



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOCARTONATOR**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOCARTONATOR**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>PACKING HALL</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



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**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)			



**PHARMA DEVILS**

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**2.0 OBJECTIVE:**

- To provide documented evidence for the Installation Qualification of Autocartonator.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

**3.0 SCOPE:**

- The scope of this installation qualification protocol cum report is limited to qualification of Autocartonator (Make: Wimco. Ltd.) to be installed in the Autocartonator .
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Autocartonator.



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**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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Qualification Activity.</li><li>• Post Approval of Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Protocol cum Report.</li><li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li><li>• Post Approval of Qualification Protocol after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in VFS Installation Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li><li>• Post Approval of Qualification Protocol after Execution.</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Autocartonator
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	Wimco Ltd.
<b>Supplier's Name</b>	Wimco Ltd.
<b>Location of Installation</b>	Packing Hall

**6.0 SYSTEM 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.



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**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P & ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

**7.1.2 Acceptance Criteria:**

- All the documents should be available, complete and approved by respective authorities.

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Installation Qualification Checklist:**

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>Grouting and Mounting</b>	Should be properly grouted and mounted.		
<b>Leveling</b>	Should be properly balanced and leveled.		
<b>Edges of parts</b>	Metal parts should be properly ground without any sharp edges.		
<b>Welding of Joints</b>	Welding of joints should be without any welding burrs.		
<b>Place of Installation</b>	Packing Hall		
<b>Room Condition</b>	RH : NMT 55 % TEMP : NMT 25 °C		
<b>Illumination</b>	NLT 300 Lux		
<b>Working space around the Equipment.</b>	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

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

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

**Inference:**

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





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**8.2 Installation Checks:**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>Utilities</b>			
Power	1.85 KW, 3Phase, 440V, 50 Hz		
Compressed Air	6 kg/cm <sup>2</sup> 100LPM-325LPM 5CFM		
Room Condition	Should be able to meet the environment		
AC inverter drive	Shall be properly connected and identified		
Light Indication For machine working Condition	Shall be properly connected and identified		
<b>General</b>			
Length	495 cm		
Width	95 cm		
Height	98 cm		
Product	Carton		
Packing Style	Tuck in		
Speed	120 carton / min.		
Minimum change over time	Approx 45 min		
<b>Product Conveyor Assembly</b>			
Description	Carries product from the input machine to the carton forming section		
Chain	Qty. : 02 Nos. MOC : MS		
Pockets Wall	Qty. : 128 Nos. MOC : AL		



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<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
Frame	Qty. : 01 Nos. MOC : MS		
<b>Product Pusher Assembly</b>			
Pusher	Qty. : 14 Nos. MOC : MS Hardened Rods		
Drive and Guard	Qty. : 02 Nos. MOC : EN8 & MS		
<b>Magazine Assembly</b>			
Magazine	Qty. : 01 Nos. MOC : SS 304, MS & EN9		
Vacuum Pump	Qty. : 01 Nos. Make : Smalz Model : SBP 25 Specification: 500lpm, SPB25		
<b>Carton Chain and Flap Folding Assembly</b>			
MOC	MS, SS304 & Al		
<b>TUCK-IN Assembly</b>			
Tuck-In Assembly	Qty. : 02 Nos. MOC : EN8 & MS, SS304		
<b>Carton Discharge Assembly</b>			
Qty.	02 Nos.		
MOC	MS, PU, SS304 & Al		
<b>Interconnecting Assembly</b>			
Qty	01 No.		
MOC	PU Belt & Al section		
Product Stopper Assembly	Qty. : 01 No. MOC : MS & EN8		

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<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
Link UP Assembly	Qty. : 01 No. MOC : MS & EN9 , PU belt		

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

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**Sign/Date:** .....

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



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**8.3 Safety:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
MCB	MCB is provided so that where is an overload in current or any short circuit then MCB shall trip		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Guards	Guards for all moving parts		
No tube no Carton sensor	To give Signal to suction station for carton erection		
Emergency stop switch on the operator panel	Should be Available in working condition		
Pusher Overload	Machine should stop when pusher overload jam during operation		

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

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

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



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**9.0 REFERENCES:**

**The Principle References is the following**

- Validation Master Plan
- Schedule- M-“Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2-Good Manufacturing Practices and Inspection.

**10.0 DOCUMENTS TO BE ATTACHED:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.

**11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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

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**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**16.0 ABBREVIATIONS:**

- URS : User requirement specification
- cGMP : Current Good Manufacturing Practice
- PO : Purchase Order
- Kg : Kilogram
- VFD : variable frequency drive
- HP : Horse Power
- Hz : Hertz
- Amp. : Ampere
- SS : Stainless steel
- AC : Alternate Current
- Hr : Hour
- mm : Millimeter
- SS : Stainless Steel
- MOC : Material of Construction
- P & ID : Piping and Instrumentation Diagram
- MCB : Miniature circuit breaker
- db : Decibel
- RH : Relative Humidity
- SS : Stainless Steel



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**17.0 POST APPROVAL:**

**INITIATED 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>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

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