OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
DYNAMIC PASS BOX

EQUIPMENT ID. No.	
LOCATION	**External Corridor to Washing & Sterilization Area**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DYNAMIC PASS BOX	PROTOCOL No.:

PROTOCOL CONTENTS

 PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR DYNAMIC 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 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 Pass Box 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 & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Dynamic Pass Box (Make – ……...)** installed between External corridor to Washing & Sterilization Area.
- This Protocol will define the methods and documentation used to perform OQ activity the Dynamic Pass Box for OQ. Successful completion of this Protocol will verify that Dynamic Pass Box 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	• Initiation, 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 Pass Box 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 Pass Box
Equipment	
Manufacturer's Name	
Model	CP- DPB-2'x2' x2'
Supplier's Name	
Location of Installation	External corridor to Washing & Sterilization Area

6.0 SYSTEM DESCRIPTION:

Dynamic pass box are 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.

The system is equipped with UV Light, sandwich doors with viewing window, and interlocking between the doors. Pass box will act as a barrier between different class area to maintain the integrity of the area.

Switch ON the main switch. Switch ON the UV light 20 mins in before starting the works.

To open the door gently turns the round handle to right and to close press the door smoothly inside so that the door will be locked. After shifting the material inside close the door gently and press the buzzer to intimate the person at other end.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- SOP for Operation & Cleaning of Dynamic pass box
- SOP for Preventive Maintenance of Dynamic pass box

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 approved. 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.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP for Operation & Cleaning of Dynamic pass box.			
4.	SOP for Preventive Maintenance of Dynamic pass box			

8.2 Test Equipment Calibration:

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 Dynamic Pass Box as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

OPERATIONAL CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Blower ON / OFF			
Press Switch ON Position	Blower should be started & blow the air.		
Press Switch OFF Position	Blower should be Stopped.		
Function of Magnehelic Gauge			
Press Switch ON Position of Blower.	Remarkable deflection of needle should be observed in Magnehelic gauge.		
	Deflection should be started from Zero set point.		
UV Light ON / OFF			
Press Switch ON Position	UV Light should get ON.		
Press Switch OFF Position	UV Light should get OFF.		
UV Light Hour Meter			
UV Light Switch ON	Reading in Hour Meter should be Started.		
UV Light Switch OFF	Reading in Hour Meter should be Stopped.		
Light ON / OFF Switch			
Press Switch ON Position	Light should get ON.		
Press Switch OFF Position	Light should get OFF.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 Interlocking:

S. No.	PARAMETERS	TEST PROCEDURE	ACCEPTANCE CRITERIA	OBSERVATIONS	OBSERVED BY (ENGINEERING) (SIGN/DATE)
1.	Interlocking between doors & UV Light.	Open the door of one side.	UV Light should get OFF.		
		Close the same door.	UV Light should get ON.		
		Open the door of another side.	UV Light should get OFF.		
		Close the same door.	UV Light should get ON.		
2.	Interlocking between both side doors.	Open the door of one side and at the same time try to open the door of another side	Both Doors should not be opened at the same time.		

8.5 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: ……

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9.0 REFERENCES:

- Design Qualification Party Document
- Installation Qualification Party Document
- Operation Qualification Party Document

10.0 DOCUMENTS TO BE ATTACHED:

- 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:

cGMP	:	Current Good Manufacturing Practice
DQ	:	Design qualification
DYP	:	Dynamic Pass Box
ID.	:	Identification
IQ	:	Installation Qualification
Ltd.	:	Limited
mm	:	Millimeter
Nos.	:	Number
OQ	:	Operational Qualification
PO	:	Purchase Order
Pvt.	:	Private

17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
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APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			