

PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

Operational Qualification for Open Front Containment Station

Pre – Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



QUALITY ASSURANCE DEPARTMENT

Operational Qualification for Open Front Containment Station

1.0 OBJECTIVE:

To determine that the Open fronted Containment Facility Equipment operates according to specifications, and to record all relevant information and data to demonstrate its functions.

2.0 SCOPE:

Scope is limited to the following

Equipment / System Name Open Fronted Containment Facility	
ID Number	S/001
Location	RM Dispensing Area

3.0 CHECKLIST FOR OPERATIONAL VERIFICATION:

S.No.	Operating Parameters	Acceptance Criteria	Actual Observation	Remarks
Operational	verification			
1.	Switch ON Power Button	Power indicator		
		shall be glow.		
2.	Switch ON the Florescent	Florescent Lights		
	Light	will be glow		



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S.No.	Operating Parameters	Acceptance Criteria	Actual Observation	Remarks
3.	Switch ON Air Flow Button	Air flow indicator		
		shall glow.		
		Operation hold		
		indicator shall		
		glow		
		Clean down digital		
		timer shall be ON		
4.	Blower tripping	On the time of		
		blower tripping.		
		Blower trip		
		indicator shall		
		glow & alarm		
		shall be ON.		
5.	Differential Pressure	Differential		
		pressure on		
		megnehelic gauge		
		shall be between		
		10-15 mm for		
		across HEPA &		
		2-4 mm across		
		HEPA.		



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4.0 ANY CHANGES/DEVIATIONS IDENTIFIED DURING OPERATING CHECKS.

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5.0 **RECOMMENDATIONS AND CONCLUSIONS:**

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6.0 **REFERENCES**:

S.No.	Documents	Doc. Ref. No.



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7.0 ANNEXURE:

S.No.	Title	Annexure No.

8.0 ABBREVIATIONS:

NWI . Naw Wateria	RM	:	Raw	Material
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- SOP : Standard Operating Procedure
- mm : Millimeter
- HEPA: High Efficiency Particulate Air Filter



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Post execution approval:

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