DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR CARTON CODING MACHINE

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

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

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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)			

2.0 OBJECTIVE:

- To prepare the installation Qualification on basis of User Requirement Specification, Purchase Order

  And information given by Supplier.
- To ensure that all Critical Aspects of Equipment / Product Requirement, cGMP and Safety have been considered in designing the Equipment and is properly documented.
- To specify the performance basis for acceptance of equipment.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for CARTON CODING MACHINE (1000 Ltr.) procured from Bright Pharma Engineering Pvt. Ltd. at the site.
- The Equipment shall operate under the Controlled Environmental Conditions as per the cGMP requirements.
- The drawings and P & IDs 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 Authorization of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • 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	• Review & Approval of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.

Engineering	• 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.
	  • 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 Equipment Description
	  • Safety Features and Alarms
	  • Review of Design Qualification Protocol cum Report after Execution.

5.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized And / 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.

The Compounding Vessel, its associated components and stirrer are designed to process pharmaceutical Products in accordance with cGMP principles.

6.0 BRIEF EQUIPMENT DESCRIPTION:

Carton Coding Machine Comprises of jacked, insulated & cladded vessel having bottom entry low shear magnetic stirrer for stirring to perform heating & cooling with stirring operations respectively during the manufacturing process. The vessel will have CIP/SIP provision to clean the vessel respectively. All utility valves will be pneumatically operated & process valves pneumatic & manual operated to fulfill process requirements. Vessel will be supported by 3 legs. The full unit with operating panel & with drain header behind the vessel will be mounted on movable trolley. The vessel will also be facilitated with temperature sensor to online monitor the content's temperature.

The operation of Carton Coding Machine will be from touch screen (HMI) to operate in auto mode & semi -auto mode. The system will have online printing facility to take the printing by connecting Epson make dot matrix printer. This is principally designed for the sugar syrup preparation and manufacturing of liquid syrup. Carton Coding Machine is provided with all pipe fittings and valves with TC fittings and silicon gasket.

7.0 EQUIPMENT SPECIFICATION :

Equipment Specification is a document provided to Manufacturer for Engineering Equipment as per the specifications mentioned in User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS / PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: The purpose of Carton Coding Machine is mixing of pharmaceutical product with magnetic stirrer.	Carton Coding Machine shall be • Able to dissolve the Solid content in the Solvent Media to provide solution • Leak free • Jacketed to control the temperature of the solution	Process Requirement
Working	Should work smoothly and should run without producing any unwanted sound.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Room Condition	Should be able to meet the requirement of Clean Environment.	

8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Equipment Name	CARTON CODING MACHINE	Design Requirement
Make		Design Requirement
Design Code & Guideline	cGMP guideline	Design Requirement
Contact Part	SS 316L	Design Requirement
Non-Contact Part	SS 304	Design Requirement
Overall Dimension	1800 (W) x 1500 (D) x 2300 (H) mm	Design Requirement
Vessel Design Data		
Working Pressure	3.0 kg/cm^2	Design Requirement
Design Pressure	3.5 kg/cm^2	Design Requirement
Hydro- Test Pressure	5.0 Kg/cm2	Design Requirement
Working Temperature	0 to121 °C	Design Requirement
Design Temperature	0 to135°C	Design Requirement
Vacuum Pressure	760mmHg	Design Requirement
Jacket Design Data		
Working Pressure	3.5 Kg/cm2	Design Requirement
Design Pressure	4.5 Kg/cm2	Design Requirement
Hydro-Test Pressure	6.0 Kg/cm2	Design Requirement
Working Temperature	0 to 140°C	Design Requirement
Design Temperature	0 to 150°C	Design Requirement
General Specification		
Vessel Shell		
Shape	Cylindrical	Design Requirement
Shell Size	1250 ID x 900 mm Height	Design Requirement
Thickness	6mm	Design Requirement
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Vessel Top		
Shape	Torrispherical dish	Design Requirement
Dish Size	1250 ID x 250 mm Height	Design Requirement
Thickness	6mm	Design Requirement

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Vessel Bottom		
Shape	Torrispherical dished	Design Requirement
Dish Size	1250 ID x 250 mm Height	Design Requirement
Thickness	6mm	Design Requirement
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Jacket Shell		
Shape	Cylindrical welded over external surface of vessel shell with spiral stiffeners.	Design Requirement
Thickness	4mm	Design Requirement
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Jacket Bottom		
Shape	Torrispherical Dished end welded over external surface of vessel bottom with spiral stiffeners	Design Requirement
Thickness	4mm	Design Requirement
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Spiral Stiffeners (Welded on main chamber shell & bottom)		
Thickness	35 x 5 mm thick	Design Requirement
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Insulation (Bounded on external surface of shell)		
Thickness	50 mm thick	Design Requirement
MOC	Glass Wool	Design Requirement
Make	K-flex	Design Requirement
Cladding Shell (Cylindrical welded over shell insulation)		
Thickness	2 mm (14 Swg)	Design Requirement
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Cladding Bottom (Torrispherical dished end welded over shell insulation)		

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Thickness	2 mm (14 Swg)	Design Requirement
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Legs (Made of SS pipes)		
MOC	SS 304	Design Requirement
No. of Legs	3 Nos.	Design Requirement
Make	BPEPL	Design Requirement
Man Hole (Nl) (Triclover type with blank)		
Man Hole Size	0400mm TC	Design Requirement
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Vessel Lamp (N2) (Combined in 4" DIN with glass & vessel lamp)		
MOC	SS 316L	Design Requirement
Glass (Make:- Diamond Glass)	Toughened glass, 0100 x 10mm thick	Design Requirement
Vessel Lamp (Make:- Bright)	Halogen	Design Requirement
- Operating Voltage	230VAC	Design Requirement
- Power rating	50 Watt	Design Requirement
Make	BPEPL	Design Requirement
CIP/SIP Inlet Connection (N3) {2" xl" TC with Detachable arrangement of spray ball and MBFV}		
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Spray Ball (Make:- Jet Spray)	Dynamic 360 degree rotating	Design Requirement
-MOC	SS 316L	Design Requirement
- Flow rate	89 LPM @ 2 bar	Design Requirement
- Process connection	1.5"	Design Requirement
CIP Inlet Valve (Manual Butterfly Valve)		
- Size	1.5"	Design Requirement
-MOC	SS 316L	Design Requirement
- Diaphragm	PTFE backed by EPDM	Design Requirement
- Process Connection	I" TC	Design Requirement

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
- Air Press. Required	4.5 to 6 bar for actuation	Design Requirement
Make	Cipriani	Design Requirement
Compound Gauge (N 4) {1.5" TC with gauge}		
MOC	SS 316L	Design Requirement
Compound Gauge	Diaphragm Type Bourdon gauge	Design Requirement
- Dial Size	0100 mm	Design Requirement
-MOC	SS 316L	Design Requirement
- Range	-760mm Hg to 4 kg/ern?	Design Requirement
Make	Baumer	Design Requirement
Pressure transmitter (N5) {1.5" TC with pressure transmitter}		
MOC	SS 316L	Design Requirement
Make	Baumer	Design Requirement
Pressure transmitter (Sanitary Diaphragm Type)		
- Model	JumodTRANS	Design Requirement
- Range	-1 to 5 bar	Design Requirement
- Output	4 to 20 rnA	Design Requirement
- Process End	1.5" TC	Design Requirement
Make	Jumo	Design Requirement
Sterile safety valve (N6) {1.5"TC with sterile safety valve}		
MOC	SS 316L	Design Requirement
Sterile Safety Valve	Spring Loaded Type	Design Requirement
-MOC	SS 316L	Design Requirement
- Set Pressure	*2.5* kg/em-	Design Requirement
- Process Connection	1.5" TC	Design Requirement
Make	BPEPL	Design Requirement
Sugar Charging Inlet (N7){1.5"TC with MBFV }		
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Sugar Inlet Valve {Manual Butterfly Valve}		
- Size	1.5"	Design Requirement
Make	Cipriani	Design Requirement

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
-MOC	SS 316L	Design Requirement
- Diaphragm	EPDM	Design Requirement
Ingredient Inlet (N8) {1.5"TC with MBFV}		
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Ingredient Valve (Manual Butterfly Valve)		
- Size	1.5"	Design Requirement
-MOC	SS 316L	Design Requirement
- Diaphragm	EPDM	Design Requirement
Make	Cipriani	Design Requirement
Vacuum Inlet (N9) {1.5"TC with MBFV }		
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Ingredient Valve (Manual Butterfly Valve)		
- Size	1.5"	Design Requirement
-MOC	SS 316L	Design Requirement
- Diaphragm	EPDM	Design Requirement
Make	Cipriani	Design Requirement
Vacuum Breaker (NI0) {l"TC with MBFV & Filter}		
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Ingredient Valve (Manual Butterfly Valve)		
- Size	1"	Design Requirement
-MOC	SS 316L	Design Requirement
- Diaphragm	EPDM	Design Requirement
Make	Cipriani	Design Requirement
Air Filter (5")		
MOC	Sintered SS316L	Design Requirement
- Size	1.5"	Design Requirement
Make	Kumar	Design Requirement
Purified Water inlet (N 11) {1.5"TC }		

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
- Size	1.5"	Design Requirement
-MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Extra Connection (NI2) {1.5"TC}		
- Size	1.5"	Design Requirement
-MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Tank Outlet Valve (N13)		
MOC	SS 316L	Design Requirement
Make	BPEPL	Design Requirement
Tank outlet valve {Manual Flush bottom Valve}		
- Size	1.5"	Design Requirement
-MOC	SS 316L	Design Requirement
- Diaphragm	EPDM	Design Requirement
Make	Flow fit	Design Requirement
Temperature Sensor (NI4) {1.5"TC with Pt-l00 type with head mounted transmitter }		
-MOC	SS 316L	Design Requirement
- Range	0 to 200°C	Design Requirement
- Probe Diameter	06mm	Design Requirement
- Probe Length	50 mm long below TC	Design Requirement
- Power Supply	24 V DC, 2 wires	Design Requirement
- Process Connection	1.5" TC	Design Requirement
- Accuracy	Class A	Design Requirement
Make	Radix	Design Requirement
Jacket Safety Valve (NI5) {*3/8"* BSP (F) coupling with safety valve }		
Safety Valve	Spring Loaded	Design Requirement
-MOC	SS 304	Design Requirement
- Set Pressure	3.5 Kg/cm2	Design Requirement
- Process Connection	3/8" BSP (M)	Design Requirement
Make	BPEPL	Design Requirement
Pressure Gauge {1;4" BSP (F) coupling with Pressure Gauge }		

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
-MOC	SS 304	Design Requirement
- Dial Size	02.5"	Design Requirement
-MOC	SS 304	Design Requirement
- Range	0 to 7 kg/ern?	Design Requirement
- Process Connection	1;4" BSP (M)	Design Requirement
		Design Requirement
Steam Inlet (NI6) 1.5" TC with valve & steam trap		
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Steam Inlet Valve (Pneumatically operated Angle Seat valve)		
- Size	I"	Design Requirement
-MOC	SS 304	Design Requirement
- Seating	PTFE	Design Requirement
- Process End	1.5" TC	Design Requirement
- Compo Air Required	4.5 to 6 Kg/ern? for actuation	Design Requirement
Make	Avcon	Design Requirement
Steam Condensate (NI7) (1.5" TC with valve & steam trap)		
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
SteamCond. Valve (Pneumatically operated Angle Seat valve)		
- Size	I"	Design Requirement
-MOC	SS 304	Design Requirement
- Seating	PTFE	Design Requirement
- Process End	I" TC	Design Requirement
- Compo Air Required	4.5 to 6 Kg/ern? for actuation	Design Requirement
Make	Avcon	Design Requirement
Cooling Inlet (NI8) (1.5" TC with valve & steam trap)		
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Cooling Inlet Valve (Pneumatically operated Angle Seat valve)		
- Size	1"	Design Requirement
-MOC	SS 304	Design Requirement

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
- Seating	PTFE	Design Requirement
- Process End	1.5" TC	Design Requirement
- Compo Air Required	4.5 to 6 Kg/ern? for actuation	Design Requirement
Make	Avcon	Design Requirement
Cooling Outlet (N19) (1.5" TC with valve & steam trap)		
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Cooling Outlet Valve (Pneumatically operated Angle Seat valve)		
- Size	1"	Design Requirement
-MOC	SS 304	Design Requirement
- Seating	PTFE	Design Requirement
- Process End	1.5" TC	Design Requirement
- Compo Air Required	4.5 to 6 Kg/ern2 for actuation	Design Requirement
Make	Avcon	Design Requirement
Jacket Air vent (N20) (1.5" TC with valve & steam trap)		
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Jacket Air vent Valve (Pneumatically operated Angle Seat valve)		
- Size	1"	Design Requirement
-MOC	SS 304	Design Requirement
- Seating	PTFE	Design Requirement
- Process End	1.5" TC	Design Requirement
- Compo Air Required	4.5 to 6 Kg/ern? for actuation	Design Requirement
Make	Avcon	Design Requirement
Jacket Drain (N21) (1.5" TC with valve & steam trap)		
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
Jacket Drain Valve (Pneumatically operated Angle Seat valve)		
- Size	1"	Design Requirement
-MOC	SS 304	Design Requirement
- Seating	PTFE	Design Requirement
- Process End	I" TC	Design Requirement

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR CARTON CODING MACHINE	PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
- Compo Air Required	4.5 to 6 Kg/ern? for actuation	Design Requirement
Make	Avcon	Design Requirement
CIP Drain (N22) (1.5" TC with valve & steam trap)		
MOC	SS 304	Design Requirement
Make	BPEPL	Design Requirement
CIP Drain Valve (Manual Butterfly Valve)		
- Size	1.5"	Design Requirement
-MOC	SS 316L	Design Requirement
- Diaphragm	EPDM	Design Requirement
Make	Cipriani	Design Requirement
Flow Switch (N23) (*1A"* BSP Sanitary Coupling with level switch)		
-MOC	SS 304	Design Requirement
Connection	114" BSP	Design Requirement
Set Flow	0.4 to 4 LPM	Design Requirement
Model	WFS-06-S-1	Design Requirement
Maximum Pressure	10 Kg/cm sq.	Design Requirement
Electric	230 V ACI 1 A	Design Requirement
Make	BPEPL	Design Requirement
Solenoid Coil Seal cooling for stirrer (N24) {*3/8"* BSP Sanitary Coupling with level switch}		
Size	*3/8"*	Design Requirement
MOC	Brass	Design Requirement
Type	9230D *104/BRlS6/E/BSP*	Design Requirement
Make	Avcon	Design Requirement
Stirrer (Propeller Type On Inclined Portion.)		
Model	5 HP / 3.75 Kw	Design Requirement
Motor Rating	CI	Design Requirement
Maximum Speed	960	Design Requirement
- Accuracy's	Class A	Design Requirement
Elect. Connections.	415 V, 3 Phase	Design Requirement
Frequency	50Hz	Design Requirement
Type	Vertical Flange	Design Requirement
Protection	IP - 55	Design Requirement

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Stirrer Shaft	38mm	Design Requirement
Make	Hindustan	Design Requirement
Stirrer Design (Propeller type with 4 Blade)		
-MOC	SS 316L	Design Requirement
Sweep Dia	150mm	Design Requirement
Shaft Seal (Double Cartridge Mech. Seal)		
-MOC	SS 316L	Design Requirement
Seal Size	38 mm dia.	Design Requirement
Seal Face Inboard	S.C vs. S.c.	Design Requirement
Seal Face Outboard	TC vs. Carbon	Design Requirement
Seal Cooling Media	Water	Design Requirement
Make	Sigma Seal	Design Requirement
Control Panel (Make Precise)		
Size	600 (W) x 300 (D) x 1000 (H) mm Approx.	Design Requirement
MOC	SS 304	Design Requirement
3 Phase Indication (Make MIMIC)	R YB Lamps	Design Requirement
Main Switch (Make Salzer)	3 Pole, 25 A	Design Requirement
HMI (Panel flush mounted)		
Model	TP700 Comfort	Design Requirement
Size	7" color touch screen	Design Requirement
Power Supply	24VDC	Design Requirement
Communication	Modbus Protocol	Design Requirement
Make	Siemens	Design Requirement
Control Start (Make Teknic)	Illuminated green push button	Design Requirement
Control Stop (Make Teknic)	Red push button	Design Requirement
Emergency Stop (Make Teknic)	Push button	Design Requirement
Filter Pads (Make Teknic)	100 x 100mm	Design Requirement
Exhaust Fan (04")		
Power Supply	230V AC	Design Requirement

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Make	Rexnord	Design Requirement
Stirrer VFD (Mounted inside the control panel)		
Model	V-20 Series With filter	Design Requirement
HP Rating	5.0HP	Design Requirement
Make	Siemens	Design Requirement
PLC (Mounted inside the control panel)		
Model	S71200	Design Requirement
Power Supply	24VDC	Design Requirement
Make	Siemens	Design Requirement
Control MCB (Make Siemens)	2 pole, 6A	Design Requirement
Stirrer MCB (Make Siemens)	3 pole, 20A	Design Requirement
Plug Point MCB (Make Siemens)	2 pole, 6A	Design Requirement
SMPS (Make Meanwell)	24 V DC power supply of 6.5 Amp.	Design Requirement
Single Phase Preventer (Make: OIC)	3 Ph., 4 Wire	Design Requirement
PLC Based Relay Cards (Make Phoenix)	24 VDC, 1CHO	Design Requirement
Pneumatic Coil (Mounted inside the control panel)		
Model	305.M58	Design Requirement
Size	1/8"	Design Requirement
Electrical supply	230 V AC	Design Requirement
Make	Pneumax	Design Requirement
Air Pressure switch (For plant compressed air supply to valves)		
Type	UT-10	Design Requirement
Range	0 to 10 bar	Design Requirement
Electrical supply	24 VDC	Design Requirement
Make	Baumer	Design Requirement
Terminal (Make: Connectwell)	Single deck	Design Requirement

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Main Incomer (Make Salzer)	25A,3P	Design Requirement
Finishing		
Vessel Internal Finishing	Ra::::: 0.5 urn, Mirror Polish	Design Requirement
Vessel External Finishing	Ra::::: 0.8 urn, Matt Polish	Design Requirement
Movable Trolley	Ra < 1.2 urn, Matt Polish	Design Requirement
Make	BPEPL	Design Requirement
Bottom entry mixer	Propeller Type Stirrer Make: Bright	Design Requirement
Process pneumatic & manual valves	2-way diaphragm valves Make: Cipriani	Design Requirement
Utility pneumatic valves	2-way angle seat valves, Make: Avcon	Design Requirement
Vacuum breaker filter	Model: 5" SS Sintered Vent Filter, Make: Kumar	Design Requirement
Compound Gauge	Sanitary bourdon gauge, Dial size- 04" Make: Baumer	Design Requirement
Pressure Gauge	Bourdon gauge, Dial size- 02.5",0 -7 kg/ern", Make: Baumer	Design Requirement
Sterile Safety Valve	Sanitary, spring loaded Make: BPEPL	Design Requirement
N on Sterile Safety Valve	Non Sanitary, spring loaded Make: BPEPL	Design Requirement
Vessel Lamp	Halogen Make: Bright	Design Requirement
Temperature sensor on shell	Pt-100, 0-200 °C, W' BSP Make: Radix	Design Requirement
Spray Ball	360^0 self-rotating Make: Jet Spray	Design Requirement
Tank outlet valve	Make: Flofit	Design Requirement
Pressure Transmitter	Sanitary diaphragm Make: Jumo	Design Requirement

8.4 MATERIAL OF CONSTRUCTION

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Vessel Shell	SS 316L
2.	Vessel Bottom	SS 316L
3.	Vessel Top	SS 316L
4.	Contact Parts	SS 316L
5.	Non-Contact Parts	SS 304
6.	Jacket Shell	SS 304
7.	Jacket Bottom	SS 304
8.	Spiral Stiffeners	SS 304
9.	Insulation	Glass Wool
10.	Cladding Shell	SS 304
11.	Cladding Bottom	SS 304
12.	Legs	SS 304
13.	Spray ball	SS 316 L
14.	Agitator	SS 316 L
15.	**Top Dish Nozzle**	SS 316L
16.	Vessel Lamp	SS 316L
17.	CIP/SIP Inlet Connection	SS 316L
18.	Compound Gauge (N 4)	SS 316L
19.	Pressure transmitter (N5)	SS 316L
20.	Sterile safety valve (N6	SS 316L
21.	Sugar Charging Inlet	SS 316L
22.	Ingredient Inlet (N8)	SS 316L

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
23.	Vacuum Inlet (N9)	SS 316L
24.	Vacuum Breaker (NI0)	SS 316L
25.	Purified Water inlet (N 11)	SS 316L
26.	Extra Connection (NI2)	SS 316L
27.	Tank Outlet Valve (N13)	SS 316L
28.	Temperature Sensor (NI4)	SS 316L
29.	Jacket Safety Valve	SS 304
30.	Steam Inlet (NI6)	SS 304
31.	Steam Condensate (NI7)	SS 304
32.	Cooling Inlet (NI8)	SS 304
33.	Cooling Outlet (N19)	SS 304
34.	Jacket Air vent (N20)	SS 304
35.	Jacket Drain (N21)	SS 304
36.	CIP Drain (N22)	SS 304
37.	Flow Switch (N23)	SS 304
38.	Solenoid Coil Seal cooling for stirrer (N24)	Brass
39.	Shaft Seal	SS 316L
40.	Stirrer	SS 316L
41.	Control Panel	SS 304

8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine, Panel and operator should be provided	Safety Requirement
Noise Level	Below 80 db	Safety Requirement
Variable Frequency Drive	Motor safety from overload	Safety Requirement
Main Supply	Main power supply should be always switched off when not in use.	Safety Requirement
Safety valve	Safety against over pressure	Safety Requirement
Air pressure switch	Protection for low air pressure for pneumatic valves	Safety Requirement
Rupture Disc	Safety against Over pressure	Safety Requirement
Insulation	For operator safety & Heat loss prevention	Safety Requirement
Emergency Button	Protection against abnormal condition	Safety Requirement
Instrument air pressure	Low air pressure protection	Safety Requirement
Overload Relay	For motor & equipment protection	Safety Requirement
Temperature Controller	To Control the temperature of vessel	Safety Requirement
Steam Control Valve	For Controlling On / Off Action of Steam Depending on the set point.	Safety Requirement
Critical Alarms		
Air pressure low	Entire process will trip with hooter activation and alarm display. The same will log in alarm history as well as in print. On acknowledging msg., hooter will be silent. On reset of air pressure, alarm will disappear & the process will resume on manual intervention.	Safety Requirement
Emergency pressed		Safety Requirement
Single phase fail		Safety Requirement
Stirrer overload		Safety Requirement
Flow Switch for Seal Cooling		Safety Requirement
Non-Critical Alarms		

No Water Flow to Seal	Stirring, heating & cooling process will not start in semi-auto mode mfg. "NoW ater flow to seal"	Safety Requirement
	Hooter will activate with alarm display	Safety Requirement
	On acknowledging msg., hooter will be silent & alarm will disappear.	Safety Requirement
No Heating	During heating in auto as well as in semi auto mode Mfg. process, if product temperature doesn't increase for set scan time, hooter will activate with alarm display.	Safety Requirement
	The same will be printed and printing will stop.	Safety Requirement
	On acknowledge alarm, hooter will be silent & if not acknowledged, hooter will be silent in 30 sec.	Safety Requirement
No Heating (Continue)	Process will continuously check for healthy condition.	Safety Requirement
	On reset of healthy condition, alarm will disappear & process and printing will resume automatically.	Safety Requirement
No Cooling	During heating in auto as well as in semi auto mode Mfg. process, if product temperature doesn't increase for set scan time, hooter will activate with alarm display.	Safety Requirement
	The same will be printed and printing will stop.	Safety Requirement
	On acknowledge alarm, hooter will be silent & if not acknowledged, hooter will be silent in 30 sec.	Safety Requirement
	Process will continuously check for healthy condition.	Safety Requirement
	On reset of healthy condition, alarm will disappear & process and printing will resume automatically.	Safety Requirement
Product Temp. high	During heating in auto as well as in semi auto mode Mfg. process, if product temperature exceeds up to upper limit as per set upper tolerance, raw steam inlet valve will close.	Safety Requirement
	Hooter will activate with alarm display	Safety Requirement
	The same will be printed and printing will continue.	Safety Requirement
	On acknowledge alarm, hooter will be silent & if not acknowledged, hooter will be silent in 30 sec.	Safety Requirement
	Process will continuously check for healthy condition of reaching heating set point.	Safety Requirement
	On reset of healthy condition, alarm will disappear & raw steam inlet valve will function to maintain the same.	Safety Requirement

Product Temp. low	During heating in auto as well as in semi auto mode Mfg. process, if product temperature falls below lower limit as per set lower tolerance, raw steam inlet valve will open.	Safety Requirement
	Hooter will activate with alarm display	Safety Requirement
	The same will be printed and printing will continue.	Safety Requirement
	On acknowledge alarm, hooter will be silent & if not acknowledged, hooter will be silent in 30 sec.	Safety Requirement
	Process will continuously check for healthy condition of reaching heating set point.	Safety Requirement
	On reset of healthy condition, alarm will disappear & raw steam inlet valve will function to maintain the same.	Safety Requirement

User Level Accessibility	
User Level	**Accessibility description**
Operator	Mimic
	Input & Output status View
	Recipe Selection **/** Recall
	Process Start & Stop
	Alarm Acknowledgement
	Alarm History View
Supervisor	All Operator level menu
	Recipe Preparation
	Recipe Save
	Print Interval setting
Engineer	Mimic
	Input & Output status View
	Maintenance Mode
Manager	All Supervisor level menu

	Change password
	User Creation **/** Deletion

8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for Carton Coding Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review includes Vendor Background (General / Financial), Technical know -how, Quality Standards, Inspection of Site, Costing, feedback from Market.	cGMP Requirement

Reference: (1) User Requirement Specifications (URS).

(2) Design & Functional Specifications provided by Vendor.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Purchase Order Copy
- Any other relevant Documents

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

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11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

AISI	:	American Iron & Steel Institute
BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
D	:	Depth
db	:	Decible
DQ	:	Design Qualification
GA	:	General Arrangement
HMI	:	Human Machine Interface
HP	:	Horse Power
Hz	:	Hertz
Kg	:	Kilograms
KW	:	Kilo Watt
LPH	:	Liter per Hours
LPM	:	liter per Minute
Ltd.	:	limited
MBM	:	Carton Coding Machine
mm	:	Millimeter
MOC	:	Material of Construction
NO	:	Number
OD	:	outer Diameter
PLC	:	Programmable Logic Controller
PO	:	Purchase Order
PT-100	:	Platinum-100
PVT.	:	Private
RPM	:	Revolution per Minute
SS	:	Stainless Steel
TC	:	Triclover
Temp.	:	Temperature
V	:	Volt
VFD	:	Variable Frequency Drive

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			