



VEGA Calibration And Validation Services LLP.Mumbai

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Thermal Qualification Study For

"Visi Cooler" (PQ)

Identification No. : VISI COOLER (°B Medical)

Located At

M/s. PAREKH INTEGRATED SERVICES PVT. LTD. (CFA-ALCON)

Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society,

Aundh, Pune-411007, Maharashtra, India.

Thermal Qualification Study Performed On	Thermal Qualification Study Next Due On
26/04/2022	25/04/2025



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Objective		Report No.		Qualification Performed On		Next Qualification Due On	
Thermal Qualification Study For "Visi Cooler" (PQ)		VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01		26/04/2022		25/04/2025	
Name Of The Customer : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.							
Address Of The Customer : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.							
Details For "Visi Cooler"							
Identification Number Of The "Visi Cooler"		CFA	Location	Make / Model No.	Acceptable Operating Range Temperature (°C)	Usage Of The "Visi Cooler"	
VISI COOLER (°B Medical)		ALCON	PUNE	B Medicals/L290	2°C to 8°C	Storage Of Medicines	
Mapping Cycle Start Date		Mapping Cycle End Date		No. Of Cycles Performed	No. Of Sensing Point		Status
23/04/2022		26/04/2022		5	13+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	
23/04/2022	26/04/2022	5°C	Continuous Operation Test Cycle	13:30:00	13:30:00	5 Minute	
26/04/2022	26/04/2022	5°C	Door Open Test Cycle-I	13:41:00	13:55:00	1 Minute	
26/04/2022	26/04/2022	5°C	Door Open Test Cycle-II	14:27:00	14:41:00	1 Minute	
26/04/2022	26/04/2022	5°C	Door Open Test Cycle-III	15:17:00	15:32:00	1 Minute	
26/04/2022	26/04/2022	5°C	Power Failure Test Cycle	16:07:00	16:44:00	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	

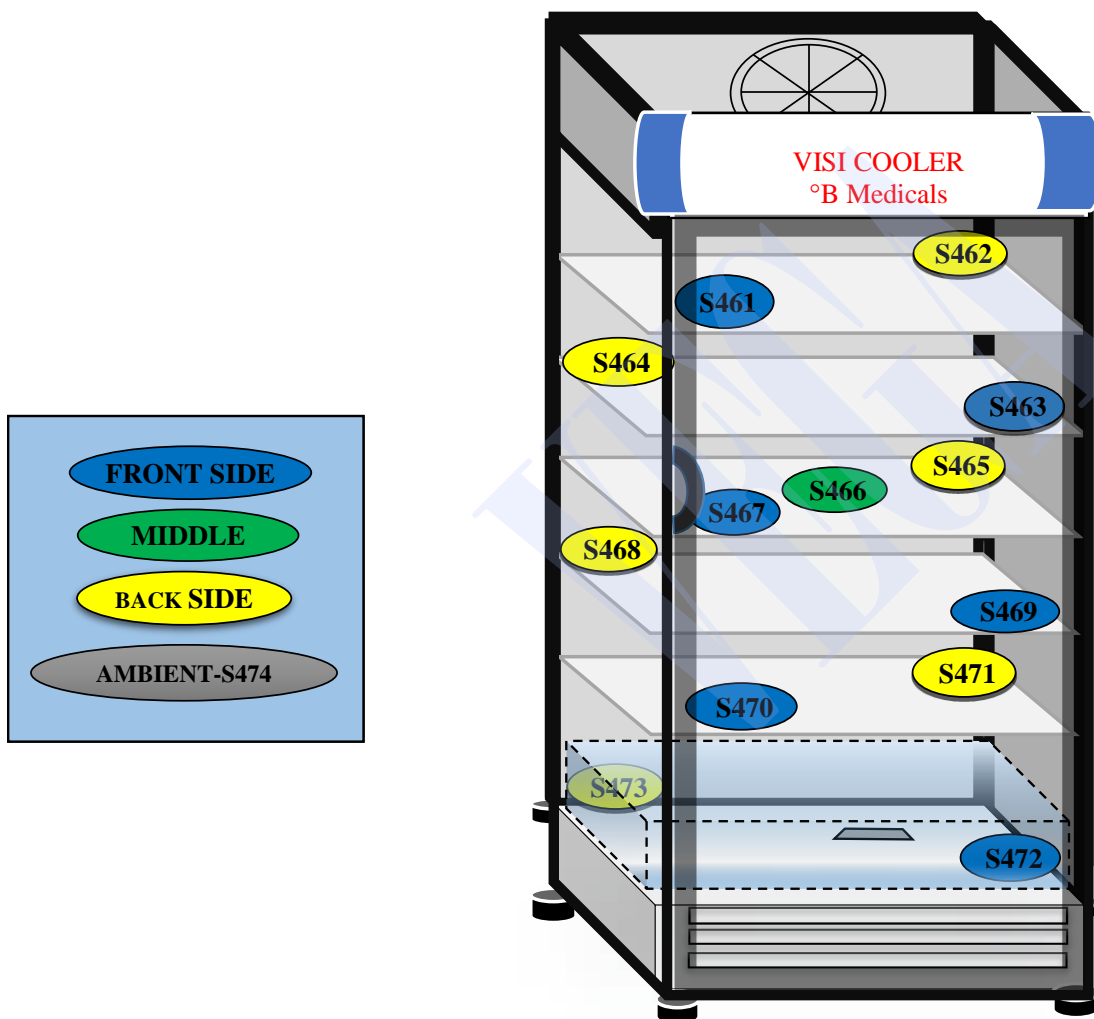


Objective : Thermal Qualification Study For "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number : VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

Location Diagram Of Data Loggers

Objective : Thermal Qualification Study For "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

Location Diagram Indicating Position Of Loggers



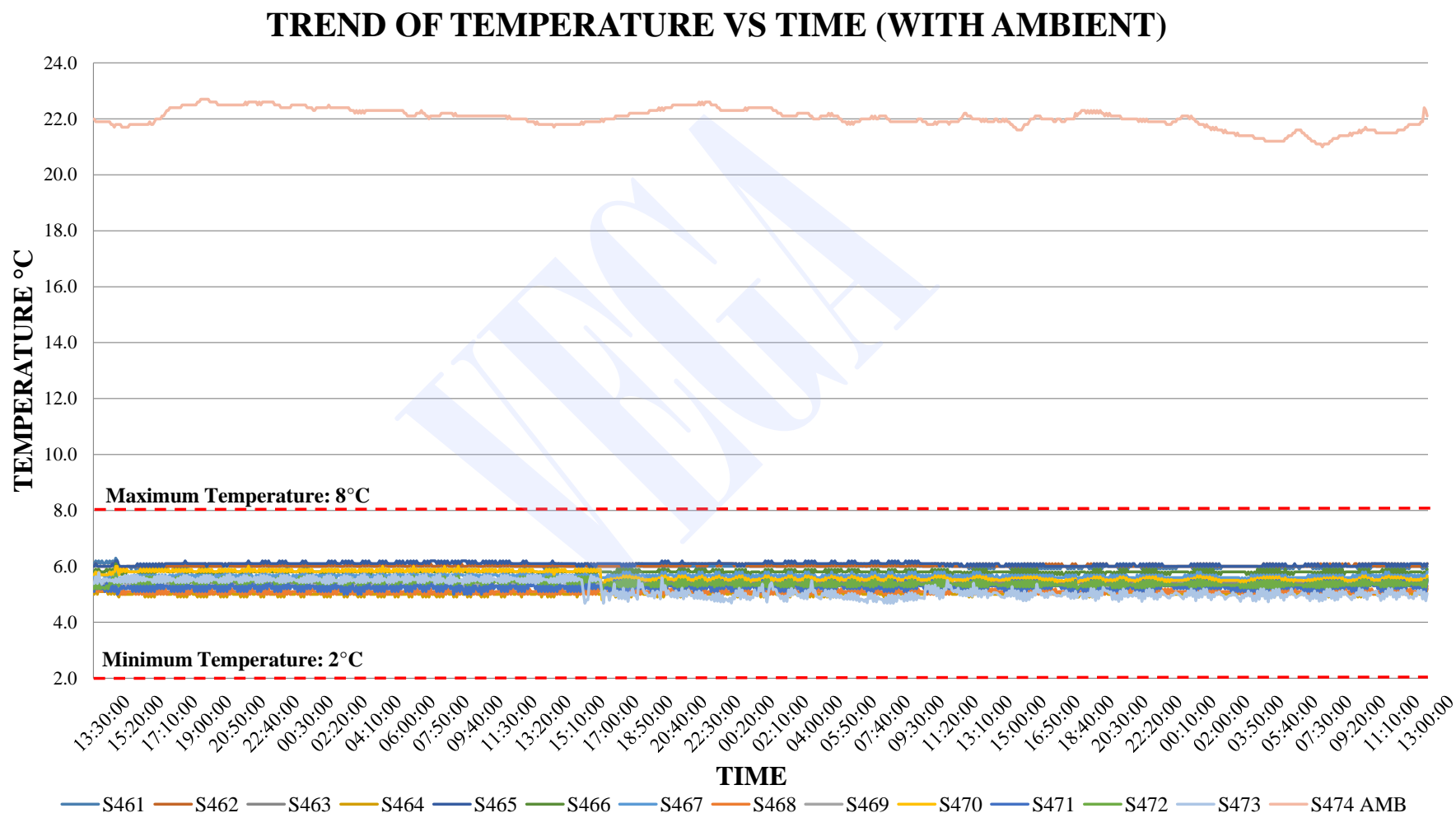


Objective : Thermal Qualification Study For "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

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

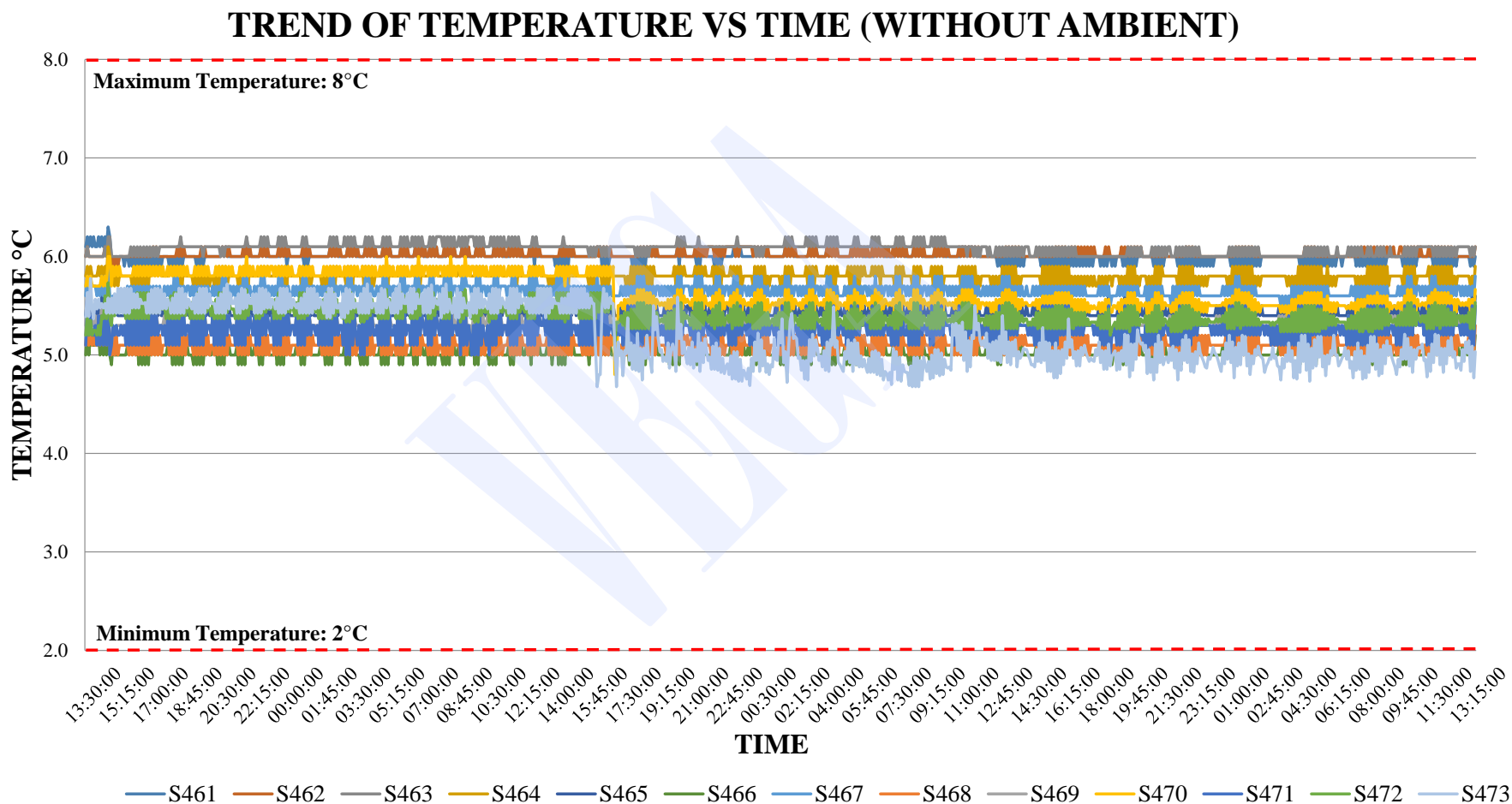


Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Continuous Operation Test Cycle	23/04/2022 13:30:00	26/04/2022 13:30:00
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.				





Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Continuous Operation Test Cycle	23/04/2022 13:30:00	26/04/2022 13:30:00
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.				
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anupama Housing Society, Aundh, Pune-411007, Maharashtra, India.				





Objective : Thermal Qualification Study Fc "Visi Cooler" (PQ)	Type Of Cycle: Door Open Test Cycle-I	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

Trend For The Cycle: (Temperature Vs Time)

Door Open Test Cycle-I

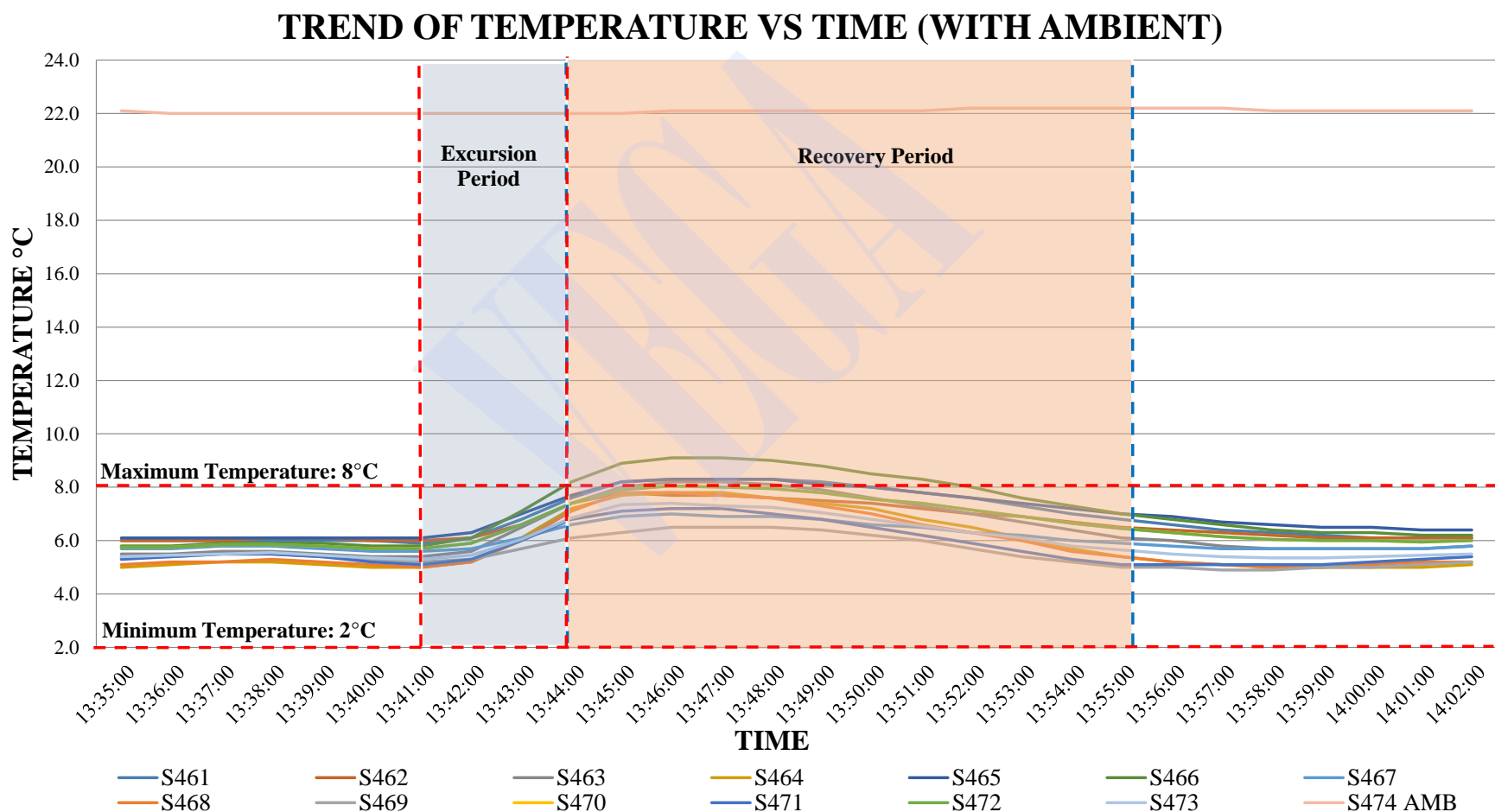


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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Door Open Test Cycle-I	26/04/2022 13:41:00	26/04/2022 13:55:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
13:41:00	13:44:00	13:44:00	13:55:00	

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

Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.



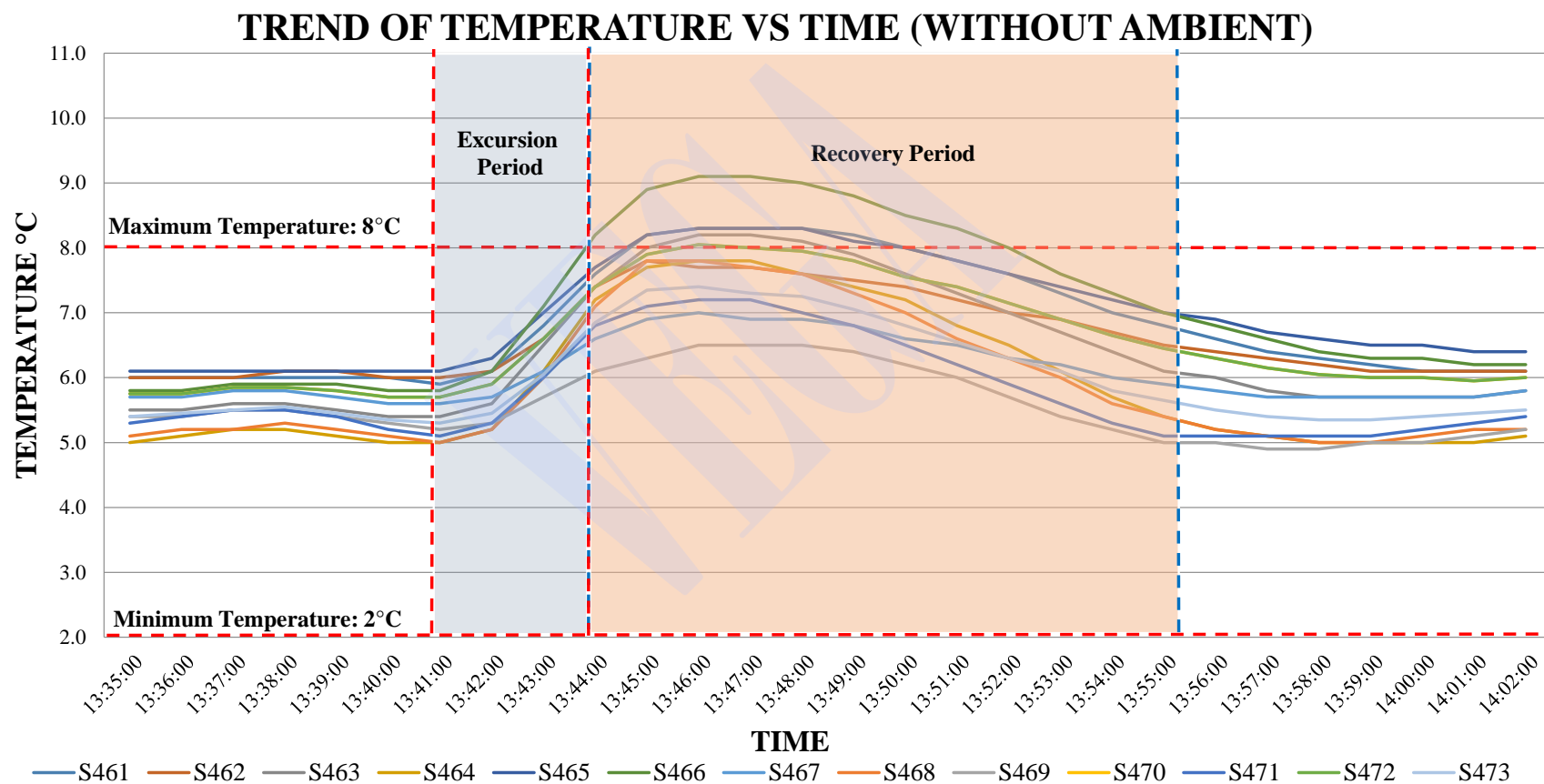


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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Door Open Test Cycle-I	26/04/2022 13:41:00	26/04/2022 13:55:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
13:41:00	13:44:00	13:44:00	13:55:00	

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

Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.





Objective : Thermal Qualification Study Fc "Visi Cooler" (PQ)	Type Of Cycle: Door Open Test Cycle-II	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

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

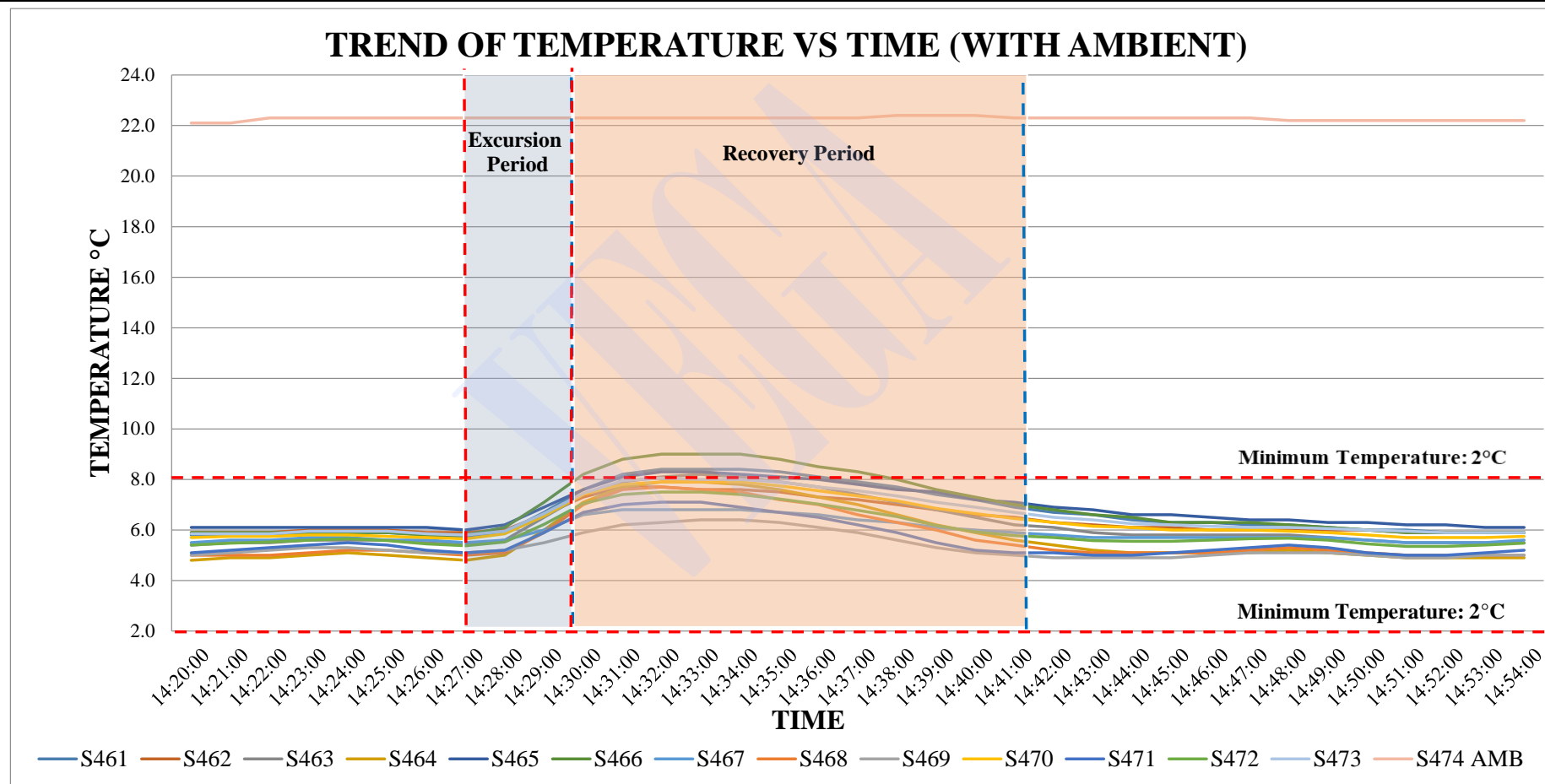


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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Door Open Test Cycle-II	26/04/2022 14:27:00	26/04/2022 14:41:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
14:27:00	14:30:00	14:30:00	14:41:00	

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

Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.



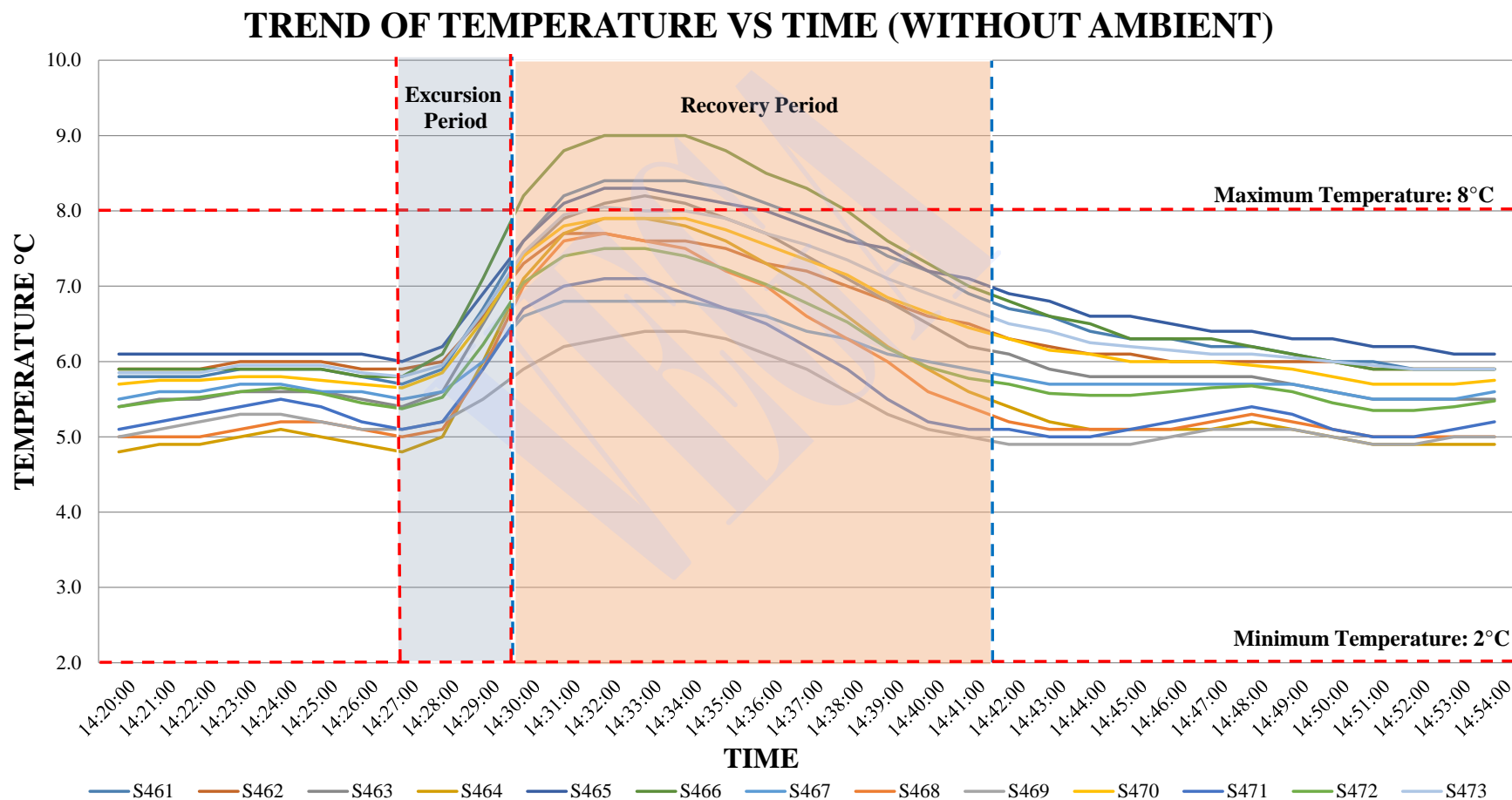


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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Door Open Test Cycle-II	26/04/2022 14:27:00	26/04/2022 14:41:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
14:27:00	14:30:00	14:30:00	14:41:00	

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

Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.





Objective : Thermal Qualification Study Fc "Visi Cooler" (PQ)	Type Of Cycle: Door Open Test Cycle-III	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

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



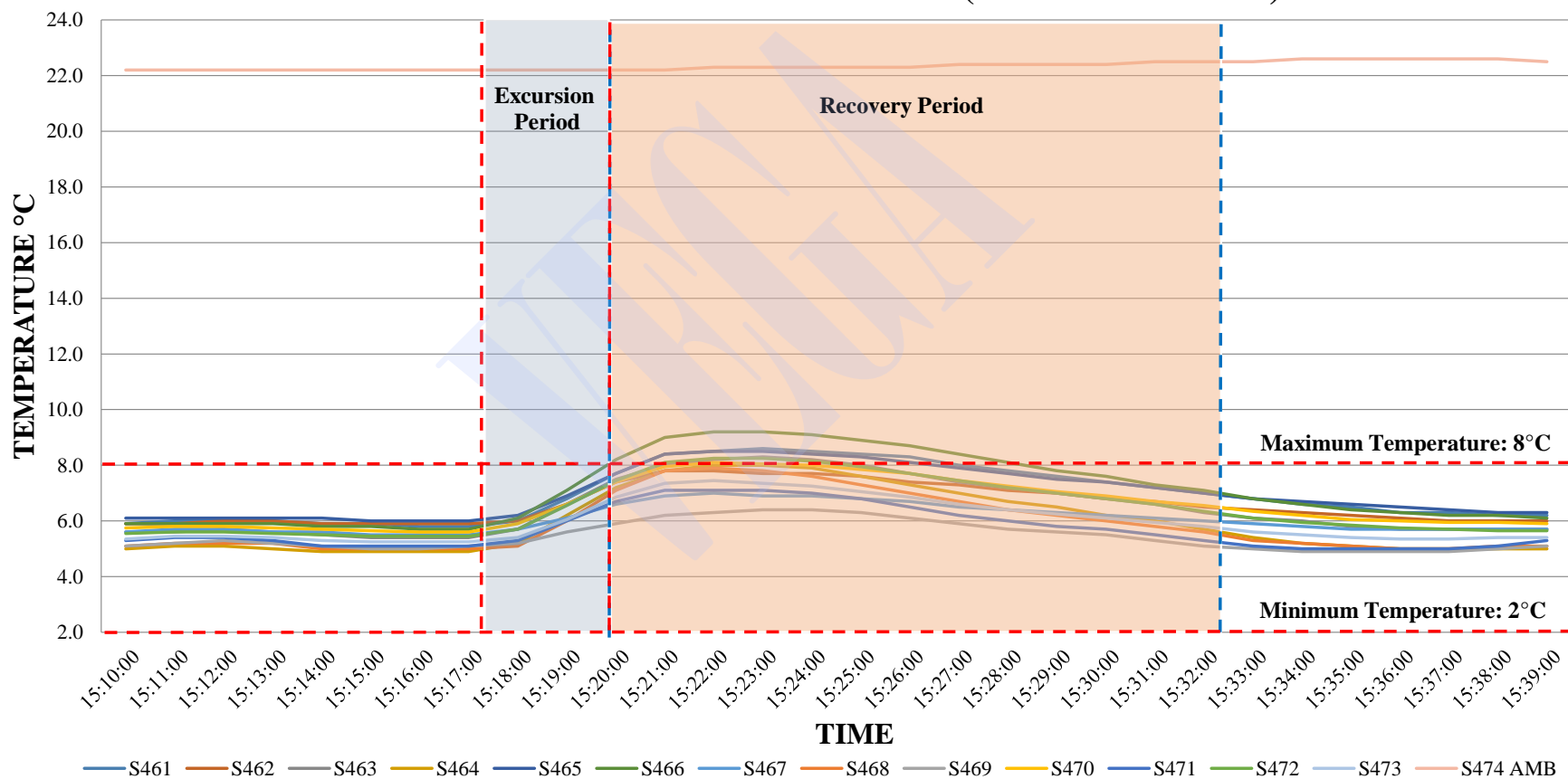
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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Door Open Test Cycle-III	26/04/2022 15:17:00	26/04/2022 15:32:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
15:17:00	15:20:00	15:20:00	15:32:00	

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

Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.

TREND OF TEMPERATURE VS TIME (WITH AMBIENT)



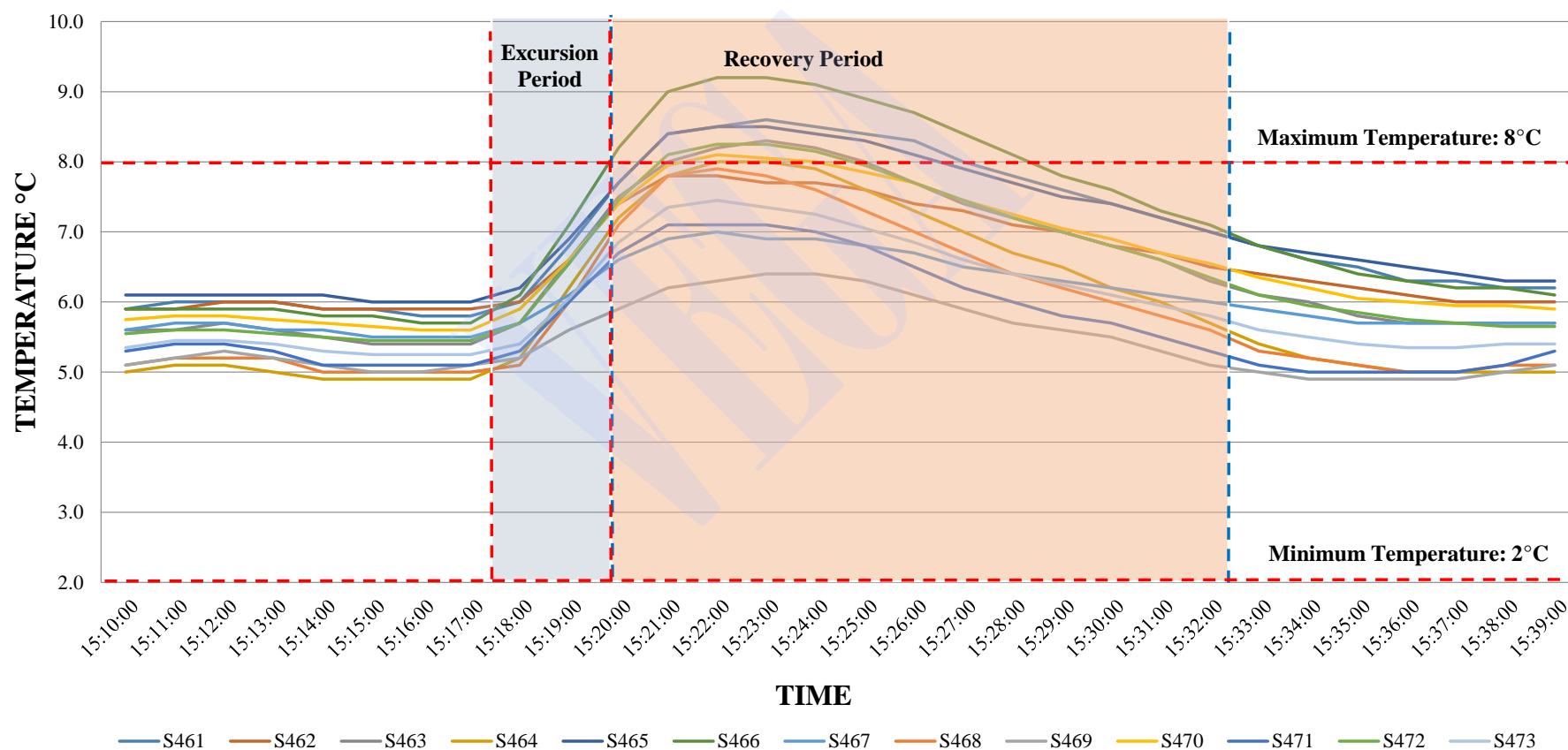


Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Door Open Test Cycle-III	26/04/2022 15:17:00	26/04/2022 15:32:00
Door Open Time	Set Limit Cross Out Time	Door Close Time	Set Limit Cross In Time	
15:17:00	15:20:00	15:20:00	15:32:00	

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

Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.

TREND OF TEMPERATURE VS TIME (WITHOUT AMBIENT)





Objective : Thermal Qualification Study For "Visi Cooler" (PQ)	Type Of Cycle: Power Failure Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number : VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

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

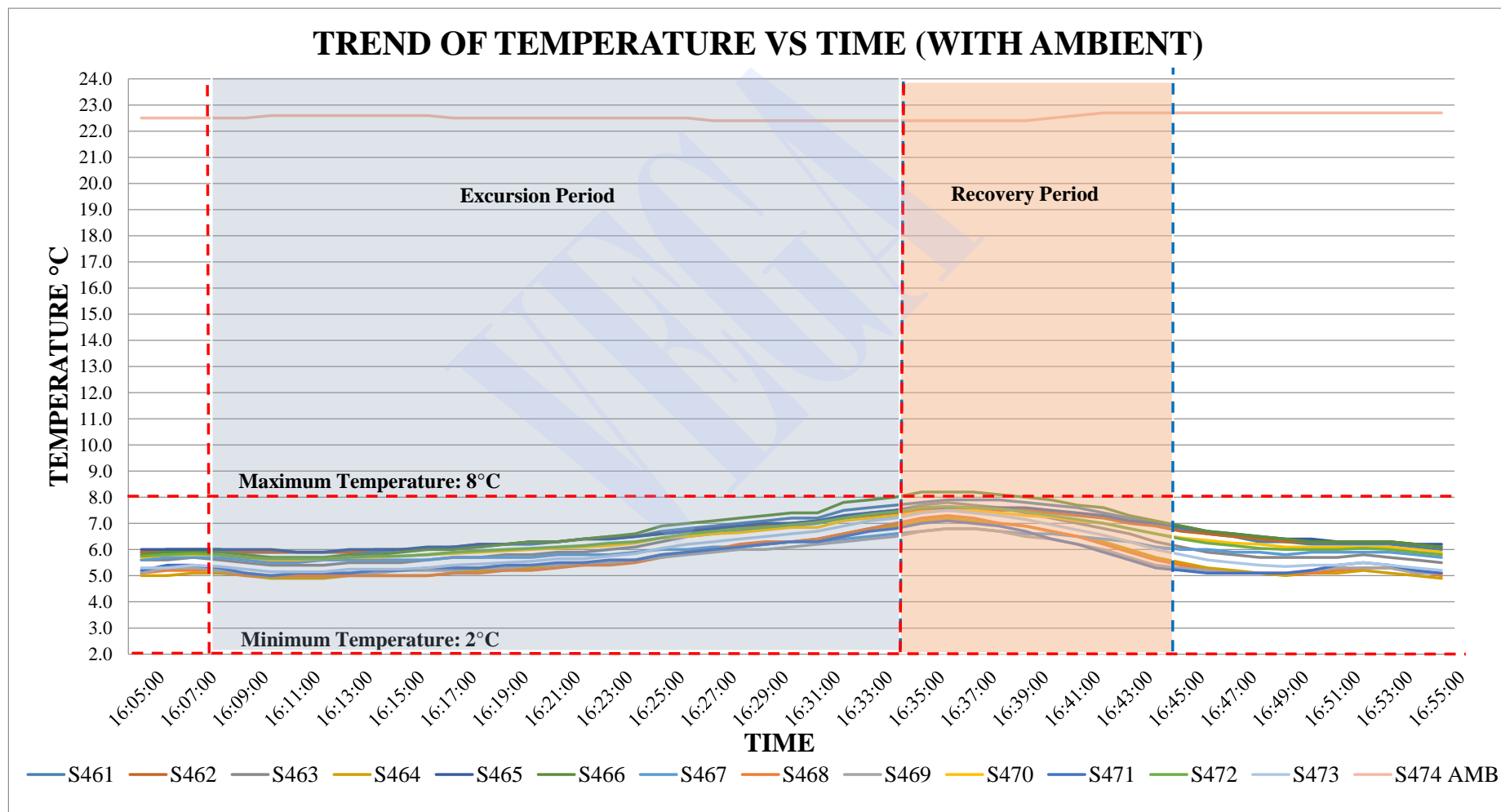


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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Power Failure Test Cycle	26/04/2022 16:07:00	26/04/2022 16:44:00
Power OFF Time	Set Limit Cross Out Time	Power ON Time	Set Limit Cross In Time	
16:07:00	16:33:00	16:33:00	16:44:00	

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

Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.





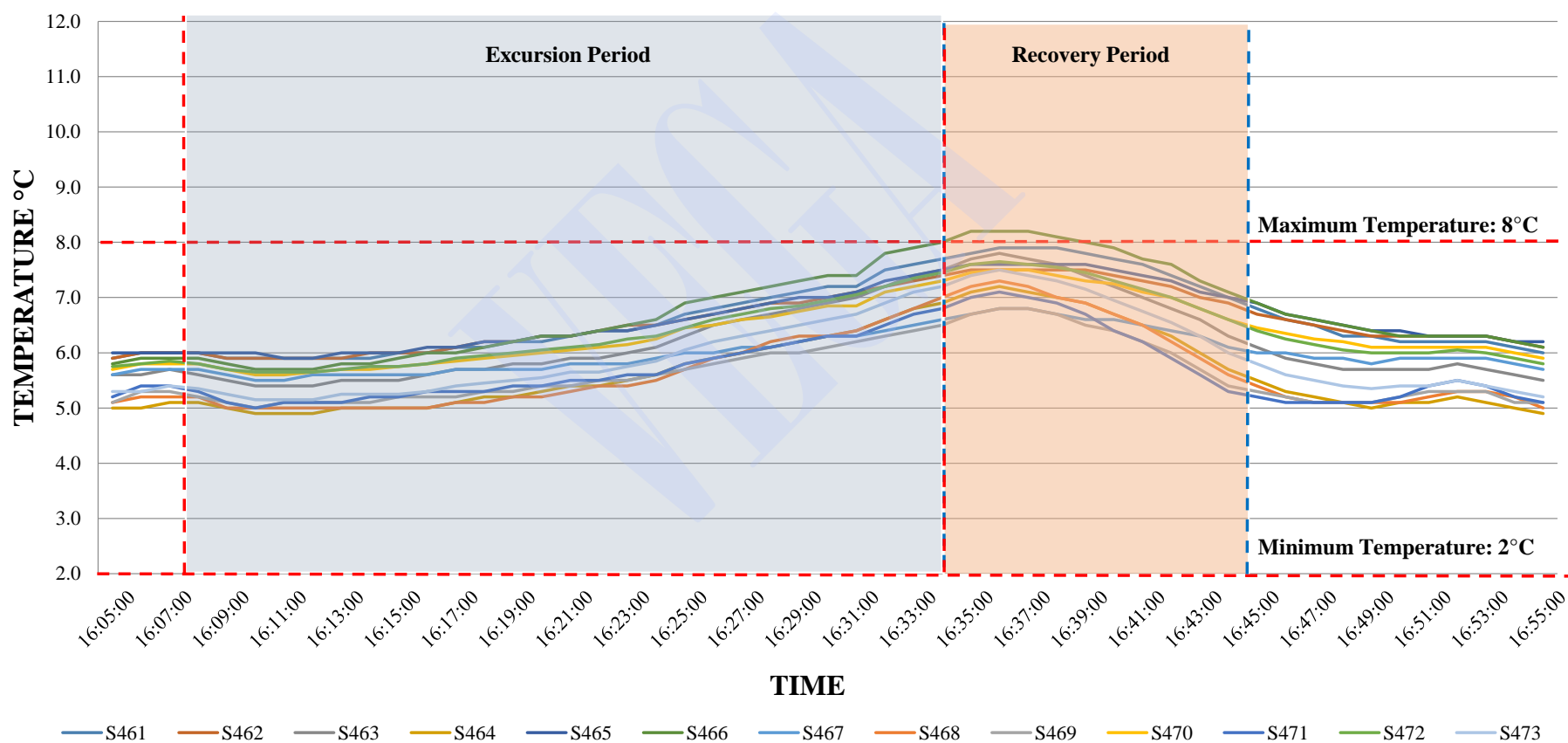
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Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	VISI COOLER (°B Medical)	Power Failure Test Cycle	26/04/2022 16:07:00	26/04/2022 16:44:00
Power OFF Time	Set Limit Cross Out Time	Power ON Time	Set Limit Cross In Time	
16:07:00	16:33:00	16:33:00	16:44:00	

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

Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.

TREND OF TEMPERATURE VS TIME (WITHOUT AMBIENT)





Objective : Thermal Qualification Study Fc "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

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



VEGA Calibration And Validation Services LLP., Mumbai

Objective : Thermal Qualification Study Fc "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

Summary of Parameters Computed During Mapping (Temperature)

POSITION	S461	S462	S463	S464	S465	S466	S467	S468	S469	S470	S471	S472	S473	S474 AMB
MINIMUM TEMPERATURE °C	5.9	5.9	6.0	5.7	5.3	4.9	5.5	5.0	5.1	4.8	5.0	5.1	4.7	21.0
MAXIMUM TEMPERATURE °C	6.3	6.1	6.2	6.1	5.8	5.4	5.9	5.5	5.6	6.0	5.6	5.7	5.8	22.7
AVERAGE TEMPERATURE °C	6.00	6.03	6.08	5.80	5.45	5.04	5.65	5.11	5.33	5.64	5.28	5.40	5.19	22.02
(MAX-MIN) TEMPERATURE °C	0.4	0.2	0.2	0.4	0.5	0.5	0.4	0.5	0.5	1.2	0.6	0.6	1.1	1.7
STANDARD DEVIATION °C	0.1	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.1	0.3	0.3

Maximum Temperature Point

HOT SPOT

FRONT

Minimum Temperature Point

COLD SPOT

MIDDLE

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



VEGA Calibration And Validation Services LLP., Mumbai

Objective : Thermal Qualification Study For "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number : VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

Observation and Concluding Remarks

1. **Point S463 (Average Temperature:6.08°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 S463. When only maximum limit needs to be controlled then treat point S463 as a HOT SPOT in Loaded condition.
2. **Point S466 (Average Temperature:5.04°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 S466. When only minimum limit needs to be controlled then treat point S466 as a COLD SPOT in Loaded condition.

Conclusion

The above given "Visi Cooler" is monitored for temperature uniformity for 72 Hours in Loaded condition and results found are as per the acceptance criteria. So the "Visi Cooler" 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



Objective : Thermal Qualification Study For "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anupama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

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

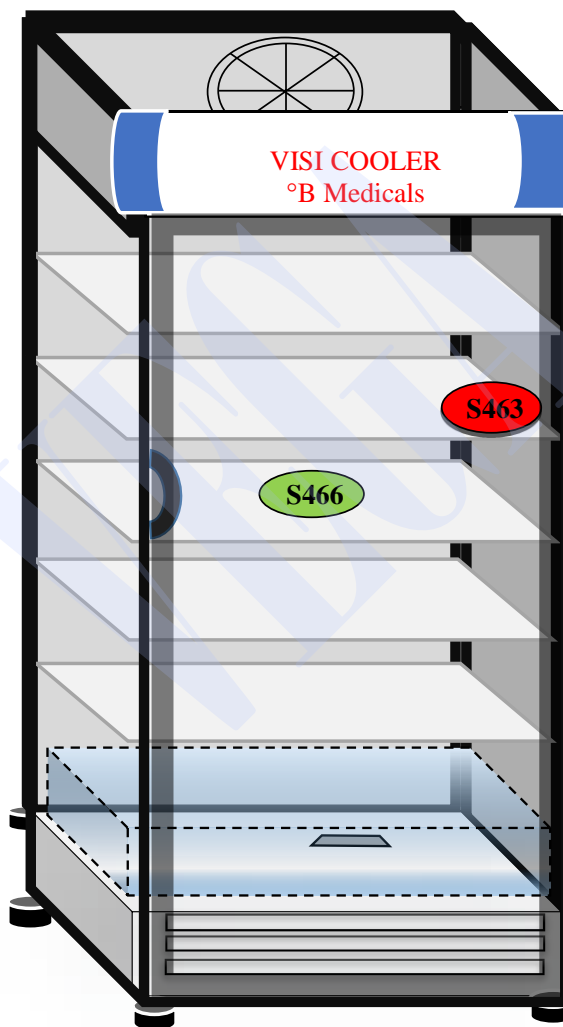
M . K . T = 5.54 °C

"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.

Objective : Thermal Qualification Study For "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

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



Maximum Temperature Point	
HOT SPOT	FRONT

Minimum Temperature Point	
COLD SPOT	MIDDLE



Objective : Thermal Qualification Study For "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.	Report Number : VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01	
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

Summary And Observation Report Of Risk Analysis Studies For "Visi Cooler"



Objective : Thermal Qualification Study Fc "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

Observation Remarks

1. During Door Open Test Cycles , when Door was Opened, Excursion was observed after 3 mins and Normal Operation Range was recovered within 11 mins.
2. During Power Failure Test Cycle, when Power Supply was Switched OFF, Excursion was observed after 26 mins and Normal Operation Range was recovered within 11 mins.



Objective : Thermal Qualification Study Fc "Visi Cooler" (PQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : VISI COOLER (°B Medical)
Customer Name : M/s. PAREKH INTEGRATED SERVICES PVT. LTD.		Report Number :VCVS/22-23/PISPL/PNE/ALC/VC/PQ/01
Customer Address : Saraswati Sr No. 2/4+5+6, Ground flr., Near Anuapama Housing Society, Aundh, Pune-411007, Maharashtra, India.		

List Of Annexures

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