



**OPERATIONAL QUALIFICATION PROTOCOL CUM
REPORT
FOR
AUTOCARTONATOR**

PROTOCOL No.:

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
AUTOCARTONATOR**

EQUIPMENT ID. No.	
LOCATION	PACKING HALL
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



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1.0 PROTOCOL 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)			



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2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Autocartonator and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Autocartonator (Make: Wimco Ltd.)** installed in the Packing hall.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Autocartonator.
- Successful completion of this Protocol will verify that Autocartonator meet all acceptance criteria and ready for Performance Qualification.



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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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review, Approval and compilation of the operational Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Operational Qualification.• Monitoring of Operation Process.• Post Approval of Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of Operational Qualification Protocol cum Report.• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.• Post Approval of Operational Qualification Protocol after Execution.
Engineering	<ul style="list-style-type: none">• Review of Operational Qualification.• To co-ordinate and support Operational Qualification Activity.• Calibration of Process Instruments.• Post Approval of Qualification Protocol cum Report after Execution.



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5.0 EQUIPMENT DETAILS:

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

6.0 EQUIPEMENT 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.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.
Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol cum Report				
2.	IQ Protocol cum Report				
3.	Draft SOP for Operation & Cleaning of Double head fully automatic filling, closing and sealing machine.				
4.	Draft SOP for Preventive Maintenance Double head fully automatic filling , closing and sealing machine				

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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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Operational and Functional Checks for Lami / plastic and Aluminum tubes:

Operate the Autocartonator as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired for Both LAMI and Aluminum tubes.

Activity Specification	Observation	Observed By (Engineering) Sign/Date
Conveyer Conveys the product when machine started		
Conveyer stop to convey the product when machine stopped		
Cam inserts the product into carton along with the leaflets		
Unfold cartons formed.		
Folded or formed cartons transferred to the carton chain for inserting the product along with leaflet.		
Side flaps are folded.		
Continuous motion chain to hold & carry the carton while the carton gets opened, filled & closed.		
Carton opening & Closing linkages operate in synchronization with the chain movement.		
Continuous motion chain to carry the Product to be packed into carton.		
Pick the folded carton with sucker arms from the carton magazine, open it with help of lever & then place it in the carton chain of the machine.		
Right hand side flap gets fold with the help of guide plate provided in the stationary flap folder.		

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Activity Specification	Observation	Observed By (Engineering) Sign/Date
Left hand side flap folds with the help of oscillating side flap folder.		
Simultaneously with rear side flap folding topside flap gets opened.		
Opening of left hand & Right hand side flap in done by stationary flap opener.		
Product is finally enclosed by closing the side flap.		
Final enclosed carton is transferred to the next machine or collected in a bin.		
Conveyer and link up assembly to interconnect the two machine for automatic feeding of product from inlet machine to the product conveyer of Cartoning machine.		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:

8.2 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

**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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8.3 Emergency Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button <ul style="list-style-type: none"> • Press Stop Push Button • Release ON Push Button 	Equipment should Stop		
	Equipment should Start		
With the Emergency Stop Pressed in, in Try to cause movement of an Operating function.	The Equipment will be inoperative.		
Emergency Stop Alarm <ul style="list-style-type: none"> • Press emergency Stop switch 	Machine stop immediately and red light blow ON tower Lamp.		

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:

- 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:

- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED 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:

- No. : Number
- WHO : World Health Organization
- cGMP : Current Good Manufacturing Practices
- DQ : Design Qualification
- IQ : Installation Qualification
- OQ : Operational Qualification
- SOP : Standard Operating Procedure
- MOC : Material of Construction
- SS : Stain less Steel
- ID : Inner Diameter



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17.0 POST 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)			