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**Temperature control facilities validation for pharmaceutical
products cold chain logistics - Technical specification for
performance qualification**

医药产品冷链物流温控设施设备验证 性能确认技术规范

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Table of Contents

Foreword	3
1 Scope	7
2 Normative References	7
3 Terms and Definitions	7
4 Assurance Requirements	8
5 Performance Qualification of Temperature-controlled Warehouses.....	8
6 Performance Qualification of Temperature-controlled Cabinet.....	12
7 Performance Qualification of Temperature-controlled Vehicles.....	14
8 Performance Qualification of Refrigerators	17
9 Performance Qualification of Insulated Containers	19
10 Performance Qualification of Temperature Monitoring System.....	21
11 Validation Methods	24
Appendix A (informative) Calculation Methods for Temperature Deviation, Uniformity and Fluctuation	25
Bibliography	27

1 Scope

This document specifies the assurance requirements for the performance qualification of temperature control facilities and equipment in the cold chain logistics of pharmaceutical products, the requirements for the performance qualification of temperature-controlled warehouses¹⁾, temperature-controlled cabinets, temperature-controlled vehicles, refrigerators, insulated containers, and temperature monitoring systems, as well as the validation methods.

This document applies to performance qualification activities involving temperature-controlled warehouses, temperature-controlled cabinets, temperature-controlled vehicles, refrigerators, insulated containers, and temperature monitoring systems during the validation process of temperature control facilities and equipment in the cold chain logistics of pharmaceutical products.

2 Normative References

This document does not have normative references.

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 Performance Qualification

The activities of testing, verification and documentation undertaken to confirm that installed and connected facilities, systems and equipment can effectively and stably operate in accordance with the approved production methods and product technical requirements.

3.2 Temperature-controlled cabinet

A small storage container with the function of temperature control.

NOTE. temperature-controlled cabinet includes refrigerated cabinet and freezer cabinet, etc.

1) Temperature-controlled warehouses include refrigerated storage, freezer storage, constant-temperature storage and cool storage, etc.

3.3 Refrigerator

An insulated enclosure with the function of temperature control.

3.4 Insulated container

An insulated enclosure made of insulating materials.

3.5 Temperature monitoring system

A system consisting of measurement point terminals, a management host, an uninterruptible power supply, and related software, capable of real-time acquisition, display, collection, processing, recording, alarming and transmission of temperature data of pharmaceutical products during storage and transportation.

4.1 Personnel Requirements

Personnel participating in performance qualification activities shall have received appropriate training and be familiar with relevant laws, regulations and professional skills.

NOTE. personnel participating in performance qualification activities include, but are not limited to, supervisors, instructors, coordinators, approvers, and implementers.

4.2.1 The temperature recorder used for validation or the validation management system shall

have data storage, export, and viewing functions, and shall be able to prevent users from

modifying or reverse-importing data.

4.2.2 The temperature recorder used for validation shall have the function of continuous data acquisition and recording, and the data acquisition interval shall not exceed 1 minute.

4.2.3 The measurement range of the temperature recorder used for validation shall be applicable to the temperature range of performance qualification, and its maximum permissible error of temperature measurement is $\pm 0.5^{\circ}\text{C}$.

4.2.4 The temperature recorder used for validation shall be periodically calibrated by a statutory metrology institution and affixed with a calibration qualification label.

5 Performance Qualification of Temperature-controlled

Warehouses

5.1.1 Testing of operating parameters and usage status of temperature control facilities and

equipment.

5.1.2 Confirmation of the installation locations of the temperature monitoring system's

allocated measurement point terminals.

5.1.3 Confirmation of the impact of door opening operations on the temperature distribution of the temperature-controlled warehouses.

5.1.4 Determination of the thermal insulation properties and variation trends of the temperature-

controlled warehouses under conditions of equipment fault or external power outage.

5.1.5 Confirmation of the temperature deviation, uniformity and fluctuation of the storage space.

5.1.6 Confirmation of temperature stability under extreme external environmental conditions,

such as high or low temperatures in the local area.

5.2.1 It shall be demonstrated that, under given operating conditions, the temperature

distribution test results for the temperature-controlled warehouses, both under no-load and full-load, are within the specified temperature control range.

5.2.2 Cold and hot points shall be identified, and measurement point terminals of the temperature monitoring system shall be installed at the locations of the cold and hot points.

When the measurement point terminals of the temperature monitoring system are not mobile, it shall be demonstrated that the difference between the temperature data collected by the measurement point terminal of the temperature monitoring system closest to the cold or hot point in the freezer storage and the average value of temperature data of the corresponding cold or hot point is within $\pm 2^{\circ}\text{C}$. The difference among the average values of other temperature-controlled warehouses shall be within $\pm 1^{\circ}\text{C}$ and representative.

5.2.3 It shall be demonstrated that the shortest door opening time that would cause any measurement point to overheat is greater than the specified value.

5.2.4 It shall be demonstrated that the insulation time limit under equipment fault or external power outage conditions is greater than the specified value.

5.2.5 The temperature deviation, uniformity and fluctuation of the refrigerated storage shall not

exceed $\pm 3^{\circ}\text{C}$. The calculation method is given in Appendix A.

5.2.6 During the periodic validation cycle, when the external ambient temperature of the

temperature-controlled warehouses is maintained above 0°C , the validation shall be conducted at least once under extreme high-temperature environmental conditions.

5.2.7 When the refrigerated storage and freezer storage experience the following situations, no-

load and full-load performance qualification shall be performed.

6 Performance Qualification of Temperature-controlled

Cabinet

6.1 Performance Qualification Content

6.1.1 Testing of operating parameters and usage status of temperature control equipment.

6.1.2 Confirmation of the installation locations of the temperature monitoring system's

allocated measurement point terminals.

6.1.3 Confirmation of the impact of door opening operations on the temperature distribution