Performance Qualification Protocol for Open Front Containment Station

Pre – Execution Approval

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

Performance Qualification Protocol for Open Front Containment Station

1.0 OBJECTIVE::

To determine that the Open fronted Containment Facility Equipment perform according to user requirement specifications, and to record all relevant information and data to demonstrate as intended purpose & consistently meeting its predefined specification & quality attributes.

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:

Critical Variable to be met	Acceptance Criteria	Actual Observation	Remarks
Air Velocity:	The average of air velocity between 90 $\pm$ 20% FPM		
DOP Test	Upstream should be between 20-100 µg/litre of air supplied. Maximum local penetration not more than 0.01% of upstream conc.		
Non-Viable Particle count	**0.5µ-** 3520000/m^3 **5.0 µ-**29300/m^3 ISO-8 (Ref. 14644-1)		
Viable count	**Settling Plate Method:** 50 cfu/4 hours **Active Air Sampling:** 100 cfu/1000 Ltr.		

4.0 ANY CHANGES/DEVIATIONS IDENTIFIED DURING PERFORMANCE CHECKS:

……
……
……
……
……

5.0 RECOMMENDATIONS AND CONCLUSIONS:

……
……
……
……
……

6.0 REFERENCES:

S.No.	Documents	Doc. Ref. No.

7.0 ANNEXURE:

S.No.	Title	Annexure No.

8.0 ABBREVIATIONS:

RM : Raw Material

HEPA: High Efficiency Particulate Air Filter

FPM : Feet Per Minute

ISO : International Organization for Standardization

DOP : Di-octyl Phthalate

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				