INTELSIUS WHITE PAPER

TEMPERATURE-CONTROLLED PACKAGING SYSTEMS: ACTIVE OR PASSIVE?

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INTRODUCTION

Be it active or passive, a thorough understanding of temperature-controlled packaging needs will ensure that the best packaging system is chosen to provide the necessary protection for valuable temperature-sensitive pharmaceutical shipments.

Delivering a temperature-sensitive product to market can be a challenge. To beat that challenge, it is necessary to identify solutions that will get the product to its destination, in the right state and at the right price. This choice will be unique to the product, market and chosen distribution methods.

Distribution models can vary from a few high-value biologics supplied to patients with a direct-to-patient delivery scheme, to lower-value mass market products sent first to regional distributors, then wholesalers and then retailers, before finally being sent to pharmacies and clinics. One solution will not fit all distribution models, and the range of available options provides evidence of the diverse requirements of temperature control distributors.

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ACTIVE VERSUS PASSIVE PACKAGING SYSTEMS

There is one clear divide in the types of system available – active temperature control systems and passive temperature control solutions. Active systems range from parcel size to full trailer or reefer systems, and provide heating, cooling or both. If a system provides heating, it is almost always done by electrical means – with some relying on heavy battery packs and others on a supply of external power. If cooling is supplied, it is either by use of a cold reservoir – typically dry ice – or by conventional refrigeration using electrically driven or fuel-powered compressors. Smaller units, down to parcel size, rely on single-use chemical reactions or pressure differences to provide finite periods of heating or cooling. The larger systems resemble transportable refrigerators and feature cooling and heating units that pass air through heat exchangers and circulate it around the product space. Large active solutions come at a high capital cost, and are almost exclusively leased or have space within them rented for specific periods. In many cases, the need to collect and return these units to a point where re-use can occur adds to the periods of use and transport costs in many cases. If a fixed amount of temperature-sensitive material is being transported at regular intervals between a few local points, then larger active systems can be utilised efficiently. With long distances, variable load sizes and irregular distribution destinations, the costs of these systems may become prohibitive. The alternative to active systems is passive packaging solutions. These more closely resemble conventional outer packaging for products, but consist internally of insulation materials and thermal media, which act in concert to resist changes in product temperature driven by adverse external temperatures. By appropriate solution specification and selection, a system suited to a product's needs can be identified. These systems require preparation of components under controlled conditions, and the system can be packed and sealed before dispatch. Once sealed, passive systems require no further temperature-specific handling until they reach their destination. These solutions do not actively respond to adverse exposures and are specified to passively handle extreme exposures.

CHOOSING BETWEEN ACTIVE & PASSIVE SYSTEMS

When making the choice between active and passive systems, an appreciation of the product and chosen distribution model will have an important impact. The value of the product and the cost of replacement will also influence the decision, along with the routes, necessary thermal protection and product volumes.

Active Systems

The use of dedicated active solutions provides the benefits of high thermal stability, which can be tailored to the exact temperature range required, be it less than -20°C or +15°C to +25°C. They can be utilised under service level and quality agreements, including operational qualification and periodic thermal mapping, availability and suitability. However, they are only available in large volumes, and partial loads incur similar costs to full loads. This is because the units still require the same level of handling and the payload does not represent a large proportion of the total system volume and weight. Active systems often require limited preparation and are often simple to pack following a standard operating procedure (SOP). They are, however, dependent on the logistics of being brought to the site, packed and collected within a fixed timeframe. The systems are high cost and, unless there is a full load, the efficiency of use may be restricted. An alternative in active thermal protection is temperature-controlled groupage. This, in principle, provides carriage of any size shipment under the appropriate conditions. Concerns with this include the diversity of products loaded alongside the sensitive materials, the diverse product's preparation states and the active system's response to the shipping environment and conditions when loading, cross loading and unloading other items in the active system with a sensitive shipment.

CHOOSING BETWEEN ACTIVE & PASSIVE SYSTEMS

Passive Systems

The use of passive temperature-controlled systems allows the shipment size to determine the solution used, from single small doses to multiple pallets. The systems comprise the payload material surrounded by thermal media, which is prepared to specific temperatures and encapsulated within an insulation material. This basic construction allows for systems to be shipped without significant handling restrictions – providing more potential carriers and routes to become available for the shipment. With an understanding of the typical and potential extreme temperatures a shipment may encounter, a passive system of suitable thermal capabilities can be identified. The systems, in comparison with active systems, have considerably lower capital cost and can be stock-held to provide volume flexibility in terms of supply. Passive systems can also be passed through whole journeys with no special handling. If you require increased durations or extreme performance, the systems can be refreshed and reset to increase their capability by trained agents at key points. Passive systems can utilise technologies across a range of budgets and performance capabilities. They can provide frozen protection below -20°C by using either the dry ice sublimation phase change at -78°C, or the melting phase change of tailored materials to maintain -25°C to -15°C. There are also passive systems that can maintain +2°C to +25°C and +15°C to +25°C, using both water and specialised phase change materials. The main use of passive systems is, however, in the maintenance of refrigerated products between +2°C and +8°C. Low cost options can use water-based gels in flexible pouches, which can be prepared in conventional freezer and refrigeration units and provide effective protection, particularly against extreme heat. Systems can be upgraded to use semi- and fully-rigid water-based packs, which allow for more consistent use of the available volume and are also more convenient to freeze. These solutions often rely on moulded or extruded insulation foams and are often regarded as single-use. Therefore, systems can travel to destinations with little or no specialised infrastructure and no obligation to return the cooling elements or the insulation materials.

USING PASSIVE SYSTEMS

All passive technologies require components to be prepared prior to the insulation systems being packed around the payload product. This preparation requires the phase change materials, to be maintained at specific temperatures until the systems are ready to be assembled. The materials being installed in the packaging ensure high levels of thermal protection for durations of several days. Additionally, a further set of controlled temperature exposures may be required to prevent adversely prepared materials from affecting the product temperature when packed together, such as in a case where material frozen in -18°C freezers is placed with refrigerated +5°C product. The preparation of material for use in passive systems can require significant temperature-controlled spaces, with some material preparation taking several days or even weeks. The capacity of these preparation spaces can often determine the number of passive systems that a dispatch site has available. With the option for a single site to dispatch hundreds of varying passive systems daily, with different payload temperatures and performance levels to hundreds of destinations worldwide, it is wise to keep distribution flexible and responsive to external events. The implementation of this flexibility requires multiple SOPs and verification of the system assembly, in addition to the documentation and courier services.

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CONCLUSION

While active systems offer high levels of protection and assurance for high levels of handling, the restrictions on these systems can limit them to direct and inflexible routing. Passive systems offer the flexibility to dispatch specified systems to diverse and flexible destinations, though they do require the provision of preparation facilities at the dispatch site. With a thorough understanding of temperature-controlled packaging needs, the best packaging system can be determined – whether it be active or passive – in order to provide the necessary protection for valuable pharmaceutical shipments.

To discover more about the passive temperature controlled systems offered through Intelsius please visit Intelsius.com or alternatively contact your local Intelsius branch using the details on the following page.

INTELSIUS™
A DGP COMPANY

EUROPE: DGP Intelsius Ltd
1 Harrier Court, Airfield Business Park,
Elvington, York, YO41 4EA,
United Kingdom

t: +44 (0) 1904 607 390
f: +44 (0) 1904 607 391

cs@intelsius.com

AMERICAS: DGP Intelsius LLC
7696 Zionsville Road,
Indianapolis, IN 46268,
United States of America

t: +1 317 452 4006
f: +1 317 290 4621

americasorders@intelsius.com

ASIA: DGP Intelsius Sdn Bhd
Plot 11, Lorong Bemban 2, Estet
Perindustrian Bemban, 31000
Batu Gajah, Malaysia

t: +605 3666 399
f: +605 3669 399

compliance@intelsius.com

GERMANY: DGP Intelsius GmbH
Berliner Allee 65, ecos office 12b
64295 Darmstadt
Germany

t: +49 6151 4936650
f. +49 (0) 6151 4936651

info@intelsius.de

IRELAND: DGP Intelsius Teo
Unit 8, Ballyvourney Industrial Estate,
Ballyvourney, Co. Cork,
P12 A527, Ireland

t: +353 (0) 26 456 99
f: +353 (0) 26 456 98

salesireland@intelsius.com

INDIA: DGP Intelsius Cold Chain Pvt Ltd
2, Palak Pluto, Off Link Road,
Kanderpada – Dahisar (West),
Mumbai 400 068, Maharashtra, India

t: +91 22 6525 6621
f: +91 22 2892 3675

compliance@intelsius.com