



Technical Report No. 72
Passive Thermal Protection Systems for
Global Distribution:
Qualification and Operational Guidance

PDA Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guidance Technical Report Team

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1.0 Introduction

This technical report discusses the qualification and operational handling of passive thermal protection systems (TPS) for temperature-controlled distribution of pharmaceutical and biological products. The intent of this information is to assist stakeholders in the supply chain to preserve the quality, safety, and efficacy of these products during distribution. This report provides specific guidance on the types of passive systems, including the materials used in their manufacture, characteristics and capabilities of these systems, qualification approach, operational use and reuse, and options for recycling at the end of the systems' life.

This report introduces the basics of thermodynamics and the effect these principles have on passive thermal protection systems, followed by a discussion on the types of passive thermal protection systems, materials used in construction and a review of their characteristics. User requirements and risk assessment are described in terms of key decision tools in choosing the appropriate technology.

Qualification is briefly discussed to provide an understanding of the best approach for each type of passive system. This report also provides guidance on the use and operation of different technologies to ensure optimum performance within the supply chain. Furthermore, opportunities for reusing systems or components are discussed in an effort to reduce cost and waste.

Appendices II and III and references at the end of the document include samples of executed Failure Modes and Effects Analysis (FMEA) for using passive technologies in the supply chain, and a table highlighting the options/examples for recovery and recycling of materials used in the construction of passive thermal protection systems.

1.1 Purpose and Scope

This guidance has been developed by members of the PDA Pharmaceutical Cold Chain Interest Group (PCCIG). The technical report team includes representatives from the pharmaceutical industry, suppliers of thermal covers, passive shipping systems and temperature monitors, logistic service providers and carriers. Stakeholders include the pharmaceutical supply chain, including manufacturers, suppliers of passive systems, suppliers of temperature monitors, logistic service providers, carriers, clinicians, handling agents, wholesalers, airlines and any other interested parties. This guidance document serves to complement the information provided in previously published PDA Technical Reports No's 39, 58, and 64 by describing in more detail the qualification and operational use of passive thermal protection systems (1-3).

The purpose of using passive thermal protection systems for the distribution of temperature-sensitive pharmaceutical products is to ensure that the product is maintained within the defined temperature range for a defined time period. The decision to use a passive system versus an active system is dictated by many factors including, but not limited to the following (list below is not in any sequential order):

- Regulatory requirements
- Size of load
- Overall cost for distribution
- Availability of systems
- Handling capabilities of stakeholders within the supply chain
- Product temperature requirements / stability data
- Shipment duration
- Environment (e.g., season, prevailing [expected] temperature)

- Available controls along the shipping lane
- Customer needs and expectations

The decision as to which technology to use is derived from a user requirements specification (URS) defined by these factors. Additionally, the successful compilation and execution of the Operational Qualification (OQ) and the Performance Qualification (PQ), is dependent on a User Requirements Specification (URS) containing clear, concise and testable requirements. Other considerations might include:

- Use of the system
- Whether any of the components require preconditioning prior to use
- Whether opportunities exist to use the system more than once
- What options are available for recycling at the end of the systems' life.