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DESIGN QUALIFICATION PROTOCOL FOR DYNAMIC PASS BOX

CUSTOMER:

EQUIPMENT: DYNAMIC PASS BOX

(_____W x _____D x _____H mm)

SUBMITTED BY:

PHARMA ENGINEERS

PLOT NO. 113/A/1, LANE 8, PHASE II,

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DESIGN QUALIFICATION PROTOCOL APPROVAL

This document is prepared by the documentation team of **M/S. PHARMA ENGINEERS** for

EQUIPMENT : DYNAMIC PASS BOX (DPB-01)

PLANT /PROJECT :

CLIENT :

Hence this document before being effective shall be approved by ***Client / Customer***

M/s. PHARMA ENGINEERS:

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				

CLIENT / CUSTOMER:

	Name	Designation	Signature	Date
Reviewed By				
Approved By				

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1. OBJECTIVE

The objective of this document is to comply with **URS** Document Number: _____ pertaining to design specification of Dynamic Pass Box DPB -01.

2. SCOPE

Design Specifications of Dynamic Pass Box Comprising of the following main Equipments.

- Material of Construction
- Blower Motor Assembly
- Filters
- Door Interlocks
- Control Panel

3. RESPONSIBILITIES

M/s. Pharma Engineers:

1. Shall agree and follow the URS.
2. To Prepare the detailed engineering drawings.
3. To submit the technical details of equipment as per the scope of supply.
4. To ensure safe delivery of equipment
5. To Complete the equipment qualification.

4. EQUIPMENT DESCRIPTION

Dynamic Pass box is designed to obtain cleanliness level complies with Class 100/ISO-5 at rest condition and ability to sweep away contaminants generated during handling and to maintain the required classified conditions.

ISO STD	MAXIMUM CONCENTRATED LIMITS (PARTICLE/M3 OF AIR) FOR PARTICLE EQUAL & LARGER THAN THE CONSIDERED SIZES AS PER ISO 14644-1 (2015)	
ISO-5	**0.5 micron**	**5 microns**
Particles per Cubic Meter	3520	29

Dynamic Pass box chamber is constructed in stainless steel of grade SS 304, 20G, with two doors of both side operation and the chamber size shall be square/rectangle. The inner top portion of Dynamic Pass box is housed with blower assembly followed by HEPA Filter and bottom portion shall have return air path.

Blower was sized to maintain the laminar air below the HEPA Filter and also to take care of pressure drop across the filter. The speed of the blower shall be adjusted with Speed regulator.

The air is drawn through pre-filter Air and blows over the HEPA Filter with a velocity of 90 feet per minute; however, the variation of velocity is accepted up to ±20 feet per minute. Thus, the chamber is maintained for a class of cleanliness confirms to Class 100 / ISO-5.

Pressure differential across the HEPA Filter shall be monitored with a differential pressure gauge.

Lights shall be provided at working area. Approx. 400 Lux intensities shall be maintained.

Required ports are provided for D.O.P and pressure drop measurement

5. SYSTEM ARCHITECTURE

DESCRIPTION	LOWER CLASSIFIED AREA	HIGHER CLASSIFIED AREA
Room Names	Corridor-1	Solvent Store
Classification Grade	CNC	NCNC
Pressure Maintained	AMB	AMB

6. TECHNICAL SPECIFICATIONS:

NOMENCLATURE:	
Equipment TAG Number	DPB – 01
Manufacturers name	M/s Pharma Engineers
Qty	01 No.
CONSTRUCTION DETAILS:	
Internal size (width x Depth x Height) mm	600 x 600 x 1000 mm
External size (width x Depth x Height) mm	740 x 680 x 1750 mm
M.O.C	SS 304, 20G, Matt Finish
BLOWER DETAILS	
Make	EBM PAPST INDIA PRIVATE LIMITED
Model	D4E 180-CA02-02
Power	405 W, 1 Ø, 50 Hz
R.P.M	1200 RPM
Qty	1 No
FILTRATION SCHEME WITH IN EQUIPMENT	
FRESH AIR FILTER	
Make	M/s. ULTRAFIL AIR SYSTEMS
Type	BOX Type
Test Method	EN 779
Filter Classification as per EN779	M-5
Media	Synthetic media
Avg.efficiency at 0.4 micron	40 ≤ Em < 60%
Equivalent particle size in terms of market language	5 microns–Un authenticated data
Size	160 X 160 X 50 mm

Qty	1No.
PRE-FILTER	
Make	M/s. ULTRAFIL AIR SYSTEMS
Type	Flange Type
Test Method	EN 779
Filter Classification as per EN779	G-4
Media	Synthetic media
Avg. arrestance of synthetic dust	90 ≤ Am
Equivalent particle size in terms of market language	10 microns –Un authenticated data
Size	450 X 305 X 50 mm
Qty	2 No.
HEPA FILTER	
Make	AAF
Type of filter	BOX
Test method	EN 1822
Filter classification	H-14
Avg.efficiency at MPPS	99.995%
Media MOC	Micro fiber glass
Washable compatibility	No
Equivalent particle size in terms of market language	99.999% down to 0.3 micron–Un authenticated data
Size	450 X 450 X 69 mm
Qty	1 No's
I.P.D of Filter (Approximate)	10 to 15 mm of WC
F.P.D of Filter (Approximate)	50 mm of WC
NOTE: I.P.D & F.P.D values change based on AIRFLOW; hence customer should set the limits after commissioning.	
INSTRUMENTATION DETAILS	
DIFFERENTIAL PRESSURE GAUGES	
Make	DWYER
Type	Analog Gauge
Range	0 to 50 mm of WC
Location	Across HEPA Filter
Qty	1 No
CFL LIGHT	
Make	Crompton

Length	**4'**
Qty	1 No
UV LIGHT	
Make	PHILIPS
Length	4'
Qty	1 No.
HOUR METER	
Make	Selec
Range	999999 Hrs
Qty	01 No's
ACCESSORIES	
ON/OFF Switch for Blower	6 Amps Selector Switches / 01 No's
ON/OFF Switch for UV/ CFL LIGHT	6 Amps Selector Switches / 01 No's
Door handles and hinges	SS 304 with Matt finish
PAO, ATM & DOP Ports	SS 304 with Matt finish
Gasket	Food grade gasket

7. SAFTEY FEATURES & INTERLOCKS

Sr.No.	ACTIVITY	ACTION	ALARMS
1.	One Side door opens	The other side door is locked. CFL light ON. UV light OFF. Display indicates "WAIT"	No Alarm Provided
2.	Door opened for more than 2min	Beep sound blows until the door closes	Indication is provided with Alarm
3.	Door release button pressed.	Door is ready to open. Display indicates "GO"	No Alarm Provided

4.	Jumpers for door interlock when door release button pressed	When one side door is opened, the another side door is locked for a period of 4sec/30sec/60sec whichever is set .	No Alarm Provided
5.	Both doors closed	UV light ON & CFL light OFF Display indicates "LOCKED"	No Alarm Provided
6.	Blower Over loaded	Beep sound blows, and blower is switched OFF	Indication is provided with Alarm

8. UTILITIES REQUIRED

S.NO	DESCRIPTION	CONSUMPTION
1.	Electricity 3Ø	

9. LIST OF DRAWINGS AND DOCUMENTS ENCLOSED

S.NO	DRAWING NAME	ENCLOSED (YES / NO)
1.	GA Drawing for Pass box	
2.	DPB location layout	
3.	Electrical Drawings	