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Thermal Qualification Study For

"Cool Room" (OQ)

Identification No. : 12

Located At

3S CORPORATION

A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway,  
Kanali East, Mumbai - 400102

Thermal Qualification Study Performed On	Thermal Qualification Study Next Due On
2021-08-08	2021-08-14



Objective	Report No.	Qualification Performed	Next Qualification Due On			
Thermal Qualification Study For "Cool Room"	1	2021-08-08	2021-08-21			
Name Of The Customer : 3S CORPORATION						
Address Of The Customer : Hiranagar Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kandivali East, Mumbai - 400102						
Identification Number Of The "Cool Room"	Location	Capacity	Make / Model No.	Acceptable Operating Range	Usage Of The "Cool Room"	
12	Kandivali East	C:\fakepath\VEGA Temp Mapping Protocol.pdf	RED STAR	Temperature (°C) -25 °C to -15 °C	Storage Of Medicines	
Mapping Cycle Start	Mapping Cycle End	No. Of Cycles	No. Of Sensing Point	Status		
2021-06-04	2021-06-13	Performed	8 +1 (Ambient)	loaded		
Details Of The Mapping Cycle						
Start Date	End Date	Set Temp.	Name Of The Cycle	Cycle Start Time	Cycle End Time	Recording Interval
2021-06-04	2021-06-07	NOB SET ON 3	Continuous Operation Test	(HH:MM:SS) 12:00	(HH:MM:SS) 12:00	5 Minute
2021-06-07	2021-06-07	NOB SET ON 3	Door Open Test Cycle	14:50	14:35	1 Minute
2021-06-07	2021-06-07	NOB SET ON 3	Power Failure Test Cycle	15:51	15:15	1 Minute
Details Of The Mapping Instrumentation						
Sr. No.	Details Of Master Instrument		Identification No.	Calibration Certificate No.		
01	Wireless Data Logger		12	As Per Attached Annexure		
For M/s. Vega Calibration And Validation Services LLP.			3S CORPORATION			
Prepared by		Checked By	Reviewed By		Approved By	



Objective : Thermal Qualification Study For"Cool Room" (OQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : 12
Customer Name : 3S CORPORATION		Report Number : 1
A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai -		
<div>400102</div> <p><b><u>Location Diagram Of Data Loggers</u></b></p>		

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

Type Of Cycle: Continuous  
Operation Test Cycle

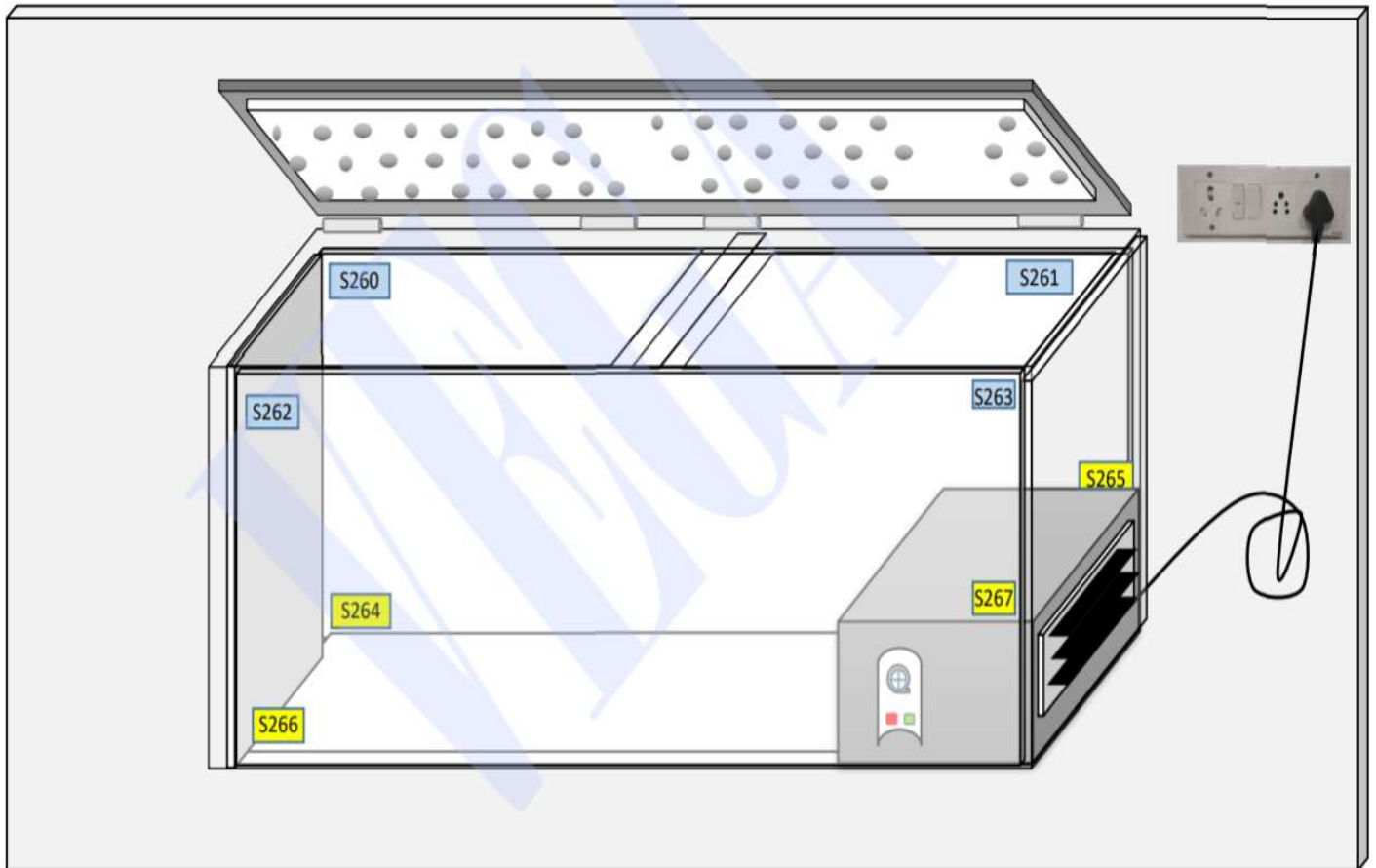
Identification No. : 12

Customer Name : 3S CORPORATION

Report Number : 1

A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai -  
400102

### Location Diagram Indicating Position Of Loggers



TOP

MIDDLE

BOTTOM

AMBIENT- S268



Objective : Thermal Qualification Study For"Cool Room" (OQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : 12
Customer Name : 3S CORPORATION		Report Number : 1
A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai - 400102		
<p style="text-align: center;"><b><u>Trend For The Cycle: (Temperature Vs Time).</u></b> <b><u>Continuous Operation Test Cycle</u></b></p>		



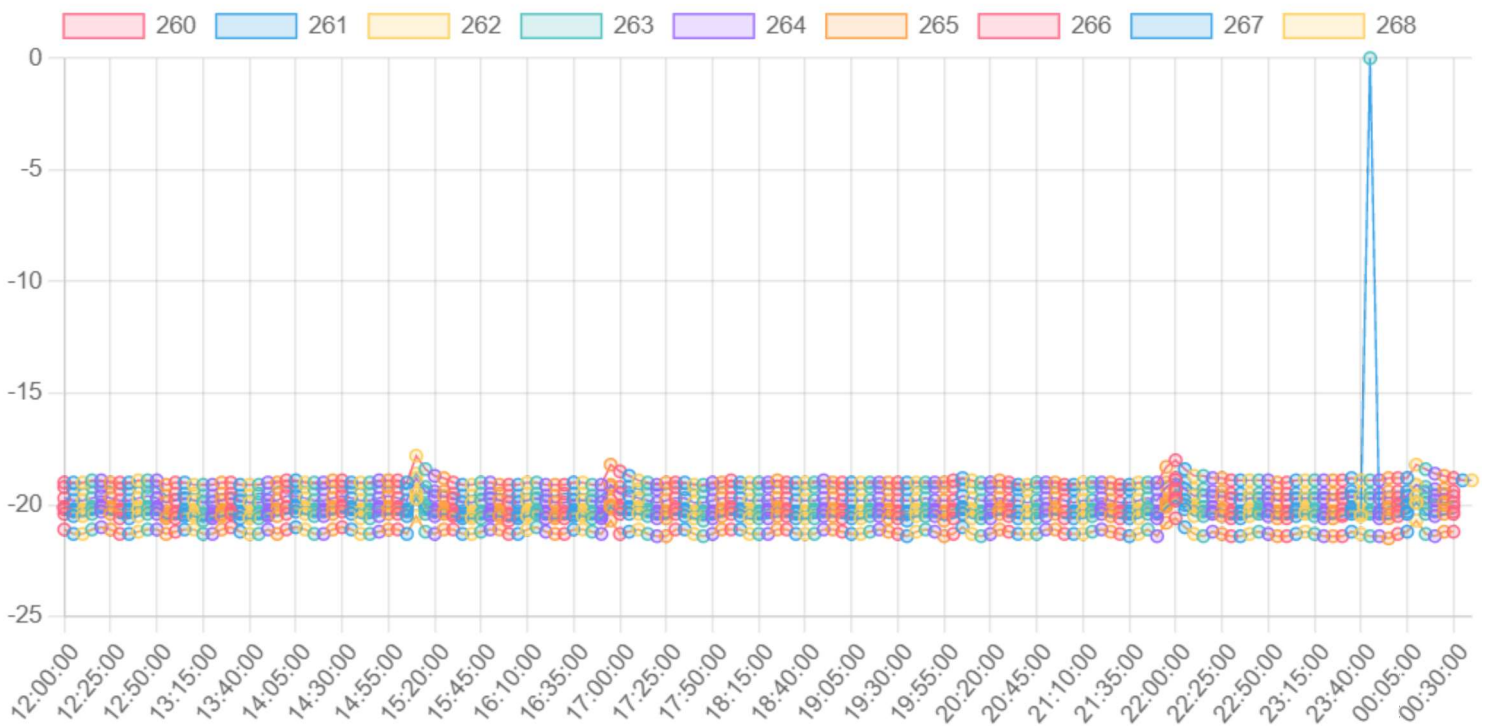
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
1	12	Continuous Operation Test Cycle	2021-06-04	2021-06-07

Customer Name : 3S CORPORATION

A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai -

## CONTINUOUS OPERATION TEST CYCLE (WITH AMBIENT)

## TREND OF TEMPERATURE VS TIME





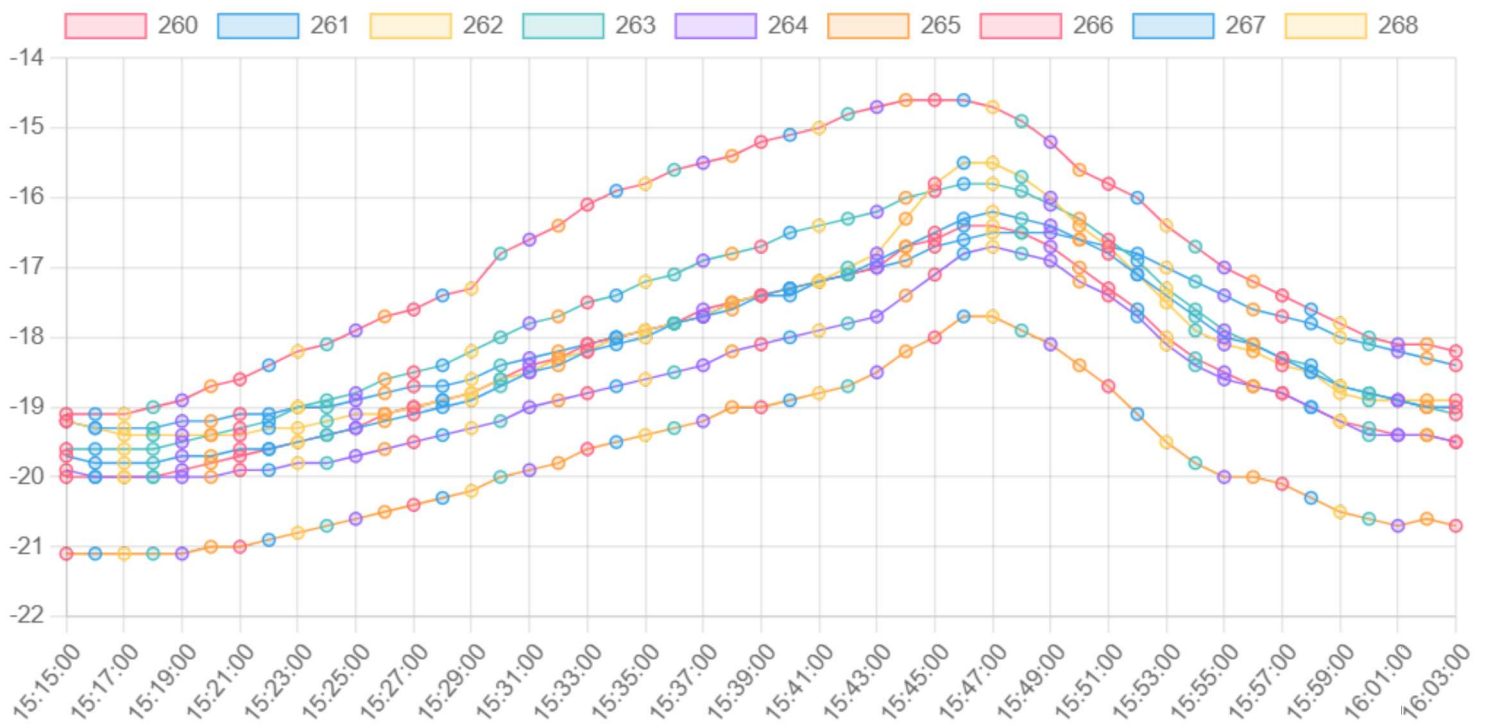
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
1	12	Continuous Operation Test Cycle	2021-06-04	2021-06-07

Customer Name : 3S CORPORATION

A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai -

## CONTINUOUS OPERATION TEST CYCLE (WITHOUT AMBIENT)

## TREND OF TEMPERATURE VS TIME







Objective : Thermal Qualification Study ForCool Room (OQ)	Type Of Cycle: Door Open Test Cycle	Identification No. : 12
Customer Name : 3S CORPORATION		Report Number : 1
Customer Address : A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai - 400102		
<p style="text-align: center;"><b><u>Trend For The Cycle: (Temperature Vs Time)</u></b> <b><u>Door Open Test Cycle</u></b></p>		

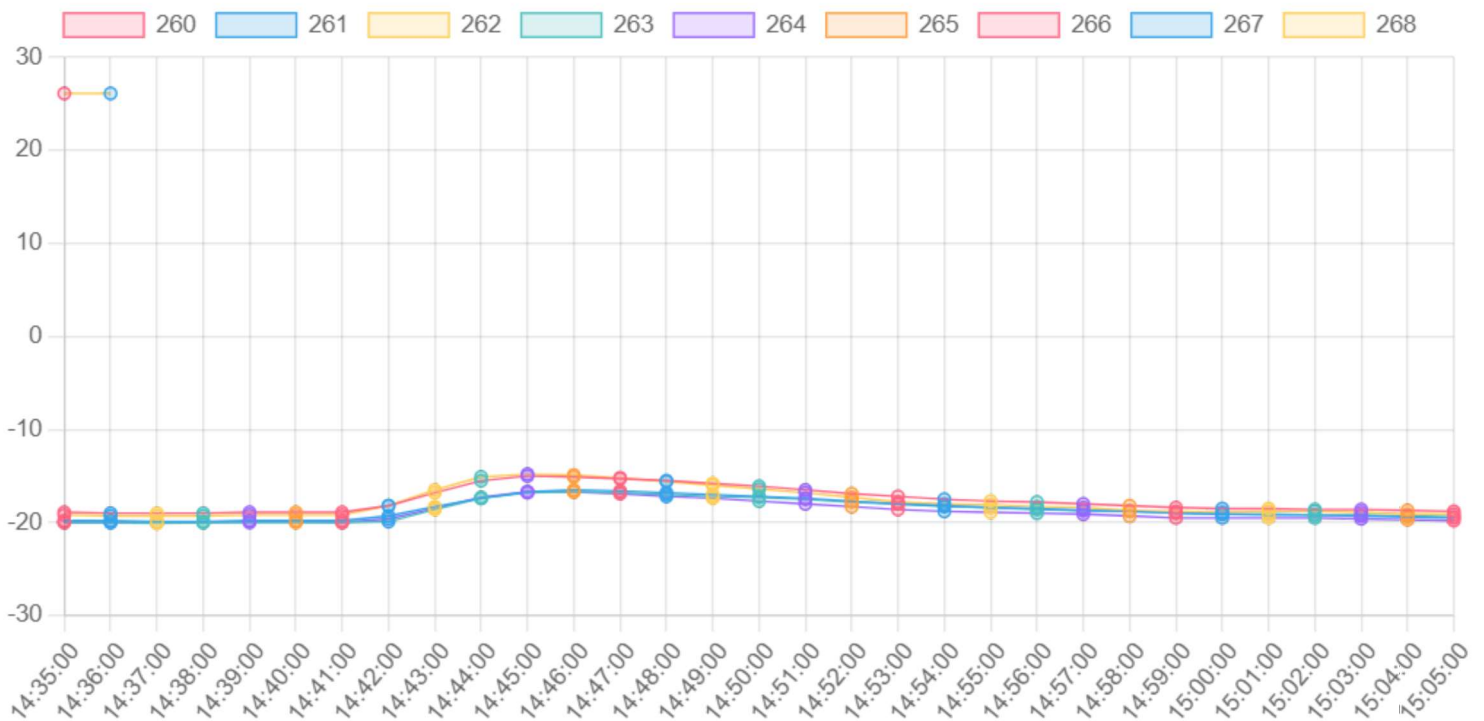
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
1	12	Door Open Test	2021-06-07	2021-06-07
Door Open Time	Set Limit Cross Out Time	Cycle Door Close Time	Set Limit Cross In Time	
14:50	14:54	14:35	14:54	

Customer Name : 3S CORPORATION

Customer Address : A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway,

## DOOR OPEN TEST CYCLE (WITH AMBIENT)

## TREND OF TEMPERATURE VS TIME





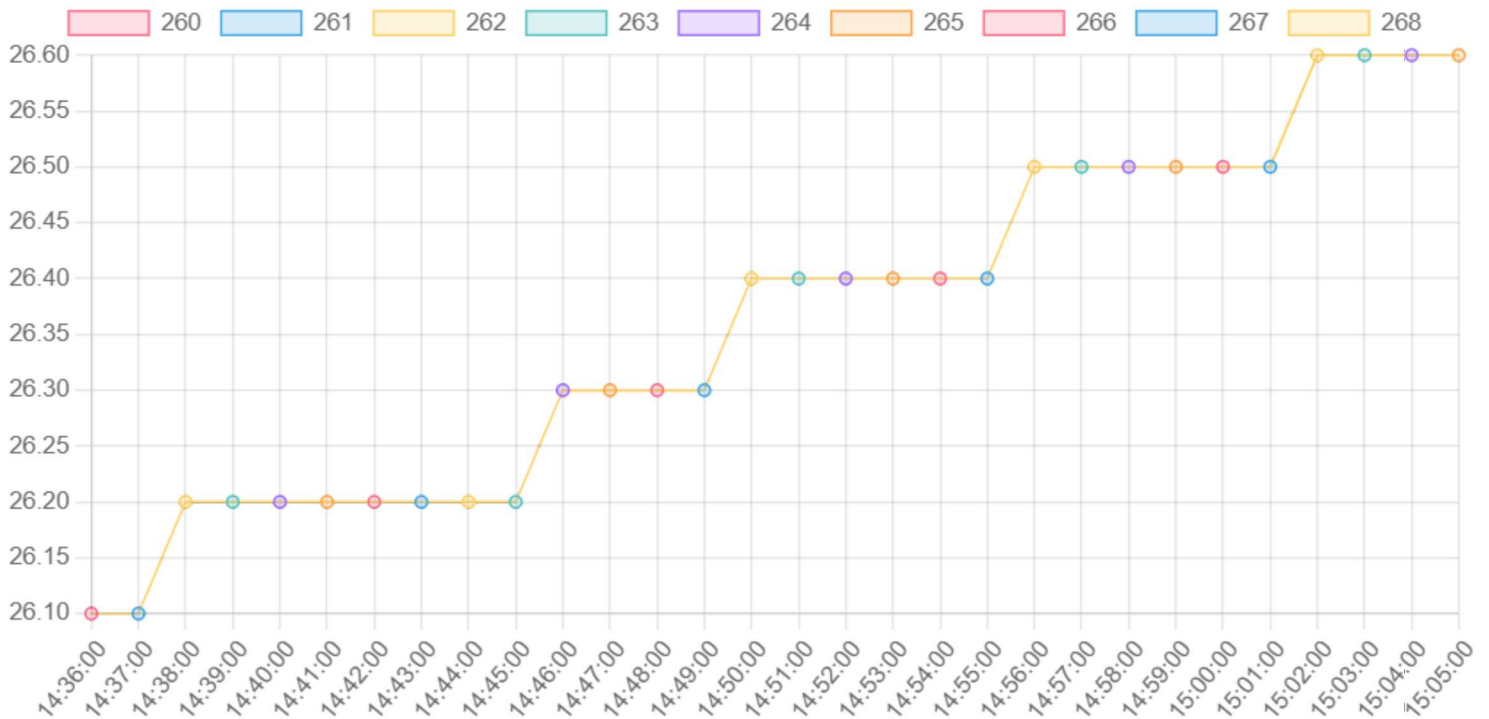
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
1	12	Door Open Test	2021-06-07	2021-06-07
Door Open Time	Set Limit Cross Out Time	Cycle	Door Close Time	Set Limit Cross In Time
14:50	14:54		14:35	14:54

Customer Name : 3S CORPORATION

Customer Address : A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway,

## DOOR OPEN TEST CYCLE (WITHOUT AMBIENT)

## TREND OF TEMPERATURE VS TIME





Objective : Thermal Qualification Study For Cool Room (OQ)	Type Of Cycle: Power Failure Test Cycle	Identification No. : 12
Customer Name : 3S CORPORATION		Report Number : 1
Customer Address : A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai - 400102		
<p style="text-align: center;"><b><u>Trend For The Cycle: (Temperature Vs Time)</u></b> <b><u>Power Failure Test Cycle</u></b></p>		



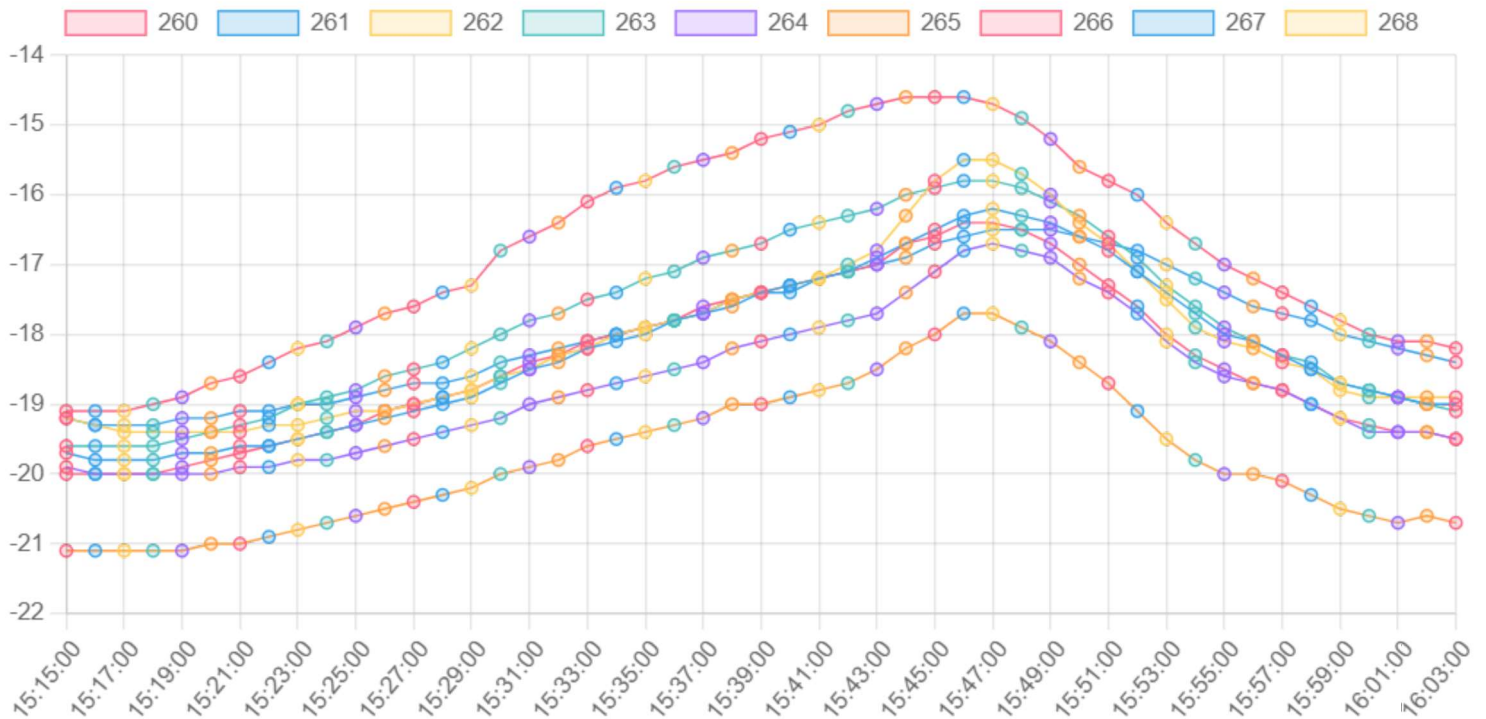
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
1	12	Power Failure Test	2021-06-07	2021-06-07
Power OFF Time	Set Limit Cross Out Time	Cycle	Power ON Time	Set Limit Cross In Time
15:51	14:54		15:15	14:54

Customer Name : 3S CORPORATION

Customer Address : A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway,

## POWER FAILURE TEST CYCLE (WITH AMBIENT)

## TREND OF TEMPERATURE VS TIME



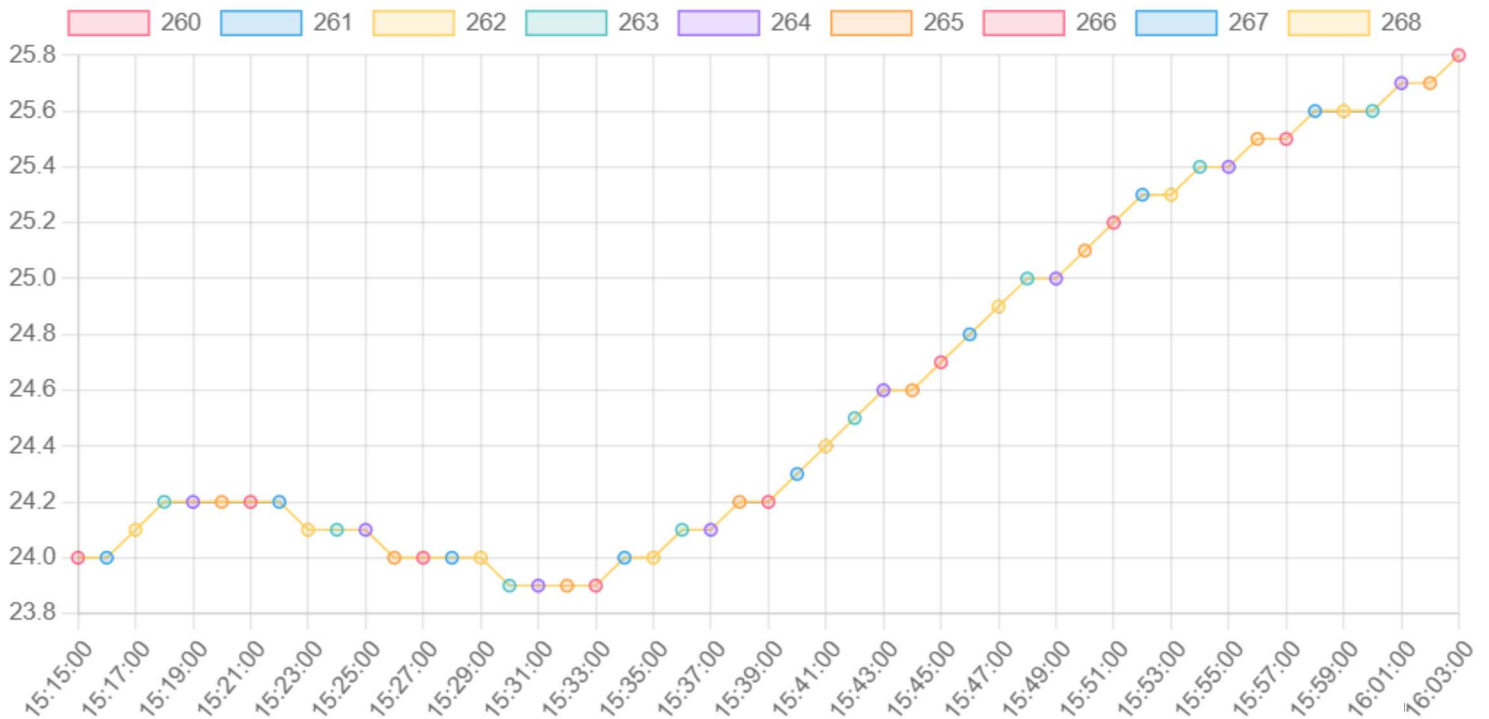
Report Number	Identification No.	Type Of Cycle	Start Date/Time	End Date/Time
1	12	Power Failure Test	2021-06-07	2021-06-07
Power OFF Time	Set Limit Cross Out Time	Cycle	Power ON Time	Set Limit Cross In Time
15:51	14:54		15:15	14:54

Customer Name : 3S CORPORATION

Customer Address :A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway,

## POWER FAILURE TEST CYCLE (WITHOUT AMBIENT)

## TREND OF TEMPERATURE VS TIME





Objective : Thermal Qualification Study For"Cool Room" (OQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : 12
Customer Name : 3S CORPORATION		Report Number : 1
A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai - 400102		
<p style="text-align: center;"><b><u>Summary and Observation Report Of Parameters Computed</u></b> <b><u>During Mapping_(Temperature)</u></b></p>		

Objective : Thermal Qualification Study For"Cool Room" (OQ)		Type Of Cycle: Continuous Operation Test Cycle		Identification No. : 12					
Customer Name : 3S CORPORATION				Report Number : 1					
A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai - 400102									
<b><u>Summary of Parameters Computed During Mapping.(Temperature)</u></b>									
Position	260	261	262	263	264	265	266	267	268
MINIMUM TEMPERATURE °C	-19	-21	-20	-20	-20	-21	-20	-20	24
MAXIMUM TEMPERATURE °C	-18	-19	-20	-20	-20	-19	-20	-19	26
AVERAGE TEMPERATURE °C	-18	-20	-19	-19	-19	-21	-20	-19	28





Objective : Thermal Qualification Study For "Cool Room" (OQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : 12	
Customer Name : 3S CORPORATION		Report Number : 1	
A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai - 400102			
<b><u>Observation and Concluding Remarks</u></b>  1. Point S260 (Average Temperature:-19.00°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 S260. When only maximum limit needs to be controlled then treat point S260 as a HOT SPOT in Loaded condition.,  2. Point S265 (Average Temperature:-21.30°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 S265. When only minimum limit needs to be controlled then treat point S265 as a COLD SPOT in Loaded condition. The above given "Deep Freezer" is monitored for temperature uniformity for 72 Hours in Loaded condition and results found are as per the acceptance criteria. So the "Deep Freezer" is in compliance with the defined criteria and qualified for its further use.			
For M/s. Vega Calibration And Validation Services		3S CORPORATION	
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 "Cool Room" (OQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : 12
Customer Name : 3S CORPORATION		Report Number : 1
A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai - 400102		
<b><u>MEAN KINETIC TEMPERATURE (M.K.T).</u></b>		
$\Delta H_{\text{---}} - \ln (e^{-\Delta H/RT_1} + e^{-\Delta H/RT_2} + \dots + e^{-\Delta H/RT_n}) n$		
<p>TK: Mean kinetic temperature in °K ΔH: Activation Energy for degradation reaction typically taken as 83.122 kJ/mole R is the universal gas constant = 8.3122x 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 = -14.5 °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>		

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

Type Of Cycle: Continuous  
Operation Test Cycle

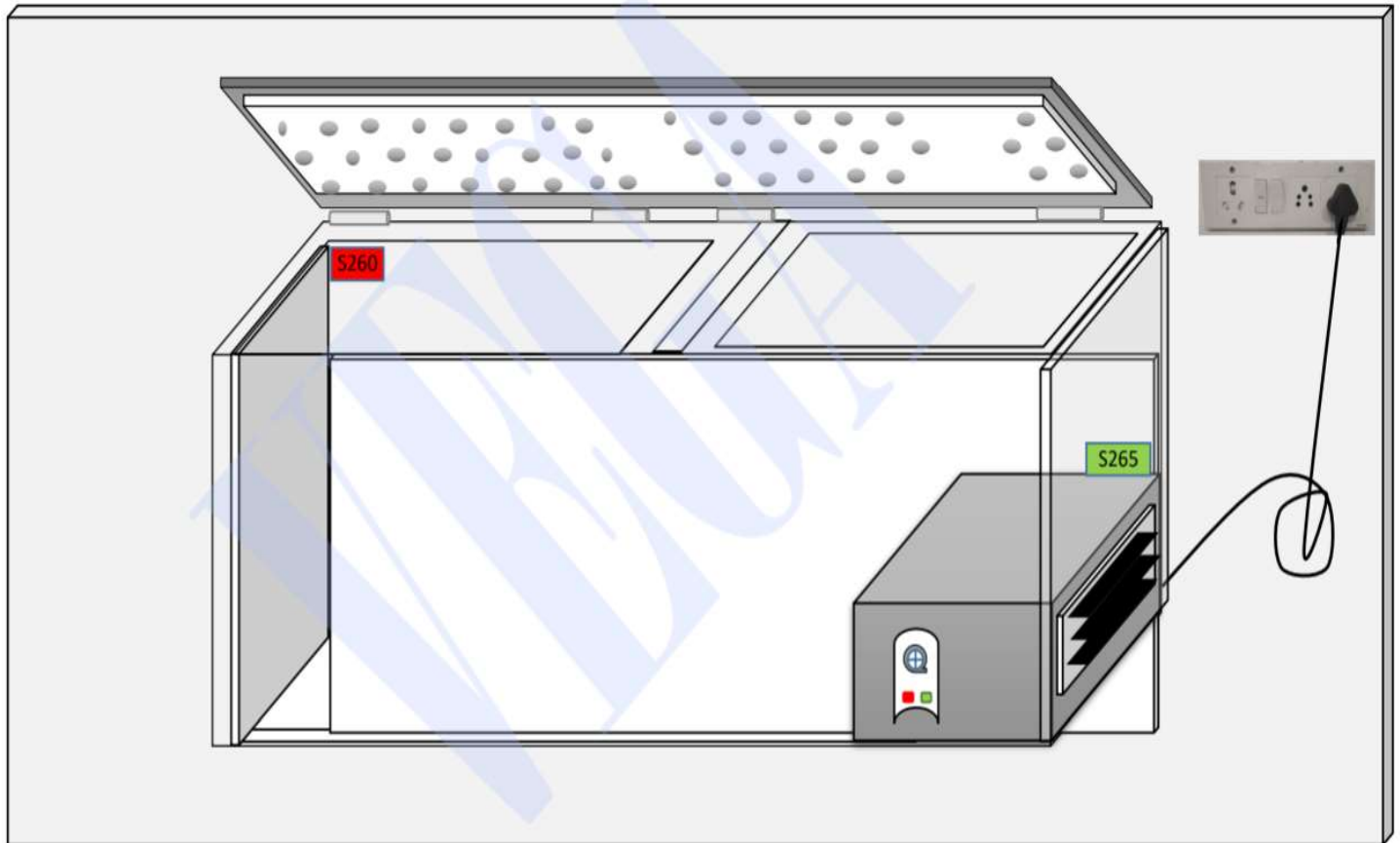
Identification No. : 12

Customer Name : 3S CORPORATION

Report Number : 1

A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai -  
400102

### Location Diagram Indicating Position Of Loggers



Maximum Temperature Point

HOT SPOT (TOP)

Minimum Temperature Point

COLD SPOT (BOTTOM)





Objective : Thermal Qualification Study For"Cool Room" (OQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : 12
Customer Name : 3S CORPORATION		Report Number : 1
A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai - 400102		
<b><u>Observation Remarks</u></b>  1. During Door Open Test Cycles, when Door was Opened, Excursion was observed after 9 mins and Normal Operation Range was recovered within 6 mins., 2. During Power Failure Test Cycle, when Power Supply was Switched OFF, Excursion was observed after 25 mins and Normal Operation Range was recovered within 11 mins.		



Objective : Thermal Qualification Study For"Cool Room" (OQ)	Type Of Cycle: Continuous Operation Test Cycle	Identification No. : 12
Customer Name : 3S CORPORATION		Report Number : 1
A/14 Bonanza Industrial Estate, Ashok Chakrabaty Road, Near Wdiv/E Highway, Kanali East, Mumbai - 400102		
<b><u>List Of Annexures</u></b>		
1. Annexure-1 <a href="#">continuous operation graph_1629200635.xlsx</a>		
2. Annexure-2 <a href="#">tests (1)_1629200636.xlsx</a>		
3. Annexure-3 <a href="#">tests_1629200636.xlsx</a>		