PERFORMANCE QUALIFICATION REPORT FOR SHRINK WRAPPING MACHINE

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

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

REPORT 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 (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: …….)** Installed in the **Packing Area**.
- 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 & Pre Approval of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Engineering	• Review & Pre Approval 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 Area

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.
- 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
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:

- 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:

cGMP	:	Current Good Manufacturing Practices
HP	:	Horse Power
IQ	:	Installation Qualification
Kg	:	Kilogram
MOC	:	Material of Construction
NLT	:	Not Less Than
RPM	:	Revolution per Minute
RSD	:	Relative Standard Deviation
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization

17.0 REPORT 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)			