

# Pit-Stop Express Operators Manual

## Maintaining the Bio- Pharma Cold Chain

Guidelines for control and management of  
Specialised Pit-Stops.



## Cold Chain **Introduction**

The Cold Chain is the management of product temperature, from source through to the consumer, thereby maintaining the quality and efficacy of the product. Maintenance of the Cold Chain is the only way to ensure quality of temperature sensitive medicines, including -

- Over heating
- Accidental freezing
- Colour changes
- Visible sedimentation
- Loss of potency

Good Cold Chain management results in the consumer receiving a medical product of “fresh” quality, leading to greater satisfaction and increased demand.

The movement of temperature sensitive products typically involves long journey times and frequent handling. This makes effective Cold Chain management critical and even more essential to ensure the product offered for final sale retains potency and quality.

**It's Everyone's Responsibility** Maintaining the Cold Chain is the responsibility of everyone who handles the product, from production to final retail. A breakdown in temperature control at any stage will impact on the final quality of the product, although the effect may not be immediately visible.

Without the cooperation of everyone involved in handling temperature sensitive products, the consumer will not be able to benefit from the medication.

**Transportation** Cold transport is the most essential means of continuing the Cold Chain. By using the right vehicle and equipment along with correct handling procedures, the product temperature and quality can be maintained through this important link in the Cold Chain.

## Objectives **Pit-Stop Express**

Gati Pit-stop express utilize the existing Thermal Management System incorporating rechargeable energy packs and insulating carrier boxes. This solution allows the customer to do away with conventional air freight by switching to a surface mode of distribution.

The objective is to offer the following to the customer-

1. Uninterrupted Cold Link: Each individual unit undergoes a pit-stop at mid-station halts; ensures long term cold-chain integrity in existing parcel packaging.
2. Small Carbon Footprint: A solution for cold-transportation via surface mode, at smaller carbon footprint than aviation offers; the customer enjoys a clean image.
3. Environment Friendly: Provides a CFC Free, Passive Cooling Solution in surface transportation.
4. Portable Transport Units: Provides the opportunity to unitise mixed loads and save costs through consolidation of loads.
5. Reusable transportation units: Each transportation unit can be used repeatedly after re-charging the thermal panels.

### BIO-PHARMA FACTS

- ◆ Temperature excursions can reduce potency, reduce shelf life, or alter a drug so as to make it harmful.
- ◆ Pharmaceuticals are not like snow blowers or sneakers. When those products are recalled or returned, they can be repaired, resold, or donated. Pharmaceuticals, in contrast, are destroyed.
- ◆ For nearly half of the new drugs entering the market, maintaining a specific temperature range is imperative.
- ◆ RFID radio transmissions may be effecting the biologics hence this is being abandoned for 2-dimensional bar codes.
- ◆ The future may involve personalised drugs so expect even more refined protocols for even more expensive medicines.

## Guidelines **Transporting the Product**

### ***Plan Ahead:***

1. Use a vehicle that offers the fastest transit time.
2. Have sufficient material ready for bracing and securing the load.
3. Arrange the pick-up and delivery times, allowing for realistic transit times.
4. Contingency plans should be developed, in conjunction with the consignor, to deal with potential problems or delays. The driver should be provided with a 24-hour phone number to call if problems develop.

### ***Prepare Before You Load:***

1. Measure and record the temperature of the chill packs one hour before doing the pit-stop. Produce should be pre-cooled, and this should be noted in the paperwork.
2. Use haste-controlled loading docks to transfer produce directly from the coolroom to the Transport unit. If these are not available, load Transport unit in the shed or shaded loading area.
3. In hot weather, consider pre-cooling to reduce the internal temperature in the shipper unit.
4. Ensure the product has adequately stabilised in the coolroom, and do not remove until the truck or vehicle is ready for loading.

### **COOL FACTS**

- ◆ Produce should be cooled before loading. Refrigerated transport is not designed to cool down the produce.
- ◆ Unless using refrigerated loading docks, pre-cooling of the Transport unit is of added value.
- ◆ All loading operation should be completed as fast as possible to extend utility life of the passive cooling material.

## Guidelines **Keep It Cool While Loading**

1. If load handling equipment is not available on site, place the TMS Transport unit on the vehicle bed first. This should be easily done by two or three persons.
2. Alternately, the produce can be stowed in the TMS Transport unit inside a coolroom (or ante-room) and the loaded unit can then be rolled onto the truck's flat bed.
3. Before loading the produce, place in the TMS panels in the designed slots inside the Transport unit.
4. The TMS Panels must be charged before using them for transport.
5. Ensure the product is properly stowed in the Transport unit.
6. Brace the load so produce will not move around during transit.
7. Ensure door of the TMS Transport Unit has sealed properly to avoid air exchange from outside.

## **Multiple Pick-Up Loads.**

1. Making multiple pick-ups is NOT RECOMMENDED. Warming of produce occurs each time the doors are opened.
2. Where multiple pick-ups are necessary, minimise the time that the doors are open on each occasion.
3. At each multiple pick-up point, place additional charged TMS panels to counter the energy loss for door opening.
4. Ensure that the core temperature of each consignment is measured and recorded before loading. At unloading, temperature measurements should include at least one measurement from each consignment.

### COOL FACTS

- ◆ Place cold shipper in conditioned rooms to safe guard premature loss of thermal energy.
- ◆ When replacing shipper box, consider pre-cooling the box for half an hour with spare chill packs before final replacement.
- ◆ When replacing a damaged shipper box, always renew the chill packs also.
- ◆ Speed is of essence when replacing chill packs – avoid weak links in the cold chain.

## Guidelines **Loading / Dispatch**

Avoid carrying mixed commodity loads whenever possible. If mixed loads are necessary, the compatibility of the products needs to be determined using the following factors:

1. Optimum storage temperature - a compromise temperature during transport will reduce the storage life of some of the products. Some products are prone to chilling injury at lower temperatures, while increased temperatures speed the loss of quality.
2. Ethylene production/sensitivity - ethylene is released by many fruit and vegetables during ripening, and can cause unwanted ripening or loss of quality in other products. Products which produce ethylene generally should not be carried with those sensitive to it.
3. Odours and off flavours - product contamination with odours or off flavours may not be visible but leads to a loss of quality for the consumer.
4. Time - the longer the journey, the greater the deterioration of the produce if compatibility is poor.

## **Inbound-Unloading**

1. If you have allocated a timeslot for unloading, make sure the load arrives at that time or notify of any delay. This will assist them in ensuring an efficient unloading schedule, thus maintaining the Cold Chain.
2. If unable to unload immediately, ensure Transport unit is kept in an area that limits exposure to harsh ambient.
3. Record any unloading delay on consignment note.
4. Unload in a cool area. Ideally, refrigerated loading docks should be used. If unavailable, unload in the shed or a shaded area, ensuring limited exposure of your product to harsh ambient.
5. Organise equipment and/or staff for unloading before opening TMS Transport unit doors.
6. It is recommended that product core temperature is measured and recorded in consignment note (see “HOW TO MEASURE CORE TEMPERATURE” in this booklet).

## Protocol

# Chill Packs



- The Chill Packs are thermal energy storing material encapsulated in easy to handle pouches. They serve as the cooling cells.
- The fluid inside these pouches is harmless and non-toxic.
- The cooling energy is stored in the molecular arrangement of this fluid. When charged, the fluid will be solidified. When all the energy is released, the fluid will behave like liquid/jelly.

### CHARGING

- The pouches to be charged in the pit-stop freezers or blast chiller.
- The Chill packs are fully charged when they turn to solid state.
- Use protective hand gloves to avoid chilling injury to handler.

### PROPER HANDLING

- The pouches should be handled gently to avoid any damage and subsequent leakage of this precious fluid.
- DO NOT drop the pouches causing damage to the skin.
- DO NOT force the pouches. This will cause abrasion damage.
- DO NOT use any pouch if found punctured or drained. Immediately mark the pouch and record damage.
- Isolate chill pack from direct contact with internal product - minimize condensate damage and chilling damage from direct contact.

# Transportation Unit - Shipper

### PROPER HANDLING

- DO NOT puncture or damage the side walls.
- Take Care of internal separation/spacers used.



Securing the Shipper



- Drain shipper of any condensate, package to isolate condensation.
- Tape up the lid and secure the shipper with strap.
- Handle each shipper individually, lifting gently onto the truck bed.
- Brace the unit on the truck bed to avoid dynamic movement during transportation. Foam pads can be used to facilitate this.

## Information **How to Measure Temperatures**

Chill pack temperature measurements require an electronic thermometer - a digital spectral thermometer. This thermometer needs to be calibrated at least every 4 weeks.

Take several measurements (minimum of 5) through the load and average these to get a representative measurement of the temperature.

Ensure measurements are carried out at different levels and on different faces of the load.

Face the measuring port towards the chill packs and press the trigger. Allow the thermometer to stabilise before reading the temperature.

To standardize readings, measurements should be taken from no more than one foot from the surface of the chill packs.

It is preferable to use the same instrument to record temperatures for the same consignment/set.

Hold the measuring instrument steady and use the same technique for all measurements.



Typical Temperature Record Chart - Chill Packs

Customer Code:					Consignment No:			
Thermometer used (ID)				Calibration Date:				
				Calibration Error:				
Date	Time	Shipper Tag	Load Temp °C	Discharge Temp °C				