DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

VIAL LABELING MACHINE

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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

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PHARMA DEVILS	DESIGN 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 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 of **Vial Labeling Machine (Make: Ambica Pharma Machines Pvt. Ltd)** to be installed in …….
- The equipment shall be operated 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	• Preparation, Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➢ Details of utilities. ➢ Identification of components for calibration. ➢ Material of construction of all components. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Review of Design Qualification Protocol cum Report after Execution.

5.0 BRIEF EQUIPMENT DESCRIPTION:

The Equipment is an automated means to Label (sticker labeling) 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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared …….. 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
Application: Vial Labeling Machine is designed to Label the Round Objects for different size with over printing in single straight line operation	Should be able to Label the vials.	Process Requirement
Working: The machine product sensor sense the presence of container and dispense the label	Dispensing of label should be immediately done as product container reaches, and should stop as there is no container	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 220 V HP : 0.25 HP Phase : 3 Phase Frequency : 50 HZ	GMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement

7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria
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/ massage plate	Quantity : 1 Nos.
Printing device	Quantity : 1 Nos. Type : Inkjet
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 Quantity : 1 Nos. **Vial sensor** Make : Lenze Electronic Quantity : 1 Nos.
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, .25 HP

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
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

7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
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	Equipment should be properly balanced & leveled.	Safety Requirement
Earthing	Proper Earthing should be provided.	Safety Requirement
Sensor	Vial Sensor sense the presence of container for labeling. Label Sensor sense the presence of upcoming label for labeling.	Safety Requirement

7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Vial Labeling Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include 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) Specifications and Requirements as specified in PO and URS.

(2) Operating and service manual for Vial Labeling Machine.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- 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:

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
db	:	Decibel
C.I.	:	Cast Iron
RH	:	Relative Humidity
VLM	:	Vial Labeling Machine
MMI	:	Man Machine Interface
HP	:	Horse Power
SS	:	Stainless steel
HDPE	:	High Density Poly Ethylene

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			