INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

DYNAMIC GARMENT CABINET

EQUIPMENT ID. No.	
LOCATION	**Entry A/L -2 For Manufacturing Area FFS Line**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION 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 provide documented evidence for the Installation Qualification of Dynamic Garment Cabinet for FFS Line.
- 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 Garment Cabinet (Make: Chempharm Industries India Ltd.) to be installed in Entry A/L -2 for Mfg Area of FFS Line.
- 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 Garment storage Cabinet.

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 Garment cabinet Installation Qualification Activity. • 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 Garment Cabinet
Equipment	
Manufacturer's Name	Chempharm Industries India Ltd.
Model	CP-GSC-3' X 1.5' X 7'
Supplier's Name	Chempharm Industries India Ltd.
Location of Installation	Entry A/L -2 for Mfg Area FFS Line

6.0 SYSTEM DESCRIPTION:

Dynamic Garment storage cabinet is 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 atmosphere contaminants from air and maintain garments in Class 100 environment.

Dynamic Garment storage cabinet consists of HEPA filter 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 & fresh air filter to suck air from atmosphere and to pass it through HEPA filter.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- instrumentation diagram
- Technical specification of equipment.
- Calibration certificate of components.
- 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 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	Entry A/L -2 for Mfg. Area, FFS Line		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

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:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA		OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment	Dynamic Garment Cabinet			
Model	CP-GSC-3' X 1.5' X 7'			
ELECTRICAL INSTALLATION:				
Electricity	Voltage	220-230 V		
	Phases	3 Phase		
	Power consumption	350 W		
	Frequency	50 -60 Hz		
Electrical connections have been provided and secured.	Should be provided & secured			
All components in the panel are properly secured	Should be properly secured			
All terminals are tightened	Should be tightened			
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.			

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.3 Installation Checks:

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Check the proper mechanical installation of Dynamic Garment cabinet		
2.	Check the proper electrical installation of Dynamic Garment cabinet		
3.	Check the parts are working properly		
4.	Check the equipment is free from any defects		
5.	Check the finishing of product contact parts		

Checked By
(Production)
Sign/Date: ……

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(Quality Assurance)
Sign/Date: ……

Inference:

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

8.4 MOC Verification List:

COMPONENTS	ACCEPTANCE CRITERIA	OBSERVED BY (ENGINEERING) SIGN/DATE
Body	SS304	
Dore Hinge	SS304	
Blower	SS	
HEPA	Micro Fiber Glass	
Fresh Air & Exhaust Filter	Al Expended+3HDPE+Al Expended	
PAO Port	SS	
Switch	SS	
Indicator	STD	
Hanging Hook Set	SS	
Hanging pipe	SS	

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(Quality Assurance)
Sign/Date: ……

Inference:

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(Manager QA)
Sign/Date: ……

8.5 EQUIPMENT VERIFICATION

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Body			
Manufacturer	Chempharm Industries		
Type	100 % Exhaust Dynamic		
Overall Dimension	1050 X 450 X 2105 mm		
Capacity	190 CFM		
Static Pressure	30 mm of water		
MOC	SS 304 Sheet of 1.0 mm		
Surface Finish	Hair Line Finish		
Door	Double Wall Sandwitch Doors—Double Door		
Door Hinge	SS 304 ,06 Nos.		
Door's Glass	125X 875 X5 mm – 4 Nos.		
Blower Assembly			
Make	Air Scanner		
MOC of Blower	SS		
MOC of impeller	Aluminium		
RPM	1350 RPM		
Motor Capacity	1/3 HP - single phase		
HEPA Filter			
Make	Chempharm		
Type	Minipleat		
Size	313 X 783 X 69 mm		
Quantity	01 No.		
Media	Micro Fiber Glass		
Efficiency	99.99% down to 0.3µ ,		
Filter class	H-14		
Pre-filter			
Make	Chempharm Industries		

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CRITICAL VARIABLE	ACCEPTANCE CRITERIA		OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Size	176 X 196 X 20 mm			
Quantity	02 No.			
Type	Box type			
Efficiency	90% Down to 5µ			
Media	Al Expended+3HDPE+Al Expended			
Fresh air filter				
Make	Chempharm Industries			
Size	270 X 510 X 50 mm			
Quantity	01 No.			
Type	Box type			
Efficiency	90% Down to 5µ			
Media	Al Expended+3HDPE+Al Expended			
Magnehelic Gauge				
Make	Dwyer			
Range	HEPA filter: 0-50 mm of			
Accessories				
UV Light	Make	Philips		
	Watt	15 W		
	Quantity	1 No.		
Hour meter	Make	Nishant		
	Quantity	1 No.		
Switch	Make	Roma		
	Qty.	03 Nos.		
	voltage	5/15 Amp.		
Tube Light	Make	Philips		
	Watt	14 W		
	Quantity	1 No.		
PAO Port	SS			

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CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Door Handle With	STD. – 01 No.		
Levelling Screw	SS – 04 Nos.		
Indicator	Make : Laptron		
Hanging Hook Set	SS --- 03 NOS.		
Hanging pipe	SS (19 mm dia)		
Electrical Supply			
Power Supply	220-230 V AC/ 50-60 Hz		
Power Consumption	350 Watts		

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Sign/Date: ……

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

Inference:

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

8.6 Safety:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
Well embedded equipment	For proper sifting		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors).		
Start ON/OFF switch: To stop the process immediately	Should be provided for safety		

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:

The Principle Reference is the following:

- Validation Master Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC
- Calibration certificates

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 Practice
CQA	:	Corporate Quality Assurance
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
IQ	:	Installation qualification
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
UV	:	Ultra Violet
V	:	voltage
W	:	Watt

17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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