



**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
AUTOCARTONATOR**

PROTOCOL No.:

**DESIGN QUALIFICATION
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FOR
AUTOCARTONATOR**

DATE OF QUALIFICATION

SUPERSEDE PROTOCOL No.

NIL



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AUTOCARTONATOR**

PROTOCOL No.:

CONTENTS

S.No.	TITLE	PAGE No.
1.0	Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Brief Equipment Description	6
6.0	Equipment Specification	6
7.0	Critical Variables to be Met	7
7.1	Process / Product Parameters	7
7.2	Utility Requirement / Location Suitability	7
7.3	Technical Specification /Key Design Features	8-9
7.4	Material of Construction	10
7.5	Safety	11
7.6	Vendor Selection	12
8.0	Documents to be Attached	12
9.0	Review (Inclusive of Follow Up Action, If Any)	13
10.0	Any Changes Made Against the Formally Agreed Parameters	13
11.0	Recommendation	13
12.0	Abbreviations	14
13.0	Reviewed By	15



**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
AUTOCARTONATOR**

PROTOCOL No.:

1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
AUTOCARTONATOR**

PROTOCOL No.:

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 Autocartonator Machine (Make: **Wimco Ltd.**).
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



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AUTOCARTONATOR**

PROTOCOL No.:

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	<ul style="list-style-type: none"> • Preparation, Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none"> • Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none"> • Review of the 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. ➤ Identification of components for calibration. ➤ Material of construction of all components. ➤ Brief Process Description. ➤ Safety Features and Alarms. • Review of Qualification Protocol after Execution.



**DESIGN QUALIFICATION PROTOCOL CUM REPORT
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AUTOCARTONATOR**

PROTOCOL No.:

5.0 BRIEF EQUIPMENT DESCRIPTION:

Horizontal Cartoning machine is used for forming and filling tubes into carton of respective sizes of tubes as per specification.

Major System Components: Cartoning machine is comprises of following major assembly / components.

1. **Product Conveyer:** Consist of chain conveyer covered with nylon & aluminum pockets for proper guiding of product during insertion process.
2. **Product Pusher Assembly:** number of pusher guided with the help of cam insert the product into carton along with the leaflet.
3. **Carton Magazine Assembly:** In this assembly Cartons are loaded in unfold form, there after cartons are formed and transferred to the Carton chain for further process and the change over setting for various carton size is done without any tool (i.e. tool less change over setting provision)
4. **Carton Chain & Flap Folding Assembly:** In this assembly after forming is further taken to the next station with the help of clit chain and the side flaps are folded & guided for further process and at the same time on one of the major flap of carton printing or coding is done with the help of rubber stereo or metal engraving unit.
5. **Tuck In Assembly:** carton along with the product in it is finally enclosed in this assembly where the side flaps are either closed by just pressing the side flaps.
6. **Carton Discharge Assembly:** In this assembly the final enclosed carton is transferred to next machine or collected in a bin.
7. **Interconnection Assembly:** This assembly mainly consists of conveyer & linkup assembly, which is used to interconnect the two machines for automatic feeding of product from inlet machine to the product conveyer of Cartoning machine.

6.0 EQUIPMENT SPECIFICATION:

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



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**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
AUTOCARTONATOR**

PROTOCOL No.:

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Double head fully automatic filling , closing and sealing machine is designed to fill ointment different weights in different sizes of tubes	Should be able to filled weight accurately with minimal spillage.	Process Requirement
Working: The machine works on vacuum filling principle.	Filling of material should be highly accurate.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 415 VAC Phase : 3 Phase Frequency : 50 HZ & 51 Amp.	GMP Requirement
Room Condition	Temperature NMT 25 °C RH : NMT 55 %	Process Requirement
Compressed Air supply	6 Kg/cm ²	Process Requirement



**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
AUTOCARTONATOR**

PROTOCOL No.:

7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

PARAMETER	SPECIFICATION	REFERENCE
General		
Product	Carton	Design Requirement
Packing Style	Tuck-in	Design Requirement
Machine Speed	120 Tubes / min.	Design Requirement
Machine Dimension	495 X 95 X 98 cm	Design Requirement
Product Conveyer Assembly		
Chain	02 Nos.	Design Requirement
Pockets wall	76 nos.	Design Requirement
Frame	01 Nos.	Design Requirement
Product Pusher Assembly		
Pusher	14 Nos.	Design Requirement
Drive and Guide assembly	01 nos.	Design Requirement
Magazine assembly	01 nos.	Design Requirement
Vacuum pump	Qty : 01 Nos.	Design Requirement
	Make : Smalz	Design Requirement
	Model : SBP 25	Design Requirement
	Spec. : 500 lpm	Design Requirement



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FOR
AUTOCARTONATOR**

PROTOCOL No.:

PARAMETER	SPECIFICATION	REFERENCE
Carton chain and flap folding assembly	01 Nos.	Design Requirement
Central Lubrication System	To provide lubrication for all the moving parts	Design Requirement
Tuck in Assembly	02 Nos.	Design Requirement
Carton Discharge Assembly	02 Nos.	Design Requirement
Interconnection Assembly	01 Nos.	Design Requirement
Link up assembly	01 Nos	Design Requirement

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Quality Assurance
Sign/Date:

Inference:

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Manager QA
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7.4 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	EN8 and 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
10.	Link up assembly	MS, EN9 and PU belt

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7.5 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	
Joints	Should be properly balanced and leveled.	
Metal Parts	Metal parts should be properly ground without any sharp edges.	
Guards	Welding of joints should be without any welding burrs.	
Lock for SS control panel	Guards for all moving parts	
No tube No Carton Sensor	To give Signal to suction station for carton erection	
Emergency Switch	Should be Available in working condition	
Pusher Overload	Machine should stop when pusher overload jam during operation	

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7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Autocartonator.	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 for Autocartonator.

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8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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AUTOCARTONATOR**

PROTOCOL No.:

12.0 ABBREVIATIONS:

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
HMI	:	Human Machine interface
db	:	Decibel
RH	:	Relative Humidity
OFS	:	Autocartonator
SS	:	Stainless Steel



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			