



VEGA Calibration And Validation Services LLP.

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Digitally Signed By : Dhiraj Barge

Reason : Authorised Signatory

Date/Time :29-02-2024 11:12:08

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Thermal Qualification Study For

"Cool Room" (PQ)

Identification No. : COOL ROOM 01

Located At

M/s. PAREKH INTEGRATED SERVICES PVT. LTD.

Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI

Thermal Qualification Study Performed On	Thermal Qualification Study Next Due On
26-12-2023	25-12-2026



VEGA Calibration And Validation Services LLP.

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Date/Time :29-02-2024 11:12:08

Objective			Report No.			Qualification Performed On		Next Qualification Due On	
Thermal Qualification Study For "Cool Room" (PQ)			VCVS/23-24/PISPL/HUB/CLR01/PQ/01			26-12-2023		25-12-2026	
Name Of The Customer : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.									
Customer address :Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI									
Details For "Cool Room"									
ID No. Of The "Cool Room"		Activity/CFA	Location	Dimensions Mtr			Volume Of Area (Mtr. ³)	Acceptable Operating Range Temperature (°C)	Usage Of The "Cool Room"
				L	W	H			
COOL ROOM 01		ALCON SURGICAL	Hubli	5.3	7	4.2	155.82 (Mtr. ³)	15°C to 25°C	Storage Of Surgical Products
Mapping Cycle Start Date		Mapping Cycle End Date		No. Of Cycles Performed			No. Of Sensing Point		Status
26-12-2023		29-12-2023		1			27+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
26-12-2023	29-12-2023	21°C	Continuous Operation Test Cycle		15:00:00		15:00:00		5 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	
Digitally Signed By : ABHISHEK SHARMA Reason : Authorised Signatory Date/Time : 29-02-2024 10:43:43		Digitally Signed By : Dhiraj Barge Reason : Authorised Signatory Date/Time :29-02-2024 11:12:08			Digitally Signed By : Reason : Authorised Signatory Date/Time : N/A			Digitally Signed By : Reason : Authorised Signatory Date/Time : N/A	



Date/Time :29-02-2024 11:12:08

Objective : Thermal Qualification Study For"Cool Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle		Identification No. : COOL ROOM 01	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01	
Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI					
<u>Details Of "Air-Conditioning System"</u>					
Volume Of Area (Length*Width*Height)		5.3 X 7 X 4.2 =155.82 (Mtr. ³)			
Type Of Air Conditioning Unit		Split AC			
Total Installed Cooling Capacity (Including Split AC's If Any)		(3 X 1.5 TONS) = 4.5 TONS			
Total No Of Cooling Units Installed		3			
No Of Blowers Installed		N/A			
Type Of Switching For Standby Unit(Automatic/Manual)		MANUAL (Note:- Out of 3 AC units, 2 AC units shall be running all the time and 1 AC unit shall be put on standby after every 24 hrs on alternative basis.)			
Identification Number Of Individual AC & Its Operating period		A		C	
		PISPL/FA/AC/HUB/079		PISPL/FA/AC/HUB/085	
		B		C	
		PISPL/FA/AC/HUB/086		PISPL/FA/AC/HUB/087	

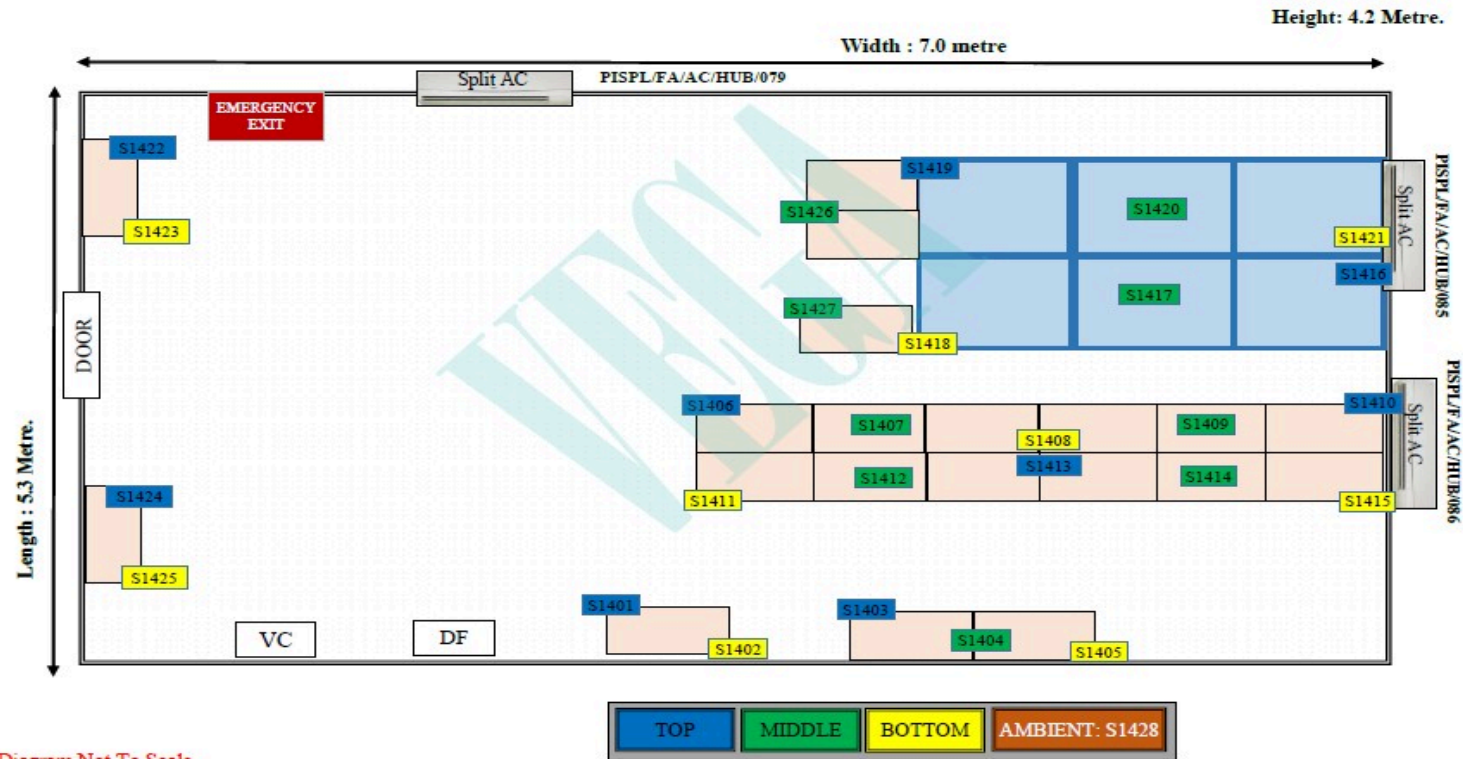


Objective : Thermal Qualification Study For"Cool Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle	Identification No. : COOL ROOM 01
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.			Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01
Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI			
<div style="text-align: center;"><u>Location Diagram And Location Chart</u></div>			



Objective : Thermal Qualification Study For"Cool Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : COOL ROOM 01
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01
Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI		

Location Diagram Indicating Position Of Loggers (Schematic)



Note : Diagram Not To Scale



Objective : Thermal Qualification Study For"Cool Room" (PQ)

Type Of Cycle: Continuous Operation Test Cycle

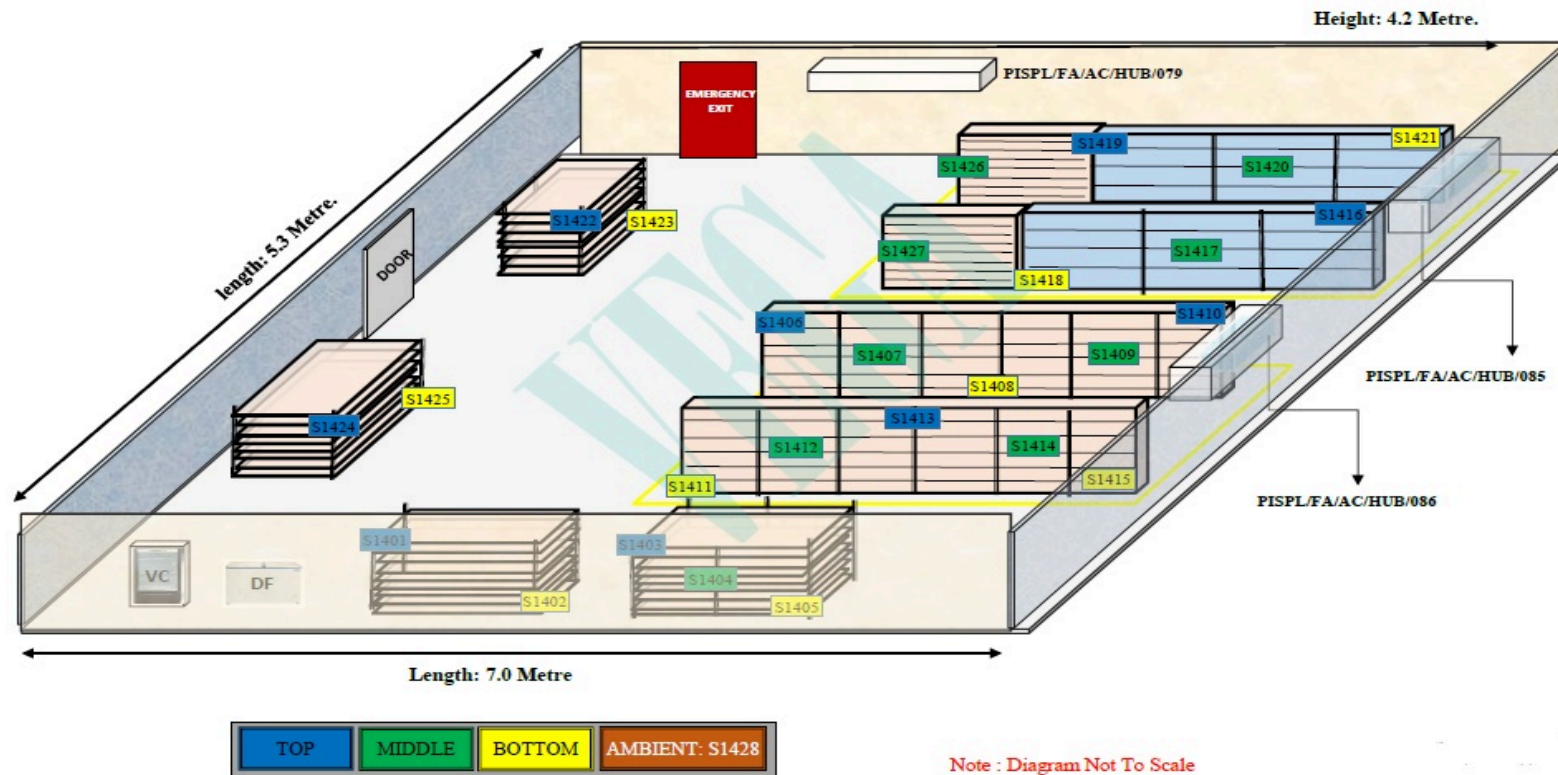
Identification No. : COOL ROOM 01

Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.

Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01

Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI

Location Diagram Indicating Position Of Loggers (Isometric)



Note : Diagram Not To Scale



Objective : Thermal Qualification Study For"Cool Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle		Identification No. : COOL ROOM 01	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01	
Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI					
Location Diagram Indicating Position Of Loggers					
Sr. No.	LOGGER ID NO.	POSITION	Distance From Left Side Wall (Mtr.)	Distance From Front Side Wall (Mtr.)	Distance From Ground (Mtr.)
1	S1401	TOP	4.7	5.8	1.8
2	S1402	BOTTOM	4.7	4.9	0.3
3	S1403	TOP	4.7	4.4	1.8
4	S1404	MIDDLE	4.7	3.5	1
5	S1405	BOTTOM	4.7	2.6	0.3
6	S1406	TOP	3.2	5.4	1.8
7	S1407	MIDDLE	3.2	4.1	1
8	S1408	BOTTOM	3.2	2.7	0.3
9	S1409	MIDDLE	3.2	1.3	1
10	S1410	TOP	3.2	0.1	1.8
11	S1411	BOTTOM	4.1	5.4	0.3
12	S1412	MIDDLE	4.1	4.1	1
13	S1413	TOP	4.1	2.7	1.8
14	S1414	MIDDLE	4.1	1.3	1
15	S1415	BOTTOM	4.1	0.1	0.3
16	S1416	TOP	2.6	0.1	1.8
17	S1417	MIDDLE	2.6	1.8	1
18	S1418	BOTTOM	2.6	3.7	0.3
19	S1419	TOP	0.7	3.7	1.8
20	S1420	MIDDLE	0.7	1.8	1



Objective : Thermal Qualification Study For"Cool Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle		Identification No. : COOL ROOM 01	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01	
Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI					
<u>Location Diagram Indicating Position Of Loggers</u>					
Sr. No.	LOGGER ID NO.	POSITION	Distance From Left Side Wall (Mtr.)	Distance From Front Side Wall (Mtr.)	Distance From Ground (Mtr.)
21	S1421	BOTTOM	0.7	0.1	0.3
22	S1422	TOP	0.4	0.7	1.8
23	S1423	BOTTOM	1.5	0.7	0.3
24	S1424	TOP	3.2	0.7	1.8
25	S1425	BOTTOM	4.1	0.7	0.3
26	S1426	MIDDLE	0.7	4.4	1.3
27	S1427	MIDDLE	2.1	4.4	1.3
28	S1428	Ambient logger Placed Outside the Cool Room	NA	NA	NA



Objective : Thermal Qualification Study For"Cool Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : COOL ROOM 01
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01
Customer Address: Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI		
<div><p><u>Trend For The Cycle: (Temperature Vs Time)</u></p><p><u>Continuous Operation Test Cycle</u></p></div>		



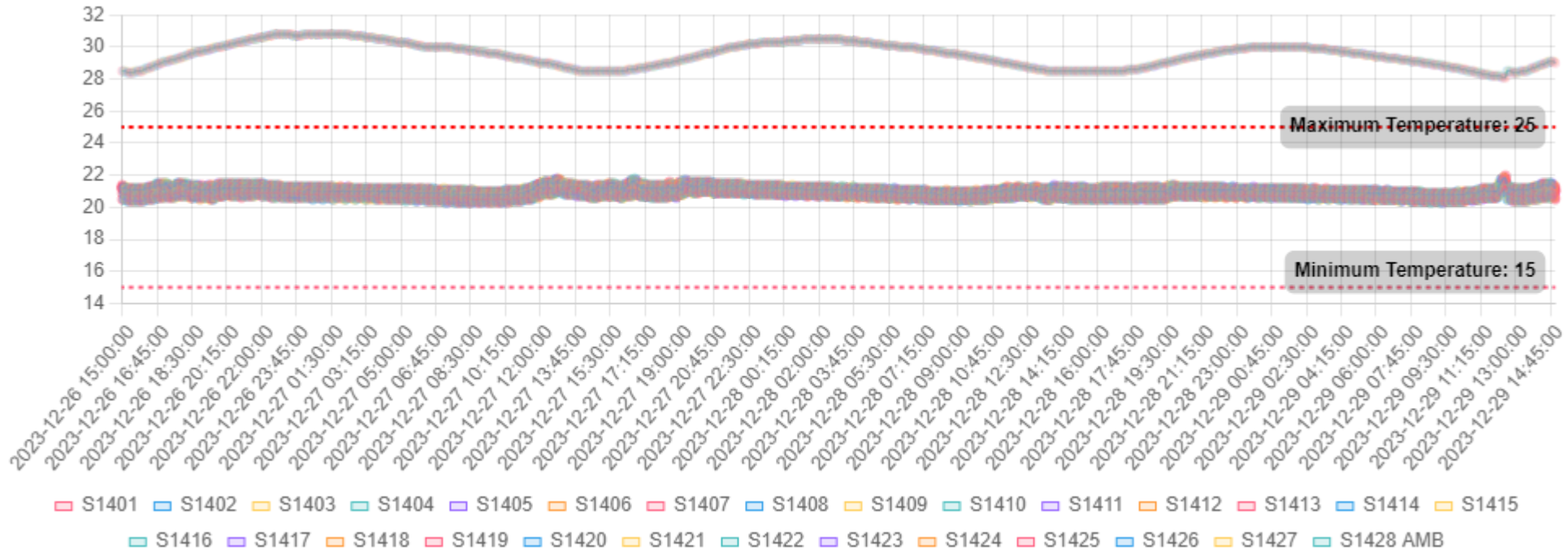
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/23-24/PISPL/HUB/CLR01/PQ/01	COOL ROOM 01	Continuous Operation Test Cycle	26-12-2023 15:00:00	29-12-2023 15:00:00

Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.

Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI

CONTINUOUS OPERATION TEST CYCLE (WITH AMBIENT)

TREND OF TEMPERATURE VS TIME





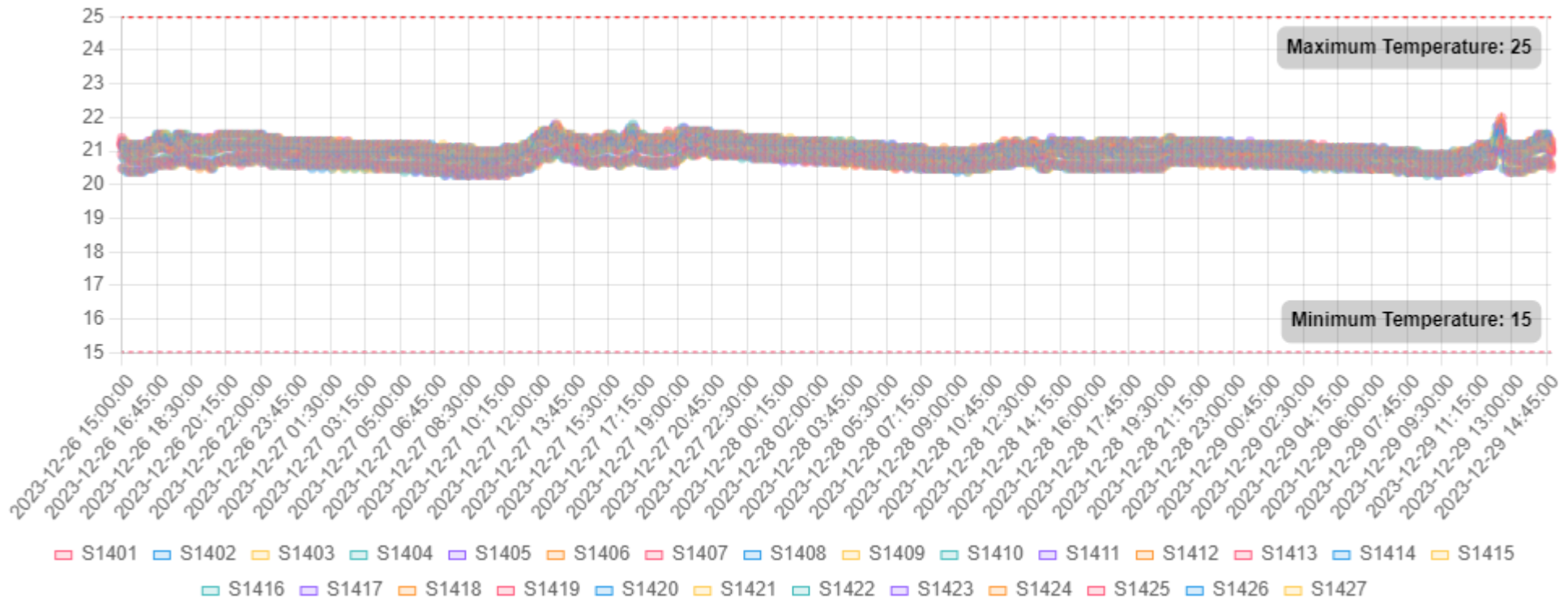
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/23-24/PISPL/HUB/CLR01/PQ/01	COOL ROOM 01	Continuous Operation Test Cycle	26-12-2023 15:00:00	29-12-2023 15:00:00

Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.

Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI

CONTINUOUS OPERATION TEST CYCLE (WITHOUT AMBIENT)

TREND OF TEMPERATURE VS TIME





Objective : Thermal Qualification Study For"Cool Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : COOL ROOM 01
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01
Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI		
<p style="text-align: center;"><u>Summary and Observation Report Of Parameters Computed</u> <u>During Mapping (Temperature)</u></p>		



Date/Time :29-02-2024 11:12:08

Summary of Parameters Computed During Mapping (Temperature)

Average Maximum Temperature Point HOT SPOT (TOP)

Average Minimum Temperature Point
COLD SPOT (BOTTOM)



Objective : Thermal Qualification Study For"Cool Room" (PQ)

Type Of Cycle: Continuous Operation Test Cycle

Identification No. : COOL ROOM 01

Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.

Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01

Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI

Summary of Parameters Computed During Mapping (Temperature)

Position	S1416	S1417	S1418	S1419	S1420	S1421	S1422	S1423	S1424	S1425	S1426	S1427	S1428 AMB
AVERAGE MINIMUM TEMPERATURE °C	20.64	20.79	20.28	20.75	20.73	20.38	20.88	20.78	20.90	20.72	20.63	20.78	28.10
AVERAGE MAXIMUM TEMPERATURE °C	21.64	21.69	21.78	21.62	21.61	21.28	21.98	21.78	22.00	21.62	21.63	21.68	30.80
AVERAGE TEMPERATURE °C	20.96	21.06	20.59	21.03	21.02	20.66	21.24	21.04	21.26	21.01	20.95	21.05	29.51
(MAX-MIN)TEMPERATURE °C	1.00	0.90	1.50	0.87	0.88	0.90	1.10	1.00	1.10	0.90	1.00	0.90	2.70
STANDARD DEVIATION °C	0.08	0.08	0.08	0.08	0.08	0.08	0.09	0.07	0.09	0.08	0.08	0.08	0.37

Average Maximum Temperature Point
HOT SPOT (TOP)

Average Minimum Temperature Point
COLD SPOT (BOTTOM)



Objective : Thermal Qualification Study For"Cool Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle		Identification No. : COOL ROOM 01	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.			Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01		
Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI					
<p><u>Observation and Concluding Remarks</u></p> <p>1. Point S1424 (Average Maximum Temperature: 21.26°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 S1424. When only maximum limit needs to be controlled then treat point S1424 as a HOT SPOT in Loaded condition.</p> <p>2. Point S1418 (Average Minimum Temperature: 20.59°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 S1418. When only minimum limit needs to be controlled then treat point S1418 as a COLD SPOT in Loaded condition.</p> <p><u>Conclusion</u></p> <p>The above given Cool Room is monitored for temperature uniformity for 72 Hours in Loaded condition and results found are as per the acceptance criteria. So the Cool 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	
Digitally Signed By : ABHISHEK SHARMA Reason : Authorised Signatory Date/Time : 29-02-2024 10:43:43		Digitally Signed By : Dhiraj Barge Reason : Authorised Signatory Date/Time :29-02-2024 11:12:08		Digitally Signed By : Reason : Authorised Signatory Date/Time : N/A	
Note : The results reported in this certificate are valid at the time of temperature mapping activity					



Objective : Thermal Qualification Study For"Cool Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle	Identification No. : COOL ROOM 01
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01	
Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI			
<p><u>MEAN KINETIC TEMPERATURE (M.K.T)</u></p> <div>$T_K = \frac{\frac{\Delta H}{R}}{-\ln \left(\frac{e^{-\Delta H/RT_1} + e^{-\Delta H/RT_2} + \dots + e^{-\Delta H/RT_n}}{n} \right)}$</div> <p>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 = 21.0°C "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.</p> <p>Note: All Parameters Are Computed Based On The Attached Raw Data.</p>			



Objective : Thermal Qualification Study For"Cool Room" (PQ)

Type Of Cycle: Continuous Operation Test Cycle

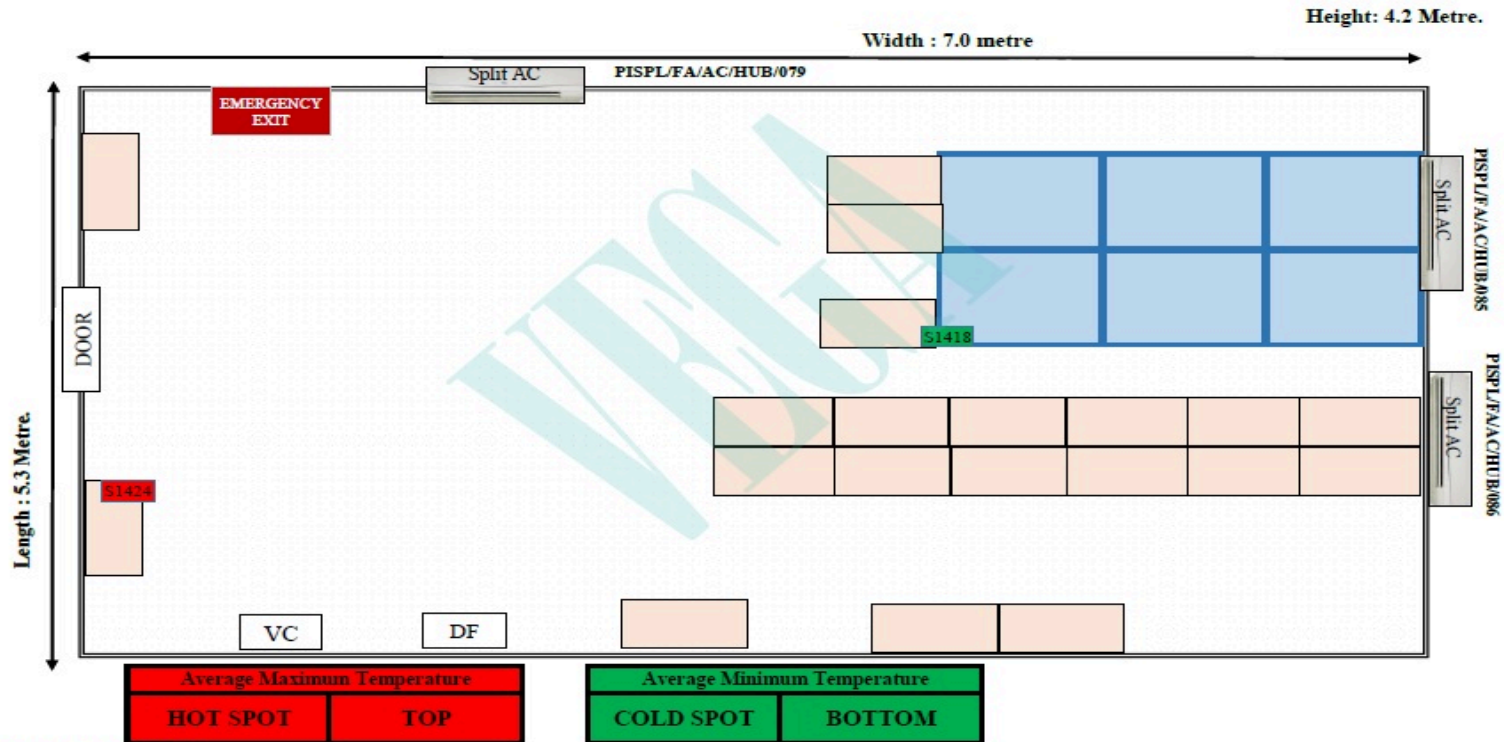
Identification No. : COOL ROOM 01

Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.

Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01

Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI

Location Chart Indicating Position Of Maximum and Minimum Average Temperature Point



Note : Diagram Not To Scale



Objective : Thermal Qualification Study For"Cool Room" (PQ)		Type Of Cycle: Continuous Operation Test Cycle	Identification No. : COOL ROOM 01
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.			Report Number : VCVS/23-24/PISPL/HUB/CLR01/PQ/01
Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI			
<p><u>List Of Annexures</u></p> <p>1. Annexure-1 HUBLI COOL ROOM RAW DATA _1709180803.pdf</p> <p>2. Annexure-2 data_logger_tracibility_1709181462.pdf</p> <p>3. Annexure-3 Training Certificate- Abdul_1709180803.pdf</p>			