INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL LABELING MACHINE

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

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL LABELING MACHINE	PROTOCOL No.:

CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL LABELING MACHINE	PROTOCOL No.:

1.0 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 provide documented evidence for the Installation Qualification of Vial Labeling Machine.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Vial Labeling Machine (Make: Ambica Pharma Machines Pvt. Ltd.,)** to be installed in the **Packing Hall**.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Vial 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 Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post approval of qualification Protocol cum Report after execution.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in VLM Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol cum report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vial Labeling Machine
Equipment ID.	……..
Manufacturer's Name	Ambica Pharma Machines Pvt. Ltd
Model	…….
Supplier's Name	Ambica Pharma Machines Pvt. Ltd
Location of Installation	Packing Hall

6.0 SYSTEM 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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P & ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

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 IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

 PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL LABELING MACHINE	PROTOCOL No.:

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Packing Hall		
Room Condition	General Room Conditions.		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……

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

8.2 Installation Checks:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Dimensions	L 850 mm x W 1000 mm x H 880 mm		
Main motor & Gear box	Make : Bonfiglioli Power : 0.25 HP RPM : 1440		
Vial separator	Quantity : 1 Nos.		
Label applicator	Quantity : 1 Nos.		
Pressing device	Quantity : 1 Nos.		
Printing device	Quantity : 1 Nos.		
On / Off Main switch	Make : Schneider		
Label counter	Make : Fritz Kubler Specification : 24 VDC Ampere : 23.3 m A Type : W15121		
Sensor	**Label sensor** Make : Auto max **Vial sensor** Make : Lenze Electronic		
AC Device	Make : Delta Model : VFD002S21A Input : 1 Phase , 200- 240 V 50/60 Hz , 4.9 Amp Input : 3 Phase,0- 240 V, 1.6 Amp, 0.25HP		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

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

8.3 MOC Verification List:

S.No.	Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
1.	Body of machine	SS304		
2.	Conveyer	MAT Finish SS304		
3.	Top plate	SS304		
4.	Pressing device	Anodized		
5.	Label applicator	Anodized		
6.	Operating panel	SS304		
7.	Control panel	SS304		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……

……

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

8.4 Utility Verification List:

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Voltage : 440 V, KW : 5 KW Phase : 3 Phase , Frequency : 50 HZ		
Room Condition	Temperature and RH required as per requirement of product.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……

……

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

8.5 Safety:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be Properly grounded without any sharp Edges.		
Leveling and Balancing	Equipment should be properly balanced & leveled.		
Earthing	Proper Earthing should be provided.		
Sensor	Vial Sensor sense the presence of container for labeling. Label Sensor sense the presence of upcoming label for labeling.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……

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

9.0 REFERENCES:

The Principle References 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:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

……

……

……

……

……

……

……

……

12.0 CHANGE CONTROL, IF ANY:

……

……

……

……

……

……

……

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

……

……

……

……

……

……

……

……

……

14.0 CONCLUSION:

……

……

……

……

……

……

……

……

15.0 RECOMMENDATION:

……

……

……

……

……

……

……

……

16.0 ABBREVIATIONS:

AC	:	Alternating Current
AMP	:	Amperes
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
MCB	:	Miniature circuit breaker
MOC	:	Material of Construction
PO	:	Purchase Order
RH	:	Relative humidity
SOP	:	Standard Operating Procedure
URS	:	User Requirement Specification
VLM	:	Vial Labeling Machine
P & ID	:	Piping & Instrumentation Diagram
NMT	:	Not More Than
NLT	:	Not Less Than
SS	:	Stain less Steel
WHO	:	World Health Organization
KW	:	Kilo-Watt
MM	:	Millimeter
HP	:	Horse power
HZ	:	Hertz

17.0 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)			