

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

CARTON PACKING MACHINE

DATE OF QUALIFICATION

SUPERSEDE PROTOCOL No.

NIL



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

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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 Carton Packing Machine (Make: ACG Pampac).
- 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
	Preparation, Review, Authorized and Compilation of the Design
	Qualification Protocol cum Report.
	• Assist in the verification of Critical Process Parameters, Drawings as per the
Quality Accurance	Specification.
Quality Assurance	• Review of Qualification Protocol cum Report after Execution.
	Co-ordination with Production and Engineering to carryout Design
	Qualification.
	Monitoring of Design Qualification Activity.
	Review of the Design Qualification Protocol cum Report.
Production	• Assist in the verification of Critical Process Parameters, Drawings as per the
riouucuon	Specification.
	• Review of Qualification Protocol cum Report after Execution.
	Review of the 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.
Engineering	Specification of the sub-components/bought out items, their Make,
Engineering	Model, Quantity and backup records/ brochures.
	Details of utilities.
	Identification of components for calibration.
	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:

HI Cart plus is Continuous Motion cartooning Packing machine, Suitable for automatic Cartoning of Product Like Ampoule Bottle Tubes and blister . the Type of Machine meets the Need of The high Volume Production, Giving an Output of up to 180 Carton /minutes Depending upon Application .the Machine Performed following Function.

- Receive unit Product From upstream machine on Product Chain.
- Storing of pre Broken Carton in flat from in the Carton Magazine.
- Picking Up The carton from Carton Magazine with rotary Pick up System.
- Opening / erecting the Carton
- Rear Side Flaps Folding Before Product Pushing
- Loading Product
- Both side Carton Closing (Front & Rear sides)
- Discharge Either to a Bin or to downstream Machine

The machine consists of following Main Functional Areas:

A. Product Chain: Product Chain transports the Product from Receipt area to the Pushing Area. Product in Feed occurs.

- On a Pair of Roller Supported, Double Transport Chains
- Guided in Plastic Plates.
- With adjusted Product Pockets

Individual Product Pocket can be adapted to the Product Size with an adjustment of Chain. Length of the Chain Extension is depends on application, Upstream integration and Room Layout

Product Chain Extension:

The product chain Extension is additional extension for the Product Chain. the Extension Provides Additional Space Between Transfer and Cartoning Machine for Customer Specific use i.e. For Manual Product Insertion Into the Product Chain.



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B. Carton Chain:

The Carton Chain Transport open Carton from carton Landing to Carton Closing. Following Process take Place on the Carton Chain:

- Transfer and final Erection of the Cartons.
- Insertion of the Product and Leaflet.
- Folding of the side Flaps front and Rear sides.
- Printing /embossing of the Flap.
- Carton Closing.

The Individual Chain Pocket can be adapted to the Carton Size with an Adjustment of Chain. **Note:** Range of Carton Depending on Chain Configuration selected while order Finalization. Machine will be Based on the Customer Need Defined during order Finalization.

C. Carton Loading Magazine :

The carton Magazine Hold Various Size of Carton .Magazine Parts can be adjusted Easily to Accommodation Various Sizes of Carton With the Help of Numeric scales. For each Type each size/ Type of Carton , Values Can be 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.

D. Carton Pick up & Transfer System: 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.

An Integrated Carton Pre Breaking system Is provided along with the Carton Pick up System this unit open /from Carton Before Placing it on the Carton Chain Various Gears along with belt drive Rotates Rotary Pick unit . this Unit rotate Continuously . Sucker arms are mounted on Bracket, which in Turn Mounted on Rotary Pickup unit Through Small Gears.



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There are Three Vacuum & air Control Valve used in the Unit. Two Valve are Connected to the Vacuum Lines of the Sucker and one to the Pre- Breaker.

In Run Mode, Whenever the Product is not Present in any Pocket of the Product Chain or the Leaflet is not Released for some Pocket, the Signal is Sent to the Vacuum & air control Valve by a Sensor.

Then the Valve for the Corresponding Sucker Operates, the Vacuum Is Vacuum is Not off and carton is Picked for the product Pocket in which the Product or Leaflet is not Present.

The Valve for the Pre Breakers Operation is Mode .the Position of the Sucker arm for which the vacuum in the Pre Breaker is to be Made on and off are Set.

Thus the operation the Position comes, making the Vacuum in the Pre Breaker On at the start of Pre Pre Braking and Cutting it OFF at the end of Pre Breaking.

Carton pre Breaking unit is Provided to Pre Break the Carton Before Placing them on the Carton Chain .

E. Carton Positioning : The Carton Position unit Consist of a Carton Toward the product Chain From Rear side of the Machine.

The Carton is pushed Forward in the Forward:

- The Carton Partially pushed Forward
- The Carton Pushed Forward Unit Flaps come in the Contact with the Outer surface of the Cell angle along with Their Full Length.

The side Flap Opener Opens the Side Flaps of the carton for Smooth Insertion of the Product from Product Chain Side.

- **F. Rear Side Flaps Closing:** The Side Flap Closing Takes Places Between Carton Loading on the Carton Chain and product Pushing. Stationary Guide Close Left Side Flap and Folding Finger closes the Right Side Flap, Folding Finger is Moveable and Driven Through the Same Drives of Carton Positioning.
- G. Product Pushing system: The Product Pushing system is Provided to Push the Carton. It Consist of Product Pusher That Push the Product and Leaflet into the Carton . Pushing Takes Places when Product and Carton Comes to the Insertion point.

Folded Leaflet Gets Release by the Leaflet Clamp at this Station and then Inserted into the Carton with the product.

Pusher assembly Consist of a Pusher With rod and pre Pusher . if Product gets Stuck in Between , due to some Reason , It Operates the Overload Safety switch that Stop the Machine .

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H. Carton Closing : After Slide Flaps Closing Carton system to Main Flap Closing station . front and Rear Flap Closing Takes Place Simultaneously in 3 step.

Flap Position for Closing is done by Creasing guide and guide Rod. These are arranged to blend locking flap with main flap.

Pre- closing: Pre closing and completed closing is done by tuck in closers. In pre closing, tuck in closer pushes the locking flap to lock the carton.

Complete closing : Pre closing and completed closing is done by tuck in closers. In pre closing , tuck in closer pushes the locking flap over the side flap to lock the carton

I. Carton Discharge

The closed carton from the carton chain are transferred to the discharge belt. Discharge belt continuously carry these carton to the next point which may be either Collection bin or Line conveyor.

Discharge belt assembly includes two flat belts, driven through the main drive. Speed of both the belts is synchronized and slightly higher than the carton chain speed.

J. Empty Carton Rejection System

This system is provided to detect and reject the empty carton from the discharge conveyor. A sensor is provided to detect the presence of the product in the carton .If the product is not available in carton , the sensor gives signal to the control system, and it operates an ejection lever, which is operated by a pneumatic cylinder. The rejected carton will then collected in a separate bin.

K. Printing Station

This station has batch code embossing provision. A metallic roller holds embossing letters for coding on the carton flap. Carton flap is passed through the metallic roller and pressure roller to get the impressions of letters on the carton flap.



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L. Pre- folded Leaflet Transfer System

This attachment is provided to transfer the folded leaflet into the carton.

Pre folded leaflets are stored in magazine. The leaflets are picked up by the sucker arm and then transferred to the transfer belts. Belts carry these leaflets up to leaflet clamps with rotary turret. Then clamps along with chain carry these leaflets to the pusher station for insertion in the carton.



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7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification. 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
Application: Carton Packing Machine suitable for automatic products Packing.	Should be continuous and automatic	Process Requirement
Working: The machine works on vacuum and pressure principle.	Autocartoning of material should be highly accurate.	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
Electrical Supply	Voltage : 415 V	GMP Requirement
	Phase : 3 Phase	
	Frequency : $50 \text{ Hz} \pm 10\%$.	
	Power consumption : 6 kW max	
Room Condition	Temperature NMT 25 °C	Process Requirement
	RH : NMT 55 %	
Compressed Air Consumption	02 CFM for Carton (with Vacuum Pump) 06CFM for Leaflet (with Vacuum Venturi)	Process Requirement
Incoming Cable	5 core x 4 mm ² Copper Cable	Process Requirement
Air Pressure	6 Bar	Process Requirement



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8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

CRITICAL VARIABLES		ACCEPTAN	CE CRITERIA	REFERENCE
Machine Specifica	ation			
Machine Type		Continuous m	otion, automatic	Design Requirements
		carton packing	g machine	
Model		HICART PLU	JS	Design Requirements
Machine Number		HI630001336	-10	Design Requirements
Output		Upto 180 carte	ons/min ,out put of	Design Requirements
		the machine d	epends on the type of	
		product to be	packed, type and size	
		of carton, leaf	let/booklet and	
		quality of cart	on and	
		leaflet/booklet	ts.	
Machine Weight (Net)	2250 kg		Design Requirements
Machine Weight (Gross)	3200Kg.		Design Requirements
		Minimum	Maximum	
	Length	65mm	180mm	Design Requirements
Carton Size	Width	20mm	75mm	Design Requirements
	Height	20mm	65mm	Design Requirements
		Minimum	Maximum	
Leaflet size (pre	Length	110mm	180mm	Design Requirements
Folded)	Folded width	20mm	35mm	Design Requirements
Leaflet Paper		45 to 60 GSM	(Gram per squre	Design Requirements
		meter)		
Noise Lavel		80 db (approx	x)	Design Requirements
Recommended Temperature Range		18 – 30 ° C		Design Requirements
Recommended Hu	midity	45- 60 % RH		Design Requirements
Mechanical comp	onents	1		1
Vacuum Pump				
Make		Beaker		Design Requirements
Model		VT 4.40		Design Requirements



CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Main Motor		
Make	Rotomotive (90 L-4)	Design Requirements
Model	Rating : 3 Phase , 415 V , 1.5 Kw	Design Requirements
	, 3.5 A, 1400RPM	
Gear Box for Main motor		
Make	Rotomotive	Design Requirements
Iodel	ROBUS 21 (Ratio = 1:10)	Design Requirements
ervo Motor for Carton Position	ning and Rear Flap	I
Make	Mitsubishi Electric	Design Requirements
Model	HG –KN23	Design Requirements
	Input : 3AC .119V, 1.3 A	
	Output : 0.91 Kg , 3000 RPM, 200	
	W	
Gear box carton Positioning and	d Rear Flan	
Make	Shimpo- Nidec	Design Requirements
Aodel	EVB-060-8-K4-14BK14	Design Requirements
Carton Chain Cluch		
Make	Comintec	Design Requirements
Model	1.90 DSR/FAMS	Design Requirements
Gear Box in front Truck in Uni	t l	
Make	KMT	Design Requirements
Model	1:2 90-5332	Design Requirements
Gear Box in Rear Truck in Unit	<u> </u>	
Make	KMT	Design Requirements
Model	1:2 90-5332	Design Requirements
Leaflet Transfer System		
Gear Box Leaflet Drive		1
Make	KMT	Design Requirements
Model	1:1-120-5330	Design Requirements
Gear Box Leaflet Drive		
Make	KMT	Design Requirements
Model	1:4-120-5331	Design Requirement



CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
HMI		
Make	Weintek Labs.	Design Requirements
Model	MT 8071 IE	Design Requirements
Power Supply		
Make	Omron	Design Requirements
Model	S8VK-C12024	Design Requirements
PLC For Machine		
Make	Mitsubishi Electric	Design Requirements
Model	FX 2N -16EX	Design Requirements
PLC Card For Input	I	1
Make	Mitsubishi Electric	Design Requirements
Model	FX2N-16EX.	Design Requirements
PLC Card For Output		
Make	Mitsubishi Electric	Design Requirements
Model	FX2N-16EYT	Design Requirements
Single Phase Preventer		
Make	Omron	Design Requirements
Model	K8AK-PM	Design Requirements
Tower Lamp		
Make	Schnedier	Design Requirements
Model	XVGB3S	Design Requirements
Encoder		
Make	Kubler	Design Requirements
Model	8.5000.835A.3600.0050	Design Requirements
Drive for Main Motor	1	1
Make	Danfoss	Design Requirements
Model	(VLT Micro Drive)	Design Requirements
Specification	Rating 1.5 kw, 2.0 HP	Design Requirements
Servo Drive For Carton Positioni	ng And Rear Flap Servo Motor	I
Make	Mitsubishi Electric	Design Requirements



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Model	MR-JE-20A	Design Requirements
Pneumatic Component		
Air pressure switch		
Make	Festo	Design Requirements
Model	SPAN-PIOR-G18M-PN-PN-L1	Design Requirements
Carton holding Actuator on , Magazine	e	
Make	Festo	Design Requirements
Model	DSR-16-180-P	Design Requirements
Pusher Diverter Actuator		
Make	Festo	Design Requirements
Model	DSR-12-180-P	Design Requirements
Pneumatic Cylinder For Empty Carte	on rejection	
Make	Festo	Design Requirements
Model	DSN-12-100-P	Design Requirements
Pneumatic Cylinder Carton Top Supp	ort Cylinder (02 Nos.)	
Make	Festo	Design Requirements
Model	DSBC-32-100-PPVA-N3	Design Requirements
Vacuum Venturi For Leaflet Pickup		
Make	Festo	Design Requirements
Model	VN-20-H-T6-PQ4-VQ5-RO2-M	Design Requirements
Sensor		
Main motor home position check		
Make	Pepperl & Fuch	Design Requirements
Model	NBB5-180GM50-E2	Design Requirements
Carton Low Level Check in Magazine	-	-
Make	Pepperl & Fuch	Design Requirements
Model	NBB4-12GM50-E2	Design Requirements
Leaflet Low level Check		
Make	IFM	Design Requirements
Model	OJ5148	Design Requirements
Leaflet Check Sensor	•	



CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Make	IFM	Design Requirements
Model	OJ5148	Design Requirements
Handwheel Out Check		I
Make	Pepperl & Fuch	Design Requirements
Model	NBB4-12GM50-E2	Design Requirements
Carton Check		
Make	IFM	Design Requirements
Model	OJ5148	Design Requirements
Product Pusher Loading Safety		
Make	Pepperl & Fuch	Design Requirements
Model	NBB4-12GM50-E2	Design Requirements
Sucker Arm Home Position Chec	k	
Make	Pepperl & Fuch	Design Requirements
Model	NBB5-18GM50-E2	Design Requirements
Half Product Insertion Check		
Make	IFM	Design Requirements
Model	OJ5148	Design Requirements
Empty Carton Rejection Check		
Make	IFM	Design Requirements
Model	KB5004	Design Requirements
Carton Chain Clutch		
Make	Pepperl & Fuch	Design Requirements
Model	NBB4-12GM50-E2	Design Requirements
Carton Rear pusher home position	on check	Į
Make	Pepperl & Fuch	Design Requirements
Model	NBB4-12GM50-E2	Design Requirements
Guard Switches (04 Nos.)		I
Make	Telemecanique	Design Requirements
Model	XCJ-110	Design Requirements



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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



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

8.5 SAFETY FEATURES & ALARM :

Description of Test	Message Displayed on HMI	Result of the Test
Emergency Switch pressed on HMI	Emergency Stop at Console	Machine should stop immediately
Emergency switch pressed on Discharge end	Emergency stop at discharge end	Machine should stop immediately
Emergency switch pressed on Infeed end	Emergency stop at infeed	Machine should stop immediately
Low Air Pressure	Air Pressure Below as per Set Limit	The Machine Should not start unless set set air Pressure is Available
Carton Vacuum Off	Carton Vacuum Key is Off	Machine should not start
Leaflet Vacuum Key Off from HMI	Leaflet Vacuum off	Machine should not start
Hand wheel Out	Hand wheel out	Machine should not start
Product Not sensed	Product not sensed by sensor	The Leaflet will not picked up
Leaflet not Sensed	Leaflet not sensed by sensor	The Machine Should Stop as per Preset Count.
Carton Not sensed	Carton not sensed by sensor	Product Pusher will Get Diverted
Product as per set count in HMI not present	No Continuous Product	The Machine should stop as per set count
Leaflet as per set count in HMI not present	No Continuous leaflet	The Machine should stop as per set count
Cartons as per set count in HMI not present	No Continuous Cartons	The Machine should stop as per set count
Low Level carton	Carton Level is Low	Machine Should stop as per set count
Leaflet Low Level	Leaflet Low Level detected by Sensor	The Machine Should Stop as per Preset Count.
Half product insertion	Product is not Completely Pushed in the Carton	Machine should Stop immediately
Carton Chain Cluch Overload	Carton Chain Clutch Overload	Machine should Stop immediately



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE			
Description of Test	Message Displayed on HMI	Result of the Test	
Pusher Loading Safety	Loading Safety at Pusher	The Machine should Stop Immediately	
Guard Open	Should be properly balanced and leveled.	Machine should Stop	

8.6 VENDOR SELECTION:

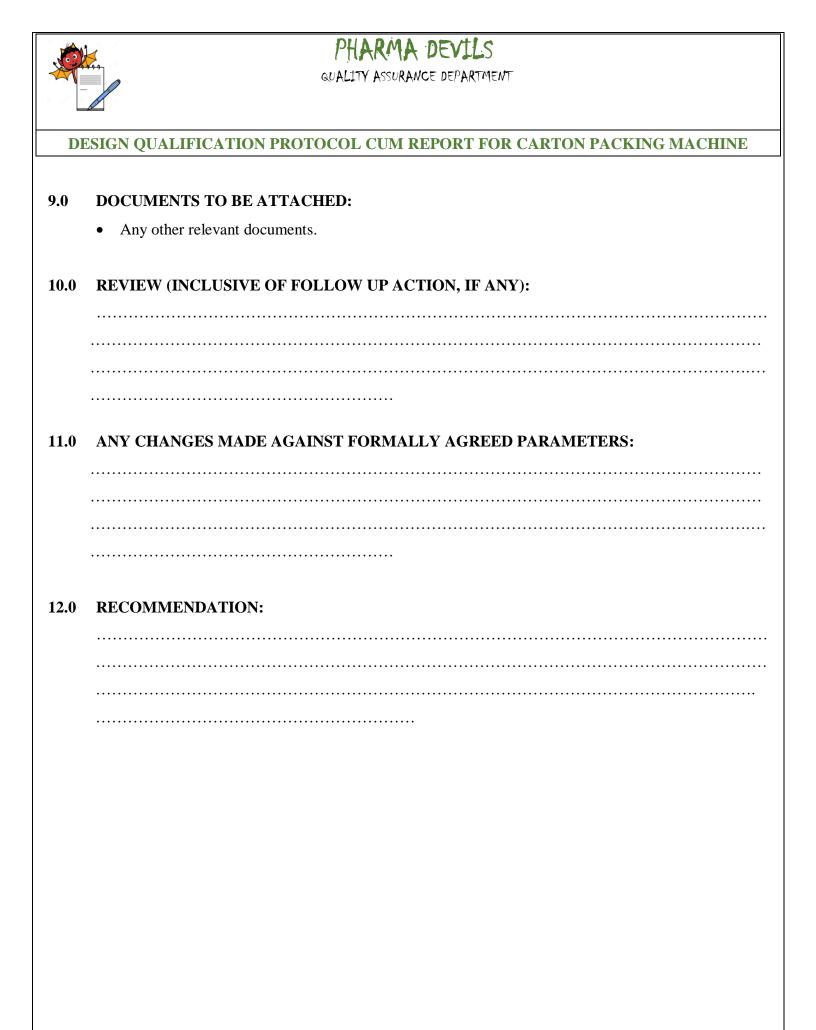
Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying	Selection of Vendor is done on the basis of	Process Requirement
the Carton Packing Machine.	review of vendor.	
	Criteria for review should include vendor	
	background (general/financial), technical	
	know how, quality standards, inspection of	
	site, costing, feedback from market	
	(customers already using the equipment)	

Checked B	У
Engineerin	g
Sign/Date:	•••••

Verified By Quality Assurance Sign/Date:

Inference:

> Reviewed By Manager QA Sign/Date:





DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

13.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
DQ	:	Design Qualification
GA	:	General Arrangement
СРМ	:	Carton Packing Machine
HMI	:	Human Machine interface
LB	:	L Block
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



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

14.0 **REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			