



**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
SHRINK WRAPPING MACHINE**

**PROTOCOL No.:**

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PROTOCOL CUM REPORT  
FOR  
SHRINK WRAPPING MACHINE**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Ampoules Line</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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**1.0 PROTOCOL PRE – 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>			



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**2.0 OBJECTIVE:**

- To carry out the Installation Qualification of Shrink Wrapping 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 **Shrink Wrapping Machine (Make: Vinpack Shrink Wrapping)** to be Install Ampoules 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:

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



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Shrink Wrapping Machine
<b>Equipment</b>	
<b>Manufacturer's Name</b>	Vinpack Shrink Wrapping
<b>Model</b>	cGMP Model
<b>Supplier's Name</b>	Vinpack Shrink Wrapping
<b>Location of Installation</b>	Packing Hall

**6.0 SYSTEM DESCRIPTION:**

Vinpack provides Shrink Wrapping 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. High speed blower system provided with continuous rating. Shrink Wrapping Machine is equipped with high quality heating elements to create a recirculating air system that forces air to all package surfaces. Independent regulate system controls temperature, air velocity and conveyer speed. The efficient heating system on machine reduces the amount of electricity needed to run the machine consequently reducing the operating costs. Upper Centrifugal fan to ensure 360 degree airflow and uniform temperature distribution.

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

Vinpack Shrink Wrapping Machine provides protection to the product and enhances its aesthetic value. Single or set of products can be elegantly packed together. 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	Observed by (Engineering) Sign/Date
1.	Check the proper mechanical installation of Shrink Wrapping Machine.		
2.	Check the proper electrical installation of Shrink Wrapping 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: .....**





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**8.2 General Checks and Location Suitability:**

S.No.	Installation Checks	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
1.	<b>Grouting and Mounting</b>	Should be grouted and mounted properly.		
2.	<b>Leveling</b>	Should be properly balanced and leveled.		
3.	<b>Edges of Parts</b>	Metal edges should be properly rounded off without any sharp edges.		
4.	<b>Welding of Joints</b>	Welding of joints should be without any welding burrs.		
5.	<b>Place of Installation</b>	Packing Hall		
6.	<b>Room Condition</b>	General working condition. As per GMP and production requirement.		
7.	<b>Illumination</b>	NLT 300 Lux.		
8.	<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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**8.3 Installation Checks:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
<b>Equipment</b>	Shrink Wrapping Machine		
<b>Overall Dimensions</b>	756 (L) mm X 565 (W) mm X 335 (H) mm		
<b>Tunnel Dimensions</b>	1225 (L) mm X 565 (W) mm X 1250 (H) mm		
<b>Main Motor</b>	Type : AC Induction 03 Phase Motor HP/kW : 0.18/0.12 Volt : 440 V RPM : 2800 AMP : 0.4		
<b>Ampere Load</b>	Range : 8.5-9.5 Ampere		
<b>Control Switch</b>	Nos. : 04 (01 each for Power, Conveyer, Heater, Blower)		
<b>Indicators</b>	Nos. : 06 (03 for Power and 01 each for Conveyer, Heater & Blower)		
<b>Conveyer Motor</b>	Make : LUCAS TVS		
<b>Conveyer Speed</b>	Speed : 0-5 (Adjustable)		
<b>MMI for Temperature Controller</b>	Make : MULTISPAN Type : TC-49 Temperature: 1-150 °C		
<b>Heating Rods</b>	Nos. : 06 (02 each side on Left, Right and Bottom). Rod Length : 630 mm		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
MCB	Make : C & S (WINTRIP 2) Type : C 16 Volt : 415 V		

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

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(Quality Assurance)  
Sign/Date: .....**

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



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**8.4 MOC Verification List:**

S.No.	Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
1.	Motor	STD		
2.	Gear box	STD		
3.	Indicator	STD		
4.	Chain	SS 304		
5.	Main Tunnel Hood	Mild Steel Powder Coated		
6.	Machine Frame	Mild Steel Powder Coated		
7.	Covers	Mild Steel Powder Coated		
8.	Castor Wheel	Polyurethane (PU)		

**Checked By  
(Production)**

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

**Verified By**

**(Quality Assurance)**

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

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**(Manager QA)**

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



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**8.5 Safety:**

Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Well embedded equipment	For Shrink Wrapping Machine.		
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.		
Electrical wiring and Earthing.	Electrical wiring should be as per approved drawings. Double external earthing to control machine panel and motors should be provided.		
Safety Guards	Guards for all moving parts should be provided for safety.		
Start On/Off switch: To Stop the process immediately.	Should be provided for equipment and operator safety.		
Noise Level	Below 80 db		

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

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

**Inference:**

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(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.
- Certificate of MOC.
- Operation and Maintenance Manual.



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**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
HP	:	Horse Power
IB	:	Injection 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
SWM	:	Shrink Wrapping Machine
V	:	Volt
WHO	:	World Health Organization





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**17.0 PROTOCOL -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>			