



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

Design Qualification for Open Front Containment Station

Pre – Execution Approval

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



Design Qualification for Open Front Containment Station

1.0 OBJECTIVE:

The purpose of Design Qualification of the Open Fronted Containment Station is to ensure that all the critical design aspects including safety, effective cleaning, maintenance, process requirements, utility requirement, product requirement, working space, assembling and dismantling of accessories have been considered while designing the equipment and they are properly documented.

2.0 SCOPE:

Scope is limited to the following

Equipment Name	Open Fronted Containment Station
ID Number	
Location	RM Dispensing Area

3.0 EQUIPMENT DESCRIPTION:

The OFCF is designed to produce the down airflow through HEPA filter without air born contamination. The environment inside OFCF should meet the Class ISO 5.

4.0 CHECKLIST FOR DESIGN VERIFICATION:

Parameters	User requirement/Technical Specification/Proposal	Vendor Design / Specification	Remarks
MOC	SS304 (URS)	SS304	



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Parameters	User requirement/Technical Specification	Vendor Design / Specification	Remarks
Size (Working Size) Overall Size	It preferred not less than 72 x 48 x 84 inches (W x D xH). (URS) 79 x 70 x 97 (Proposal)	75 x 50 x 85 inches 79 x 80 x 98 inches	
Motor Specifications	Custom-built direct drive type motor with impellers. (Proposal)	0.5 HP, Three phase, 1440 r.p.m. Qty. 2 no.	
Blower	Impeller size shall provide adequate air flow volume. (Proposal)	210ø x 85 mm Qty: 2 sets each	
Pre-filter	Scavenging prefilter: EU-5 Efficiency: 40-60% (Proposal)	Size: 912 x 605 x 45 mm (WxDxH) Grade: EU-5 Qty.: 3 nos.	
Intermediate filter	EU-7 rating Efficiency: 80-90% (Proposal)	Size: 820 x 585 x 45 mm (WxDxH) Grade: EU-7 Qty: 2 nos.	
Exhaust Filter	EU-13 Grade Efficiency: 99.99% down to 0.3µ (Proposal)	Size: 910 x 175 x 75 mm (WxDxH) Grade: EU-13 Qty.: 2 nos.	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Supply Filter	HEPA filter shall be provided with surface screen. (URS) EU-13 Grade Efficiency: 99.99% (Proposal)	Size: 610 x 1220 x 75 mm (WxDxH) Grade: EU-13 Qty.: 3 nos.	
Magnehelic Gauges	One Magnehelic gauges of 0-25 mm WC capacity for the indication of differential pressure of HEPA w.r.t. atmosphere. Make: Dwyer (URS) One Magnehelic gauges of 0-25 mm WC capacity for the indication of differential pressure of Intermediate Pre-filter w.r.t. atmosphere. Make: Dwyer The accuracy of gauge shall be $\pm 3\%$. (URS)	0-25 mm WC capacity Magnehelic gauge. 0-10 mm WC capacity Magnehelic gauge.	



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Bleed filter bank	Bleed filter bank for 10% of the total air displacement for slight negative pressure in workplace. (URS & Proposal)	10% air displacement through exhaust filter.	
DOP Port	DOP port to be provided for the upstream challenge of HEPA filter. (URS)	Not Mentioned	
Florescent Light	Capacity: Approximately 300 Lux (URS)	40 Watts; 4' L Qty: 5 nos.	
Sodium Vapor Lamp	Provision for sodium vapor lamp shall be provided. (URS)	Qty: 2 nos.	
Acceptable Tolerance for Control Parameter			
Air Velocity	90 feet/min. \pm 20 %	90 feet/min. \pm 10 %	
Vibration	As per URS	Vibro-Isolator provided.	
Noise	Less than 65 decibels @ 1 meter distance. (URS)	Not mentioned	
Cleanliness clean	ISO-8 (Ref.14644-1)	ISO-5 (Ref. 14644-1)	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Type of Control			
Indicator & switch	Power ON indicator Blower ON indicator Light switch (URS)	Indicators & switch provided on the Panel.	
Safety			
Alarm	Audio-visual alarm for motor blower trip. (URS)	Audio-visual alarm for motor blower trip.	
Timer	Multifunctional digital timer for cleans down. (Proposal)	Multifunctional digital timer for cleans down.	

5.0 ANY CHANGES IDENTIFIED TOWARDS EQUIPMENT DESIGN / LAY OUT.

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6.0 RECOMMENDATIONS AND CONCLUSIONS:

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8.0 ANNEXURE:

S.No.	Title	Annexure No.

9.0 ABBREVIATIONS:

- OFCF : Open Fronted Containment Facility
- MOC : Material of Construction
- HEPA : High Efficiency Particulate Air Filter
- URS : User Requirement Specification
- mm : Millimeter
- WC : Water content
- w.r.t. : With Respect to
- RM : Raw Mater



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