

Chapter 8

I. Sea Transport

The sea transportation for temperature sensitive products it's the cheaper solution and it's usually chosen for long distances and big volumes of freight.

All equipment needs to be clean and in good conditions. Refrigerated containers should be checked before loading to verify its functioning, the setting of the right temperature, the pre-cooling system and the hygiene conditions. The cleanliness of the container is important to avoid contamination and damages to the pharmaceutical products that will be loaded into the container. It's necessary to check with your supplier that the equipment has the mapping documentation; mapping needs to be done at least in extreme seasons – winter and summer.

All the calibration, repair and maintenance operation should be recorded and carried out without compromising the integrity of the product.

If a temperature monitoring system is installed, it should follow these conditions:

- **It should be qualified and documented**
- **It needs to have an alarm system with its respective procedures**
- **It needs to be linked to a SOP in order to correct the possible anomalies which can occur also during the transportation**
- **In addition, it's preferable that it is in compliance with the Food and Drug Administration normative – CFR21, PART 11.**

Suppliers, like shipping companies and tracking companies are **critical suppliers** and need to be qualified for the pharmaceutical product and to be subject to regular controls.