



**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
REVERSE LAMINAR AIR FLOW**

PROTOCOL No.:

**DESIGN QUALIFICATION
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DATE OF QUALIFICATION

SUPERSEDES PROTOCOL CUM REPORT No.

NIL




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1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (WAREHOUSE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification document for Reverse Laminar Air Flow (Dispensing Booth) on basis of URS and information given by Supplier.
- To ensure that all critical aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Reverse Laminar Air Flow**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none"> • Initiation, Authorization and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Warehouse	<ul style="list-style-type: none"> • Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Design Qualification Protocol cum Report after Execution
Engineering	<ul style="list-style-type: none"> • Review of Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. <ul style="list-style-type: none"> ➤ GA Drawing ➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures. ➤ Details of utilities Required. ➤ Identification of components for calibration ➤ Material of construction of Product Contact Parts ➤ Brief Process Description ➤ Safety Features and Alarms • Review of Design Qualification Protocol cum Report after Execution.



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5.0 BRIEF EQUIPMENT DESCRIPTION:

Reverse Laminar Air Flow is a vertical flow work station, used to maintain class 100 through HEPA filter having an efficiency of 99.997% down to 0.3 μ , with a velocity of 90 \pm 20 FPM, at its face to remove dust and atmosphere containments from air and maintain flow in class 100 environment.

Dispensing booths consists of HEPA filters with an efficiency of 99.997% down to 0.3 μ with permitted pressure drop. The system is equipped with a motor blower assembly and pre filter to suck air from atmosphere and to pass it through HEPA filter.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for manufacturer of equipment ensures complies with User Requirement Specification.



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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: Reverse Laminar Air Flow unit is capable of delivering sufficient air volumes and to avoid the cross-contamination under the HEPA filters.	Reverse Laminar Air Flow should meet the requirement to provide a clean environment for Dispensing of materials.	Process Requirement
Working: Working of Reverse Laminar Air Flow	To provide a clean environment for Dispensing of Material.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Switch.	Design Requirement

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	<ul style="list-style-type: none"> • Voltage: 230 V • Phases: 1 Phase • Frequency: 50 Hz • 310 Watts 	cGMP Requirement
Room Condition	Should be able to meet the requirement of clean environment.	Process Requirement



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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria	Reference
Body	Body is made up of SS304 Sheets hair line finish of grit 160 and thickness 1.2 mm.	Design Requirement
Overall size	1960 x 1810 x 2180 mm	Design Requirement
Working area	1830 x 1220 mm	Design Requirement
Class Required	Class 100	Design Requirement
Cabinet	MOC : SS304 Finish : GRIT 160 Thickness : 18 SWG	Design Requirement
Motor	Make : BLOTECH Rpm : 1200 Type : Single Ball Bearing	Design Requirement
Blower assembly	Make : BLOTECH & MARATHON Capacity : 1 / 4 HP Dynamically balanced AL blower with high static pressure. Low vibration level- 04 Nos.	Design Requirement
Electric switch	Make : Roma Quantity : 3 Nos.	Design Requirement
Tube light	Make : Philips Size : 4' Watt : 36 Watt Quantity : 01 Nos.	Design Requirement
Pre Filter	Make : Airtech Size : 800 x 565 x 50 mm Quantity : 03 Nos.	Design Requirement
Fine Filter	Size : 905 x 305 x 100 mm	Design Requirement



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Critical Variables	Acceptance Criteria	Reference
HEPA filter	Make : Global filtration Size : 915 x 610 x 75 Quantity : 04 Nos.	Design Requirement
Magnehelic gauge	Make : Dwyer Quantity : 01 Nos.	Design Requirement
Grill	MOC : SS304 Type : Capsule Perforated	Design Requirement



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7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction
1.	Cabinet/ Body	SS 304
2.	HEPA Mounting Frame	SS 304
3.	Working Table	SS 304
4.	Grill Perforated	SS 304
5.	Blower Housing	GI
6.	Blower Impeller	Aluminum
7.	Filter Housing	Aluminum Anodized

7.5 SAFETY:


Critical Variables	Acceptance Criteria	Reference
PVC Curtain	For isolation of equipment	Safety Requirement
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Earthing to control machine (panel and motors) and operator should be provided.	Safety Requirement

7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Reverse Laminar Air Flow	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowledge, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) User Requirement Specifications (URS).

(2) Design & Functional Specifications provided by Vendor.

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8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Any other relevant documents.

9.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

μ	:	Micron
cGMP	:	Current Good Manufacturing Practice
HEPA	:	High Efficiency Particulate Air
Hr	:	Hour
Hz	:	Hertz
Kg	:	Kilogram
Ltd.	:	Limited
mm	:	Millimeter
MOC	:	Material of Construction
PO	:	Purchase Order
QA	:	Quality Assurance
RLAF	:	Reverse Laminar Air Flow
RPM	:	Revolution per Minute
SS	:	Stainless Steel
URS	:	User Requirement Specification.
UV	:	Ultra Violet
V	:	Volt



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			