Importance of Temperature mapping study in the Middle East

The Middle East countries go through extreme climatic conditions with temperature crossing 50 Degree Centigrade during peak of summer. The external temperature and atmospheric conditions affect the temperature of ware houses, cold room, vans, trucks, reefers etc. which are used for storage and distribution of medicines. The Middle East countries referred here are generally United Arab Emirates, Saudi Arabia, Qatar, Kuwait, Oman, Bahrain, Iran, Iraq etc.

Regulatory requirement of Temperature mapping study in the Middle East

While this is not a regulatory requirement in most of these countries, it is desirable for most of the pharmaceutical manufacturers and distributors that a study is carried out atleast once in every three years. The reason for recommending once in three years is that various critical parameters inside the enclosed area keep on changing including the performance of the cooling units. Also the number and arrangement of storage racks are changed many times which are not advisable after carrying out a mapping study. Even adding a small rack will have its own effects in uniform temperature distribution. Such a study need to be carried out for entire cold chain including ware houses, cold room, vans, trucks,reefers etc.

Do you require Temperature mapping study for your facilities?

How do you decide whether you need to carry out the study for your facilities? If you are dealing with manufacture, storage and transportation of temperature sensitive products such as medicines, vaccines, frozen or fresh food items etc., you need to ensure that the products are always within the specified temperature levels at all stages.

Temperature & Humidity Mapping study of Warehouse

A warehouse is affected extremely by the climatic conditions and hence it is extremely important and essential that the mapping study is carried out in different climatic conditions such as summer and winter in the Middle East. Aware house is typically studies for 7 days continuously in both the seasons. It is practically difficult to carry out ware house study under different loading conditions such as empty and full loaded conditions because the goods in the ware house will have to be moved outside. This is generally possible only if the study is carried out immediately upon construction of the ware house. A ware house is generally studied for a temperature range of 15 to 23 Deg C

Temperature & Humidity Mapping Study of Cold Room

A cold room is very sensitive since the temperature has to be always maintained between 2 and 8 Deg C. Humidity has to be maintained within a limit of 70% if not specified other wise by the medicine manufacturers. Any corner of the room should not exceed these temperature levels and hence the mapping is very elaborate in ascertaining the practical conditions. The test is done under two loaded conditions viz. Partial and fully loaded conditions. Various tests done are:

- Power failure test to determine the duration for which the temperature will be maintained if power fails
- Temperature recovery test to determine the time taken to reach the specified time limits after a power failure
- Door opening test to determine the duration for which a door can be kept opened without affecting the inside temperature
- Mapping of Partially loaded (typically 60-70%) cold room
- Mapping of Fully loaded cold room

Temperature & Humidity Mapping Study of Vans , Reefers & trucks

The vehicles are always on the move under loaded conditions and the inside parameters cannot be monitored to a great extent. Hence it is very important to analyse the inside conditions for all practical conditions and certify the vehicle. Various tests done are:

- Power failure test to determine the duration for which the temperature will be maintained if power fails
- Temperature recovery test to determine the time taken to reach the specified time limits after a power failure
- Door opening test to determine the duration for which a door can be kept opened without affecting the inside temperature
- Mapping of empty vehicle
- Mapping of Partially loaded (typically 60-70%) vehicle
- Mapping of Fully loaded vehicle

Protocol & SOP for Mapping study of Reefer truck with Thermoking

A brief of a typical procedure for a 40 ft. reefer truck fitted with Thermoking cooling unit can be viewed at our website

Case Study : Mapping Study and Qualification of Reefer truck

Project Code of Vacker LLC	Xxxxxxxxxxxxxx

Client Name	xxxxxxxxxxxxxxxxxxxx Dubai United Arab Emirates
Asset Type	Truck for transportation of Pharmaceutical Products
Asset Description	Reefer TruckManufacturer: MammutCooling Unit : ThermokingIdentification no. xxxxxxxxxxxxxxxxCooling Unit : Thermoking Sl.No. xxxxxxxxxxxxxx
Size of the vehicle in meters (LxWxH)	13.2 x 2.5 x 2.615
Temperature Range to be mapped	2- 8 Deg C Mapping Study Low Limit 2° C High Limit 8° C Set point: 4° C15-25 Deg C Mapping Study Low Limit 15° C High Limit 25° C Set point: 19° C
Duration	2- 8 Deg C Mapping Study17 hours – Empty 12 hours – 60% loaded 16 hours – 100% loaded15-25 Deg C Mapping Study 17 hours – Fully loaded 12 hours – 60% loaded 16 hours – 100% loaded
Mapping Type	Operational Test 1.0 ; System Start up verification Operational Test 2.0 ; Empty Load Test Operational Test 3.0 ; Partial Load Test Operational Test 4.0 ; Fully Loaded Test Operational Test 5.0 ; Door opening Test Operational Test 6.0 ; Power Failure Verification Operational Test 7.0 ; Temperature Recovery
Date of Test	xxxxxxxxxxxxxxxx2014
Place of Test	Yard of xxxxxxxxxxxxxxxxxxx at Jabel Ali Free Zone, Dubai, UAE
Test carried out by:	xxxxx Vacker LLC

Test was carried out as per summary indicated above. All results were satisfactory. Brief details are as under:

Summary : 2- 8 Deg C Mapping Study

1. Summary of Operational Test 1.0 ; System Start up verification:

Power switched ON and Door closed at : xxxxxxxxx , 14:36:02 hours
Time taken for first data logger to reach below 8 ° C from Ambient : 36 Minutes
Time taken for all data loggers to reach below 8 ° C from Ambient: 48 Minutes

2. Summary of Operational Test 2.0 ; Empty Load Test:

Empty load test started after stabilization at : xxxxxxxxx , 16:24:02 hours
Empty load stopped at : xxxxxxxxx, 09:33:02 hours (Total 17 hours)
Result : All data loggers remained within the range throughout the test

3. Summary of Operational Test 3.0 ; Partial Load Test:

Empty load test started after stabilization at : xxxxxxx , 12:00:02 noon
Empty load stopped at : xxxxxxxx, 16:18:02 hours (Total 4 hours)
Result : All data loggers remained within the range throughout the test

4. Summary of Operational Test 4.0 ; Fully Loaded Test:

Fully load test started after stabilization at : xxxxxxxxx , 18:09:02 hrs
Fully load test stopped at : xxxxxxxxx, 09:54:02 hrs (Total 16 hours)
Result : All data loggers remained within the range throughout the test

5. Summary of Operational Test 5.0 ; Door opening Test:

Door opened at : xxxxxxxxxxx , 14:27:02 hours
Time taken for first data logger to reach above 8 ° C : 3 Minutes
Time taken for all data loggers to reach above 8 ° C : 6 Minutes

6. Summary of Operational Test 6.0 ; Power Failure Verification:

Power switched OFF at : xxxxxxxxx , 10:06:02 hours
Time taken for first data logger to reach above 8 ° C : 21 Minutes
Time taken for all data loggers to reach above 8 ° C : 42 Minutes

7. Summary of Operational Test 7.0 ; Temperature Recovery:

Power switched OFF at : xxxxxxxxx , 11:36:02 hours
Time taken for first data logger to reach below 8 ° C : 33 Minutes
Time taken for all data loggers to reach below 8 ° C : 54 Minutes

Detailed report and graph of the mapping study are available at our website

Please read more:

http://www.temperaturemonitoringuae.com/services/temperature-mapping-validation/cold-chain-temperature-mapping/

http://www.temperaturemonitoringuae.com/services/temperature-qualification/