoice for receiver/driver.

1.15. Deliverer of vehicles identifies themselves and present appropriate documentation to demonstrate that he/she had authorized to transport the load.

1.16. The deliverer record (discrepancy report format) and report damage containers and any other event or problem that occurs during transit to the relevant department, entity or authority, and investigated.

1.17. Deliverer passes the invoice to responsible person at receiver's institution.

1.18. Unload the items from vehicle. The receiver is responsible for unloading of items.

1.19. The deliverer together with the receiver's responsible person count and verify items against invoice.

1.20. If there is no discrepancy or defect the responsible person from the receiver signs and put a seal on the invoices for approval of receipt.

1.21. If there is discrepancy (overage/shortage) or defect the receiver is required to specifically mention the same on the location provided on the invoice and signed by both the deliverer and the receiver.

1.22. Deliverer receives a copy of stamped invoice from the receiver of the products.

1.23. Up on return deliverer submits the invoices for documentation (including discrepancy (damaged, overage/shortage) for follow up if any.

8. Document distribution

The procedure shall be distributed to:

- General Manager office
- Technical manager office
- Warehouse manager office
- Sales man/promoters office
- Finance department

9. Records

1.24. After the completion of each activity, all documents and correspondences should be recorded and filed in a proper folder. File numbers should be kept electronically and/or in hard copy for ease of tracing folders.

1.25. The amendment and revision of this procedure is the responsibility of the technical manager with the direction of the top management of the institution. Amendment of this procedure will be done when it is deemed necessary and the revision shall not be beyond 2 years.

1.26. The change histories of this SOP should be kept and filed properly including all versions.

10. Amendment histories

This SOP will be revised every two years or amended as appropriate**.**

Revision Number	Summary of Changes	Effective date
R0		
R1		
R2		

11. References

- WHO good distribution practices for pharmaceuticals product, annex 5, TRS No. 957, 2010.
- GDP, GSP and recall guidelines, Ethiopian Food, Medicine and Healthcare Administration and Control Authority, 2015, first edition.

Title: -Standard Operation Procedure for Receiving		
Status:		Doc Nº:
Prepared by	Approved by	Revision Nº:
Name:	Name:	Effective date:
Position	Position	Supersedes:
Sig:	Sig:	
Date:	Date:	

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1. Abbreviation

COA	Certificate of Analysis
EFMHACA	Ethiopia Food, Medicine and healthcare Administration and Control Authority of Ethiopia
PO	Purchase Order
ISO/IEC	International Standard Organization/International Electronics Cooperation
SOP	Standard Operation Procedure

2. Introduction:

Pharmaceutical company conducts good receiving of Pharmaceutical products, in accordance with a predetermined procedure to verify that its operations continue to comply with the requirements of the management system.

3. Purpose:

The purpose of this receiving SOP is to mitigate risks to receive pharmaceutical products and lay down the procedures to monitor the implementation and compliance with good receiving.

4. Scope:

This SOP is applying on organization engaged in receiving of Pharmaceutical products.

5. Responsibilities

5.1. Storekeeper;

- Get copies of invoices/documents of newly received products and conduct physical inspection on vehicle and medicinal products
- Receiving, recording and reporting of new arrivals.

5.2. Technical Manager:

- Ensure all documents of newly arrived products
- Ensure receiving vouchers /recorded reports
- Ensure appropriate segregations of products

6. Materials

- Receipt voucher
- Receipt log book
- Inspection check list
- Bin Card/Stock Card/any other record System

7. Procedure

7.1. Arrange warehouse space before the arrival of Pharmaceutical products

7.2. Get copies of invoices/documents of the consignment (like invoice, COA, et) and examine carefully whether the products belong to them, whether products as per purchase order/request and also check whether they come from approved vender, if not immediately inform to technical manager/purchase team.

7.3. Conduct physical Inspection on incoming trucks for the following:

- The trucks must van/ be covered.
- Floorboards are dry and clean.
- No evidence of chemical spills, garbage, waste.
- Insect and rodent activity

7.4. Unload the shipment at receiving area/bay and inspect the condition of the shipment to ensure:

- All products are on clean pallets.
- Separate damaged/suspected /altered products during transportation
- Check availability of Temperature monitoring equipment if required,

7.5. Notify the technical manager/ warehouse manager the result of the physical inspection

7.6. Count the products and compare the quantity, name, and lot numbers to the information stated on the shipping documents/delivery invoice and company purchase order (PO).

7.7. Complete the receiving log sheet/receipt invoice and signs for approval of receipt.

7.8. When a discrepancy exist technical / warehouse manager/purchase team will verify whether the driver/carrier is accountable or not. If the driver is accountable, a discrepancy verification report is filled in and an appropriate measure will be taken.

7.9. A copy of record of Incoming products will be given to technical/warehouse manager and the driver/deliverer

7.10. On receipt of damaged shipment/defective package/suspected products take a photo of the damaged product defective package/suspected products and ensure the truck driver signs the receiving document as evidence and store to designated area and notify purchasing manager /technical manager to return or destroy, if important

7.11. Label damaged product, defective package/suspected products with all information: name, lot number, quantity, invoice number & date and store at designated area

7.12. Recorded pharmaceutical products on correspondent Bin cards /appropriate sheets and attach a card on each pallet containing that products.

7.13. De-dust all products before moving into the store

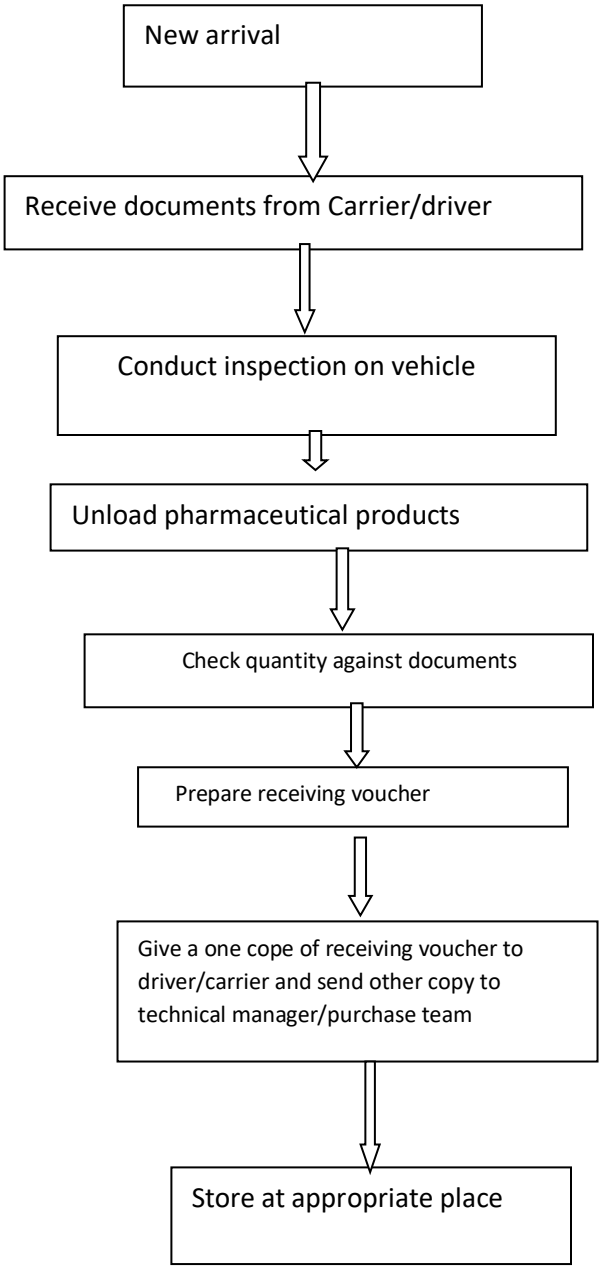
7.14. Arrange the items on pallets or other location according to the expiry and batch number. Use the packing list for easy reference of batch number and expiry dates.

7.15. File all records

8. Reference

- ES ISO/IEC 17020:2012

Annex1: Flowchart for warehouse receiving products



Annex 2: Physical inspection checklist for receiving

SN	Variables	Yes	No	Not available
CONTENT FOR LABELLING				
1	Is the labelling has an English /Amharic language version?			
2	Is the labels display the following information?			
2.1	International Nonproprietary Name (INN) of the active ingredients			
2.2	Dosage form			
2.3	Quantity of active ingredient(s) in the dosage form and the number of units per package			
2.4	Batch number			
2.5	Date of manufacture			
2.6	Expiry date (in clear language, not in code)			
2.7	Pharmacopoeia standard (e.g. BP, USP,)			
2.8	Instructions for storage			
2.9	Name and address of the manufacturer			

PHYSICAL INSPECTION FOR DOSAGE FORM

3.1) TABLETS and CAPSULES				
S/N	Variables			
3.1.1	Is Tablets/ Capsules are identical in size and shape?	Yes	No	Not Available
3.1.2	Is Tablets/ Capsules are identical in color (variation of shade of color from batch to batch			

	may be normal. However, if it is within the same batch it may indicate poor quality)?			
3.1.3	Is Tablets/ Capsules markings are identical (example : -lettering , numbering			
3.1.4	Is there any defects (check for colored spots , hollows, fragments/ breaks, /friability behavior / , uneven edges , cracks , embedded or adherent foreign matter, stickiness)?			
3.1.5	Is there any odor when a sealed bottle is opened except for flavored tablets and those with active ingredients normally having a characteristic odor?			
3.1.6	Is there any odor after tablets have been exposed to room air for 20 -30 minutes?			
3.1.7	For capsules only is there any empty, broken, crack and open capsule?			
3.2) PARENTRAL FORMULATION				
3.2.1	Is the solution free from un dissolved particles (solutions should clear)?			
3.2.2	Is the dry solids for uses in injections are entirely free from visible foreign particles?			
3.2.3	Is there any leaking containers (bottles, vials, ampoules, bags etc)?			

3.3 ORAL LIQUID/SEMISOLID DOSAGE FORMS

3.3.1	Is the bottle size/shape the uniform?			
3.3.2	Is there is a gas evolving when sample bottles are opened that indicates fermentation?			
3.3.3	Is there leakages, breakages, label deformities?			
3.3.4	Is there any color changes in the same batch?			
3.3.5	Is there any foreign particles			

Annex 3: Record of Incoming Goods (RIG)

Name the organization: _____

Document no. (invoice, etc.): _____

Name and tel. no. of the person who delivered the pharmaceutical products_____ signature----------Track number----------

Ser.no.	Received date	Product name	Batch No.	Quantity received	PO Number	Vehicle visual inspection	Rodent/pest activities	Damaged Quantity	Discrepancy	Remark

Name and signature of Storekeeper/receiver _____

Title: Standard Operating Procedure for Inventory			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
Name:	Name	Name	Effective date:
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Date:	Date:	Date:	Supersedes:

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1. Introduction

A critical activity of the inventory control function is to verify that the physical inventory matches inventory records. Physical inventories ensure and promote confidence in the inventory records. There are two kinds of physical inventory count. Complete physical inventory count which also known as fiscal count or wall to wall count where all products are counted at the same time. It is takes place at least once a year

Cyclic or random physical inventory**:** Selected products are counted and checked against the stock keeping records on a rotating or regular basis throughout the year.it is usually appropriate at facilities that manage larger quantities of products. It is a continuous counting, for example every week or each month by dividing the inventory in different group, with reconciliation of discrepancies.it is take place without interrupting normal operations.

2. Purpose

The purpose of this SOP is to describe the inventory processes bring the demand management functions of the companies and to verify physical inventory with the quantity on bin/stock card

3. Scope

The scope of this SOP applies to perform counting of all or part of inventory of the organization engaged in Storage, transportation and distribution of medical products.

4. Responsibility

4.1.The inventory committee/officers responsible to:

- 4.1.1 Conduct the annual or as needed physical inventory in accordance with the procedures.
- 4.1.2 Verify physical counts with forms and if necessary make adjustments to till 10% deviation and consider recount if it is beyond this value.
- 4.1.3 Report the inventory report to the technical manager or other responsible body as needed.
- 4.1.4 Investigate and review all previous and current error or discrepancies occurred during inventory, fix it and report deviation to the technical manager or other the responsible body.

4.2. The store manager responsible to:

4.2.1. Maintaining and updating the inventory records such as bin cards throughout the year and obsolete items.

4.2.2. Classifying of stocks for counting based on health values and business criticality.

4.3. The technical manager or other responsible body responsible to:

4.3.1 Develop annual inventory plan and procedure.

4.3.2 Select appropriate staff to as the Inventory committee/ officer as needed.

4.3.3 Assure and verify that the inventory is performed and the records are maintained.

4.3.4 Provision training for store manager or inventory committee/ officer as needed.

4.3.5 Keep stock cards securely.

5. Material and equipment

- Stationary materials
- Inventory sheet formats
- Bin card/stock cards
- Computer as needed

6. Procedure

6.1. Classifying of stocks for counting based on health values and business criticality.

6.2. Maintaining and updating the inventory records such as bin cards throughout the year and also for discarded/obsolete items.

6.3. Conduct the annual or as needed physical inventory in accordance with the procedures as per plan and as per health values and business criticality

6.4. Verify physical counts with forms and if necessary adjust till 10% deviation.

6.5. Perform and submit an inventory report to the technical manager or other responsible body as needed.

6.6. Check that the inventory is performed and the records are maintained.

6.7. Conduct a second recount if differences occur. If differences still occur after a second recount of specific storage bin card, the entire batch of that product be counted in an attempt to locate the error.

6.8. Conduct count to the entire stock of that products if then the difference still evident.

6.9. Investigation include reviewing all previous receipt and issued transaction on the material code, any entry error, any discrepancies occurred during receipt, issue, reject and return of that material, if the error is found fix it accordingly.

6.10. If still error is found, the committee raise deviation report (DR) and contact inventory with warehouse manager and account manager to clear the stock difference.

6.11. Use blue or black pen only to fill in quantity or stock data. Each page must have count date, the initial and signature in the space provided (refer annex 1).

7. Distribution

This document is distributed to

- Technical managing office
- Warehouse manger
- Inventory committee

8. Revision history

Revision number	Summary of change	Effective date
R0		
R1		
R2		
R3		
R4		

Annexures:

Annexure 1: Format Sheet for Warehouse Periodic Inventory Count

Title: warehouse periodic inventory count sheet format										
Item code										
Month:			Year:							
prepared by:			Signature:		Date:					
Product name	unit	Batch no	Manufactured date	Expired date	manufacturer	Qty. received	Qty issued	Complete /cyclic count	balance	difference

Title: Standard Operating Procedure for Cleaning			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

1. Introduction

Cleaning is the removal of gross contamination, organic material, and debris from the premises or respective structures, via mechanical means like sweeping (dry cleaning) and/or the use of water and soap or detergent (wet cleaning). Pharmaceutical Premises and storage facilities should be clean and free from litter and dust. Cleaning equipment should be chosen and used in order not to be a source of contamination.

2. Purpose

The purpose of this SOP is to ensure that the medical product store is maintained clean, tidy at the highest level of cleanliness

3. Scope

This SOP applied in all the [company XXX] warehouse that describe the methods by which the cleaning of floors, walls, windows, shelves and stock will be done in the medicine store.

4. Responsibility

- Cleaners are responsible to follow the SOP
- It is the responsibility of the head of medicine store to ensure that these procedures are followed

5. Equipment and material

- Sponge mop
- Rubber mop
- Broom
- dustbin
- Disinfectant and Detergents
- Personal Protective equipment

6. Procedure

6.1. All areas in which medicinal products are stored or held (i.e. goods inwards and receipt areas, storage areas, quarantine areas and dispatch areas and delivery vehicles) should be cleaned on an on-going basis.

6.2. The [company] execute a cleaning schedule as required (i.e. on a daily, weekly, monthly and annual basis

6.3. Use protective equipment like gloves, aprons, boots, face mask etc., as necessary during cleaning procedures

6.4. All cleaning chemicals and materials are properly labelled and stored separately from medical warehouse/ kept in utility room

6.5. Daily cleaning basis

6.5.1. All rubbish and non-essential product packaging and wrapping should be removed from the warehouse and disposed off.

6.5.2. Sweep floors of all storage areas receiving, dispatch areas every morning.

6.5.3. Clean shelves and stock after cleaning/sweep the floors

6.5.4. Dust all shelve in the medicine store with a dry duster

6.5.5. Avoid messing up the labels of containers

6.5.6. Squeeze the mop or duster hard to leave it almost dry before cleaning shelves and containers

6.5.7. All waste bins should be emptied and fresh bin liners put in place

6.6. Cleaning floors under the pallet [Monthly cleaning basis]

6.6.1. Remove the pallets and clean the floor of all storage area

6.6.2. Start sweeping from the furthest point of the store

6.6.3. Collect clean water for a quantity enough to clean the store

6.6.4. Collect a clean mop and soap to use for mopping the floors

6.6.5. Dissolve soap in the clean water

6.6.6. Squeeze the mop as dry as is possible before mopping the floor

6.6.7. Do not use dirty water

6.7. Wall and window cleaning [Monthly cleaning basis]

6.7.1. Store person shall cover all shelves and pallets laying on by polythene sheet before cleaning.

6.7.2. Remove free dust and dirt using a dry duster

6.7.3. Apply window cleaner onto clean cloth and wipe off the dirt from the window

6.7.4. Use water and hose for cleaning the outside of high windows.

6.7.5. Make sure the windows are tightly closed

6.7.6. Wipe away dirt from the walls using a mop and clean water with soap or detergent

6.8. Tube lights & high area [Annually basis]

6.8.1. Switch of the power supply and clean high-level areas clean high-level areas by using clean and dry closes.

6.9. All cleaning recorded in the Cleaning Log (Annex 1 ---/----). This should include a description of the area cleaned and cleaning agents used.

6.10. The person performing the cleaning sign and date the log.

6.11. The cleaning should be checked by a second person and this check should be recorded in the log.

6.12. Cleaning records should be reviewed on a regular basis and this review should be recorded on the Cleaning Log

7. Document distribution

- Warehouse manager
- Janitors

ANNEX 1: CLEANING PROCEDURE

Form No: _____

Date	Cleaning agent used	Area cleaned	Name Cleaner	Time

Reviewed by:_____ Checked by_____

Signature and date_____ Signature and date_____

Title: Standard Operating Procedure for Self-inspection			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

Disclaimer: This is a model standard operating procedure. It incorporates generic guidance principles only. Firms are encouraged to adapt their own SOPs as necessary to suit their in-house procedures.

Table of Contents

1. Introduction:

Pharmaceutical company conducts self - audit periodically, in accordance with a predetermined schedule and an internal procedure, internal audits to verify that its operations continue to comply with the requirements of the management system.

2. Purpose:

The purpose of this SOP is to lay down procedures to conduct self- inspection (Internal-audit) to monitor the implementation and compliance with good distribution and storage practices, principles and to propose necessary corrective measures.

3. Scope:

This SOP applies to conduct self -inspection of good storage, transport and distribution practices of medical products.

4. Acronyms and Abbreviations

CAPA	Corrective and preventive action
EFMHACA	Ethiopian Food, Medicine and Healthcare Administration and Control Authority
GDP	Good Distribution practice
GSP	Good storage practice
QA	Quality assurance
SOP	Standard Operating Procedures

5. Definition

- **Audit Means** a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. When addressing the regulatory requirements, the term 'inspection' has been used to indicate the same meaning as the term 'audit'.
- **Auditee means** any organisation whose quality systems are to be audited for compliance with the relevant regulatory requirements.
- **Auditor means** a person with relevant qualifications and competence to perform audits or specified parts of such audits and who belongs to or is authorised by the auditing organisation.

- **Lead auditor** means an auditor designated to manage an audit process (also known as an audit team leader).
- **Minor deviation** means deviation from standard operating procedure or guidelines which cannot lead to what is described under major or critical
- **Major deviation** means any deviation from the established procedure, process, system and practice
- **Critical deviation** means **c**ritical point is any non-conformance, which can affect the purity, strength and safety of the medicines, which pose serious health risk to the users.

6. Responsibility:

6.1. Head- Quality assurance/quality manager/Technical manager shall be:

6.1.1. Responsible to establish audit team

6.1.2. Responsible for approval of annual calendar for internal audit

6.1.3. Responsible for ensuring the conduction of internal audit as per schedule

6.1.4. Responsible for review and approval of summary report of internal audit report.

6.2. The audit Team shall be:

6.2.1. Responsible for conducting the audit as per schedule.

6.2.2. Responsible for checking the compliance of observations made during previous audit

6.2.3. Responsible for preparation of internal audit report

6.3. The Auditee shall be:

6.3.1. Responsible for implementing the corrective action recommendation by audit team

6.3.2. Responsible for preparation of audit compliance report

6.3.3. Responsible to coordinate auditors and provide required information

7. Material and equipment:

- Stationary materials
- Checklists
- Previous audit report/external audit report/customer audit report
- National GDP and GSP guidelines and/or international recognized guidelines

8. **Procedure**

8.1. Annual calendar for internal audit will be prepared by [Quality assurance/ technical manager] and approved by responsible head (Refer Annexure-1)

8.2. During Internal audit, check compliance level of audits done by any external agency or regulatory body and access the compliance level of audit carried by customers

8.3. Apart from annual calendar, audits may be carried out when there are any failure/ compliant/recall/regulatory findings etc.

8.4. The list of auditors (Annexure-2) will be prepared from different departments considering members from cross functional area with no conflict of interest.

8.5. Internal auditors shall be selected by quality assurance/quality manager/Technical manager based on his/her experience, qualification, subject matter expertise and knowledge.

8.6. Each area shall be audited/ inspected at least once in six months.

8.7. The parameters to be covered shall include at least good storage practice, good distribution practice, quality management system, personnel etc.

8.8. The audit scope may be narrowed down to cover only a particular segment/activity as needed.

8.9. The auditors jointly inspect the respective areas as per checklist as applicable

8.10. Auditors shall verify data integrity related issues of each department as applicable

8.11. The observations may not be limited to the checklist. It can be extended towards the criticality of findings.

8.12. The auditor report will be agreed on findings based on factual evidence necessary to record all the observation in audit report.

8.13. The deficiencies observed during audit shall be categorized as Critical. Major, Minor (other) deficiencies.

8.14. Based on the observations in the audit, the auditor shall prepare the separate audit report as per the format given in annexure I and send a copy to the auditee [within agreed working days] of audit date.

8.15. A copy of audit report shall be submitted to [Head of Quality assurance/Technical manager] depending on the size of the organization. The audited department shall send their CAPA plan within 15 days after receipt of audit report.

8.16. Follow up will be organized after the execution of CAPA.

8.17. Audit report and compliance report should be available for regulatory review.

9. Distribution

This SOP should be distributed to

- Technical managing office
- Warehouse manger
- Quality assurance department or General managing office
- To other necessary departments

10. Revision history

Revision number	Summary of change	Effective date
R0	New SOP	To be assigned
R1		
R2		

11. References:

1. Ethiopian Food, Medicine and Health Care Administration and Control Authority, Good Storage, Distribution and Pharmaceutical Recall guideline, 2014
2. World Health Organization: Good Storage Practice Guidelines

12. Annexes

Annexure 1: Annual Calendar Format for Internal Audit

SN	Department	Jan	Feb	mar	App	may	June	July	Aug	Sep	Oct	Nov	Dec
1.	Warehouses												
2.	Distribution and delivery												
4.	Procurement												

Annexure 2: Format for list of Auditors

SN	Name of auditors	Department	Name and department for audit
1.			
2.			
3.			

Annexure 3: Format For Audit Report and Compliance report

Date of inspection: _____

Members of inspection team: _____

Auditee department: _____

Reason for self-audit: _____

Status of Previous self-inspection: _____

SN	Observation	Category (Critical, Major and Other)

Annexure 4: Corrective and preventive action plan for self-inspection

Department: _____

Focal person: _____

SN	Category	Observations	Proposed CAPA	Indicator for accomplishment	Proposed closing date	Status (closed or pending)

Annexure 5: Checklist for premises & Facilities, and Sanitation & hygiene

SN	**Premises and Facilities**			
1.	Unauthorized access to all areas of the authorized premises is prevented	In	NC	NA
2.	Receiving and dispatch bays protect products from prevailing weather conditions			
3.	Segregated areas are designated for the storage of any product suspected of falsification, returned product, rejected product, product awaiting disposal, recalled product			
4.	Radioactive materials other hazardous products and products presenting special risks of fire or explosion are stored in a dedicated area(s) with appropriate safety and security measures			
5.	There is adequate separation between the receipt and dispatch areas and storage areas			
6.	Rest, wash and refreshment rooms for employees are adequately separated from the storage areas			
7.	Is there receiving SOP and there check list that should be filled during receiving of products, is record maintained			
8.	Is there approved supplier list			
9.	Is there Dispatch SOP and there check list that should be filled during dispatching of products, is record maintained			
Sanitation and Hygiene				

1.	Procedures relating to personnel hygiene like health, hygiene and clothing are established and observed			
2.	Storage of food, drink, smoking materials or medication for personal use in the storage areas is prohibited			
3.	Cleaning instructions and records are in place			
4,	Facilities are designed and equipped so as to afford protection against the entry of insects, rodents or other animals			
5,	A preventive pest control programme is in place			

Annexure 6: Checklist for temperature & environmental monitoring and equipment & computer system

SN	**Temperature and environmental control**	In	NC	NA
1.	Suitable equipment and procedures are in place to ensure adequate control of the environment			
2.	Storage areas are temperature mapped for all seasons			
3.	Temperature monitoring equipment is located according to the results of the mapping exercise			
4.	Controls are adequate to maintain all parts of the relevant storage area within defined temperature, humidity or light parameters			
5	Equipment used to control or to monitor the environment, are calibrated and their correct operation and suitability is verified at defined intervals by the appropriate methodology			
6	Appropriate alarm systems are in place to provide alerts when there are deviations from pre- defined storage conditions			
7	Alarms are regularly tested			
8	Power back generator or other means			
Equipment and computer systems				
1	Planned preventive maintenance is in place for key equipment			
2	Calibration of equipment is traceable to a primary standard			
3	Adequate records of repair, maintenance and calibration activities for			

	key equipment is made and the results are retained			
4	Detailed written descriptions of the systems are available (describing the principles, objectives, security measures and scope of the system and the main features, how the computerized system is used and the way it interacts with other systems			
5	Data is entered into the computerized system or amended only by persons authorized to do so			
6	Data is secured by physical or electronic means against wilful or accidental damage			
7	Data is protected by backing up at regular intervals			

Annexure 7: Checklist for Documentation, records, supplier & customer qualification and Receipt of Goods

SN	**Documentations**	IN	OUT	NA
1.	Documents are/ is retained for a period stated in national legislation but at least for five years at a separate, secure location			
	Standard Operating Procedures			
2.	SOPs are reviewed regularly and kept up-to-date			
3.	SOPs are approved, signed and dated by appropriate authorized persons			
4.	Superseded or obsolete SOPs are removed from workstations			
	Records			
5.	For any transaction in medicinal products received, supplied or brokered, records are kept either in the form of purchase/sales invoices, delivery slips, or on computer or in any other form			
6.	Records include the following information:			
	• Date			
	• name of the medicinal product			
	• quantity received, supplied or brokered			
	• name and address of the supplier, broker or consignee, as appropriate			

	• batch number where required			
7.	Distribution records contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and quantities delivered), including those for exported products and medicinal product samples			
Distribution Operation /supply chain operation				
8.	All medicinal products distributed in Ethiopia have a marketing authorization/ Waiver granted by the EFMHACA			
9.	**Supplier Qualification**			
10.	All supplies of medicinal products are obtained only from persons/ organizations who are in possession of an import/ wholesale distribution authorization, or who are in possession of a manufacturing authorization which covers the product in question			
11.	The purchase of medicinal products is controlled by written procedures			
12.	The supply chain of medicinal products/pedigree is known and documented			
13.	Appropriate qualification is performed prior to any procurement			
14.	Qualification and approval of suppliers is controlled by a standard operating procedure			
15.	The results of qualification and approval of suppliers are periodically rechecked			
	Qualification of Customers			
16.	Medicinal products are only supplied to persons/organizations who are themselves in possession of a distribution authorization or who are authorized or entitled to supply medicinal products to the public			
17.	Qualification of customers and periodic re-checks include:			
	• Requesting copies of customer's authorizations			
	• Verifying status on an authority website			
	• Requesting evidence of qualifications or entitlement according to			

	national legislation.			
	• Qualification of customers are appropriately documented			
	• Additional Questions which might be asked for verification:			
	Receipts of Goods			
18.	Ensured that the arriving consignment is correct, the medicinal products originate from approved suppliers and have not been damaged or altered during transportation			
19.	Medicinal products which require special storage or security measures, are transferred to appropriate storage facilities immediately after appropriate checks have been conducted			
20.	In the event of any suspicion of falsified medicinal product, the batch is immediately segregated			
21.	In the event of any suspicion of falsified medicinal product, the batch is immediately reported to the EFMHACA			
22.	In the event of any suspicion of falsified medicinal product, the batch is immediately reported to the marketing authorization holder (where applicable)			
	Incoming containers of medicinal products are cleaned, if necessary, before storage.			

Annexure 8: Checklist for inspection Storage and Distribution Practice

SN	**Storage**	**IN**	**NC**	**NA**
1.	Medicinal products are stored separately from other products			
2.	Medicinal products are protected from harmful effects of light, temperature, moisture or other external factors.			
3.	Attention is paid to products where specific storage conditions are required			
4.	Stock rotation according to the expiry dates of batches of medicinal products is performed ("first expired first out" –FEFO- basis.)			
5.	Medicinal products beyond their expiry date or shelf life are withdrawn immediately from saleable stock either physically or through other			

	equivalent electronic segregation.			
6.	Physical removal of unsuitable stock is performed regularly			
7.	Medicinal products are not stored directly on the floor.			
8.	Stock inventories are performed regularly (timings are defined using a risk based approach)			
9.	Inventory irregularities are investigated and documented			
10.	Medicinal products are stored separately from other products			
Segregation of Goods				
11.	Segregation is provided for the storage of rejected, expired, recalled or returned products and suspected falsified medicinal products.			
12.	Any system replacing physical segregation such as electronic segregation based on a computerized system provides equivalent security and is validated			
Destruction of obsolete goods				
13.	Medicinal products intended to be destroyed are kept separately and handled in accordance with a written procedure.			
14.	Destruction of medicinal products is in accordance with EFMHACA disposal guidelines and/ or international requirements for disposal of such products			
15.	Records of all destroyed medicinal products are maintained			
Complaints		IN	NC	NA
16.	A written procedure is in place for the handling of complaints			
17.	In the case of a complaint about the quality of a medicinal product, the manufacturer and/or marketing authorization holder is informed without delay			
18.	A person is appointed for handling the complaints with sufficient supporting personnel			
19.	Any complaint concerning a potential product defect or a potential falsified product is recorded with all the original details and investigated			
20.	The national competent authority is notified without delay in case of a potential product defect or a potential falsified product			

21.	Any product distribution complaint is thoroughly investigated and appropriate follow-up actions are taken after investigation and evaluation of the complaint			
Returned Medicinal Products				
22.	Written procedures are in place for the handling and acceptance of returned			
23.	Medicinal products which have left the premises of the distributor are only returned medicinal products to saleable stock if:			
	• The medicinal products are in their unopened and undamaged secondary packaging and in good condition			
	• Demonstrated that the medicinal products have been transported, stored and handled under proper specified/predefined conditions			
	• The distributor has reasonable evidence that the product was supplied to that customer			
	• The batch number of the dispatched product is known			
	• A copy of the original delivery note is attached			
	• There is no reason to believe that the product has been falsified			
	• There is evidence that the product has been stored within the authorized storage conditions throughout the entire time			
	• A risk assessment is performed by taking into account the product concerned, any specific storage requirements and the time elapsed since the medicinal product was originally dispatched			
Suspected falsified medicinal products				
24.	The staff is aware of the risks of falsified medicinal products entering the supply chain			
25.	A procedure is in place describing immediate information to EFMHACA/regional regulatory bodies and, where applicable, the marketing authorisation holder of the medicinal products they identify as falsified or suspect to be falsified			
26.	Any suspected falsified medicinal products found in the supply chain is immediately physically and securely segregated from legitimate medicinal			

	products			
27.	Record available when there is suspecsion			
Medicinal Product Recalls				
28.	There is a written procedure for the management of recalls			
29.	The management of recalls and its effectiveness is periodically tested and evaluated by Mock Recall			
30.	Any recall operation is recorded at the time it is carried out			
Transportation				
	Vehicles and equipment			
31.	Required storage conditions are maintained during transportation			
32.	Vehicles and equipment are suitable and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind			
33.	Procedures are in place for the operation and maintenance of all vehicles and equipment, including cleaning and safety precautions			
34.	Validated temperature-control systems (e.g. thermal packaging, temperature controlled containers, and refrigerated vehicles) are used to ensure correct transport conditions			
35.	If refrigerated vehicles are used temperature mapping is performed under representative conditions including seasonal variations			
36.	Equipment used for temperature monitoring during transport within vehicles and/or containers, is maintained and calibrated at regular intervals at least once a year			
37.	If cool-packs are used in insulated boxes, they are located such that the product does not come in direct contact with the cool-pack			
38.	If cool-packs are used in insulated boxes, staff is trained on the procedures for assembly of the insulated boxes (seasonal configurations) and on the reuse of cool-Packs.			
Delivery				
39.	Delivery drivers (including contract drivers) are trained in the relevant areas of GDP			

40.	Deliveries are made directly to the address stated on the delivery note			
41.	Deliveries are handed into the care of the consignee.			
42.	Deliveries are not left on alternative premises			
Deviations				
43.	Deviations are reported to the distributor and recipient			
44.	Where necessary in the case of deviations, the manufacturer of the medicinal product is contacted for information about appropriate steps to be taken			
45.	Container and packaging is selected based on:			
	• the storage and transportation requirements			
	• the space required for medicines			
	• the anticipated external temperature extremes			
46.	A document is enclosed to ascertain the following:			
	• Date			
	• Name and pharmaceutical form of the medicinal product			
	• Batch number at least for products bearing the safety features, where required			
	• Quantity supplied			
	• Name and address of the supplier			
	• Name and delivery address of the consignee (actual physical storage premises, if different)			
	• applicable transport and storage conditions			
47.	Containers bear labels providing sufficient information on handling and storage requirements and precautions			
48.	Containers bear labels enable identification			
49.	Requirements laid down by the concerned member states are met			
50.	Transportation is performed in safe, dedicated and secure containers and vehicles			

Annexure 9: Checklist for Quality Management System and Personnel

SN	Quality Management System	In	Out	NA
1.	Does the company have a written policy including management's active			

	commitment to quality			
2.	Is the policy signed by top management			
3.	Is there an approved quality manual and written procedures describing all related processes?			
4.	Do management reviews consider:			
	• Findings of internal audits, recommendations made and corrective actions taken?			
	• The overall effectiveness of the system in achieving quality objectives?			
	• Opportunities for updating and/or improving the system?			
5.	Is there a copy of the manufacturers' documents (such as COA or COC) supplied with each delivery?			
6.	Is there procedure for corrective and preventive actions			
7.	Trend Reports of findings and recommendations from Regulatory Inspection of the past 2 years			
8.	Certificate of Competency displayed and displayed Certificate of Competency validity documentation of disposition of out dated products maintained for 3 years			
Personnel				
9.	Organizational structure of the distributor is defined in an organizational chart.			
10.	The responsibility, role and interrelationships of all personnel is clearly indicated			
11.	Responsibilities and roles of employees working in key positions is defined in written job descriptions, incl. deputyship arrangements			
12.	All personnel involved in wholesale distribution activities is qualified in GDP requirements			
13.	Training includes aspects of product identification and avoidance of falsified medicines entering the supply chain			
14.	Specific training is provided where indicated (e.g. handling of hazardous products, radioactive materials as well as products presenting special risks of abuse, narcotics			

	or psychotropic substances, or temperature sensitive products)			
15.	Personnel receives initial and continuing training relevant to their tasks, based on written standard operating procedures (SOPs) according to a written training programme			
16.	The practical effectiveness of training is periodically assessed and documented			
17.	Has the company a sufficient number of qualified employees for these operations?			
18.	Are employee training and qualification records maintained?			
19.	Are there procedures in place ensuring good hygiene of the personnel			
20.	Proper Personnel Identification, ethical behaving and clothing			

Title: Standard operating procedure for **corrective and preventive action**			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

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Table of Contents

1. Introduction

Corrective and Preventive actions are taken when deviations or nonconforming work from the policies and procedures in the management system or technical operations have been identified. The root cause investigation process will provide objective evidence to implement corrective and possibly preventive actions as part of the CAPA system.

2. Purpose

The purpose of this SOP is to lay down the procedure for the initiation, evaluation, approval, implementation, tracking, effectiveness and verification of effectiveness of corrective and preventative actions, closure.

3. Scope

This SOP applies to all concerned departments of [X pharmaceutical Facility]

4. Acronyms:

APQR	Annual Product Quality Review
CAPA	Corrective and Preventive Action
HOD	Head of Department
OOT	Out of Trend
OOS	Out of Specification
QA	Quality assurance
SOP	Standard Operating Procedure

5. Responsibility

- Initiating department: responsible to initiate CAPA whenever there is non-conformity work

- Respective department: Responsible to initiate, rectify non- conformity work accordingly.
- Quality assurance unit (QA approver, QA reviewer, QA closure)/ Technical manager/ general manager/CEO)
  - Responsible to approve completeness, adequacy and, review
  - Responsible to assure necessary corrective and preventive action are taken and close the CAPA.
- Cross functional team: responsible to perform the recommended activity and attach supporting documents.

6. Definition

6.1. **Corrective and preventive action (CAPA):** CAPA is a tool of quality management system of implementation of corrective and preventative actions resulting from the investigation of incident/recall/component rejection/out of specification/change control/market compliant/internal or external audit observation/Annual product quality review/regulatory compliance action/non-compliance report/risk analysis/validation summary report.

6.2. **Corrective Actions** are taken to eliminate the root causes of deviations, and should be based on good quality investigations.

6.3. **Preventative action**: Pro-active in nature which is action executed to eliminate the cause of potential non-conformity and implemented independently from the occurrence of deviations (Preventive action i.e. act on potential deviation) and prevent occurrence.

7. Procedures

7.1. General CAPA management

7.1.1. All the corrective and preventative actions that are finalized as part of the respective system or procedure shall be monitored through the CAPA management SOP.

7.1.2. Each department shall initiate their respective finalized CAPA's as per the annex II below.

7.1.3. All CAPA's total time line period from initiation to closure shall not exceed 180 working days.

7.1.4. The time period from initiation to approval of the CAPA is 30 working days, 60 working days from approval of CAPA to closure of CAPA, 90 working days for extension of closure.

7.1.5. Any supporting documents wherever required, has to be attached in their original template or format, signed off and attached to CAPA initiated as applicable.

1.1 Intiation of CAPA

1.1.1 CAPA initiated in theinvestigation Incidents,OOS, OOT, Market compliants, deviations, component rejections, change controls, internal audits , external audits, validation, product recall, product quality review, risk analysis,or regulatory compliance and informed to the concern person from the intiating department by [QA personnel] **(Equivalent personnel**) responsible for the coordination of CAPA.

1.1.2 The responsible person from the intiating department intiate the CAPA as per the Annexure 2.

1.1.3 The CAPA intiator shall fill in the below given details in the template (Annexure II) and forward the same to the HOD or designee.

1.1.4 Evaluation of CAPA by HOD of designee of intiator department

1.1.5 In case of any discrepancy observed, the HOD or his designee shall send back the CAPA temepate for the intiator for corrections.

1.1.6 The initiatorrectifies the discrepancy and send back to HOD for review and approval.

1.1.7 The HOD forwards the filled Template to QA approval for review and approved the CAPA.

1.2 Review and Approval of CAPA by QA approver:

1.2.1 The QA approval review the CAPA for the completeness, adequacy and accuracy

1.2.2 On review of the above, the QA approver, approve the CAPA and sign off.

1.2.3 In case of any discrepancy noticed, the same shall be returned to both the initiator and HOD for rectifications.

1.2.4 On rectifications of the discrepancies, the initiator shall forward the CAPA to the HOD for the approval.

1.2.5 Up on approval by the HOD, QA-Approver shall review and approve the same.

1.2.6 On approval of CAPA, the QA-approver shall assign the CAPA number and the CAPA number should be generated on logical order.

1.2.7 On approval, the QA Approver shall inform the concerned person of the initiating department for the execution of the CAPA.

1.3 Execution of CAPA (Individual department and cross functional team)

1.3.1 The Initiator and concerned department perform the recommended activity and attach the supporting document (if any) as mentioned in the CAPA temperate.

1.3.2 Any change in the existing systems, procedures or documents required based on the recommended CAPA, shall be routed through SOP of change control.

1.3.3 If CAPA is related to certain department, the recommendations or action taken shall be communicated to the respective departments.

1.4 Review of CAPA implementation by QA Reviewer

1.4.1 On completion of the implementation activity by the initiating department, the QA reviewer review the implementation activities for the CAPA and supporting documents of each department for the completeness, accuracy and adequacy.

1.4.2 In case any discrepancy noticed, send CAPA back to the respective initiating or the cross function department for rectifications.

1.5 The initiating or cross functional department complete the rectifications and send back the CAPA format to the QA reviser.

1.5.1 QA reviewer, review the same and sign off.

1.5.2 On successful review, the QA reviewer inform for CAPA effectiveness check to the concerned department.

1.6 CAPA effectiveness verification by individual or cross functional departments

1.6.1 Each department that has been assigned the CAPA implementation carry out the effectiveness verification for their respective CAPA implemented.

1.6.2 Once done, each department attach any supporting documents against the respective CAPA format and sign off.

1.7 Review of Effectiveness verification by QA Reviewer

1.7.1 On completion of the effectiveness verification activity by the initiating department or the cross function team, the QA Reviewer review the effectiveness verification and supporting documents for each department for completeness, adequacy and accuracy.

1.7.2 In case discrepancy noticed, the same shall be informed to the respective cross functional department for rectifications and the cross functional team shall complete the rectification and send back CAPA template to QA reviewer

1.7.3 The QA reviewer, review the same and sign off.

1.8 Closure of the CAPA by QA closure

1.8.1 Based on the review by the QA reviewer, QA closure, close the CAPA with comments and sign off.

1.9 Extension of the CAPA closure

1.9.1 If activities related CAPA are not executed within 60 working days, in such case initiating department head shall request for extension with justification along with proposed date for completion of the same.

1.9.2 Period implementation of CAPA and further extension shall be proposed based on the risk assessment of existing process and impact on product quality.

1.9.3 QA approval shall review the reason and approve/reject the extension by signing off.

1.9.4 On approval, the CAPA closure shall be extended by not exceeding by 90 working days or can be with appropriate Justification of extension.

1.10 Review and Trending of CAPA

1.10.1 CAPA shall be reviewed by quality assurance every two weeks for its status, the details for the same shall be provided to concern HOD, CEO and concerned higher officials.

1.10.2 QA prepared Trends of CAPA on periodical basis by means of graphs/charts including details of type and category and information.

2 Distribution

This SOP will be distributed to:

- Technical manager office
- All concerned departments
- Original copy: Quality assurance/Managing director

3 Revision history

Revision number	Summary of change	Effective date
R0	New SOP	To be assigned
R1		
R2		

4 Annexures

- Annexure 1: CAPA log
- Annexure 2: CAPA format

5 References

- World Health Organization: deviation handling and quality risk management
- ISO13485: Quality management System

Annexure 1: CAPA log

Date	Product/system /Area	Tracking ref.No		Reference of parent Inv. format	Description		Status	Verified / sign/date
		Corrective action	Preventive action		Corrective Action	Preventive action		
1.								
2.								
3.								

Annex 2: CAPA Format

CAPA initiation
Source of information
CAPA No: Date:
Problem/observation/Information is related to:
• Equipment/process/vendor/material/ storage/warehouse/ distribution/…. • Feedback from regulatory agency/marketing/ managing directors • Internal /external audit • Any other source
Reference Document Number:
Brief description of parent document
Root cause summary:

Descriptive of corrective action:
Descriptive of preventive action:
Department: Initiated by: date
Review of the CAPA by HOD (head of department)
Review of CAPA (comments) Name: sign/date:
Approval of CAPA by QA
Review of comments Name: sign/date:
CAPA implementation by initiating department
Corrective Action implemented:

Preventive action Implemented:
Reference document attached:
CAPA implemented by: Name: sign/date
Review of CAPA implementation by QA
Review of corrective action implementation:
Review of preventive Action implementation:
Reviewed by Quality assurance: Name: sign/date
Effectiveness check of the implemented CAPA by department
Effectivenesscheck comments Effeteness check by: Name: sign/date
Effectiveness check by QA

Effectiveness comment by QA Checked by:
Extension of CAPA closure
Reason/ Justification of extension:
Approval of extension of closure:
Comments
Review and closure of CAPA
Comments
CAPA closed by: sign/ date

Title: Standard Operating Procedure for Complaints Handling			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

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Disclaimer: This is a model standard operating procedure. It incorporates generic guidance principles only. Firms are encouraged to adapt their own SOPs as necessary to suit their in-house procedures.

1. Background

Complaint is any written, electronic or oral communication that alleges deficiencies related to the identity, quality, reliability, safety, effectiveness or performance of medical product. All complaints and other information concerning potentially defective medicinal products must be collected and reviewed. [This company] must maintain a record of all customer complaints received relating to medicinal products. There should be a distinction made between complaints about the quality of a medicinal product and those relating to distribution related matters.

2. Purpose

The purpose of this SOP is to describe effective and uniform compliant handling procedures including initiation, review and reporting of quality related problems of medical product.

3. Scope

This SOP is applicable to compliant handling of quality defective medical product. For reported incidents of safety and efficacy; [this Company] should use this SOP when an action is required to protect public health.

4. Acronyms and Abbreviations

Nil

5. Definition

- **Critical quality defects:** Is potentially life threatening or could pose a serious risk to patient which is categorized under Class I product recall guideline of EFMHACA.
- **Major quality defects:** are those which could cause illness or improper treatment but are not critical, defect that could be categorized under Class II product recall guideline of EFMHACA.
- **Minor quality defects:** are those which are unlikely to pose a risk to patient, Class III recall guideline of EFMHACA

6. Responsibility

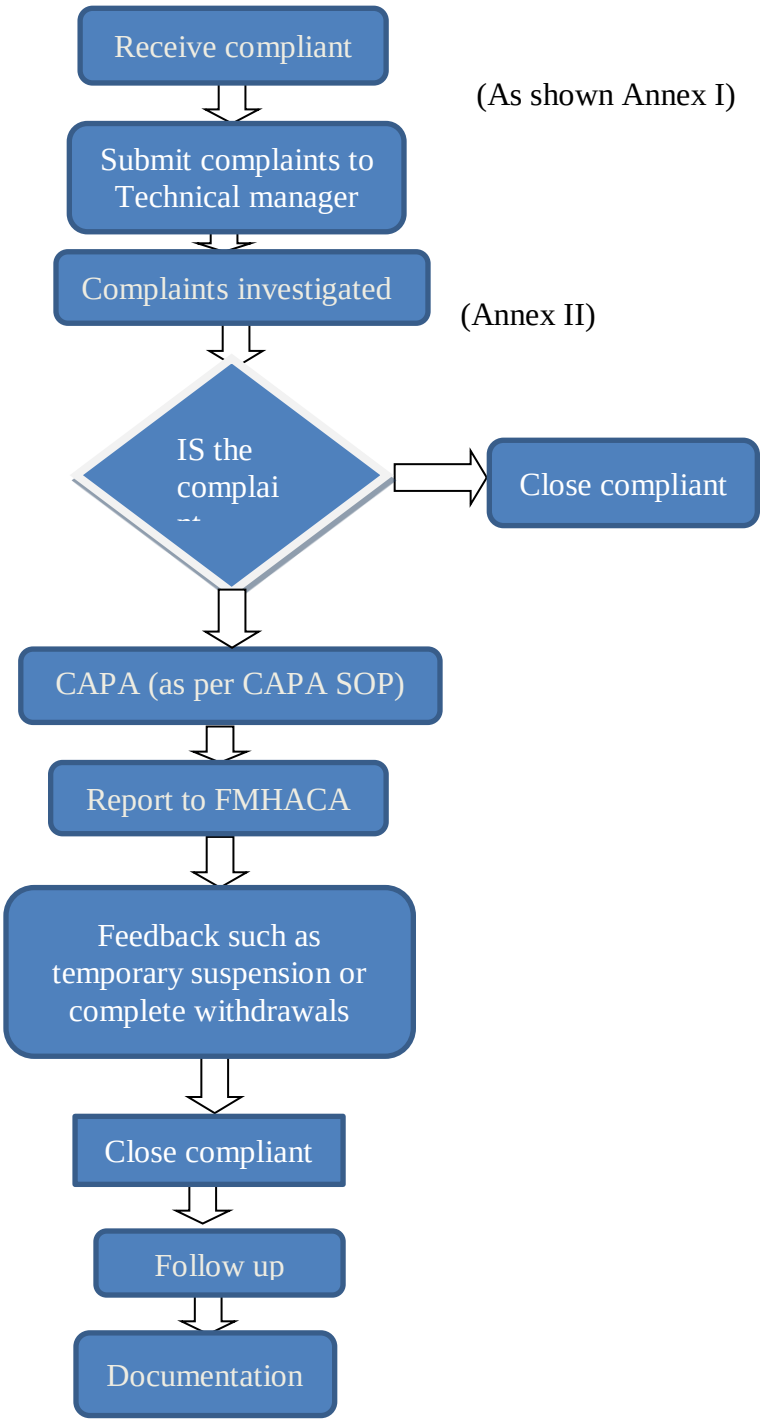
6.1. It is the responsibility of the technical manager to receive complaints; conducting the investigation and compile reports based on their investigation. The technical manager should deliver a complete report to the compliant handling team (which composed of ware house manager, sales man/promoters) and if necessary, appropriate follow-up action should be taken after investigation and evaluation of the complaint.

6.2. Marketing department/Sales man are responsible to collect any written, electronic or oral communication that alleges deficiencies related to the identity, quality, reliability, safety, effectiveness of product and forwarding the complaints to the technical manager.

7. Materials and equipment

- Customer complaints receiving format
- Investigation of market compliant format

8. Procedure flow chart



9. Procedure

9.1. Receive complaints in written or oral or electronic or any other form. Record the details of the complaints from the originator in prescribed format (as shown in annexure I).

9.2. Receive the product from the customer, if any (as shown in annexure I)

9.3. Upon receipt of complaint, the Technical manager or Quality Assurance department or assigned personnel should enter the complaint in the complaint register (as per the Annexure 2). The following details should be included;

- Serial Number
- Date of receipt
- Complaint Reference
- Complainant details
- Details of complaint (Product Name, Batch No., Quantity of sample & relevant information as appropriate)
- Nature of Complaint (To be filled during investigation)
- Preventive Action (To be filled after investigation)
- Remarks: Reply Date (To be filled after investigation)

9.4. Review and evaluate all complaints to determine whether investigation is necessary

9.5. If investigation is required, after logging the complaints, the QA department or formed team or any other responsible person has to start investigation of complaints (Annex II). Check the condition of the stock and the stock card to confirm the lot no and expiration date and if it is the same with the old stock. Besides, check the nature of complaint, verify the complaint sample if any; and on the basis of initial investigation, then categorize the complaints into critical/major /minor

9.6. During the investigation, include possible impact to other batches/units, the complaint history for the particular batch/unit and a review of [the company] profile that could have led to the complaint.

9.7. If investigation is not required, maintain records including the reasons why the investigation was not done.

9.8. Appropriate corrective and preventive actions should be documented and completed for each confirmed complaint.

9.9. Prepare a reply based on the complete investigation.

9.10. Provide feedback to the customer or complainant. [the company] must write a response letter to the complainant to explain the investigation approach, the results obtained and any implications, in case the quality problem was confirmed.

9.11. When the corrective action has been completed, the conclusion should also be recorded and Corrective Actions technical manager should sign off on the form and close the complaint.

9.12. Follow up

9.13. Maintain all documentations and records

10. Document distribution

The SOP shall be distributed to:

- Technical manager office
- Warehouse manager office
- Sales man/promoter office

11. Records

11.1. After the completion of each activity, all documents and correspondence should be recorded and filed in folder.

11.2. File numbers should be kept electronically and/or in hard copy for easy of tracing folders.

11.3. The change histories of this SOP should be kept and filed properly including all versions.

11.4. The different versions should be kept for _____years in traceable manner.

12. Amendment histories

This SOP will be revised every two years or amended as appropriate**.**

Revision Number	Summary of Changes	Effective date
R0		
R1		
R2		

13. Reference

- Food, Medicine and Healthcare Administration and Control Proclamation No. 661/2009. [http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf. Accessed 28 Mar 2013];
- https://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/UCM061481.
- Product Recall guideline (2015).1st edn. Available at: (http://www.fmhaca.gov.et/documents/GDP,%20GSP%20and%20Recale%20Guideline%202015.pdf)
- https://www.SOP for Handling of Market Complaints in Pharmaceuticals Pharmaceutical Guidelines.htm
- https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM379139.pdf

14. Annexes

Annex 1: Customer complaints Receive form

Date:_____

Complaint recorded by: _____

Complaint reported through Email, Fax, Oral, P.O box, other

Received from: _____

Address: _____

Contact details: _____

Product name, _____

Strength _____

Pack size_____

Bache no._____ _Expiry date_____

Quantity_____

Received by_____ sign_____

Annex 2: Investigation of compliant form

Ref.no---------- date of receipt----------

Bach no--------

Product name---------- expired date ----------

Incidence----------

Nature of compliant Critical/Major/Miner_____

Interpretation----------

Scientific or practical reason_____

Corrective action_____

Conclusion_____

Technical manager (sign, Date)_____

Title: Standard Operating Procedure for Return products Handling			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

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1. Introduction

It is essential to define the management of returned products that are sent back to the initial distributors for any reason whatsoever. These returns must be carefully analyzed prior to any salvaging, redistribution or disposal because products that have left the control of the warehouse should only be returned to saleable stock if they are proven to meet the product's appropriate standards of safety, identity, strength, quality and purity.

This Standard Operating Procedure will describe the site's roles and responsibilities and the order of events for products returned from the market to the warehouse.

2. Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for handling of the returned products.

3. Scope

This SOP is applicable for handling of the returned products.

4. Responsibilities

- Sales/distribution manager is responsible to inform the technical and warehouse managers about the returned product.
- Warehouse officer is responsible to identify the product returned, reconcile against documents received and to verify the physical conditions of the received drug product
- Warehouse manager is responsible to manage, coordinate and assess the returned product management
- Technical manager is responsible to conduct assessment on returned products and to decide on disposition of those products

5. Procedures

5.1. Sales/distribution manager receive notification on the returned product and pre-notify warehouse manager and the technical manager before returned product arrive the warehouse.

5.2. While receiving returned product, warehouse officer shall identify the returned product batch by name of the product, batch number, Expiry date against received documents and shall check the following:

a. The specific reasons for the return product
b. Customer name & address who returned the product
c. Physical condition of all containers, and note the number of damaged containers and inform warehouse manager
d. Quantity of shippers received and mentioned in returned document
e. Integrity of seal on each container/shipper
f. Storage condition of the material before returning the product.
g. Storage condition after product returned.

5.3. Warehouse manager receive and log in the returned product log book. Assign unique sequential number for each returned product on the log book.

5.4. Identify all product as “Returned Good” with status label.

5.5. Move the product to the designated and secure Returned Good Storage area.

5.6. The warehouse manager and technical manager examine the assess the returned product. This assessment should be recorded on the Returned Product Assessment Form (annex II). The warehouse manager and technical manager formally decide on the disposition of the product either return the product to saleable stock or reject the product.

5.7. The Warehouse manager shall update the Returned Medicinal Products Log (Annex 1) with the disposition of the product.

5.8. If the product is rejected warehouse officer shall transfer to the ‘reject area’ and recorded in Rejected Products Log.

5.9. If the product is returned to saleable stock warehouse officer shall transfer the product saleable stock area and enter onto the inventory management system.

6. Document distribution

This SOP shall be distributed to:

- Technical manager office
- Warehouse manager office
- Sales/distribution manager

7. Records

1.1. After the completion of each activity, all documents and correspondence should be recorded and filed in folder.

1.2. File numbers should be kept electronically and/or in hard copy for easy of tracing folders.

1.3. The change histories of this SOP should be kept and filed properly including all versions.

1.4. The different versions should be kept for _____years in traceable manner.

8. Amendment histories

This SOP will be revised every two years or amended as appropriate**.**

Revision Number	Summary of Changes	Effective date
R0		
R1		
R2		

Annexes

Annex 1: Returned products Log

Date of product returned	Name of the product	B.no	Exp. Date	Quantity	Returned by	Reason for return	Condition of the product	Disposition details (S/R)*	Checked by

* S (Saleable stock), R (Reject)

Annex 2: Returned product assessment form

Date	Product name	Product strength	Batch no.	Expiry date	Quantity

Returned from: _____

Reason: _____

Date of original delivery to customer: _____

(must be within 10 days of receipt of return)

Description of the condition	**Response**	
Acceptable shelf-life remaining?	Yes	No
Products in original unopened pack?	Yes	No
Products in good condition?	Yes	No

Evidence that the product was transported, stored and handled under proper conditions?	Yes	No
Evidence that the product was originally supplied to the customer from the company (e.g. copy of delivery note attached)?	Yes	No
Reason to believe that product is / has been falsified?	Yes	No

Product assessed by: _____Date: _____

Disposition_____

(Return to Saleable Stock or Reject)

Approved by: _____(RP) Date: _____

Title: Standard Operating Procedure for Recall Handling			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

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1. Introduction

Product recall is indicated when a product distributed could represent a hazard to the consumer. During this event recall program will effectively remove products from circulation. All products distributed have production dates, expiry dates, and batch number attached to them. In the event of a problem with any product, contacting all customers who received the product by letters, phone fax or any means of communication to recall the products.

In the case of a serious health hazard, a public warning via the media, either on a local or regional basis to ensure the public safety should be released.

2. Purpose

The purpose of this SOP id to establish the procedure for prompt and efficient recall of products known or suspected to be defective, from the market.

3. Scope

This SOP applies to all types of recalls either initiated by [XXX company] by its initiative or by the Ethiopian Food, Medicine and Healthcare Administration and Control Authority (EFMHACA).

4. Responsibilities

- It is the responsibility of the Technical Manager/responsible person to notify the product recall to the regulatory authority and to other relevant organizations.
- The designated responsible person/Technical manager shall ensure that product recall can be executed effectively and promptly upon receiving the recall instruction from the Managing Director or recall order from any regulatory authority.

5. Procedure

5.1. Recall can be initiated in the following situations:

a. A recall instruction decision from the Managing Director in response to a complaint received, where serious product quality problem was detected in product and/or product was found to have potentially caused adverse reactions in consumers;

b. A recall instruction decision from the Managing Director in response to any in-house detected defective products;
c. A recall order from any Regulatory Authority including EFMHACA

5.2. Recalls are classified into the following categories:

Class 1 Recall

Initiated when the product defect poses a life-threatening situation to users or could cause a serious risk to health. Some examples of defects that will result in Class 1 recall are contamination with toxic substances and products with major labelling errors. Such recalls shall be notified licensee's clients with highest urgency and reported to EFMHACA immediately (within 24 hours).

Class 2 Recall

Initiated when the problem or defect could result in illness or improper treatment, but the consequences unlikely to cause serious harm to users as in class 1 recall. Some examples of defects that will result in Class 2 recall include products with minor labelling errors or products which fail to meet product specification or pharmacopoeia standards but are likely to cause minimal hazard to users.

Class 3 Recall

Initiated when there is a situation in which the product to be recalled contains defects that may not pose a significant hazard to health. Example: labelling violations.

5.3. The designated responsible person/Technical manager shall inform the sales/marketing department or inventory control section to generate the distribution records of the affected batch. The information should include: name product, batch number, manufacturing & expiry dates, the quantity to be recalled and the areas of were the product was distributed.

5.4. All sales of defective products will be ceased immediately and the designated responsible person/technical manager shall instruct the storekeeper to immediately remove any balanced

stock of the affected batch from the warehouse and quarantine the goods at designated quarantine area.

5.5. All recipients of the affected product shall be notified the nature of the recall by telephone. For end-user recall, means of appropriate mass media communication should be considered.

5.6. A recall letter will be prepared by the designated responsible person/technical manager to be sent to all recipients of the affected batch listed in the distribution record to inform them that recall operation is activated, and to stop selling and remove the affected product from the racks with immediate effect

5.7. The designated responsible person/technical manager shall notify EFMHACA for which the affected product batch is exported should be notified of the recall in situations 1.1 and 1.2. Report must be made to the Authority within 24 hours from the receipt of the defective reports.

5.8. The designated responsible person/technical manager shall instruct the delivery personnel to collect the recalled product back from the market, the pharmacies, hospitals, distributors or any other outlets as stated in the distribution record.

5.9. The warehouse manager shall clearly identify and store all recalled goods collected from the market in the designated secure area while awaiting management's decision or the Authority's instruction on their fate.

5.10. The designated responsible person/technical manager shall record the progress of the recall process and issue the final report, including a reconciliation between the delivered and recovered quantities of the products.

5.11. The designated responsible person/technical manager should file the records in the Recall file kept. Detail of the product should be written in pharmaceutical product recall log (appendix 1) and pharmaceutical recall log (appendix 2).

5.12. The designated responsible person/technical manager shall carry out a mock recall on a yearly basis to assess the effectiveness recall system put in place. Any gaps found in the

system during the mock recall shall be appropriately addressed so that operation can be activated immediately and promptly during an actual recall.

6. Reference to other documents

- Product Recall Form (FORM-XXX)

7. Document distribution

The SOP shall be distributed to:

- Technical manager office
- Warehouse manager office
- Sales/distribution office

8. Records

1.1. After the completion of each activity, all documents and correspondence should be recorded and filed in folder.

1.2. File numbers should be kept electronically and/or in hard copy for easy of tracing folders.

1.3. The change histories of this SOP should be kept and filed properly including all versions.

1.4. The different versions should be kept for _____years in traceable manner.

9. Amendment histories

This SOP will be revised every two years or amended as appropriate**.**

Revision Number	Summary of Changes	Effective date
R0		
R1		
R2		

Annexe

Annex 1: Pharmaceutical product recall log

Notification receipt date	Product name	Product strength	Dosage form	Batch no(s)	Expiry date	Product distributed (Y/N)	Date recall closed	Entry by

Annex 2: Pharmaceutical product recall record

I. Details of the Recall	
Product name	
Product strength	
Product form (e.g. tablets, sachets, powder)	
Product packaging (e.g. tablets in a tub, blisters in a carton)	
Batch no(s)	
Expiry date	
PA number	
Name of the marketing authorisation holder	
Reason for recall	
Classification of recall	
Level of recall (e.g. to wholesale level, to retail level, to consumer level)	
Supplier details	
Total quantity received from supplier for each batch	
Total quantity distributed for each batch	
Cause of the quality defect	

(Note this only applies if the recall action was taken as a result of an error that occurred at the company)	
Specific corrective actions to be implemented by the company addressing the issue which led to the recall (Note this only applies if the recall action was taken as a result of an error that occurred at the company)	
Section I completed by: Date:	
II. Results of the Recall – Reconciliation	
(a) Number of packs of recalled product received from supplie	
(b) Number of packs of recalled product in stock	
c) Number of packs of recalled product distributed	
(d) Number of packs of recalled product received back from customers	
(e) Number of packs of recalled product not returned	

Percentage of packs reconciled (i.e. number of packs received back as a % of the number of packs distributed) (d) / (c) x 100	
Unaccounted stock (b) – {(a)– (c)}	
Section II completed by: Date:	
III. Chronological Account of the Recall	
Date quality defect identified	
Date quality defect reported to supplier/EFMHACA	
Date of approval of recall notification by the EFMHACA	
Date recall notification received	
Date of quarantining of stock held	
Dates within which recalled packs were received back from customers	
Dates within which recalled packs received back from customers was quarantined	

Date of sending Recall Report to the supplier/manufacturer/EFMHACA	
Section III completed by: Date:	

Report reviewed by (RP):_____Date:_____

Title: Standard Operating Procedure for Medicine Waste Handling and Disposal			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

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1. Introduction

Medical products may arrive past or near their expiry date, may be inappropriate for the needs, become unfit for use or may be damaged because of unforeseen reasons. Segregation of unfit for use medical products from usable medical products and disposing them at regular intervals in environmentally friendly disposal firm or area is one of the principles that must be followed.

2. Purpose

This Standard Operating Procedure (SOP) is to detail the good practice of safe and appropriate handling and disposal of medicine waste in compliance with current national legislative requirements.

3. Scope

This SOP applies to safe and appropriate medicine waste handling and disposal.

4. Acronyms

Nill

5. Definition

a) **Biodegradable** means a type of waste, typically originating from plant or animal sources, which may be degraded by other living organisms.

b) **Central disposal site** means a site established and operated by appropriate organ which provides medicines waste management and disposal services.

c) **Disposal Firm** means any waste Management Company licensed to dispose medicines waste. It can be a medicines importer, wholesaler, distributor, manufacturer or any private or public business authorized to dispose medicines wastes for fee.

d) **Disposal Referral System** means a system to pass on medicines wastes to a licensed disposal firm, medicines supplier, manufacturer or central disposal site for disposal services for fee.

e) **Hazardous Substance** means a waste that poses substantial or potential threats to public health or the environment ignitability, reactivity, corrosiveness and toxicity.

f) **High Temperature Incinerator** means an incinerator that generates at least 1200°C in the secondary chamber, and is fitted with gas cleaning equipment.

g) **Highly Engineered Sanitary Landfill** means an engineered landfill with landfill gas extraction, groundwater monitoring and leachate treatment facilities and monitored by trained staff

h) **Medicine waste** means waste which encompass the following:

- All properly unsealed bulk products or loose tablets and capsules. If unexpired these shall only be used when the container is still sealed, properly labeled or still within the original unbroken blister packs,
- All cold chain damaged, unexpired medicines that should have been stored in a cold chain but were not,
- Counterfeit, substandard and adulterated,
- Discarded items used in the handling of medicines,
- Expired, unused, spilt, and contaminated,
- Improperly sealed or labeled or stored,
- Expired, damaged, and improperly sealed or labeled or stored laboratory reagents,
- Expired, damaged, and improperly sealed or stored medical supplies;
- Prohibited or unauthorized medicines,
- Expired, damaged, and improperly sealed or labeled or stored raw materials, and
- Discarded packing materials.

i) **Medium Temperature Incinerator** means a two-chamber incinerator with minimum temperature of 850^{o}C.

j) **Open Controlled landfill** means a landfill where medicines waste is covered with large amount of municipal wastes but it is still left open.

k) **Open uncontrolled landfill** means a landfill where medicines waste is not covered with large amount of municipal wastes and it is left open.

l) **Sewer** means a flushing of medicines wastes to the sewerage system after proper dilution and regulation.

m) **Waste Inertization** means a variant of encapsulation and involves removing the packaging materials including blister packs, paper, cardboard and plastic from the medicines and then crushing and mixing medicines with cement, lime and water.

n) **Waste Encapsulation** means a landfill approach to reduce the risk of medicine waste through immobilizing the medicine in a solid block within a plastic or steel.

6. Responsibilities

Title	**Responsibility**
Storage and Distribution Head/ Warehouse manager	• Verify proper segregation of unfit for use item from usable items. • Ensure placement of unfit for use item in designated quarantine room. • Confirm retention of medicine waste records • Ensure timely and proper disposal of medicine waste in-line with national regulatory authority procedure.
Warehouse personnel	• Timely segregation of unfit for use products from usable items • Placement medicine waste in secure quarantine room • Maintenance of medicine waste record before placement to quarantine room. • Ensure timely disposal medicine waste in-line with national authority procedure.
Technical Manager	• Verify proper and timely disposal of quarantined medicine waste. • Ensure placement of medicine waste in safe and secure quarantine room

7. Materials and Equipment

- Personal protective equipment such as gown, glove, face masks, boots etc
- Stationary materials
- Appropriate disposal equipment

8. Procedures

8.1. Check the presence of unfit for use medical products such as expired, damaged, returned products by looking on bin cards or other stock controlling mechanisms such as electronic data base and confirm the stock present in the warehouse. Investigate when there is discrepancy.

8.2. Separate unfit for use medicines from useable stocks including expired, damaged and returned products in to designated quarantine room.

8.3. Record each medicine waste on the register book and compile appropriately, made ready for regulatory inspection as per annexed format **(Annex II).**

8.4. Establish a disposal team consisting of supervising pharmacists, store house keepers, who are experienced pharmaceutical warehouse personnel.

8.5. Sorting out of each pharmaceutical from stockpiles into separate categories for which different disposal methods are required. Sorting is done in the open or in a well-ventilated area as close as possible to the stockpile in an orderly way, with all sorted material clearly labelled and separated at all times.

8.6. Supply staffs with protective equipment (gown, gloves, boots, dust masks, etc.), and works under the direct supervision of a pharmacist.

8.7. Train disposal team on sorting criteria, and health and safety risks associated with handling wastes.

8.8. The first step in dealing with stockpiles is to remove and dispose of non-drug, non-chemical items. All such items should be clearly separated from pharmaceuticals and chemicals.

8.9. For those to be disposed a decision is made on the best method of disposal. The pharmaceuticals to be disposed should be separated from their packaging at disposal site.

8.10. The remaining unwanted pharmaceuticals that should never be used and considered pharmaceutical waste must be:

a. Sorted by active ingredients
   - Controlled substances; e.g. narcotics, psychotropic substances
   - Anti-infective drugs
   - Antineoplastic
   - Antiseptics and disinfectants etc.

b. Sorted by dosage form:
   - Solids, semi-solids and powders such as tablets, capsules, granules, powders for injection, mixtures, creams, lotions, gels, suppositories, etc.;
   - Liquids such as solutions, suspensions, syrups, etc.; and ampoules;
   - Aerosol canisters such as propellant driven sprays and inhalers.

8.11. Once sorted, the pharmaceuticals wastes should be carefully packed into steel drums or into containers such as sturdy cardboard boxes, with the contents clearly indicated on the outside of the containers.

8.12. Label containers containing sorted medicines waste and kept in a dry, secure and preferably a separate room.

8.13. Submit recorded medicine waste along with application letter as per **annex II and III** and communicate with appropriate regulatory body ahead of disposal date.

8.14. Disposal site is selected in agreement with appropriate regulatory body considering Environmental Impact Assessment

8.15. Transporting of sorted medicines waste to agreed disposal sites in closed motor vehicles to avoid pilferage.

8.16. Dispose sorted medicines with appropriate disposal method in the presence of EFMHACA inspectors as per national disposal legislatives.

8.17. Formal request of Disposal Certificate from the Authority and document disposal certificate for regulatory purpose and show to inspectors when requested.

9. Distribution

This SOP distributed to:

- Original copy kept in quality assurance department/general managing/ technical manager
- Warehouse manger

10. Records

1. After the completion of each activity, all documents and correspondence should be recorded and filed in folder.
2. File numbers should be kept electronically and/or in hard copy for easy of tracing folders.

3. The change histories of this SOP should be kept and filed properly including all versions.
4. The different versions should be kept for _____years in traceable manner.

11. Revision History

Revision number	Summary of change	Effective date
R0	New SOP	To be assigned
R1		
R2		
R3		

12. References

1. Food, Medicine and Healthcare Administration and Control Authority of Ethiopia Medicines Waste Management and Disposal Directive, 2011
2. World Health Organization: Guidelines for safe disposal of unwanted pharmaceuticals

13. Annexes

Annex I: Summary of Disposal Methods

Category	Disposal methods	Comments
Solids Semi-solids Powders	Landfill Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	
Liquids	Sewer High temperature incineration (cement kiln incinerator)	Antineoplastics shall not be disposed in sewer.
Ampoules	Crush ampoules and flush diluted fluid to sewer	Antineoplastics shall not be disposed in sewer.
Anti-infective medicines	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to sewer.
Antineoplastics	Return to supplier, manufacturer or Donor, Waste encapsulation, Waste inertization, High temperature incineration (cement kiln incinerator)	Antineoplastics shall not be disposed into landfill unless encapsulated, and shall not be disposed by sewer or by medium temperature incineration.
Controlled substances	 Waste encapsulation Waste inertization Medium and high temperature Incineration (cement kiln incinerator)	Shall not be disposed into Landfill unless immobilized.
Aerosol canisters	Landfill, waste encapsulation	Not to be burnt: may explode.
Disinfectants	To sewer: small quantities of diluted disinfectants (max. of 50 liters per day under supervision)	No undiluted disinfectants shall be disposed to sewer.
PVC plastic, Glass	Landfill	Shall not be disposed by burning.
Paper, cardboard	Recycle, burn or landfill	

Annex II: Medicines Waste Register Book

S.no	Description of Medicines Wastes (generic & brand name, strength and dosage form)	Unit Type and Size	Quantity	Batch number	Expired date	Reason for Disposal (expired, damaged, spilled, etc)	Manufacturer/ Supplier	Store location	Purchase Value

Annex III: Medicines Waste Disposal Application Form

To: Appropriate Organ (when the applicant has its own disposal facility)

Subject: Request for Medicines Waste Disposal

I/We ----------of (address) ----------undertaking the business of (specify) ---------- hereby apply for disposal of medicines waste.

License Number----------issued on----------

Location of Business----------

Name of person in charge ----------

Reason for disposal----------

Weight (in Kg) ----------

Value (in Birr) ----------

Attached herewith is the list of products to be disposed

Declaration

I certify that the information provided in the application form is true and correct.

Date of application---------- Signature of Applicant----------

----------Stamp----------

Title: Standard Operating Procedure for Security			**Logo**
Status:			**SOP Nº.**
Prepared by	**Approved by**	**Revised by**	Version **Nº.**
Name:	Name	Name	Effective date:
Sig:	Sig:	Sig:	Review date:
Date:	Date:	Date:	Supersedes:

Table of Contents

1. Introduction

There are different critical barriers that adversely impact supply chain operations such as theft during storage, distribution and transportation. Well-functioning pharmaceutical supply chains system that will effectively deliver medicines to the end user is very important. This can be ensured by developing and implementing security procedures to assure the availability of quality and effective medical products.

2. Purpose

The purpose of this SOP is to detail the procedures for mitigating security risks to the supply chain, such as theft during storage, distribution and transportation processes.

3. Scope

This SOP is applied on organization engaged in storage, distribution and transportation of pharmaceutical products.

4. Responsibility

4.1 The security guards are responsible to:

- Ask security badge to approve someone to be on site
- Ensure adequate lighting inside and outside the facility
- Check the pharmaceutical products to be transported before delivery

4.2 The store managers are responsible to:

- Aware of the procedures to address a situation and how to report it
- Assure fire suppression and alarm systems are secured, monitored.
- Receive and dispatch medical products as per receiving and dispatching SOPS.
- Assure warehouse integrity by periodic inspection.
- Maintain all necessary records.

4.3 **The technical manager or other responsible body is responsible to:**

- Develop the Security Plan
- Verify the works of the store manger
- Maintained all necessary records for reasonable period of time
- Use monitoring systems to prevent unauthorized access to storage areas and during transportation as needed.
- Designate appropriate staff as security personnel as needed.
- Provide specific training in maintaining integrity and protecting access controls in storage area in warehouse and during transportation.
- Develop security management system integrated with the quality management system

4.4 **The driver is responsible to:**

- Assure all pharmaceutical products in delivery are distributed without any theft.

5. Procedures

5.1. Develop the Security Plan

5.2. Designate appropriate staff as security personnel as needed.

5.3. Provide specific training in maintaining supply chain integrity and protecting access controls in storage area in warehouse and during transportation.

5.4. Use monitoring systems to prevent unauthorized access to storage areas and during transportation as needed.

5.5. Maintained all necessary records for reasonable period

5.6. Develop security management system integrated with the quality management system

5.7. Aware of the procedures to address a situation and how to report it

5.8. Assure fire suppression and alarm systems are secured, monitored and maintain necessary all records.

5.9. Receive and dispatch pharmaceutical products as per receiving and dispatching SOPS.

5.10. Assure warehouse integrity by periodic inspection and maintain all necessary records

5.11. Ask security badge to approve someone to be on site

5.12. Ensure adequate lighting inside and outside the facility

5.13. Check the Pharmaceutical products to be transported before and after delivery to assure any theft

6. Distribution

This document is distributed to

- Technical managing office
- Warehouse manager
- Security guards
- Deliver/Drivers

7. Records

1. After the completion of each activity, all documents and correspondence should be recorded and filed in folder.
2. File numbers should be kept electronically and/or in hard copy for easy of tracing folders.
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