

Equipment/System ID:	Document Number:
Effective Date:-	Version Number: 00
	Trial Run #:
<u>/</u>	Appendix 3.5.1
Temperature Mapping Dur	ing Empty Chamber Lyophilization Cycle
Equipment Name : Lyophilizer	
Equipment ID :	Contents
Date	Cycle No.

1) PLC Set Parameter:

Step		Temperature	Vacuum	Tir	ne
No.	Step Type	(⁰ C)	(µBar)	HH:MM	HH:MM
01	Loading	+ 25.0	-	-	-
02	Freezing	- 50.0	-	01:10	-
03	Freezing	- 50.0	-	00:30	-
04	Evacuation	-	-	-	-
05	Drying	0.0	-	00:45	-
06	Drying	0.0	-	01:00	-
07	Drying	+ 50.0	-	00:40	-
08	Drying	+ 50.0	_	01:00	-

2) Sensor Location:

Shelf No. Sensor No.		Sensor Location	Remarks
	1	Right side rear corner of shelf	
	2	Right side front corner of shelf	
01	3	Middle of the shelf	
	4	Left side rear corner of shelf	
	5	Left side front corner of shelf	
	6	Right side front corner of shelf	
02	7	Middle of the shelf	
	8	Left side rear corner of shelf	
	9	Right side rear corner of shelf	
03	10	Middle of the shelf	
	11	Left side front corner of shelf	
	12	Right side front corner of shelf	
04	13	Middle of the shelf	
	14	Left side rear corner of shelf	



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Shelf No.	Sensor No.	Sensor Location	Remarks
	15	Right side rear corner of shelf	
05	16	Middle of the shelf	
	17	Left side front corner of shelf	
	18	Right side front corner of shelf	
06	19	Middle of the shelf	
	20	Left side rear corner of shelf	
	21	Right side rear corner of shelf	
07	22	Middle of the shelf	
	23	Left side front corner of shelf	
	24	Right side front corner of shelf	
08	25	Middle of the shelf	
	26	Left side rear corner of shelf	
	27	Right side rear corner of shelf	
09	28	Middle of the shelf	
	29	Left side front corner of shelf	
	30	Right side front corner of shelf	
10	31	Middle of the shelf	
	32	Left side rear corner of shelf	
	33	Right side rear corner of shelf	
11	34	Middle of the shelf	
	35	Left side front corner of shelf	
	36	Right side front corner of shelf	
12	37	Middle of the shelf	
	38	Left side rear corner of shelf	
	39	Right side rear corner of shelf	
	40	Right side front corner of shelf	
13	41	Middle of the shelf	
	42	Left side rear corner of shelf	
	43	Left side front corner of shelf]



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Effective Date:-		Ve	ersion Nun	n ber: 00	
	I	Drawing No. 1			Trial Run #:
	_			Bellow	
					⊨> Shelf 1
	• 2 • 1	• 3	5 🔴	•4	├ Shelf 2
	• 6	• 7	:	8.	⊨> Shelf 3
		• 10			
			11	14	⊏> Shelf 4
	12	• 13			□ → Shelf 5
		• 16	17		⊨⇒ Shelf 6
Mushroom Valve	18	• 19		20	⊨⇒ Shelf 7
	•:21	• 22	23	/	⊨⇒ Shelf 8
	• 24	• 25		26	r
	24				≓> Shelf 9
		• 28	29 🌒	•32	⊨⇒ Shelf 10
	30	• 31			⊨_> Shelf 11
	• 33	• 34	35	/	⊨> Shelf 12
	36	, 37		38	Shelf 13
	40	• 41	43	.42	ţ



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3) Observation of Temperature Mapping at -50.0°C:

Shelf No.	Probe No.	Average Temp. of Probe	All sensors average temperature	Average Temp. of Shelf (a)	Variation of Average Temp. of shelf (Shelf to Shelf) (NMT ± 1.5°C) (b)	Difference Between Shelf Averages Temp. And All Sensors Average Temp. (NMT ± 1.5°C)	Total hold time (NLT 30 min.)
	1						
1	2						
1.	3						
	4						
	5						
	6						
2.	7						
	8						
	9						
3.	10						
	11						
	12						
4.	13						
	14						
	15						
5.	16						
	17						
	18						
6.	19						
	20						
7.	21						
/.	22						



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Effect	ive Date:-			v	ersion Number: 0	0		
Trial R								
Shelf No.	Probe No.	Average Temp. of Probe	All sensors average temperature	Average Temp. of Shelf (a)	Variation of Average Temp. of shelf (Shelf to Shelf) (NMT ± 1.5°C) (b)	Difference Between Shelf Averages Temp. And All Sensors Average Temp. (NMT ± 1.5°C)	Total hold time (NLT 30 min.)	
	23							
	24							
8.	25							
	26							
	27							
9.	28							
	29							
	30							
10.	31							
	32							
	33							
11.	34							
	35							
	36							
12.	37							
	38							
	39							
	40							
13.	41							
	42							
	43							



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4) Observation of Temperature Mapping at 0.0^oC:

Shelf No.	Probe No.	Average Temp. of Probe	All sensors average temperature	Average Temp. of Shelf (a)	Variation of Average Temp. of shelf (Shelf to Shelf) (NMT ± 1.5°C) (b)	Difference Between Shelf Averages Temp. And All Sensors Average Temp. (NMT ± 1.5°C)	Total hold time (NLT 30 min.)
	1						
1.	2						
1.	3						
	4						
	5						
	6						
2.	7						
	8						
	9						
3.	10						
	11						
	12						
4.	13						
	14						
	15						
5.	16						
	17						
	18						
6.	19						
	20						
7.	21						
/.	22						



Equip	oment/System	ID:		D	Document Number:			
Effect	ive Date:-			v	ersion Number: 0	0		
Trial R								
Shelf No.	Probe No.	Average Temp. of Probe	All sensors average temperature	Average Temp. of Shelf (a)	Variation of Average Temp. of shelf (Shelf to Shelf) (NMT ± 1.5°C) (b)	Difference Between Shelf Averages Temp. And All Sensors Average Temp. (NMT ± 1.5°C)	Total hold time (NLT 30 min.)	
	23							
	24							
8.	25							
	26							
	27							
9.	28							
	29							
	30							
10.	31							
	32							
	33							
11.	34							
	35							
	36							
12.	37							
	38							
	39							
	40							
13.	41							
	42							
	43							



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5) Observation of Temperature Mapping at 50.0^oC:

Shelf No.	Probe No.	Average Temp. of Probe	All sensors average temperature	Average Temp. of Shelf (a)	Variation of Average Temp. of shelf (Shelf to Shelf) (NMT ± 1.5°C) (b)	Difference Between Shelf Averages Temp. And All Sensors Average Temp. (NMT ± 1.5°C)	Total hold time (NLT 30 min.)
	1						
1	2						
1.	3						
	4						
	5						
	6						
2.	7						
	8						
	9						
3.	10						
	11						
	12						
4.	13						
	14						
	15						
5.	16						
	17						
	18						
6.	19						
	20						
7.	21						
/.	22						



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Trial R								
Shelf No.	Probe No.	Average Temp. of Probe	All sensors average temperature	Average Temp. of Shelf (a)	Variation of Average Temp. of shelf (Shelf to Shelf) (NMT ± 1.5°C) (b)	Difference Between Shelf Averages Temp. And All Sensors Average Temp. (NMT ± 1.5°C)	Total hold time (NLT 30 min.)	
	23							
	24							
8.	25							
	26							
	27							
9.	28							
	29							
	30							
10.	31							
	32							
	33							
11.	34							
	35							
	36							
12.	37							
	38							
	39							
	40							
13.	41							
	42							
	43							



	QUALITY ASSURANCE DEPARTMENT						
	Document Name: Performance Qualific	ation Appendix 3.5.1 for Lyophilizer					
Equipmen	t/System ID:	Document Number:					
Effective D	Date:-	Version Number: 00					
		Trial Run #:					
Accept	tance Criteria:						
a)	The Shelf inlet temperature and shelf outlet	temperature probes should not vary more than $\pm 2^{\circ}$ C.					
b)	The average of all external probe temperatu	re on each shelf should not vary more than $\pm 1.5^{\circ}$ C from					
	the average of all external sensors temperate	ure during hold time					
c)	The average temperature from shelf to shelf	should not vary more than $\pm 1.5^{\circ}$ C.					
d)	The shelf inlet probe temperature average	e should not vary by more than 1.5 $^\circ \mathrm{C}$ from the set					
	temperature as per the recipe.						
Remark							
	Checked By (Sign. /Date)	Verified By (Sign. /Date)					
<u> </u>							