# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

| | |
|---|---|
| **EQUIPMENT ID. No.** | |
| **LOCATION** | **Packing Hall** |
| **DATE OF QUALIFICATION** | |
| **SUPERSEDE PROTOCOL No.** | **NIL** |

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## PROTOCOL CONTENTS

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 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) | | | |

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 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 Sticker Labeling 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 **Sticker Labeling Machine (Make: ……)** Installed in the **Packing Hall**.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Sticker Labeling Machine.
- Successful completion of this Protocol will verify that Sticker Labeling Machine meet all acceptance criteria and ready for Performance Qualification.

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 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.<br>• Co-ordination with Production and Engineering to carryout Operational Qualification.<br>• Monitoring of Operation Process.<br>• Post approval of Operational Qualification Protocol cum Report after execution. |
| **Production** | • Review of Operational Qualification Protocol cum Report.<br>• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.<br>• Post Approval of Operational Qualification Protocol cum Report after Execution. |
| **Engineering** | • Review of Operational Qualification Protocol cum Report.<br>• To co-ordinate and support Operational Qualification Activity..<br>• Post approval of Operational Qualification Protocol cum Report after execution. |

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 5.0 EQUIPMENT DETAILS:

| | |
|---|---|
| **Equipment Name** | Sticker Labeling Machine |
| **Equipment ID.** | |
| **Manufacturer's Name** | |
| **Supplier's Name** | |
| **Sr.No.** | |
| **Location of Installation** | Packing Hall |

## 6.0 EQUIPEMENT DESCRIPTION:

The Equipment means to Label the Round Objects for different size with over printing in single straight line operation.

The filled & sealed containers load on turn table and turn table will feed the containers in signal track to the transport conveyor. Now container convey on conveyor in signal track in a queue position and reaches to the container separator. The separator picks container one by one and releases the container at a specified pitch to the conveyor for labeling operation. When containers are arriving below the product sensor, product sensor gives signal of presence of the container at labeling station and microprocessor will start dispense label and as soon as one label is applied to the container, the label sensor give signal to stop the label. Then the container moves through pressing device for firmly stick the label.

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 7.0 PRE - QUALIFICATION REQUIREMENTS:

### 7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Sticker Labeling Machine.
- SOP for Preventive Maintenance of Sticker Labeling Machine.

### 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.

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 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 Sticker Labeling Machine. | | | |
| 4. | SOP for Preventive Maintenance Sticker Labeling Machine | | | |

**Checked By**
**(Production)**
**Sign/Date:** ……

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

**Inference:**

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

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 8.2 Operational and Functional Checks:

Operate the Sticker Labeling Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

| Component | Acceptance Criteria | Observations | Observed By (Engineering) Sign/Date |
|---|---|---|---|
| **Machine ON/OFF Switch** | | | |
| Turn the Knob ON Position. | Green light will glow on panel. | | |
| Turn the Knob OFF Position | Green light will not glow on panel. | | |
| **Function of Conveyor Belt Start / Stop Knob** | | | |
| Turn the Knob on start Position. | Conveyor Belt will start | | |
| Turn the Knob on stop Position. | Conveyor Belt will stop | | |
| **Function of Speed Setting Knob of Conveyor Belt** | | | |
| Turn the Knob for desired speed. | Speed will Increase / Decrease. | | |
| **Function of Label Start / Stop Knob Washing scheme** | | | |
| Turn the Knob on start Position. | Labeling device will start | | |
| Turn the Knob on stop Position. | Labeling device will stop. | | |
| **No Sticker No Label Sensor** | | | |
| If there is no Sticker on conveyor belt | There should no Label. | | |

**Checked By**
**(Production)**
**Sign/Date:** ……

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

**Inference:**

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

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE**

**8.3 Power Failure Verification:**

| Item | Acceptance Criteria | Observation | Observed By (Engineering) Sign/Date |
|---|---|---|---|
| **Main Power Shut Down** | Equipment stops in a 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:** ……

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE**

**8.4 Emergency Operation Verification:**

| Item | Acceptance Criteria | Observation | Observed By (Engineering) (Sign/Date) |
|---|---|---|---|
| ON/OFF Push button<br>• Press Stop Push Button<br>• Release ON Push Button | Equipment should Stop | | |
| | Equipment should Start | | |
| With the OFF button Pressed in, Try to cause movement of an Operating function. | The Equipment will be inoperative. | | |

**Checked By**
**(Production)**
**Sign/Date:** ……

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

**Inference:**

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

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 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:

- Operation and Maintenance Manual.
- 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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# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 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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# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 16.0 ABBREVIATIONS:

| | | |
|---|---|---|
| cGMP | : | Current Good Manufacturing Practices |
| DQ | : | Design Qualification |
| HP | : | Horse Power |
| ID. | : | Identification |
| IQ | : | Installation Qualification |
| Kg | : | Kilo Gram |
| KW | : | Kilo Watt |
| mm | : | Millimetre |
| No. | : | Number |
| OQ | : | Operational Qualification |
| SS | : | Stainless Steel |
| WHO | : | World Health Organization |

# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

## 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) | | | |