OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

DYNAMIC GARMENT CABINET

EQUIPMENT ID. No.	
LOCATION	**Entry A/L-2 for Mfg Area, FFS Line**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL 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 verify that the equipment operates in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Dynamic Garment Cabinet and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up and Safety Features.

3.0 SCOPE:

- The Scope of this Operational 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 Mfg. Area of FFS line.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Dynamic Garment Cabinet for OQ. Successful completion of this Protocol cum Report will verify that Dynamic Garment Cabinet meet all acceptance criteria and ready for Performance 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 the Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operational Qualification Activity. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Operational Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Dynamic Garment storage Cabinet Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Operational 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 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 & 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:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- SOP for operation & Cleaning of Dynamic Garment storage Cabinet.

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 OQ 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 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	DOCUMENT/SOP NO.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	Executed and approved Design Qualification document			
2.	Executed and approved Installation Qualification document			
3.	SOP for operation & Cleaning of Garment Cabinet			

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the equipment will be in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

EQUIPMENT/ INSTRUMENTS NAME	EQUIPMENT/ INSTRUMENT ID	CALIBRATION ON	DUE ON	OBSERVED BY SIGN/DATE

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.3 Operational and Functional Checks:

Operate the **Garment Cabinet** as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

S.No	Operation	Observation	Observed By (Engineering) Sign/Date
1.	Verify the cabinet & door are properly fixed		
2.	HEPA filters pre & fresh filter properly fixed		
3.	Grill fitment should be proper		
4.	Magnehelic gauges should start from 0 reading		
5.	All electrical (socket lights) operating		
6.	No abnormal sound is found under working condition		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

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:

- Operation And Maintenance Manual
- Any Other Relevant Documents

11.0 DEVIATION FROM PREDEFINED 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:

µ	:	Micron
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate quality assurance
DQ	:	Design qualification
FFS	:	Form Fill Seal
FPM	:	Feet per minute
HEPA	:	High Efficiency Particulate Air
ID.	:	Identification
IQ	:	Installation Qualification
IQ	:	Installation Qualification
No.	:	Number
OQ	:	Operational Qualification
OQ	:	operational qualification
QA	:	Quality Assurance
SOP	:	Standard operating procedure
WHO	:	World Health Organization

17.0 PROTOCOL POST 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)			