PERFORMANCE QUALIFICATION REPORT FOR SHRINK WRAPPING MACHINE

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

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

CONTENTS

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

1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

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 Qualification for the **Shrink Wrap Machine (Make: Vinpack Shrink Wrapping)** to be installed in the **Packing Hall**.
- The report provides all the relevant information of Performance 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 Qualification.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification. • Post Approval of Performance Qualification Report after Execution.
Production	• Review of Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Quality Control	• Review of Report. • Analytical Support (Chemical Testing/Analysis).
Engineering	• Reviewing of qualification report for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule. • Post Approval of Performance Qualification Report after Execution.

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 Hall

6.0 PRE - QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of Shrink Wrapping Machine.
- Preparation of SOP for Preventive Maintenance of Shrink Wrapping Machine.

7.0 TESTS AND CHECKS:

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	Executed and approved Design Qualification document.				
2.	Executed and approved Installation Qualification document.				
3.	Executed and approved Operational Qualification document.				
4.	PQ Protocol approved.				
5.	SOP for Operation & Cleaning of Shrink Wrapping Machine.				
6.	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: ……

7.2 Observations for Evaluation of Performance by Visual Inspection of the Package of Drug Product:

7.2.1 Test Product Details:

S.No.	Product Name	Product Code	B. No.	B. Size	Manufacturing Date	Expiry Date

7.2.2 In Process Checks: During 1st Batch:

Product Name		**Batch No.**	
Date		**Frequency**	Every 15 Minute
Equipment ID		**Machine Run Time**	1 Hour

Time	Number of Samples	Test	Acceptance Criteria	Accepted (Yes/No)	Checked By Sign/Date
		Visual Inspection	**There should be no visual defects of Shrink Wrap Pack**		
		Visual Inspection	**Temperature should be remaining within specified limits (with respect to product specifications).**		

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

In Process Checks: During 2nd Batch:

Product Name		**Batch No.**	
Date		**Frequency**	Every 15 Minute
Equipment ID		**Machine Run Time**	1 Hour

Time	Number of Samples	Test	Acceptance Criteria	Accepted (Yes/No)	Checked By Sign/Date
		Visual Inspection	There should be no visual defects of Shrink Wrap Pack		
		Visual Inspection	Temperature should be remaining within specified limits (with respect to product specifications).		

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

In Process Checks: During 3rd Batch:

Product Name		**Batch No.**	
Date		**Frequency**	Every 15 Minute
Equipment ID		**Machine Run Time**	1 Hour

Time	Number of Samples	Test	Acceptance Criteria	Accepted (Yes/No)	Checked By Sign/Date
		Visual Inspection	There should be no visual defects of Shrink Wrap Pack		
		Visual Inspection	Temperature should be remaining within specified limits (with respect to product specifications).		

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

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

Inference:

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

8.0 CHECKLIST OF ALL TESTS & CHECKS:

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

Tests or Checks	Executed (Yes/No)	Remarks
Verification of DQ, IQ & OQ & other documents.		
Verification of performance using Visual Inspection of the Package of drug product.		

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

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

Inference:

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

9.0 DOCUMENTS ATTACHED:

- Operation and Maintenance Manual.
- Copy of SOPs.
- Raw data of analysis.
- Any other Relevant Documents.

10.0 NON COMPLIANCE:

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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:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QC	:	Quality Control
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
Kg	:	Kilogram
RSD	:	Relative Standard Deviation
MOC	:	Material of Construction
RPM	:	Revolution per Minute
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo watt
SS	:	Stainless Steel
ID.	:	Identification

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			