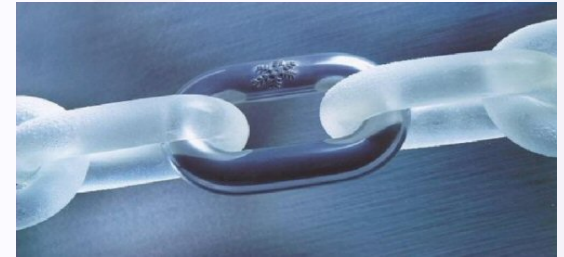




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## Cold chain



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*Wholesale Distribution Information Day, 25/2/2010*

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Greg McGurk  
Executive Inspector

# Cold Chain

- Scope:
  - Factors affecting transportation
  - Small scale transportation
  - Large scale transportation



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# Cold Chain

- Controlled storage and transportation of medicinal products of temperatures between 2° – 8°C



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# Cold Chain

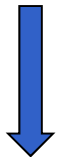
- Manufacturer



- Wholesaler / distributor



- Customer



- Patient



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# Cold Chain Transportation - Considerations

- **Controllable Factors**
  - Packaging
  - Routes
  - Carriers
  - Delivery Time (to a degree)
- **Uncontrollable Factors**
  - Weather
  - Delays
  - Handling



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# Cold Chain Transportation - Considerations

- Nature & Size of the load
- Temperature control requirements of the load
- Method of transportation
- Duration of transportation
- Local seasonal temperatures

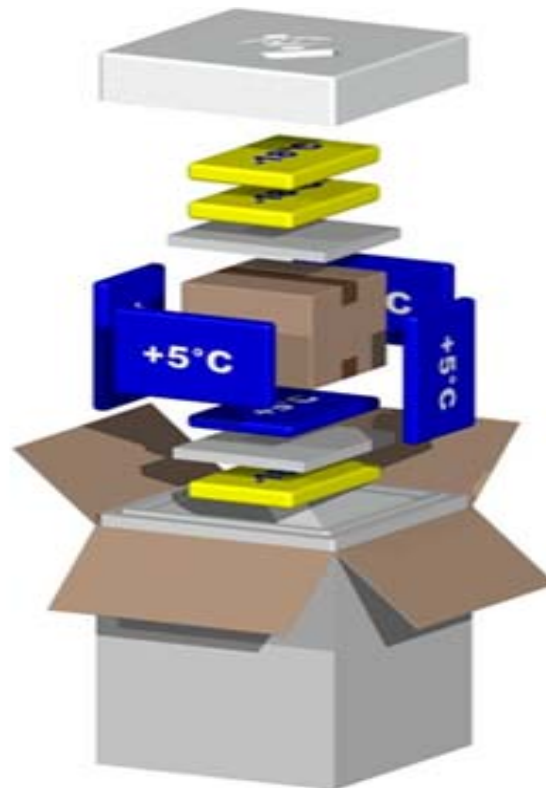


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# Cold Storage: Small Volume Transportation Systems

## Small Volume Systems

Insulated containers using ice-packs as a cool source



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## Small Volume Systems

- Chill packs may also be incorporated
- May be of different sizes to incorporate smaller, medium, and larger volumes with the relevant capacity range
- Typically suitable for smaller volume loads where the transit times are of limited duration e.g. deliveries from a wholesaler to a pharmacy



## Operational Issues

- Qualification

The system should be qualified to demonstrate its ability to maintain the required product temperature storage conditions

Qualification should take into account

- Maximum transit times
- Minimum and maximum packaging capacities
- Maximum seasonal variation in temperatures



# Cold Storage: Small Volume Transportation Systems

Qualification should also take into account

- Packaging configuration for the systems
- Required freezing times for the ice packs and cooling times for the chill packs
- Conditioning time for the ice packs



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# Cold Storage: Small Volume Transportation Systems

- System In-Use
  - The system should be used in accordance with the parameters utilised in the qualification study
  - Additional requirements to support use of the system include:-
    - Rotation and control of the ice packs and chill packs
    - Corrective actions in the case of goods having been transported outside of the required temperature range
    - Labelling
    - All operational aspects should be proceduralised
    - Temperature monitoring within the load
  - Training



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# Cold Storage: Large Volume Transportation Systems

## Large Volume Systems

Refrigerated transport vehicles or transportation containers which incorporate a chiller unit.



## Large Volume Systems

- Suitable for large volume loads where the transit times are prolonged in duration
- May be used as a primary or secondary means of environmental control



## Operational Issues

1. Mapping to determine hot/cold spots with respect to storage.
2. Qualification

Consideration should be given to

- Ensuring the air flow within the refrigeration unit
- Capacity of the load
- Configuration of the load
- Orientation of product with respect to the chiller and air circulation units



## Operational Issues

### 3. System In-Use

- Temperature Monitoring of the refrigeration unit.
- Use of temperature monitoring within the load.
- The system should be used in accordance with the parameters utilised in the mapping & qualification studies.
- All operational aspects should be proceduralised.

### 4. Training



# Cold Chain Product Returns

Cold chain products may only be returned to saleable stock where there is no reasonable possibility that the chain has been compromised.



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# Cold Chain – Duration of Validation

IMB involved in EMA / EDQM coordinated sampling and analysis programme for CAP.

- 24 hours – standard validated hold time for cold chain
  - Product losses occurred due to freight handling issues
  - Re-sampling and additional costs incurred
- Request consideration for extending this to 72 hours to avoid such occurrences



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# Reference Material

## IMB Guide to Control & Monitoring of Storage & Transportation Temperature Conditions For Medicinal Products & Active Substances

Link

[http://www.imb.ie/uploads/publications/194333\\_IND\\_003\\_01.pdf](http://www.imb.ie/uploads/publications/194333_IND_003_01.pdf)

### Guide Developed For

- Manufacturers
- Distributors
- Transporters

### Provides Guidance On

- Controlled Temperature Storage
- Cold Storage/Cold Chain



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