DESIGN QUALIFICATION

NAME OF THE ITEM: STICKER LABELLING MACHINE

FUNCTIONAL AREA: PRODUCTION BLOCK

PROTOCOL No.:

CONTENT

1.0 PROTOCOL APPROVAL:

Protocol Prepared By:

Functional area	Name	Signature	Date
Engineering			

Reviewed By:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality Assurance			

Approved By:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

2.0 Objective:

The purpose of this document is to ensure that all the critical aspects of the Equipment, cGMP & Safety features have been considered in designing the equipment/instrument and is properly documented

3.0 Responsibilities:

In accordance with the document, following functions shall be responsible for initiation and finalization of Equipment user requirement specification.

3.1 Preparation of Document

- User department to prepare the DQ.
- Ensures that the document is in compliance with current policies and procedures of cGMP regulations.
- Ensures that the content is sufficient, clearly defined, technically sound and accurate.
- It is a Guidance document to prepare the DQ.

3.2 Review of Document

- To be reviewed by Head of the user department and functional department (Engineering & Quality assurance)

3.3 Approval of Document

- Approval of document by Head Manufacturing/Head Engineering/Head Quality.

4.0 Equipment Description & Identification:

4.1 Scope: Automatic Sticker labeling machine.

4.2 Purpose: Purpose of automatic sticker labeling machine is used to apply sticker label on the bottle and vials.

4.3 Process Equipment Description:

FIXONAME-VSC/VLC-240 Model itself indicates the machine identity as a vertical Small / large container for the Standard Rated Speed up to 240 CPM depending upon the Size of the Labels & Bottles. The machine is compatible to handle various flat/oval/round Containers i.e. bottles, jars, jerry cans etc. up to 95 mm label width w/o change parts. This machine comes with additional automation feature as per client's requirements, like Roll ending alarm system.

5.0 USER REQUIREMENTS

5.1 System Requirements:

S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
1.	Identification (In case of Equipment /Instrument)	Automatic sticker labeling machine
2.	Model/Type	FIXONAME – VSC/VLC-240
3.	Capacity	Up to 240 CPM (Depending up on Label / Product Size)
4.	Potential Suppliers	Maharishi UDYOG
5.	Non-contact parts (In case of Equipment)	SS-304 with matt finish

S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
6.	Non-metallic contact parts (In case of Equipment /Instrument)	1. Any material with food grade quality having no Potential impact on the products. 2. Durable. 3. Must be easily cleanable.
7.	Motor & Electrical installations (In case of Equipment /Instrument)	Machine should be operated through PLC mounted on separate electrical control panel.
8.	Machine assemblies (In case of Equipment /Instrument)	Must be covered with SS 304 with mirror finish.
9.	Machine adjustments (In case of Equipment /Instrument)	Setting with Zero clearance with good accuracy.
10.	Packaging & Transport	Should be packed and transported in such a way to avoid any damage during transportation.
11.	No. of requirements	01
12.	Requirements for any power failure backup's (In case of Equipment /Instrument)	To be backed up by installed in-house DG set. After any power failure PLC show continuous counting of dispensed sticker labels.
13.	Gear box specifications(In case of Equipment /Instrument)	As per cGMP model
14.	Machine specification	Container Size : Up to 90 mm. Dia. Containers Label Width (Height) Range: 8 to 95 mm. Label Length Range: 8 to 300 mm. Max. Label Stock (Roll) Dia.: 300 mm.
15.	Material of Construction	▪ Non-contact components are of S.S.304 or as per the machine requirements ▪ Exterior easy to clean & non-corrosive.
16.	Safety features	Adequate safety features for men and material are provided along with the equipment.
17.	Qualifications/ Documentations	The manufacturer shall complete and provide the documents pertaining to Design, Installation, and Operation Qualification.
18.	Operating System	The equipment shall be operated through PLC system.
19.	Control System	▪ The electrical system of the equipment shall be housed as per cGMP and cGEP standards, with adequate safety. ▪ Electrical panel and electro pneumatic panel to be installed on the base structure inside the machine. ▪ Control panel to be housed inside the machine.

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5.2 Technical Description

5.2.1 Specification of components.

S.No.	Components	Descriptions
1.	Name	Automatic sticker labeling machine
2.	Specification	Non-contact parts – SS 304 with matt finish.
3.	Output (Tablet / Hour.)	Up to 240 CPM (Depending up on Label / Product Size)
4.	Design	Left to Right
5.	Label Dispenser	New Aluminium –115 mm. Ht. Unit, Servo Motor
6.	Dispenser Motor	Fuji Make Small Servo Motor, MP-F
7.	Product Conveyor	88 mm. S. S. Chain Conveyor , 1500 mm Lg.
8.	Dispensing Speed	02 - 60 Mtr. / Min.
9.	Max. Pre-Dispensing of Label	25 mm.
10.	Label Width (Height) Range	8 to 95 mm.
11.	Stop Tolerance.	+/- 0.5 mm.
12.	Label Length Range	8 to 300 mm.
13.	Max. Label Stock (Roll) Dia.	300 mm.
14.	Core Dia. Of Label Stock	76 mm.
15.	Midi-Un winder Dia.	300 mm With Suspended Spring And Automatic Paper Break with Roll ending alarm system
16.	Micro Processor Control Panel (PLC)	MP-F (With Feather Touch Keypad)
17.	Product Separating Device	Aluminium Casted ‘O’ Ring type Space Creator With Geared DC. Motor
18.	Label Pressing System	Wrap-Around System (Synchronized)
19.	Main Drive	‘Megha’ Make, 0.5 HP, 3 Phase, 220 V AC Motor
20.	Gear Box	‘Rotomotive’ Make
21.	Variable Frequency Drive (VFD)	‘Allen Bradley’ Make, 0.5 HP

S.No.	Components	Descriptions
22.	Over all Measurements (L x W x H)	As Per Drawing.
23.	Product sensor	'Wenglor' Make HK 12 NB
24.	Label Sensor	'Leuze' Make, GS 06/66-2
25.	Roll Ending Alarm & Sensor	'Wadia' Make NPN-NO Metal Proxy Sensor For Low level & roll ending alarm system with Machine stop.

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5.2 Utility Requirement:

S.No.	Specification	Requirement
1.	Power supply	220/240V AC, 50Hz, Single Phase (Stabilized, Through 1 KVA CVT)

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5.3 Material of Construction

5.4 5.5.1 Contact and Non-contact surfaces

S.No.	Component Description	MOC
Main body and Product conveyor		
1	Main Body & Top plate	S. S. 304 & M.S. duly S.S. 304 Sheet cladded
2	Doors & Covers	S. S. 304 Sheet
3	Conveyor Side Channel	S. S. 304 Sheet
4	Conveyor Slat	S. S. 304 / Delrin Slat
5	Sprockets	EN 24 Duly Hardened
6	Fixing Spacers	S. S. 304
7	General Nuts & Bolts	S. S.304 / M.S. Chrome Plated
8	Product Guide	S. S. 304
9	Guide Bracket	S. S. 304 / Aluminum / Polyamide (plastic)
Dispenser assembly		
10	Dispenser Body	Reinforced Polyamide / Aluminium
11	Traction Roller	Aluminium duly Abrasive coated, 115 mm
12	Pressure Roller	Aluminium Rubber coated
13	Rewinding Roller	Aluminium
14	Label guide rollers	S. S. 304 / Aluminium
15	Label Guide Ring	Nylon
16	Dispenser Parts	Aluminium
17	Dancing Roll Assembly	S. S. 304 & Aluminium
18	Modular Rail	Aluminium

S.No.	Component Description	MOC
19	Rail Bracket	C. I. Duly Powder Coated
20	Sensor Holding Clamp	Aluminium
21	Label Release Plate	S. S. 304
Product separating device		
22	Separator Wheel	Aluminium. Casted 'O' Ring type Space Creator With Geared DC. Motor
Label Pressing System		Wrap Around System (Synchronized)
23	Wrap-Around Message Belt	Sponge Rubber Belt, 770 X 50 X 10 mm.
24	Label Pressing Plate	Aluminium lined with Sponge rubber & Covered with S. S. sheet
Electronics		
25	Main Drive Motor	'Megha' Make, 0.5 HP, 3 Phase, 220 V AC Motor
26	Main Drive Gear Box	Rotomotive Make
27	Micro Processor Control Panel (PLC)	MP-F
28	Electronic Counter	In –Built in PLC
29	Variable Frequency Drive (VFD) for main motor	Allen Bradley Make, 0.5 HP
30	Label Sensor	'Leuze' Make, Model : GS 06/66-2
31	Product Sensor	'Wenglor' Make HK 12 NB
32	Roll Ending Sensor & Alarm	'Wadia' Make NPN-NO Metal Proxy Sensor For Low level & roll ending alarm System with machine stop.

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6.0 COMPLEMENTARY ASPECTS

6.1 Training

S.No.	Specification	SYSTEM REQUIREMENTS
1	The vendor Shall supply all available information for the adequate exploitation of equipment. For the Compliance of this purpose at the Job site and/ or at the Vendors Shop. Vendor's technical staff shall train customer's personnel. The scope of the Training will be agreed during the contract signature.	YES
2	The supplier is to include the personnel training activities. The supplier is to specify the foreseen time for: • Operator/Supervisor training • Manager Training • Electrical maintenance training • Mechanical Maintenance training	YES
3	The supplier is to specify the personnel background needed for each of the operators maintenance.	YES

6.2 Pre Delivery Qualifications (FAT)		
S.No.	**Specification**	**SYSTEM REQUIREMENTS**
1	The System or its parts as provided for in the scope of supply shall be pre-installed at the vendors shop prior to delivery to customer site. Installation will be completed and documented including mechanical parts as well as electrical connections of all parts to facilitate taking over tests at Vendors shop prior to delivery.	YES

6.3 Supplier Technical Documentation Requirements:

S.No.	COMPONENTS	REQUIREMENTS
1.	Technical Documents	Operation Instruction Manual (In CD) ❖ G.A. Drawing Of Machine (In Manual) ❖ Programming Procedure (In Manual) ❖ Electrical Wiring Diagram (In Manual)
		Data Sheet of Allen Bradley, PowerFlex-4M AC. Drive
		Data Sheet of Sensors
		Test reports & Certificates ❖ S.S. 304 sheet → Laboratory test reports ❖ Motor & Gear box → Manufacturer Test certificate
		DQ, IQ, OQ documents

6.4 Technical Manuals

S.No.	Specification	Requirements
1.	Operation manual -02 copies	

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7.0 SAFETY AND ENVIRONMENTAL PROTECTION

S.No.	Specification	Requirements
1.	Environment	NA
7.1 Safety and Interlocking		
S.No.	**Alarm Messages**	**Description**
1.	**"No Container, No Label"**	The machine shall not start. But avoid wastage of labels.

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8.0 CLEANING MAINTENANCE AND SERVICE

S.No.	Specification
1.	In accordance with cGMP guidelines the units must be easy to clean, to disinfect, and where
2.	The Supplier should guarantee that, if required, a service team can be on site within one working day.
3.	The design should be such as to allow mechanical cleaning of the surface and that the cleanliness of the surface can be checked easily.
4.	All machine parts, in particular instrumentation, should be constructed so that they can be easily removed and calibrated.
5.	All special tools required for running and maintenance should be best.
6.	A spare parts delivery guarantee with in time.

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9.0 RULES AND REGULATION:

These standards, recommendation and requirements are considered the minimum. Specifications that are more stringent or expansive take the precedence. In case of conflict between published requirements, final determination is the responsibility of the Owners Representative.

10. SCOPE OF DELIVERY

S.No.	Specification	Requirements
1.	Units described in the specific system requirements including all necessary controls and instrumentation.	YES
2.	The complete mechanical and electrical installation.	YES
3.	The Connections to all the necessary utilities, exhaust, and waste lines necessary for its operation.	YES
4.	All piping and cabling of the units itself.	YES
5.	Wiring and cable run: all wiring and cable run is part of the supply. The site will supply the main power switches to be located in correspondence to the electrical and control cabinets delivered by the equipment supplier.	YES
6.	All internal contacts of the supplied equipment for the required utilities.	YES
7.	Unload on site of the equipment: the supplier is required to define all the necessary handling devices required to the unloading operation. The supplier will inform at least 4 weeks in advance the day of delivery and the list of required handling devices.	YES
8.	Assembling operation: the required consumable, the internal transportation, the assembling tools and the required personal are part of the supply.	YES
9.	A complete set of commissioning spare parts.	YES
10.	All special tools necessary for use and maintenance of the supplied equipment.	YES
11.	A complete set of two years spare parts should be listed quoted and offered as option.	YES

S.No.	Specification	Requirements
12.	All test activities as specified in this document.	YES
13.	Training in the use and maintenance of the equipment.	YES
14.	A complete set of documentation as specified In this document.	YES

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11.0 INSTALLATION, COMMISSIONING AND TESTS

11.1 General

S.No.	Specification	Requirements
1.	The Supplier must specify for each piece of equipment the Guaranteed performance and the guaranteed system performance. These values will be tested during the acceptance tests.	YES
2	In addition the functionality described in the user requirements and detailed in the system specifications will be tested.	YES

11.2 INSTALLATION, COMMISSION

S.No.	Specification	Requirements
1	The commissioning tests will be carried out in accordance with a written test plan developed by the supplier with clearly stated test procedures and acceptance criteria.	YES
2	The supplier will approve successfully completed tests and will specify items requiring additional work. Representatives from site. Will attend and participate in the commissioning tests as required.	YES
3	The installation and commissioning of the system will be performed at the site. Facility by the supplier.	YES
4	The commissioning can only start once all the foreseen documents have been delivered by the supplier to site.	YES
5	All equipment should be properly installed, adjusted, leveled, tagged, and connected with utilities.	YES
6	Point to point checks on wiring and pneumatic should be performed.	YES
7	All instruments should be properly calibrated.	YES

S.No.	Specification	Requirements
8	An equipment (instrument) used for qualification must be listed and approved by site.	YES
9	The calibration equipment must have all the necessary documents to demonstrate their maintenance & use.	YES
10	The last calibration of all this equipment must be less than 6 months old, and evidenced by certificate.	YES
11	Verification that the interior surfaces of equipment are free of practices and dirt and all points of product contact meet the specified material requirements.	YES
12	All the clearances and tolerances specified in the drawing or recommended by component manufacturers are correct.	YES
13	On site verification that valves and other equipment with moving parts are in their normal position if in a power down condition and move in the correct direction with the correct speed and precision.	YES
14	Verification that all the Input and Output points are connected and labeled according to the documentation and that all the along the input values have been scaled in accordance with the system specification and process requirements. That all equipment components requiring configuration	YES
15	The commissioning should demonstrate that the system supplied by the supplier has been properly installed and that the functions are in accordance with site. User Requirements specifications, Vendors System specifications Manuals and other Documentation.	YES

11.3 Site Acceptance Test (SAT)

S.No.	Specification	Requirements
1.	This test will be carried out once the commissioning will be completed. The scope will be to verify the performance and the functionality of the system integrated with the other factory systems	YES
2	The test will be carried out to verify the system response with the expected productivity of the system.	YES
3	Details on the test realization will be defined during the project Phase. The supplier is asked to specify the proposed duration for SAT and the standard procedure proposed.	YES
4	During SAT the required functionality, performances and system reliability are met.	YES
5	The Functionality described in the User Requirements Specification and in the System Specifications are verified and met.	YES

S.No.	Specification	Requirements
6	All the documentation agreed has been delivered.	YES

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12.0 QUALIFICATION / VALIDATION

S.No.	Specification	Requirements
1.	The maintenance Qualification is responsibility of the customer. However, the supplier is responsible for delivering the basic documents for maintenance qualification.	YES
2.	This includes all side costs such as: calibration measuring equipment and instruments: manpower (IQ and OQ will take place completely on site)	YES
3	Time Schedule for IQ/OQ execution will be developed by site. With the supplier.	YES
4	Suppliers personnel used for IQ/OQ must be well trained and experienced. This should be documented.	YES
5	The onsite test run performed by the supplier might become part of the IQ.	YES
6	Main IQ/OQ steps such as calibration must be performed and documented in accordance to a SOP approved by site.	YES
7	All equipment used for qualification must be listed and approved by site. The calibration equipment should be well documented.	YES
8	The last Recalibration of all this equipment should be less than 06 month old. Proofed by Certificate.	YES
9	OQ can only start after IQ approved by site.	YES
10	IQ will be carried out by site. During Installation phase. IQ will include the tests performed by the supplier.	YES
11	Part of the OQ will be carried out by site. During commissioning and SAT phase. OQ will include the tests performed by the supplier.	YES
12	After installation of the equipment at customers site. Complementary IQ & OQ tests will be performed by the Customer and may be supervised by a member of Technical staff.	YES
13	Qualification documents (In case of equipments/Instruments)	IQ, OQ

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13.0 GAURANTEE/WARRANTEE

S.No.	Specification	Requirements
1.	The System must be guaranteed including all the sub- system and components for a period of 12 months from the date of the system acceptance for a 03- shift operation.	YES
2	The servicing companies involved for the Sub- systems maintenance must be declared and the maintenance group organization described. Furthermore, the supplier will be directly responsible of the system assistance and the required operation will be co- ordinate by him.	YES

S.No.	Specification	Requirements
3	In case of failures, the intervention will be guaranteed by the supplier within a maximum time limit. The supplier is asked to specify the maximum time limit.	YES
4	The supplier is asked to propose as option maintenance and assistance contract after the guarantee expiration.	YES

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14.0 Deviation

15.0 Annexure

16.0 Summary and Conclusion

17. Approval of Design Qualification.

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

18. Acceptance By vendor

Name of Vendor:

Sign/Date: