DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VISUAL INSPECTION BOOTH

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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

PROTOCOL CONTENTS

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

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for **Visual Inspection Booth** to be installed in Control Sample Area.
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by vendor shall be verified during Design 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, Review Authorization and Compilation of Design Qualification Protocol cum Report • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Quality Control	• Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of Design Qualification Protocol cum Report • Assist in Design Qualification Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • Review of Design Qualification Protocol cum Report after Execution.

5.0 PROJECT REQUIRMENT:

- To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and/or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented. The Visual Inspection Booth its associated components are designed in accordance with cGMP principle

6.0 BRIEF PROCESS 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 & Compression

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 2000 lux to 3750 lux

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

All body of Visual Inspection booth made of SS304

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

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

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared. The manufacturer of equipment ensures complies with User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
• Tube light • White Board • Black Board.	• Tube Light Provide Sufficient Light Intensity ie; 2000 lux to 3750 lux for perfect Visualization • White board use for Visualization of Colored or black particle, Fiber • Black board use for foreign, Fiber, white Particle., low Volume, high Volume	Process Requirement

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Electrical Supply:	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety with Electrical fixture	GMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Critical Variable	Acceptance Criteria	Reference
1.	**Equipment Name**	Visual Inspection booth	cGMP Requirement
2.	**Overall Dimension**	24 x24 Inch	Design Requirement
3.	**Working Area**	24 x20 Inch	Design Requirement
4.	**LED Light**	Watt : 14 w Qty : 1 Nos	cGMP Requirement
5.	**White Board**	MOC : White Acrylic Sheet Qty : 1 Nos Size : 12 x 20 Inch	Process Requirement
6.	**Black board**	MOC : Black Acrylic Sheet Qty : 1 Nos Size : 12 x 20 Inch	Process Requirement
7.	**Plug**	MOC : PVC Cable With Plug Qty : 1 nos	Process Requirement
8.	**Legs**	MOC : SS304 Length : 4 Inch Qty : 4 nos	Process Requirement
9.	**ON/OFF/Switch**	Qty : 1 Nos	Process & Safety Requirement

8.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction	Reference
1.	**Main Body**	SS 304	GMP Requirement
2.	**White board**	Acrylic Sheet	GMP Requirement
3.	**Black board**	Acrylic Sheet	GMP Requirement
4.	**Wire**	PVC	GMP Requirement
5.	**legs**	SS 304	GMP Requirement

8.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
ON/OFF Switch	ON/OFF Switch Provided for Close tube light	Safety Requirement
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp edges.	Safety Requirement
Leveling and Balancing	Booth should be properly balanced & leveled.	Safety Requirement
Electrical Wiring	Wire Covered with PVC Insulation	Safety Requirement
Noise Level	Should be silent	Safety Requirement

8.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Visual Inspection booth.	Selection of Vendor is done on the basis of review of vendor. Criteria for review were vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment).	Process Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement.

(2) PO of Visual Inspection booth.

9.0 DOCUMENTS TO BE ATTACHED:

- Purchase Order Copy.
- Any other relevant documents.

10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

……

……

……

……

11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

……

……

……

……

……

……

……

……

12.0 RECOMMENDATION:

……

……

……

……

……

……

13.0 ABBREVIATIONS:

cGEP	:	Current Good Engineering Practice
db	:	Decibel
DQ	:	Design Qualification
LED	:	Light Emission Diode
mm	:	Millimeter
MOC	:	Material of Construction
PO	:	Purchase Order
PVC	:	Poly Vinyl Chloride
SS	:	Stainless Steel
URS	:	User Requirement Specification
VBT	:	Visual Inspection Machine
W	:	watt

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
MANAGER (QUALITY ASSURANCE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			