



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

S.No.	ITEM DESCRIPTION	PAGE No.
1.0	PROTOCOL APPROVAL	3
2.0	OVERVIEW:	4
2.1	Objective	4
2.2	Purpose	4
2.3	Scope	4
2.4	Responsibility	4-5
2.5	Execution Team	6
3.0	ACCEPTANCE CRITERIA	7
4.0	REQUALIFICATION CRITERIA	7
5.0	INSTALLATION QUALIFICATION PROCEDURE	8
5.1	System Description	8
5.2	Instruction for filling the checklist	9
5.3	Installation checklist	10-11
5.4	Identification of major components	12-13
5.5	Verification of material of construction	14
5.6	Identification of supporting utilities	14
5.7	Identification of safety features	15
5.8	Identification of component to be calibrated	16
5.9	Identification of standard operating procedure (sop)	17
5.10	Verification Of Drawing And Documents	18
5.11	Abbreviation	19
5.12	Deficiency And Corrective Action(s) (Reports)	20
5.13	Annexure (S)	21
6.0	INSTALLATION QUALIFICATION FINAL REPORT	22
6.1	Summary	22
6.2	Conclusion	22
6.3	Final Report Approval	23



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

This Installation Qualification protocol of Automatic Vertical Round Bottle Sticker Labeling Machine has been reviewed and approved by the following persons:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Automatic Vertical Round Bottle Sticker Labeling Machine and define the installation qualification requirements and acceptance criteria for the Automatic Vertical Round Bottle Sticker Labeling Machine. Successful completion of these installation qualification requirements will provide assurance that the Automatic Vertical Round Bottle Sticker Labeling Machine was installed as required in the manufacturing area.

The Qualification of Automatic Vertical Round Bottle Sticker Labeling Machine performed in view of Dry Syrup in manufacturing facility.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Automatic Vertical Round Bottle Sticker Labeling Machine received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

This Protocol is applicable to installation of Automatic Vertical Round Bottle Sticker Labeling Machine in Dry Syrup in Production Cepha Oral Block of the manufacturing facility.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Production/ Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

3.0 ACCEPTANCE CRITERIA:

- 3.1 The Automatic Vertical Round Bottle Sticker Labeling Machine shall meet the system description given in design qualification.
- 3.2 The Automatic Vertical Round Bottle Sticker Labeling Machine shall meet with the acceptance criteria mentioned under the topic “Identification of major components”
- 3.3 The safety feature of machine should be in place

4.0 REQUALIFICATION CRITERIA:

The machine shall be requalified if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1	SYSTEM DESCRIPTION:	
1	Equipment Name	: Automatic Vertical Round Bottle Sticker Labeling Machine
2	Supplier/Manufacturer	: Parth Engineers & Consultant
3	Model	:
4	Serial no.	:
5	Capacity	: Up to 100-120 BPM
6	Dimension	: 1800 mm (L) X 550 mm (W) X 1332 mm (H)
7	Location	: Dry Syrup

5.1.1 Brief process description:

The round containers positioned on conveyor are released at equal distance by creating space between two containers with the help of roller spacing device. At the labeling point, an electronic product sensor senses container & releases a label from self adhesive label roll. If machine is equipped with batch printing device, then batch printing device prints the batch no. & other matter on the label while label is satisfactory between dispensing of two labels. The sensed round container moves on conveyor & picks the released label. Then the labeled container moves further through a rubber pressing belt & stationary rubber pad which ensures neat & perfect fixing of label on the container diameter.

5.1.2 MACHINE DESCRIPTION

The Automatic Vertical Round Bottle Sticker Labeling Machine is used for full/partial wrap around labeling on different size of round containers. It is capable of labeling up to 240 containers per minute depending on the products & label size. The automatic model is equipped with roller spacing device resulting in a simple operation with “No change parts required”.



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.2 INSTRUCTION FOR FILLING THE CHECKLIST:

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down P.O. number	Physically		
2	Verify that there is no observable physical damage	Physically		
3	Examine All access ports are cleared of any debris.	Physically		
4	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
5	Verify that all electrical connections are properly done and safe	Physically		
6	Verify that the equipment is properly earthed	Physically		
7	Verify that utility line is properly connected	Physically		
8	Verify the proper leveling of equipment	Physically		
9	Verify that there is sufficient space provided for operation, cleaning, preventive maintenance	Physically		
10	Equipment/system identification no. Is visible	Physically		

Remark: -----

Reviewed by (Sign/Date)



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Main Motor	Location	Bottom of the machine	Physically		
	Make	Bonfiglioli	Physically		
	Spec.	1.07 A/0.37 KW/415 V/ 50 Hz/ 1370 RPM	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Conveyor Motor	Make	Bonfiglioli	Physically		
	Spec.	0.72 A/ 0.18 kw/ 415v/ 1320 RPM/ 50 Hz	Physically/ Test Certificate		
Main Gear Box	Make	Bonfiglioli	Physically		
	Ratio	20:1	Physically/ Test Certificate		
Conveyor Gear Box	Make	Bonfiglioli	Physically		
	Ratio	20:1	Physically/ Test Certificate		
Label Dispenser Motor	Make	Panasonic	Physically		
	Spec.	0.4 kw, 230 V	Physically/ Test Certificate		
AC Drive	Make	Allen Bradley	Physically		
	Spec.	0.5 HP, Input Single phase, Output: 3 Phase	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

PLC	Make	Delta	Physically/ Technical Specification		
	Model	DVP-12SA211T	Physically/ Technical Specification		
HMI	Make	Delta	Physically/ Technical Specification		
	Model	B03S211	Physically/ Technical Specification		
MCB	Make	Schneider	Physically/ Technical Specification		
Sensors	Make	Lauze	Physically/ Technical Specification		
Contactator	Make	Schneider	Physically/ Technical Specification		

Remark: -----

Reviewed by (Sign/Date)



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Name of Components	Material of Construction	Method of Verification	Observation	Verified By Sign/Date
Machine Frame Structure	M.S. Angle Structure duly powder coated & fully covered with SS 304 Sheet	Physically		
Door Set	SS 304,- Hair-lined pre-finished sheet	By Molybdenum Kit/ Test Certificate		
Chain Wheel for Conveyor	Nylon	Visually		
Conveyor Belt	Nylon Endless	Test Certificate		

Remark: -----

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method of Verification	Observation	Checked By Sign/Date
1.	Electrical Power Supply: 3 phase, 230- 400 V, 50Hz supply with neutral and proper earthing	Physically with clamp meter		

Remark: -----

Reviewed by (Sign/Date)



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.7 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety/interlocking features (if any) and their function in following tables:

Safety Features Description	Location/Identification	Method of Verification	Observation	Identified By Sign/Date
Earthing	Equipment connected with earthing strip	Physically		
Emergency stop	To stop the machine immediately	Physically		
Label sensor	No label no labeling	Physically		
Product sensor	No bottles No Labeling.	Physically		

Remark: -----

Reviewed by (Sign/Date)



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED:

Name of Components	Range	Make	Location	Identified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were identified as important for effective performance of Automatic Vertical Round Bottle Sticker Labeling Machine operation

S.No.	SOP Title	Verified By Sign/ Date

Remark: -----

Reviewed by (Sign/Date)



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing And Document Detail	Verified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.11 ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Automatic Vertical Round Bottle Sticker Labeling Machine

MOC: Material of construction

Spec.: Specification

V: Voltage

Hz: Hertz

A: Ampere

SS: Stainless Steel

RPM: Rotation per minute

HP: Horse Power

NA: Not Applicable



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

**Deviation accepted by
(Sign/Date)**

**Deviation Approved by:
(Sign/Date)**



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

5.13 Annexure (S)

Annexure No.	Details of Annexure

Remarks (if any):

Done By & Date:

Verified By & Date:



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

6.0 INSTALLATION QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign/Date**

**Checked By
Sign/Date**



INSTALLATION QUALIFICATION FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELING MACHINE

6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. All amendments and discrepancies are documented, approved and attached to this protocol, If applicable. Signature in the block below indicates that all items in this qualification report of Automatic Vertical Round Bottle Sticker Labeling Machine have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. After the successful installation qualification of the Automatic Vertical Round Bottle Sticker Labeling Machine the equipment can be taken for operational qualification.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		