TITLE:	TEMPERATURE MAPPING PROTOCOL FOR REEFER/ TRUCKS / VANS ; Procedure no. VAC/P/008

COMPANY NAME: **SITE:** **VAN ID NUMBER:**	**Jabel Ali Free zone, Dubai, UAE**

PROTOCOL WRITTEN BY		
NAME	**SIGNATURE**	**DATE**
Name: **Company:** Vacker LLC.		

PROTOCOL APPROVAL		
NAME	**SIGNATURE**	**DATE**
Name: **Title:** **Company:**		
Name: **Title:** **Company:**		
Name: **Title:** **Company:**		

CHANGE HISTORY			
NAME	**REASON FOR CHANGE**	**REVISION**	**ISSUED DATE** (yyyy-mm-dd)

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1. IDENTIFICATION OF QUALIFICATION TEAM

In order to identify the persons who have participated in the execution of this qualification, a specimen of their signature and initial is shown below, beside their name and title.

Name	Title	Signature	Initial

2. DEFINITIONS AND ACRONYMS

In order to facilitate the comprehension of terms and acronyms used in this document, a brief technical definition is shown below.

Terms	Definitions
Auxiliary Equipment	Equipment mostly used in conjunction with the equipment to be qualified but not included in the qualification package.
Change Parts	Parts to fit different size / format or application.
Component	Any major piece, part or assembly of the main equipment or sub-equipment that does not have its own power supply and could not operate as a standalone unit (valves, switches, etc.).
Controller	A device that interprets a mechanical, digital or analog signal, generated by a sensor, to control an equipment or component.
Controller, critical	A controller for which control have a direct impact on the quality of the product or proper operation of the equipment.
Controller, non-critical	A controller for which control have no direct impact on the quality of the product or proper operation of the equipment.
Deviation	For IQ: Any discrepancy between the installation specifications and the actual (as found) installation. For OQ: Any discrepancy between the protocol and the actual performed test, test function methodology, testing equipment, testing material etc.
Instrument	A device that interprets a mechanical, digital or analog signal generated by a sensor, and converts it into engineering units (°C, % RH, mA, etc.) through scaling.
Instrument, critical	An instrument for which measurements have a direct impact on the quality of the product or proper operation of the equipment.
Instrument, non-critical	An instrument for which measurements have no direct impact on the quality of the product or proper operation of the equipment.
Key Operating Parameters	Parameters that must be maintained to process or produce products with consistent quality attributes and those that may have an impact on the proper operation of the equipment.
Main Equipment	Major equipment installed.
Sensor	A mechanical device (pressure switch, bimetal temperature switch, etc.), a digital or analog transducer (limit switch, pressure sensor, temperature sensor, etc.) that generates an electrical or mechanical signal to an instrument or a controller in order to be interpreted.
Sensor, critical	A sensor for which detection has a direct impact on the quality of the product or proper operation of the equipment.
Sensor, non-critical	A sensor for which detection has no direct impact on the quality of the product or proper operation of the equipment.
Sub-equipment	Piece of equipment, part of major equipment that possesses its own power supply that could usually operates as a standalone unit (pump, conveyor etc.).

Terms	Definitions
GPS	Global Positioning System
OQ	Operational Qualification
PM	Preventive Maintenance
PQ	Performance Qualification
SOP	Standard Operating Procedure
D	Deviation
ID	Identification
N/Ap.	Not Applicable
N/Av.	Not Available
N/Sp.	Not Specified
NIST	National Institute of Standards and Technology
OQ	Operational Qualification
PM	Preventive Maintenance
V.I.N.	Vehicle Identification Number

3. SCOPE

This procedure is for carrying out Temperature mapping study of proper installation and operation of the Truck / Reefer / Van

3.1. Mapping Protocol summary

Project Code	VAC/D/WO 84
Client Name	xxxxxxxxxxxxxxxx Dubai United Arab Emirates
Asset Type	Truck – Pharmaceutical Products
Asset Description	Reefer Truck Manufacturer: XXXXX Year of Manufacture: XXXX Plate no.
Size of the vehicle in meters (LxWxH)	
Temperature Range to be mapped	Low Limit 2° C High Limit 8° C Set point: 4° C
Duration	6 hours – Empty 12 hours – 60% loaded 12 hours – 100% loaded
Mapping Type	1. Temperature Only – Summer Profile 2. Working conditions: Empty, Partial and Full 3. Power shutdown test 4. Recovery time test 5. Door open test
Number of Loggers & positions	The number and placement of the loggers is detailed in the Floor plans / Placement plans section of this report
Logging Interval (minutes)	3 minutes
Logger Type	Cryopak Data Logger

3.2. Data Logger Specification & configuration data

Probe Measurement Range	-40… 80 °C
Probe Accuracy Range	± 0.5 °C (-10 – 40 °C) , ±1.0 °C (-20 – 70 °C)
Memory Capacity	16,000 measurements
Memory Type	Non-volatile EEPROM
Logging Interval (Minutes)	3 minute
Alarm Range	Low Limit 2° C High Limit 8° C
Calibration Date of the Loggers	Apr 2014
Next Calibration Date of the Loggers	Apr 2015

4. OBJECTIVE

The purpose of this study is to:

- Briefly describe the equipment, its major components and their roles.
- Verify that the van is properly installed according to the manufacturer and xxxxxxxxxx LLC specifications thus permitting operation as per design specifications.
- Carry out appropriate identification and documentation of the installed equipment.
- Verify that the physical characteristics are compatible with planned equipment utilization.
- Verify that appropriate calibration (if necessary) is in place.
- Carry out complete temperature mapping study at various operational conditions