



**PHARMA DEVILS**

**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
CARTON PACKING MACHINE**

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
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FOR  
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**DATE OF QUALIFICATION**

**SUPERSEDE PROTOCOL No.**

**NIL**



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**1.0 PROTOCOL PRE – APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



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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 Carton Packing Machine (Make: .....).
- 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 un-authorized 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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review and Compilation of the Design Qualification Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Review of Qualification Protocol cum Report after Execution.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of the Design Qualification Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li><li>• Review of Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of the Design Qualification Protocol cum Report.</li><li>• Assist in the Preparation of the Protocol cum Report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none"><li>➤ GA Drawing.</li><li>➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures.</li><li>➤ Details of utilities.</li><li>➤ Identification of components for calibration.</li><li>➤ Material of construction of all components.</li><li>➤ Brief Process Description.</li><li>➤ Safety Features and Alarms.</li></ul></li><li>• Review of Design Qualification Protocol Cum Report after Execution.</li></ul>



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**6.0 BRIEF EQUIPMENT DESCRIPTION:**

The carton Packing machine, Model VP 120 is Continuously Operating Machine. Particularly suited for Semi Automatic Packing of Variety of Good.

**The machine consists of following parts:**

**A. Carton Chain:** Carton chain transports the Carton from one Work Station to the Next Station.

Following Process have Taken Place on the Carton belt.

- Transfer And final Erection of The Carton,
- Folding of Side flap – Bottom Side,
- Folding of the Main Flap- Bottom
- Printing / Embossing of the Flap
- Insertion of the Leaflet
- Product Loading( Manually
- Folding of the Side Flaps- Top
- Folding of the main Flaps- Top Side

**B. Carton Loading Magazine:** The carton Blanks Loaded Vertically in the Magazine on Conveyor belt. This Conveyor is Drive Intermittently, Though Unidirectional Bearing and Pneumatic Cylinder . A Pressure plate with a dead Weight put Constant Pressure on the Carton Stack. two Plunger Cylinder hold the Cartons During Carton Pick up. Two Cylinder are Provided, one another on the Bottom.

**C. Carton Pick up :** The carton are Picked up with pickup arms from the carton Magazine and Then Place it the Carton holder . Pick and Place is done by Vacuum, which is Generated either by air venture or Vacuum pump . Suction cups Mounted at the end of Sucker arm do Main pick up Function .these are Rubber Cups, flexible Enough with Cushioning Action makes Carton Pick up easy up arms driven Through the Main Motor and shaft, Oscillating Movement for pick up arms generated through Linkage in Connection with main Shaft. , Carton Vacuum can be enabled or disabled from Main Screen of HMI.

**D. Carton Transfer:** The Sucker arms pick up the Carton and place in the Carton holder, A Carton Assembly Includes Top Carton Holder, Bottom Carton and Bottom Support Plate. top and Bottom holder hold the Carton whereas Support plate Supports Like Carton From Bottom during Transfer



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Carton Holder Assembly is Mounted on Rods with Sliding hub ,the Carton Holder Transfer the Carton from Magazine to a Carton Chain. Carton Holder Parts are Adjustable According to the Carton Length, Height and Width to Accommodate Various Size.

- E. Bottom Side Flaps Closing:** When the Carton Travels on the Chain , a Satisfactory and a Movable Finger Open Upper side Flaps this Facilities easy Product Loading Simultaneously, the Satisfactory and Movable Finger Close the Bottom Side Flap.
- F. Bottom Main Flaps Closing:** The Closing of Bottom Main flap is done in the Three Stages. First tuck- in Folded. In Second Stage tuck-in flap Is positioned in the Carton and about to Close and Finally Tuck-in Flap is Closed in the Third Round.
- G. Top Side flap Closing:** After the Feeding into Carton, the Stationary and Movable Finger Close the Top Side Flap. .
- H. Top Main Flap Closing:** The Closing of Top Main Flap is done in Three Stages tuck in Flap is Folded. In Second Stage Tuck in Flap is Positioned in the Carton and About to close and Finally tuck-in Flap is Totally closed in the third Round.
- I. Printing Unit:** The Station Use to Give the Batch Code Printing Provision on Top flap is Passed Through the Stereo Roller and Pressure Roller to Get the Stereo Roller and Carton Flap is Passed Through Roller and Pressure Roller to get the Implementation of Stereo on the Carton Flap. This Provision Can be Done on top Flap
- J. Pre- Folded Leaf let Transfer System.**
- K. Area for Manual Product Feeding:**
- L. Half Filled Product Inspection:**
- M. Empty Carton Rejection System**
- N. Carton Discharge:**
- O. Head Wheel:.**



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**7.0 EQUIPMENT SPECIFICATION:**

Equipment Specifications are based on User Requirement Specification prepared. The manufacturer of equipment ensures complies with User Requirement Specification.

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 PROCESS/PRODUCT PARAMETERS:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<b>Application:</b> Carton Packing Machine suitable for Semi Manual products Packing .	Should be continuous and automatic	Process Requirement
<b>Working:</b> The machine works on vacuum and pressure principle.	Autocartoning of material should be highly accurate.	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement

**8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<b>Electrical Supply</b>	Voltage : 415 V Phase : 3 Phase Frequency : 50 Hz $\pm$ 10%. Power consumption : 4 kW	GMP Requirement
<b>Room Condition</b>	Temperature NMT 25 °C RH : NMT 55 %	Process Requirement
<b>Compressed Air Consumption</b>	18 CFM for Carton ( with Vacuum Venturi ) 06 18 CFM for Leaflet ( with Vacuum Venturi )	Process Requirement
<b>Incoming Cable</b>	5 core x 4 mm <sup>2</sup> Copper Cable	Process Requirement
<b>Air Pressure</b>	6 Bar	Process Requirement





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**8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:**

CRITICAL VARIABLES		ACCEPTANCE CRITERIA	REFERENCE
<b>Machine Specification</b>			
Type		Continuous ,Motion Vertical Carton Packing Machine	Design Requirements
Model		.....	Design Requirements
S.No.		.....	Design Requirements
Machine Size		Refer machine layout (9119483-001)	
Output		Upto 120 cartons/min Depending Upon The Product	Design Requirements
Machine Weight ( Net)		1600 Kg.	Design Requirements
Machine Weight ( Gross)		2400 Kg.	Design Requirements
Carton Size	Length	60 to 320 mm	Design Requirements
	Width	20 to 135 mm	Design Requirements
	Height	15 to 90 mm	Design Requirements
Leaflet size (pre Folded)	Length	110 mm-170 mm	Design Requirements
	Width	20-35 mm	Design Requirements
Leaflet Paper		45 to 60 GSM	Design Requirements
Noise Level			Design Requirements
		80 db ( approx)	Design Requirements
Recommended Temperature Range		18 – 30 ° C	Design Requirements
Recommended Humidity		45- 60 %	
<b>Main Motor</b>			
Make		Rotomotive (90 L-4)	Design Requirements
Model		Rating : 3 Phase ,415 V, 50 Hz, 1.5 Kw,1400 RPM, 3.5 A	Design Requirements
<b>HMI</b>			
Make		Weintek Labs.	Design Requirements
Model		MT 8071 IE	Design Requirements
<b>Power Supply</b>			
Make		Omron	Design Requirements
Model		S8VK-C12024	Design Requirements
<b>PLC</b>			



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<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Make	Mitsubishi	Design Requirements
Model	FX 3G -60 M	Design Requirements
<b>Single Phase Preventure</b>		
Make	Omron	Design Requirements
Model	K8AK-PM2	Design Requirements
<b>Vacuum Pump</b>		
Make	Festo	Design Requirements
<b>Tower Lamp</b>		
Make	Schnedier	Design Requirements
Model	XVGB3S	Design Requirements
<b>Transformer</b>		
Make	Shilchar Technology	Design Requirements
Model	S-RC465-0550 PRI: 0-220-380-415 V, 50 Hz SEC: 0-220 V, 2.5 A	Design Requirements
<b>Encoder</b>		
Make	Kubler	Design Requirements
Model	8.5000.835A.0360.0050	Design Requirements
<b>Driven For Main Motor</b>		
Make	Danfoss ( VLT Micro Drive)	Design Requirements
Model	Rating 1.5 Kw, 2.0 HP	Design Requirements
<b>Pneumatic Cylinder For Carton Holding</b>		
Make	Festo	Design Requirements
Model	AEVC -20- 5-I-P	Design Requirements
<b>Vacuum Venturi for Carton Pickup</b>		
Make	Festo	Design Requirements
Model	VN-30-H-T6-PQ4-VQ5-RO2-M (02)	Design Requirements
<b>Peunamatic Cylinder for Carton Pusher</b>		
Make	Festo	Design Requirements
Model	DSN-20-25-P	Design Requirements
Vacuum Venturi for Leaflet Picup	Festo	Design Requirements



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<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Model	VN-20-H-T6 PQ4-VQ5-RO2M (1)	Design Requirements
<b>Air Pressure Switch</b>		
Make	Festo	Design Requirements
Model	PEV-1/4 SC-OD	Design Requirements
<b>Pneumatic Cylinder for Product Pusher</b>		
Make	Festo	Design Requirements
Model	ADN-20-50-A-P-A	Design Requirements
<b>Pneumatic Cylinder for Empty Carton Rejection</b>		
Make	Festo	Design Requirements
Model	DSNS-20-50-P	Design Requirements
<b>Carton Low Level Check in Magazine</b>		
Make	Telemecanique	Design Requirements
Model	XCJ110	Design Requirements
<b>Guard Switch</b>		
Make	Telemecanique	Design Requirements
Model	XCJ110	Design Requirements
<b>Carton Check Sensor</b>		
Make	IFM	Design Requirements
Model	OJ5148	Design Requirements
<b>Leaflet Check Sensor</b>		
Make	IFM	Design Requirements
Model	OJ5148	Design Requirements
<b>Carton Stage at Discharge</b>		
Make	IFM	Design Requirements
Model	OJ5148	Design Requirements
<b>Hand wheel Out Check</b>		
Make	Pepperi & Fuchs	Design Requirements
Model	NBB4-12 GM50-E2	Design Requirements
<b>Empty Carton Check</b>		
Make	IFM	
Model	KB 5004	



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**8.4 MATERIAL OF CONSTRUCTION:**

S.No.	Parts Name	Material of construction
1.	Chain	MS
2.	Pockets Wall	Plastic
3.	Pusher	MS Hardened rods
4.	Drive and guide assembly	MS
5.	Magazine assembly	SS304, MS, EN9
6.	Carton chain and Flap folding assembly	MS, SS304 and alluminum
7.	Tuck in assembly	MS, SS304 and EN8
8.	Carton discharge assembly	MS, PU, SS304 and aluminum
9.	Interconnection assembly	PU belt and Aluminum section

**8.5 SAFETY:**

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that where is an overload in current or any short circuit then MCB shall trip	Safety Requirements
Joints	Should be properly balanced and leveled.	Safety Requirements
Metal Parts	Metal parts should be properly ground without any sharp edges.	Safety Requirements
Guards	Welding of joints should be without any welding burrs.	Safety Requirements
Lock for SS control panel	Guards for all moving parts	Safety Requirements
Emergency Switch	Should be Available in working condition	Safety Requirements
Safety Interlocks	Safety interlocks should provided for doors	Safety Requirements
Pusher Overload	Machine should stop when pusher overload jam during operation	Safety Requirements



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**8.6 VENDOR SELECTION:**

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Carton Packing 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

**Checked By**  
**Engineering**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

.....  
.....  
.....

**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....





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**13.0 ABBREVIATIONS:**

cGMP	:	Current Good Manufacturing Practice
DQ	:	Design Qualification
GA	:	General Arrangement
CPM	:	Carton Packing Machine
HMI	:	Human Machine interface
Kg	:	Kilogram
MCB	:	Miniature circuit breaker
MOC	:	Material of Construction
NMT	:	Not more than
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RH	:	Relative Humidity
SS	:	Stainless Steel
URS	:	User requirement specification



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**14.0 REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (ENGINEERING)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			