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Thermal Qualification Study For

"Cold Room" (PQ)

Identification No. : Cold Room-02 (Manufacturing Area)

Located At

M/s. PAREKH INTEGRATED SERVICES PVT. LTD.

Thermal Qualification Study Performed On	Thermal Qualification Study Next Due On
04-05-2022	06-05-2025

CoolRoomPrint

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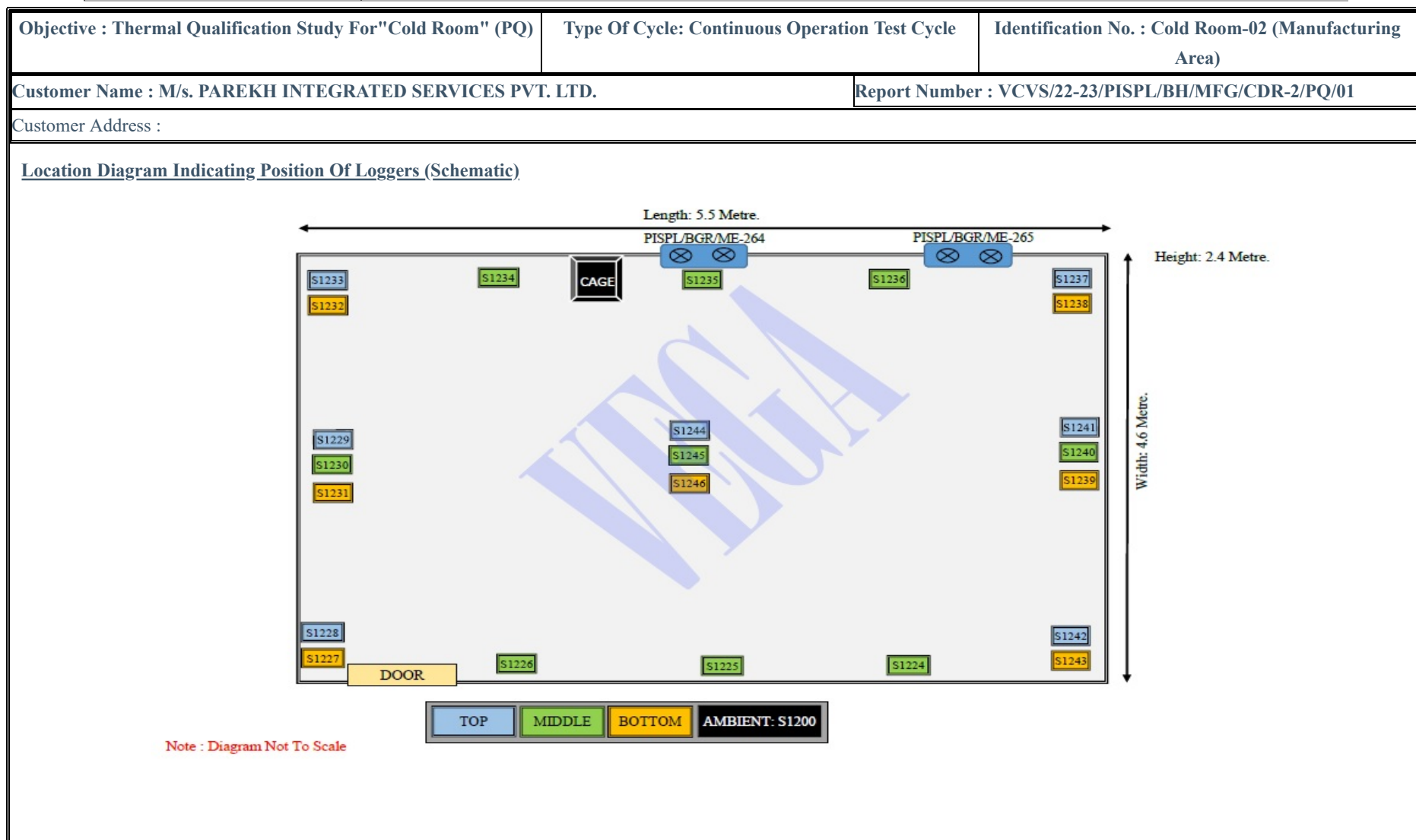
Objective		Report No.		Qualification Performed On		Next Qualification Due On							
Thermal Qualification Study For "Cold Room"		VCVS/22-23/PISPL/BH/MFG/CDR-2		04-05-2022		06-05-2025							
Name Of The Customer : M/s. PAREKH INTEGRATED SERVICES PVT. LTD. Customer address :													
Details For "Cold Room"													
Identification Number Of The "Cold Room"	CFA	Location	Dimensions Mtr			Volume Of Area (Mtr. ³)	Acceptable Operating Range Temperature (°C)	Usage Of The "Cold Room"					
			L	W	H								
Cold Room-02 (Manufacturing Area)	NA	Bhiwandi	5.5	4.6	2.4	60.72 (Mtr. ³)	2°C to 8°C	Storage Of Medicines					
Mapping Cycle Details													
Mapping Cycle Start Date		Mapping Cycle End Date		No. Of Cycles Performed		No. Of Sensing Point		Status					
04-05-2022		07-05-2022		5		23+1 (Ambient)		Loaded					
Details Of The Mapping Cycle													
Start Date	End Date	Set Temp.	Name Of The Cycle		Cycle Start Time (HH:MM:SS)	Cycle End Time (HH:MM:SS)	Recording Interval						
04-05-2022	07-05-2022	4	Continuous Operation Test Cycle		11:00:00	11:00:00	5 Minute						
07-05-2022	07-05-2022	4	Door Open Test Cycle-I		12:45:00	12:55:00	1 Minute						
07-05-2022	07-05-2022	4	Door Open Test Cycle-II		14:09:00	14:31:00	1 Minute						
07-05-2022	07-05-2022	4	Door Open Test Cycle-III		15:49:00	16:05:00	1 Minute						
07-05-2022	07-05-2022	4	Power Failure Test Cycle		17:15:00	17:43:00	1 Minute						
Details Of The Mapping Instrumentation													
Sr. No.		Master Instrument		Identification No.		Calibration Certificate No.							
01		Wireless Data Logger		As Shown In Diagram		As Per Attached Annexure							
For M/s. Vega Calibration And Validation Services LLP.				M/s. PAREKH INTEGRATED SERVICES PVT. LTD.									
Prepared by		Checked By		Reviewed By		Approved By							
Krishnakumar Vishwakarma 30-12-2022 11:23:32		Signed By : Ashwin Masurkar Reason : Authorised Signatory Date/Time : 30-12-2022 11:23:32		30-12-2022 11:23:32		30-12-2022 11:23:32							

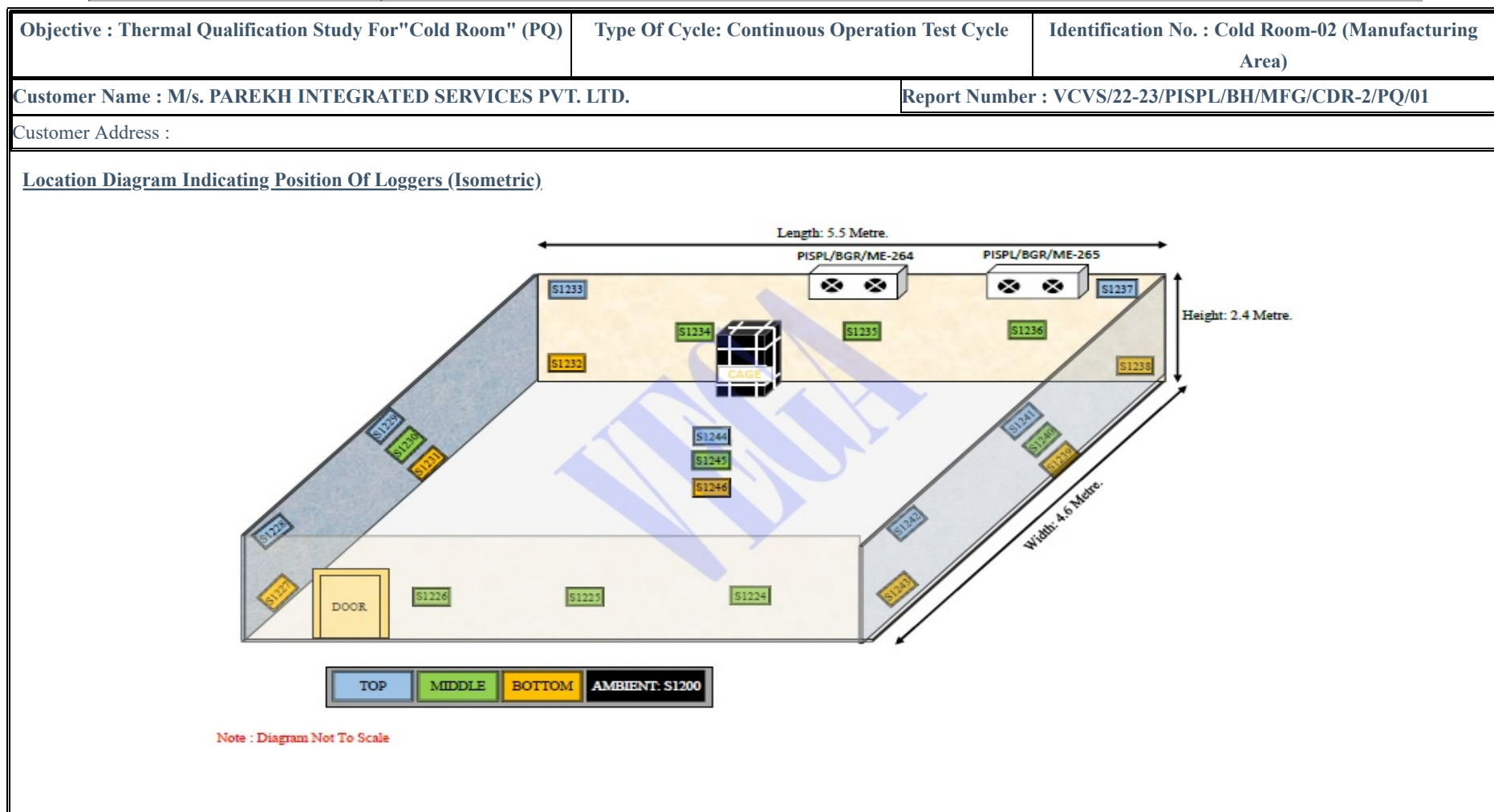
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Objective : Thermal Qualification Study For"Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address :		
<u>Details Of "Air-Conditioning System"</u>		
Volume Of Area (Length*Width*Height)	5.5 X 4.6 X 2.4 =60.72 (Mtr. ³)	
Type Of Air Conditioning Unit	Blowers	
Total Installed Cooling Capacity (Including Split AC's If Any)	20000 BTU X 2 = 40000 BTU	
Total No Of Cooling Units Installed	2	
No Of Blowers Installed	4	
Type Of Switching For Standby Unit(Automatic/Manual)	Automatic	
Identification Number Of Individual AC & Its Switching Frequency	A	B
	PISPL/BGR/ME-264 (12 HRS)	PISPL/BGR/ME-265 (12 HRS)

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Objective : Thermal Qualification Study For"Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address :		
<div style="text-align: center;"><u>Location Diagram And Location Chart</u></div>		





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Objective : Thermal Qualification Study For"Cold Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle		Identification No. : Cold Room-02 (Manufacturing Area)	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	
Customer Address :					
<u>Location Diagram Indicating Position Of Loggers (sheet)</u>					
Sr. No.	LOGGER ID NO.	POSITION			
1	S1224	MIDDLE	4.9	4.6	1.4
2	S1225	MIDDLE	3.1	4.6	1.4
3	S1226	MIDDLE	1.3	4.6	1.4
4	S1227	BOTTOM	0	4.5	0.3
5	S1228	TOP	0	4.5	2.2
6	S1229	TOP	0	2.4	2.2
7	S1230	MIDDLE	0	2.4	1.4
8	S1231	BOTTOM	0	2.4	0.3
9	S1232	BOTTOM	0	0	0.3
10	S1233	TOP	0	0	2.2
11	S1234	MIDDLE	1.3	0	1.4
12	S1235	MIDDLE	3.1	0	1.4
13	S1236	MIDDLE	4.9	0	1.4
14	S1237	TOP	5.5	0	2.2
15	S1238	BOTTOM	5.5	0	0.3
16	S1239	BOTTOM	5.5	2.4	0.3
17	S1240	MIDDLE	5.5	2.4	1.4
18	S1241	TOP	5.5	2.4	2.2
19	S1242	TOP	5.5	4.5	2.2
20	S1243	BOTTOM	5.5	4.5	0.3


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Objective : Thermal Qualification Study For"Cold Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle		Identification No. : Cold Room-02 (Manufacturing Area)	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	
Customer Address :					
<u>Location Diagram Indicating Position Of Loggers (sheet)</u>					
Sr. No.	LOGGER ID NO.	POSITION			
21	S1244	TOP	2.7	2.4	2.2
22	S1245	MIDDLE	2.7	2.4	1.4
23	S1246	BOTTOM	2.7	2.4	0.3
24	S1200	OUTSIDE	Ambient Logger Placed Outside The Cold Room		


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Objective : Thermal Qualification Study For"Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address:		
<div><p><u>Trend For The Cycle: (Temperature Vs Time)</u></p><p><u>Continuous Operation Test Cycle</u></p></div>		

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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Continuous Operation Test Cycle	04-05-2022 11:00:00	07-05-2022 11:00:00
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				
Customer address :				
<p style="text-align: center;">CONTINUOUS OPERATION TEST CYCLE (WITH AMBIENT)</p> <p style="text-align: center;">TREND OF TEMPERATURE VS TIME</p> <p style="text-align: center;"></p>				


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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Continuous Operation Test Cycle	04-05-2022 11:00:00	07-05-2022 11:00:00
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				
Customer address :				
<p style="text-align: center;">CONTINUOUS OPERATION TEST CYCLE (WITHOUT AMBIENT)</p> <p style="text-align: center;">TREND OF TEMPERATURE VS TIME</p> <p style="text-align: center;"></p>				


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Objective : Thermal Qualification Study ForCold Room (PQ)	Type Of Cycle: Door Open Test Cycle-I	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address :		
<div><p><u>Trend For The Cycle: (Temperature Vs Time)</u></p><p><u>Door Open Test Cycle-I</u></p></div>		

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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Door Open Test Cycle-I	07-05-2022 12:45:00	07-05-2022 13:31:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
12:45:00	12:55:00	12:55:00	13:31:00	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				
Customer address :				
DOOR OPEN TEST CYCLE-I (WITH AMBIENT)				
TREND OF TEMPERATURE VS TIME				
				


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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Door Open Test Cycle-I	07-05-2022 12:45:00	07-05-2022 13:31:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
12:45:00	12:55:00	12:55:00	13:31:00	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				
Customer address :				
DOOR OPEN TEST CYCLE-I (WITHOUT AMBIENT)				
TREND OF TEMPERATURE VS TIME				
				


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Objective : Thermal Qualification Study For Cold Room (PQ)	Type Of Cycle: Power Failure Test Cycle	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address :		
<div><p><u>Trend For The Cycle: (Temperature Vs Time)</u></p><p><u>Power Failure Test Cycle</u></p></div>		

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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Power Failure Test Cycle	07-05-2022 17:15:00	07-05-2022 18:21:00
Power OFF Time	Set Limit Cross Out Time	Power ON Time	Set Limit Cross In Time	
17:15:00	17:43:00	17:43:00	18:21:00	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				
Customer address :				
POWER FAILURE TEST CYCLE-I (WITH AMBIENT)				
TREND OF TEMPERATURE VS TIME				
				

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Report Number		Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01		Cold Room-02 (Manufacturing Area)	Power Failure Test Cycle	07-05-2022 17:15:00	07-05-2022 18:21:00
Power OFF Time	Set Limit Cross Out Time		Power ON Time		Set Limit Cross In Time
17:15:00	17:43:00		17:43:00		18:21:00
<div>Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.</div> <div>Customer address :</div>					
<div>POWER FAILURE TEST CYCLE-I (WITHOUT AMBIENT)</div> <div>TREND OF TEMPERATURE VS TIME</div> <div></div>					

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Objective : Thermal Qualification Study For"Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address :		
<div><p><u>Summary and Observation Report Of Parameters Computed</u> <u>During Mapping (Temperature)</u></p></div>		

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Objective : Thermal Qualification Study For"Cold Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle		Identification No. : Cold Room-02 (Manufacturing Area)	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.			Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01		
Customer Address :					
<p><u>Observation and Concluding Remarks</u></p> <p>1. Point S1233 (Average Temperature: 5.05°C) shown in Red color has registered MAXIMUM TEMPERATURE in Loaded condition. So a daily temperature monitoring instrument is suggested to be placed at the location of S1233. When only maximum limit needs to be controlled then treat point S1233 as a HOT SPOT in Loaded condition.</p> <p>2. Point S1244 (Average Temperature: 4.53°C) shown in Green color has registered MINIMUM TEMPERATURE in Loaded condition. So a daily temperature monitoring instrument is suggested to be placed at the location of S1244. When only minimum limit needs to be controlled then treat point S1244 as a COLD SPOT in Loaded condition.</p> <p><u>Conclusion</u></p> <p>The above given Cold Room is monitored for temperature uniformity for 72 Hours in Loaded condition and results found are as per the acceptance criteria. So the Cold Room is in compliance with the defined criteria and qualified for its further use.</p>					
For M/s. Vega Calibration And Validation Services LLP.			M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		
Prepared by	Checked By	Reviewed By	Approved By		
Krishnakumar Vishwakarma					
Note : The results reported in this certificate are valid at the time of temperature mapping activity					

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Objective : Thermal Qualification Study For"Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address :		

MEAN KINETIC TEMPERATURE (M.K.T)

mkt

TK: Mean kinetic temperature in °K

ΔH: Activation Energy for degradation reaction typically taken as 8.3144 kJ/mole

R is the universal gas constant = 8.3144x 10⁻³ kJ per degree per mol

T1 to Tn are the average temperatures at each of the sample points in °K

n is the number of temperature sample points

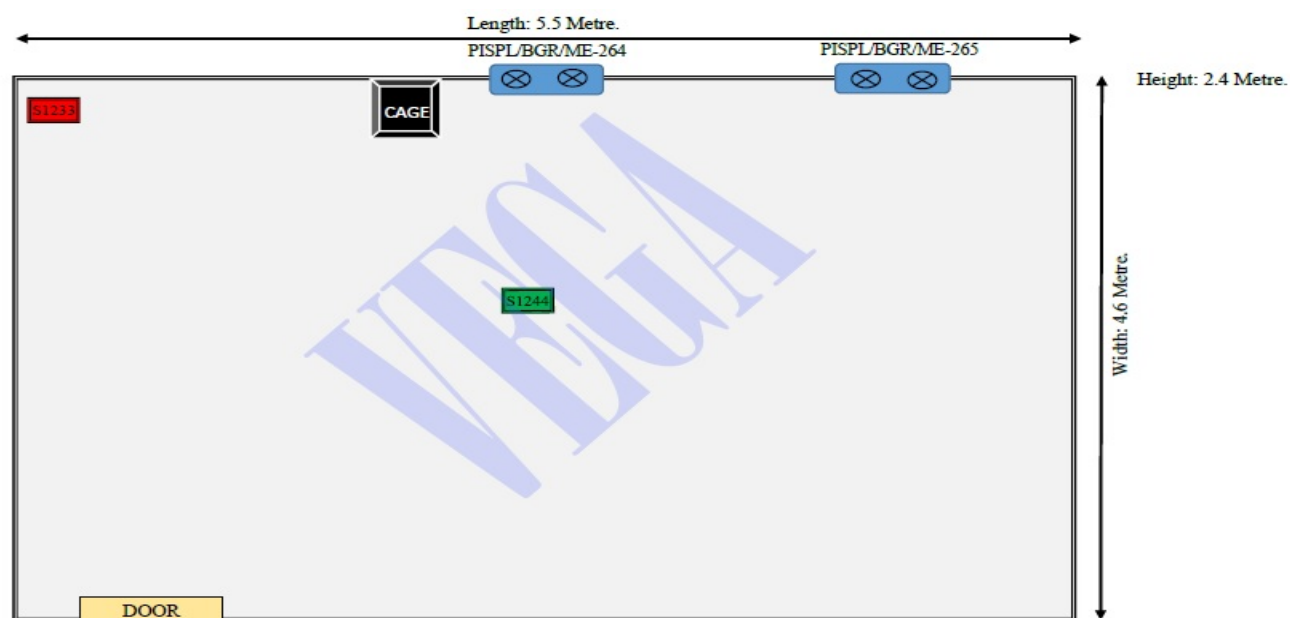
M . K . T = 4.8

"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.

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Objective : Thermal Qualification Study For"Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address :		

Location Diagram Indicating Position Of Loggers



Note : Diagram Not To Scale

Average Maximum Temperature	
HOT SPOT	TOP

Average Minimum Temperature	
COLD SPOT	TOP

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Objective : Thermal Qualification Study For"Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address :		
<u>Observation Remarks</u> 1. During Door Open Test Cycles, when Door was Opened, Excursion was observed after 16 mins and Normal Operation Range was recovered within 35 mins. 2.During Power Failure Test Cycle, when Power Supply was Switched OFF, Excursion was observed after 28 mins and Normal Operation Range was recovered within 38 mins.		

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Objective : Thermal Qualification Study For"Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01
Customer Address :		
<p><u>List Of Annexures</u></p> <p>1. Annexure-1 BGR COLD ROOM 2 PQ_1672384390.pdf</p> <p>2. Annexure-2 no_file_4.pdf</p> <p>3. Annexure-3 User Certificate:Please upload user certificate</p> <p>4. Sensor Certificates:</p> <p> Please upload Sensor certificate</p>		