SAHPRA & SAPC Cold Chain Management Guidelines

Various requirements:

SAHPRA:

Guideline on South African Good Wholesaling Practice for Wholesalers Sept 2022:

3.7. Quality Management System

3.7.4. Validation

3.7.4.1. Wholesalers should have a Validation Master Plan. The Validation Master Plan provides a summary of the companies' philosophy, policy, intentions, and approach to validation

3.7.4.2. The following should be validated as a minimum:

3.7.4.2.1. Warehouse premises: ambient and cold chain storage conditions including temperature mapping

3.7.4.2.2. Lagged containers

3.7.4.2.3. Cold Chain processes

3.7.4.2.4. Computerized Systems

3.7.4.2.5. Transportation Systems

3.7.4.3. Validation should be conducted in accordance with a validation protocol. A written Validation Report should be available after completion of a validation.

3.7.5. Calibration

3.7.5.1. All measuring equipment must be calibrated in accordance with an approved schedule that details which equipment requires calibration, as well as the frequency of the calibration. The frequency will depend on the type of equipment used, as well as the purpose for which it is used.

3.7.6. Electronic records

3.7.6.1. Records of temperature monitoring data should be available for review. There should be defined intervals for checking temperature. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf life of the stored pharmaceutical product plus one year, or as required by the relevant national legislation.

3.7.6.2. Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be in areas that are most likely to show fluctuations.

3.10. Premises, Warehousing and Storage

3.10.3. Ambient storage conditions for Pharmaceutical Products

3.10.3.3. All Warehouses should be temperature mapped over a period of at least one year to determine the temperature distribution under seasonal extremes.

3.10.3.4. Temperature mapping should be repeated every two to three years and after every significant modification to the premises, stock layout or ventilation system.

3.10.3.5. Temperature monitoring should be done at strategic locations (hot and cold spots) covering the stock containment areas and must be read and data recorded at least twice daily. Temperatures should be recorded in the morning and in the afternoon.
3.10.3.6. Continuous temperature monitoring devices or systems should be validated.
3.10.4. Monitoring of storage conditions
3.10.4.1. Temperatures should be controlled and monitored, using calibrated monitoring devices.
3.10.4.2. Monitoring is conducted at points representing the extremes of the temperature range (hot spots and cold spots) based on the temperature mapping
3.10.4.3. Recorded temperature monitoring data should be available for review
3.10.4.5. Monitoring equipment should be calibrated once a year.
3.10.4.6. All monitoring records should be kept for at least the shelf life of the pharmaceutical product plus one year.
3.10.5. Storage conditions for Thermolabile Products
3.10.5.3. The temperatures of the freezers for all products including coolants must be temperature monitored.
3.10.5.4. Refrigerator, Freezer, or cold room must be connected to an alarm system – in the event of a power failure or if the temperature limits are not met.
3.10.5.7. Refrigerators, cold rooms and freezers used to store thermolabile pharmaceutical products should:
3.10.5.7.5. Have sensors for continuous temperature monitoring and alarms located at he points representing the temperature extremes.
3.10.5.8. The refrigerator, freezer or cold room must be mapped in terms of temperature.
3.11. Shipment containers and Container labelling
3.11.6. Validated Lagged Container:
3.11.6.2. There should be a written procedure available for the validation of lagged containers
3.13. Vehicles
3.13.10. Where special storage (e.g. temperature, and or relative humidity) different from the expected environmental conditions are required during transportation, these should be provided, checked, monitored, and recorded.
3.13.11. All monitoring records should be kept for a minimum of the shelf life of the product distributed plus one year, or as required by national legislation. Records of monitoring data should be made available for inspection by the regulatory or other oversight body.
3.13.12. Equipment used for monitoring conditions e.g. temperature and humidity, within vehicles and containers, should be calibrated at regular specified intervals.
3.19 Returned and rejected products
3.19.8. In the event of cold chain items that are returned, a “No Returns” may be in place unless under exceptional circumstances:
3.19.8.3. For the “Product Quality Evaluation”, the Responsible Pharmacist must request a copy of the customers’ “Fridge log” as well as a letter from the customer’s Responsible Pharmacist stating that the pharmaceutical products were handled and stored in the required manner whilst in their custody.

Myfridgeonline

South African Pharmacy Council

Good Pharmacy Practice Manual and associated SAPC rules:

SAPC

1.1 INTRODUCTION

1.11 MINIMUM STANDARDS FOR INSTITUTIONAL PUBLIC PHARMACY OPERATING A REMOTE AUTOMATED DISPENSING UNIT (RADU)

1.11.7 Record keeping

(b) Records must be available for inspection at all times and must include the following:

(vii) continuous temperature monitoring records

1.2 MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT

1.2.8 Environment in pharmacy premises

(b) Refrigerators used for the storage of thermolabile medicine must be calibrated regularly.

2.3 MINIMUM STANDARDS FOR PROCUREMENT, STORAGE AND DISTRIBUTION

2.3.5 Minimum standards for the procurement, storage and distribution of thermolabile pharmaceutical products

2.3.5.3 Storage area

Storage areas may include inter alia cold rooms, refrigerators and freezers. Thermolabile pharmaceutical products require controlled temperature storage and therefore must be identified on receipt and be stored in accordance with written instructions. Temperatures must be monitored and recorded twice daily. Records must be reviewed regularly. Controlled temperature storage areas must be equipped with temperature recorders. Control must be adequate to maintain all parts of the area within the specified temperature range. This control is essential in maintaining the quality of thermolabile pharmaceutical products and in helping to protect the end user from substandard or ineffective thermolabile pharmaceutical products as a result of inadequate control.

(c) The storage area must be kept clean. Internal air temperature distribution must be mapped on installation of the storage area while empty and thereafter fully stocked. This must be done annually under conditions of normal use. Thermolabile pharmaceutical products must not be stored in areas shown by temperature mapping to present a risk (e.g. in the airflow from the refrigeration unit).

(d) All storage areas, such as refrigerators or cold rooms must be properly maintained in order to maintain the factory standards for such storage areas. Proof of maintenance must be provided.

(f) A suitable number of temperature recording instruments that complies with or meets WHO specifications, being at least a logging device, must be installed to record temperatures and to provide temperature and profiles as per the temperature mapping of the storage area. Monitors that comply with or meet WHO specifications, must be adequate to monitor and record temperature ranges in all parts of the area within the specified temperature range.

(g) Temperatures must be monitored and recorded at least twice daily, with a minimum of seven-hour interval and the records from such monitoring must be reviewed daily.
(h) Large commercial refrigerators and walk-in cold rooms must be monitored with an electronic temperature-recording device that measures load temperature in one or more location, depending on the size of the unit.
(i) In the monitoring of large commercial refrigerators and walk-in cold rooms, portable data-loggers that can be downloaded onto a computer may be used instead of a fixed device.
k) The refrigerator, cold room or freezer must be connected to an alarm system and/or warning system in the event of a power failure or if the storage area temperature limits are exceeded.
(l) Any recording devices/instruments must be calibrated annually against a certificated standard.

2.3.5.4 Distribution

Thermolabile pharmaceutical products must be transported by appropriately specialised means in such a way that they are secure and are not subjected to unacceptable degrees of heat/cold.
(a) Packaging system of thermolabile pharmaceutical products, for purposes of distribution must be quality assured to ensure that it occurs within the cold room environment, fulfils the manufacturers' specifications requirements, is thermally designed and validated, and is related to Temperature Profile(s)/Logistic history.

2.3.5.5 Transportation

(c) In the event of the mode(s) of transport not being specific for the transportation of thermolabile pharmaceutical products, the specialised packaging like validated cooler bag packaging must be used.
(d) For purposes of transportation, the route must be planned and assessed and/or validated to ensure that delays and/or exposure to extreme temperatures are correctly assessed. Transportation between South Africa and other neighbouring countries and within South Africa, due to large geographical areas, must be treated as unique in terms of the range of temperatures that the thermolabile pharmaceutical products may experience.
(h) Temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards that comply with or meet WHO specifications must monitor the temperature of the loaded area of the transportation throughout the trip, and the validated cooler box packaging must have at least a temperature monitoring device that complies or meets with WHO specifications.

2.3.5.6 Receiving

(e) Check temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards to ensure the temperature history of the transport and the temperature history of the thermolabile pharmaceutical product being transported were maintained within in limits.
(j) Delivery documents must be signed off on temperature data and condition of other control devices used.

2.3.5.9 Disruption in the procurement, storage and distribution of thermolabile pharmaceutical products (cold chain)

(e) Refrigerator temperature must be recorded by noting the current reading and recording the maximum and minimum temperatures.
(I) Monitoring of the temperature must be maintained on at least an hourly basis and recorded up until the point of restoration to working order of the storage area or removal and transfer to another cold store.

2.13 MINIMUM STANDARDS FOR SCREENING AND MONITORING SERVICES IN PHARMACIES SCREENING AND TESTING BIOCHEMICAL AND PHYSIOLOGICAL PARAMETERS

2.13.2 Minimum standards regarding testing

2.13.2.1 Minimum standards regarding test materials and instruments

(j) Instruments must be kept clean and in good working order and be calibrated regularly.