



VEGA Calibration And Validation Services LLP.

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Reason : Authorised Signatory

Date/Time :29-02-2024 10:28:49

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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.

Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN

Thermal Qualification Study Performed On	Thermal Qualification Study Next Due On
05-02-2024	04-02-2027



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Objective			Report No.			Qualification Performed On		Next Qualification Due On	
Thermal Qualification Study For "Cool Room" (PQ)			VCVS/23- 24/PISPL/ALC/DDN/CLR/PQ/02			05-02-2024		04-02-2027	
Name Of The Customer : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.									
Customer address :Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN									
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	DEHRADUN	7.4	4.9	3	108.78 (Mtr. ³)	15°C to 25°C	Storage Of Surgical Products	
Mapping Cycle Start Date									
05-02-2024		Mapping Cycle End Date		08-02-2024		No. Of Cycles Performed		1	
						No. Of Sensing Point		21+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
05-02-2024	08-02-2024	20°C - 22°C	Continuous Operation Test Cycle		10:00:00		10:00:00		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 : Akash Shinde Reason : Authorised Signatory Date/Time : 17-02-2024 11:09:16		Digitally Signed By : Dhiraj Barge Reason : Authorised Signatory Date/Time :29-02-2024 10:28:49			Digitally Signed By : Reason : Authorised Signatory Date/Time : N/A			Digitally Signed By : Reason : Authorised Signatory Date/Time : N/A	



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Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				Report Number : VCVS/23-24/PISPL/ALC/DDN/CLR/PQ/02	
Customer Address : Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN					
<u>Details Of "Air-Conditioning System"</u>					
Volume Of Area (Length*Width*Height)		7.4 X 4.9 X 3 =108.78 (Mtr. ³)			
Type Of Air Conditioning Unit		Split AC			
Total Installed Cooling Capacity (Including Split AC's If Any)		(1 X 1.5 TON) + (2 X 2 TON) = 5.5 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		C	
		PISPL/N/DDN/ALC/AC/001 (24 HRS) (2 TON)		PISPL/N/DDN/ALC/AC/004 (24 HRS) (2 TON)	
				PISPL/N/DDN/ALC/AC/002 (STANDBY) (1.5 TON)	



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



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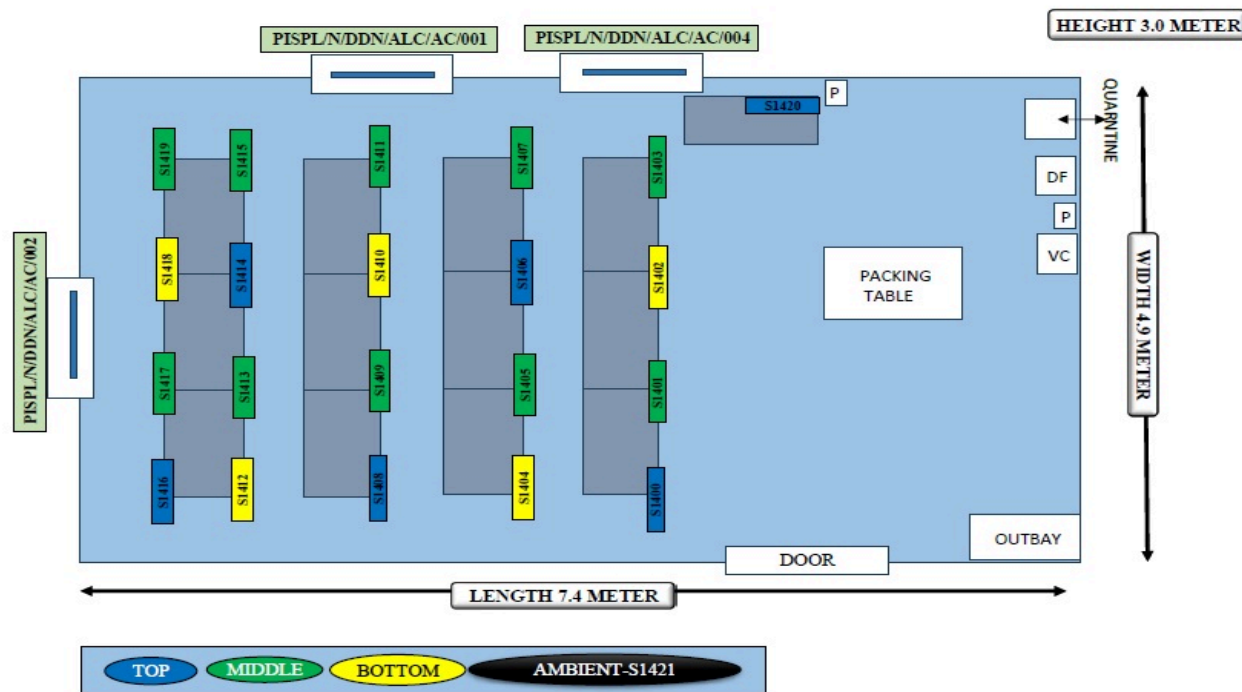
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Location Diagram Indicating Position Of Loggers (Schematic)





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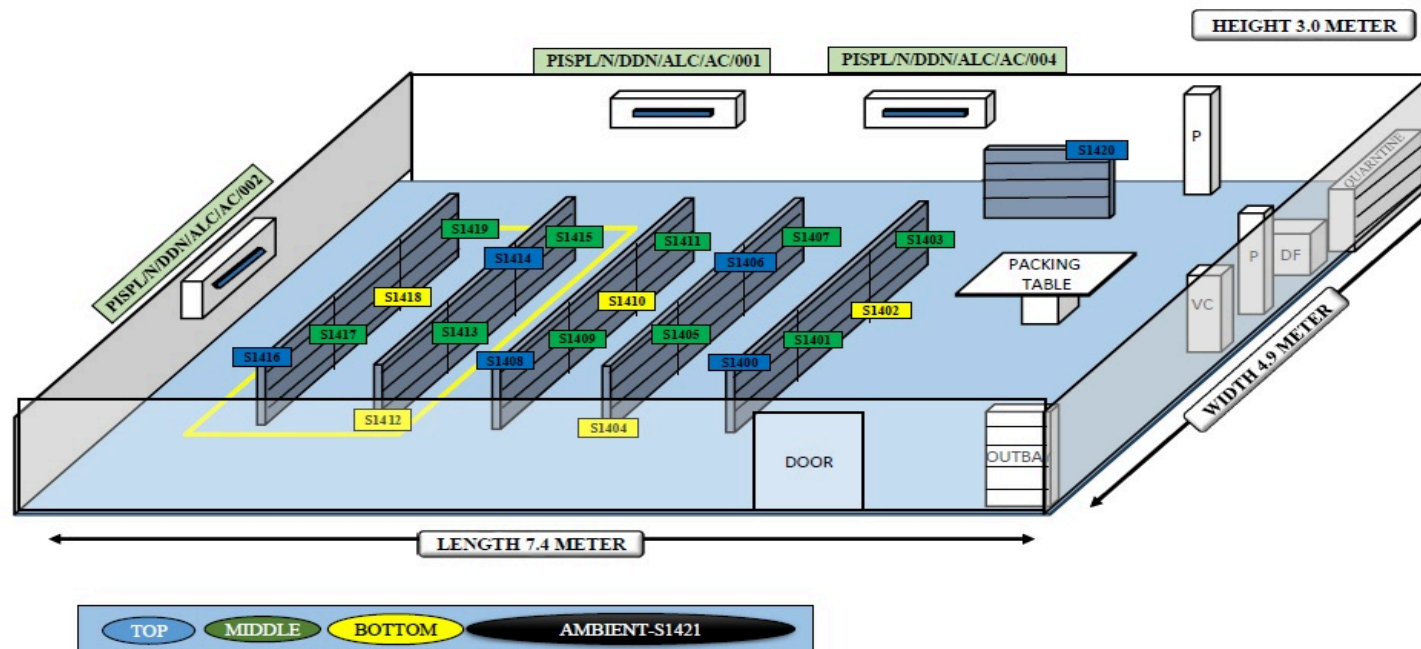
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Location Diagram Indicating Position Of Loggers (Isometric)





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Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				Report Number : VCVS/23-24/PISPL/ALC/DDN/CLR/PQ/02		
Customer Address : Khasra No. 413, Chakki Tola, Moja Niranjanpur, Dehradun, Uttarakhand - 248001. DEHRADUN						
<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	S1400	TOP	4.7	4.2	2	
2	S1401	MIDDLE	4.7	3	1	
3	S1402	BOTTOM	4.7	1.8	0.3	
4	S1403	MIDDLE	4.7	0.6	1	
5	S1404	BOTTOM	3.5	4.2	0.3	
6	S1405	MIDDLE	3.5	3	1	
7	S1406	TOP	3.5	1.8	2	
8	S1407	MIDDLE	3.5	0.6	1	
9	S1408	TOP	2.3	4.2	2	
10	S1409	MIDDLE	2.3	3	1	
11	S1410	BOTTOM	2.3	1.8	0.3	
12	S1411	MIDDLE	2.3	0.6	1	
13	S1412	BOTTOM	1.1	4.2	0.3	
14	S1413	MIDDLE	1.1	3	1	
15	S1414	TOP	1.1	1.8	2	
16	S1415	MIDDLE	1.1	0.6	1	
17	S1416	TOP	0.6	4.2	2	
18	S1417	MIDDLE	0.6	3	1	
19	S1418	BOTTOM	0.6	1.8	0.3	
20	S1419	MIDDLE	0.6	0.6	1	

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Customer Address : Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN					
<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	S1420	TOP	6	0.8	2
22	S1421 AMB	AMBIENT LOGGER PLACED OUTSIDE THE COLD ROOM			



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Customer Address: Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN		
<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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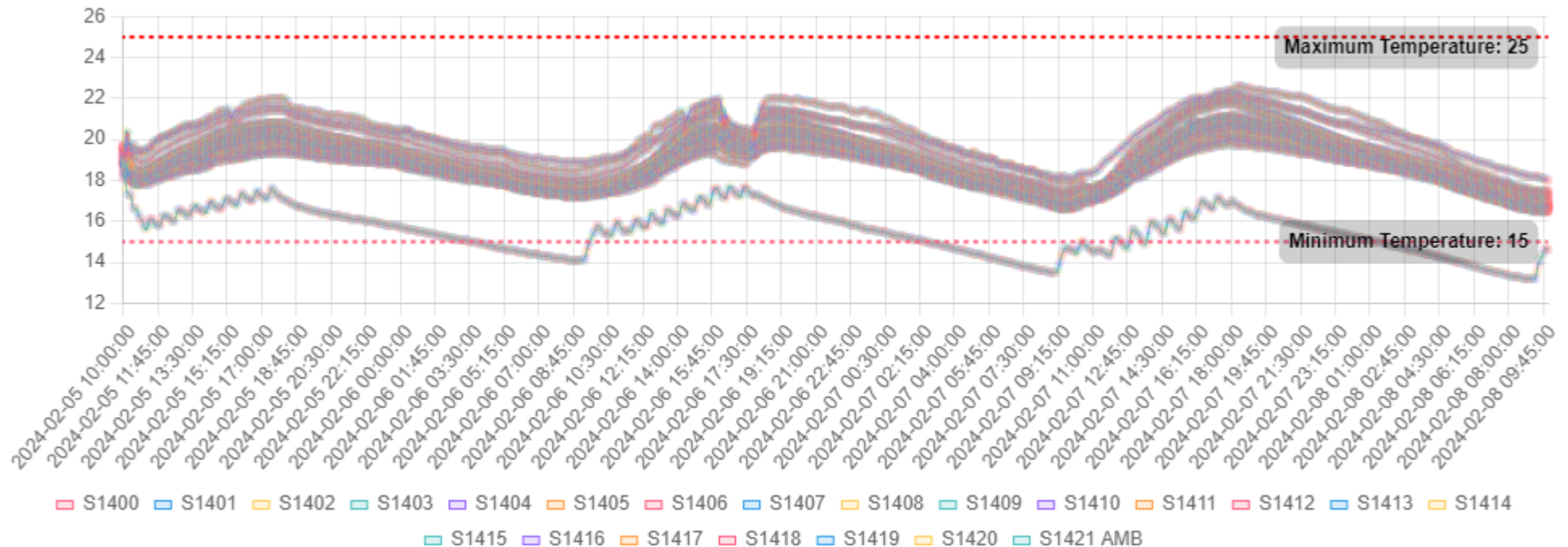
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/23-24/PISPL/ALC/DDN/CLR/PQ/02	Cool Room 01	Continuous Operation Test Cycle	05-02-2024 10:00:00	08-02-2024 10:00:00

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

Customer Address : Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN

CONTINUOUS OPERATION TEST CYCLE (WITH AMBIENT)

TREND OF TEMPERATURE VS TIME





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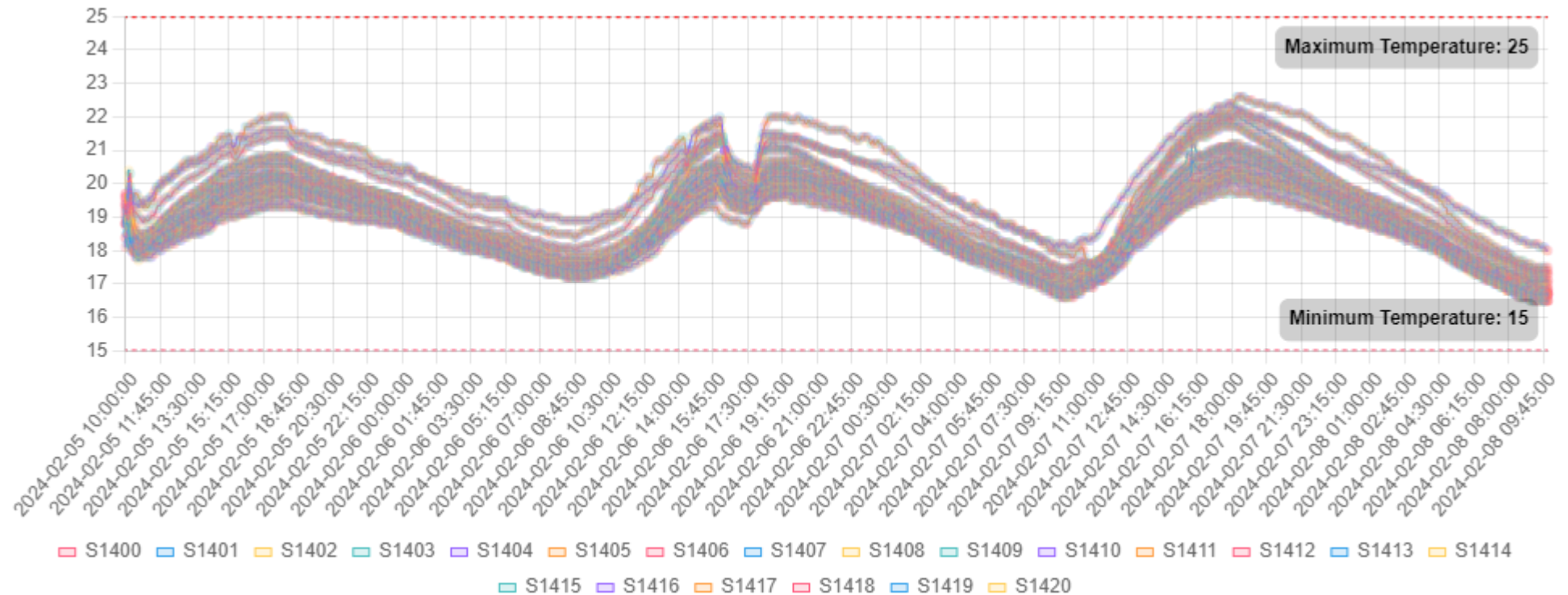
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/23-24/PISPL/ALC/DDN/CLR/PQ/02	Cool Room 01	Continuous Operation Test Cycle	05-02-2024 10:00:00	08-02-2024 10:00:00

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

Customer Address : Khasra No. 413, Chakki Tola, Moja Niranjanpur, Dehradun, Uttarakhand - 248001. DEHRADUN

CONTINUOUS OPERATION TEST CYCLE (WITHOUT AMBIENT)

TREND OF TEMPERATURE VS TIME





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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/ALC/DDN/CLR/PQ/02
Customer Address : Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN		
<p style="text-align: center;"><u>Summary and Observation Report Of Parameters Computed</u> <u>During Mapping (Temperature)</u></p>		



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Customer Address : Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN															
<u>Summary of Parameters Computed During Mapping (Temperature)</u>															
Position	S1400	S1401	S1402	S1403	S1404	S1405	S1406	S1407	S1408	S1409	S1410	S1411	S1412	S1413	S1414
AVERAGE MINIMUM TEMPERATURE °C	17.40	16.70	17.00	16.63	18.00	17.50	16.70	16.70	16.70	16.50	16.50	17.30	16.80	16.60	17.00
AVERAGE MAXIMUM TEMPERATURE °C	22.15	20.75	21.70	21.10	22.40	22.60	20.70	21.30	20.40	21.80	20.00	21.20	20.90	22.00	20.30
AVERAGE TEMPERATURE °C	19.78	18.79	19.33	18.89	20.19	20.23	18.95	18.87	18.71	19.11	18.41	19.30	18.95	19.27	18.71
(MAX-MIN)TEMPERATURE °C	4.75	4.05	4.70	4.47	4.40	5.10	4.00	4.60	3.70	5.30	3.50	3.90	4.10	5.40	3.30
STANDARD DEVIATION °C	0.74	0.63	0.71	0.69	0.63	0.78	0.62	0.68	0.58	0.82	0.53	0.60	0.65	0.84	0.51
<div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="background-color: red; color: white; padding: 10px; text-align: center;"> Average Maximum Temperature Point HOT SPOT (MIDDLE) </div> <div style="background-color: green; color: white; padding: 10px; text-align: center;"> Average Minimum Temperature Point COLD SPOT (BOTTOM) </div> </div>															



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Customer Address : Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN							
<u>Summary of Parameters Computed During Mapping (Temperature)</u>							
Position	S1415	S1416	S1417	S1418	S1419	S1420	S1421 AMB
AVERAGE MINIMUM TEMPERATURE °C	17.10	16.50	17.10	16.77	16.87	16.87	13.20
AVERAGE MAXIMUM TEMPERATURE °C	20.20	20.50	19.80	20.40	20.17	20.33	19.00
AVERAGE TEMPERATURE °C	18.78	18.63	18.52	18.69	18.63	18.71	15.52
(MAX-MIN)TEMPERATURE °C	3.10	4.00	2.70	3.63	3.30	3.46	5.80
STANDARD DEVIATION °C	0.48	0.63	0.41	0.56	0.50	0.54	0.64
<div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="background-color: red; color: white; padding: 10px; text-align: center;"> Average Maximum Temperature Point HOT SPOT (MIDDLE) </div> <div style="background-color: green; color: white; padding: 10px; text-align: center;"> Average Minimum Temperature Point COLD SPOT (BOTTOM) </div> </div>							



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Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				Report Number : VCVS/23-24/PISPL/ALC/DDN/CLR/PQ/02	
Customer Address : Khasra No. 413, Chakki Tola, Moja Niranjapur, Dehradun, Uttarakhand - 248001. DEHRADUN					
<p><u>Observation and Concluding Remarks</u></p> <p>1. Point S1405 (Average Maximum Temperature: 20.23°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 S1405. When only maximum limit needs to be controlled then treat point S1405 as a HOT SPOT in Loaded condition.</p> <p>2. Point S1410 (Average Minimum Temperature: 18.41°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 S1410. When only minimum limit needs to be controlled then treat point S1410 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	Approved By		
Digitally Signed By : Akash Shinde Reason : Authorised Signatory Date/Time : 17-02-2024 11:09:16	Digitally Signed By : Dhiraj Barge Reason : Authorised Signatory Date/Time :29-02-2024 10:28:49	Digitally Signed By : Reason : Authorised Signatory Date/Time : N/A	Digitally Signed By : Reason : Authorised Signatory Date/Time : N/A		
<p>Note : The results reported in this certificate are valid at the time of temperature mapping activity</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 10⁻³ 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 = 19.0 °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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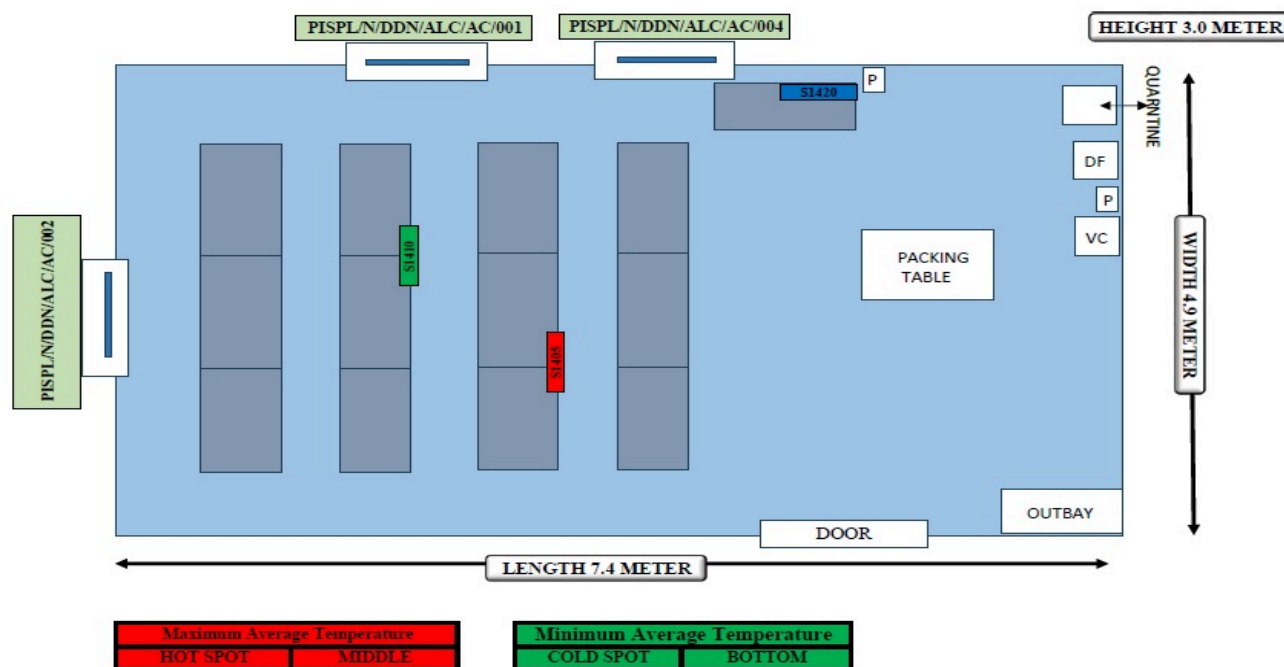
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Location Chart Indicating Position Of Maximum and Minimum Average Temperature Point



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<p><u>List Of Annexures</u></p> <p>1. Annexure-1 Raw_data_pispl_1709007243.pdf</p> <p>2. Annexure-2 data_logger&_Master_traceability_1709007243.pdf</p> <p>3. Annexure-3 Training_Certificate_Imran_1709007243.pdf</p>		