OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SHRINK WRAPPING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Packing Area**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SHRINK WRAPPING MACHINE

PROTOCOL CONTENTS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SHRINK WRAPPING MACHINE

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 Shrink Wrapping Machine 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 **Shrink Wrapping Machine (Make: ……..)** Installed in Packing Area.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Shrink Wrapping Machine.
- Successful completion of this Protocol will verify that Shrink Wrapping Machine 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	• 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 Operational Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval 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 cum Report after Execution.
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Operational Qualification Protocol cum Report after Execution.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Shrink Wrapping Machine
Equipment	
Manufacturer's Name	Vinpack Shrink Wrapping
Model	cGMP Model
Supplier's Name	Vinpack Shrink Wrapping
Location of Installation	Packing Area

6.0 EQUIPEMENT 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:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Shrink Wrapping Machine.
- SOP for Preventive Maintenance of Shrink Wrapping Machine.

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 OQ 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 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
1.	DQ Protocol cum Report			
2.	IQ Protocol cum Report			
3.	SOP for Operation & Cleaning of Shrink Wrapping Machine.			
4.	SOP for Preventive Maintenance of Shrink Wrapping 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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8.2 Operational and Functional Checks:

Operate the Shrink Wrapping Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

ITEM	OPERATION	ACCEPTANCE CRITERIA	OBSERVATION
Power supply	Connect 3Phase, 415V, AC supply to the panel through proper isolation.	Machine will be ready for operation.	
Motor & drive	Check the direction of motor shows on machine by direction arrow.	Motor should not run in opposite direction as arrow shows.	
Conveyer Speed Adjustor	Run the Conveyer at different speed.	Motor can be allowed to run at adjustable speed.	
Earthing	Proper earthing should be provided to machine.	Earthing will secure from shocks to operator of machine.	
Temperature Controller	Provided on panel to see the actual temperature.	Temperature can be allowed to adjust as per the requirement.	
PU Wheel	For easy shifting of the machine.	Smooth handling & easy handling can be done.	

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SHRINK WRAPPING MACHINE

8.3 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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8.4 Emergency Operation Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
ON/OFF button • Press ON Button • Press OFF Button	• Equipment should Start • Equipment should Stop		
With the Press OFF Button pressed, try to cause movement of an operating function.	The Equipment will be inoperative.		

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:

- Operation and Maintenance Manual.
- Any other Relevant Documents.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SHRINK WRAPPING MACHINE

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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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SHRINK WRAPPING MACHINE

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

AC	:	Alternating Current
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
HP	:	Horse Power
ID.	:	Identification
IQ	:	Installation Qualification
KW	:	Kilo Watt
MCB	:	Miniature Circuit Break
mm	:	Millimetre
MOC	:	Material of Construction
NLT	:	Not Less Than
No.	:	Number
OQ	:	Operational Qualification
SS	:	Stainless Steel
SWM	:	Shrink Wrapping Machine
V	:	Volt
WHO	:	World Health Organization

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17.0 PROTOCOL 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)			