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A Comparative Study For Cold Chain Packaging Options.

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By

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CERTIFICATE OF APPROVAL

M.S. DEGREE THESIS

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A Comparative Study For Cold Chain Packaging Options.

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DEDICATION

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ABSTRACT

This thesis will evaluate the possibility of eliminating EPS from the cold chain packaging system by replacing it with Vacuum Insulated Panels in Greenbox to create a sustainable and reusable packaging system.

The most widely used packaging materials in the cold chain system have been compared amongst each other for their Design, R value, Cost, Availability and End use. While these are generally the primary concerns in making decisions about packaging, it is also important to consider recyclability and reusability and overall presentation. This paper will briefly examine these issues while looking at some of the more common types of cold chain shipping containers. Expanded Polystyrene is in the vast majority of cold chain packaging systems used for the distribution of Temperature sensitive products. It is also the major contaminant in the landfills. With developing technologies there are solutions to reduce the contamination piled up in the landfill. Hence a comparison study is conducted with a reusable packing system to test if it performs equally well thermally and will also withstand the shock and vibrations from the distribution system.

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HISTORY

Commodity chains are fairly modern expansions in the transportation industry, the refrigerated movement of temperature sensitive goods is a practice that dates back to 1797 when British fishermen used natural ice to preserve their fish stock piles. This process was also seen in the late 1800s for the movement of food from rural areas to urban consumption markets, namely dairy products. The first refrigerated boxcars were used in 1851, but they were able to operate only during cold winter months (Ron, 2009). Cold storage was also a key component of food trade between colonial powers and their colonies.

The temperature controlled movement of pharmaceuticals and medical supplies is a much more modern transit option than the shipping of refrigerated or frozen food. Since the 1950s, logistical third party companies began to emerge and instituted new methods for successfully transporting these global commodities (Jean-Paul, 2005).

In the United States, Food and Drug Administration restrictions and accountability measures over the stability of the cold chain incited many of these companies to rely on specialty couriers rather than completely overhauling their supply chain facilities. A specialized industry was thus born. The value of the cold chain in the preservation of expensive vaccines and medical supplies was only beginning to be recognized when these logistical providers started to appear. As awareness began to grow, so did the need for efficient management of the cold chain.

1. INTRODUCTION

Since globalization has made the relative distance between regions of the world much smaller, the physical separation of these same regions is still a very important reality. The greater the physical separation, the more likely freight can be damaged in one of the complex cold chain transport operations involved.

The cold chain refers to the transportation of temperature sensitive products along a supply chain from the manufacturer to the consumer through thermal and refrigerated packaging methods and the logistical planning to protect the integrity of these shipments (Jean-Paul, 2005). An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range. It is used to help extend and ensure the shelf life of products. This is very important since medicines lose potency over time, especially if exposed to heat, and in addition, some also lose their potency when frozen.

In the cold chain, the ultimate responsibility lies with the package for maintaining the proper temperature for the Time and temperature-sensitive pharmaceutical product (TTSPP) as it moves through the cold chain distribution system. Shown in (Fig-1) is the distribution path for the cold chain products from the manufacturer to the consumer.

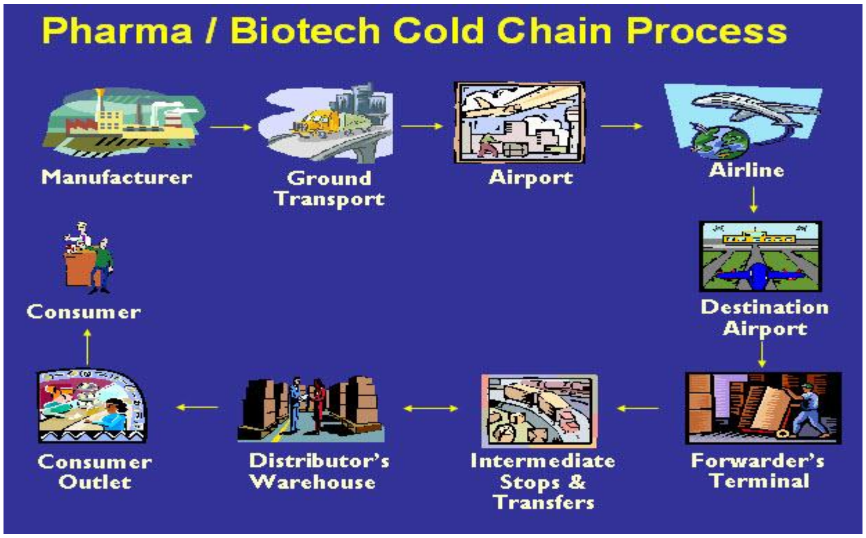


Figure 1 Biotech distribution path.

There are many options regarding the container you choose to transport the temperature controlled products. This decision will affect the cost and performance of the cold chain packaging system.

Most commonly used thermal packaging materials today are Expanded Polystyrene (EPS) and Polyurethane (PUR).

1.1 **Expanded polystyrene -**

In EPS the main component is styrene (C_8H_8), which is derived from petroleum or natural gas and formed by a reaction between ethylene (C_2H_4) and benzene (C_6H_6); benzene is produced from coal or synthesized from petroleum (Anon, 2011a). Next, the styrene is subjected to suspension polymerization and treated with a polymerization initiator, which together convert it into polystyrene. To produce smooth-skinned Expanded Polystyrene Foam, the beads are pre-expanded, dramatically reducing their density. Next it is heated and expanded before allowing them to sit for 24 hours so that they can cool and harden. The beads are then fed into a mold of the desired shape (Anon, 2011a).

EPS can provide a lower cost alternative to many other materials. However, there are many variables to the cost of an EPS container such as mold costs, density, complexity of design and overall size. Note that reducing the density may also reduce the thermal and protective properties of the container. EPS as a material can weigh less than many other options. For example, a 1” wall EPS container with outer dimensions of 12” x 12” x 14” with a 1.5 pounds per cubic foot density would weigh approximately 3.5 pounds. A comparable PUR container could weigh as much as 9.0 pounds. They can be produced in mass quantities using multi-cavity tools. This ability to manufacture large numbers of containers helps keep the cost of EPS containers low and availability high. In some cases, used EPS containers can be ground down and used as filling material in other products.

EPS has a lower R-value than PUR and vacuum insulated containers and will be less effective in preventing outside temperatures from affecting the temperature-sensitive product. The R-value of EPS is between 3.5 and 5.0 and varies based on density. The lack of insulating property could require more refrigerant or a need for express shipping methods which creates the possibility of increasing the total cost of shipments. If a custom container is required, the cost associated with building a new tool can be substantial. Depending on the complexity of the design, an EPS tool could cost anywhere from $15,000 to $60,000. Also these containers can crack and separate during shipment if overloaded with weight from product and refrigerants. This is a problem rarely encountered in molded PUR or Vacuum insulated boxes. For this reason, many avoid using EPS in larger and longer range shipments (Anon, 2011b)

Table 1 Properties of EPS.

Table 1. ***Typical Properties of EPS Molded Packaging (70F Test Temperature)***

Density (pcf)	Stress @ 10% Compression (psi)	Flexural Strength (psi)	Tensile Strength (psi)	Shear Strength (psi)
1.0	13	29	31	31
1.5	24	43	51	53
2.0	30	58	62	70
2.5	42	75	74	92
3.0	64	88	88	118
3.3	67	105	98	140
4.0	80	125	108	175

Note: Values based on ASTM short-term, laboratory-load conditions. Both temperature and time period of loading may affect end-point values.

1.2 **Polyurethane** -

PUR containers can withstand thousands of pounds of static pressure without any noticeable deflection. The strength of the containers allow them to be stacked high without worry about product damage and allows for heavier and larger containers to remain intact throughout the shipment. The R-value of PUR is greater than that of EPS and can be used to hold tighter temperature ranges for longer periods of time. This increase in insulation value can effectively reduce the amount of refrigerant weight required and/or allow for longer shipments under more rigorous temperatures. In many cases, the increased R-value allows for fewer refrigerants to be used to thermally protect the product, therefore potentially reducing the overall size of the insulated container needed.

The drawback of this material is that the manufacturing is a permanent chemical reaction and cannot be broken down for recycling like EPS. The cost of a PUR container is significantly higher than that of a comparable EPS container. This can make PUR containers cost prohibitive for many applications. Also unlike EPS containers, PUR containers are not mass-produced. Individual tools create one container at a time. For larger, thicker-walled PUR containers, a single container may “cure” in the mold for over 30 minutes. Obviously, multiple tools are utilized at once in order to produce in higher quantities. PUR as a material weighs more than EPS. Balancing the possible weight savings due to a reduction in refrigerant is key in comparing with EPS (Geoffrey, 2011) .

1.3 **Vacuum Insulated Panel -**

Vacuum Insulated Panel (VIP) containers have the highest insulation value of all containers available on the market for small shipments. This advantage comes at a price. VIP containers are generally the most expensive container when compared to EPS or PUR. A medium-sized VIP container could cost $60-$80, depending on the manufacturer.

They are constructed by assembling five vacuum insulated panels (VIPs) for the base and using the sixth panel for the lid. Commonly used core materials are precipitated silica and nanogel (Mukhopadhyaya, 2010)

Figure 2 VIP panels.

Vacuum insulated containers have the highest R-value of any containers, allowing them to resist extreme heat or extreme cold for long durations and therefore extend shipping times and allow for tighter product temperature control. Depending on the manufacturer the range is between 35 and 40 per inch. This advantage can come at a price; vacuum insulation is in nearly all cases the most expensive material when compared to EPS or PUR. It is important to point out that most vacuum insulated containers on the market are not molded. In most cases they are constructed by assembling five vacuum insulated panels (VIPs) for the base and using the sixth panel for the lid. The base panels are often taped together in an attempt to eliminate air gaps. Because of their increased insulation value, vacuum insulated containers require fewer refrigerants and in most cases weigh less than a comparably-designed PUR and EPS containers. Analysis of the total cost of ownership should be made to see if reduced shipping costs outweigh the material cost difference. As long as the vacuum insulated containers remain undamaged and the vacuum is not lost, the containers can be reused multiple times.

The shortcoming of this technology is that the cost of the vacuum insulated containers can make them a luxury of low-volume, high-value products or restrict them to being used in longer shipping durations and tighter temperature criteria situations.

The effectiveness of a vacuum insulated container is dramatically reduced once the vacuum is lost in any of the panels. Assuming that the value of the product is high, these containers can have a risk associated with them. Manufacturers of vacuum insulated containers often include extra materials to buffer the insulation from damage. Availability is another concern as fewer manufacturers offer vacuum insulated containers than EPS or PUR and production speed is generally slower.

Shown in (Fig-3) are the R values for different materials.

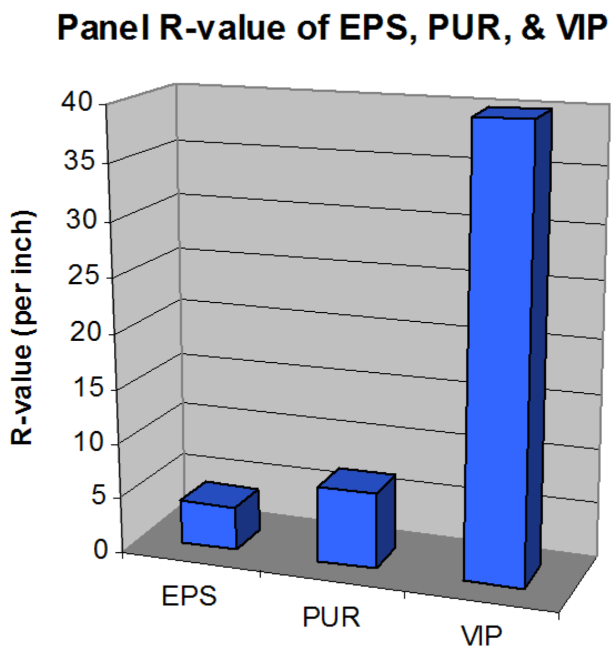


Figure 3 Panel R value graphs.

Given below in (Fig-4) is the comparison for the R values in the system.

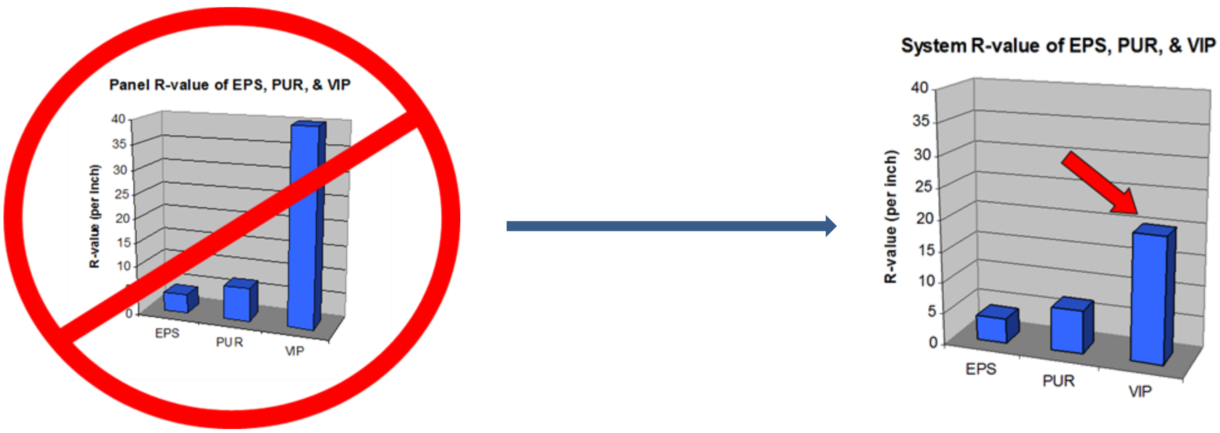


Figure 4 Comparing R value.

Greenbox packaging comprises a tinted-green, reusable, outer HDPE shipping container that resembles a corrugated shipping container. Resistant to moisture, crushing and scuffing, the outer plastic-corrugated container is practically impervious to repeated exposure to packing tape.

The above mentioned VIP panels go into the Greenbox, an emerging reusable and sustainable cold chain packaging system for temperature sensitive pharmaceutical products. It also comprises what it refers to as a vegetable oil-based phase-change material (PCM) that protects the medication from either heat or cold, regardless of the outside weather. Vegetable oil-based PCMs can achieve virtually any temperature range and maintain it for extended durations of time (currently available vegetable oil-based PCMs exceed 120 hours). They're also non-toxic, and experience no thermal degradation after 20,000 uses (Eric, 2009b). When these PCMs reach the temperature at which they change phase (either melting or solidifying temperature), they absorb/release large amounts of energy (hot or cold), at an almost constant temperature.

The PCMs will continue to absorb energy without a significant rise in temperature until all of the material is transformed to the liquid or solid phase, it depends if the PCM is protecting from heat or cold (Eric, 2009b). When the ambient temperature around a liquid material falls, the PCMs solidify, releasing their stored latent heat. If the temperature rises, they liquefy.

The proprietary materials are renewable, biodegradable, nontoxic and reusable. A single Greenbox can be used as many as 20 times through reclamation but, tracking reveals an average of 55 uses in a FedEx/UPS circulation. Also, a damaged Greenbox component can be is recycled into a new Greenbox component (Eric, 2009a)

Once a customer receives their medication, they can use an enclosed return-address label and ship the package to one of Entropy's reclamation centers where it's inspected and cleaned according to FDA standards.

2. PROBLEM DEFINITION

EPS's excellent isothermal properties help to boost its market shares in areas where logistics chain constraints make it a necessity: in 1999, 45% of EPS packaging used nationally was used to maintain packaged products at the right temperature. Presently throughout the world, EPS consumption continues to grow, especially in Asia, the world leader with a 38% market share. Western Europe follows with a 28% share, while the USA is in third place with 21% of the market (sources Chemical Market Associates (CMAI), Houston).

The building and packaging industries, represent the biggest shares of the EPS market, with relative world shares of 50% and 40% respectively. Out of 37,000 tones used in 1999, the use of EPS packaging alone for cold chain applications reached 16,000 tones, that is to say 45% of all EPS packaging (Serge, 2011).

As the cold chain industry grows it is becoming clearer that not only do all those involved have a responsibility to ensure price and payload protection factors of the products, but also to examine their impact on the environment. Now that temperature controlled packaging, methods of refrigeration and transport are more advanced, we are in a position to consider – are they green enough? Some components leave a minimal carbon footprint, while others may be around for generations to come.

Since EPS is an inexpensive, an efficient insulating material very commonly used in Cold Chain Industry it will not be surprising to know that today more than one-third of the nation's landfill is already full of EPS. Studies have shown that polystyrene makes up approximately 1% of the weight in landfills. EPS is composed almost entirely of air (98%). Due to the light weight of the material, it can be determined that the material makes up a large portion of landfill waste. With many of today's top brands implementing corporate social responsibility (CSR) initiatives, the reusability of our packaging solution or phase-change material may be required soon. Europe, China, and Japan all are implementing packaging waste laws around the use of reusable or recyclable packaging. It's time we all consider sustainability when thinking about temperature-controlled packaging solutions.(Eric, 2009b)

After an intense research on available Thermal packaging materials used for temperature sensitive products and new packaging materials now available in market to create a sustainable package, it was found that Greenbox system utilizes a durable, reusable, recyclable, high-density polyethylene outer container. This high-quality container is water-resistant, scuff-resistant, crush-resistant, and is impervious to repeated exposure to packing tape. Greenbox has positive impact on everything from simple logistics to the global environment. Not only can important medical supplies now be shipped via ground transport any day of the week, but it also allows companies to ship larger payloads and results in up to 65 percent reduction in distribution-related expenses.

3. HYPOTHESIS

Greenbox reduces a significant percentage of waste and performs as well as EPS system (current system) thermally and will withstand shocks and vibrations from the distribution environment.

4. LITERATURE REVIEW

EPS today is the most popular thermal packaging material as stated in (Temperature control packaging in transit) (Anon, 2007). EPS consists of 98% air, which makes it the lightest and lowest cost thermal insulator. Expanded polystyrene packaging offers outstanding performance in transporting items such as fresh and frozen foods, vaccines, body organs and pharmaceutical products that require both insulation and protection. The microscopically small air bubbles that make up the closed cell foam give an average thermal conductivity of 0.038W/mK at 15g/liter density. Increasing the density up to 28g/liter further enhances the insulating properties. The incorporation of ice or other coolant devices in the boxes can also extend the time period over which the low temperatures can be maintained. A pack for all seasons (Anon, 2003) mentions about a UK company Laminar Medica that specializes in the manufacture of expanded polystyrene components for use packaging for the pharmaceutical and biomedical industries where the strict control of the core temperature and protection against extremes of ambient temperature are required. It is now the largest manufacturer of this type of packaging in the UK and Europe, manufacturing all its products on site, enabling it to control the quality of the components. The company molds about 15-20 different EPS components. Since the major part of the landfill consists of EPS it is time that alternatives be considered.

In the 3rd Annual Cold Chain Distribution for Pharmaceuticals conference (J, 2005) discussions were held concerning cold chain distribution challenges. Several attendees and speakers highlighted that maintaining the 2°C to 8°C temperature range, the temperatures in refrigerators, was particularly challenging and several suppliers offered containers designed specifically for transporting products in this common temperature range. NanoCool system has been developed as an alternative to traditional ice packs. Heat is transferred, at the touch of a button, by evaporating small quantities of water at low pressure. Aspen Aerogels' technology incorporates thin, flexible nonporous aerogel insulation blankets to meet extreme thermal requisites.

Although some carriers state they have qualified or validated their vehicles to monitor and track temperature fluctuations, this was questioned by several members of the audience. Several speakers encouraged manufacturers to test day, night, seasonal temperature and humidity levels throughout the distribution chain and also spoke of the requirement for packaging materials to be able to keep temperatures as consistent as possible. Temperature Controlled Packaging Reliable Inc, Edison, NJ, USA, has introduced thermal control panels that interlock to form a continuous cube around the payload, with each panel containing a phase change material revealed in (Scaling up controlled temperature shippers) (Blair, 2004). The KoolGuard insulated pallet shippers from Cold Chain Technologies Inc, Holliston, MA, USA, use corrugated sleeves, which hold Koolit refrigerant bricks in place and line the inside of the shipper. The company also plans to introduce a rigid, molded vacuum insulated panel pallet shipper, the Vac-Q-Tainer. ThermoSafe Brands, IL, USA, offers rotationally molded insulated shippers with capacities of up to 69cu ft or more, some of which are built specifically for daily deliveries, while others can hold frozen and refrigerated temperatures for 3-5days. The active thermostat controlled bulk shippers from Envirotainer, Sweden, are cooled by a bunker of dry ice and a battery operated fan for air exchange and active temperature control. The company is also developing a tracking and tracing service for containers. The AcuTemp thermal pallet shipping container from Energy Storage Technologies, Dayton, OH, USA, is constructed of VacuPanel vacuum insulated panels and can both cool and heat.

Public health programs in the US validated various methods for packing vaccines to enhance the quality assurance of vaccine distribution in were validated. Validation involved both tests in an environmental chamber and actual shipping of packages by commercial overnight delivery service and the insulation material used were polystyrene and polyurethane. This study only intended to assist those concerned with the vaccine cold chain in two ways. First, ways assortments of vaccines may be packed that enable them to arrive without exposure to potentially damaging temperatures under a full range of climatic conditions (ranging from summer heat to winter cold). Materials used for packing are affordable and readily available within the US. Next is the procedures and equipment required for validating vaccine packaging and distribution. The equipment and facilities needed should be readily available in many locations in the US, and the validation procedures should therefore he reproducible by others who desire to undertake similar tests tailored to their own circumstances (P., 2011).

Every company today is looking for new technologies and to improve the existing system (David, 2005), Cold Chain Technologies Inc, Holliston, MA, USA stated uses 0 deg Koolit foam bricks and polyurethane (PU) for its latest range of KoolTemp PUR containers, where frozen and refrigerated bricks are used in the KoolTemp Global Transportation Solution (GTS) prequalified shipper to maintain 20°C-80°C temperatures for 48hr under year round conditions.

The company is currently testing its va-Q-Tainer, a transport container for pallets that is constructed of vacuum insulated panels (VIPs) protected by layers of PU, birch wood, and metal and fibreglass sheathing. Envirocooler, Huntington Beach, CA, USA, uses pre-molded PU designs, such as its Ice Locker and Convection Engine, in solutions such as its BioSphere and Cryosphere pallet shipper solutions. Kodiak Thermal Technologies Inc, Houston, TX, USA, has developed its premoulded, reusable Cold Chain shipping system where the phase change refrigerant is contained in a lid, encased in VIPs. NanoCool, a joint venture between NanoPore Inc. and MeadWestvaco Corporation, has launched a shipper featuring a lid mounted cooling unit in which water evaporates at low pressure. ThermoCor, the solution developed by AcuTemp, achieves an insulation R factor value of 40-50 in thickness and comprises ThermoGor, an open celled polymer fiber material.

Details provided by (R., 2008) and (Eric, 2009b) about companies switching from traditional cardboard boxes to reusable shipping containers to ship their temperature sensitive products Wal-Mart Specialty Pharmacy, Lake Mary, FL, USA, provides prescription services and follow-up care directly to individuals throughout the country. Transporting more than 110,000 temperature sensitive packages annually via common carrier was posing some challenges. They used Greenbox packaging that maintains the required temperature for the medicines for the required amount of time. Since the panels reportedly have a thermodynamic insulating capacity that is 10 times greater than expanded polystyrene (EPS) or polyurethane (PU) foam. A specially designed vegetable oil based phase change material (PCM), moderates temperatures by either absorbing or releasing energy. The PCM is contained in a flat rigid E-Pack, or in the case of the new Inflater Pack, clear pillow pouches made of a proprietary film. Cold-chain logistics provider Warehouse Asset Management (WAM), partnered with Entropy Solutions, implemented an innovative reverse logistics model and established its first reclamation center. Using Entropy Solutions' reverse logistics model it ensures that a company's purchased or leased Greenboxes are used over and over again. A single box can be used 50 or more times, significantly minimizing packaging waste and reducing shipping and logistics costs.

At a reclamation center, the Greenbox is scanned and undergoes a rigorous inspection and cleaning process. An operative carefully inspects each component of the Greenbox and if any component requires replacement, it is removed and replaced, prior to being put back into circulation. The box is then thoroughly cleaned, first removing all labels and mailing tape. Then an environmentally friendly cleaning solution is applied to ensure the removal of all residues. The box then goes through an UV tunnel where sanitation takes place, before it is finally shipped back to its original owner in palletized unit loads. Each box has a barcode and serial number unique to that box and customer and together with Entropy's proprietary tracking software, this information enables customers to track various pieces of data. Not only does a Greenbox provide better temperature protection in a more cost effective way, but it also has less impact on the environment.

Currently, (Eric, 2009a) says Entropy is working on introducing more of the technology. One version aims to maintain thermal insulation for as many as 30 days. “We have technology that has gone 30 days in a controlled environment, but haven't released it to the market yet,” he says.

5. METHODOLOGY

The present package used for one of the temperature sensitive pharmaceutical product was chosen to be replaced with a Greenbox.

Based on the organization standards where the study was performed, the length of time for Thermal testing is 33 hours as this is the maximum length of transit the organization uses for its Cold Chain products for US shipments in both winter and summer.

5.1 **Packaging materials**

Present pack out:

1. Pay load box
2. Outer corrugated box
3. Molded EPS shipper base & lid
4. Koolit refrigerant bricks

Greenbox pack out:

1. Payload box
2. HDPE shipper
3. PCMs
4. Vacuum Insulated panels

Diagram of present pack out shown in (Fig-5).

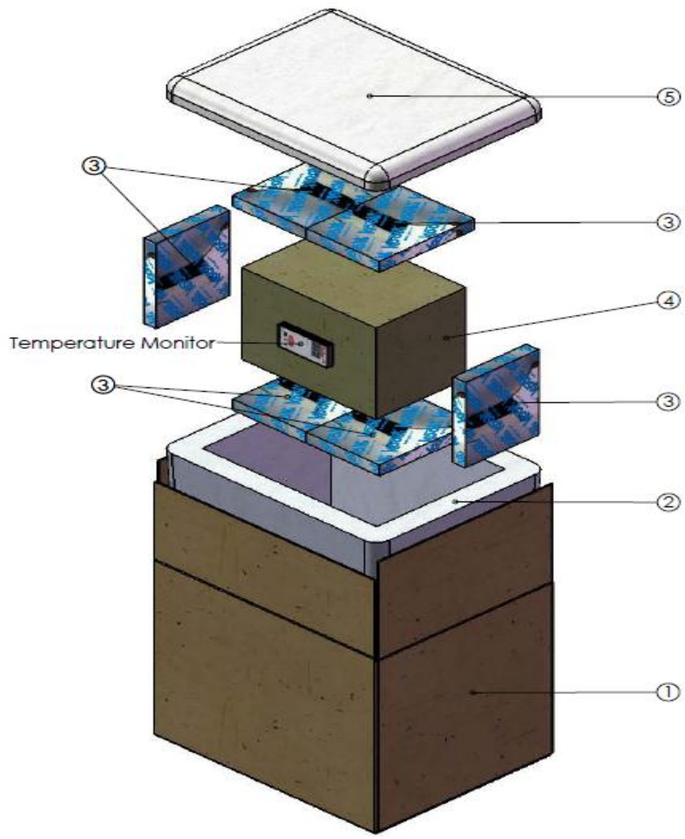


Figure 5 Present packout.

Table 2 Present packout parts and dimension.

ITEM NO.	PART NAME	PART INFORMATION	WEIGHT (lbs.)	QTY	TOTAL WEIGHT (lbs.)	PRE-CONDITION (24 Hrs.)
1	FF-20-C	Outer Corrugated Box, ID 18.125 x 14.375 x 15.5	2.00	1	2.00	22°C ± 3°C
2	FF-20-B	1.75" Molded EPS Shipper Base - ID: 14.25 x 10.5 x 12 & OD: 17.75 x 14 x 15.5	1.14	1		22°C ± 3°C
3	317F	Koolit Refrigerant Brick: 7.75 x 6 x 1	1.60	6	9.60	-5°C ±3°C
4	PRODUCT BOX	Product Box (Tertiary Container)	0.65	1	0.65	5°C ± 3°C
5	FF-20-L	1.75" Molded EPS Shipper Lid - OD: 17.75 x14 x 15.5	0.37	1	0.37	22°C ± 3°C

2°C to 8°C summer / winter profile.

Table 3 Dimension of HDPE shipper.

HDPE	LENGTH OD(in.)	WIDTH OD (in.)	HEIGHT OD(in.)
Shipper	12.25	12.25	12.75

Diagram of Greenbox 12 packout shown in (Fig-6).

Step	Action	Picture	Materials
1	Open pre-assembled reusable GREENBOX™ thermal shipping container, and remove top THERMAL-LOK™ insulation panel.		Pre-Assembled Reusable GREENBOX™ Shipping Container
2	Place **one** frozen (solid) 0.8 kg E1™ (green) PCM panel in bottom of GREENBOX™ shipping container.		One **Frozen** (solid) 0.8 kg E1™ PCM Panel
3	Place **one** refrigerated (liquid) 0.75 kg E4™ (orange) PCM panel in GREENBOX™ shipping container **directly on top** of frozen (solid) 0.8 kg E1™ PCM (green) panel.		One **Refrigerated** (liquid) 0.75 kg E4™ PCM Panel
4	Position temperature-sensitive payload in payload box, add environmentally-friendly void-fill **around** payload in payload box to provide physical damage protection. Place closed payload box directly on orange PCM panel.		Payload Box with Void-Fill Material for 2°C to 8°C Temperature Sensitive Payload
5	Place **one** refrigerated (liquid) 0.75 kg E4™ (orange) PCM panel in GREENBOX™ shipping container directly on top of payload box.		One **Refrigerated** (liquid) 0.75 kg E4™ PCM Panel
6	Place **one** frozen (solid) 0.8 kg E1™ (green) PCM panel in GREENBOX™ shipping container **directly on top** of 0.75 kg E4™ liquid (orange) PCM panel.		One **Frozen** (solid) 0.8 kg E1™ PCM Panel
7	Replace top horizontal THERMAL-LOK™ insulation panel with seam facing up.		Previously-Removed THERMAL-LOK™ Insulation Panel
8	Close and tape top of GREENBOX™ shipping container appropriately.		Closed GREENBOX™ shipping container, tape appropriately.

Figure 6 Diagram of Greenbox packout procedure.

5.2 **Instruments used for testing -**

1. Vibration table

   Manufacturer: L.A.B Equipment Inc., Model 400V

2. Drop tester

   Manufacturer: Gaynes Engineering Inc., Model AD 125

3. Environmental chamber

   Manufacturer: Thermotron, Model WP- 867-THCM3-15-15

4. Freezer

   Manufacturer: So-low, Model: A18-120

5. Refrigerator

   Manufacturer: Harris Mfg., Model: LR4500ABA

6. IRTD probe

   Manufacturer: Kaye, Model: M2801-IRTD 400

7. Temperature loggers and Thermocouples

   Manufacturer: Techmatron, Model: U10-001

Lab testing conducted to test Distribution and Thermal integrity of the Greenbox.

5.3 **Distribution test** -

Distribution test should be followed as defined by ISTA 1A procedure on both the present and proposed packages to challenge the capability of the package to withstand transport hazards.

Drop test -

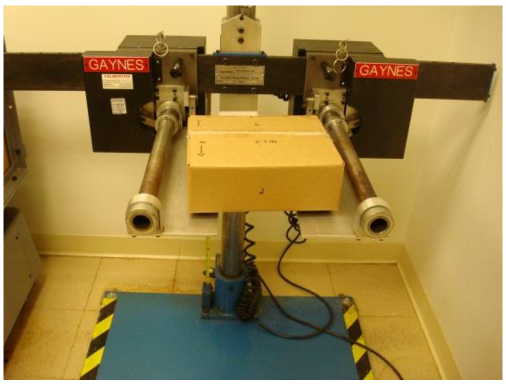


Figure 7 Drop tester

The package is dropped from 30 inch height. The box is dropped 10 times on all 6 sides, 3 edges and 1 corner.

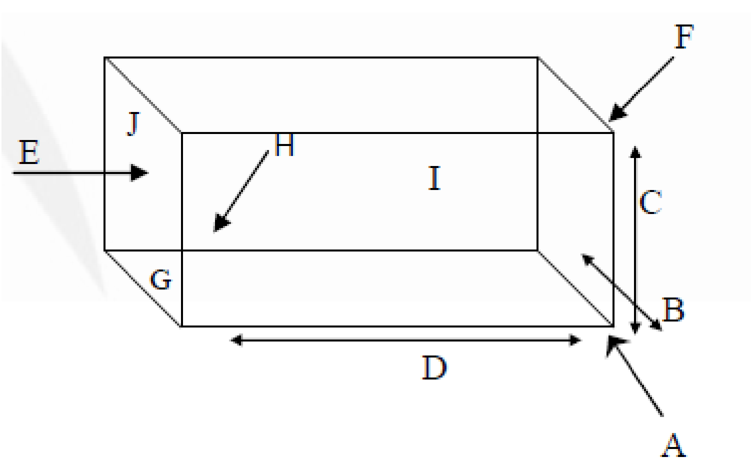


Figure 8 Indicating 10 points of drop

A. Corner

B. Shortest edge radiating horizontally from corner A

C. Next shortest edge radiating from same corner

D. Longest edge radiating vertically from corner A

E. Flat on one of smallest sides

F. Flat on opposite smallest side

G. Flat on one base

H. Flat on top

I. Flat on one largest side

J. Flat on opposite largest side

Vibration Test -

Figure 9 Vibration tester.

The package is placed on the vibration table and run 240 Cycles per minute for 60 minutes.

The package was inspected visually after Vibration and Drop test to assure there is no damage which could impede proper functioning of the package, such as cracks, holes and any other such damages to the outside or inside of the unit.

5.4 **Thermal Testing -**

Thermal testing is a process of determining if a packing configuration will be successful in holding the temperature of a temperature-sensitive product within its acceptable temperature criteria when it is exposed to ambient conditions. First, a packaging configuration generally refers to a combination of insulated containers and refrigerants that are put together in a unique way. Developing this custom configuration can be a difficult process depending on other project factors. Second, this type of testing is used for temperature-sensitive products, which is essentially any material that, for any reason, must be kept from getting too warm or too cold. Third, the goal of the configuration is to keep a temperature-sensitive product within its acceptable temperature range. This may mean “refrigerated”, such as 2°C-8°C or “frozen” below -20°C. Finally, the custom packaging configuration is tested against pre-specified ambient profiles, which are the temperature profiles programmed into the larger environmental chambers that will simulate the temperature conditions a package may be exposed to during transport.

Performing thermal testing -

Although there are many reasons not to perform testing, such as the cost, the time to test, and the time required to work on the project, there are many stronger reasons in favor of testing. First and foremost is the safety of the consumer. This is especially true for pharmaceuticals and other industries where temperature can create conditions that effect the safety and efficacy of the product. For example, insulin shots that arrive frozen will not be as effective and may cause harm to the end-user. Many companies lose sight of this as the ultimate reason for performing testing. Another primary reason to perform testing is requirement by the Food and drug administration (FDA) that thermal packaging is qualified under realistic conditions to prove that products arrive unadulterated to the patients. FDA audits are often dreaded events by regulated companies, especially if they result on a 483 warning letter detailing the processes within the company which are not done correctly.

Finally product quality and the cost of poor quality must be considered. If summertime chocolate shipments reach the consumer melted, the cost of processing complaints, of re-sent shipments, and of falling consumer confident will pale in comparison to the cost of a validated summer packaging configuration.

Worst-Case Bracketing -

The process of thermal testing for temperature-sensitive is designed to challenge the container under worst-case conditions. There are many factors in a testing project where worst-case bracketing is used to ensure the final configuration will be successful in the real world of shipping. The ambient profile chosen are designed to bracket the coldest and warmest temperatures that a shipping container would be reasonably exposed to. See discussion about ambient profiles for more information. The locations within the product loads where temperatures are recorded are also chosen to be the worst-case location. This is done to ensure the entire product within the shipping container remains with the required temperature range, not just some of it. For example, a biotech company shipping 200 vial is remaining within their required 2°C-8°C range. They do this by showing the thermocouple probe locations used by thermal lab, which include top and bottom corners of the product load, the most extreme locations.

The process of thermal testing -

Although many of the labs in the cold chain industry have different methods and equipment to perform thermal testing, the general process is similar. First the packaging engineer reviews the basic parameters of the customer's project, temperature criteria, ambient profiles, performance duration and other customer requirements. Based on this information, the packaging engineer will design a custom packaging configuration using an insulated shipping container and refrigerants. The refrigerants may be frozen, refrigerated, ambient or a combination of the three, depending on the temperature criteria. In order to collect real time data during the test, the packaging engineer will precondition the product loads and the refrigerant at the appropriate temperatures well in advance of the beginning of the test.

This will ensure all materials are at the correct temperature when the container is packaged. When the materials are ready, the packaging engineer will assemble the configuration using the preconditioned container, product and refrigerants before placing the packed container into the test chamber. The ambient profile will be programmed into the test chamber and data logger will be started. The test chamber simulates the temperature conditions the package will experience for the times and temperatures specified in the ambient profile. Later, when the test is complete, the packaging engineer can review the temperature data and redesign the packaging configuration if needed.

Ambient Profiles -

Developing an ambient profile for validation testing can be a difficult task. An ambient profile is a combination of reasonable worst-case temperatures and reasonable worst-case time durations. It is best to have an intimate knowledge of the distribution path for the majority of the shipments in order to develop an accurate temperature profile. An excellent resource for the creation of an ambient temperature profile can be found in the 2002 ISTA 5B standard. This standard discusses the accepted methods for validating shipping configurations and is a valuable source of information. It is important to note that developing an ambient profile by theoretically determining the worst case time and temperatures for each step along the package's journey is not a better way to develop an ambient profile than collecting actual temperature data from shipments. However, collecting ambient data is a time-consuming and expensive project. These steps can help determine a theoretical ambient profile before data has been collected.

Duration -

Duration refers to the amount of time the ambient profiles is run. The duration of performance for the ambient profile depends heavily on the shipping method used. In most cases, the duration is longer than you might expect when you consider time to reach the recipient. For example, the duration for overnight shipments is generally much longer than 18 hours.

From the time the package is assembled to the time it is received (and unloaded), the package may experience up to thirty hours in transit. In fact FedEx recommends using 30 hours as an estimate for shipping temperature-sensitive products using FedEx standard overnight service. For example, a package may be assembled at 9am in anticipation of the day's orders, picked up by the carrier at 3pm, and received by 3pm the next day. It may be delivered before this, but not unpacked and stored at the proper temperature until this time. This is thirty hours and often used by pharmaceutical companies as the standard for overnight shipments. Similar estimations are used for two-day shipments where it is common to see sixty hours as the required duration. The best way to estimate shipment duration is to theoretically walk through the distribution line and determine reasonable worst-case times for each step. Knowledge of the distribution center, as well as the modes of transportations used, will be key in developing this information. When shipping internationally, it is important to leave adequate time for delays from customs, perhaps up to an extra 48 hours.

It is extremely important to understand the difference performance duration and test duration. For qualification studies, assigning the performance duration at thirty hours for an overnight shipment will assure that the product remains with its temperature requirements for this amount of time. However, it is generally a good practice to test for a longer period of time in order to gain additional information about the temperature stability of the package.

Temperature -

Once the distribution path for the package is determined and each segment defined, the next step is to assign temperatures. Determining reasonable extreme temperature is often a difficult step in developing the ambient profile. For each segment of the trip, determine the trip, determine the reasonable worst-case low (winter) and high (summer) temperature. With these temperatures in place, the ambient profile is justifiable and defendable for internal and external quality audits.

5.5 **Testing -**

The package design (Greenbox) is also desired to provide thermal insulation to maintain product temperature between 2°C and 8°C for entire 33 hours when tested against the simulated summer and winter temperature cycle. Only one sample from both the packouts for each profile was tested to set up an initial methodology.

Conditioning -

The temperature of the testing materials should be monitored prior to testing to assure proper conditioning. The minimum length of conditioning time for outer box and VIPs are 24 hours and PCMs are conditioned for a minimum of 48 hours.

Pre-test stabilization temperature

Product Load: 5°C ± 3°C (2°C to 8°C)

Refrigerants: - 5°C ± 3°C (-8°C to -2°C)

Shipper: 22°C ± 3°C (19°C to 25°C)

Table 4 Temperature profile.

Test no.	Test discription	Test days (excluding conditioning)
1	33 hour Summer profile. (requires programmable chamber)	2
	MAX PROFILE TEMP: 30ºC **MIN PROFILE TEMP:** 15ºC	
2	33 hour Winter profile. (requires programmable chamber)	2
	MAX PROFILE TEMP: 20ºC **MIN PROFILE TEMP:** -10ºC	

Conditioning of the Vegetable Oil based PCM -

The phase change material (PCM) in these panels begins changing phase, from solid to liquid or liquid to solid, at very close to 4°C. During change of phase, energy (heat) is either absorbed or released. The solid (orange) panels protect against heat and the liquid (orange) panels against cold. Simply stated, as the temperature rises the solid panels absorb heat and begin to slowly melt. Conversely, as temperature drops the liquid panels release heat as they solidify.

During the lengthy time that the panels are “changing phase” (days or even weeks depending on the outside ambient temperature), the temperature of the payload stays at a constant 2°C – 8°C.

Conditioning Process -

Liquid Panel - To properly condition liquid (orange) panels, place them in a refrigerated environment until the temperature of the panels is below 8°C and the panel is still completely liquid. If placed in an adequate refrigerated environment between 2°C – 8°C (~35°F – ~46°F) the panels should condition to the proper conditioning temperature within 24 hours. If the conditioned liquid panels are stored in an environment cooler than 8°C (~46°F) and they are completely liquid, the panels are ready for packing.

Solid Panel - To solidify panels, place them in a freezer environment that is preferable at or below -20°C (-4°F) until solid. If the panels are placed in a proper freezer environment this should take 24 hours depending on the capabilities of the freezer and the number of panels being conditioned. The solidification process will take less time as the freezer temperature is lowered from -20°C.

Conditioned panels should be stored in an environment at or below -20°C (-4°F). The panels must be completely solid at the time they are packed.

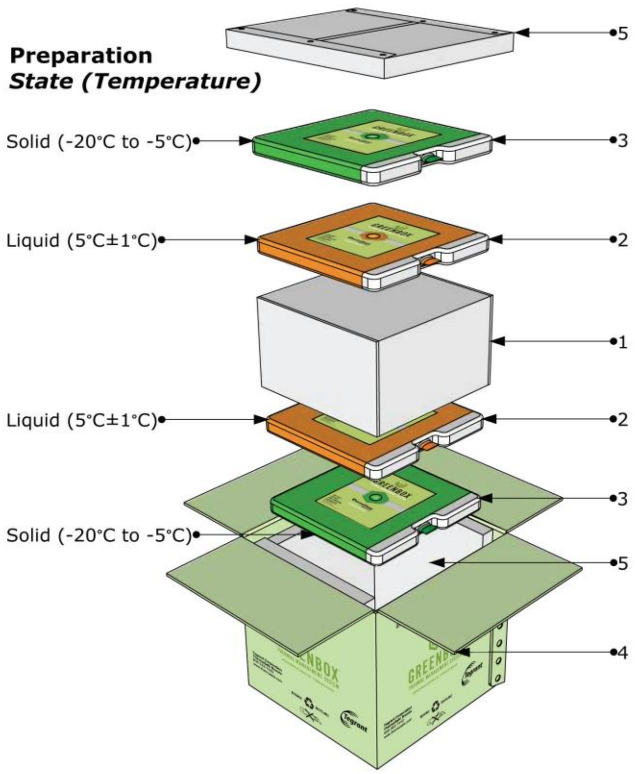


Figure 10 Geenbox preparation state of conditioned panels.

Load chamber after closing and securing containers, load the shipping containers into the environmental chamber and start the temperature profile. Observe and record the time on the data acquisition unit at the beginning of the test. A minimum of one thermocouple probe should be placed within the thermal chamber to verify the correct programming and operation of the thermal chamber. Thermocouples used during testing should have insulated, welded tips. Each corner of the proposed shipper should be monitored. Where symmetry exists with respect to the product payload shape and its relative position to thermal packaging components (i.e. insulation, gel pack components), only opposing corners need to be monitored (two corners, opposed in three dimensional terms).

Position of thermocouples for summer profile.

Table 5 Position for thermocouples summer profile.

Box #	TC #	POSITION
1	1	Center
	2	Center
	3	Bottom corner
	4	Top corner
	5	

63	Ambient
64	

Position of the thermocouples for winter profile

Table 6 Position for thermocouples winter profile.

BOX #	TC #	POSITION
2	1	Center
	2	Center
	3	Bottom corner
	4	Top corner
	5	

63	Ambient
64	

The data recording interval should be every 15 minutes.

End of test – At the end of the test cycle, stop the data acquisition unit. Download the data files.

6. DATA ANALYSIS

Data is collected from -

1. Distribution test and thermal test.

2. Table showing the amount of waste produced by the present pack out per year.

3. Cost analysis.

6.1 **Drop and vibration test observations** -

Table 7 Observation for distribution tests.

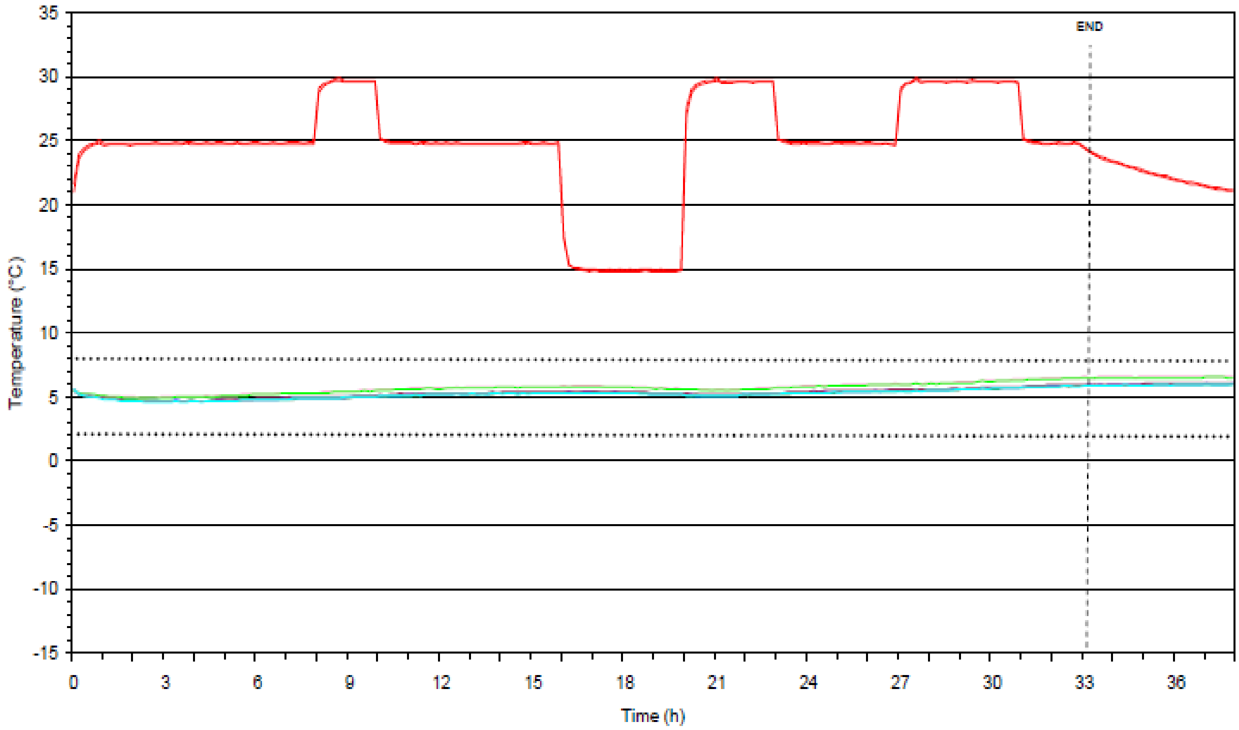
Distribution Test Observations				
	Drop Test		Vibration Test	
	Damage	No Damage	Damage	No Damage
PRESENT PACK OUT				
EPS (lid + base)	√ (lid)	√ (base)		√
Product Box		√		√
Gel packs		√		√
Corrugated shipper		√		√
GREENBOX				
Product box		√		√
PCMs		√		√
VIPs		√		√
HDPE Shipper		√		√

6.2 **Thermal test observation -**

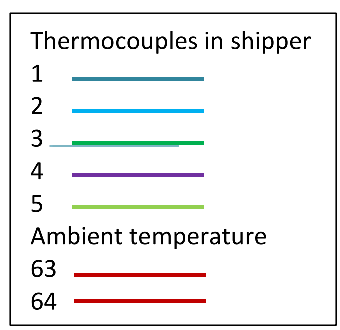
GRAPHS

Present shipper summer profile.

Box 1a Test # 1

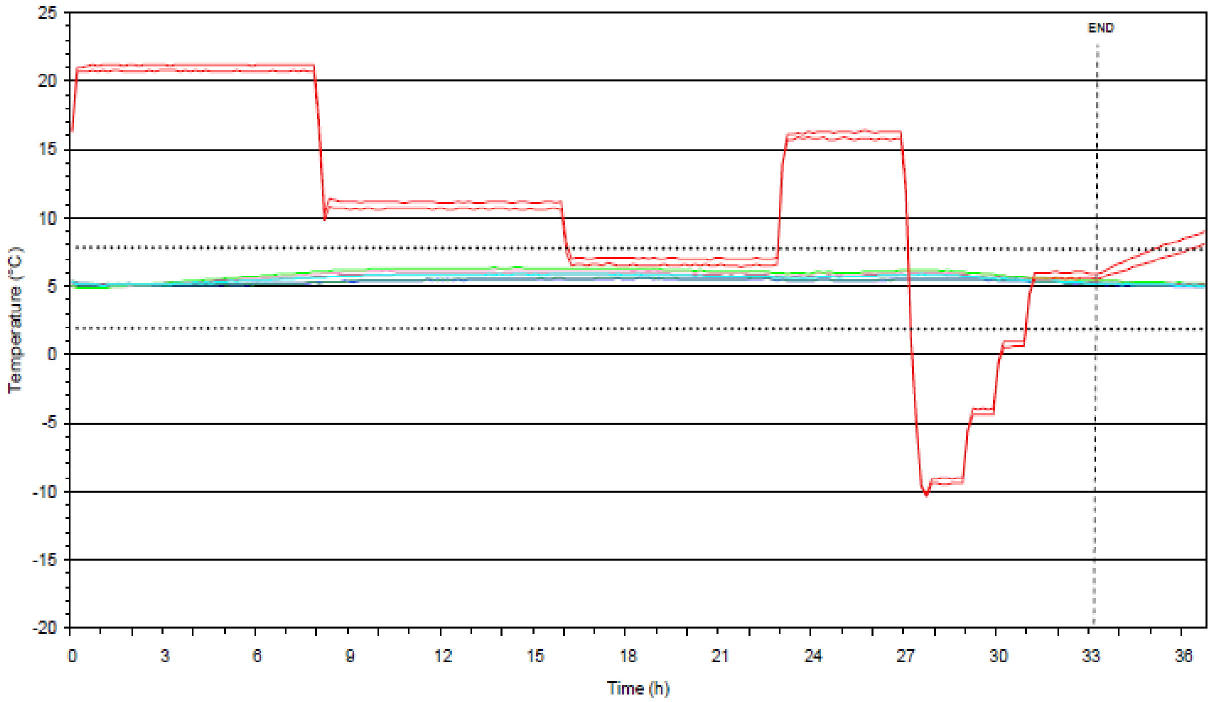


Graph 1 33 hour summer profile.

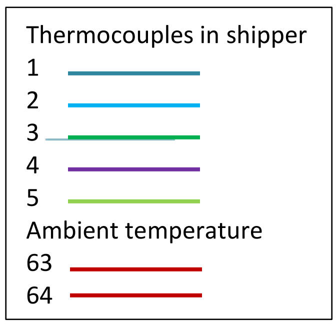


Present shipper winter profile

Box 1b Test # 2

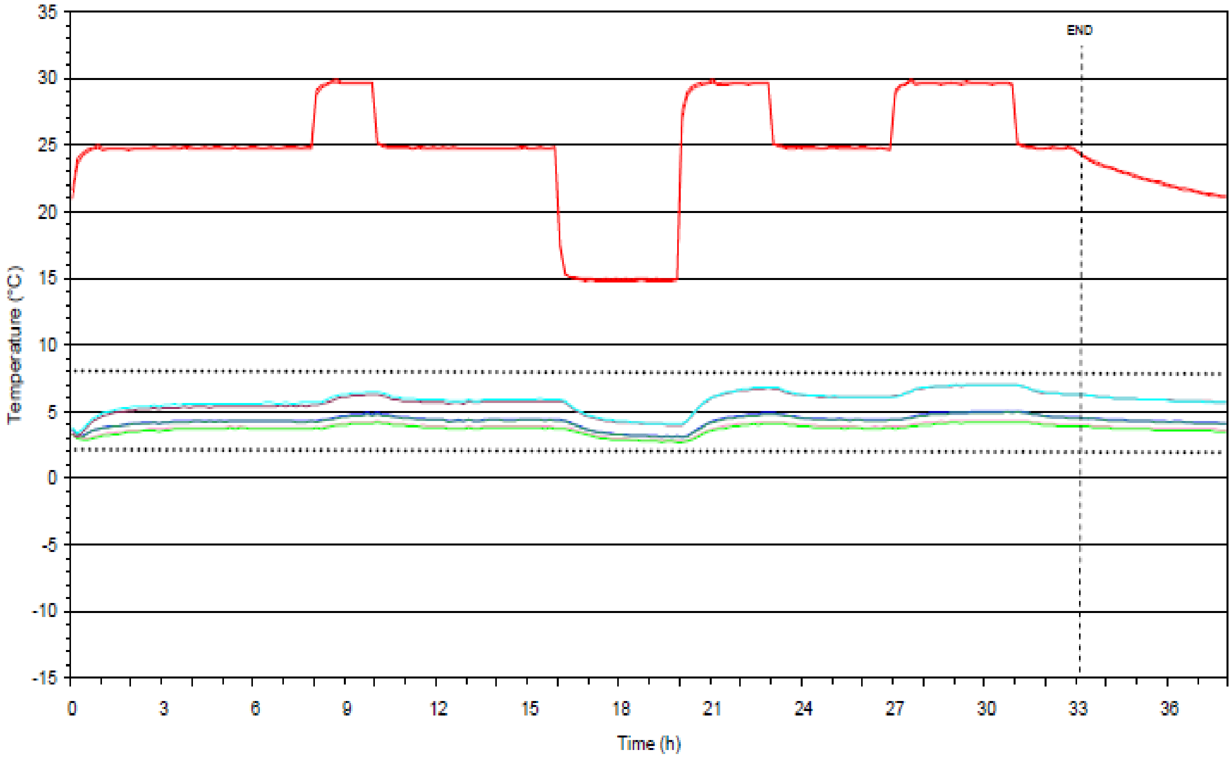


Graph 2 33 hours winter profile.

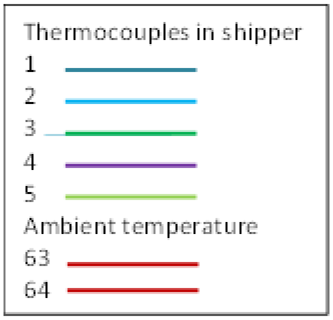


Greenbox summer profile

Box 2a Test # 3

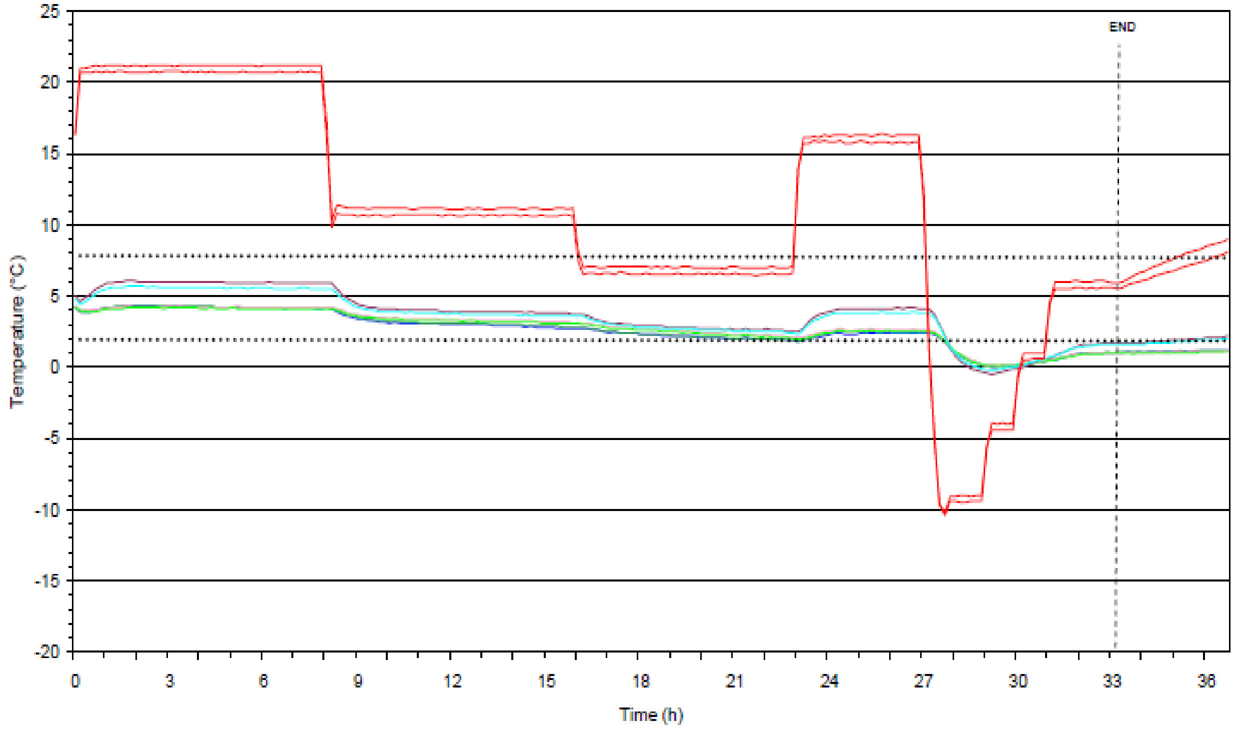


Graph 3 33 hours summer profile.

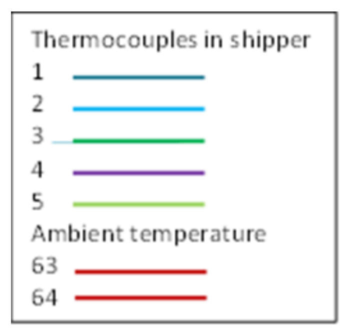


Greenbox 33 Hour Winter Profile

Box 2b Test #4



Graph 4 33 hours winter profile.



Thermal Test Summary Result-

Table 8 Thermal test summary results.

Summer standard 33 hour profile	Winter standard 33 hour profile
Test #1	Test #2
Present Shipper Passed thermal test	Present Shipper Passed thermal test
maintained temperature 2°C ~ 8°C for 33 hrs.	maintained temperature 2°C ~ 8°C for 33 hrs.
Test #3	Test #4
The thermocouples show that Greenbox	Unfortunately the Greenbox could hold
Maintained temperature 2°C ~ 8°C for 33 hrs.	Temperatures 2°C ~ 8°C for only 27 hrs.

Size Comparison of Greenbox vs. Existing Shipper shows the amount of material that can be reduced when switch to Greenbox system.

Figure 11 Size comparison between Greenbox and present container.

Table showing waste generated by the present cold chain pack out per year -

Table 9 Waste generated.

Cold chain container	Weight of the Container Com-ponents(lbs)	Total Weight of Container (lbs)	Shipments/ Year	Waste year 1(lbs)		Waste year 2(lbs)	Volume per unit (ft2)	Waste per year (ft3)	Year 2 impact (ft3)
Present shipper									
Corrugated	2	13	15660	203580		407160	2.37	37114.2	74228.4
EPS	1.51								
PCMs	9.6								
Greenbox 12					Box Damage				
VIP	4.2	16.1	15660	0	2042	32876	1.06	2164.52	4329.04
PCMs	10.8								
HDPE container	1.1								

There are chances of some damages and not gaining 100% recovery of the Greenboxes from year two. But a Greenbox has a life span of more than 20 cycles which will immensely reduce the wastes going to landfill.

6.3 **Product loading comparison -**

EPS system **-**

```
Product Name   Pallet Group
Product Code   Cases/Trays/Ovals
Datafile Name  present (5/18/2011)
Load Ref.        1 I
Cube Used       91.5 %                              161          Case / Layer
Area Used       99.7 %                                6         Layer / Load
Pallet type    40HICUBE                             966          Case / Load

              Length    Width    Height         Net     Gross       Volume
Case     (ID)  18.125   14.375   15.500 in     2.000     2.000 lb     2.34 cuft
Case     (OD)  18.445   14.695   16.140 in     2.000     2.000 lb     2.53 cuft
Product       473.990   92.225   96.840 in 1932.000 1932.000 lb  2449.79 cuft
Load          474.500   92.250  105.500 in 1932.000 8325.000 lb  2672.46 cuft
```

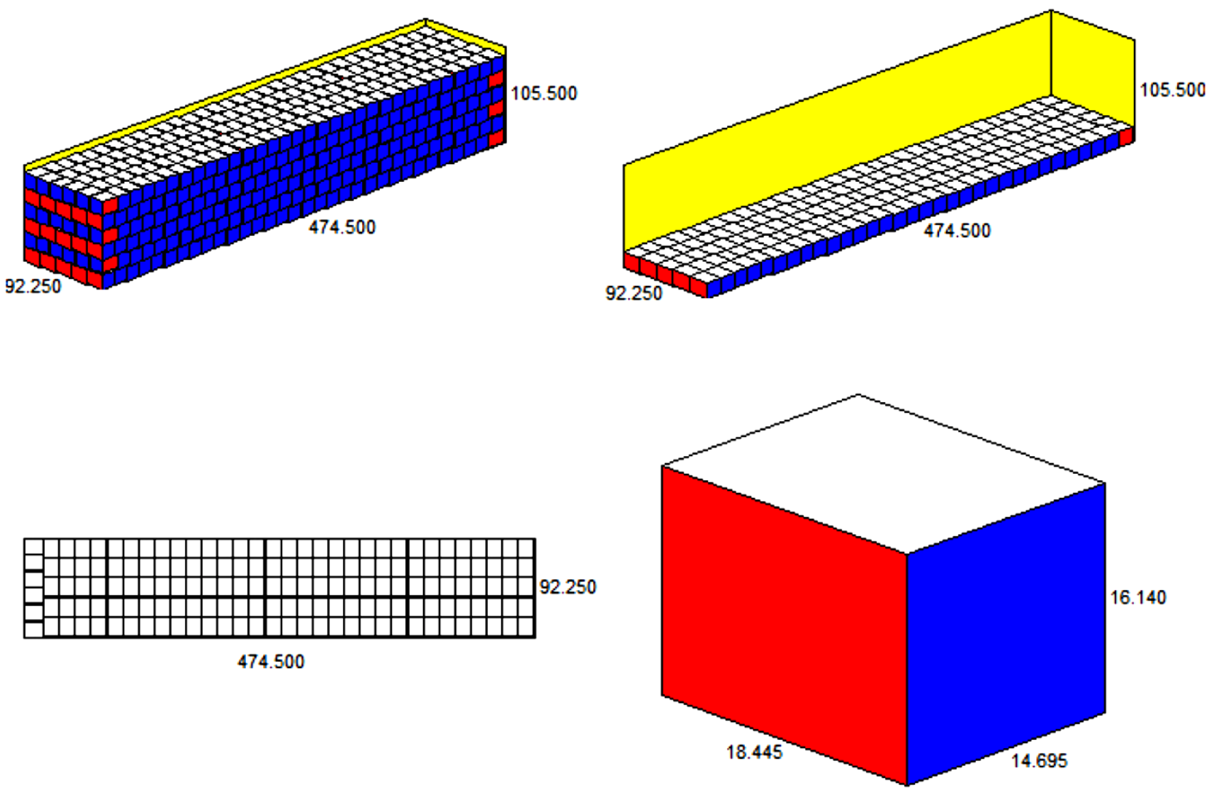


Figure 12 EPS system product load.

Greenbox -

Product Name	Pallet Group		
Product Code	Cases/Trays/Ovals		
Datafile Name	greenbox (5/18/2011)		
Load Ref.	1 C		
Cube Used	88.2 %	266	Case / Layer
Area Used	91.2 %	8	Layer / Load
Pallet type	40HICUBE	2128	Case / Load

		Length	Width	Height	Net	Gross	Volume
Case	(ID)	12.250	12.250	12.750 in	1.100	1.100 lb	1.11 cuft
Case	(OD)	12.250	12.250	12.750 in	1.100	1.100 lb	1.11 cuft
Product		465.500	85.750	102.000 in	2340.800	2340.800 lb	2356.19 cuft
Load		474.500	92.250	105.500 in	2340.800	8733.800 lb	2672.46 cuft

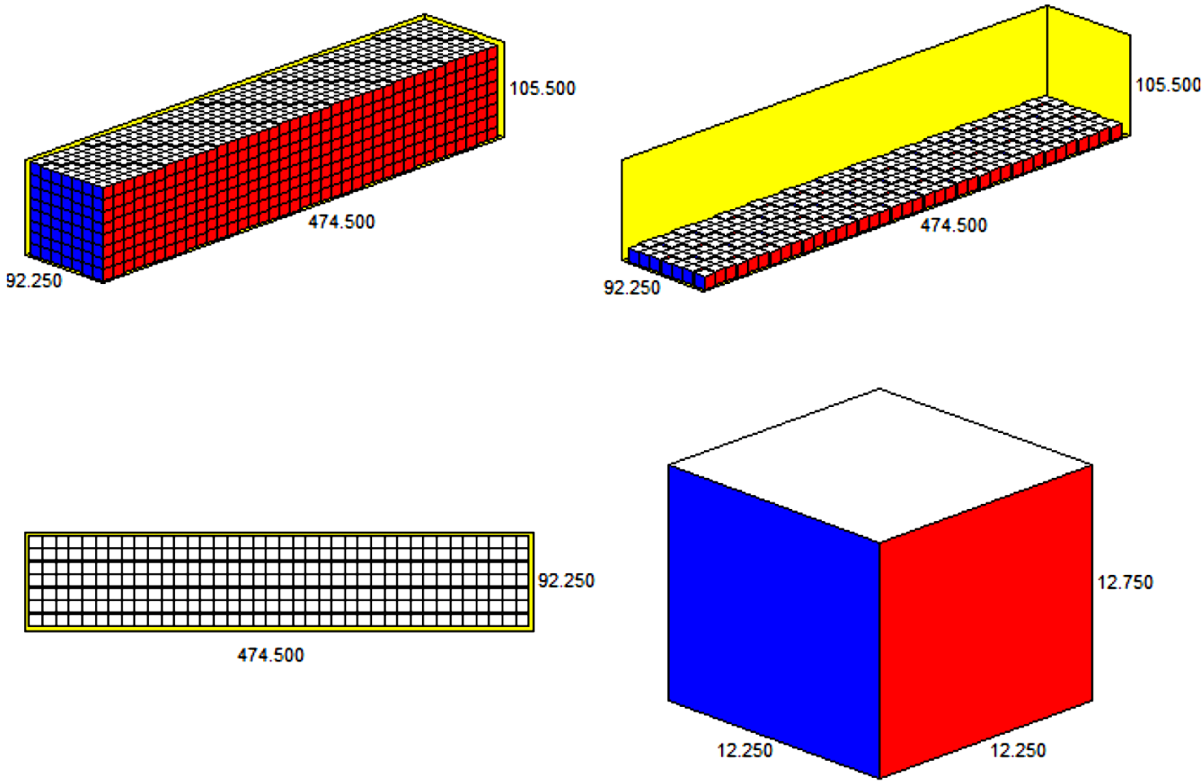


Figure 13 Greenbox system product load.

6.4 **Cost -**

Distribution of Parcel Shipments - There can be savings form the Greenbox distribution pattern.

Conventional EPS shipper Distribution Greenbox Distribution

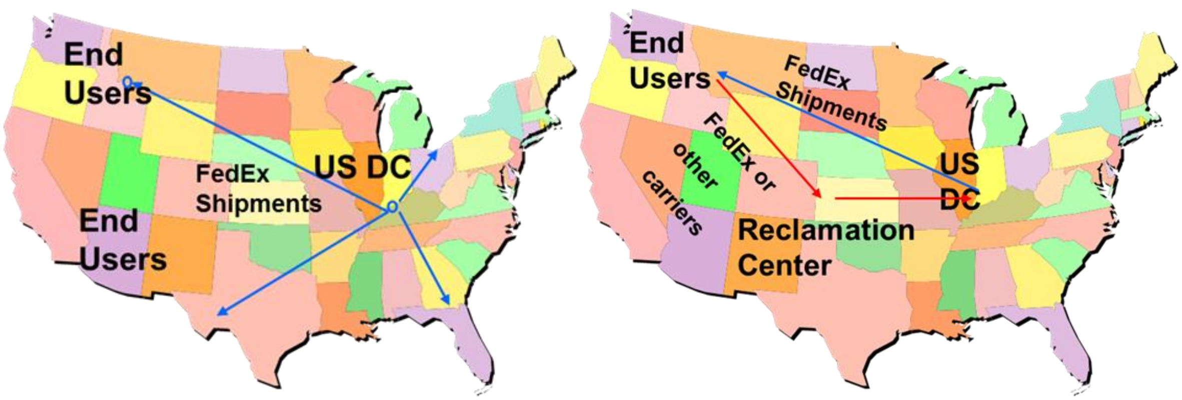


Figure 14 Distribution of parcel shipment.

Table 10 Basic cost data.

Basic Data	Greenbox	Current System
Annual Shipments/Year	50,000	50,000
Days/Year	240	240
# Days in Loop Transit	10	0
Annual Number Turns/System	24	
Recovery Percentage	90%	0%

Table 11 Inventory comparison.

Inventory Requirements	Greenbox	Current System
Monthly Shipments	4,167	4,167
Daily Shipments	208	208
Initial Inventory Required	2,083	0
Purchase Qty for Non-Recoveries	5,000	50,000

Table 12 Financial data comparison.

Financial Data	Greenbox	Current System
Box Cost	$ 99.00	$ 11.00
Shipping Out	$ 63.00	$ 71.00
Shipping Back	$ 8.00	$ -
Reclamation Expense	$ 6.00	
Capital Expenditure	$ 701,250	$ 550,000

Table 13 System financial comparison.

	Greenbox Daily	Current System Daily	Greenbox Annually	Current System Annually
Total Product Cost	$ 2,922	$ 2,292	$ 701,250	$ 550,000
Freight Expense				
one way freight cost	$ 13,125	$ 14,792	$ 3,150,000	$ 3,550,000
return freight cost	$ 1,500	$ -	$ 360,000	$ -
Total Freight Expense	$ 14,625	$ 14,792	$ 3,510,000	$ 3,550,000
Reclamation Expense	$ 1,125		$ 270,000	
Total Distribution Expenses	$ 18,672	$ 17,083	$ 4,481,250	$ 4,100,000
	Daily		Annually	
GREENBOX Savings	$ (1,589)	-9.30%	$ (381,250)	-9.30%

Note - One-way freights going to the chemists demands an overnight shipment due to the temperature sensitive product. Hence the huge difference between the one-way and return freight costs.

- Reclamation costs exclude specific cleaning costs.

Table 14 Additional saving.

	Greenbox Daily		Current System Daily		Greenbox Annually		Current System Annually	
Packing Protocols		1		1		1		2
Packing Costs	**$**	**26.04**	**$**	**104.17**	**$**	**6,250**	**$**	**25,000**
# minutes		0.5		2.00				
avg. hourly wage	$	15.00	$	15.00				
Warehouse Expense	**$**	**3,760.00**	**$**	**6,160.00**	**$**	**902,400**	**$**	**1,478,400**
# SKU's stocked		1		3				
Avg cu in per SKU		1728		3028				
Avg required sq. ft		940		1540				
warehouse cost per sq. ft	$	4.00	$	4.00				
					$	908,650	$	1,503,400
Additional Annual Greenbox Saving	**$**	**594,750**						
TOTAL Greenbox SAVINGS	**$**	**213,500**						

To explain the difference in the time required to set up the packages specified in (Table-14) shows that the present packout takes 1.5 minutes more than the proposed packout. This is due to the frozen gels used in the EPS system which is sealed in a flexible envelope. These refrigerants when frozen form irregularly resulting in uneven surface and require lots of effort to place them between the EPS container and the payload box unlike the PCMs in Greenbox which are flat molded containers that can be placed one on top of another conveniently.

There can be potential saving from Greenbox as per (Table-13) the total freight expenses saves us $40,000 annually when switched over to proposed shipper. The above cost table (Table-14) shows that packaging costs and ware house expenses has additional savings of $594750 annually. Put together the total Greenbox savings from (Table-13) and (Table-14) would be $213500 annually.

7. CONCLUSION

The data collected from the tests and comparisons indicate Greenbox performs well during the shocks and distribution test as displayed in (Table-7) in comparison to EPS system where the EPS Lid cracks when the box was dropped on top smallest side (side F, shown in (Fig-8)). It is due to the frozen refrigerant weight that the cracks the EPS when it hits the edges of the EPS foam with force after the box dropped.

The R value of a packaging system with VIP as shown in (Fig-4) is 15 - 20 (per inch) which is higher than the packaging system with EPS. The data received from the thermal testing of Greenboxes showed that it performed well in the summer profile holding temperatures 2°C - 8°C for complete 33 hours but failed the winter test profile as it could hold the required temperatures in the system for only for 27 hours. This issue can be solved by increasing the number of refrigerated (Liquid) PCMs in the pack out.

It is observed that EPS is most widely used in the cold chain packaging system and can effectively maintain the temperature of the payload containing temperature sensitive products but has severe effects on the environment. The visual comparison shown in (Fig-11) indicates the amount of packaging material that could be reduced due to size reduction in the packaging system when switching to the proposed system. Data shown in the waste analysis table (Table-9) indicate that there is a huge amount of waste from the present pack out going to the landfill i.e. 37114.2 ft^3 per year. Expanded Polystyrene makes up approximately 1% of the weight in the landfills. Due to the light weight of the material, it can be determined that the material makes up a large portion of the landfill waste and some scientists have argued that the material can decompose in a landfill in 1 million years, although the number is simply unknown.

Since the proposed system is reusable as shown in (Fig-12) there is an additional step in the distribution cycle that is the packages are sent to the reclamation center after being used by the customer. But the proposed Greenbox is $88.00 more than the current system as shown in (Table-12) but this can be recovered by saving on the freight and storage expenses as Greenbox is smaller in size compared to the EPS system as shown in (Fig-11). The product load comparison in (Fig-12) and (Fig-13) displays that the number of proposed system the container holds is 2.2 times more than the EPS system. Since the Greenbox recovery is 90% as shown in (Table-10); the system can also recuperate the initial investment cost by reusing the proposed box for more than 20 cycles. There are additional savings made through reduced packaging costs for Greenbox which is $ 18750 less than current system annually and the warehouse expenses for current system is $576,000 more than the ware house expenses for Greeenbox as shown in (Table-14).

Therefore after analyzing and comparing the data of presently used cold chain packaging system with the proposed packaging system it was found that Greenbox is an environment-friendly, reusable shipping solution of its kind for the Cold Chain Industry with the potential to keep EPS out of landfills.

7.1 **Need for further research** –

Since Greenbox fails to hold the temperatures between 2°C ~ 8°C in the winter profile (Graph-4), additional research can be performed to demonstrate that Greenbox could pass the winter profile by adding more of liquid PCMs or using minimum freezing temperatures for solid PCMs in the packout.

New materials emerging to be better options for cold chain products -

Green cell foam - This biodegradable foam has been developed as a possible alternative to EPS foams. Single-use coolers made from high-grade, cornstarch naturally anti-static, also performs as a desiccant. It has been stated that this foam dissolves in water and biodegrades in seawater and freshwater. It is believed to be excellent for pharmaceuticals, nutritional supplements, and specialty foods. Cooling materials such as dry-ice and cold ice packs can be used with Green cell coolers. Further research can be carried to compare this new material with EPS and Greenbox systems using the same test protocol.

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