INTERNATIONAL STANDARD

ISO 23416

First edition
2023-01

General specifications and testing methods for temperature-sensitive medicinal packages in good distribution practice principles

Spécifications générales et méthodes d'essais relatives aux emballages de médicaments thermosensibles selon les principes de bonnes pratiques de distribution

Reference number
ISO 23416:2023(E)

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Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 122, *Packaging*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Good distribution practice (GDP) is considered as an essential aspect of compliance for all temperature-sensitive medicinal products and to ensure systematic distribution.

Temperature-sensitive medicinal products are susceptible to temperature changes. Those products can become less effective or destroyed when exposed to excessive environments. They need to be kept within a specific range of temperatures from the place of manufacture to the point of administration to the users. Despite increasing awareness and the need of safe handling, transport and storage of temperature-sensitive medicinal products, an international standard of testing methods for their packaging is in great need.

For temperature-sensitive products, qualified equipment like thermal packaging, temperature-controlled containers or temperature-controlled vehicles should be used to ensure correct transport conditions are maintained between the manufacturer, the wholesale distributor and the customer. In case of temperature-controlled vehicles, the temperature monitoring equipment used during transport/storage should be maintained and calibrated at regular intervals. Temperature mapping under representative conditions should be carried out first and should take into consideration seasonal variations if relevant.

Harmonized methods can be a guideline to maintain the recommended temperature range inside an insulated container and physical performance. This document works through enhancing the capacity to distribute and handle the products effectively. This document is intended for anyone involved in transport, storage and handling of them, especially manufacturers, importers, distributor, wholesalers, transporter, etc.

Test methods are based on Australia National Temperature-sensitive Pharmaceutical Storage Guidelines Strive for 5 (2nd Edition), Guidelines on the international packaging and shipping of temperature-sensitive vaccines (WHO/IVB/04.23 Annex 1 and WHO/PQS/E004/CB01-VP.3), ISO 22982-1 and ISO 22982-2.

General specifications and testing methods for temperature-sensitive medicinal packages in good distribution practice principles

1 Scope

This document describes the general specifications of temperature-sensitive medicinal packaging based on the principles of good distribution practice (GDP). It also specifies test methods to validate the package performance for temperature-sensitive medicinal products. This covers the procedures of temperature-recording and testing methods on the performance of insulated containers such as dimensions, weights, storage capacity and robustness in temperature-controlling.

This document does not guarantee the quality and safety of all medicinal products. Under special circumstances where the weight or the characteristics of the products and environment show specific conditions, agreements are followed. This document does not cover the active packaging system, but only covers the passive packaging system able to control the desired temperature without any power sources.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 21067-1, *Packaging — Vocabulary — Part 1: General terms*

ISO 22982-1, *Transport packaging — Temperature-controlled transport packages for parcel shipping — Part 1: General requirements*

ISO 22982-2, *Transport Packaging — Temperature controlled transport packages for parcel shipping — Part 2: General specifications of testing*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21067-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
good distribution practice
GDP
part of quality assurance which ensures that quality of medicinal products is maintained throughout all stages of the supply chain from the site of manufacturer to the pharmacy or person authorized or entitled to supply medicinal products to the public

[SOURCE: Guidelines of the European Commission, Annex of 2013/C343/01]