



Medicines Control Authority of Zimbabwe

LICENSING AND ENFORCEMENT DIVISION

INSPECTION REPORT FOR WHOLESALE - ROUTINE

**CURLEW CHEMICALS (PVT) LTD T/A NEOMED PHARMACEUTICALS, NO
129 A G. SILUNDIKA 13TH& 14TH AVENUE, BULAWAYO**

Permit Holder: Curlew Chemicals (Pvt) Ltd
Supervisor: Miss Duduzile Dube,
Inspection Date: 22-5-2026
Inspector: Calvin Nyakanda and Trishie Chikerema
Type of inspection: Routine Inspection
Contact details: hadebedx17@gmail.com/duduedube@ecloud.com
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Key

Italics: Shortcomings noted during inspection

Bold: Issues noted during re-inspection and sub-headings

Regular: The rest of the body of the inspection

1. Preamble

This was an inspection of premises that was last inspected on the 19th of February 2025 and the following shortcomings were noted:

- There were inadequate temperature and humidity monitoring devices in the warehouse. There was only 1 (one) Victor® (Model: VC330) digital thermometer and hygrometer in the warehouse.
- The receiving of cold chain products did not include checks for transit data loggers and their downloading to check for any excursions. In the absence of pharmaceutical GDP certified delivery trucks, the delivery vehicles were not being checked for cleanliness status during the receiving.
- Temperature mapping was claimed to have been conducted by Chapleton© however the documents which were presented were invalid. Positioning of the temperature monitoring devices was not guided by temperature mapping studies.

- Signs of leakage were noted in the warehouse on the day of inspection.
- There was no training program and there was an obsolete SOP for training. SOP for self-inspections was available however the procedure was not being adhered to.

1.1 Staff Compliance

Key personnel interviewed during the inspection (non-exhaustive) are as follows;

1. Miss Duduzile Dude

Personnel/ Staff complement

Qualified personnel manned all the storage areas. They had the support of other stores' personnel, including sales and marketing personnel. The institution was encouraged to have scientific and continuous improvement inspired constructive engagement with the regulatory inspectorate on capacity development. On the day of inspection, the sales representative had a valid permit issued by the Authority.

General conduct of the inspection

This was a routine Good Storage Practice/ Good Distribution Practice (GSP/GDP) inspection conducted to encourage compliance and improve quality assurance of medical products. The inspection was conducted in a cooperative, transparent and open environment with constructive engagement on the quality systems in place.

The inspection was conducted in the presence of Miss Duduzile Dude. The supervisor's technical aptitude, cooperation, openness and drive to continuously improve, set the tone for a successful assessment of the system in place.

Areas inspected

1. Review of the quality management system
 - a. Quality risk management, deviation, change control, CAPA, Document Control,
2. The wholesale business
 - a. Receiving of stock, quarantine, storage and dispatch
 - b. Sanitation and hygiene
 - c. Environmental control and monitoring
 - d. Equipment- cold rooms, and data loggers, racking system.

3. Information Technology

- a. Inventory stock management system.
- b. Environmental Monitoring and Control for temperature and humidity in the warehouse areas and cold chain facility.

1.2 Suitability of Premises

The premises were generally well maintained in a clean state. There was adequate light and ventilation on the premises. There was unidirectional flow of medicines. *The floor was not smooth (Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, Section 2(a))*. All the four areas of receiving, quarantine, warehouse and dispatch were physically separated and adequately labelled. The premises were out of reach of the public. There was a program for rodent and pest control. Waste collection was done at different designated points outside the warehouse. Toilet and canteen areas were separated from where medicines were kept.

1.3 Receiving Area

There was adequate space for conducting receiving operations. There was an overlapping roof to protect medicines from environmental conditions upon receipt of medicines.

There was a receiving table provided for and pallets for staging the medicines before clearance for the warehouse.

1.4 Quarantine Area

This area was generally satisfactory and pallets were available. There was provision for adequately labelling and physically separating different categories of medicines kept in the quarantine room. There were no medicines in the quarantine area on the day of inspection.

1.5 Warehouse

This area was satisfactory and there were pallets and shelves on which medicines were stored. The storage of medicines was adequate to ensure routine inspection of medicines and adequate air circulation. Medicines stored according to FEFO. Temperature mapping studies have been conducted. There were temperature control mechanisms in place. There were three (3) devices present for monitoring temperature and humidity. Positioning of the devices was guided by temperature mapping studies. On the day of inspection, the

devices recorded 25.0°C, 23.4°C, and 24.7°C respectively. The warehouse had a lockable door which restricted access to the warehouse when the supervisor was not around.

There was a functional Capri® refrigerator for storage of cold chain medicines on the premises. The refrigerator was free of mold; there were no food items in the refrigerator. There was use of a digital Brannan® thermometer which was calibrated.

1.6 Dispatch

This area was provided for and there was a dispatch table and pallets available. The invoices contained all the necessary information. There was provision for monitoring and regulation of transportation temperature and humidity conditions of materials during delivery to patients.

1.7 Cleanliness and Hygiene

The premises were generally clean and tidy.

1.8 Control of Materials

Stocks were controlled through a computerized system which captured all the required information. There was use of external drives to back up the system.

1.9 Dangerous Drugs

There were no Dangerous Drugs (DD) on the premises.

1.10 Documentation and Records

The following documents were reviewed:

1. SOP for receiving
2. SOP for CAPA
3. SOP for Receipt and checking of deliveries
4. SOP for Storage of products
5. SOP for Cleaning and maintenance
6. SOP for Securing of stock
7. SOP for returned products and recalls
8. SOP for Rejected goods
9. SOP for Dispatch of goods
10. SOP for Handling complaints

11. SOP for Transportation of medicinal products

There was a training program, and a training SOP was available. There was a defined procedure for writing SOPs. There was a procedure in place for managing CAPA. There was a procedure for conducting self-audits and records for self-audits which had been conducted were present.

1.11 Legislation

Soft copies of all statutes were available at the premises. There was access to the internet, hence the registers could be accessed online in real time.

1.12 Security

There was a metal roller shutter at the entrance of the premises. Burglar bars were installed on all the windows. Security guards were available for provision of 24-hour security daily.

2.0 Observations

For the observations the reference numbers given below in the right-hand column refer to the relevant references of the Medicines and Allied Substances Control Act, Medicines and Allied Substances Control Regulations and Good Dispensing or Good Wholesaling Guidelines

Observations are classified into the risk categories “Critical”, “Major”, “Other (Minor)” and also in accordance with the functions related to GMP/GSP/GDP as provided for in the WHO 986 and WHO TRS 1025.

2.1 Critical observations are those observations that pose a great risk to the general public

2.2 Major observations are those observations which pose considerable risk to the public

2.3 Minor observations are those observations which pose minimal risk to the public but are still contraventions to the statutory instruments and departure from the guidelines.

Nr	Observations	Ref
	Critical	

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	None	
	Major	
1	The floor was not smooth.	Medicines and Allied Substances Control (General) Regulations, SI 150 of 1991, Section 2(a)
	Minor	
	None	

3.0 Recommendations

- The licensee should pay particular attention to the repeat shortcomings in italics.
- The inspection was generally satisfactory.

Inspector: Calvin Nyakanda
Name


Signature

11-6-2026
Date

Inspector: Trishie Chikerema
Name


Signature

11-6-2026
Date

Reviewed by: Martha Mwatseteza
Name


Signature

20-6-2026
Date