



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

PROTOCOL No.:

**DESIGN QUALIFICATION
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DATE OF QUALIFICATION

SUPERSEDES PROTOCOL No.

NIL



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STICKER LABELING MACHINE**

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PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	Protocol Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Brief about Equipment	6
6.0	Equipment Specification	6
7.0	Critical Variables to be met	7
7.1	Process Parameters	7
7.2	Utility Requirements / Location Suitability	7
7.3	Technical Specifications / Key Design Features	8
7.4	Material of Construction	9
7.5	Safety	10
7.6	Vendor Selection	11
8.0	Documents to be attached	12
9.0	Review (Inclusive of Follow up action, if any)	12
10.0	Any Changes made against the formally agreed Parameters	12
11.0	Recommendation	12
12.0	Abbreviations	13
13.0	Reviewed by	14



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

PROTOCOL No.:

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)			



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

PROTOCOL No.:

2.0 OBJECTIVE:

- To prepare the Design Qualification document for Sticker Labeling Machine on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for Sticker Labeling Machine procured.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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PROTOCOL No.:

4.0 RESPONSIBILITY:

The Validation team, 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	<ul style="list-style-type: none"> • Preparation, Approval and Authorization of the Protocol cum Report. • Assist in the verification of Critical Process Parameters & Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none"> • Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters & Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution
Engineering	<ul style="list-style-type: none"> • Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Design Qualification Activity. • To assist in Verification of Critical Process Design Feature & Drawings as per the Specification. • Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures. • Details of utilities • Material of construction of all components • Brief Process Description • Safety Features and Alarms • Post Approval of Qualification Protocol cum report after Execution



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**DESIGN QUALIFICATION PROTOCOL CUM
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PROTOCOL No.:

5.0 BRIEF ABOUT EQUIPMENT:

The Automatic Sticker Labeling Machine is compact unit totally made of SS structure with height adjustment legs, are provided to adjust the machine height and highly efficient machine with elegant look. This multifunctional multi featured machine meets the GMP requirements of labeling for glass and plastic Bottles. The machine requires manual loading and automatic unloading of Bottles.

PROCESS:

The whole design of VSAL-120 labeling machine is reasonable, easy to operate, the flexibility to switch to deferent round bottle bodies, easy to change for customers, suit for most of the round bottle labeling requirements; extrusion between high elastic scraper and non-powered sponge, to ensure that no bubbles; machine used to strengthen the rigidity of the mechanical structure design, simple, generous and stable. Designed for the application of labels to the side surfaces or wraparound of continuously fed products in oval, round or rectangular shape. The automatic labeler is a versatile high speed machine which can be integrated easily into existing filling or packaging lines. The whole machine is made of 304 stainless steel and aluminum materials, the standardized design, interchangeable parts, completely according with GMP requirements.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specification document is provided to manufacturer for engineering equipment & Some critical variables to be met during designing the equipment.



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

PROTOCOL No.:

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: Line Speed	Conveyor Speed Should be facilitate the easy and efficient as per product requirement i.e. 40-50 CPM	Process Requirement
Working: Working on Automatic Two Head capping Machine	Sticker Labeling Machine should be facilitate the easy & efficient working during the course of the Sealing operations.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Approved Design Requirement

7.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	The electrical system of the equipment shall be housed as per the cGMP and GEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in the service area.	Approved Design Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement



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PROTOCOL No.:

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S.No	Parameter	Specifications	Reference
1.	Model	BEW-60	Approved Design Requirement
2.	Output	40-50 CPM	Process Requirement
3.	Conveyor Motor	Make : Rotomotive 0.25 HP/0.18KW/0.5A/230-400V/3 Phase/ 50 Hz/1380RPM	Design Requirement
4.	Main Device	Make: Rotomotive 1 HP/0.75KW/1.9A/230-400V/3 Phase/ 50 Hz/ 1380RPM	Design Requirement
5.	Conveyor A.C Drive	Make: Delta 0.5 HP, 220-240V, Input: Single Phase Output: 3 Phase	Design Requirement
6.	Main A.C Drive	Make: Delta 1 HP, 220-240V, Input: Single Phase Output: 3 Phase	Design Requirement
7.	Conveyor Gear Box	Make : Rotomotive Gear Box Ratio : 15:1	Design Requirement
8.	Main Gear Box	Make : Rotomotive Gear Box Ratio : 40:1	Design Requirement
9.	Contactora	Make: C&S	Design Requirement
10.	MCB	Make: C&S	Design Requirement
11.	Machine Dimension	2210 mm (L) X 775 mm (W) X 920 mm (H)	Design Requirement

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Verified By
Quality Assurance
Sign/Date:

Inference:

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Manager QA
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REPORT
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PROTOCOL No.:

7.4 MATERIAL OF CONSTRUCTION :

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Machine shell	SS304
2.	Conveyer	AISI 316
3.	Star wheel	SS 304
4.	Capping Bowl	AISI 316
5.	Platform	SS304
6.	Turret	AISI 316
7.	Cabinet	Acrylic

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7.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MCB	MCB should be provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts should be provided	Safety Requirement
Joints	Welding of joints should be Leaving	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
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (panel and motors) and operator should be provided.	Safety Requirement
Noise Level	Below 80 db.	cGMP Requirement
Emergency Switch	Provided easy access position.	Safety Requirement

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Quality Assurance
Sign/Date:

Inference:

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Manager QA
Sign/Date:

7.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Sticker 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, feed back from market (customers already using the equipment)	Process Requirement

Reference: (1) the equipment shall confirm to the specifications and requirement as specified in PO and URS
 (2) Operating and service manual for Sticker Labeling Machine.

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PROTOCOL No.:

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 THE FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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PROTOCOL No.:

12.0 ABBREVIATION:

URS	:	User Requirement specification
DQ	:	Design Qualification
PO	:	Purchase Order
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
Ltd.	:	Limited
QA	:	Quality Assurance
PO	:	Purchase Order
Kg	:	Kilogram
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
Db	:	Decibel



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			