



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

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DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT
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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)			



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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 Automatic Horizontal Sticker Labeling Machine (**Make:** M/s Harikrushna Machinetech Pvt. Ltd.) to be installed in Packing Hall.
- 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 PROJECT REQUIREMENTS:

- To confirm that safe delivery of the equipment from the supplier site. To ensure that no unauthorized or unrecorded design modification shall take place.
- If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.



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5.0 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	<ul style="list-style-type: none">• Preparation, Review Authorization & Compilation of Design Qualification Protocol cum Report.• Review of Design Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.• Review of Design Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Approval of Design Qualification 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.
Quality Control	<ul style="list-style-type: none">• Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of Design Qualification 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.<ul style="list-style-type: none">➤ GA Drawing.➤ 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.• Review of Design Qualification Protocol cum Report after Execution.



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6.0 BRIEF EQUIPMENT DESCRIPTION:

The purpose of the Automatic Horizontal Sticker Labeling Machine (Model: HMPL/BSHL-80) is to fix the horizontal label one side/ both side (two side of product) on specified size and diameter of I.V. fluid bottles. This machine is designed to give High Output of Labeling on Bottle. After inspection the Bottle are loaded on In-feed turn table. From in feed turn table, Bottle entered in to infeed conveyer belt. Before the discharge the label device is positioned. Label device having a Printer for printing of batch no/mfg. date/expiry date & then camera system to inspect the printing matter OCR, Pharma code, Barcode etc. & once camera inspect the matter & if found any error then same Bottle with Rejected label is collected into a Box provided for rejected Bottle. The label applicator gets activated as soon as Bottle comes in the position of label; it gets sticks on the Bottles. After this, Bottles move toward the pressing belt meant for proper fixing of label. After pressing of the labels, good Bottles are move forward for further process.

Complete machine can be divided in following sub sections.

- Dispenser assembly
- Belt conveyer with side guide
- Main electric panel with HMI, Power Supply, VFD.
- Machine structure
- Vision system

7.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: Automatic Horizontal Sticker Labeling Machine is designed to Label the Round Objects for different size with over printing in single straight line operation	Should be able to Automatic Horizontal Sticker Labeling Machine	Process Requirement
Electrical Control Panel	The electrical system of the equipment shall be housed as per the standard with adequate safety.	Design Requirement



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8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Supply	Voltage : 415 V ($\pm 10\%$) Phase : 3 Phase Frequency : 50 HZ	Process Requirement
Compressed Air	4 to Kg/Cm ²	Process Requirement
Power Requirement	1 Phase, 230 V AC, 50 HZ	Process Requirement

8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
1	Equipment description:-		
	Name	Automatic Horizontal Labeling Machine	Design Requirement
	Capacity	Up to 120 BPM	Design Requirement
	specification	Non-flame proof construction	Design Requirement
	Model	HMPL/BSHL	Design Requirement
	Weight	235 Kg.	Design Requirement
	Surface finish	Matt finish(grit 320)	Design Requirement
	Machine Dimension	2745 mm L X 688 mm W X 1688 \pm 50 mm H	Design Requirement
1	VFD -01 No.		
	Make	Delta Electronics	Design Requirement
	Model	VFD004L21A	Design Requirement
	KW/HP	0.5/0.4	Design Requirement
	I/P	1 Phase, 6.5A/3PH 2.7A , 200-240V AC, 50/60 HZ	Design Requirement
	O/P	3Phase, 0 - 240 V, 2.5A, 1.0KVA, 0.5HP	Design Requirement
	Frequency Range	1 – 400HZ	Design Requirement
	Sr. No.	004L21A6W17110919	Design Requirement
3	Motor -01 No.		
	Make	Rotomotive	Design Requirement
	Type	3 Phase Squirrel cage induction motor (71B - 4)	Design Requirement



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S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
	KW/HP	0.37/0.5	Design Requirement
	RPM	1350	Design Requirement
	Sr. No.	M05171060	Design Requirement
4	Reduction gear box- 01 Nos.		
	Make	Rotomotive	Design Requirement
	Type	BOX 040	Design Requirement
	Ratio (I)	10:1	Design Requirement
	PAM	71B5	Design Requirement
	Sr. No.	G03171553	Design Requirement
5	Conveyor Belt - 01 Nos.		
	MOC	PVC Endless rubberized belt -Black	Design Requirement
	size	3005mm L X 50mm W X 2.1mm Thick 2410mm L X 50mm W X 2.1mm Thick	Design Requirement
6	Timing belt -01 Nos.		
	Make	HARIKRUSHNA	Design Requirement
	size	184 XL	Design Requirement
7	MCB -01		
	Make	Schneider	Design Requirement
	Model	XC 60	Design Requirement
	Rating	C 6 Amps.	Design Requirement
	Pole	2 Pole	Design Requirement
8	Product sensor with reflector - 01 No.		
	Make	Banner	Design Requirement
	Model	QS18VP6LP	Design Requirement
	I/P Supply	I/p : 24 V DC	Design Requirement
9	Label gap sensor -01 No.		
	Make	Leuze	Design Requirement
	Model	GS 61/6	Design Requirement
	I/P Supply	10-30 V DC	Design Requirement
10	Dispenser -01 No.		
	Make	Harikrushna	Design Requirement
	Model	HMPL/DSP/65	Design Requirement



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S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
11	HMI -01 No.		
	Make	Delta Electronics	Design Requirement
	Model	TP02G – AS1	Design Requirement
	Power I/P	24V DC, 3W	Design Requirement
	Sr. No.	TP02GAS1W17050067	Design Requirement
12	PLC Unit -01No.		
	Make	Harikrushna	Design Requirement
	Model	HMPL/HTEC STD SYS	Design Requirement
	Sr. No.	2017-18/07	Design Requirement
13	ON/OFF Switch -01		
	Make	Salzer Electronics	Design Requirement
	I/P Supply	1 Phase, 230 V AC, 50HZ	Design Requirement
	Cap	3 Phase, 440 V AC, 50 HZ	Design Requirement
	Cat No.	61003SAB13TDYR075	Design Requirement
14	Legs Pad – 04 Nos.		
	Size	78 mm Dia.	Design Requirement
	MOC	SS 304	Design Requirement
15	Legs Bolt -04 Nos.		
	Size	125mm Length	Design Requirement
	MOC	SS 304	Design Requirement
16	Stepper Motor -01 No.		
	Make	Harikrushna	Design Requirement
	Model	SM85STH118-4004A	Design Requirement
	Amp	4	Design Requirement
17	Emergency Switch – 01 No.		
	Make	Teknic	Design Requirement
	Element	NC	Design Requirement
18	Tower Light – 01 No.		
	Make	Pulsate	Design Requirement
	Model	PTLB-R-230	Design Requirement
19	SSR -01 No.		



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S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
	Make	Elmex	Design Requirement
	Model	SR24VADC1CO	Design Requirement
20	SSR -02 Nos.		
	Make	Schneider	Design Requirement
	Model	RXM 24V DC	Design Requirement
21	Brush -01 No.		
	Make	Nylon	Design Requirement
	Size	50mm Width	Design Requirement
22	Selector Switch -01 No.		
	Make	Teknik	Design Requirement
	Element	NC	Design Requirement
LOW LABEL ROLL : 01 Set			
1	Make	Leuze	Design Requirement
	Model	KFX-ET-605 + LV461.1/P2	Design Requirement
	I/P Supply	10-30 V DC	Design Requirement
VISION SYSTEM : 01 Set			
1	SMPS -01 No.		
	Make	Meanwell	Design Requirement
	Model	NES-100-24	Design Requirement
	I/P	100-120V AC/200-240 V AC, 2.0 A	Design Requirement
	O/P	24V DC, 5.0A	Design Requirement
2	Fuse card -02 No.		
	Make	Connect well	Design Requirement
	Type	6V, 60V	Design Requirement
3	PLC - 01 No.		
	Make	Panasonic	Design Requirement
	Model	FPOR-T32MT (RS 485 Type)	Design Requirement
	Power	24V, 0.3A class 2	Design Requirement
	O/P	0.2 A	Design Requirement
	Sr. No.	17012001	Design Requirement
4	MCB -01 No.		



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S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
	Make	Schneider	Design Requirement
	Model	XC6	Design Requirement
	Rating	6 Amp	Design Requirement
	Pole	02	Design Requirement
5	Relay -08 Nos.		
	Make	Phonix	Design Requirement
	Part No.	2966595	Design Requirement
	I/P	24 V DC, 2A	Design Requirement
6	Main ON/Off Switch - 01 No.		
	Make	L&T	Design Requirement
	Type	Salzer	Design Requirement
	Cap	16 Amp, 440 V AC	Design Requirement
7	Air vent Filter - 02 No.		
	Make	Electro	Design Requirement
	Size	90mm X 90mm - 01 No. 130mm X 130mm - 01 No.	Design Requirement
8	Burger - 01 No.		
	Make	Buzzer cum Flasher	Design Requirement
	Model	Bz	Design Requirement
	Voltage	24V AC/DC	Design Requirement
9	Tower Light – 01 No.		
	Make	Banner	Design Requirement
	Model	K50LGRA2YP	Design Requirement
	Voltage	18-30VDC, 40mA	Design Requirement
10	CPU Unit : 01 No.		
	Make	Advantech	Design Requirement
	Model	I3, Intel Processor	Design Requirement
11	Industrial Monitor - 01 No.		
	Make	Advantech	Design Requirement
	Type	Industrial Touch Monitor	Design Requirement
	Model	IDS3215R-40XGA1E	Design Requirement



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S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
	Sr. No.	IDA0197698	Design Requirement
12	Wireless Keyboard -01 No.		
	Make	Logitech	Design Requirement
	Type	K400 PLUS Wireless Laptop Keyboard	Design Requirement
	Design for	Windows® 7 and later Chrome OS™ Android™ 5.0.2 and later	Design Requirement
	USB version	3.0	Design Requirement
13	LED Flash Light - 02 No.		
	Make	Local	Design Requirement
	Type	8 X 2	Design Requirement
14	Camera -01 Nos.		
	Make	Matrix Vision	Design Requirement
	Model No.	SH-CX120AGIN	Design Requirement
	Type	Monochrome Camera	Design Requirement
	Sr. No.	GX014262	Design Requirement
MISSING LABEL DETECTION SYSTEM - 01 No.			
1	Make	Sick	Design Requirement
	Type	Luminescence sensors	Design Requirement
	Model	LUTM – UP81162P	Design Requirement
	Part No.	1067295	Design Requirement
	Cable -01 No.		
	Make	Sick	Design Requirement
	Model	DOL-1204-G05M	Design Requirement
	Part No.	6009866	Design Requirement
	2	Fiber Optics + Amplifier set – 01 No. (For trigger Luminous sensor)	
Make		Leuze	Design Requirement
Model		KFX-ET-605 + LV461.1/P2	Design Requirement
I/P Supply		10-30 V DC	Design Requirement
REJECTION SYSTEM			
1	FRL Unit -01 No.		
	Make	Festo	Design Requirement
	Model	LFR – D – MINI	Design Requirement



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S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
	Prod Code	162718	Design Requirement
	Gauge Range	0-16 Bar	Design Requirement
2	PU-6 Connector (Push In fitting) - 02 Nos.		
	Make	Festo	Design Requirement
	Model	QS -B -1/8 -6 -20	Design Requirement
	Prod. Code	130915	Design Requirement
3	PU-4 Connector (Push In fitting) - 01 Nos.		
	Make	Festo	Design Requirement
	Model	QS -B -1/8 -4 -20	Design Requirement
4	PU - 6 "T - Connector (Blanking Plug) - 01 No.		
	Make	Festo	Design Requirement
	Model	B -1/8	Design Requirement
	Prod. code	3558	Design Requirement
5	Silencer -01 Nos.		
	Make	Festo	Design Requirement
	Model	U -1/8	Design Requirement
	Prod. code	2307	Design Requirement
6	PU-4 Tube - 2 Mtr		
	Make	Festo	Design Requirement
	Model	PUN 4X1-BL	Design Requirement
	Prod. code		Design Requirement
7	PU-6 Tube - 2 Mtr		
	Make	Festo	Design Requirement
	Model	PUN 6X1-BL	Design Requirement
8	Solenoid Valve & Coil Set - 01		
	Make	Festo	Design Requirement
	Model	MFH-3-1/8 & MSFG - 24/42 - 50/60	Design Requirement
9	Rejection Flat Cylinder - 01 No.		
	Make	Festo	Design Requirement
	P. Max	12 bar	Design Requirement
	Type	EZH	Design Requirement



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S.No.	DESCRIPTION	SPECIFICATION	REFERENCE
LOW AIR PRESSURE - M/C STOP SYSTEM :			
1.	Make	Danfoss	Design Requirement
	Model	KP-36	Design Requirement
	Range	2-14 bar	Design Requirement

8.4 LOGICAL SECURITY SPECIFICATIONS:

8.4.1 LOGIN AND PASSWORDS FOR HMI:

The Programmable Logic Controller of the Automatic Horizontal Sticker Labeling Machine can be accessed using authorized password.

8.4.2 USER POLICY:

S.No.	USER GROUP NAME	RIGHTS & AUTHORIZATION	REFERENCE
1.	Administrator	All rights	Design Requirement
2.	Manager	Change in the process parameters, Operation, Recipe Creation, Deletion & edit, Print reports	Design Requirement
3.	Supervisor	Operation, Variable parameters change, Print report, Recipe download, alarm ack.	Design Requirement
4.	Maintenance	I/O list	Design Requirement
5.	Operator	Operation, print reports alarm acknowledge	Design Requirement

8.5 MATERIAL OF CONSTRUCTION:

S.No.	COMPONENT	MOC	REFERENCE
01.	Conveyor Assy.	SS 304	Design Requirement
02.	Roller for conveyor	SS 304	Design Requirement
03.	Motor and gearbox cover	SS-304	Design Requirement
04.	Drive Shaft	MS	Design Requirement
05.	Non Drive Shaft	MS	Design Requirement



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S.No.	COMPONENT	MOC	REFERENCE
06.	Chain Wheel	MS	Design Requirement
07.	Machine Structure	SS 304	Design Requirement
08.	Base Plate	MS with cladding SS 304	Design Requirement
09.	Dispenser pipe assembly	SS-304	Design Requirement
010.	Panel Box	SS-304	Design Requirement
011.	All nuts & bolts	SS-304	Design Requirement
012.	Dispenser parts & it's mounting stand	Aluminum, MS, SS-304	Design Requirement
013.	Wrapping Assembly	Aluminum, MS, SS-304	Design Requirement
014.	Camera Mounting Assembly	Aluminum with Powder coating	Design Requirement
015.	Console	SS 304	Design Requirement
016.	Control Panel for vision system	SS 304	Design Requirement



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

S.No.	FEATURE	REFERENCE
1.	4 Level Password protected operating system	Safety Requirement
2.	No Product - No Labeling	Safety Requirement
3.	Low level label roll – Alarm (M/C Running)	Safety Requirement
4.	No Label Roll/Label Missing/Paper Break – Alarm with M/C STOP	Safety Requirement
5.	Low Air pressure - Alarm with Machine STOP	Safety Requirement
6.	2 Color light stack display tower light. Orange Light - Machine Healthy condition Red Light : M/C Fault/ Error	Safety Requirement
7.	Missing Label detection system. Missing label found - Product reject through Rejection system	Safety Requirement
8.	Vision system: Online inspection system with help of camera for inspection of print coder, correct matter, proper position of printing & incase of incorrect or illegible print - Product reject through rejection system.	Safety Requirement
9.	Emergency Stop – Machine Stop	Safety Requirement



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8.7 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Automatic External Ampoules Washing, Drying & Self Adhesive Labeling .	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 P.O. and URS.
(2) Operating and service manual

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

9 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant documents.

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

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.....
.....

11 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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.....
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12 RECOMMENDATION:

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.....

13 ABBREVIATIONS:

- cGEP : Current Good Engineering Practice
- cGMP : Current Good Manufacturing Practice
- CI. : Cast Iron
- DQ : Design Qualification
- HP : Horse Power
- Hr : Hour
- Hz : Hertz
- Kg : Kilogram
- KW : Kilo Watt
- MCB : Miniature circuit breaker
- mm : Millimeter
- MMI : Man Machine Interface
- MOC : Material of Construction
- MS : Mild Steel
- No : Number
- P & ID : Piping and Instrumentation Diagram
- PO : Purchase Order
- RPM : Revolution per minute
- SS : Stainless steel
- URS : User requirement specification
- VFD : Variable Frequency Drive



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14 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			