DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STATIC PASS BOX SIZE (3’ X 3’ X 3’)

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

PROTOCOL CONTENTS

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STATIC 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 Static 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 Static Pass Box (Make: Chempharm Industries India Pvt Ltd.) between RM Dispensing to Day Store.
- 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 Static pass box &, its associated components are designed in accordance with cGMP principles.

6.0 BRIEF EQUIPMENT DESCRIPTION:

Pass box is installed between two rooms, generally clean room & non clean room. 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.

When the door is opened, UV light will get off automatically and the other door will get inter-locked the system is equipped with UV & florescent lights, sandwich doors with viewing window, buzzer, and electromagnetic locks for interlocking between the doors and UV.

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: Static Pass Box unit is capable of delivering suitable environment to avoid the cross-contamination.	Static Pass Box should meet the requirement to provide a clean environment for critical aspects.	Process Requirement
Working: Working of Static 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- PB-3' X 3' X 3'	Design Requirement
Type		Static	Design Requirement
Body MOC		Body is made up of SS304 sheet of 1.0 mm thick.	Design Requirement
Overall size		1110 x 1080 x 1220 mm	Design Requirement
Working area		1000 x 1000 x 1000 mm	Design Requirement
Viewing window	**Type**	Toughened glass	Design Requirement
	Size	400 x 400 x 5 mm	
	Nos.	04 Nos.	
Surface finish		Hairline finish	Design Requirement
Door		Double Wall Sandwich Doors	Design Requirement
Door Hinge		SS304 , 04 Nos.	Design Requirement
Switch		Make – Roma. ,5/15 Amp	Design Requirement
		Nos. - 02 Nos.	Design Requirement
Bell switch		Make – Roma. ,5/15 Amp	Design Requirement
		Nos. - 02 Nos.	Design Requirement
Tube Light		Make- Philips ,14 Watts Nos. 01Nos.	Design Requirement
U.V Light		Make – Philips, 15 Watts	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	80 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.	Door with view panel	SS 304/glass
3.	Door Hinge	SS304
4.	Service panel	SS 304
5.	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 Static 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.
cGMP	:	Current Good Manufacturing Practice
Ltd.	:	Limited
QA	:	Quality Assurance
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
UV	:	Ultra Violet
SPB	:	Static Pass Box
Hz	:	Horse Power
W	:	Watt
Pvt.	:	Private
DQ	:	Protocol design qualification
%	:	Percent
EU	:	European Union
µ	:	Micron
Amp	:	Ampere
AC	:	Alternate current
V	:	voltage
ID.	:	Identification
WC	:	Water Column
GI	:	Galvanized Iron

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)			