# 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:

**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 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 (Make: Ambica Pharma Machines Private Limited)** to be installed in Packing 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 and Approval of Design Qualification Protocol cum Report<br>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.<br>• Co-ordination with Production and Engineering to carryout Design Qualification.<br>• Monitoring of Design Qualification Activity.<br>• Review of Design Qualification Protocol cum Report after Execution. |
| **Production** | • Review of Design Qualification Protocol cum Report.<br>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.<br>• Review of Design Qualification Protocol cum Report after Execution. |
| **Engineering** | • Review of Design Qualification Protocol cum Report<br>• Assist in Design Qualification Preparation of the Protocol cum Report.<br>• To co-ordinate and support the Activity.<br>• Review of Design Qualification Protocol cum Report after Execution. |

## 5.0 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, Filling & 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 of SS304

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.

## 6.0 EQUIPMENT SPECIFICATION:

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

## 7.0 CRITICAL VARIABLES TO BE MET:

### 7.1 PROCESS/PRODUCT PARAMETERS:

| Critical Variables | Acceptance Criteria | Reference |
|---|---|---|
| • Tube light<br>• White Board<br>• Black Board. | • Tube Light Provide Sufficient Light Intensity ie; 1750 lux to 3500 lux for perfect Visualization<br>• White board use for Visualization of Colored or black particle, Fiber<br>• Black board use for foreign, Fiber, white Particle., low Volume, high Volume | Process Requirement |

### 7.2 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 |

## 7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

| S.No. | Critical Variable | Acceptance Criteria | Reference |
|---|---|---|---|
| 1. | **Equipment Name** | Visual Inspection booth | cGMP Requirement |
| 2. | **LED Light** | Make : Delite LED pride<br>Watt : 40 w<br>Qty : 2 Nose ( in Each booth) | cGMP Requirement |
| 3. | **White Board** | MOC : White Acrylic Sheet<br>Qty : 1 Nos ( In each Chamber) | Process Requirement |
| 4. | **Black board** | MOC : Black Acrylic Sheet<br>Qty : 1 Nos ( In each Chamber) | Process Requirement |
| 5. | **Plug** | MOC : PVC Cable With Plug<br>Qty : 1 nos (In each booth) | Process Requirement |
| 6. | **Legs** | MOC : SS304<br>Qty : 4 nos ( in Each Booth) | Process Requirement |
| 7. | **ON/OFF/Switch** | Qty : 1 Nos | Process & Safety Requirement |

## 7.4 Other Specification: Visual Inspection booth Comprises as Group

| ID.No | Parameter | Dimension (Inch) | Chamber Size (In inch) | Chamber (In Nos) |
|---|---|---|---|---|
| …… | L x W X H | 47.5 x 21.5 x 57.5 | 23.5 x 21.5 x 22.5 | 1 Nos. |
| …… | L x W X H | 47.5 x 21.5 x 57.5 | 23.5 x 21.5 x 22.5 | 1 Nos. |
| …… | L x W X H | 47.5 x 21.5 x 57.5 | 23.5 x 21.5 x 22.5 | 1 Nos. |
| …… | L x W X H | 47.5 x 21.5 x 57.5 | 23.5 x 21.5 x 22.5 | 1 Nos. |
| ….. | L x W X H | 94 x 21.5 x 57.5 | 23.5 x 21.5 x22.5 | 1 Nos. |
| …… | L x W X H | 94 x 21.5 x 57.5 | 23.5 x 21.5 x22.5 | 1 Nos. |
| …… | L x W X H | 94 x 21.5 x 57.5 | 23.5 x 21.5 x22.5 | 1 Nos. |

## 7.5 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 |

## 7.6 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 |

## 7.7 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.<br>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.

## 8.0 DOCUMENTS TO BE ATTACHED:

- Purchase Order Copy.
- Any other relevant documents.

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

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## 10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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## 11.0 RECOMMENDATION:

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## 12.0 ABBREVIATIONS:

| | | |
|---|---|---|
| cGEP | : | Current Good Engineering Practice |
| cGMP | : | Current Good Manufacturing Practice |
| CQA | : | Corporate Quality Assurance |
| db | : | Decibel |
| LED | : | Light Emission Diode |
| mm | : | Millimeter |
| MOC | : | Material of Construction |
| PO | : | Purchase Order |
| PVC | : | Poly Vinyl Chloride |
| RH | : | Relative Humidity |
| SS | : | Stainless Steel |
| URS | : | User Requirement Specification |
| VBT | : | Visual Inspection Machine |
| W | : | watt |

**13.0 REVIEWED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (ENGINEERING) | | | |

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (PRODUCTION) | | | |

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