



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DYNAMIC PASS BOX**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
DYNAMIC PASS BOX**

<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

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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 (PRODUCTION)			
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 Dynamic Pass Box on basis of Design Qualification document 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: .....).
- 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.



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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:

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



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### **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 PROCESS 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. The manufacturer of equipment ensures complies with User Requirement Specification.



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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Equipment Parameters:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Application:</b> 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
<b>Working:</b> Working of Dynamic Pass Box	To provide a clean environment for critical aspects.	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Switch.	Design Requirement

**8.2 Utility Requirements/Location Suitability:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Utility connections should be available as per the manufacturer's specification.		
<b>Electrical Supply</b>	<ul style="list-style-type: none"><li>• Voltage: 220-230 V AC</li><li>• Phases: 1 Phase</li><li>• Frequency: 50-60 Hz</li><li>• Power consumption :310 Watts</li></ul>	cGMP Requirement
<b>Room Condition</b>	Should be able to meet the requirement of clean environment.	Process Requirement



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**8.3 Technical Specifications/Key Design Features:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Manufacturer</b>	Chempharm Industries India Pvt.Ltd	Design Requirement
<b>Model</b>	CP-DPB-2'x2'x 2'	Design Requirement
<b>Type</b>	Recirculatory Type Class-100	Design Requirement
<b>flow</b>	Vertical	Design Requirement
<b>Static Pressure</b>	25 mm of Water	Design Requirement
<b>Velocity at grill</b>	90 ± 20 % FPM	Process Requirement
<b>Overall Dimension</b>	810 x 690 x 1350 mm	Design Requirement
<b>Capacity (in CFM)</b>	500 CFM	Design Requirement
<b>Working area</b>	610 x 610x 610 mm	Design Requirement
<b>Door Hinge</b>	SS304, 06 Nos.	Design Requirement
<b>View Glass</b>	Type :Toughned Glass Size : 300 x 305 mm Qty : 4 Nos	Design Requirement
<b>Motor &amp; Blower Assembly</b>	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	Design Requirement
<b>HEPA Filter</b>	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	Design & process Requirement





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<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Fresh Air Filter</b>	Make : Chempharm Type : Box type Size : 285 x 305 x 50 mm Quantity : 1 Nos. Media : Al Expanded + 3 HDPE + Al Expanded Efficiency : 90.0% down to 5 $\mu$	Design & process Requirement
<b>Return Air Filter</b>	Make : Chempharm Type : Box type Size : 180 x 540 x 20 mm Quantity : 02 Nos. Media : Micro Fiber Glass Efficiency : 90% down to 5 $\mu$ Class : EU-4 Media : Al Expanded + 3 HDPE + Al Expanded	Design & process Requirement
<b>Magnehelic gauge</b>	Make : Dwyer Range : 0-50 mm WC Quantity : 01 nos.	Design & process Requirement
<b>Switch</b>	Make - Roma Nos. - 06 Nos.	Safety Requirement
<b>Tube Light</b>	Make- Havells Power - 8 Watts Nos. 01Nos.	Process & Safety Requirement
<b>U.V Light</b>	Make – Philips Power- 15 Watts	Process & Safety Requirement
<b>POA Port</b>	SS	Design Requirement
<b>Door Handle</b>	Round Handle Latch Type	Design Requirement
<b>Door Interlocking</b>	Electromagnetic Lock	Design Requirement
<b>Indicator</b>	Laptron Make (Green)	Process & Safety Requirement



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<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Hour Meter</b>	Make -Nishant	Process & Safety Requirement
<b>Electrical Supply</b>	Power Supply : 220- 230 V AC Frequency : 50 Hz Watts : 310 W	Design Requirement

**7.3.1 Material of Construction:**

<b>S.No.</b>	<b>PARTS NAME</b>	<b>MATERIAL OF CONSTRUCTION</b>
1.	Body	SS 304
2.	HEPA Mounting Frame	SS 304
3.	Grill Perforated	SS304
4.	Blower Impeller	Aluminum
5.	Filter Housing	Al Expended + 3 HDPE + Al Expended
6.	Door with view panel	SS 304/view panel-glass
7.	Service panel	SS 304
8.	Base support angle	SS 304
9.	DOP Port	SS304



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**8.4 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

**8.5 VENDOR SELECTION:**

Critical Variables	Acceptance Criteria	Reference
<b>Selection of Vendor for supplying the Dynamic Pass Box</b>	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

**Verified By**  
**(Quality Assurance)**  
**Sign/Date: .....**



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**9.0 DOCUMENTS TO BE ATTACHED:**

- Technical details for Equipment Requirement with Engineering Drawings.
- 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:**

%	:	Percent
μ	:	Micron
AC	:	Alternate current
Amp	:	Ampere
cGMP	:	Current Good Manufacturing Practice
CP	:	Chempharm
DQ	:	Design Qualification
DYP	:	Dynamic Pass Box
FPM	:	Feet per minute
GA	:	General Arrangement
HEPA	:	High Efficiency Particulate Air
HP	:	Horse Power
Hr	:	Hour
Hz	:	Horse Power
Ltd.	:	Limited
mm	:	Millimeter
MOC	:	Material of Construction
Nos.	:	Number
PAO	:	Poly alpha olefin
Pvt.	:	Private
QA	:	Quality Assurance
RPM	:	Rotation per minute
SS	:	Stainless Steel
UV	:	Ultra Violet
V	:	voltage
W	:	Watt
WC	:	Water column



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**14.0 REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (ENGINEERING)</b>			

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION)</b>			

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			