# OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC STICKER LABELING MACHINE

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

# PROTOCOL CONTENTS

| PHARMA DEVILS | OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC STICKER LABELING MACHINE | 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) | | | |
| HEAD (PRODUCTION) | | | |

**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 Automatic 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 Automatic Self Adhesive Vertical Labeling Machine **(Make:** Maharshi") Installed in Packing Hall.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Automatic Sticker Labeling Machine.
- Successful completion of this Protocol will verify that Automatic Sticker Labeling Machine. meet all acceptance criteria and ready for Performance 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** | • Preparation, Review, Authorization 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** | • Pre Approval 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. |

## 5.0 EQUIPMENT DETAILS:

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

## 6.0 EQUIPEMENT DESCRIPTION:

This machine is designed to give High Output of Labeling on Bottle. (With automation) Model itself indicates the machine the machine identify as a vertical small / large container double side ( front & back) labeling machine for standard rated speed up to 150 CPM depending upon the size of the labels & bottles.

This ,machine is compatible to handle various size of flat , rectangular, square , oval & round bottle & its labels back up to 150 mm label width (vertical height) with the help of minimum change parts & additional round bottle attachment ( wrap around system) is applicable up to 70% of periphery of round bottle & not fully wrap around labeling. Online coded device can be install on this machine, which is used to print predetermined data such as mfg. date, retail price (MRP) and batch no. etc. on label .

This machine will supply with some additional automation feature i.e. touch screen HMI 'With **Fatech**' make PLC , Roll ending alarm system with machine stop facility, missing label detection with pneumatic rejection system & tower light show.

## 7.0 PRE - QUALIFICATION REQUIREMENTS:

### 7.1 Verification of Documents:

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

## 8.0 CRITICAL VARIABLES TO BE MEET:

### 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 | COMPLETED (YES/NO) | CHECKED BY (ENGINEERING) SIGN/DATE |
|---|---|---|---|
| 1. | Executed and approved Design Qualification protocol cum report | | |
| 2. | Executed and approved Installation Qualification protocol cum report | | |
| 3. | Draft SOP for Operation & Cleaning of Automatic Sticker Labeling Machine. | | |
| 4. | Draft SOP for Preventive Maintenance of Automatic 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:** ……

## 8.2 OPERATIONAL AND FUNCTIONAL CHECKS:

| FUNCTIONAL CHECK | ACCEPTANCE CRITERIA | OBSERVATIONS | OBSERVED BY (ENGINEERING) SIGN/DATE |
|---|---|---|---|
| Main Power Supply | Tower blink & Yellow color show. | | |
| All Function key or Touch key from HMI | As stated in related operating manual. | | |
| Emergency stop push button. | To stop machine in Emergency. | | |
| Power UP after Power failure | The machine should start smoothly after recovery of Power from power failure | | |
| **SYSTEM SETTING** | | | |
| System start up is OK | Should be Satisfactory | | |
| AUTO Mode entry is ok | Should be Satisfactory | | |

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

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

**Inference:**

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

**8.3 Safety Features, Alarms & Interlock:** The equipment shall be provided with safety features as listed below.

| SENSOR | FUNCTION | METHOD OF CHALLANGE | ACCEPTANCE CRITERIA | OBESERVATION | OBSERVED BY (ENGINEERING) SIGN/DATE |
|---|---|---|---|---|---|
| Product sensor (**Leuze :Make**) | If there is no product on conveyor then no Labeling | Manually simulate the condition like no product on conveyor | No bottle, No Labeling. | | |
| Metal proxy sensor 2 nos. **( Leuze** : **Make**) | To check the level of label roll, in case of low level or label roll ending | Manually simulate the condition like low level or label roll ending | Machine should Stop and alarm should be display on HMI Screen. | Front Side Label Roll: | |
| | | | | Back Side Label Roll: | |
| Missing label sensor 2 nos. ( **Panasonic : Make)**<br><br>2nd product & rejection sensor 2 nos. (**Leuze: Make)** | Check the presence of label on both side of container | Manually simulate the condition like no Labeling on container | If No labeling on Front/Back side of container. Bottle should be rejected | Front Side: | |
| | | | | Back Side: | |
| Emergency Stop | Machine should stop after pressing emergency stop button | During running of machine, press the emergency stop button. | The machine should stopped. | | |

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

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

**Inference**……

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

**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:**……

**8.5 Power Failure Verification:**

| ITEM | ACCEPTANCE CRITERIA | OBSERVATION | OBSERVED BY (ENGINEERING) SIGN/DATE |
|---|---|---|---|
| **Power up after power Failure** | Machine should not start automatically with power. | | |
| **Main Power Restored** | Equipment can be restarted with no problems or adverse conditions by Pressing start button. | | |

**Checked By**
**Production**
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**Verified By**
**Quality Assurance**
**Sign/Date:** ……

**Inference:**

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**Reviewed By**
**Manager QA**
**Sign/Date:** ……..…

## 8.6 USER ACCESS / RIGHTS VERIFICATION

| Mode | | (Supervisor) | |
|---|---|---|---|
| | | As specified | Actual |
| Auto | | √ | |
| Data Entry | Edit | √ | |
| | Load | √ | |
| | Change Password | √ | |
| **Complies / Does not complies** | | | |
| **Observed by (Production) (Sign. / Date)** | | | |

(*√ – Authorized, X – Not authorized)

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

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

**Inference:**

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

## 8.7 SECURITY LEVEL VERIFICATION (PASSWORD PROTECTION)

| User Level | Method of Verification | Acceptance Criteria | Observation | Complies / Does not complies | Observed By (Sign. / Date) |
|---|---|---|---|---|---|
| Level 1 (Supervisor) | Login with correct user name and password | The system should be accessible | | | |
| | Login with incorrect user name and password | The system should not be accessible | | | |

**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, 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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## 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 |
| HP | : | Horse Power |
| ID. | : | Identification |
| IQ | : | Installation Qualification |
| Kg | : | Kilo Gram |
| KW | : | Kilo Watt |
| mm | : | Millimetre |
| No. | : | Number |
| OQ | : | Operational Qualification |
| SOP | : | Standard Operating Procedure |
| WHO | : | World Health Organization |

## 17.0 PROTOCOL POST- APPROVAL:

**PREPARED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OFFICER/EXECUTIVE (QUALITY ASSURANCE) | | | |

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