



Document Name: Performance Qualification Appendix 3.5.1 for Lyophilizer

Equipment/System ID:

Document Number:

Effective Date:-

Version Number: 00

Trial Run #: _____

Appendix 3.5.1

Temperature Mapping During Empty Chamber Lyophilization Cycle

Equipment Name : Lyophilizer

Equipment ID :

Contents

Date	Cycle No.
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1) PLC Set Parameter:

Step No.	Step Type	Temperature (°C)	Vacuum (µBar)	Time	
				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
01	1	Right side rear corner of shelf	
	2	Right side front corner of shelf	
	3	Middle of the shelf	
	4	Left side rear corner of shelf	
	5	Left side front corner of shelf	
02	6	Right side front corner of shelf	
	7	Middle of the shelf	
	8	Left side rear corner of shelf	
03	9	Right side rear corner of shelf	
	10	Middle of the shelf	
	11	Left side front corner of shelf	
04	12	Right side front corner of shelf	
	13	Middle of the shelf	
	14	Left side rear corner of shelf	



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



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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 $\pm 1.5^{\circ}\text{C}$) (b)	Difference Between Shelf Averages Temp. And All Sensors Average Temp. (NMT $\pm 1.5^{\circ}\text{C}$)	Total hold time (NLT 30 min.)
	23						
8.	24						
	25						
	26						
	27						
9.	28						
	29						
	30						
10.	31						
	32						
	33						
11.	34						
	35						
	36						
12.	37						
	38						
	39						
13.	40						
	41						
	42						
	43						



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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						
8.	24						
	25						
	26						
	27						
9.	28						
	29						
	30						
10.	31						
	32						
	33						
11.	34						
	35						
	36						
12.	37						
	38						
	39						
13.	40						
	41						
	42						
	43						



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	23						
8.	24						
	25						
	26						
	27						
9.	28						
	29						
	30						
10.	31						
	32						
	33						
11.	34						
	35						
	36						
12.	37						
	38						
	39						
13.	40						
	41						
	42						
	43						



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Acceptance Criteria:

- a) The Shelf inlet temperature and shelf outlet temperature probes should not vary more than $\pm 2^{\circ}\text{C}$.
- b) The average of all external probe temperature on each shelf should not vary more than $\pm 1.5^{\circ}\text{C}$ from the average of all external sensors temperature during hold time
- c) The average temperature from shelf to shelf should not vary more than $\pm 1.5^{\circ}\text{C}$.
- d) The shelf inlet probe temperature average should not vary by more than 1.5°C from the set temperature as per the recipe.

Remarks:

Checked By (Sign. /Date)	Verified By (Sign. /Date)