Tec4med

Qualifification documentation High-Performance Inlay

Revision History

Version	Date	Author	Changes / Reason for Changes
V01	2021-05-05	Niklas Stäter	Initial Version

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Contents

1 Introduction

The transport of healthcare products (medicines, especially vaccines, laboratory reagents, stable blood products, tissues, transplants, etc.) exposes the goods in transit to significant temperature differences with the environment, which can alter and compromise the quality of these products.

These temperature differences between the required storage temperature of the products and the environment, can change the quality of these products or even lead to irreversible spoilage of these products.

Isothermal packaging and refrigerated packaging must be able to maintain the temperature of the transported products within a defined temperature range in summer and winter and over periods ranging from a few hours to several days. The thermal behaviour of this packaging is therefore crucial for maintaining the properties and characteristics of the products. It is an essential contribution to the control of the cold chain.

The qualification of High Performance multi-use packages is strongly referenced to the NF S 99-700 (AFNOR) and ISTA 7E qualification standards and tested on performance for insulated packaging solutions. These reference systems include protocols and procedures for characterising containers and verifying their ability to keep the load items within the required temperature range.

2 Test conditions

Qualification of a package consists of demonstrating that for defined conditions of use (package configuration, transported load, etc.), ambient temperature and duration, a package allows the temperature of the transported products to be maintained within a specified temperature range.

During the qualification tests, the insulation containers are placed in an environment that reproduces a predefined temperature profile for typical transports in summer as well as in winter. Temperatures must be recorded at the most critical points in the loading volume. The tests are carried out with an empty loading space, without additional thermal masses in the form of product samples.

The temperature profiles used are intended to simulate the temperature conditions of the ambient air in the shipping circuit. The AFNOR NF S 99-700 ST-48-a and the ISTA 7E temperature profile are used to simulate transport in summer and the AFNOR NF S 99-700 ST-48-d for transport in winter.

2.1 Positioning of measuring transducers in the packaging

In the transport simulation, the two positions at which the transport material experiences the lowest and the highest temperature must be taken into account. Symmetries can be exploited, taking into account the geometry and other properties of the container. The largest temperature amplitudes are to be expected in the edge areas. In the qualification tests, 10 measuring points were considered in each case. One sensor was placed in the centre of each of the lowest, middle and top levels, one in the corner and another in the centre of the edge of the longer side in the corresponding level (cf. Figure 1):

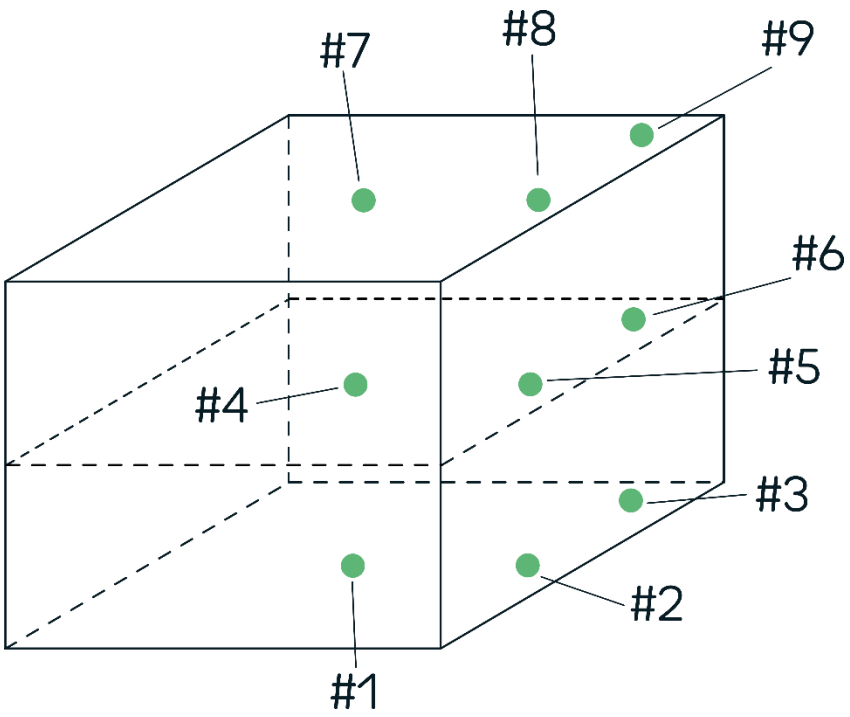

Figure 1 Positionierung Messwertaufnehmer im Innenraum der Isolationsverpackung

Another measuring point is located in the recess provided for the product in the holder for the upper cooling elements (cf. Figure 2):

Figure 2 Position Messwertaufnehmer in Halterung für obere Kühlelemente

3 Description of the materials and test equipment used

3.1 Sheathed resistance thermometer type Pt 100

Sheathed resistance thermometers of the type Pt 100 (SPEC-PT100 1/3-2M-GO) from TC-Direct were used to record the ambient temperatures, with a temperature range from -50 to +250 °C. The resolution is 0.1 °C and the accuracy is 0.1 °C + 0.167%. The resolution is 0.1 °C and the accuracy is 0.1 °C + 0.167%. The sheath resistance thermometers are factory calibrated by Tec4med Lifscience GmbH.

3.2 Temperature logger

The temperatures in the loading room were recorded using SmartBeacons from Tec4med LifeScience Gmbh, which are based on the hardware of the ASPION G-Log2. The temperature range of the SmartBeacons is between -40 and +85 °C, the accuracy is 0.2 °C and the resolution is 0.1 °C. The temperature loggers are factory calibrated by Tec4med Lifescience GmbH.

3.3 Climate chamber

A climate chamber from Weiss DU11/300/40 was used for the environmental simulation. The temperature constancy over time is +/- 0.2...+/- 0.5 °C and the operating range is between -40 and +180 °C. The test chamber is ventilated turbulently by a blade fan.

3.4 Insulation

Vacuum insulation panels

3.5 Cooling elements

- 4°C accumulator 700ml phase change accumulator
    - Preconditioning:
        - At least 14 h at -20°C +/- 5°C
        - After freezing, allow to thaw for approx. 30 min at RT 23 °C +/- 5°C
- 4°C accumulator 700ml phase change accumulator
    - Preconditioning:
        - At least 14 h at -40°C +/- 5°C
        - After freezing, allow to thaw for approx. 15 min at RT 23 °C +/- 5°C

Note: When freezing and thawing, it is advisable to position the batteries individually and free-standing, so that as much of the outer surface of the accumulators as possible is surrounded by air. They should be placed at least 10 cm away from other objects. The times given apply to free-standing batteries.

4 Temperature profiles

4.1 AFNOR NF S99-700 ST-48-a

Table 1 Temperature profil AFNOR ST-48-a

Segment	Duration in h	Temperature in °C
1	3	22
2	4	28
3	9	22
4	8	28
5	4	40
6	3	28
7	9	22
8	8	25

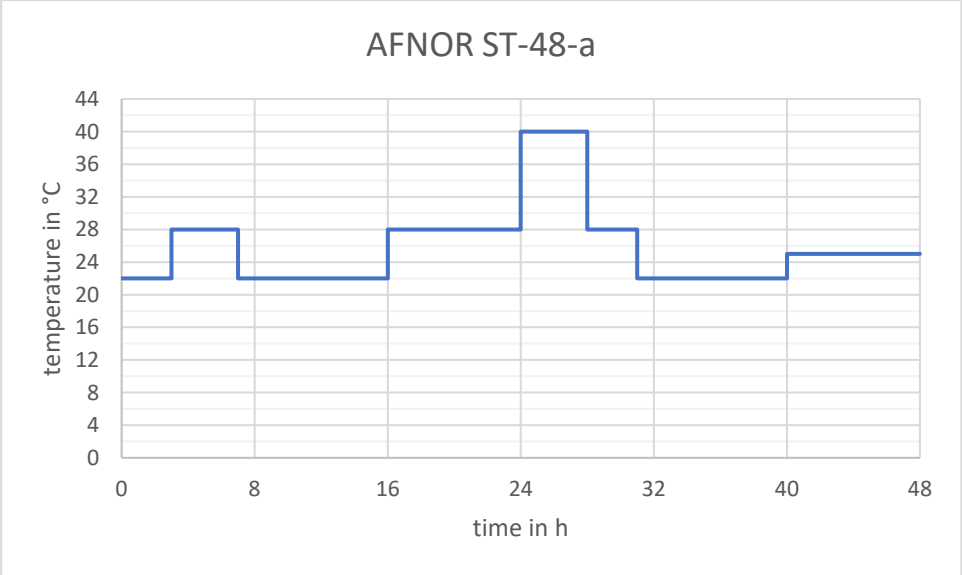

Figure 3 Diagram temperature profileAFNOR ST-48-a

Examples of cases represented by profile no. ST-48-a:

- for national dispatch, this profile may cover the following situations:
  - period of the year corresponding to episodes of a prolonged summer configuration (example: the months of July or August);
- for the rest of Europe, this profile can cover shipments, to and from destinations with a Mediterranean or continental climate (e.g. Italy, Spain, etc.) during the summer period

4.2 ISTA 7E Sommer

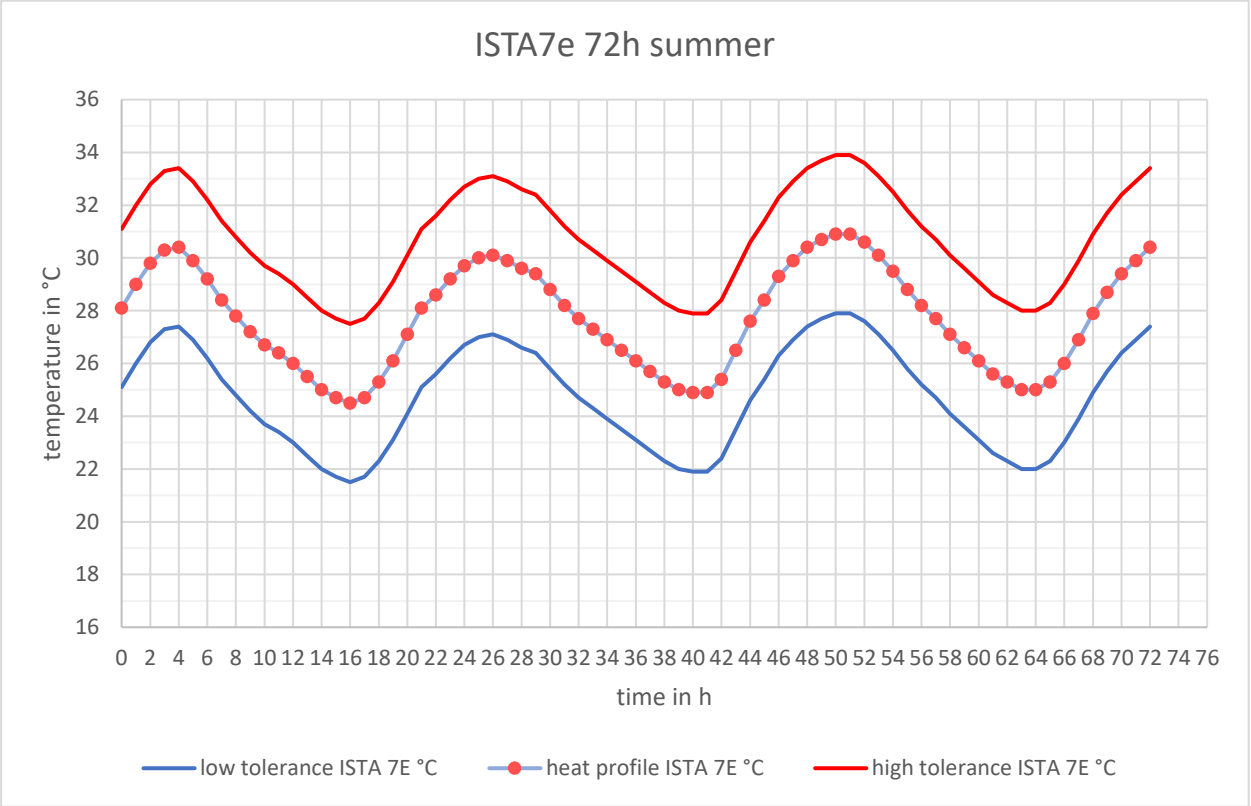

Figure 4 Diagramm Temperaturverlauf ISTA 7E

4.3 AFNOR NF S99 700 ST-48-d

Table 2 Temperature profil AFNOR ST-48-d

Segment	Duration in h	Temperature in °C
1	3	15
2	4	5
3	9	9
4	2	-2
5	13	5
6	9	9
7	2	-2
8	6	5

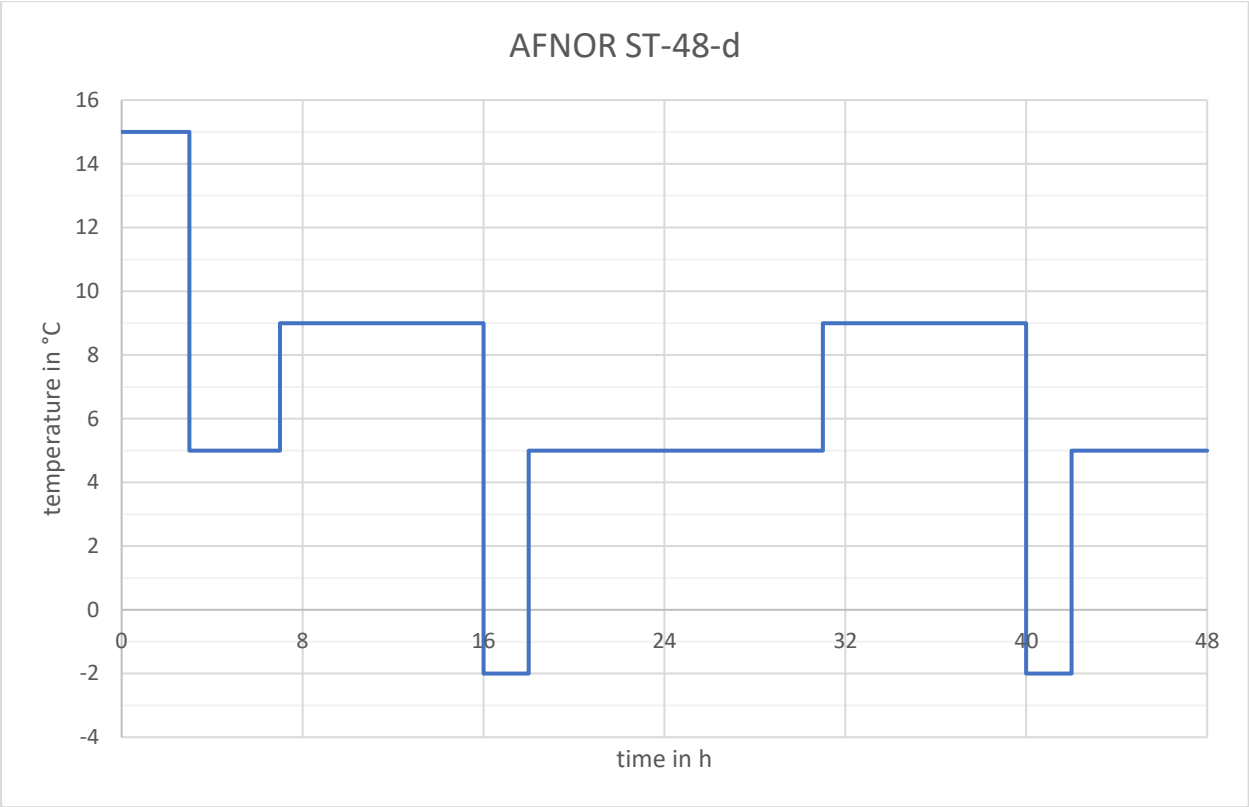

Figure 5 Diagram temperature profileAFNOR ST-48d

Examples of cases represented by profile no. ST-48-a:

- for national dispatch, this profile can cover the following situations:
  - period of the year corresponding to episodes of a prolonged winter configuration (example: the months of January or February);
- for the rest of Europe, this profile can cover consignments, to and from destinations with a continental climate during the winter period.