



VEGA Calibration And Validation Services LLP.Mumbai

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Thermal Qualification Study For

"Cold Room" (PQ)

Identification Number : Cold Room-02 (Manufacturing Area)

Located At

M/s. PAREKH INTEGRATED SERVICES PVT. LTD.

Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha,

Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.

Thermal Qualification Study Performed On	Thermal Qualification Study Next Due On
07/05/2022	06/05/2025



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Objective		Report No.		Qualification Performed On		Next Qualification Due On	
Thermal Qualification Study For "Cold Room" (PQ)		VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01		07/05/2022		06/05/2025	
Name Of The Customer : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.							
Address Of The Customer : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.							
Details Of The "Cold Room"							
Identification Number Of The "Cold Room"	CFA	Location	Dimensions Mtr.			Volume Of Area (Mtr. ³)	Acceptable Operating Range Temperature (°C)
			L	W	H		
Cold Room-02 (Manufacturing Area)	NA	BHIWANDI	5.5	4.6	2.4	60.72	2°C to 8°C
Usage Of The "Cold Room"							
Storage Of Medicines							
Mapping Cycle Start Date		Mapping Cycle End Date		No. Of Cycles Performed		No. Of Sensing Point	
04/05/2022		07/05/2022		5		23+1 (Ambient)	
Status							
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°C	Continuous Operation Test Cycle		11:00:00	11:00:00	5 Minute
07/05/2022	07/05/2022	4°C	Door Open Test Cycle-I		12:45:00	13:31:00	1 Minute
07/05/2022	07/05/2022	4°C	Door Open Test Cycle-II		14:09:00	15:07:00	1 Minute
07/05/2022	07/05/2022	4°C	Door Open Test Cycle-III		15:49:00	16:38:00	1 Minute
07/05/2022	07/05/2022	4°C	Power Failure Test Cycle		17:15:00	18:21:00	1 Minute
Details Of The Mapping Instrumentation							
Sr. No.	Details Of 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.				For M/s. PAREKH INTEGRATED SERVICES PVT. LTD.			
Prepared by		Checked By		Reviewed By		Approved By	



Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Details Of "Air-Conditioning System"

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)



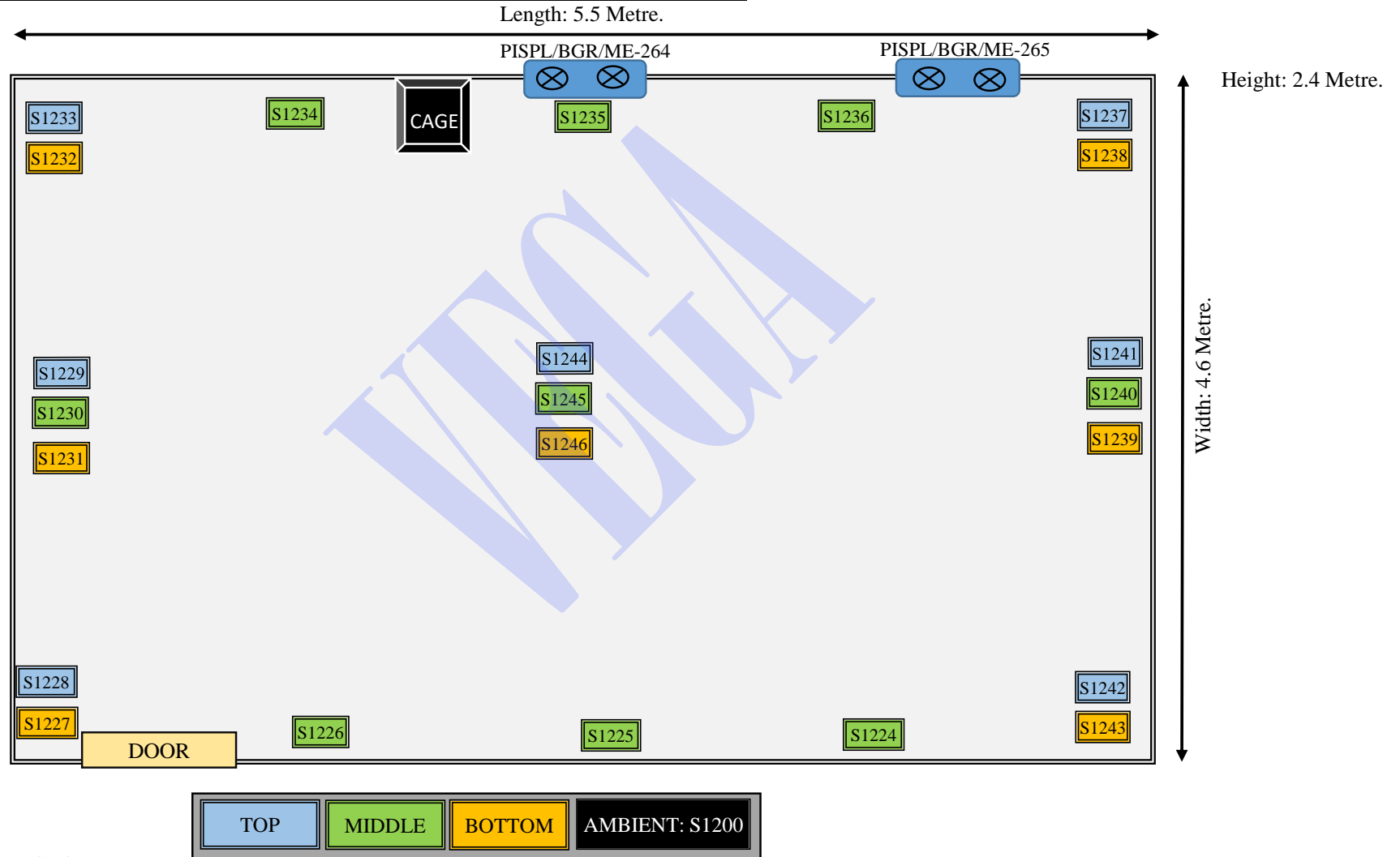
Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	
Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Location Diagram And Location Chart



Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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
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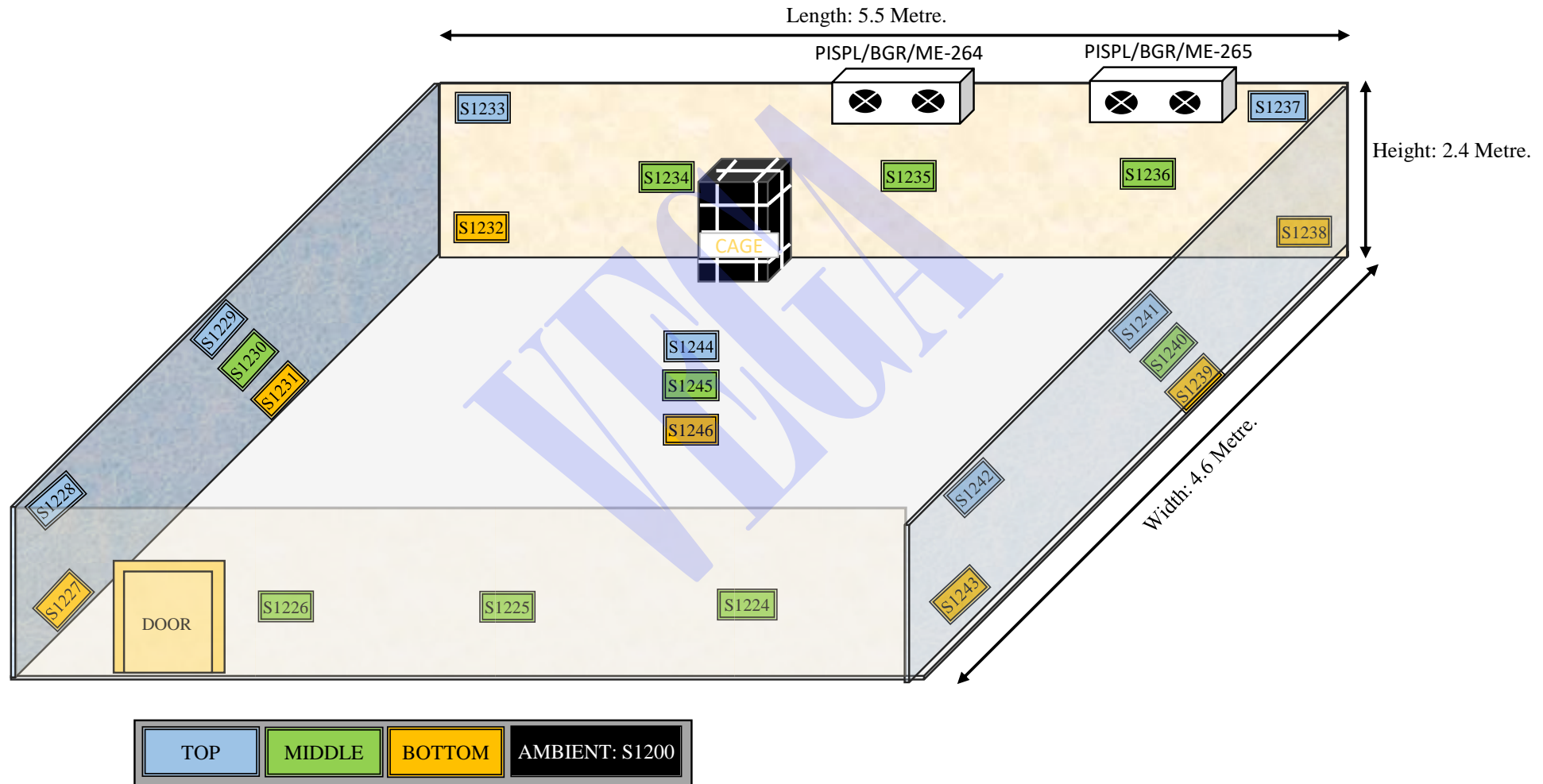
Location Chart Indicating Position Of Loggers (Schematic View).



Note : Diagram Not To Scale

Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Location Chart Indicating Position Of Loggers (Isometric View).



Note : Diagram Not To Scale



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Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Location Chart 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	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	0.0	4.5	0.3
5	S1228	TOP	0.0	4.5	2.2
6	S1229	TOP	0.0	2.4	2.2
7	S1230	MIDDLE	0.0	2.4	1.4
8	S1231	BOTTOM	0.0	2.4	0.3
9	S1232	BOTTOM	0.0	0.0	0.3
10	S1233	TOP	0.0	0.0	2.2
11	S1234	MIDDLE	1.3	0.0	1.4
12	S1235	MIDDLE	3.1	0.0	1.4
13	S1236	MIDDLE	4.9	0.0	1.4
14	S1237	TOP	5.5	0.0	2.2
15	S1238	BOTTOM	5.5	0.0	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
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	Ambient Logger Placed Outside The Cold Room			



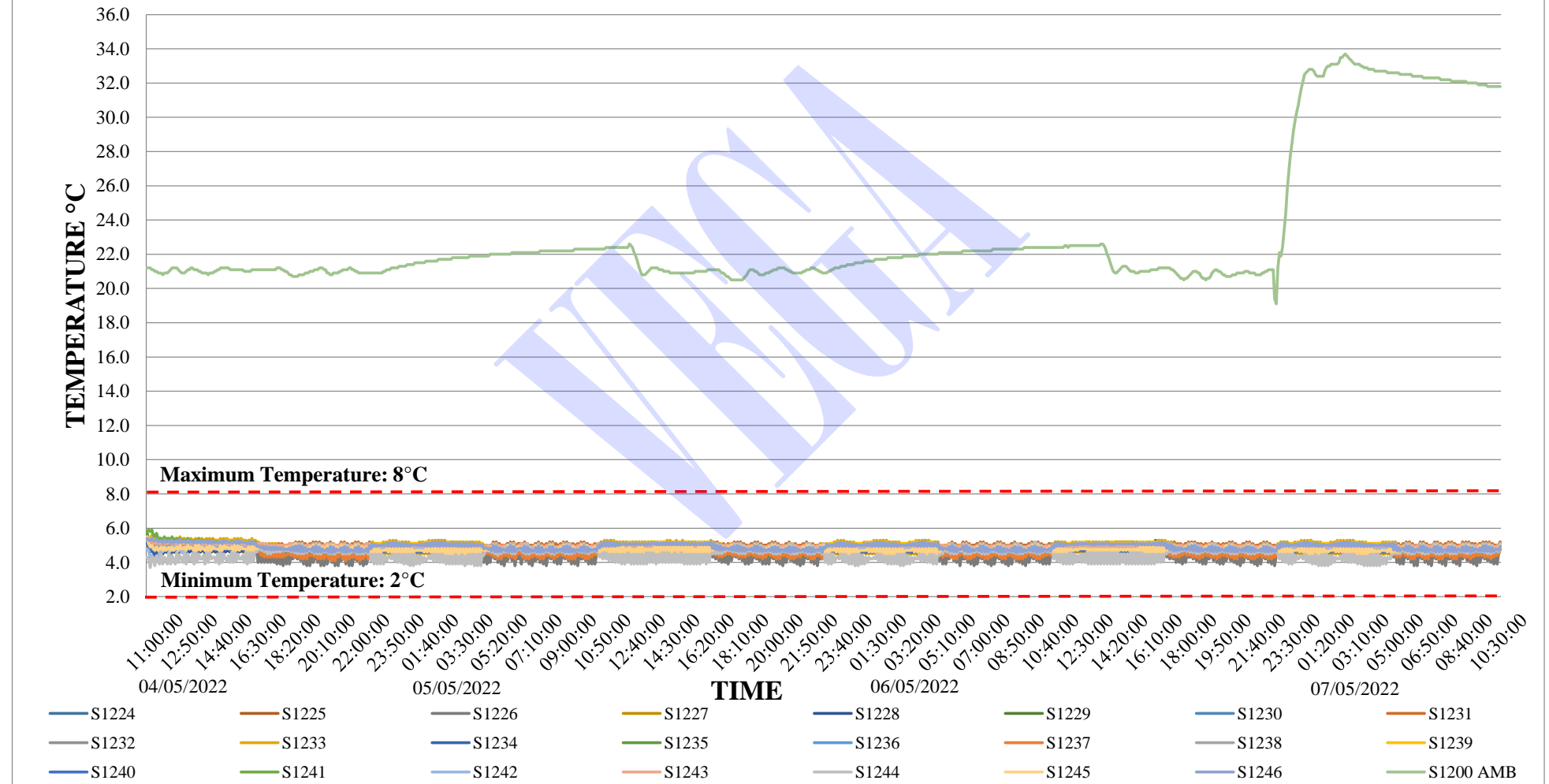
Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	
Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Trend For The Cycle: (Temperature Vs Time)
Continuous Operation Test Cycle



Report Number	ID 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.				

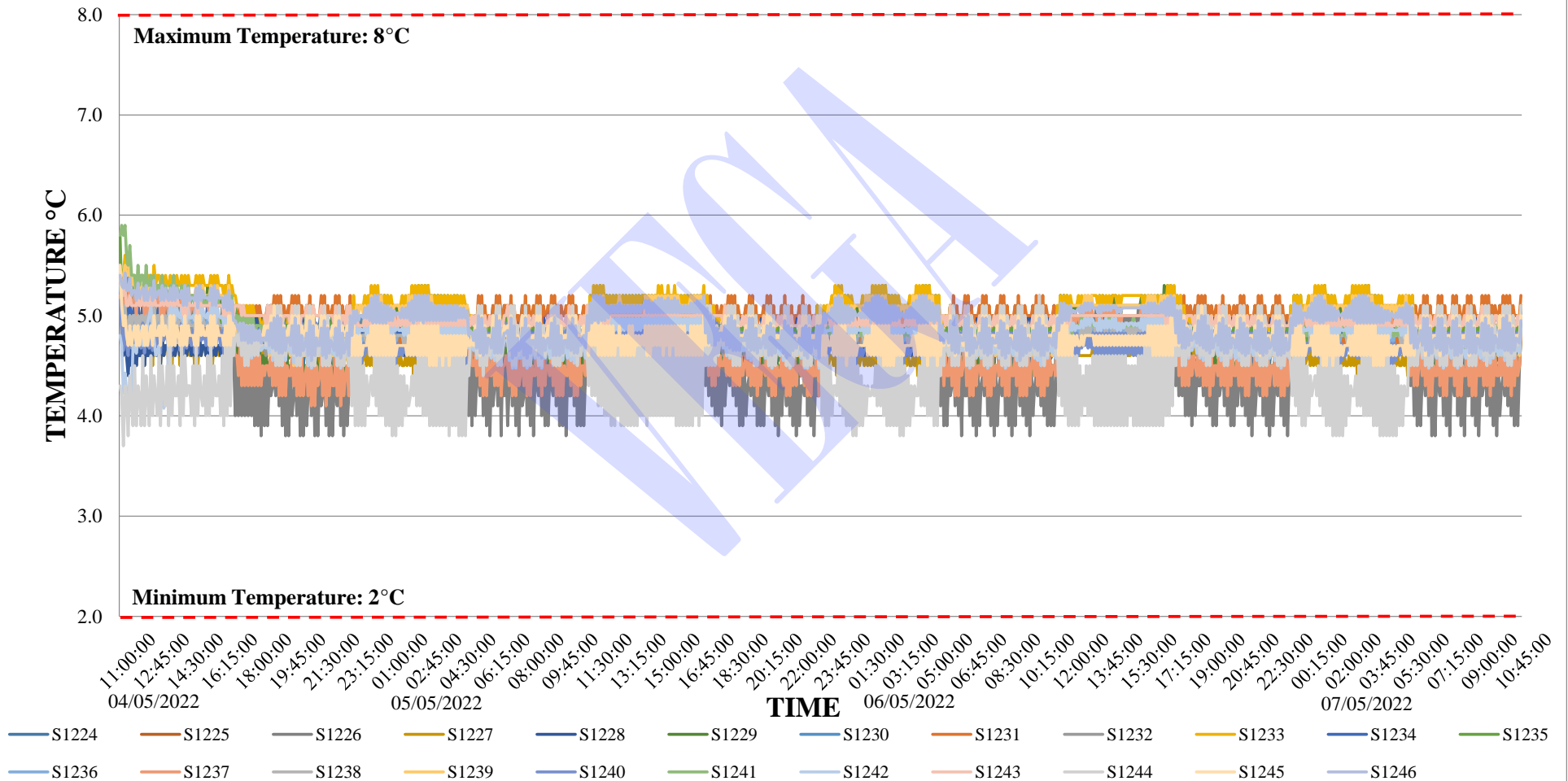
TREND OF TEMPERATURE VS TIME (WITH AMBIENT)





Report Number	ID 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.				

TREND OF TEMPERATURE VS TIME (WITHOUT AMBIENT)





Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Door Open Test Cycle I	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Trend For The Cycle: (Temperature Vs Time)
Door Open Test Cycle-I

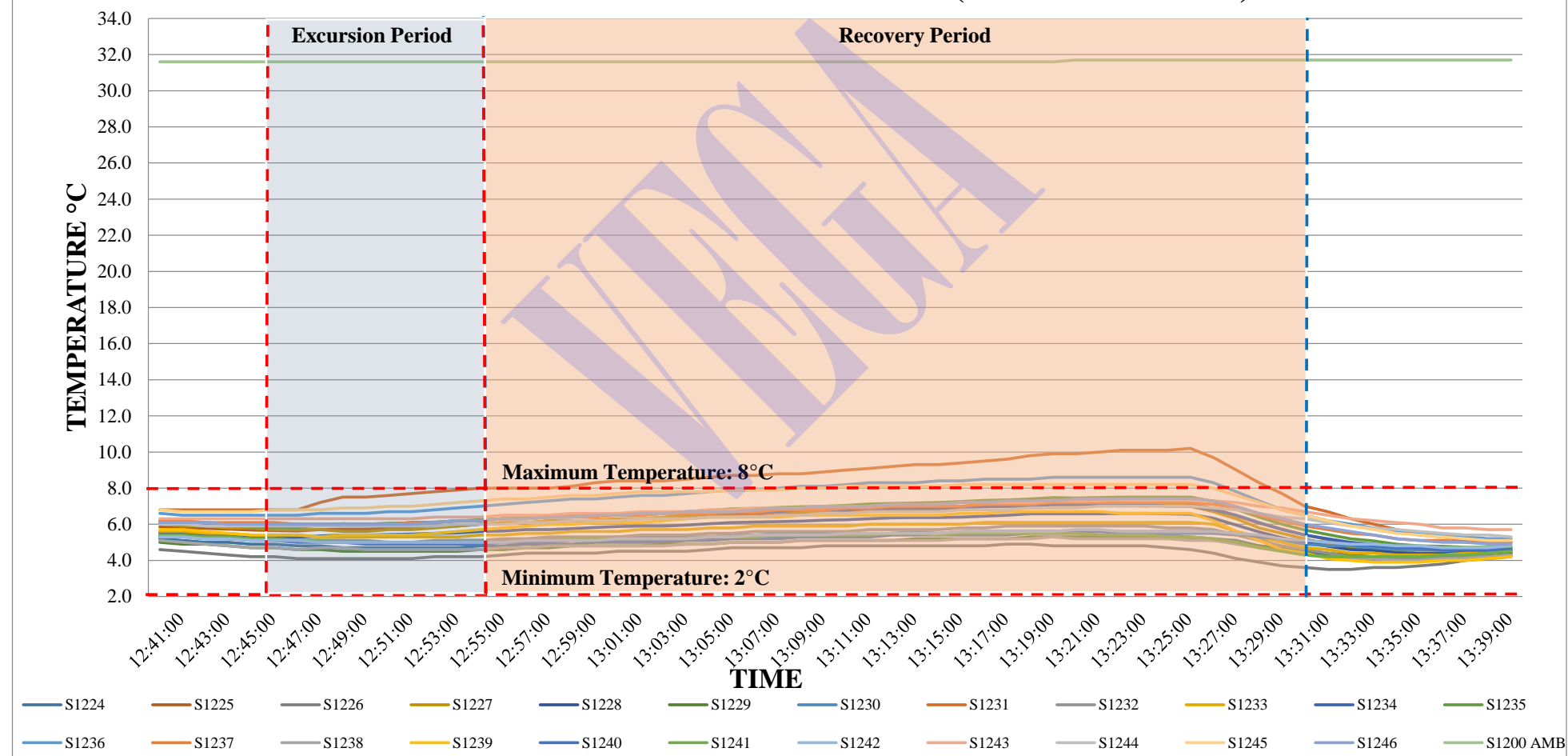


Report Number	ID No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Door Open Test Cycle-I	07/05/2022 12:45:00	07/05/2022 13:31:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
12:45:00	12:55:00	12:55:00	13:31:00	

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

Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.

TREND OF TEMPERATURE VS TIME (WITH AMBIENT)



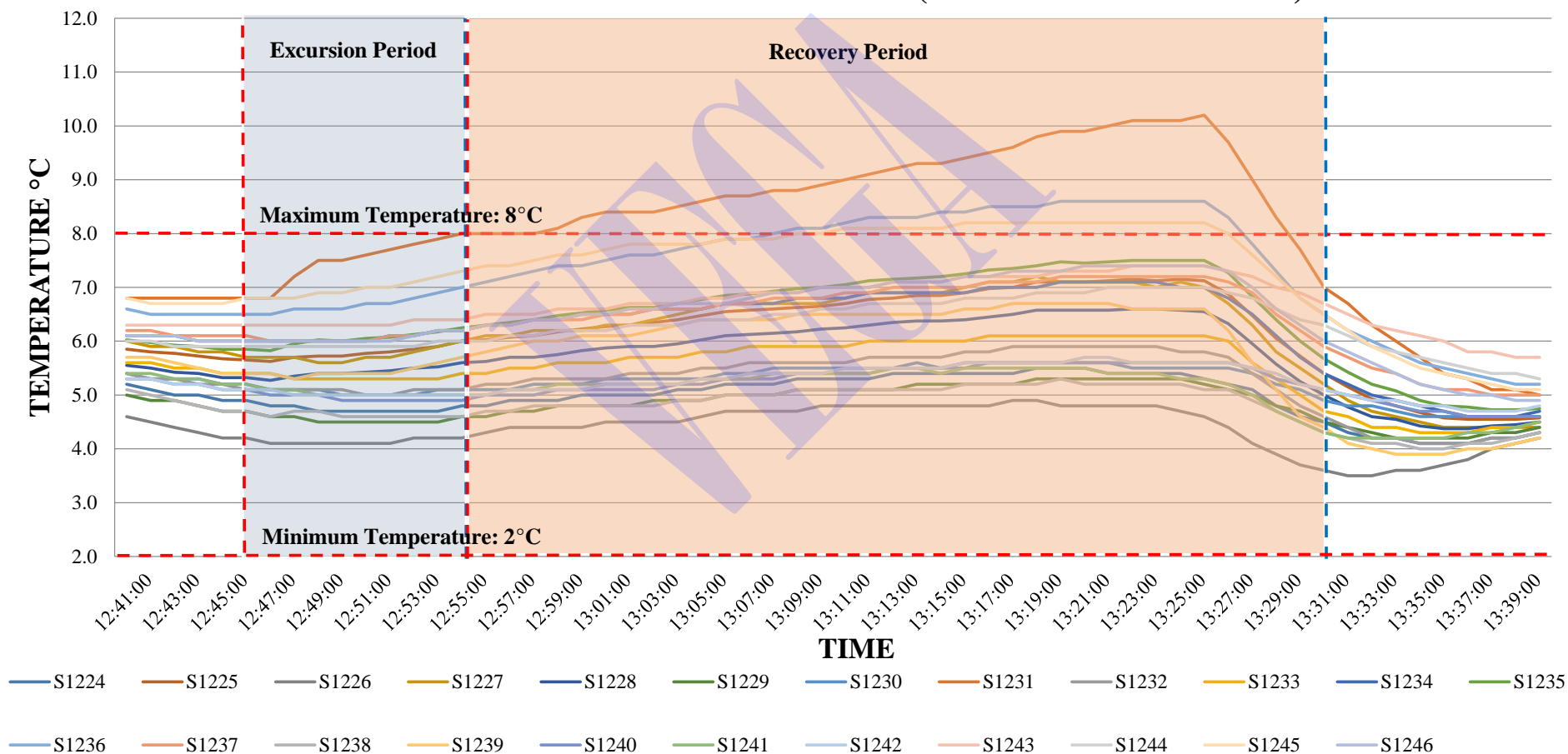


Report Number	ID No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Door Open Test Cycle-I	07/05/2022 12:45:00	07/05/2022 13:31:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
12:45:00	12:55:00	12:55:00	13:31:00	

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

Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.

TREND OF TEMPERATURE VS TIME (WITHOUT AMBIENT)





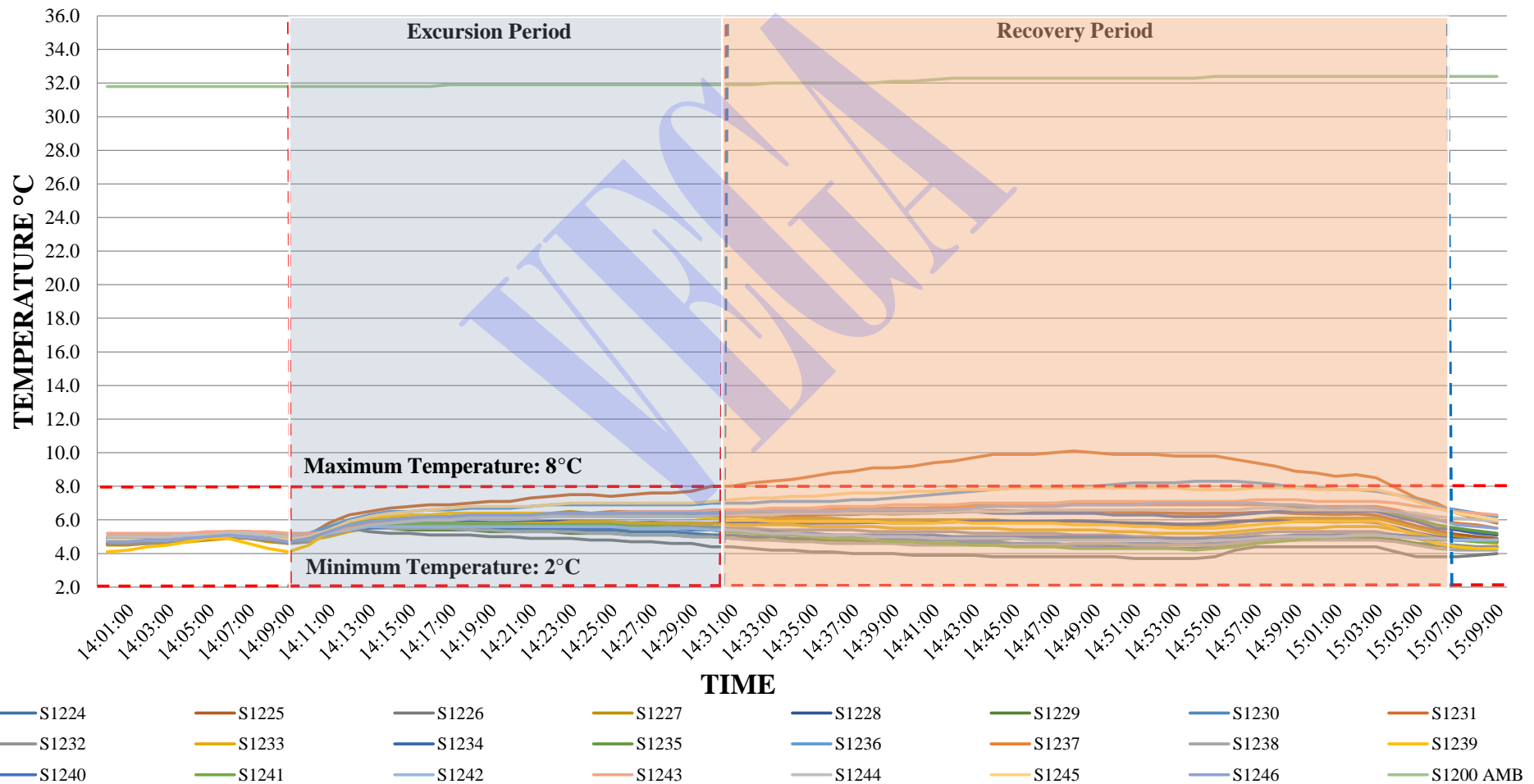
Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Door Open Test Cycle - II	Identification Number : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	
Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Trend For The Cycle: (Temperature Vs Time)
Door Open Test Cycle-II



Report Number		ID 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-II	07/05/2022 14:09:00	07/05/2022 15:07:00
Door Open Time	Set Limit Cross Out Time		Door Close Time	Set Limit Cross In Time	
14:09:00	14:31:00		14:31:00	15:07:00	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.					
Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.					

TREND OF TEMPERATURE VS TIME (WITH AMBIENT)



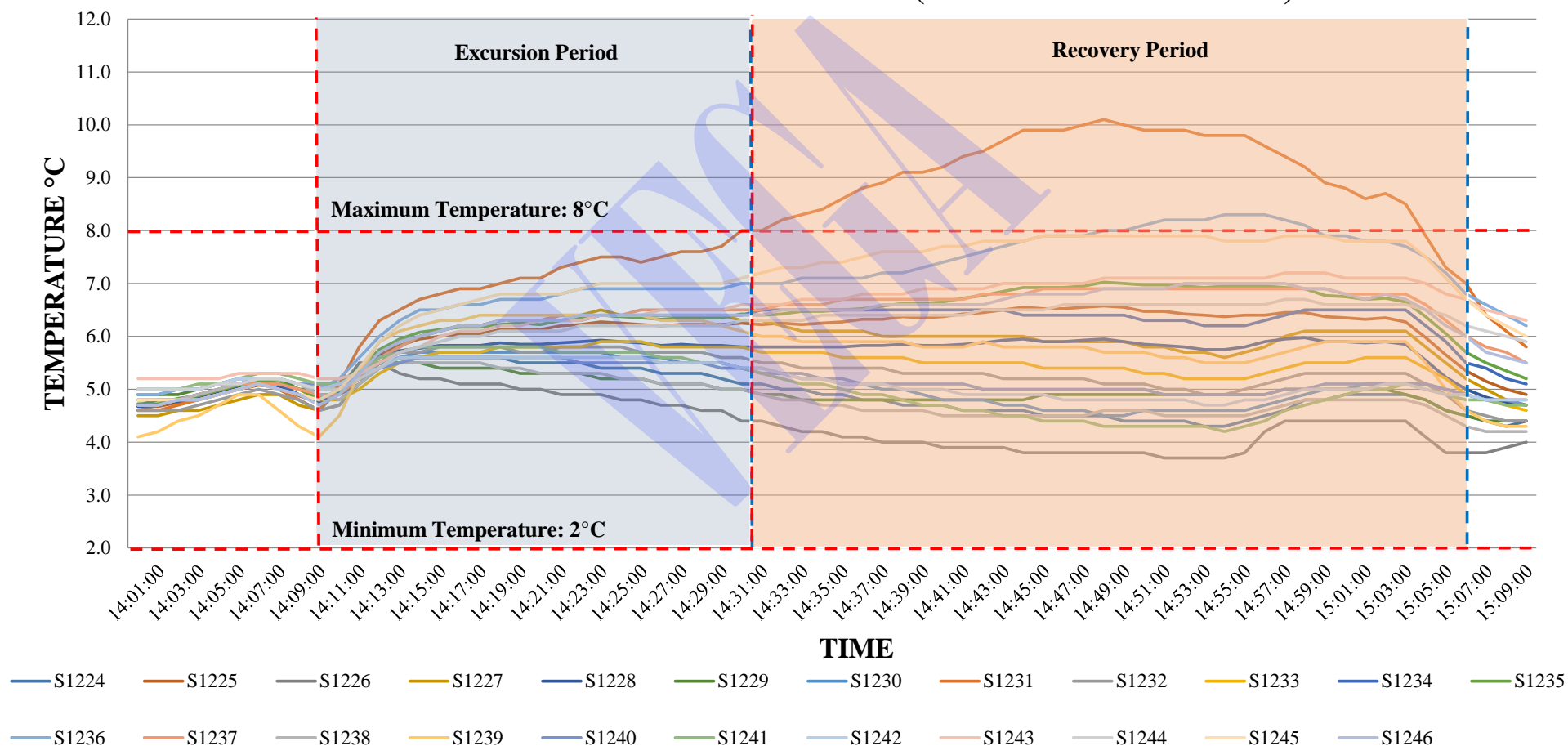


Report Number	ID No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Door Open Test Cycle-II	07/05/2022 14:09:00	07/05/2022 15:07:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
14:09:00	14:31:00	14:31:00	15:07:00	

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

Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.

TREND OF TEMPERATURE VS TIME (WITHOUT AMBIENT)



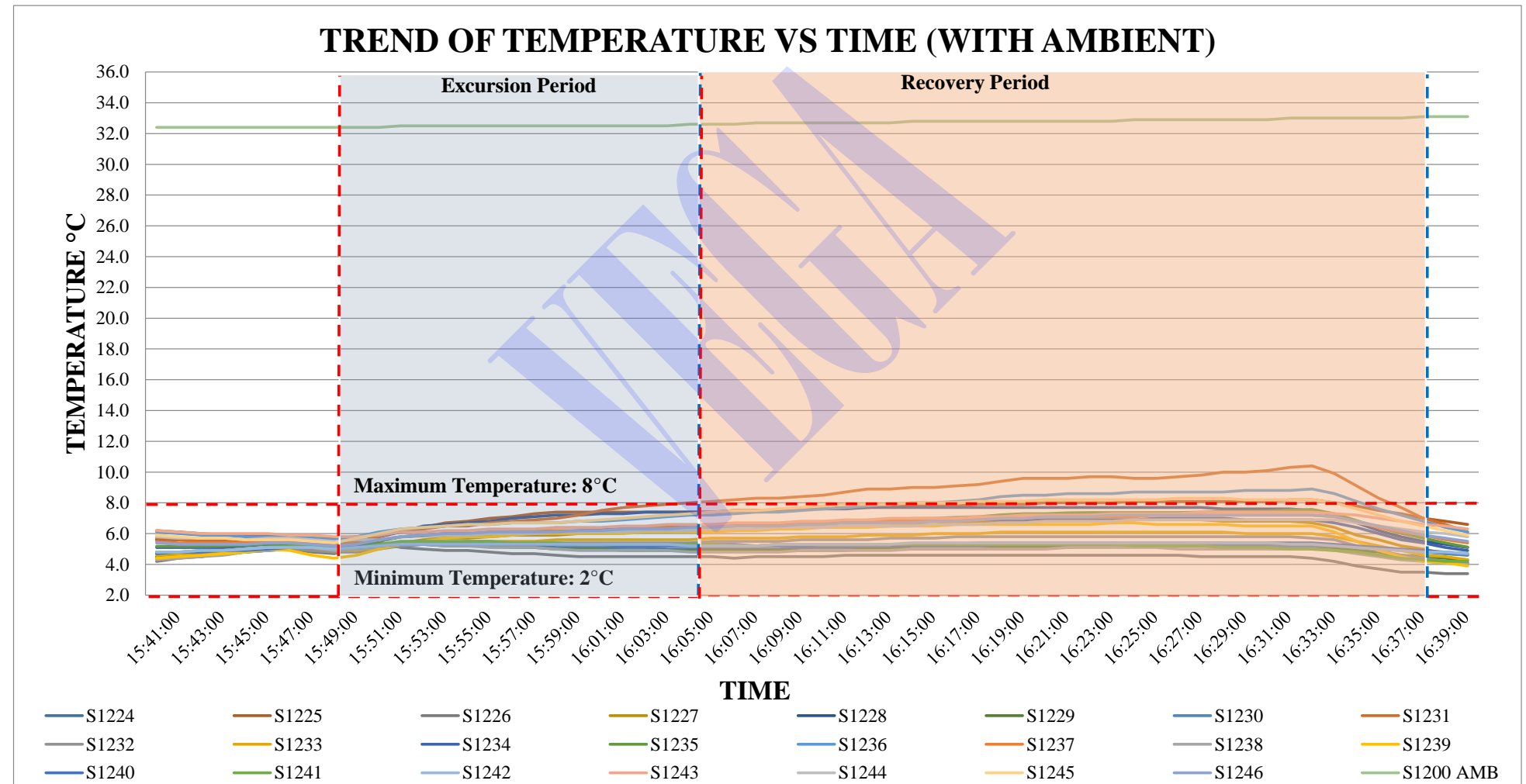


Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Door Open Test Cycle III	Identification Number : Cold Room-02 (Manufacturing Area)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number :VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	
Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Trend For The Cycle: (Temperature Vs Time)
Door Open Test Cycle-III



Report Number		ID 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-III	07/05/2022 15:49:00	07/05/2022 16:38:00
Door Open Time	Set Limit Cross Out Time		Door Close Time	Set Limit Cross In Time	
15:49:00	16:05:00		16:05:00	16:38:00	
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.					
Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.					



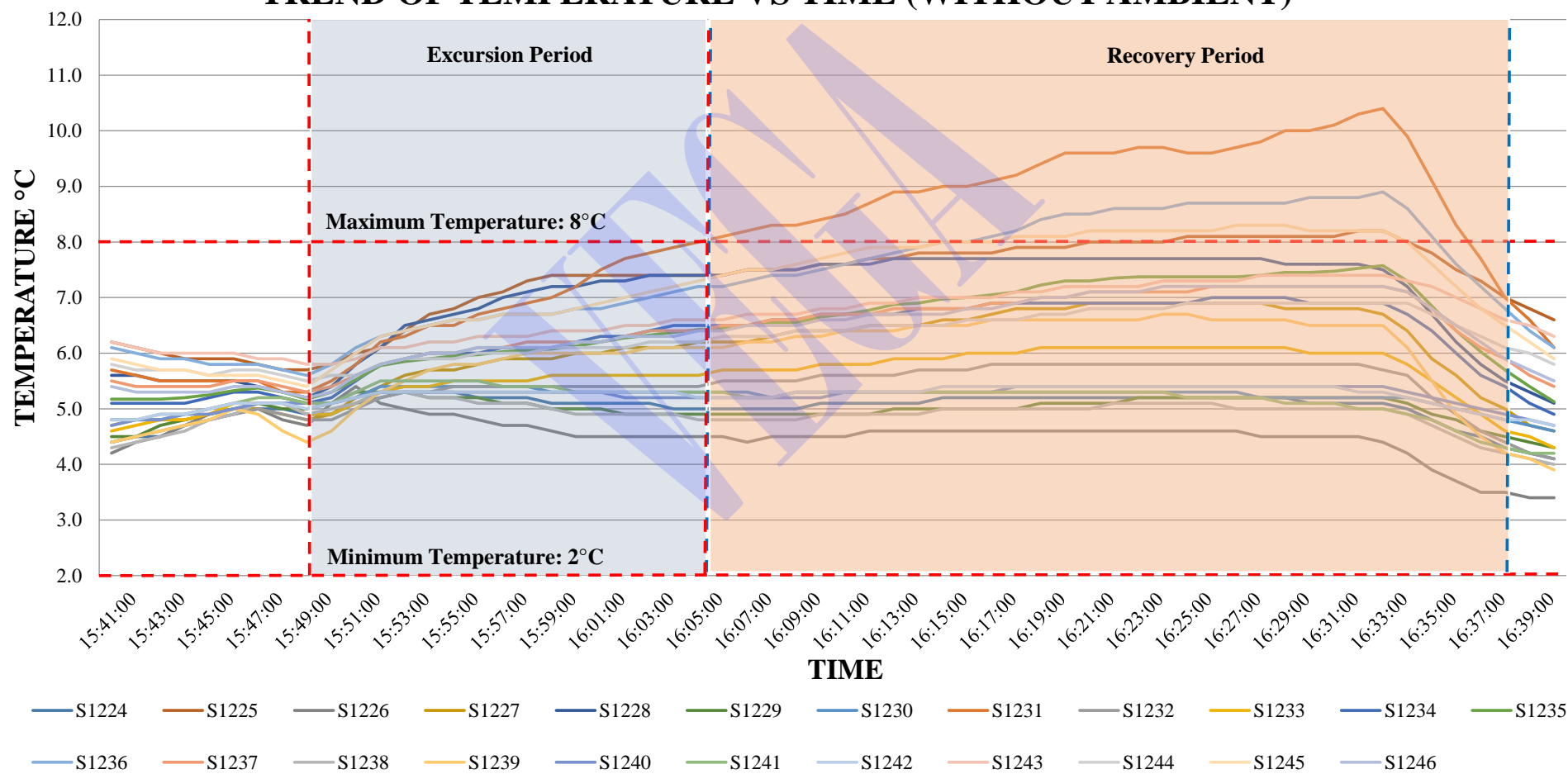


Report Number	ID No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Door Open Test Cycle-III	07/05/2022 15:49:00	07/05/2022 16:38:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
15:49:00	16:05:00	16:05:00	16:38:00	

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

Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.

TREND OF TEMPERATURE VS TIME (WITHOUT AMBIENT)





Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Trend For The Cycle (Temperature Vs Time)
Power Failure Test Cycle

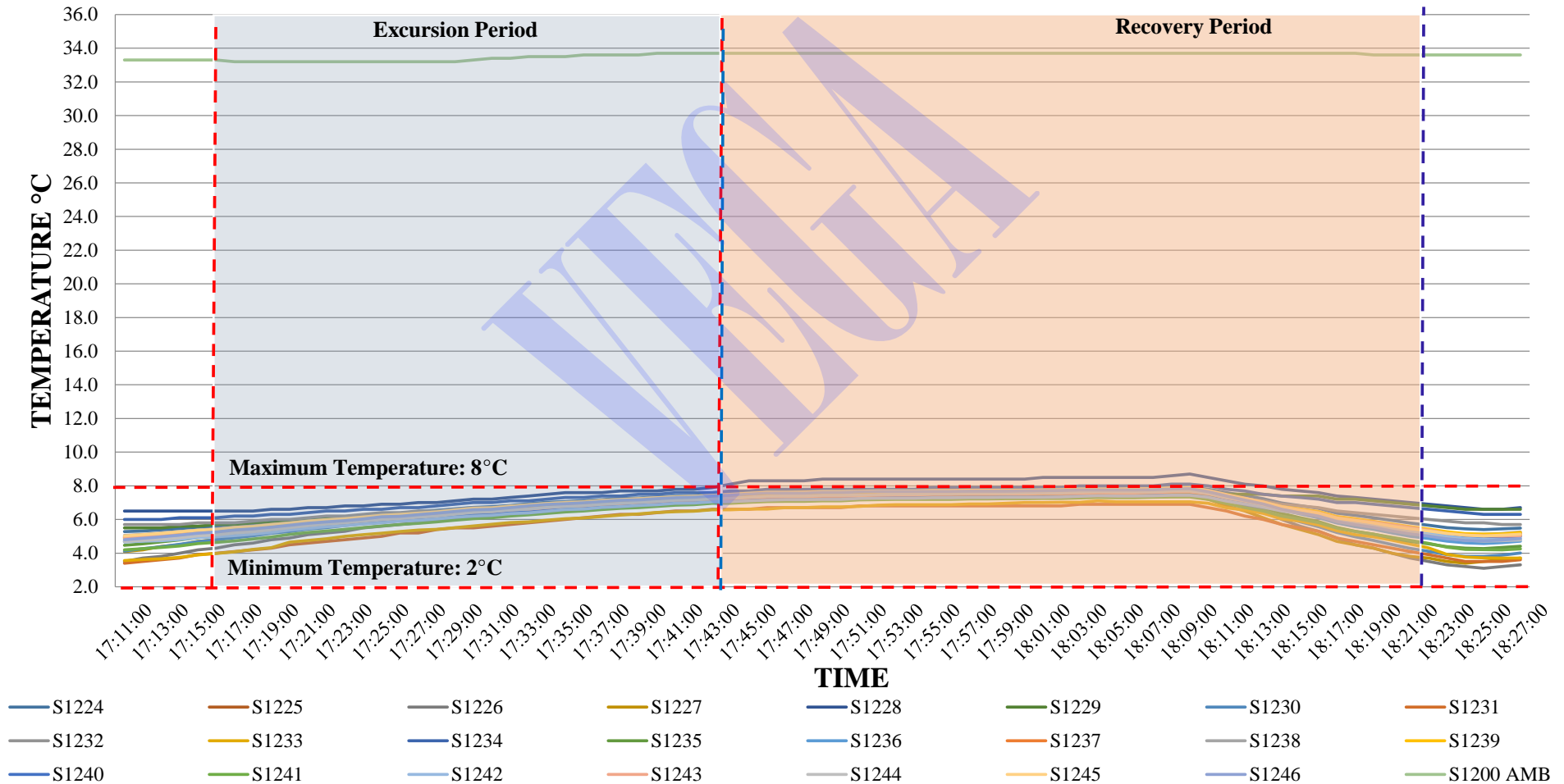


Report Number	ID No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Power Failure Test Cycle	07/05/2022 17:15:00	07/05/2022 18:21:00
Power OFF Time	Set Limit Cross Out Time	Power ON Time	Set Limit Cross In Time	
17:15:00	17:43:00	17:43:00	18:21:00	

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

Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.

TREND OF TEMPERATURE VS TIME (WITH AMBIENT)



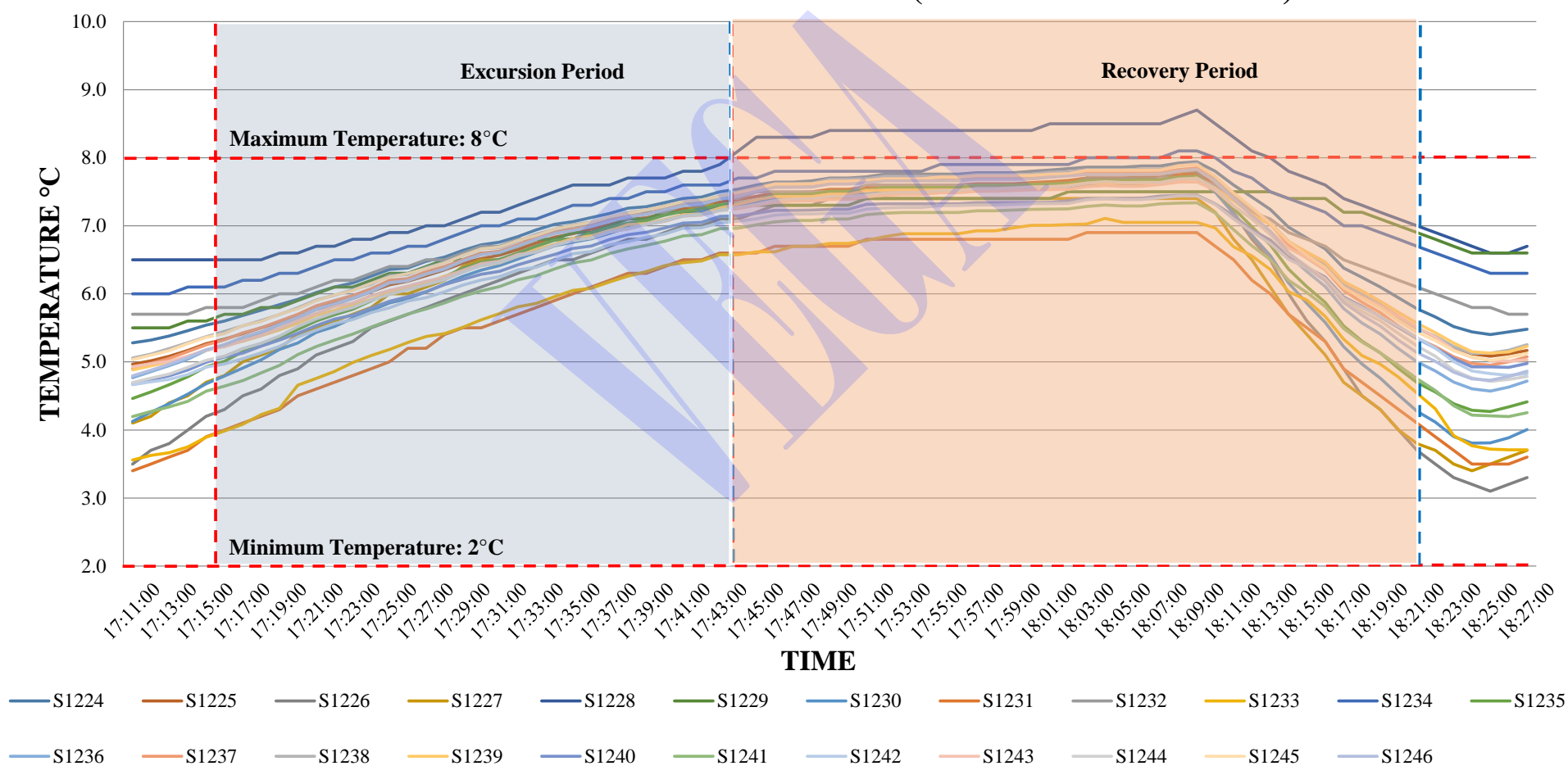


Report Number	ID No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	Cold Room-02 (Manufacturing Area)	Power Failure Test Cycle	07/05/2022 17:15:00	07/05/2022 18:21:00
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17:15:00	17:43:00	17:43:00	18:21:00	

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Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.

TREND OF TEMPERATURE VS TIME (WITHOUT AMBIENT)





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Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number : VCVS/22-23/PISPL/BH/MFG/CDR-2/PQ/01	
Customer Address : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Summary and Observation Report Of Parameters Computed During Mapping (Temperature)



VEGA Calibration And Validation Services LLP., Mumbai

Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Summary of Parameters Computed During Mapping (Temperature)

POSITION	S1200 AMB	S1224	S1225	S1226	S1227	S1228	S1229	S1230	S1231	S1232	S1233	S1234	S1235	S1236	S1237	S1238	S1239	S1240	S1241
MINIMUM TEMPERATURE °C	19.1	4.5	4.7	3.8	4.4	4.4	4.2	4.6	4.6	4.4	4.7	4.6	4.6	4.6	4.1	4.6	4.5	4.5	4.6
MAXIMUM TEMPERATURE °C	33.7	5.3	5.5	5.3	5.4	5.4	5.3	5.5	5.4	5.1	5.6	5.4	5.8	5.3	5.3	5.4	5.5	5.2	5.9
AVERAGE TEMPERATURE °C	23.18	4.76	4.90	4.61	4.63	4.84	4.82	4.88	4.92	4.72	5.05	4.85	4.86	4.83	4.74	4.82	4.91	4.78	4.87
(MAX-MIN) TEMPERATURE °C	14.6	0.8	0.8	1.5	1.0	1.0	1.1	0.9	0.8	0.7	0.9	0.8	1.2	0.7	1.2	0.8	1.0	0.7	1.3
STANDARD DEVIATION °C	4.0	0.2	0.1	0.4	0.2	0.2	0.3	0.2	0.2	0.1	0.2	0.2	0.1	0.1	0.3	0.1	0.2	0.2	0.2

POSITION	S1242	S1243	S1244	S1245	S1246
MINIMUM TEMPERATURE °C	4.1	4.8	3.7	4.5	4.6
MAXIMUM TEMPERATURE °C	5.2	5.5	5.2	5.5	5.4
AVERAGE TEMPERATURE °C	4.78	4.98	4.53	4.78	4.92
(MAX-MIN) TEMPERATURE °C	1.1	0.7	1.5	1.0	0.9
STANDARD DEVIATION °C	0.2	0.1	0.4	0.1	0.2

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

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 Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Observation and Concluding Remarks

- Point S1233** (Average Maximum 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.
- Point S1244** (Average Minimum 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.

Conclusion

The above given "Cold Room" is monitored for temperature uniformity for 72 Hours in Loaded condition and results are found as per the acceptance criteria. So the "Cold Room" is in compliance with the defined criteria and qualified for its further use.

For M/s. Vega Calibration And Validation Services LLP.		For M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	
Prepared by	Checked By	Reviewed By	Approved By

Note : The results reported in this certificate are valid at the time of temperature mapping activity.



Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

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 83.144 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 °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.

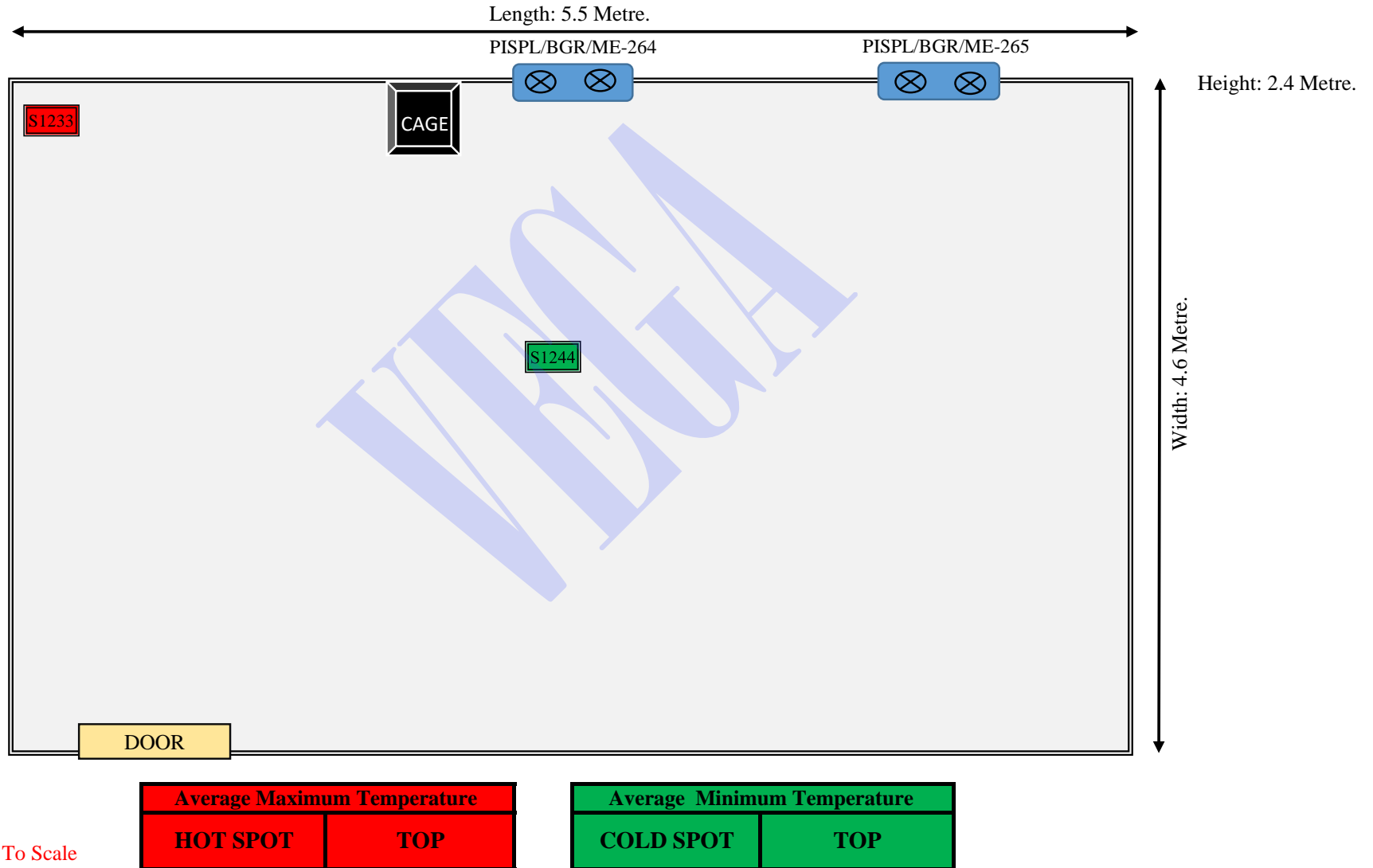
Note: All Parameters Are Computed Based On The Attached Raw Data.



VEGA Calibration And Validation Services LLP., Mumbai

Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Location Diagram Indicating Position Of Loggers Showing Maximum And Minimum Temperature Point



Note : Diagram Not To Scale



Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Summary And Observation Report Of Risk Analysis Studies For "Cold Room"



Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

Observation Remark

1. During Power Failure Test Cycle, excursion observed after 28 mins when Power Supply was Switched OFF and when Power Supply was Switched ON, normal operation range recovered within 38 mins.
2. During Door Open Test Cycle, considering 3 number of door opn tests, excursion was observed after average 16 mins when Door was kept Open and when Door was closed, normal operation range recovered on average within 35 mins.

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Objective : Thermal Qualification Study For "Cold Room" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification Number : 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 : Premise No. 2, Building No 6, BGR Logistics Park, Village- Vahuli, Padgha, Tal.- Bhiwandi, Dist.- Thane-421302, Maharashtra.		

List Of Annexures

1. Annexure-1 (Raw Data)
2. Annexure-2 (Data Loggers Details & Master Traceability Reports)
3. Annexure-3 (Training Certificate)

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