Good Storage and Distribution Practices audit report

Auditee name	XXXXXXXX Pharmaceuticals
Site	XXXXXXXX
Country	XXXXXXXXX.
Date	XXXXX 20XX
Reference no.	XXXX_GSA_XX_00XXX

Foreword

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About QUAMED

QUAMED is a non-profit association whose goal is to contribute to improving access to quality medicines. Further information at: www.quamed.org

Author(s)

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QUAMED internal approval

Laurine LAVERGNE, QUAMED technical coordinator		

Report validity

This report is valid for three years from the date of approval, unless major changes impacting the report outcomes occur during this period.

EXECUTIVE SUMMARY

This WHO Good Storage Distribution Practices (GSDP) audit was organized by QUAMED and requested by XXXXXXXXXXXXXXXXXXXXXXXXXX (XXX).
The purpose of the audit was to assess the compliance of XXXXXXXXXXXXXXX against the current World Health Organization (WHO) Good Storage Distribution Practices (GSDP) guidelines[1].

Summary and conclusions:

XXXXXXXXXXXXXXXX Pharmaceuticals XXX is a pharmaceutical and medical devices import and distribution company with warehousing premises located at XXXXXXXXXXXXX, and head offices located XXXXXXXXXXXXXX. The company was established in the year 20XX and is licensed by the XXXXXXXXXXX to engage in the importation and distribution of pharmaceuticals and medical devices.

XXXXXXXXXXXX was audited for compliance with the WHO GSDP guidelines. A summary of the audit findings is discussed below:

XXXXXXXXXX has all the required licenses and official documents required by the XXXX to operate an import and distribution business for pharmaceuticals and medical devices. A basic quality management system was established, although this was observed to have significant weaknesses especially with the documentation system. The preparation, format, approval process and distribution system for SOPs was not defined, as such it was observed that several SOPs at the company were neither approved nor appropriately structured. Furthermore, SOPs for key QMS elements such as deviations management, CAPA management, non-conforming products, returned products management among others were not in place. The content of available SOPs and thereby the practice relating to these activities was observed to be deficient in several instances; including the management of trainings, self-inspections, and recalls.

Implementation of the Quality assurance function was observed to be inadequate in that although an appointment was made for the QA function, these responsibilities were not detailed in the job description of the responsible person.

The warehousing capacity was adequate for the volume of products handled. The structure was fair, although some weaknesses in maintenance and cleaning of the warehousing facilities was observed. Furthermore, several gaps were observed in the storage practices of products at the warehouse: for example, products were not stored off the wall, pallets were observed to be damaged and not well spaced, cartons were damaged during storage, hazardous products were not appropriately segregated, among other issues.

The storage conditions at the warehouse were within expected limits, although these limits were not defined by the company. Mapping studies were not appropriately conducted to determine the hot and cold spots in the warehouse, consequently thermohygro loggers were not appropriately located within the warehouse.

Although transport facilities for medical products were available, some weaknesses regarding inadequate monitoring of transport conditions, and validation of routes was noted.

[1] *WHO good storage and distribution practices for medical products, Annex 7, WHO Technical Report Series 1025, 2020*

This audit in summary identified the following observations:

Type of observations	Number
Critical	0
Major	11
Other	12
Remarks	0

Based on the current audit performed, XXXXXXXXXXXXXXXX is deemed:

- **<u>to operate at an unacceptable level of compliance</u> with the requirements of World Health Organization Good Storage and Distribution Practices**. The corrective and preventive action plan must be implemented to ensure all observations are adequately resolved.

QUAMED GSDP level		
XXXXXXXXXXXXX Pharmaceuticals XXX	**Level 1**	Distribution sites with an unacceptable level of GSP compliance, after a GSDP or MQAS audit by QUAMED and/or other official or recognized organizations.

CONTENT

ACRONYMS

API	Active Pharmaceutical Ingredient
BP	British Pharmacopoeia
CAPA	Corrective Action Preventive Action
CE	European Conformity
CTD	Common Technical Dossier
DG ECHO	Directorate General for European Community Humanitarian Office
EDQM	European Directorate for the Quality of Medicines
EMA	European Medicines Agency
EP	European Pharmacopoeia
FDA (US)	Food and Drug Administration (United States Regulatory Authority)
FEFO	First Expired First Out
FIFO	First In First Out
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
GSDP	Good Distribution Practices
GSDP	Good Storage and Distribution Practices
HQ	Headquarters
IAPQ	Inter-Agency Product Questionnaire
ICH	International Conference on Harmonization
INN	International Non Proprietary Name
ISO	International Organization for Standardization
LMA	Local Market Assessment
ML	Maturity Level
MOH	Ministry of Health
MQAS	Model Quality Assurance System (for Procurement Agencies)
NGO	Non-Government Organization
NRA	National Regulatory Authority
PA	Procurement Agency
PIC/S	Pharmaceutical Inspection Cooperation Scheme
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RH	Relative Humidity
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authority
USAID	United States Agency International Development
WHO	World Health Organization
WHO PQP	WHO Pre-Qualification Program
WLA	WHO-listed authority

INTRODUCTION AND BACKGROUND INFORMATION

This WHO Good Storage Distribution Practices (GSDP) audit was organized by QUAMED and requested by the XXXXXXXXXXXXXXXXXXXXX, (XXX).

The purpose of the audit was to assess the compliance of XXXXXXXXXXXXXXX Pharmaceuticals, against the current World Health Organization (WHO) Good Storage Distribution Practices (GSDP) guidelines[2].

The GSDP audit was performed on XXth and XXth April 20XX by XXXXXXXXXXXXXXX, QUAMED auditor. Dr. XXXXXXXXXXXXXXX declared no conflict of interest with regards to this assignment.

The agenda of the audit is presented in **Annex 1.**

GENERAL INFORMATION ON THE AUDIT

XXXXXXXXXXXX Pharmaceuticals PLC is a pharmaceutical and medical devices import and distribution company with warehousing premises located at XXXXXXXXXXXX, and head offices located at XXXXXXXXXXXX Industrial zone. The company was established in the year 20XX and is licensed by the XXXXXXXXXXXX to engage in the importation and distribution of pharmaceuticals and medical devices. The company imports pharmaceuticals and devices from several countries including India and China, among others. The company's main customers are hospitals, universities, NGOs and other wholesale pharmacies. According to the company presentation, its annual turnover in the previous year XXXXXXXXXXXX.

Organization name	XXXXXXXXXXXX Pharmaceuticals	
Web site	XXXXXXXXXXXX	
Facility physical address	XXXXXXXXXXXX	
Postal address	Same as above	
Telephone	XXXXXXXXXXXX	
Contact information	Name	XXXXXXXXXXXX
	Position	XXXXXXXXXXXX
	Email	XXXXXXXXXXXX
Audit targets	QA system general requirements Purchasing receiving and Storage Distribution and transport	
Product category supplied (e.g. pharmaceuticals, medical devices, diagnostics, laboratory items etc.)	Pharmaceuticals	
Audit date	XXXXXXXXXXXX	
Auditor(s)	XXXXXXXXXXXX	

[2] *WHO good storage and distribution practices for medical products, Annex 7, WHO Technical Report Series 1025, 2020*

METHODOLOGY

The current audit was conducted against the WHO Good Storage and Distribution Practices (GSDP) guidelines.

The WHO GSDP guidelines cover the general requirements regarding the Quality Management System, as well as the supply chain processes, as receiving, storage and distribution. Good Storage Practices (GSP) are defined by WHO as *'that part of quality assurance that ensures that the quality of medical products is maintained by means of adequate control throughout the storage thereof'* and Good Distribution Practices as *'that part of quality assurance that ensures that the quality of a medical product is maintained by means of adequate control of the numerous activities that occur during the trade and distribution process'.*

The status of compliance with the WHO GSDP is determined by the nature and number of observations according to SOP-Q-025 'Technical aspects of a GSDP audit'.

Any deficiency observed is classified as critical, major or other (as defined below) and reference is given to related chapters of WHO GSDP guidelines.

CRITICAL	A critical observation is a departure from current WHO Good Storage and Distribution Practices guidelines that may result in a medical product causing a significant risk to the patient and public health. This includes an activity increasing the risk of falsified medical products reaching the patients. This may also involve fraud, misrepresentation or falsification (of products, information). A combination of several major observations that indicates a serious systems failure may be also classified as a critical observation. Critical observations require immediate actions.
MAJOR	A major observation is a non-critical deficiency which indicates a major deviation from current WHO Good Storage and Distribution Practices guidelines that may increase the risk to public health and safety. A combination of several observations classified as 'other', none of which on their own may be major, may together represent a major deficiency. Major observations require high priority actions.
OTHER	An observation classified as 'other' may be defined as a deficiency which cannot be classified as either critical or major, but which indicates a departure from current WHO Good Storage and Distribution Practices guidelines. A deficiency may be other either because it is judged as minor or because there is insufficient information to classify it as major or critical. Observations classified as 'other' require actions within a reasonable timeframe.
REMARK	A remark is an issue which is not specifically a deviation from a requirement of the current WHO Good Storage and Distribution Practices guidelines. A remark should be seen as supportive for further improvements. Actions may or may not be taken based on the decision of the management of the auditee.

Notes:

- *Several observations on the same activity, none of which on its own may be critical or even major, but which may together represent a critical or major deficiency, should be explained and reported as such.*
- *Classification of an observation is based on the assessed risk level and may vary depending on the nature of the products, e.g. in some circumstances an example of an other observation may be categorized as major.*

- *An observation that was reported at a previous audit and was not corrected may be reported with a higher classification.*
- *One-off minor lapses or less significant issues are usually not formally reported, but are brought to the attention of the supplier during the audit.*

QUAMED also implemented a classification called 'QUAMED GSDP levels' which aims to categorize the suppliers according to their level of compliance with GSDP, the type of assessments and/or source of information. QUAMED adopted a classification with 4 GSDP levels, from '4', the highest proven GSDP compliance, to '1', for proven unsatisfactory GSDP compliance. Refer to the **Annex 2** for further information on the GSDP levels.

OPERATING CONDITIONS

1. Regulatory status

XXXXXXXXXXXXX pharmaceuticals is authorized by the XXXXXXXXXXXXX to engage in the importation, storage and distribution of pharmaceutical products and medical devices. The authorization was documented in the form of a certificate of competence for medicine and medical devices ref number XXXXXXXXXXXXX, issued on the XXXXXXXXXXXXX and valid till the XXXXXXXXXXXXX. A technical manager with a qualification in pharmacy was overall responsible for the activities at the premises. The certificate was renewable annually following a satisfactory inspection by XXXXXXXXXXXXX.

2. Personnel

An organizational chart showing the positions and reporting interrelationships of personnel within the company was in place, although this was not dated or signed. The CEO of the company was the overall in charge at the company, however, his job description was not available. Below the CEO was the deputy general manager for operations management and deputy general manager for resources. The QMS, procurement, and marketing and sales promotion positions were direct reports to the Deputy General manager of operations management. However, in practice, the organizational chart was not aligned with the actual positions at the company. It was observed that the position of deputy general manager operations management was non-existent, instead a technical manager with a pharmacy qualification was in charge of the technical operations at the company. Job descriptions and appointments for the store keeper, and technical manager were selected for review. It was observed that the job descriptions in place were not dated or signed by the job holders. Furthermore, although it was mentioned in the appointment letter that the technical manager is in charge of the QMS functions at the company, the QMS roles were not described or mentioned in his job description. A staff establishment of XX personnel with various qualifications such as pharmacy and marketing were in charge of warehousing, distribution and sales at the company. Employee code of conducts and ethics, and confidentiality agreements were not established to guide the ethical conduct of employees at the company.
A procedure on training of personnel was available, although this was not coded, dated or approved. The scope of the SOP was not accurately defined, and content was not sufficient in describing the training program at the company. A training plan for the year XXXXXXX dated July 20XX was available, and included 3 training areas on: communication skills and customer handling, Good distribution and dispatch practice, and equipment storage and handling. Records for the above trainings were available and included attendee training sheets with names and signatures. However, it was observed that there were no assessments for the effectiveness of the conducted trainings.
The following observations were noted relating to the personnel.

Observations

No. 1	*Other*	*The organizational chart presented was neither approved, dated nor identified in accordance with good documentation practices. Furthermore, it was observed that the job positions presented in the organizational chart were different from the actual job positions in existence, for example the Deputy general manager Operations versus Technical manager. (WHO TRS 1025, Annex 7: 5.5)*
No. 2	*Major*	*Although it was mentioned that the technical manager was in charge of QMS functions at the company, the QMS roles were not detailed in his job description. The independence of QA from other operations could not be demonstrated (WHO TRS 1025, Annex 7: 5.5, 5.6, 5.7, 16.3).*
No.3	*Other*	*The job description for the store keeper, and technical manager were neither approved, nor signed by the job holders. Employee code of conduct and ethics code of practice was not established. (WHO TRS 1025, Annex 7: 5.6).*
No. 4	*Other*	*The following deficiencies were noted regarding the training program at the company: (WHO TRS 1025, Annex 7: 16.7)* *a) The training SOP was neither coded with a unique document number nor approved. Furthermore, it didn't describe in sufficient detail the following elements:* • *The types of training at the company. i.e. induction, ongoing and external trainings.* • *Training needs assessment for staff at the company.* • *The criteria for selection of trainers and list of approved trainers.* • *Evaluation of the training effectiveness.* • *Re-training of staff*

QUALITY MANAGEMENT SYSTEMS

1. Documentation system

A quality management system manual dated January 20XX was in place. Although it was not uniquely identified, and approval and revision due dates not indicated. The document referenced the ISO 13485, ISO 9001 and XXXXXXX guidelines and directives, although the particular XXXXXXX guidelines referenced was not mentioned. The purpose of the document was to define the management policies with respect to quality assurance functions at the company. The elements included in the manual was the document structure of the company, quality policy, management commitment, customer focus, resource management, traceability of purchased products, complaints handling, control of non-conformances and improvements.

There was no procedure guiding the preparation, format, distribution and review of QMS documents such as SOPs. It was observed that available SOPs were bound together in one document known as standard operating procedures, dated January 2023. This document was not signed or approved, and individual SOPs were not identified with unique document codes, revision numbers and period of validity.

Observations

No. 5	*Other*	*The following observations were noted regarding the documentation system at the company: (WHO TRS 1025, Annex 7: 17.2- 17.5, 17.8)* *a) There was no approved procedure describing the preparation, format, review, approval, control and distribution of SOPs at the company.* *b) The validity period and storage period for QMS documents at the company was not defined.* *c) The "scope" section for the SOPs reviewed was inaccurate as it instead mentioned the responsible persons.*

		d) All available SOPs were bound together in one document, this questioned how the review of SOPs could be done. *e) The content of reviewed SOPs was generally insufficiently detailed to describe the corresponding activities being mentioned in the SOP.* *f) Records such as invoices were inappropriately observed to have been stored on a staircase landing.* *g) Most SOPs were not identified, signed or approved.*

2. Management of deviations, non-conformities and CAPA

A brief description of the company policy on the management of CAPAs was described in the quality manual. This referenced CAPAs arising from complaints, self-inspections, and non-conformities. However, there was no approved SOP describing in detail the management of deviations, non-conformities and CAPA. No records were available at the time of audit of either deviations, non-conformities or CAPA.

Observations

No. 6	*Major*	*There were no established SOPs for the management of CAPAs, deviations or non-conformities at the company. No register or records of deviations, non-conformities or CAPA was available at the time of audit.* *(WHO TRS 1025, Annex 7: 13.2, 16.4, 18.40, 21.7)*

3. Management review

A section of the quality manual briefly described the conduct of management review meetings on a bi-annual basis. It mentioned points for discussion during the meeting, including: complaint handling, self-audits, reports to regulatory authorities, feedback, corrective and preventive action, follow-up from previous management reviews and changes that could affect the QMS. Although the company claimed to hold routine management meetings, there were no records or meeting minutes available.

Observations

No. 7	*Other*	*The following observations were noted regarding management review meetings:* *a) Management review meetings were not formalized through applicable SOPs, consequently aspects such as quality metrics and KPIs were not described, monitored and opportunities for continual improvement of the quality management system identified and implemented.* *b) Minutes for meetings purported to have been held were not available.* *c) The composition of the management team responsible for the periodic reviews was not defined.* *(WHO TRS 1025, Annex 7: 17.1-2).*

4. Complaints management

A procedure for the management of complaints was in place, although this was not uniquely identified with a document number or signed, dated and approved. The purpose of the SOP was mentioned as “to establish and implement a system for the management of customer complaints” at the company. The procedure mentioned the receipt, classification, investigation, response to clients and follow-up and QA closure of complaints. Complaints were classified as priority I (urgent - potential high business impact) and Priority II (non-urgent, lower business impact). The timelines indicated for the management of complaints was stated as 3 working days and 2 weeks respectively for the management of priority I and priority II complaints. No register or list of complaints was available at the time of audit.

Observations

No. 8	*Major*	*The complaints handling procedure was observed to have the following weaknesses:* *a) The SOP only referenced complaints having an impact on the company business. There was no mention of the quality related aspects of complaints and their risks to patients.* *b) There was no detail on how the root cause investigation to establish the cause of complaints was to be done.* *c) There was no register or record of complaints received by the company.* *d) The procedure did not detail the responsibilities for the various aspects of the complaint handling process at the company.* *e) There was no requirement to notify the National Regulatory Authority of high risk complaints.* *. (WHO TRS 1025, Annex 7: 8.1 to 8.6)*

5. Self-inspection (internal audit)

A procedure describing the conduct of self-inspections at the company, revised on August 20XX was in place, although it was not identified, signed or approved. The head quality assurance was responsible for establishing the audit team, approval of the annual calendar for self-inspections, review and approval of the summary report. According to the procedure, self-inspections were to be conducted once in every 6 months. Auditors were to be selected from different departments and a list was to be maintained. The non-conformances were to be categorized as critical, major and minor, however this categorization was not described in terms of what constitutes either a critical, major or minor observation. CAPA plans were to be prepared within 15 days after receipt of the report. A check list in the local language "Amharic" was available and claimed to have been adopted from the XXXXXXX guidelines. Records of self-inspections conducted in January 20XX and December 20XX were available.

Observations

No. 9	*Other*	*The self-inspection program was observed to be deficient in the following ways:* *a) The self-inspection SOP was not identified, signed or approved.* *b) There was no self-inspection schedule for the year 2023.* *c) There was no list of authorized auditors.* *d) The categorization of critical, major and minor was not defined. Neither was there a mention of the actions to be undertaken in case of critical observations.* *e) The self-inspection report format was not annexed to the SOP.* *f) Timelines for preparation of the self-inspection report was not mentioned.* *g) There was no evidence that CAPAs were implemented following self-inspections.* *(WHO TRS 1025, Annex 7: 11.1 to 11.5)*

PREMISES AND EQUIPMENT

1. Organization of warehouse

The warehousing areas were located at XXXXXXX, a different location from the head offices. The premises comprised of one building block of permanent structure, with the storage areas housed on the ground floor, and protected by a lockable steel door. The rest of the building belonged to a textiles operation. The warehouse comprised of the following sections; invoicing area, offices, two storage areas and a common dispatch and receipt area. The first storage area of approximately XXXXXXX square meters was dedicated to imported pharmaceuticals and medical devices, while the second storage section of approximately XXXXXXX square meters was dedicated

to the wholesale of products. These were observed to be of sufficient capacity for the operations conducted and were about fifty percent stocked at the time of audit. The warehouses were ventilated naturally, and fairly lit, although this could be improved in the wholesale section, the floor was fairly smooth, although the junction between the floor and wall at some points was not smoothly done and created a rough and dirty surface. The ceiling and walls were made of concrete although this was not smoothened and evenly painted. A cleaning SOP for the warehouse was available although this was not identified with a unique document number or approved. The procedure briefly described the cleaning of premises and sanitization rules such as prohibition against eating, drinking and smoking within warehousing premises, however it did not elaborate in detail the areas to be cleaned and frequency of cleaning. The premises were observed to be fairly clean, although the ceiling was observed to have cob webs, and underneath some pallets were observed to have trapped dirt. A staircase landing was used to store some records such as invoices, however this area was observed to also store other non-medical products such as old pieces of furniture that had gathered dust and cobwebs.
Medical products were generally stored on wooden pallets, and bin cards maintained next to each product. However, it was observed that in some cases goods (absorbent cotton, batch number XXXXXXX) were observed stored against the wall, and pallets were not always arranged with space in between to allow for easy movement and cleaning. Cartons of products were stacked according to batch numbers, however in some cases, the stacking arrangement damaged the cartons (e.g. dextrose 5% Iv infusion, batch number XXXXXXX was observed with damaged cartons due to poor storage arrangements). Dangerous and flammable goods such as formalin and alcohol products were stored in the same area, however these were not segregated and appropriate precautions such as labelling provided. Two fire extinguishers were located within the warehouse for the control of any incidental fires. These were appropriately located and serviced.

A pest control contract dated October 20XX was in place. However, there were no records for any pest control activities performed at the site.

Observations

No. 10	*Major*	*The warehousing premises were not appropriately designed or maintained in a suitable state. The following were observed:* *a) The junction between the floor and wall at some points was not smoothly done and created a rough and dirty surface.* *b) The lighting in the warehouse section was inadequate.* *c) The ceiling and walls were not evenly smoothed and painted. In some cases, black patches were observed on the ceiling.* *d) There were no sections for the storage of quarantined or returned products.* *(WHO TRS 1025, Annex 7: 12.1, 12.2)*
No. 11	*Major*	*Cleaning of the storage areas for medical products was not adequately done to ensure avoidance of potential contaminants. Specifically,* *a) The SOP for cleaning of the storage areas was not identified with a unique document number or approved. Furthermore, it did not elaborate in sufficient detail, the areas to be cleaned and the frequency of cleaning.* *b) Cleaning of premises was not sufficiently done; the ceiling was observed to have cob webs, dirt was observed to have been trapped underneath several pallets.* *c) Records for cleaning of the warehousing areas did not detail the areas to be cleaned.* *(WHO TRS 1025, Annex 7: 12.7)*
No. 12	*Other*	*Medical products were not stored appropriately. The following instances were noted:* *a) Products were not stored off the wall. E.g. Absorbent cotton, batch number XXXXX.* *b) Some wooden pallets used in the storage of products were damaged and showed signs of deterioration. Furthermore, they were not arranged with space in between to allow for ease of movement and cleaning.* *c) Dangerous, hazardous and flammable products such as formalin, and alcohol were not stored in segregated areas with appropriate precautions provided.*

		d) The stacking arrangement and cautious handling for cartons was not defined and emphasized. Several cartons were observed to have been damaged during storage. *(WHO TRS 1025, Annex 7: 12.23, 12.28, 12.29)*

2. Computerized systems.

A computerized software, XXXXXXXXXX was used in the management of inventory at the company alongside the manual records maintained in form of bin cards. Access to the computer software was not controlled as user login details and passwords were shared. The software was used to manage records of sales, purchases and inventory of stock at the company. A verification of stock of XXXXXXXXXX tablets batch number XXXXXXXXXX, expiry date 01/XX was conducted. It was observed that neither the physical quantity nor batch details in the system were aligned with the actual stock. Backup of data was not periodically conducted and documented.

Observations

No. 13	*Major*	*The following observations were made relating to the software "XXXXXXXXXX" used in the management of inventory at the company. (WHO TRS 1025, Annex 7: 14.1, 14.2, 14.5).* *a) There were no unique user login credentials, privileges and rights for access to the computer software.* *b) The inventory records within the software were not in tandem with the actual physical stock available. A discrepancy was observed between the software inventory records and physical stock for XXXXXXXXXX tablets batch number XXXXXXXXXX found in the warehouse.* *c) There was no procedure or records for the backup of software data.* *d) The computer software was not validated.*

RECEPTION AND STORAGE OF PRODUCTS

1. Control at reception

A goods reception area was designated with sufficient space and protection of incoming consignments from weather conditions during receipt. A procedure guiding the receipt of goods, document number XXXXXXXXXX version 3 was in place. The procedure described the checks to be performed on each consignment of product, including checks on label details, expiry date, batch numbers, product quantity, among others. However, no checklist was annexed to the procedure. The parameters to be checked however was observed not to include checks for appropriate transport conditions where applicable, and checks for damages to products. Products were not quarantined, and formally released as part of the receipt process prior to transfer to saleable goods. Records related to the receipt of XXXXXXXXXX tablets batch number XXXXXXXXXX were selected and reviewed.

Observations

No. 14	*Major*	*Although a receipt procedure, XXXXXXXXXX version 3 was in place, it was not detailed enough to elaborate the different checks to be performed on goods, including checks for damages, appropriate storage conditions during transport, product manufacturer and documents such as certificates of analysis. Goods were not formally released prior to transfer to saleable stock.* *(WHO TRS 1025, Annex 7: 12.10, 12.12, 12.16, 12.17).*

2. Physical storage conditions.

An SOP for temperature monitoring within the warehouse was available, although this was neither identified with a unique document number nor approved. The procedure briefly mentioned the requirement to store products in accordance with the recommended temperature and humidity conditions, and required daily monitoring of these conditions. Two data loggers both identified as XXXXXXXXXX and calibrated on the 30.3.20XX were available for the measurement of temperature and humidity within the warehouse, however it was observed that these were placed on top of cartons of product, and not in permanent locations. The storage condition readings at the time of audit was T-17^{0}C/46% RH and T-17.6^{0}C/69% RH respectively. The monthly records showed temperatures were generally below 21^{0}C, while maximum humidity value was 76% over the last 4 months. However, records for environmental monitoring did not contain acceptable limits for temperature and humidity. Neither were these records signed by the personnel responsible for this activity. A brief temperature mapping study report was presented, showing temperature and humidity readings for 8 days. However, this was observed to be deficient in several ways detailed below.

Observations

No. 15	*Major*	*The following observations were noted regarding the monitoring of storage conditions within the warehousing areas:* *a) The SOP for monitoring temperature and relative humidity conditions for storage of products was not identified with a unique document number, signed or approved. Furthermore, it did not define the temperature and RH acceptable limits or detail the management of excursions to recommended storage conditions.* *b) Data loggers were not uniquely identified. Furthermore, they were not placed in permanent locations identified through temperature mapping studies.* *c) Temperature monitoring records did not include acceptable limits and were not signed and reviewed.* *d) There was no procedure in place for calibration of thermohygrometers used in the monitoring of storage conditions. Furthermore, the calibration certificates presented could not be traced to the equipment as unique identification numbers were not mentioned. No contracts had been established with XXXX medical equipment services, the calibration service provider.* *(WHO TRS 1025, Annex 7: 18.26, 19.2, 12.34, 12.37).*
No. 16	*Other*	*The temperature mapping study was observed to be deficient in the following ways:* *a) There was no SOP or protocol providing detailed instructions on the conduct of the temperature mapping study.* *b) There was no mention of the number of seasons for which the studies would be conducted, sensor locations in relation to the warehouse size, types and calibration details of data loggers used, hot and cold spots identified.* *(WHO TRS 1025, Annex 7: 12.36, 12.37).*

3. Stock control and rotation

A procedure for the management of inventory was in place, although this was not uniquely identified with a document number or signed and approved. The procedure required the proper recording of received and issued items, continuous update of inventory and periodic quarterly and yearly stock taking. Principles of FEFO were detailed and monitored manually. No violations of the FEFO principle were observed.

Observations

No. 17	*Other*	*There was no policy on the management of short expiry items to ensure short expiry products are neither received nor distributed. (WHO TRS 1025, Annex 7: 13.4)*
No. 18	*Other*	*The procedure for management of inventory was not uniquely identified with a document number, signed and approved.*

DISTRIBUTION

1. Dispatch

A procedure for product dispatch was in place, although this was not uniquely identified with a document number, signed and approved. Orders for clients had to be authorized by the technical manager prior to issuance. The documents related to the dispatch of medical products to XXXXXXXXXX, including: customer order, requisition from sales, stores issuance voucher, invoice from finance and 3 copies of delivery notes were verified. These were found in order. Products were only dispatched to clients authorized by the XXXXXXXXXX to handle medical products. A dispatch area that also served as the receipt area was demarcated.

Observations

No. 19	*Other*	*The procedure for product distribution was neither uniquely identified with a document number nor signed and approved.*

2. Transport

A procedure for product transportation and handling was in place, although this was not uniquely identified with a document number, signed and approved. The procedure mentioned the need to maintain products within recommended storage conditions during transportation. Two delivery vans and a lorry were available for the transportation of medical products. These were observed to be suitable in design, well covered and well maintained. Although it was observed that no records were in place for their cleaning, temperature monitoring and transport validation.

Observations

No. 20	*Major*	*The following observations were noted regarding the transportation of medical products:* *a) The procedure describing the transportation of medical products was not uniquely identified with a document number, signed and approved.* *b) Transport conditions were not monitored and recorded during transportation of medical products.* *c) Although the transport vehicles were observed to be clean and tidy at the time of audit, there were no records for their cleaning.* *d) Transportation routes were not validated.* *e) Procedures and schedules for vehicle maintenance were not in place.* *(WHO TRS 1025, Annex 7: 18.24, 18.39)*

HANDLING SPECIFIC PRODUCTS

1. Handling of regulated/controlled products (narcotics and psychotropics)

XXXXXXXXXX did not handle any controlled products such as narcotics.

2. Handling of non-compliant products

Observations

No. 21	*Other*	*There were no approved procedures for the management of non-compliant products at the company. (WHO TRS 1025, Annex 7: 9.6)*

3. Management of returned products

Observations

No. 22	*Major*	*There was no procedure for handling of returned products to ensure defective/falsified products are not inadvertently returned or introduced to saleable products. (WHO TRS 1025, Annex 7: 9.1 to 9.8)*

4. Management of product recalls

A procedure for the management of product recalls was available, although this was not identified with a unique document number, signed or approved. The procedure mentioned that recalls were to be done in accordance with the XXXXXXXXXX guidelines, however the content of the procedure was not adapted into the company's own procedure. It was observed that there was no detail regarding several aspects of a recall process, including categorization of recall levels, timelines, responsible persons, communication strategies during recalls, reconciliations, and mock recalls. No recalls or mock recalls had been conducted at the company by the time of the audit.

Observations

No. 23	*Major*	*The product recall provisions were observed to be deficient in the following ways:* *a) The recall procedure mentioned that recalls would be conducted as per the XXXXXXXXXX guidelines, however the content of the procedure was not detailed or adapted into the company's own procedure.* *b) The recall procedure lacked several aspects of a recall process including: categorization of recall levels, timelines for recall activities, responsible persons, communication strategies during recalls, reconciliations and effectiveness checks for recalls.* *c) No mock recalls had been conducted to evaluate the effectiveness of the recall procedures.* *(WHO TRS 1025, Annex 7: 10.1 to 10.8)*

COLD CHAIN MANAGEMENT

No cold chain medical products were handled by the company. A refrigerator was available for the storage of laboratory reagents. Storage conditions in the refrigerator were maintained at 2-8^{0}C.

MANAGEMENT OF OUTSOURCED ACTIVITIES

1. Outsourced activities related to storage

The outsourced services related to the storage of products at the company included pest and rodent control and calibration services. Observations related to these services are reported under the premises and equipment section.

2. Outsourced activities related to distribution

No outsourced activities were related to distribution.

DISCUSSION AND CONCLUSION

XXXXXXXXXX Pharmaceuticals XXXXXXXXXX is a pharmaceutical and medical devices import and distribution company with warehousing premises located at XXXXXXXXXX, and head offices located at XXXXXXXXXX Industrial zone. The company was established in the year 20XX and is licensed by the XXXXXXXXXX to engage in the importation and distribution of pharmaceuticals and medical devices.

XXXXXXXXXX XXXXXXXXXX was audited for compliance with the WHO GSDP guidelines. A summary of the audit findings is discussed below:

XXXXXXXXXX has all the required licenses and official documents required by the XXXXXXXXXX to operate an import and distribution business for pharmaceuticals and medical devices. A basic quality management system was established, although this was observed to have significant weaknesses especially with the documentation system. The preparation, format, approval process and distribution system for SOPs was not defined, as such it was observed that several SOPs at the company were neither approved or appropriately structured. Furthermore, SOPs for key QMS elements such as deviations management, CAPA management, non-conforming products, returned products management among others were not in place. The content of available SOPs and thereby the practice relating to these activities was observed to be deficient in several instances; including the management of trainings, self-inspections, and recalls.

Implementation of the Quality assurance function was observed to be inadequate in that although an appointment was made for the QA function, these responsibilities were not detailed in the job description of the responsible person.

The warehousing capacity was adequate for the volume of products handled. The structure was fair, although some weaknesses in maintenance and cleaning of the warehousing facilities was observed. Furthermore, several gaps were observed in the storage practices of products at the warehouse: for example, products were not stored off the wall, pallets were observed to be damaged and not well spaced, cartons were damaged during storage, hazardous products were not appropriately segregated, among other issues.

The storage conditions at the warehouse were within expected limits, although the acceptable limits were not defined by the company. Temperature mapping studies were not appropriately conducted to determine the hot and cold spots in the warehouse, consequently thermohygro loggers were not appropriately located in permanent locations within the warehouse.

Although transport facilities for medical products were available, some weaknesses regarding inadequate monitoring of transport conditions, and validation of routes was noted.

This audit identified the following observations:

Type of observations	Number
Critical	0
Major	11
Other	12
Remarks	0

Based on the current audit performed, XXXXXXXXXX Pharmaceuticals XXX is deemed:

- **<u>to operate at an unacceptable level of compliance</u> with the requirements of World Health Organization Good Storage and Distribution Practices**. The corrective and preventive action plan must be implemented to ensure all observations are adequately resolved.

QUAMED GSDP level		
XXXXXXXXXX Pharmaceuticals XXX	**Level 1**	Distribution sites with an unacceptable level of GSP compliance, after a GSDP or MQAS audit by QUAMED and/or other official or recognized organizations.

ANNEXES

Annex 1: Audit agenda

Proposed audit agenda and general information about the audit

AUDIT OBJECTIVE AND SCOPE

The aim of this audit is to assess the compliance of the auditee against the World Health Organization's Good Storage and Distribution Practices[3] and to define its GSDP levels as per QUAMED standardized assessment system.
The scope of the audit is XXXXXXXXXX Pharmaceuticals located at the physical address below.

GENERAL INFORMATION ABOUT THE SUPPLIER

Organization name	XXXXXXXXXX Pharmaceuticals	
Facility physical address	XXXXXXXXXX.	
Key contact information	Name	XXXXXXXXXX
	Position	XXXXXXXXXX
	Email	XXXXXXXXXX
	Phone	XXXXXXXXXX
Audit date	XXXXXXXXXX	
Auditor name(s)	XXXXXXXXXX	

PROPOSED AGENDA

[3] WHO good storage and distribution practices for medical products, *Annex 7, WHO Technical Report Series 1025, 2020*

The audit will be conducted as follows:

Day 1 – [09:00 am] – [17:00 pm]

- Presentation of QUAMED, Expectations and purpose of the visit (QUAMED auditor)
- General presentation of **XXXXXXXXXX Pharmaceuticals,** the company profile and the quality systems in place; description of significant changes since the last visit in case of re-audit.
- Review of quality assurance system and documentation:
  - Quality manual
  - Review of the main SOPs and tools
  - Clarification of roles and responsibilities
- Visit of the premises according to the product flow:
  - Receiving process
  - Storage area: organisation, storage conditions, compliance with Good Storage Practices
  - Quarantine area / rejected products area
  - Preparation of orders, dispatch and transport
  - Controlled substances management
  - Returned products management
  - Cold chain management (if any)

Day 2 [09:00am] – [17:00pm]

- Review of documentation related to:
  - Recalls
  - Deviations and non-conformities
  - Complaints
  - CAPA
- Time for extra investigations as/if needed
- Conclusion preparation (QUAMED auditor alone)
- Debriefing (all): Presentation of the key findings. Clarifications. Presentation of the next steps.

Please note that this proposed agenda may be subject to changes during the course of the audit based on findings.

AUDIT PREPARATION

Hereafter is a non-exhaustive list of documents that may be requested by the QUAMED team during the GSDP audit. Preparing these documents in advance will save time during the QUAMED visit.

- Operating licenses, GDP/GSDP certificate, ISO certificate(s)
- Product list (with if possible, manufacturer names, country of origin and/or manufacturing sites)
- Quality manual
- Organisation chart (organigram) and job descriptions
- Standard operating procedures / work instructions folder

- Last self-inspection / internal audit reports and action plans
- Complaints records
- Deviations and non-conformities records
- Corrective Action / Preventive action records
- Training plan and training records
- Temperature and relative humidity records for the last year (for stores and cold chain equipment)
- Calibration records of monitoring devices
- Warehouse cleaning records
- Pest control records
- Samples of recent reception documents
- Samples of recent shipping documents
- Inventory records
- Last recall records
- Returned products records
- And any others relevant documentation if required.

information on reporting steps

- *Draft audit report stage*

The auditor will prepare a draft report, which will be reviewed by the QUAMED operational team. This standardised report will contain a list of observations based on findings from the audit. This draft report will be sent to the auditee within 4 weeks after the audit. During this timeframe, the auditee may be contacted for further clarifications by the auditor.

- *CAPA plan stage*

The auditee will have 4 weeks to provide any comments on the draft report and send a proposal of CAPA plan. If the auditee does not respond within 4 weeks, the conclusion will be based on the original audit findings and the final report will be issued.

- *Final audit report stage*

The auditor will review the proposed actions to assess if they address well and in a timely manner the identified observations. He/she will update the draft report accordingly and the QUAMED operational team will review the report and the changes. The report will be signed and shared with stakeholders.

Annex 2: QUAMED GSDP levels

QUAMED adopted a classification with 4 GSDP levels, from '4', the highest proven GSDP compliance, to '1', for proven unsatisfactory GSDP compliance.

GSDP Levels	
Level 4	• GSDP / GDP approved distribution sites by an SRA, or by a WLA. GSDP / GDP inspections should have been conducted not more than 3 years ago, unless otherwise justified.
Level 3	• Distribution sites having successfully passed a QUAMED GSDP or MQAS audit by QUAMED, or • Distribution sites GSDP/GDP approved by an organization officially recognized by QUAMED. GSDP / GDP audits/inspections should have been conducted not more than 3 years ago, unless otherwise justified.
Level 2	• Distribution sites with an acceptable level of GSDP compliance (Global GSDP compliance ≥ 60%) during a GSDP technical visit or a remote GSDP technical visit by QUAMED, or • Distribution sites with an acceptable level of GSP compliance with restrictions, after a GSDP or MQAS audit by QUAMED and/or other official or recognised organisations. GSDP/GDP audits/technical visits must have been performed within the last 3 years, unless otherwise justified.
Level 1	• Distribution sites that had an unsatisfactory level of GSDP compliance with the GSDP requirements (Global GSDP compliance < 60%) during a GSDP technical visit by QUAMED. • Distribution sites with an unacceptable level of GSP compliance, after a GSDP or MQAS audit by QUAMED and/or other official or recognized organizations. GSDP/GDP audits/technical visits must have been performed within the last 3 years, unless otherwise justified.

Annex 3: CAPA

Obs. number	Classification of the observation	Observations (with Reference to the WHO GSDP)	Auditee proposed Corrective actions / preventive actions	Timeline	Comment(s) from QUAMED auditor
1	other	The organizational chart presented was neither approved, dated nor identified in accordance with good documentation practices. Furthermore, it was observed that the job positions presented in the organizational chart were different from the actual job positions in existent for example Deputy general manager Operations versus Technical manager. (WHO TRS 1025, Annex 7: 5.5).	The company's management team has revised the organizational chart. It is re-written and the job positions on the organizational chart reflects the actual job positions of the company. The job descriptions of all the employees will be revised and completed till July 30, 2023.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
2	major	Although it was mentioned that the technical manager was in charge of QMS functions at the company, the QMS roles were not detailed in his job description. The independence of QA from other operations could not be demonstrated (WHO TRS 1025, Annex 7: 5.5, 5.6, 5.7, 16.3).	The organizational chart has already been modified. The QMS activities are under the QC and QA head. The QC and QA head reports directly to the General Manager.		The QA function should not be under the QC. It should be independent of the QC function.
3	Other	The job description for the store keeper, and technical manager were neither approved, nor signed by the job holders. Employee code of conduct and ethics code of practice was not established. (WHO TRS 1025, Annex 7: 5.6).	All job descriptions will be revised, approved and signed by the employees until July 30, 20XX. XXXXXXXXXX already has employee code of conduct and ethics. However, it will be revised, approved and signed.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
4	Other	The following deficiencies were noted regarding the training program at the company: b) The training SOP was neither coded with a unique document number nor approved. Furthermore, it didn't describe in sufficient detail the following elements:	▪ XXXXXXXXXX has started coding all SOPs. ▪ A format for training need assessment is being revised. The collected data will be analyzed. Besides the management team will discuss on the following points	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.

		• The types of training at the company. i.e. induction, ongoing and external trainings, among others. • Training needs assessment for staff at the company. • The criteria for selection of trainers and list of approved trainers. • Evaluation of the training effectiveness. • Re-training of staff (WHO TRS 1025, Annex 7: 16.7)	and decide on the need for training. ○ What organizational goal are we trying to achieve? ○ Which job behaviors contribute to achieving this goal? ○ Which skills and knowledge components are required to display the relevant behaviors? ○ What are the levels of the required skills and knowledge on a scale 1-5 (1 - lowest level, 5 -highest level)? ○ What is the level of need for training? ○ What type of training is needed to close the skills and knowledge gaps? ▪ Trainers who are certified/licensed by an authorized body will be selected. ▪ Effectiveness of training will be evaluated by pre and post exams of training. ▪ Trainees who failed to pass the post training exam will be re-trained.		
5	Other	The following observations were noted regarding the documentation system at the company: h) There was no approved procedure describing the preparation, format, review, approval, control and distribution of SOPs at the company. i) The validity period and storage period for QMS documents at the company was not defined.	a. The company is developing an SOP for the preparation, format, review, approval, control and distribution of SOPs. b. The company's management team has decided to make the	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.

		j) The "scope" section for the SOPs reviewed was inaccurate as it instead mentioned the responsible persons. k) All available SOPs were bound together in one document, this questioned how the review of SOPs could be done. l) The content of reviewed SOPs was generally not adequately detailed to describe the corresponding activities being mentioned in the SOP. m) Most SOPs were not identified, signed or approved. (WHO TRS 1025, Annex 7: 17.2- 17.5, 17.8).	validity period of QMS document to be one year. QMS document has to be revised every year between July 1 to 15. c. The scope of the SOPs will be replaced with appropriate one. d. The SOPs will be bound separately. e. It could have been very helpful if XXXXXXXXXX could clarify the statement and/or give us an example. f. All the SOPs will be revised, approved and signed until July 30 of 20XX.		
6	Major	There were no SOPs established for the management of CAPAs, deviations or non-conformities at the company. No register or records of deviations, non-conformities or CAPA was available at the time of audit. (WHO TRS 1025, Annex 7: 13.2, 16.4, 18.40, 21.7).	The SOP for the management of CAPAs, deviations or non-conformities will be revised, approved and signed.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
7	Other	The following observations were noted regarding management review meetings: d) Management review meetings were not formalized through applicable SOPs, consequently aspects such as quality KPIs were not described, monitored and opportunities for continual improvement of the quality management system identified and implemented. e) Minutes for meetings purported to have been held were not available. f) The composition of the management team was not defined. (WHO TRS 1025, Annex 7: 17.1-2)	a. An SOP for management review meetings will be developed. b. The documentation of minutes of meetings will be defined in the SOP. c. The composition of the management team will be defined in the SOP.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.

8	Major	The complaints handling procedure was observed to have the following weaknesses: f) The SOP only referenced complaints having an impact on the company business. There was no mention of the quality related aspects of complaints and their risks to patients. g) There was no detail on how the root cause investigation to establish the cause of complaints was to be done. h) There was no register or record of complaints received by the company. i) The procedure did not detail the responsibilities for the various aspects of complaint handling at the company. j) There was no requirement to notify the National Regulatory Authority of high risk complaints.	a. The SOP for complaints focused on the quality of products. The risks to patients will be included in the newly revised SOP. b. The procedure to investigate root causes will be included in the new SOP. c. No compliant have been received. However, the procedure and format to keep records will be included in the SOP. d. The new SOP will detail the responsible personnel for the different aspects of complaint handling. e. There is a requirement to notify the XXXXXXXXXX) about high risk complaints. We had presented the format by XXXXXXXXXX during auditing.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
9	Others	The self-inspection program was observed to be deficient in the following ways: h) The self-inspection SOP was not identified, signed or approved. i) There was no self-inspection schedule for the year 2023. j) There was no list of authorized auditors. k) The categorization of critical, major and minor was not defined. Neither was there a mention of the actions to be undertaken in case of critical observations. l) The self-inspection report format was not annexed to the SOP. m) Timelines for preparation of the self-inspection report was not mentioned.	a. SOP for Self-inspection will be revised, approved and signed. b. The annual schedules for self-inspection will be clearly indicated in the new SOP. c. We do have a QMS officer who is solely responsible for the self-inspection and quality control and assurance of the company. The responsible personnel will be clearly indicated in the new SOP and organogram. d. We use the XXXXXXXXXX format for self-inspection. The format do not categorize risks. We just have		The proposed CAPA plan is acceptable and will be verified once implemented. Please include the timelines for its implementation

		n) There was no evidence that CAPAs were implemented following self-inspections. (WHO TRS 1025, Annex 7: 11.1 to 11.5))	to fulfil every criterion set by XXXXXXXXXX. e. The self-inspection report format will be annexed to the SOP. f. Timeline for preparation of report will be clearly scripted in the new SOP. g. The CAPAs after self inspection will be formalized into a single document.		
10	Major	The warehousing premises were not appropriately designed or maintained in a suitable state. The following were observed: e) The junction between the floor and wall at some points was not smoothly done and created a rough and dirty surface. f) The lighting in the warehouse section was dim. g) The ceiling and walls were not evenly smoothed and painted. In some cases, black patches were observed on the ceiling. h) There were no sections for the storage of quarantined or returned products. (WHO TRS 1025, Annex 7: 12.1, 12.2)	a. The junction between the floor and wall will be reconstructed to make it smooth. b. The lighting has been corrected. Extra bulbs have been added to improve lighting. c. The ceilings and walls observed to be not evenly smooth will be reconstructed. d. A space/corner has been dedicated and labeled as "quarantined products" after Dr. Solomon commented on that.	Sep 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
11	Major	Cleaning of the storage areas for medical products was not adequately done to ensure avoidance of potential contaminants. Specifically, d) The SOP for cleaning of the storage areas was not identified with a unique document number or approved. Furthermore, it did not elaborate in sufficient detail, the areas to be cleaned and the frequency of cleaning. e) Cleaning of premises was not sufficiently done; the ceiling was observed to have cob webs, dirt was observed to have been trapped underneath several pallets.	a. The SOP for cleaning will be revised to include the mentioned concerns. b. An immediate action has been taken to clean the cob webs and dirt after the auditor's comment. c. The format for documentation of cleaning will be improved and annexed to the new SOP.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.

		f) Records for cleaning of the warehousing areas did not detail the areas to be cleaned. (WHO TRS 1025, Annex 7: 12.7)			
12	Other	Medical products were not stored appropriately. The following instances were noted: e) Products were not stored off the wall. E.g. Absorbent cotton, batch number XXXXXXXXXX. f) Some wooden pallets used in the storage of products were damaged and showed signs of deterioration. Furthermore, they were not arranged with space in between to allow for ease of movement and cleaning. g) Dangerous, hazardous and flammable products such as formalin, and alcohol were not stored in segregated areas with appropriate precautions provided. h) The stacking arrangement and cautious handling for cartons was not defined and emphasized. Several cartons were observed to have been damaged. (WHO TRS 1025, Annex 7: 12.23, 12.28, 12.29)	a. Immediate action has been made to store the products off the wall, 50cm. b. Immediate action was taken. Old pallets are replaced with new ones and rearranged to allow easy movement of personnel and cleaning. c. A space is now specifically dedicated and labeled for the dangerous, hazardous and flammable products. d. A training manual for the handling and arrangement of cartoons is under preparation.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
13	Major	The following observations were made relating to the software "XXXXXXXXXX" used in the management of inventory at the company. (WHO TRS 1025, Annex 7: 14.1, 14.2, 14.5). e) There were no unique user login credentials, privileges and rights for access to the computer software. f) The inventory records within the software were not in tandem with the actual physical stock available. A discrepancy was observed between the software inventory records and physical stock for XXXXXXXXXX tablets batch number XXXXXXXXXX found in the warehouse. g) There was no procedure or records for the backup of software data. h) The computer software was not validated.	a. As mentioned during the auditing, we were recruiting a new finance manager and log in credentials and privileges are well defined now. b. There was discrepancy between software inventory and physical stock. However, we have made an inventory after we hired a new finance manager, adjustments have been made, and the software inventory matches with the physical count. c. The company has decided to have a backup of the software data into an external hard drive which will be updated daily.		The proposed CAPA plan will be verified once implemented. Please include a comment on the validation of the computer software and appropriate timelines for its implementation.

14	Major	Although a receipt procedure, XXXXXXXXXX version 3 was in place, it was not detailed enough to elaborate the different checks to be performed on goods, including checks for damages, product manufacturer, appropriate transport conditions, and documents such as certificates of analysis. Goods were not formally released prior to transfer to saleable stock. (WHO TRS 1025, Annex 7: 12.10, 12.12, 12.16, 12.17).	▪ We do perform different checks including physical damages, color changes, appropriate packaging and transport. For products imported from abroad we always present the certificates of analysis to XXXXXXXXXX. XXXXXXXXXX releases the products after revising the certificate of analysis. Similarly, for products that are purchased from local manufacturers, we only purchase after the manufacturers receive certificate of release by XXXXXXXXXX after they presented their certificate of analysis. Goods are released after a request is presented by sales people and Store Issue Voucher is signed by the store manager and approved by the technical manager.		Please ensure that your SOPs speak to the practices mentioned in your response, and there should be records available for each consignment.
15	Major	The following observations were noted regarding the monitoring of storage conditions within the warehousing areas: e) The SOP for monitoring temperature and relative humidity conditions for storage of products was not identified with a unique document number, signed or approved. Furthermore, it did not define the temperature and RH acceptable limits or detail the management of excursions to recommended storage conditions. f) Data loggers were not uniquely identified. Furthermore, they were not placed in permanent locations identified through temperature mapping studies. g) Temperature monitoring records did not include acceptable limits and were not signed and reviewed.	a. The SOP for monitoring temperature and relative humidity conditions will be revised, approved and signed. The mentioned issues will be addressed. b. The data logger is the store manger. It will be identified in the new SOP. Even though we did temperature mapping that was not properly documented. We did a new temperature mapping and identified permanent places.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.

		h) There was no procedure in place for calibration of thermohygrometers used in the monitoring of storage conditions. Furthermore, the calibration certificates presented could not be traced to the equipment as unique identification numbers were not mentioned. No contracts had been established with XXXXXXXXXX medical equipment services, the calibration service provider. (WHO TRS 1025, Annex 7: 18.26, 19.2, 12.34, 12.37).	c. The format has been already modified. The format will be annexed in the new SOP. d. The calibrations are done by XXXXXXXXXX, a company licensed by the responsible authority. We have approached the company and promised to re-calibrate the thermohygrometer and indicate the serial number of the equipment on the certificate of calibration.		
16	Other	The temperature mapping study was observed to be deficient in the following ways: c) There was no SOP or protocol providing detailed instructions on the conduct of the temperature mapping study. d) There was no mention of the number of seasons for which the studies would be conducted, sensor locations in relation to the warehouse size, types and calibration details of data loggers used, hot and cold spots identified. (WHO TRS 1025, Annex 7: 12.36, 12.37).	a. An SOP to conduct temperature mapping is being developed. b. The number of seasons will be defined after revising data from Ethiopian Meteorology |Agency.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented. Please ensure all aspects of a temperature mapping study are addressed in your SOP and protocol.
17	Other	There was no policy on the management of short expiry items to ensure short expiry products are neither received nor distributed. (WHO TRS 1025, Annex 7: 13.4)	• The company's management has decided not to purchase medications with expiry date of <16months.		Please incorporate this as a policy/SOP, that should be communicated to all responsible staff.
18	Other	The procedure for management of inventory was not uniquely identified with a document number, signed and approved.	• The company already has an SOP for management of inventory. The SOP for management of inventory will be revised, approved and signed.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
19	Other	The procedure for product distribution was neither uniquely identified with a document number nor signed and approved.	• The company already has an SOP for product distribution. The SOP	July 30, 2023	The proposed CAPA plan and timelines is

			for product distribution will be revised, approved and signed.		acceptable and will be verified once implemented.
20	Major	The following observations were noted regarding the transportation of medical products: f) The procedure describing the transportation of medical products was not uniquely identified with a document number, signed and approved. g) Transport conditions were not monitored and recorded during transportation of medical products. h) Although the transport vehicles were observed to be clean and tidy at the time of audit, there were no records for their cleaning. i) Transportation routes were not validated. j) Procedures and schedules for vehicle maintenance were not in place. (WHO TRS 1025, Annex 7: 18.24, 18.39)	a. Medical products are transported according to the XXXXXXXXXX guidelines. The document will be adapted, revised, approved and signed. b. A format for the record of transportation record will be prepared, approved and signed. c. A format for the record of cleaning of transport vehicles will be prepared, approved and signed. d. Transportation routes will be validated by the technical manager. e. Procedures and schedules for vehicle maintenance are according to Ethiopian National policy.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
21	Other	There were no approved procedures for the management of non-compliant products at the company. (WHO TRS 1025, Annex 7: 9.6)	Non-compliant products are managed according to XXXXXXXXXX guidelines. The document will be adapted, approved and signed.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
22	Major	There was no procedure for handling of returned products to ensure defective/falsified products are not inadvertently returned or introduced to saleable products. (WHO TRS 1025, Annex 7: 9.1 to 9.8)	Defective products are managed according to XXXXXXXXXX guidelines. The document will be adapted, approved and signed.	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be verified once implemented.
23	Major	The product recall provisions were observed to be deficient in the following ways:	Recall procedure document will be adapted, revised, approved and	July 30, 2023	The proposed CAPA plan and timelines is acceptable and will be

		d) The recall procedure mentioned that recalls would be conducted as per the XXXXXXXXXX guidelines, however the content of the procedure was not detailed or adapted into the company's own procedure. e) The recall procedure lacked several aspects of a recall process including: categorization of recall levels, timelines for recall activities, responsible persons, communication strategies during recalls, reconciliations and effectiveness checks for recalls. f) No mock recalls had been conducted to evaluate the effectiveness of the recall procedures. (WHO TRS 1025, Annex 7: 10.1 to 10.8)	signed. And all the issues mentioned in 'a', 'b', and 'c' will be addressed.		verified once implemented.