INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
DYNAMIC PASS BOX

EQUIPMENT ID. No.	
LOCATION	**External Corridor to Washing & Sterilization Area**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION 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 provide documented evidence for the Installation Qualification of Dynamic Pass Box.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Dynamic Pass Box (Make –…….)** to be installed between external corridor to Washing & Sterilization Area.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Dynamic Pass Box.

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, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production, and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Installation Qualification Protocol Cum Report after Execution.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol Cum Report after Execution.
Engineering	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Dynamic Pass Box Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol Cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Dynamic Pass Box
Equipment	
Manufacturer's Name	
Model	
Supplier's Name	
Location of Installation	External corridor to Washing & Sterilization Area

6.0 SYSTEM DESCRIPTION:

Dynamic pass box are 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, sandwich doors with viewing window, and timer 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 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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Instrumentation diagram
- Technical specification of equipment
- Certificate of material of construction of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	External corridor to Washing & Sterilization area		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		
Check that all components are installed in the location specified in Equipment Location Diagram**.**	All components are installed in the location specified in Equipment Location Diagram**.**		
Check any physical damage to the equipment.	No any physical damage to the equipment.		
Check the proper electrical installation of Dynamic Pass Box.	The proper electrical installation of Dynamic Pass Box.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.2 Equipment Verification:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATIONS	OBSERVED BY (ENGINEERING) SIGN/DATE
Manufacturer	Chempharm Industries India Pvt.Ltd		
Model	CP-DPB-2'x2'x 2'		
Type	Recirculatory Type Class-100		
Flow	Vertical		
Static Pressure	25 mm of Water		
Velocity at grill	90 ± 20 % FPM		
Overall Dimension	810 x 690 x 1350 mm		
Capacity (in CFM)	500 CFM		
Working area	610 x 610x 610 mm		
Door Hinge	SS304, 06 Nos.		
View Glass	Type :Toughned Glass Size : 300 x 305 mm Qty : 4 Nos		
Motor & Blower Assembly	Make : Air Scanner HP : 1/3 HP Phase : Single Phase RPM : 1350 RPM Blower Type : Al. Impeller Make Size : 8'' X 6" Qty : 1 Nos		

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATIONS	OBSERVED BY (ENGINEERING) SIGN/DATE
HEPA Filter	Make : Chempharma Type : Minipleat Size : 610 x 610 x 69 mm Qty : 1 Nos Efficiency : 99.99 % down to 0.3 Micron Filter Class : H-14 Filter Media : Micro Glass Fiber		
Fresh Air Filter	Make : Chempharm Type : Box type Size : 285 x 305 x 50 mm Quantity : 1 Nos. Media : Al Expended + 3 HDPE + Al Expended Efficiency : 90.0% down to		
Return Air Filter	Make : Chempharm Type : Box type Size : 180 x 540 x 20 mm Quantity : 02 Nos. Media : Micro Fiber Glass Efficiency : 90% down to 5 µ Class : EU-4 Media : Al Expended + 3 HDPE + Al Expended		

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATIONS	OBSERVED BY (ENGINEERING) SIGN/DATE
Magnehelic gauge	Make : Dwyer Range : 0-50 mm WC Quantity : 01 nos.		
Switch	Make - Roma Nos. - 06 Nos.		
Tube Light	Make- Havells Power - 8 Watts Nos. 01Nos.		
U.V Light	Make – Philips Power- 15 Watts		
POA Port	SS		
Door Handle	Round Handle Latch Type		
Door Interlocking	Electromagnetic Lock		
Indicator	Laptron Make (Green)		
Hour Meter	Make -Nishant		
Electrical Supply	Power Supply : 220- 230 V AC Frequency : 50 Hz Watts : 310 W		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.3 MOC Verification List:

COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATIONS	OBSERVED BY (ENGINEERING) SIGN/DATE
Body	SS 304		
HEPA Mounting Frame	SS 304		
Grill Perforated	SS304		
Blower Impeller	Aluminum		
Filter Housing	Al Expended + 3 HDPE + Al Expended		
Door with view panel	SS 304/view panel-glass		
Service panel	SS 304		
Base support angle	SS 304		
PAO Port	SS304		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 REFERENCES:

- Design Qualification Party Document
- Installation Qualification Party Document
- Calibration certificates
- Certificate of MOC

10.0 DOCUMENTS TO BE ATTACHED:

- Certificate of MOC
- If any other Document Required.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

%	:	Percent
µ	:	Micron
AC	:	Alternate current
cGMP	:	Current Good Manufacturing Practices
DYP	:	Dynamic Pass Box
FPM	:	Feet per minute
HEPA	:	High Efficiency Particulate Air
HP	:	Horse Power
mm	:	Millimeter
MOC	:	Material of Construction
Nos.	:	Number
PAO	:	Poly Alpha olefin
Pvt.	:	Private
RPM	:	Rotation per minute
SS	:	Stainless Steel
UV	:	Ultra Violet
V	:	voltage
WC	:	Water Colum

17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
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