TITLE:	VALIDATION OF DELIVERY PROCESS OF MEDICINE (2-8°C) FROM COLD ROOM TO CUSTOMER- 2017				
Protocol Number	IOPQ-VAN-xxx-xxx-P	**Revision**	0	**Issued Date**	dd-mm-yyy

COMPANY NAME:	**XXXXX**
ASSET :	**VAN #**
LOCATION:	**xxxxxx**

PROTOCOL PREPARED BY		
NAME	**SIGNATURE**	**DATE**
Name: **Title:** **Company:** Vacker Global		dd-mm-yyyy
PROTOCOL APPROVED BY		
NAME	**SIGNATURE**	**DATE**
Name: **Title:** **Company:** Vacker Global		dd-mm-yyyy

PROTOCOL APPROVAL & REVIEWED BY		
NAME	**SIGNATURE**	**DATE**
Name: **Title:** **Company:**		
Name: **Title:** **Company**		
Name: **Title:** **Company**		

CHANGE HISTORY			
NAME	**REASON FOR CHANGE**	**REVISION**	**ISSUED DATE**
	New document	0	dd-mm-yyyy

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SCOPE OF THIS PROTOCOL :

Study type	Validation of Delivery Process of Medicine (2-8°C) From Cold Room to Customer
Client name	XXXXX
Asset Type	Cold Room, Van and Passive Boxes
Description and Location	Dubai UAE
Sl No. of the Asset	**xxxxx**
Temperature range to be mapped	2-8°C
Duration of testing	2-3 days
Date of Testing	

Reference Standards : This mapping study is carried out as per WHO Technical Report Series, No. 961, 2011.

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1 IDENTIFICATION OF THE 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

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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 to be qualified.
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.).
D	Deviation
ID	Identification
IQ	Installation Qualification

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Terms	Definitions
IOPQ	Installation / Operational / Performance Qualification
	Not Applicable
	Not Available
N/Sp.	Not Specified
NIST	National Institute of Standards and Technology
OQ	Operational Qualification
PQ	Performance Qualification
PM	Preventive Maintenance
QA	Quality Assurance
QC	Quality Control
S/N	Serial number
SOP	Standard Operating Procedure
V.I.N.	Vehicle Identification Number

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3 SCOPE

The medicines are packed in a passive box inside a cold room. The passive box is then taken across the warehouse to the loading bay and loaded into a reefer van. The reefer van contains boxes for different destinations. The scope of this protocol is to verify that the temperature of the medicine remains at 2-8°C while the customer receives the passive box. The cold room, Van and the Passive \box have been already qualified for 2-8°C and hence same is not covered under this protocol.

4 OBJECTIVE

The purpose of this validation process is to:

- Temperature Qualification study to analyze the temperature of the medicine at the time of the delivery.
- Briefly describe the equipment, its major components and their roles.
- Record all major activities including the time from the beginning to the end.
- Record all door openings of the van after commencement of the journey.
- Ensure that appropriate identification and documentation are in place.
- Ensure that appropriate operation procedures are done as per recommendations of the qualification process of each asset.
- Analyze all the recorded data along with the operational sequence and duration.
- Recommend a proper procedure for daily operations as per this validation report.

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5 RATIONALE

The sequence of the process is as below, further to be verified as per SOP of each assets.

- Decide the Cold Room opening time after the last door opening as per the SOP.
- Pre cool the passive box as per the SOP.
- Pack the medicine in the passive box as per the SOP
- Different Passive Boxes should have different loading percentage such as 40%, 60%, 80% and 100%.
- Each of the boxes should have a data logger.
- Precool the van as per the relevant SOP
- Load the passive boxes in the van.
- Record how much percentage of the van is loaded.
- Drive the vehicle to the destinations as per routine delivery.
- Record the time of each of the above activities.

At the time of delivery, the data logger inside each of the passive boxes should be within 2-8°C. Otherwise the validation is considered to be failed.

All tests must be conducted by trained and experienced technical personnel and must be documented in a scientific manner using this established format.

IMINI temperature data loggers will be used to measure and record temperature. Each data logger has been calibrated and calibration certificates, generated in the PDF report, will be placed in Supporting Documents section. These electronic instruments are calibrated yearly and associated document will be part of the report.

Any test function that does not have results which support the parameters defined in the approved protocol must be conclusively rationalized for their deviation and approved or the qualification will be considered invalid.

Note: We will use any equivalent data loggers with calibration certificate as per actual site conditions and test schedule.

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6 APPLICABILITY

All Vacker Global and Xxxxx personnel, when performing the qualification of the Van ID shall follow this protocol.

7 RESPONSIBILITY

This qualification protocol must be respected by all Vacker Global and Xxxxx employees during processing.
The responsibility of the validation process is attributed to the following:

Responsibilities		
Task	**Vacker Global**	**Xxxxx**
Make available all documentation required for the qualification of the Van.		✓
Collect information.	✓	
Write the protocol.	✓	
Review and approve the protocol.	✓	✓
Verify that all critical instrument of the equipment have calibrated valid date.	✓	
Arrange loading and unloading of goods for the tests		✓
Coordinate activities.	✓	✓
Execute the test described in the protocol.	✓	
Compile and analyze data.	✓	✓
Issue the final report.	✓	
Make available all documentation required for the validation process.	✓	✓

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8 QUALIFICATION DOCUMENTATION

8.1 MANUAL ENTRIES IN PROTOCOL

- All manual entries will be written in indelible blue ink.
- Any error must be crossed out with a single line stroke, and the correct information must be entered below or above the error.
- All corrections must be initialed and dated.

8.2 DEVIATION REPORTS

Any discrepancy between the protocol and the actual performed test (test methodology, testing equipment, testing material etc.) or failure of the application to meet the test function acceptance criteria specified in the OQ section of this protocol must be documented on a Deviation and Corrective Action Report form.
The Deviation Report numbers are to be indexed according to the section of the protocol to which they pertain. For example, reports pertaining to OQ Test Verification in section 13.1 of this protocol will be sequentially numbered D13.1-1, D13.1-2, etc.
All Deviation Reports associated with the execution of this protocol are to be enclosed in Attachment 1 of this protocol.

8.3 DATA SHEETS

8.3.1 OQ Section

Information pertaining to Operational Qualification will be directly recorded in the OQ Section «Test Data Sheet» of this protocol. Here is a brief description of each section:

Section	Description
Objective	Define the purpose of the test.
Acceptance Criteria	Description of the acceptance criteria.
Prerequisite	Conditions, files, equipment, diagrams, tables. Any supporting documents or equipment needed to execute the test, which are not obvious in the standard operation of the equipment.
Methodology	Description of the course of actions that need to be executed in order to produce the expected result.
Pass / Fail	Indication that the functionality tested is compliant with specifications. - A «**Pass**» result indicates that the functionality tested is found compliant with specifications. - A «**Fail**» results indicates that the functionality tested is found not compliant with specifications and therefore will be reported as deviation.
Deviation Report Number	Reference to Deviation Report Number (if applicable) pertaining to the test.
Comments	Discussion of any unusual observations during the test or significant test conditions not defined in the test procedure.
Tested by	Signature and corresponding date for the person performing the test.
Verified by	Signature and corresponding date for the person verifying the test data.

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8.3.2 PQ Section

Information pertaining to Performance Qualification will be directly recorded in the PQ Section «Test Data Sheet» of this protocol. Here is a brief description of each section:

Section	Description
Objective	Define the purpose of the test.
Acceptance Criteria	Description of the acceptance criteria.
Prerequisite	Conditions, files, equipment, diagrams, tables. Any supporting documents or equipment needed to execute the test, which are not obvious in the standard operation of the equipment.
Methodology	Description of the course of actions that need to be executed in order to produce the expected result.
Pass / Fail	Indication that the functionality tested is compliant with specifications. - A «**Pass**» result indicates that the functionality tested is found compliant with specifications. - A «**Fail**» results indicates that the functionality tested is found not compliant with specifications and therefore will be reported as deviation.
Deviation Report Number	Reference to Deviation Report Number (if applicable) pertaining to the test.
Comments	Discussion of any unusual observations during the test or significant test conditions not defined in the test procedure.
Tested by	Signature and corresponding date for the person performing the test.
Verified by	Signature and corresponding date for the person verifying the test data.

8.3.3 Validation Report

The Validation Report will be written following the execution of the protocol and will include the sections listed below.

Section	Description
Objective	Description of the objective of the validation process.
Summary	Summary of the results of the execution of each major section of this protocol including a summary of deviations (if any).
Conclusion	General conclusion for all verifications and observations indicating the acceptability of the equipment for operation.

8.4 CHANGE CONTROL

Changes, upgrades and / or configuration modifications made to the equipment will be executed and documented according to the current Xxxxx Change control procedure (Change Control SOP). All change control documents for the equipment qualified under this protocol are to be referenced in Attachment 4 of this protocol.

8.5 ANALYSIS

Mean Kinetic Temperature

Mean kinetic temperature (MKT) is a simplified way of expressing the overall effect of temperature fluctuations. Mean Kinetic Temperature (MKT) is defined as the single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

A single derived temperature that, if maintained over a defined period of time, affords the same thermal challenge to a drug substance or drug product as would be experienced over a range of both higher and lower temperatures for an equivalent defined period. The mean kinetic temperature can be expressed as:

$$T_K = \frac{\frac{\Delta H}{R}}{-\ln\left(\frac{t_1 e^{\left(\frac{-\Delta H}{RT_1}\right)} + t_2 e^{\left(\frac{-\Delta H}{RT_2}\right)} + \cdots + t_n e^{\left(\frac{-\Delta H}{RT_n}\right)}}{t_1 + t_2 + \cdots + t_n}\right)}$$

Where:

T_K is the mean kinetic temperature in kelvins

ΔH is the activation energy (typically within 60–100 kJ·mol-1 for solids or liquids)

R is the gas constant

T_1 to T_n are the temperatures at each of the sample points in kelvins

t_1 to t_n are time intervals at each of the sample points

When the temperature readings are taken at the same interval (i.e., $t_1 = t_2 = \cdots = t_n$), the above equation is reduced to:

$$T_K = \frac{\frac{\Delta H}{R}}{-\ln\left(\frac{e^{\left(\frac{-\Delta H}{RT_1}\right)} + e^{\left(\frac{-\Delta H}{RT_2}\right)} + \cdots + e^{\left(\frac{-\Delta H}{RT_n}\right)}}{n}\right)}$$

Where:

n is the number of temperature sample points

Note: In this study MKT is not considered as an acceptance criteria. The acceptance criteria is specified that all data loggers should remain within the specified limits.

Software;

MKT is calculated using our software which is freely available at **http://bit.ly/MKT-calculation**

The above page also explains the step by step method for calculation of MKT

Hot and Cold Points

Hot and cold points are identified by analyzing the individual value of all data loggers

9 EQUIPMENT INSTALLATION/OPERATION DESCRIPTION

The Refrigerated Van is designed to maintain product temperatures between ***2°C to 8°C*** to meet Xxxxx requirements.

The Refrigerated Cold Room is designed to maintain product temperatures between ***2°C to 8°C*** to meet Xxxxx requirements.

The Passive Box is designed to maintain product temperatures between ***2°C to 8°C*** to meet Xxxxx requirements.

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