OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
VISUAL INSPECTION BOOTH

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

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

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL 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 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 Vial Optical Inspection Machine 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 **Visual Inspection booth (Make: ……)** to be installed in the **Visual Inspection Area.**
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Visual Inspection booth.
- Successful completion of this Protocol will verify that Visual Inspection booth meet all acceptance criteria and ready for Use.

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, Review, Approval and compilation of the operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review of Operational Qualification Protocol cum Report.. • To co-ordinate and support Operational Qualification Activity. • Post Approval of Operational Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Visual Inspection Booth
Equipment	
Manufacturer's Name	
Model	cGMP
Supplier's Name	
Location of Installation	Visual Inspection Area, Ampoules Line

6.0 EQUIPEMENT 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.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Visual Inspection booth.
- SOP for Preventive Maintenance of Visual Inspection booth.

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 Visual Inspection booth..			
4.	SOP for Preventive Maintenance Visual Inspection booth..			

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:

Test Instrument should be Calibrated, Calibration Certificate & Calibration Status Should be Verify Before checking the Intensity of LED Light or Operation.

EQUIPMENT/ INSTRUMENTS NAME	EQUIPMENT/ INSTRUMENT I.D.	CALIBRATION ON	DUE ON	CHECKED BY (ENGINEERING) 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 Visual Inspection booth as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

COMPONENT	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
ON/OFF Switch	Light Should be ON/OFF as per Requirement by Switch		

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 a safe and secure condition.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5 Verification of Illumination:

ID. No.	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)	VERIFIED B (QA) SIGN/DATE
Chamber -01			
Chamber -02			
Chamber -01			
Chamber -02			
Chamber -01			
Chamber -02			
Acceptance Criteria : Light Illumination Should be 1750 Lux to 3500 lux			

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:

- Copy of Draft SOP's.
- Calibration Certificate of Test Instrument.
- 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 Practices
DQ	:	Design Qualification
LED	:	Light Emission Diode
OQ	:	Operational Qualification
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
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)			