



INSALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
FLOW WRAP MACHINE**

EQUIPMENT ID. No.	
LOCATION	Packing Hall
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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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 carry out the Installation Qualification of Flow Wrap Machine to be used for sealing of bulk shippers of filled Vials/Bottles, prevent them from getting damp and protected against knocks.
- To confirm that the equipment and its components are as per the Specifications and installed as per the Approved Design and complies with cGMP practices.
- To ensure that there is sufficient information available to operate and maintain the equipment safely, effectively and consistently.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Flow Wrap Machine (Make: Uflex Limited-Engineering Division)** to be Install in LVP Line, Packing Area.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.



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



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5.0 EQUIPMENT DETAILS:

Equipment Name	Flow Wrap Machine
Equipment	
Manufacturer's Name	Uflex Limited-Engineering Division
Model	FW-1001
Sr. No.	
Supplier's Name	Uflex Limited-Engineering Division
Location of Installation	Packing Area

6.0 SYSTEM DESCRIPTION:

Uflex Limited-Engineering Division provides Flow Wrap Machine is a very efficient machine, all around close design ensures less heat, thus less electricity consumption. Heavy duty conveyor system having insulated surface is provided to avoid any damage to product or shrink sleeve. Flow Wrap Machine is equipped with high quality heating. Independent regulate system controls temperature and conveyer speed. The efficient heating system on machine reduces the amount of electricity needed to run the machine consequently reducing the operating costs.

Machine can be attached with any other packing machine or operation to give online application.

Uflex Limited-Engineering Division Flow Wrap Machine provides protection to the product and enhances its aesthetic value. Single set of products can be packed. This is one of the widely accepted tamper proof packing method for a variety of consumer and industrial products. It provides complete protection to the product from heat, moisture and dust, which enhances shelf life of the product.



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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.
- 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.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	Installation Check	Observation (Satisfactory/Non Satisfactory)	Observed by (Engineering) Sign/Date
1.	Check the proper mechanical installation of Flow Wrap Machine.		
2.	Check the proper electrical installation of Flow Wrap Machine.		
3.	Check the parts are working properly.		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of machine parts.		

**Checked By
(Production)
Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

Inference:

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**Reviewed By
(Manager QA)
Sign/Date:**



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

8.2 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation (Complies/ Non Complies)	Observed by (Engineering) Sign/Date
Grouting and Mounting	Should be grouted and mounted properly.		
Leveling	Should be properly balanced and leveled.		
Edges of Parts	Metal edges should be properly rounded off without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	LVP Line Packing Hall, 'L' Block		
Room Condition	General working condition. As per GMP and production requirement.		
Illumination	NLT 300 Lux.		
Working space around the equipment	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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8.3 Installation Checks:

Critical Variables	Acceptance Criteria	Observation (Complies/Non Complies)	Observed By (Engineering) Sign/Date
Equipment	Flow Wrap Machine		
Overall Dimensions	756 (L) mm X 565 (W) mm X 335 (H) mm		
Temperature Controllers	a) Quantity : 06 b) Range: 0-800 · C. c) Make : Omron d) Type: J Type		
Motor detail	a) Quantity: 01 b) Capacity :1 H.P., 1440 rpm, 230 V AC c) Make : Crompton Greaves d) Type: AC Motor		
Heaters	a) For Die Roller Heaters: Length- 190 mm, Dia-15.5 mm; Watt: 500; Quantity: 06 b) For Sealer Heaters: Length-150 mm, Dia-10 mm; Watt: 350; Quantity: 02		
PLC detail	a) Quantity : 01 b) Make : Omron c) Model : CP1E-N30DR-D		
Drive	a) Make : Omron b) Capacity : 1 hp c) Quantity: 01 Nos.		
Photocell	a) Make : Datalogic b) Capacity : 24 V D.C c) Quantity :1		



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8.4 MOC Verification List:

Parts Name	Material of construction	Observation (Complies/Non Complies)	Observed By (Engineering) Sign/Date
Basic Structure	M.S.		
Former	S.S 304.		
Die roller	E N 9		
Sealer	E N 9		
Electrical Panel	M.S.		
Shafts	S.S 304		
Sprockets (Gears)	E N 353		
Chain	M S		
Cutter	HSS		
Unwinding Shaft	Al with Powder coating		
Cladding	SS 304		
Reel Bob	AL		

**Checked By
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Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

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**Reviewed By
(Manager QA)
Sign/Date:**



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8.5 Safety:

Checks	Acceptance Criteria	Observation (Complies/Non Complies)	Observed By (Engineering) Sign/Date
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.		
Mechanical Guard	Mechanical guard for all rotating parts.		
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be properly grounded without any sharp edges.		
Leveling and Balancing	Equipment should be properly balanced & leveled.		
Electrical Wiring and Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine panel and motors and operator should be provided.		
Noise Level	Below 80 db		

**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 Reference 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.
- Operation and Maintenance Manual.

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:

AMP	:	Ampere
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
HP	:	Horse Power
LB	:	L Block
IQ	:	Installation Qualification
kW	:	Kilo Watt
MCB	:	Miniature Circuit Breaker
mm	:	Millimetre
MOC	:	Material of construction
No.	:	Number
P & ID	:	Piping and Instrumentation Diagram
RPM	:	Revolution per Minute
SS	:	Stainless Steel
STD	:	Standard
FWM	:	Flow Wrap Machine
V	:	Volt
WHO	:	World Health Organization



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17.0 PROTOCOL -POST 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)			