DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DYNAMIC GARMENT CABINET

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

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DYNAMIC GARMENT CABINET	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DYNAMIC GARMENT CABINET	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 protocol for Dynamic Garment storage Cabinet 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 Garment Cabinet (Make: Chempharm Industries India Pvt Ltd.) for FFS Line
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawing 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	• Preparation, Approval and Compilation of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Reviewed of Design Qualification Protocol cum Report after Execution
Production	• Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Reviewed of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of Design Qualification 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 Garment Contact Parts. ➢ Brief Process Description ➢ Safety Features and Alarms • Reviewed 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 Garment Cabinet &, its associated components are designed in accordance with cGMP principles

6.0 BRIEF PROCESS DESCRIPTION:

Dynamic Garment storage cabinet are used to maintain Class 100 through HEPA filter having an efficiency of 99.99% down to 0.3µ, with a velocity of 90±20 % FPM , at its face to remove dust and atmosphere contaminants from air and maintain Garments in Class 100 environment.

Dynamic Garments Cabinet consists of HEPA filters with an efficiency of 99.99% down to 0.3µ with permitted pressure drop. The system is equipped with a motor blower assembly and Pre-filter to suck air from atmosphere and to pass it through HEPA filter.

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared. The 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 Garment storage Cabinet unit is capable of delivering sufficient air volumes and to avoid the cross-contamination under the HEPA filters.	Dynamic Garment storage Cabinet unit should meet the requirement to provide a clean environment for sterilized Garments.	Process Requirement
Working: Working of Garment Cabinet.	To provide a clean environment for Garments.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	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	Single Phase 3 Wire Line Up To The Panel Board Terminal. Voltage- **220 - 230 V** Frequency- **50 -60 Hz** Power required **-350 watt**	cGMP Requirement
Room Condition	Should be able to meet the requirement of clean environment.	Process Requirement

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

PARAMETERS	ACCEPTANCE CRITERIA	REFERENCE
Body		
Manufacturer	Chempharm Industries India. Ltd.	Design Requirement
Model	CP-GSC-3' x 1.5 ' x 7'	Design Requirement
Flow	Vertical	Design Requirement
Type	100 % Exhaust Dynamic Garment Cabinet	Design Requirement
Overall Dimension	1050 X 450 X 2105 mm	Design Requirement
Capacity	190 CFM	Design Requirement
Static Pressure	30 mm of water	Design Requirement
MOC	SS 304 Sheet of 1.0 mm thickness	Design Requirement
Surface Finish	Hair Line Finish	Design Requirement
Door	Double Wall Sandwitch Doors—Double Door	Design Requirement
Door Hinge	SS 304 ,06 Nos.	Design Requirement
Door's Glass	125X 875 X5 mm – 4 Nos.	Design Requirement
Blower Assembly		
Make	Air Scanner	Design Requirement
MOC of Blower Housing	SS	Design Requirement
MOC of impeller	Aluminium	Design Requirement
RPM	1350 RPM	Design Requirement
Motor Capacity	1/3 HP - single phase	Design Requirement

PARAMETERS	ACCEPTANCE CRITERIA		REFERENCE
HEPA Filter			
Make	Chempharm Industries India. Ltd.		Design Requirement
Type	Minipleat		Design Requirement
Size	313 X 783 X 69 mm		Design Requirement
Quantity	01 No.		Design Requirement
Media	Micro Fiber Glass		Design Requirement
Efficiency	99.99% down to 0.3µ ,		Design Requirement
Filter class	H-14		Design Requirement
Exhaust Pre-filter			
Make	Chempharm Industries India. Ltd.		Design Requirement
Size	176 X 196 X 20 mm		Design Requirement
Quantity	02 No.		Design Requirement
Type	Box type		Design Requirement
Efficiency	90% Down to 5µ		Design Requirement
Media	Al Expended+3HDPE+Al Expended		Design Requirement
Fresh air filter			
Make	Chempharm Industries India. Ltd.		Design Requirement
Size	270 X 510 X 50 mm		Design Requirement
Quantity	01 No.		Design Requirement
Type	Box type		Design Requirement
Efficiency	90% Down to 5µ		Design Requirement
Media	Al Expended+3HDPE+Al Expended		Design Requirement
Magnehelic Gauge			
Make	Dwyer		Design Requirement
Range	HEPA filter: 0-50 mm of water column		Design Requirement
Accessories			
UV Light	Make	Philips	Design Requirement
	Watt	15 W	Design Requirement
	Quantity	1 No.	Design Requirement
Hour meter	Make	Nishant	

PARAMETERS	ACCEPTANCE CRITERIA		REFERENCE
	Quantity	1 No.	Design Requirement
Switch	Make	Roma	Design Requirement
	Qty.	03 Nos.	
	voltage	5/15 Amp.	
Tube Light	Make	Philips	Design Requirement
	Watt	14 W	Design Requirement
	Quantity	1 No.	Design Requirement
PAO Port	SS		Design Requirement
Door Handle With Lock	STD. – 01 No.		Design Requirement
Levelling Screw	SS – 04 Nos.		Design Requirement
Indicator	Make : Laptron		Design Requirement
Hanging Hook Set	SS --- 03 NOS.		Design Requirement
Hanging pipe	SS (19 mm dia)		Design Requirement
Electrical Supply			
Power Supply	220-230 V AC/ 50-60 Hz		Design Requirement
Power Consumption	350 Watts		Design Requirement

8.4 MOC:

COMPONENTS	ACCEPTANCE CRITERIA	REFERENCE
Body	SS304	Design Requirement
Dore Hinge	SS304	Design Requirement
Blower	SS	Design Requirement
HEPA	Micro Fiber Glass	Design Requirement
Fresh Air & Exhaust Filter	Al Expended+3HDPE+Al Expended	Design Requirement
PAO Port	SS	Design Requirement
Switch	SS	Design Requirement
Indicator	STD	Design Requirement
Hanging Hook Set	SS	Design Requirement
Hanging pipe	SS	Design Requirement

8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Joints	Welding of joints without any welding burrs	Safety Requirement
Metal Parts	All the metal parts should be properly grind without any sharp edges.	Safety Requirement
Leveling and balancing	Equipment should be properly balanced & leveled	Safety Requirement
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
Emergency Switch	Provided easy access position.	GMP & Safety Requirement

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

8.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Dynamic Garment Cabinet	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, 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 Specifications for Equipment
- Approved Engineering Drawings Design
- 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:

%	:	Percent
µ	:	Micron
AC	:	Alternate current
cGMP	:	Current Good Manufacturing Practice
CQA	:	Corporate Quality Assurance
DQ	:	design qualification
EU	:	European Union
FFS	:	Form Fill Seal
FPM	:	Feet per minute
GA	:	General Arrangement
HEPA	:	High Efficiency Particulate Air
HP	:	Horse Power
Hz	:	Horse Power
IB	:	Injection block
ID.	:	Identification
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
SSG	:	Sterile storage cabinet
STD.	:	Standard
URS	:	User Requirement Specification.
UV	:	Ultra Violet
V	:	voltage
W	:	Watt

14.0 REVIEWED BY:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

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HEAD (QUALITY ASSURANCE)			