



PHARMA DEVILS

DESIGN QUALIFICATION PROTOCOL CUM REPORT

PROTOCOL No.:

**FOR
SHRINK WRAPPING MACHINE**

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DATE OF QUALIFICATION

SUPERSEDE PROTOCOL No.

NIL



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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)			



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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 for **Shrink Wrapping Machine (Make: Vinpack Shrink Wrapping)**.
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by vendor shall be verified during Design 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">• Initiation, Review and Approval of the Qualification 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 Qualification 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 Required.➤ Identification of components for calibration.➤ Material of construction of Product Contact Parts.➤ Brief Process Description.➤ Safety Features and Alarms.• Review of Qualification Protocol cum Report after Execution.



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5.0 BRIEF PROCESS 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.

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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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The Shrink Wrapping Machine should be able to seal bulk shippers of filled Vials, prevent them from getting damp and protected against knocks.	Shrink Wrapping Machine should meet the requirement for sealing of bulk shippers of filled Vials, prevent them from getting damp and protected against knocks.	Process Requirement
Working: Working of Shrink Wrapping Machine.	Shrink Wrapping Machine should be able to seal bulk shippers of filled Vials, prevent them from getting damp and protected against knocks.	Process 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:	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in service area.	GMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement



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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Critical Variables	Acceptance Criteria
1.	Equipment	Shrink Wrapping Machine
2.	Overall Dimensions	756 (L) mm X 565 (W) mm X 335 (H) mm
3.	Tunnel Dimensions	1225 (L) mm X 565 (W) mm X 1250 (H) mm
4.	Main Motor	Make : K- SWATI Type : AC Induction 03 Phase Motor HP/kW : 0.18/0.12 Volt : 440 V RPM : 2800 AMP : 0.4 Sr. No. : 5.14
5.	Ampere Load	Range : 8.5-9.5 Ampere
6.	ON/OFF Control Switch	Make : "ABB"
7.	Control Switch	Nos. : 04 (01 each for Power, Conveyer, Heater, Blower) Make : L & T (Salzer)
8.	Indicators	Nos. : 06 (03 for Power and 01 each for Conveyer, Heater & Blower)
9.	Conveyer Motor	Make : LUCAS TVS Sr. No. : 26971039
10.	Conveyer Speed	Speed : 0-5 (Adjustable)
11.	MMI for Temperature Controller	Make : MULTISPAN Type : TC-49 Temperature: 1-150 °C
12.	Heating Rods	Nos. : 06 (02 each side on Left, Right and Bottom). Rod Length : 630 mm
13.	MCB	Make : C & S (WINTRIP 2) Type : C 16 Volt : 415 V



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7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction	Reference
1.	Motor	STD	Process Requirement
2.	Gear box	STD	Process Requirement
3.	Indicator	STD	Process Requirement
4.	Chain	SS 304	GMP Requirement
5.	Main Tunnel Hood	Mild Steel Powder Coated	Process Requirement
6.	Machine Frame	Mild Steel Powder Coated	Process Requirement
7.	Covers	Mild Steel Powder Coated	Process Requirement
8.	Castor Wheel	Polyurethane (PU)	GMP Requirement



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7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
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.	Safety Requirement
Noise Level	Below 80 db	Safety Requirement

7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Shrink Wrapping Machine	Selection of Vendor is done on the basis of review of vendor. Criteria for review were 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) The equipment shall confirm to the specifications and requirement.

(2) Operating and service manual for Shrink Wrapping Machine.



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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.

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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12.0 ABBREVIATIONS:

URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
PO	:	Purchase Order
DQ	:	Design Qualification
Kg	:	Kilogram
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature Circuit Breaker
db	:	Decibel
RH	:	Relative Humidity
RPM	:	Revolution per Minute
HP	:	Horse Power
AMP	:	Ampere
V	:	Volt
STD	:	Standard
SWM	:	Shrink Wrapping Machine



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			