COMPANY NAME:	**xxxxx**
SITE	**COLD ROOM**
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		
NAME	**SIGNATURE**	**DATE**
Name: xxxx **Title:** **Company:**		
Name: xxxx **Title:** **Company:**		
Name: xxxx **Title:** **Company:**		

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

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SCOPE OF THIS PROTOCOL :

Study Type	Temperature & Humidity - Mapping Study &Qualification
Client name	Xxxxxx
Asset Type	Cold Room
Description and Location	Cold Room, Xxxxxx
Temperature range to be mapped	Low limit 2°C High limit 8°C
Humidity range to be mapped	
Duration of testing	4-5 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 & Humidity switch, etc.), a digital or analog transducer (limit switch, pressure sensor, Temperature & Humidity 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.

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Terms	Definitions
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
IOPQ	Installation / Operational / Performance Qualification
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

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3 SCOPE

The Installation / Operational / Performance Qualification protocol is a comprehensive document, which will be used to guide the executants, in the verification of the proper installation and operation of the Cold Room located at Xxxxxx.

4 OBJECTIVE

The purpose of this Installation / Operational / Performance Qualification is to:

- Temperature mapping study to analyze distribution of Temperature inside the whole area.
- Humidity mapping study to analyze distribution of humidity inside the whole area.
- Briefly describe the equipment, its major components and their roles.
- Verify that the Cold Room is properly installed according to the manufacturer and Xxxxxx specifications thus permitting operation as per design specifications.
- Ensure that appropriate identification and documentation are in place.
- Ensure that the physical characteristics are compatible with planned equipment utilization.
- Ensure that appropriate operation procedures and training program are in place.
- Ensure that appropriate calibration (if necessary) and maintenance program are in place.
- Ensure that all features of the equipment described are functioning in the proper manner as required to perform all operations associated with its use. Specific tests are designed to verify that the equipment operates within all applicable design.
- Hot and Cold points of the Cold Room will be identified.
- Maximum and Minimum percentage of the humidity zones of the Cold Room will be identified.
- Locations for placing sensors for continuous monitoring will be recommended based on the hot and cold points.
- This mapping study will be carried out for two seasons.ie, summer and winter. The recommendations issued in first climatic study will be reviewed and revised after the second climatic study. The results of summer will be considered as worst case scenario and the final recommendations will be considered accordingly.
- Number of data loggers are determined based on the volume of the Cold Room and as per relevant WHO Standards.

Detailed technical information can be found in the technical documents supplied by the manufacturer (refer to Section 12.1: Documentation for Installation).

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5 RATIONALE

Installation / Operational / Performance Qualification is the establishment of documented evidence that the Cold Room is installed in accordance with manufacturer's specification and consistently performs according to design specifications and intended use.

The Installation / Operational / Performance Qualification protocol is designed to allow technical analysis of all applicable installation requirements and operational functions. Proper installation and operation will be established based on the following characteristics:

- Proper installation as per manufacturer Xxxxxx specifications.
- Proper operation of Temperature & Humidity controller buttons as proposed by manufacturer.
- Temperature & Humidity alarms verification
- **Proper Temperature & Humidity control and distribution under empty conditions**
- **Power failure under empty condition.**
- **Proper Temperature & Humidity recovery following a door opening under empty conditions.**
- **Proper Temperature & Humidity control and distribution under 40% loaded conditions.**
- **Proper Temperature & Humidity recovery following a door opening under 40% loaded conditions.**
- **Power failure under 40% loaded condition.**
- **Proper Temperature & Humidity control and distribution under 70% loaded conditions.**
- **Proper Temperature & Humidity recovery following a door opening under 70% loaded conditions.**
- **Power failure under 70% loaded condition.**

One data logger will be placed outside the Cold Room for recording external temperature.

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 & Humidity & humidity data loggers will be used to measure and record temperature. Each data logger has been calibrated and calibration certificates are included in each

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report generated (included in this document). These electronic instruments are verified and calibration reports will be part of the final 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.

This protocol is only applicable for the Cold Room.

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 Xxxxxx personnel, when performing the Installation / Operational / Performance Qualification of the Cold Room shall follow this qualification protocol.

7 RESPONSIBILITY

This qualification protocol must be respected by all Vacker Global and Xxxxxx employees during processing.

The responsibility of the Installation / Operational / Performance Qualification of the Cold Room is attributed to the following:

Responsibilities		
Task	**Vacker Global**	**Xxxxxx**
Make available all documentation required for the Installation / Operational / Performance Qualification for the Cold Room.		✓
Collect information.	✓	
Write the protocol.	✓	
Review and approve the protocol.	✓	✓
Verify that all critical instrument of the equipment have a valid calibration date.	✓	
Arrange loading and unloading goods for the test		✓
Coordinate activity.	✓	✓
Execute the test described in the protocol.	✓	
Log door openings during testing.		✓
Compile and analyze data.	✓	
Write the final report.	✓	
Issue the final report.	✓	

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8 QUALIFICATION DOCUMENTATION

8.1 MANUAL ENTRIES IN PROTOCOL

- All manual entries will be written in edible 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.
- Data applicable in the shaded areas will be gathered during protocol execution.

8.2 DEVIATION REPORTS

Any discrepancy between the installation specifications and the actual (as found) installations, 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 Report.

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.

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8.3 DATA SHEETS

8.3.1 IQ Section

Information pertaining to the Installation Qualification will be directly recorded in the IQ section of this protocol. Here is a brief description of each section.

Section	Description
Specified	Item that should be in place in order to satisfy the specified condition as stated by the manufacturer or regulation (if any). If no specified condition is stated by manufacturer, then «**Not specified**» should be written in the corresponding field.
As Found	Item found at the time of qualification. Should meet or exceed the specified condition. If condition is not specified, «**As Found**» data will then be considered for information purpose.
Pass / Fail	Indication that the item found is compliant with specifications or specified conditions. - A «**Pass**» result indicates that the item is found compliant with specified condition. - A «**Fail**» result indicates that the item is found not compliant with specified condition 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.
Documented by	Signature and corresponding date for the person performing the test.
Verified by	Signature and corresponding date for the person verifying the test data. .(By representatives from Vacker Global and Xxxxxx)

8.3.2 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.

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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 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.

8.3.4 Installation / Operational / Performance Qualification Report

The Installation / Operational / Performance Qualification 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 Installation / Operational / Performance Qualification.

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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 Xxxxxx 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.

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8.5 ANALYSIS

Mean Kinetic Temperature

Mean kinetic Temperature & Humidity (MKT) is a simplified way of expressing the overall effect of temperature fluctuations. Mean Kinetic Temperature & Humidity (MKT) is defined as the single calculated Temperature & Humidity 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 & Humidity 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 & Humidity 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 & Humidity 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 & Humidity 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 & Humidity 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

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9 EQUIPMENT INSTALLATION/OPERATION DESCRIPTION

The Cold Room is installed at Xxxxxx Facilities located at Xxxxxx.

The Cold Room is designated to store the pharmaceuticals products at a Temperature & Humidity between 2°C and 8°C.

The Cold Room have an external dimension of xxx sqm and the layout is as per the attached drawing and photos.

The Cold Room is equipped with 1 Door.

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Please contact us for a free consultation: sales@vackerglobal.com

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