INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VISUAL INSPECTION BOOTH

EQUIPMENT ID. No.	
LOCATION	**Visual Inspection Area**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VISUAL INSPECTION BOOTH	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VISUAL INSPECTION BOOTH	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 carry out the Installation Qualification of Visual Inspection booth to be used for inspection of vial contains any foreign particles, broken Ampoules, Black Particle or not properly sealed Ampoules.
- To confirm that the equipment and its components are as per the Specifications and installed as per the Approved Design and complies with cGMP practices.
- To ensure that there is sufficient information available to operate and maintain the equipment safely, effectively and consistently.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Visual Inspection Booth (Make: ……)** to be installed in the **Visual Inspection area, Ampoules Line**.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.

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, Review, 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 Visual inspection booth 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	Visual Inspection Booth
Equipment	
Manufacturer's Name	Ambica Pharma Machines Private Limited
Model	cGMP
Supplier's Name	Ambica Pharma Machines Private Limited
Location of Installation	Visual Inspection Area

6.0 SYSTEM DESCRIPTION:

Visual Inspection booth, are Chamber which contain two LED tube light, one White Board & one Black Board for Visual Inspection of Ampoules. Which may be occur during time of Manufacturing, Filing & Sealing.

Visual Inspection booth Operate manually by Visual Inspector with The help of visual light which produced by ordinary tube light. consuming 240 volt. And hand operated ON/OFF Switch, provide Light Intensity 1750 lux to 3500 lux

Visual Inspection booth contains four legs which provide mechanically support for balancing.

All body of Visual Inspection booth made SS 304.

Chamber of booth Contains Sufficient space for Visual inspection of Ampoules.

During Inspection by Visual Inspector checked foreign particle, fiber, sealing, low volume, high Volume, White particle & glass particle etc.

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7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents :

- Certificate of Material of Construction of Components.
- Executed Design Qualification protocol cum report

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 IQ Protocol cum report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VISUAL INSPECTION BOOTH	PROTOCOL No.:

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	INSTALLATION CHECK	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Check the proper mechanical installation of Visual Inspection booth		
2.	Check the proper electrical installation of Visual Inspection booth.		
3.	Check the properly Fitting of tube light		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of Black & white acrylic board.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VISUAL INSPECTION BOOTH	PROTOCOL No.:

8.2 Technical specification:

S.No.	CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	**Equipment Name**	Visual Inspection booth		
2.	**LED Light**	Make : Delite LED pride Watt : 40 w Qty : 2 Nose (in Each booth)		
3.	**White Board**	MOC : White Acrylic Sheet Qty : 1 Nos (In each Chamber)		
4.	**Black board**	MOC : Black Acrylic Sheet Qty : 1 Nos (In each Chamber)		
5.	**Plug**	MOC : PVC Cable With Plug Qty : 1 nos (In each booth)		
6.	**Legs**	MOC : SS304 Qty : 4 nos (in Each Booth)		
7.	**ON/OFF/Switch**	Qty : 1 Nos		
8.	**Dimension of booth (inch)**	47.5(L) x 21.5 (W)x 57.5(H) Qty: 4 Nos 94(L) x 21.5(W) x 57.5(H) Qty : 3 Nos		
9.	**Dimension of chamber**	23.5(L) x 21.5(W) x 22.5(H) (of Each Chamber)		

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:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Grouting and Mounting	Should be grouted and mounted properly.		
Tube Light Fitting	Tube Light Should be Fitted Properly.		
Leveling	Should be properly balanced and leveled.		
Edges of Parts	Metal edges should be properly Rounded off without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Visual Inspection area, Ampoules line		
Room Condition	General working condition. As per GMP and production requirement.		
LED Tube Light Illumination	NLT 1750-3500 Lux (Should be sufficient for easy operation)		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		
Plug Fitting	Plug Should be fitted Properly in Electric Fixture		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 MOC Verification List:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	**Main Body**	SS 304		
2.	**White board**	Acrylic Sheet		
3.	**Black board**	Acrylic Sheet		
4.	**Wire**	PVC		
5.	**legs**	SS 304		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5 SAFETY:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Electrical wiring	Electrical wiring should are covered.		
Start On/Off switch: To Stop the process immediately.	Should be provided for equipment and Visual Inspector 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:

- Any other Relevant Documents.

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:

cGMP	:	Current Good Manufacturing Practices
LED	:	Light Emission Diode
MOC	:	Material of construction
No.	:	Number
V	:	Volt
VBT	:	Visual Inspection booth
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)			