PERFORMANCE RE-QUALIFICATION REPORT FOR SHRINK WRAPPING MACHINE

EQUIPMENT ID. No.	
LOCATION	
DATE OF RE-QUALIFICATION	
MASTER REPORT No.	

PHARMA DEVILS	PERFORMANCE RE-QUALIFICATION REPORT FOR SHRINK WRAPPING MACHINE	PROTOCOL No.:

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE RE-QUALIFICATION REPORT FOR SHRINK WRAPPING MACHINE	PROTOCOL No.:

1.0 REPORT 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)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Report covers all aspects of Performance Re-qualification for the Shrink Wrap Machine (Equipment ID: …….., Make: Vinpack Shrink Wrapping) Installed in the Ointment section, Packing Area.
- The report provides all the relevant information of Performance Re-qualification Activity for Shrink Wrap Machine and all the observation of in-process checks.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the execution of performance re-qualification.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Re-qualification Report. • Co-ordination with Production and Engineering to carryout Performance Re-qualification Activity. • Monitoring of Performance Re-qualification Activity.
Production	• Review of Performance Re-qualification report. • To Execute Performance Re-qualification Activity.
Engineering	• Review of Performance Re-qualification report. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

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

6.0 EQUIPMENT 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.

7.0 REASON FOR RE-QUALIFICATION:

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8.0 SITE OF STUDY:

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9.0 FREQUENCY OF RE-QUALIFICATION:

- Once in a two year ± 01 month.

10.0 PRE - RE-QUALIFICATION REQUIREMENTS:

10.1 Training of re-qualification Team:

Training shall be imparted to all concern persons involve in performance re-qualification activity and shall be recorded as follows;

S.No	Name of Employee	Employee Code	Department	Designation	Sign. / Date

Training Given By:

Sign & Date:……

10.2 Calibration of Test Instrument: Test Instrument Should be Calibrated.

NAME OF INSTRUMENT	INSTRUMENT ID No.	DATE OF CALIBRATION	DUE DATE

Inference:

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Verified By
(QA)
Sign/Date: ……

11.0 TESTS AND CHECKS:

11.1 Installation checks:

S. No.	Installation Check	Acceptance criteria	Observation
1.	Equipment Name	Shrink wrapping machine	
2.	Equipment Identification number	……	
3.	Manufacturer Name	Vinpack Shrink Wrapping	
4.	Location of Installation	Packing area	
5.	Check the proper mechanical installation of Shrink Wrapping Machine	Should be satisfactory	
6.	Check the proper electrical installation of Shrink Wrapping Machine	Should be satisfactory	
7.	Check the parts are working properly	Should be Properly working	
8.	Check the equipment is free from any defects	Should be free from any defects.	
9.	Check the finishing of machine parts	Should be satisfactory	

Inference:

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

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

11.2 Functional checks

S.No.	Operation	Acceptance criteria	Observation
1.	Check correct working of machine	The machine should be Operational	
2.	Press start switch	Machine should started by Pressing	
3.	Press Stop switch	Machine should stopped by Pressing	

Inference:

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

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

11.3 Power failure Verification:

Item	Acceptance criteria	Observation
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	

Inference:

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

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

11.4 Batch Detail

Product Name		**Batch No.**	
Batch Size		**Pack Size**	

11.5 Evaluation of Performance:

11.5.1 Temperature observation and Shrink Quality during initial of batch

Date	Knob Setting (Speed)	Set Temperature in Machine Display	Observed Temperature in Machine Display	Time	Temperature Observed In Data Logger	
					CH-01	CH-02

Shrink Pack Number	Visual Defects	Shrink Pack Appearance
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Acceptance Criteria:

- There should be no visual defects of shrink wraps.
- Shrink pack appearance should be uniform.
- Temperature should be recorded for information purpose.

Inference:

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

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

11.5.2 Temperature observation and Shrink Quality during middle of batch

Date	Knob Setting (Speed)	Set Temperature in Machine Display	Observed Temperature in Machine Display	Time	Temperature Observed In Data Logger	
					CH-01	CH-02

Shrink Pack Number	Visual Defects	Shrink Pack Appearance
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Acceptance Criteria:

- There should be no visual defects of shrink wraps.
- Shrink pack appearance should be uniform.
- Temperature should be recorded for information purpose.

Inference:

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

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

11.5.3 Temperature observation and Shrink Quality during end of batch

Date	Knob Setting (Speed)	Set Temperature in Machine Display	Observed Temperature in Machine Display	Time	Temperature Observed In Data Logger	
					CH-01	CH-02

Shrink Pack Number	Visual Defects	Shrink Pack Appearance
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Acceptance Criteria:

- There should be no visual defects of shrink wraps.
- Shrink pack appearance should be uniform.
- Temperature should be recorded for information purpose.

Inference:

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

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

12.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

S.No.	Tests or Checks	Executed (Yes/No)	Remarks
1.	Installation checks		
2.	Functional checks		
3.	Power failure Verification		
4.	Evaluation of performance		

Inference:

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

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

13.0 DOCUMENTS ATTACHED:

- Any other Relevant Documents.

14.0 NON COMPLIANCE:

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15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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16.0 CHANGE CONTROL, IF ANY:

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17.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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18.0 CONCLUSION:

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19.0 RECOMMENDATION:

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20.0 ABBREVIATIONS:

MRP	:	Master Re-qualification Protocol
S. No.	:	Serial Number
cGMP	:	Current Good Manufacturing Practices
ID.	:	Identification
PPQ	:	Performance Qualification Protocol
PRQ	:	Performance Re-qualification Protocol
QB	:	Quality Block
SOP	:	Standard Operating Procedure
SWM	:	Shrink Wrap Machine

21.0 REPORT 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:

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HEAD (QUALITY ASSURANCE)			