



# VEGA Calibration And Validation Services LLP.

Lab Add:C/105, Jaswanti Allied Business Center, Ramchandra Lane Extn., Kachpada, Malad(W). Mumbai-400064

Email : support@vegacalibrations.com Website : www.vegacalibrations.com

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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



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<b>Objective</b>			<b>Report No.</b>			<b>Qualification Performed On</b>		<b>Next Qualification Due On</b>	
Thermal Qualification Study For "Cool Room" (PQ)			VCVS/23-24/PISPL/HUB/CLR01/PQ/01			26-12-2023		25-12-2026	
<b>Name Of The Customer : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.</b>									
Customer address :Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI									
<b>Details For "Cool Room"</b>									
<b>ID No. Of The "Cool Room"</b>	<b>Activity/CFA</b>	<b>Location</b>	<b>Dimensions Mtr</b>			<b>Volume Of Area (Mtr.<sup>3</sup>)</b>	<b>Acceptable Operating Range Temperature (°C)</b>	<b>Usage Of The "Cool Room"</b>	
			<b>L</b>	<b>W</b>	<b>H</b>				
COOL ROOM 01	ALCON SURGICAL	Hubli	5.3	7	4.2	155.82 (Mtr. <sup>3</sup> )	15°C to 25°C	Storage Of Surgical Products	
<b>Mapping Cycle Details</b>									
<b>Mapping Cycle Start Date</b>		<b>Mapping Cycle End Date</b>		<b>No. Of Cycles Performed</b>		<b>No. Of Sensing Point</b>		<b>Status</b>	
26-12-2023		29-12-2023		1		27+1(Ambient)		Loaded	
<b>Details Of The Mapping Cycle</b>									
<b>Start Date</b>	<b>End Date</b>	<b>Set Temp.</b>	<b>Name Of The Cycle</b>		<b>Cycle Start Time (HH:MM:SS)</b>		<b>Cycle End Time (HH:MM:SS)</b>		<b>Recording Interval</b>
26-12-2023	29-12-2023	21°C	Continuous Operation Test Cycle		15:00:00		15:00:00		5 Minute
<b>Details Of The Mapping Instrumentation</b>									
<b>Sr. No.</b>		<b>Master Instrument</b>			<b>Identification No.</b>		<b>Calibration Certificate No.</b>		
01		Wireless Data Logger			As Shown In Diagram		As Per Attached Annexure		
<b>For M/s. Vega Calibration And Validation Services LLP.</b>					<b>M/s. PAREKH INTEGRATED SERVICES PVT. LTD.</b>				
<b>Prepared by</b>		<b>Checked By</b>			<b>Reviewed By</b>		<b>Approved By</b>		
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		



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## Details Of "Air-Conditioning System"

Volume Of Area (Length*Width*Height)	5.3 X 7 X 4.2 =155.82 (Mtr. <sup>3</sup> )		
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		
Identification Number Of Individual AC & Its Operating period	A	B	C
	PISPL/FA/AC/HUB/079	PISPL/FA/AC/HUB/085	PISPL/FA/AC/HUB/086

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.



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<div style="text-align: center;"><u>Location Diagram And Location Chart</u></div>		



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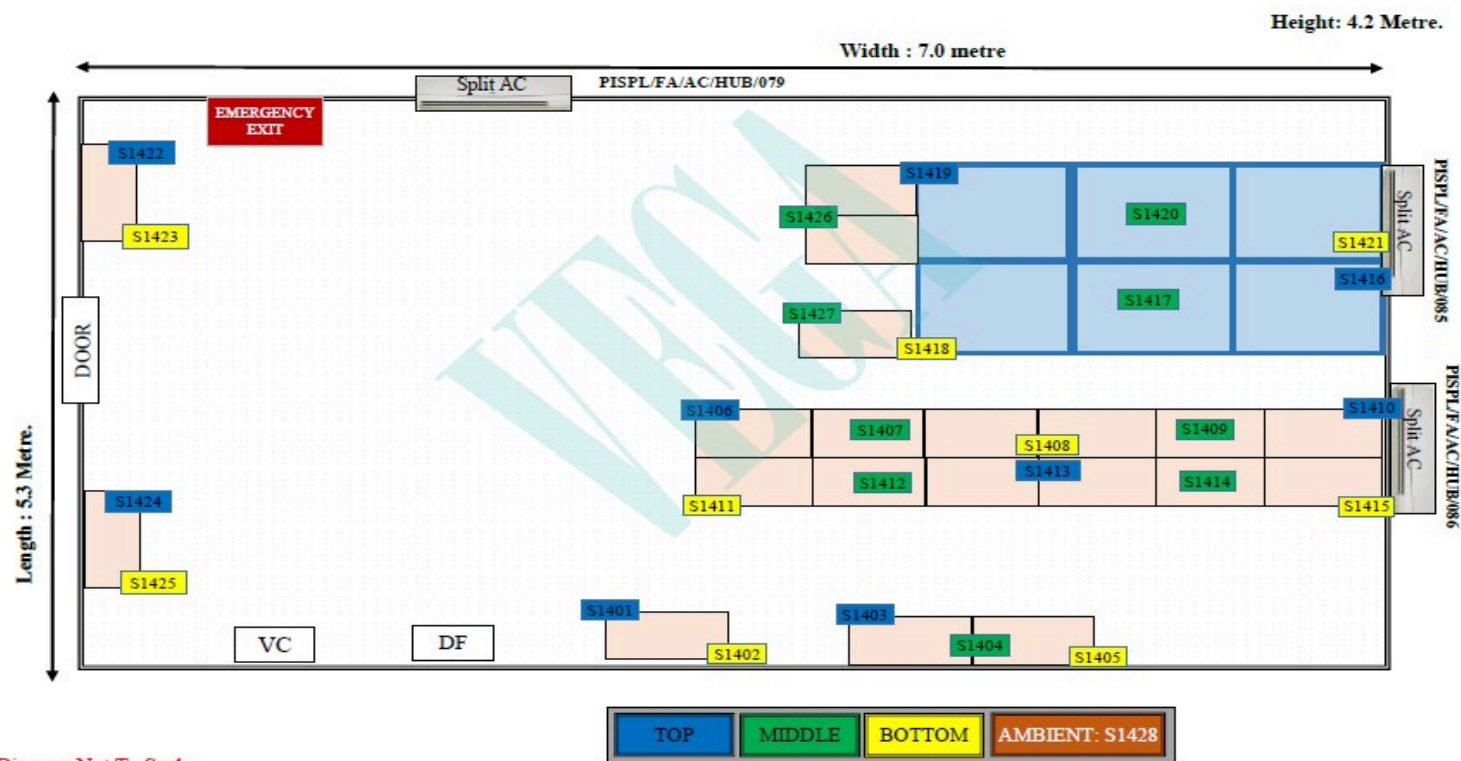
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## Location Diagram Indicating Position Of Loggers (Schematic)



Note : Diagram Not To Scale



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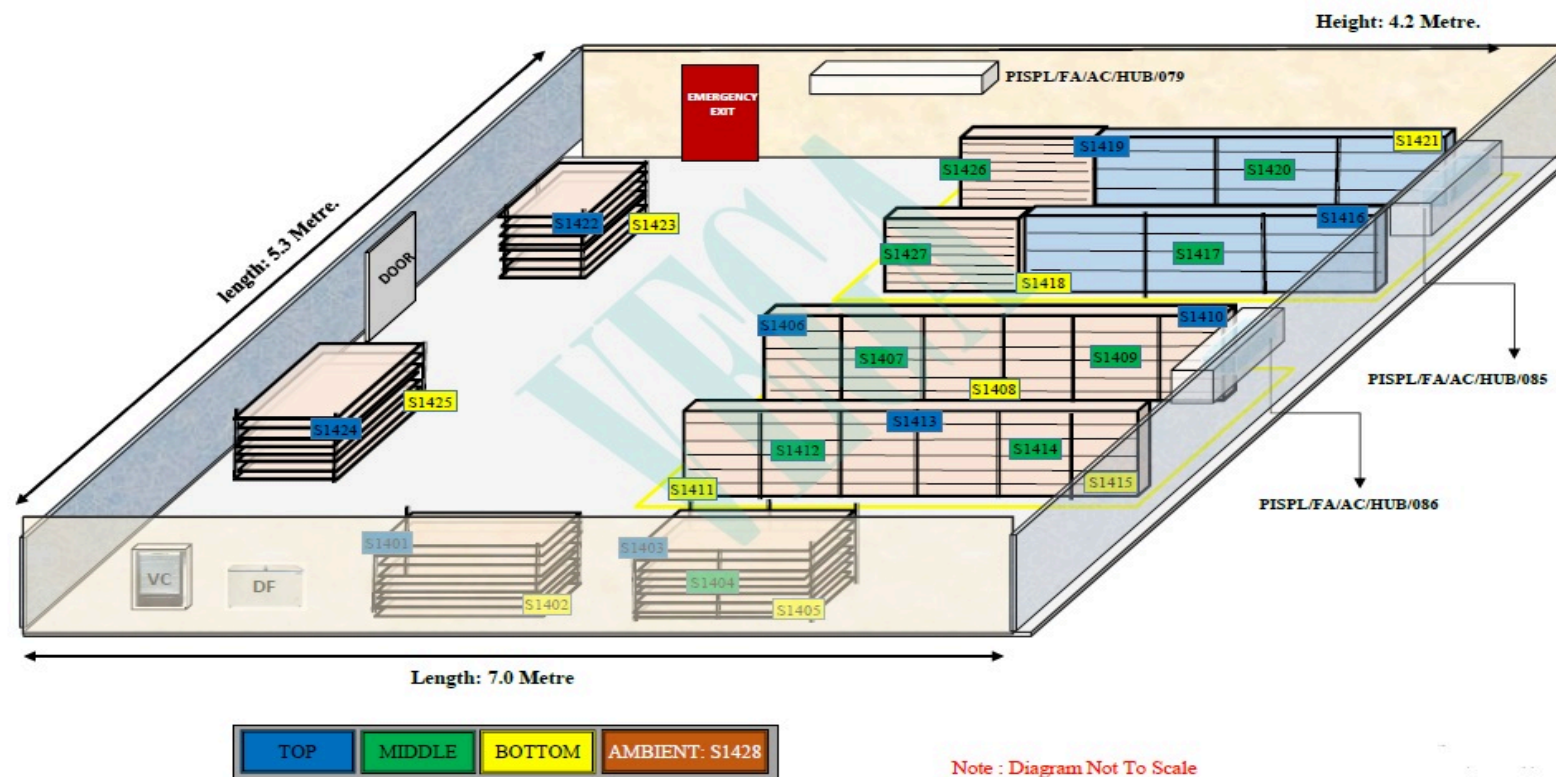
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## Location Diagram Indicating Position Of Loggers (Isometric)





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<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.)	
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	





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<b>Customer Address : Basava Shri, C.S. No. 4776, Shed No. B-3, Industrial Estate, 1st Gate, Gokul Road, Hubli-580030. HUBLI</b>					
<b><u>Location Diagram Indicating Position Of Loggers</u></b>					
<b>Sr. No.</b>	<b>LOGGER ID NO.</b>	<b>POSITION</b>	<b>Distance From Left Side Wall (Mtr.)</b>	<b>Distance From Front Side Wall (Mtr.)</b>	<b>Distance From Ground (Mtr.)</b>
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



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<p style="text-align: center;"><u>Trend For The Cycle: (Temperature Vs Time)</u> <u>Continuous Operation Test Cycle</u></p>		



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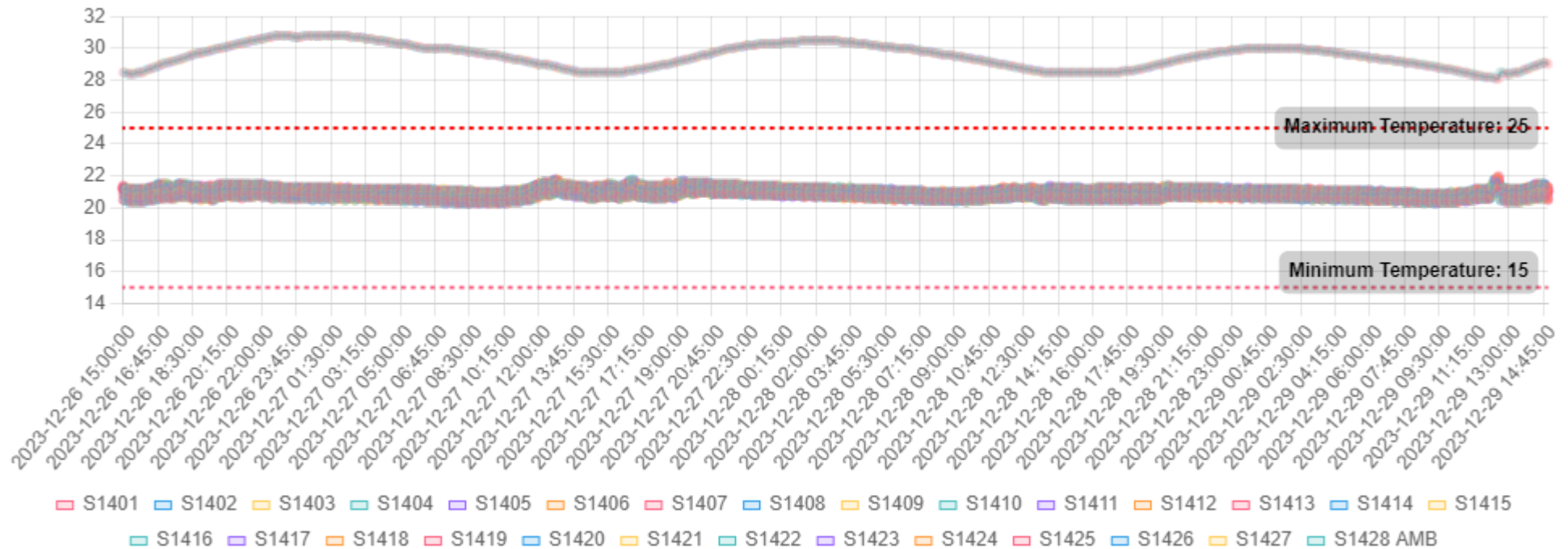
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/23-24/PISPL/HUB/CLR01/PQ/01	COOL ROOM 01	Continuous Operation Test Cycle	26-12-2023 15:00:00	29-12-2023 15:00:00

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





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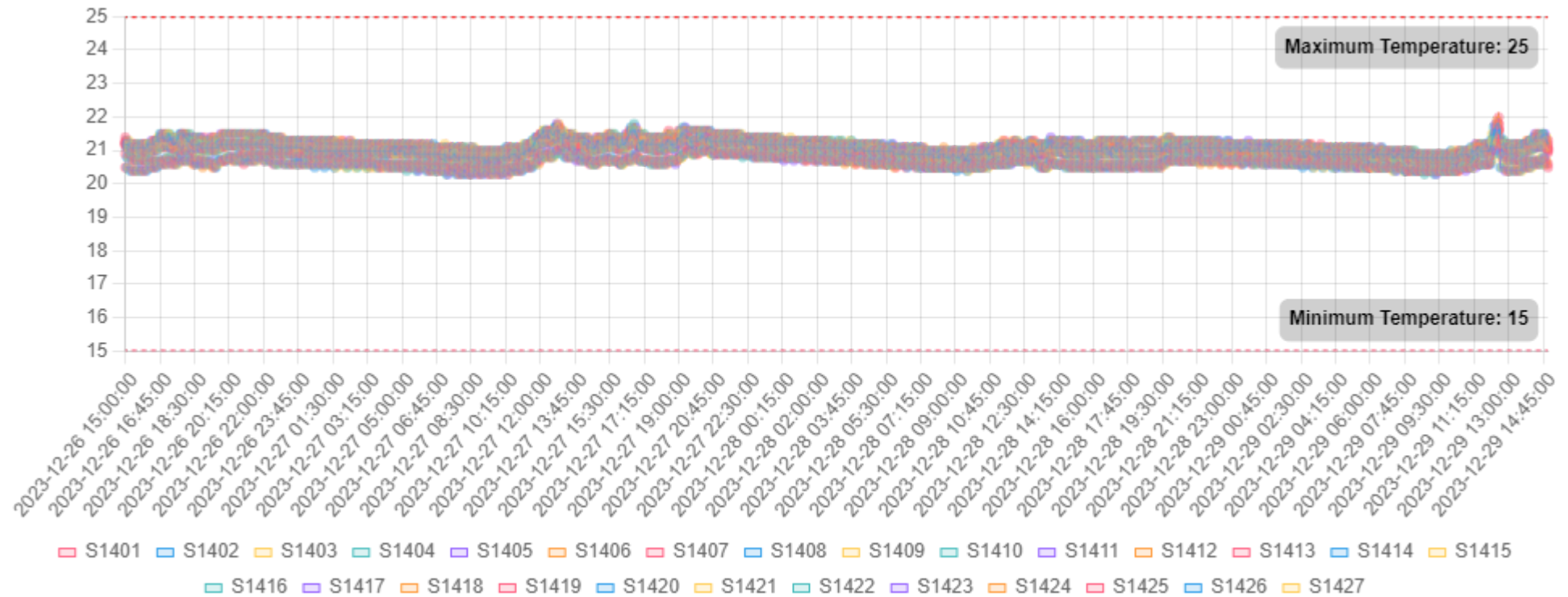
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VCVS/23-24/PISPL/HUB/CLR01/PQ/01	COOL ROOM 01	Continuous Operation Test Cycle	26-12-2023 15:00:00	29-12-2023 15:00:00

**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





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<p style="text-align: center;"><u>Summary and Observation Report Of Parameters Computed</u> <u>During Mapping (Temperature)</u></p>		



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<u>Summary of Parameters Computed During Mapping (Temperature)</u>															
Position	S1401	S1402	S1403	S1404	S1405	S1406	S1407	S1408	S1409	S1410	S1411	S1412	S1413	S1414	S1415
AVERAGE MINIMUM TEMPERATURE °C	20.40	20.68	20.80	20.70	20.30	20.65	20.80	20.73	20.76	20.74	20.39	20.89	20.79	20.69	20.29
AVERAGE MAXIMUM TEMPERATURE °C	21.30	21.78	21.80	21.80	21.80	21.65	21.70	21.63	21.63	21.62	21.29	21.99	21.79	21.79	21.79
AVERAGE TEMPERATURE °C	20.68	21.05	21.06	21.07	20.61	20.97	21.07	21.02	21.04	21.03	20.67	21.25	21.05	21.06	20.60
(MAX-MIN)TEMPERATURE °C	0.90	1.10	1.00	1.10	1.50	1.00	0.90	0.90	0.87	0.88	0.90	1.10	1.00	1.10	1.50
STANDARD DEVIATION °C	0.09	0.10	0.08	0.10	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.10	0.08	0.10	0.09
<div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="background-color: red; color: white; padding: 10px; text-align: center;"> <b>Average Maximum Temperature Point HOT SPOT (TOP)</b> </div> <div style="background-color: green; color: white; padding: 10px; text-align: center;"> <b>Average Minimum Temperature Point COLD SPOT (BOTTOM)</b> </div> </div>															



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<u>Summary of Parameters Computed During Mapping (Temperature)</u>													
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	0.09	0.09	0.09	0.09	0.09	0.09	0.10	0.08	0.10	0.09	0.09	0.09	0.43
<div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="background-color: red; color: white; padding: 10px; text-align: center;"> <b>Average Maximum Temperature Point HOT SPOT (TOP)</b> </div> <div style="background-color: green; color: white; padding: 10px; text-align: center;"> <b>Average Minimum Temperature Point COLD SPOT (BOTTOM)</b> </div> </div>													



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<p><b><u>Observation and Concluding Remarks</u></b></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><b><u>Conclusion</u></b></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.		
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<p><b>Note : The results reported in this certificate are valid at the time of temperature mapping activity</b></p>					





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## MEAN KINETIC TEMPERATURE (M.K.T)

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

**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<sup>-3</sup> 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.

**Note: All Parameters Are Computed Based On The Attached Raw Data.**



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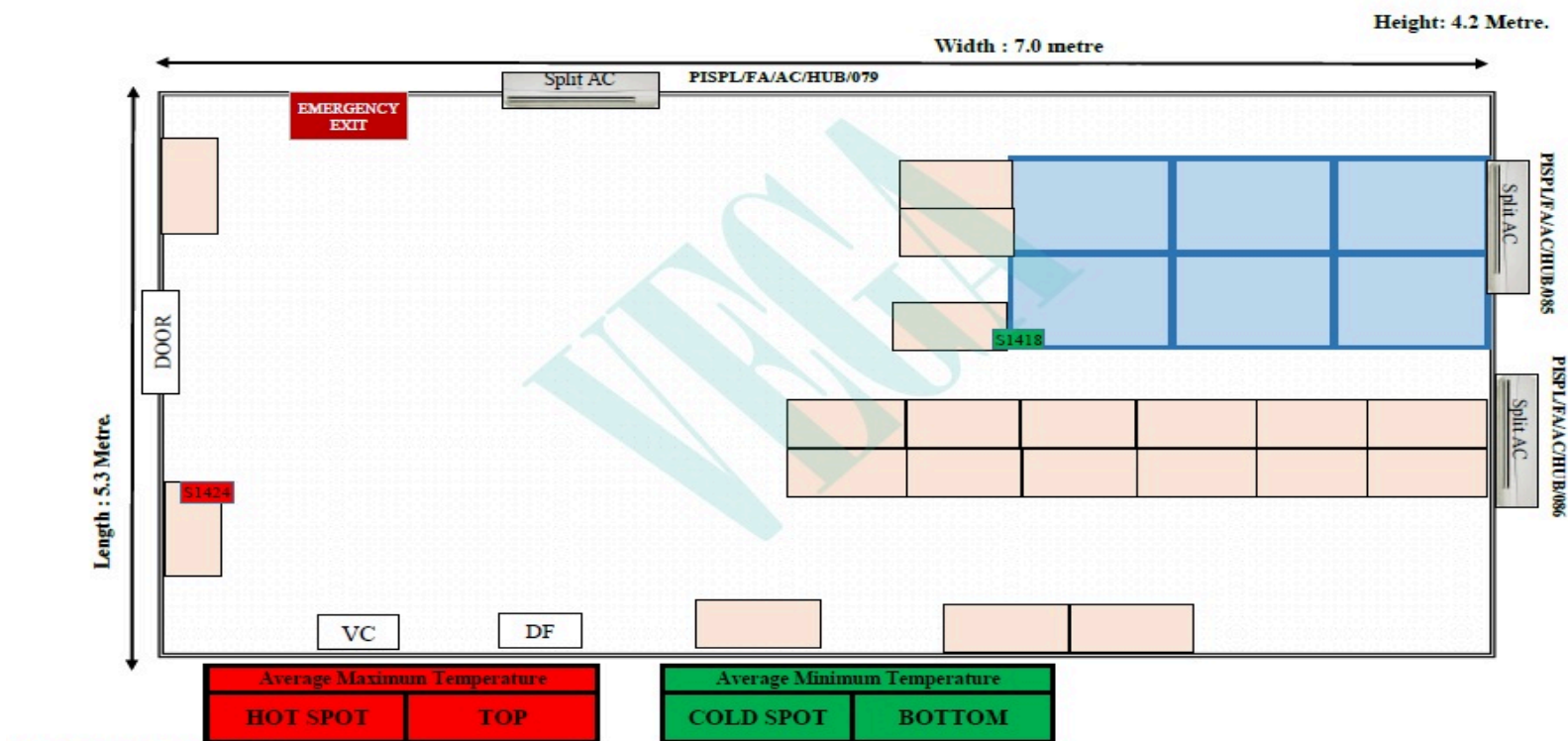
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## Location Chart Indicating Position Of Maximum and Minimum Average Temperature Point



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<p><b><u>List Of Annexures</u></b></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>		