DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DYNAMIC PASS BOX

SIZE (3’ x 3’ x 3’)

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DYNAMIC PASS BOX	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DYNAMIC PASS BOX	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To prepare the Design Qualification document for Dynamic Pass Box 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 Dynamic Pass Box (Make: Chempharm Industries India Pvt Ltd.) between Approved RM to RM Dispensing.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings provided by Vendor shall be verified during Design Qualification.

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	• Initiation and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production &Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of the 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. ➢ 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.

5.0 PROJECT REQUIRMENT:

- To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no unauthorized and / or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.
- The Dynamic pass box &, its associated components are designed in accordance with cGMP principles.

6.0 BRIEF EQUIPMENT DESCRIPTION:

Dynamic pass box is installed between two rooms, of different class. Through which the materials are transferred from one room to another to protect the interference and is equipped with interlocking system. Only one door can be opened at a time. The door will get inter-locked. The system is equipped with UV lights, sandwich doors with viewing window, and interlocking between the doors. Pass box will act as a barrier between different class area to maintain the integrity of the area. Switch ON the main switch. Switch ON the UV light 20 minutes in before starting the works. To open the door gently turns the round handle to right and to close press the door smoothly inside so that the door will be locked. After shifting the material inside, close the door gently and press the buzzer to intimate the person at other end.

7.0 EQUIPMENT SPECIFICATION:

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Process/Product Parameters:

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

8.2 Utility Requirements/Location Suitability:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	• Voltage: 220-230 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

8.3 Technical Specifications/Key Design Features:

Critical Variables		Acceptance Criteria	Reference
Manufacturer		Chempharm	Process Requirement
Model		CP-DPB-3'x3'x 3'	Design Requirement
Type		Recirculatory Type Class-100	Design Requirement
Body MOC		Body is made up of SS304 sheet of 1.0 mm thick.	Design Requirement
Capacity (in CFM)		500 CFM	Design Requirement
Overall size		1200 X 1080 X 1760mm	Design Requirement
Working area		1000 X 1000 X 1000 mm	Design Requirement
Viewing window	**Type**	Toughened glass	Design Requirement
	Size	400 x400 x 5 mm	
	Nos.	04 Nos.	
Surface finish		Hairline finish	Design Requirement
Static Pressure In mm Of Water		25	Design Requirement
Door		Sandwich panel of SS304 sheets hair line finish.	Design Requirement
Door Hinge		SS304 , 06 Nos.	Design Requirement
Motor & Blower assembly		**Motor** Make : Air scanner -01 Capacity : 1/3 HP single phase RPM : 1350 RPM Blower size : Al. Impeller 8" X 6" – 01 No.	Design Requirement
HEPA Filter		Make : Chempharm Type : Minipleat Size : 915x460x69 mm Quantity : 2 Nos. Media : Micro Fiber Glass Efficiency : 99.99% down to 0.3 µ Class : H-14	Design Requirement

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Critical Variables	Acceptance Criteria	Reference
Fresh Air Filter	Make : Chempharm Type : Box type Size : 263 x 693x 50 mm Quantity : 1 Nos. Media : AL Expended +3HDPE +AL Expanded Efficiency : 90.0.% down to 05 µ Class : EU-4	Design Requirement
Return Air Filter	Make : Chempharm Type : Box type Size : 183 x 928x 20 mm Quantity : 02 Nos. Media : Micro Fiber Glass Efficiency : 90% down to 05 µ Class : EU-4 Media : AL Expended+3hdpe+Al Expended	Design Requirement
Magnehelic gauge	Make : Dwyer Range : 0-50 mm WC Quantity : 01 nos.	Design Requirement
Velocity at grill	90 ± 20% FPM	Design Requirement
Switch	Make - Roma. ,5/15 Amp Nos. - 03 Nos.	Design Requirement
Tube Light	Make- Philips ,8 Watts Nos. 01Nos.	Design Requirement
U.V Light	Make – Philips, 15 Watts	Design Requirement
DOP Port	SS	Design Requirement
Door Handle	Round Handle Latch Type	Design Requirement
Door Interlocking	Electromagnetic Lock	Design Requirement
Indicator	Laptron Make (Green)	Design Requirement

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Critical Variables	Acceptance Criteria	Reference
Hour Meter	Make -Nishant	Design Requirement
Power Supply	220-230 V AC/ 50-60 Hz	Design Requirement
Power Consumption	310 Watts	Design Requirement

Checked By
Engineering
Sign/Date:……..

Verified By
Quality Assurance
Sign/Date:……..

Inference:

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Reviewed By
Manager QA
Sign/Date:…….

8.4 Material of Construction:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Body	SS 304
2.	HEPA Mounting Frame	SS 304
3.	Grill Perforated	SS304
4.	Blower Housing	GI
5.	Blower Impeller	Aluminum
6.	Filter Housing	Aluminum Anodized
7.	Door with view panel	SS 304/glass
8.	Service panel	SS 304
9.	Base support angle	SS 304

Checked By
Engineering
Sign/Date:……..

Verified By
Quality Assurance
Sign/Date:……..

Inference:

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Reviewed By
Manager QA
Sign/Date:…….

8.5 Safety:

S.No.	Parameters	Safety / Interlocking Provision	Reference
1.	Interlocking facility should be provided between the both doors.	Both doors should not be opened at the same time.	cGMP Requirement
2.	Interlocking facility should also be provided between the doors & UV light.	UV light should get OFF when any one of the door is opened and again should be ON when both door is closed.	Safety & cGMP Requirement
3	Electrical wiring and earthing	Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided	Safety Requirement

Checked By
Engineering
Sign/Date:……..

Verified By
Quality Assurance
Sign/Date:……..

Inference:

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Reviewed By
Manager QA

Sign/Date:…….

8.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Dynamic Pass Box	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.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

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

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

URS	:	User Requirement Specification.
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
HEPA	:	High Efficiency Particulate Air
UV	:	Ultra Violet
DYP	:	Dynamic Pass Box
Hz	:	Horse Power
W	:	Watt
DPB	:	Dynamic pass box
%	:	Percent
EU	:	European Union
µ	:	Micron
Amp	:	Ampere
FPM	:	Feet per minute
DOP	:	Di Octyl Pthalate
AC	:	Alternate current
V	:	voltage
RPM	:	Rotation per minute
HP	:	Horse Power
WC	:	Water Column
GI	:	Galvanized Iron
WC	:	Water column

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			