



**Document Name:** Performance Qualification Appendix 3.3.1 for Lyophilizer

**Equipment/ system ID:**

**Document Number:**

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**Appendix 3.3.1**

**Cleaning in Performance Check and SIP**

**Equipment Name :** Lyophilizer

**Equipment ID :** .....

**Contents**

Date	Cycle No
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**1) PLC Set & Observed Parameter:**

Parameter	Value
Evacuation set point	600 mbar
No of Purge Cycles	3 Nos.
Sterilization Set Point	123°C
Sterilization time	30 min
Drying Time	60 min
Purge Pressure	1250 mbar
Sterilization Time Abort Temperature	<121°C
Filter Drying Time	10 min
Condenser Cooling Temperature	-10°C
Shelf Cooling Temperature	10°C
Condenser Cooling Abort Time	60 min
Shelf Cooling Abort Time	150 min



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**2) Location of Probes:**

<b>Location No</b>	<b>Location Detail</b>	<b>Shelf No.</b>	<b>Justification</b>
1.	In the chamber drain, near to inbuilt chamber drain probe.	NA	Worst location due to condensate deposition.
2.	Right side rear corner of shelf	1	To check uniform chamber sterilization
3.	Right side front corner of shelf	1	To check uniform chamber sterilization
4.	Center of the shelf	1	To check uniform chamber sterilization
5.	Left side front corner of shelf	1	To check uniform chamber sterilization
6.	Left side rare corner of shelf	1	To check uniform chamber sterilization
7.	Right side front corner of shelf	2	To check uniform chamber sterilization
8.	Center of the shelf	2	To check uniform chamber sterilization
9.	Left side rare corner of shelf	2	To check uniform chamber sterilization
10.	Right side rear corner of shelf	3	To check uniform chamber sterilization
11.	Center of the shelf	3	To check uniform chamber sterilization
12.	Left side front corner of shelf	3	To check uniform chamber sterilization
13.	Right side front corner of shelf	4	To check uniform chamber sterilization
14.	Center of the shelf	4	To check uniform chamber sterilization
15.	Left side rare corner of shelf	4	To check uniform chamber sterilization
16.	Right side rear corner of shelf	5	To check uniform chamber sterilization
17.	Center of the shelf	5	To check uniform chamber sterilization
18.	Left side front corner of shelf	5	To check uniform chamber sterilization
19.	Right side front corner of shelf	6	To check uniform chamber sterilization
20.	Center of the shelf	6	To check uniform chamber sterilization
21.	Left side rare corner of shelf	6	To check uniform chamber sterilization
22.	Right side rear corner of shelf	7	To check uniform chamber sterilization
23.	Center of the shelf	7	To check uniform chamber sterilization
24.	Left side front corner of shelf	7	To check uniform chamber sterilization
25.	Right side front corner of shelf	8	To check uniform chamber sterilization
26.	Center of the shelf	8	To check uniform chamber sterilization



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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Location No	Location Detail	Shelf No.	Justification
27.	Left side rare corner of shelf	8	To check uniform chamber sterilization
28.	Right side rear corner of shelf	9	To check uniform chamber sterilization
29.	Center of the shelf	9	To check uniform chamber sterilization
30.	Left side front corner of shelf	9	To check uniform chamber sterilization
31.	Right side front corner of shelf	10	To check uniform chamber sterilization
32.	Center of the shelf	10	To check uniform chamber sterilization
33.	Left side rare corner of shelf	10	To check uniform chamber sterilization
34.	Right side rear corner of shelf	11	To check uniform chamber sterilization
35.	Center of the shelf	11	To check uniform chamber sterilization
36.	Left side front corner of shelf	11	To check uniform chamber sterilization
37.	Right side front corner of shelf	12	To check uniform chamber sterilization
38.	Center of the shelf	12	To check uniform chamber sterilization
39.	Left side rare corner of shelf	12	To check uniform chamber sterilization
40.	Right side rear corner of shelf	13	To check uniform chamber sterilization
41.	Right side front corner of shelf	13	To check uniform chamber sterilization
42.	Center of the shelf	13	To check uniform chamber sterilization
43.	Left side front corner of shelf	13	To check uniform chamber sterilization
44.	Left side rare corner of shelf	13	To check uniform chamber sterilization
45.	Rear wall of chamber in upper left corner	NA	Worst location due to farthest point from steam insertion point.
46.	Rear wall of chamber in lower right corner	NA	Worst location due to farthest point from steam insertion point.
47.	Inner side of door of the chamber	NA	Chances of temperature variation due to non-insulated side.
48.	In the condenser drain	NA	Worst location due to condensate deposition.
49.	Inside the vaccum break filter	NA	Due to deep pleated membrane, penetration of steam is difficult.



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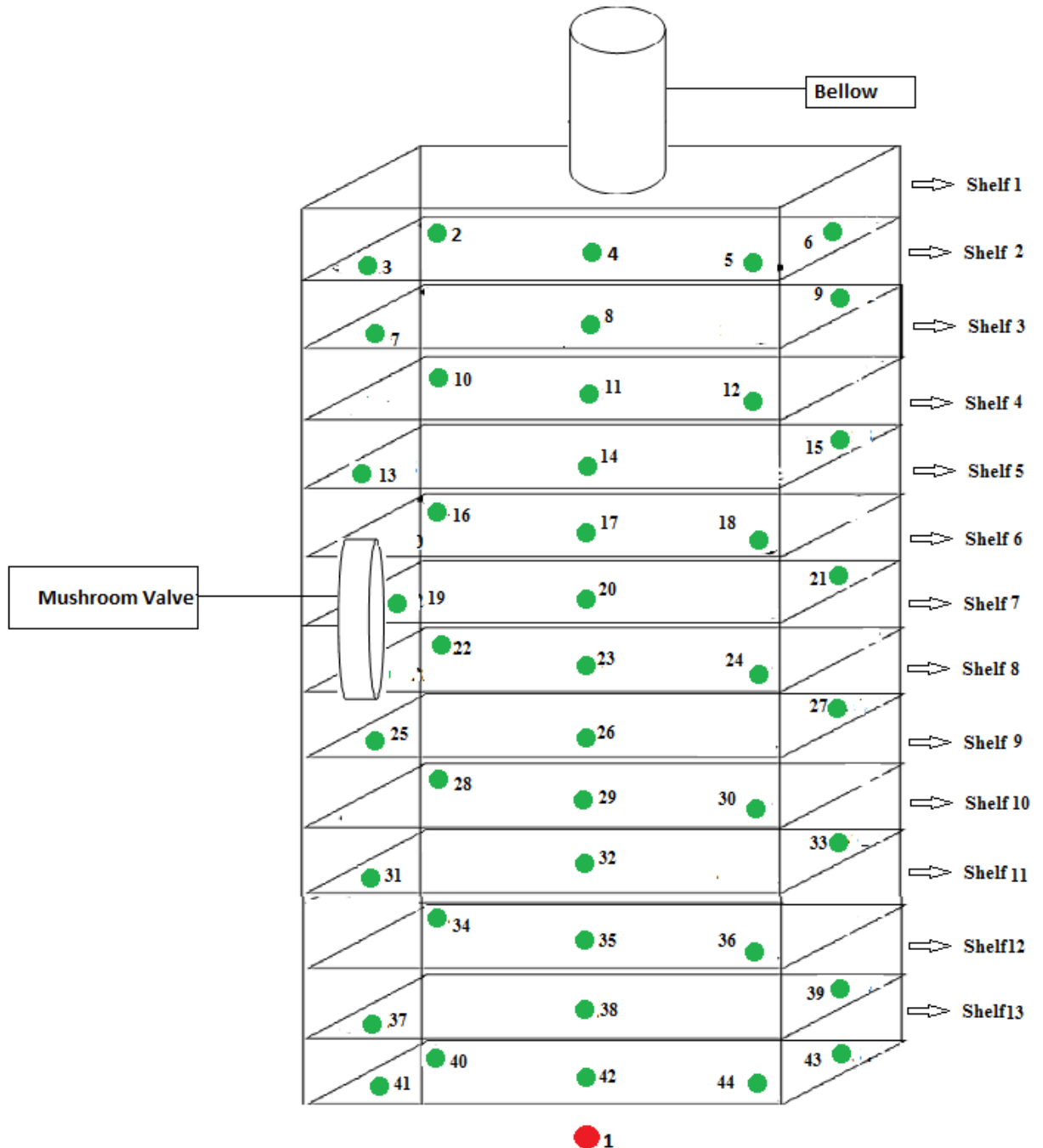
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Drawing No. 1





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**3) Chamber Pressure Monitoring During Sterilization Hold Time:**

<b>ACCEPTANCE CRITERIA</b>	<b>1100 TO 1320 mbar</b>	<b>For Not less than 30 minutes</b>	
<b>Observation</b>			
Minimum observed pressure (mbar)		<b>Time</b>	
Maximum observed pressure (mbar)		<b>Time</b>	
Total hold time			













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**5) Observations of Lag Time**

Parameter	Time
Drain sensor achieved 122.0 °C	
All Sensors achieved 122.0 °C	
Lag time (second)	

**6) Observations of Fluctuation**

S.No.	Fluctuation Temperature	Acceptance Criteria	Observed Value
01.	Minimum Value (°C)	NMT ±1 °C	
02.	Maximum Value (°C)		

**7) Observations of Variation**

S.No.	Variation Temperature	Acceptance Criteria	Observed Value
01.	Minimum Value (°C)	NMT 2 °C	
02.	Maximum Value (°C)		

**8) Observations of F<sub>0</sub> Value**

S.No.	F <sub>0</sub> Value	Acceptance Criteria	Observed Value
01.	Minimum Value (Minutes)	NLT 30 Minutes	
02.	Maximum Value (Minutes)		

**9) Observations of Chamber pressure**

S.No.	Chamber pressure	Acceptance Criteria	Observed Value
01.	Minimum Value	2.11to 2.33 BarA	
02.	Maximum Value		



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**10) Summary & Conclusion:  
Chamber & Condenser**

S. No.	Parameter	Acceptance Criteria	Observed Value	Remarks
01.	Minimum temperature	NLT 122 <sup>o</sup> C		
02.	Maximum Temperature	NMT124.5 <sup>o</sup> C		
03.	Variation	NMT 2 <sup>o</sup> C		
04.	Fluctuation	NMT ±1 <sup>o</sup> C		
05.	Sterilization Hold time	NLT 30 Minutes		
06.	Minimum F <sub>o</sub> Value	NLT 30 Minutes		
07.	Lag time	NMT 30 sec.		
08.	Biological Indicator	No Growth		
09.	Chemical Indicator	Color change to green		
10	Pressure during ster. hold	2.11 to 2.33 BarA		

**Filter:**

S. No.	Parameter	Acceptance Criteria	Observed Value	Remarks
01.	Minimum temperature	NLT 122.0 <sup>o</sup> C		
02.	Maximum Temperature	For information only		
03.	Sterilization Hold time	NLT 30 Minutes		
04.	Minimum F <sub>o</sub> Value	NLT 30 Minutes		
05.	Biological Indicator	No Growth		
06	Chemical Indicator	Color change to green		

**Remarks:**

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