



PERFORMANCE QUALIFICATION REPORT FOR FLOW WRAP MACHINE

**PERFORMANCE QUALIFICATION
REPORT
FOR
FLOW WRAP MACHINE**

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



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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)			



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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: Uflex Limited-Engineering Division) 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.



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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 execution of Performance Qualification.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review, Approval and Compilation of the Performance Qualification Report.• Co-ordination with Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.• Post Review of Performance Qualification Report after Execution.
Production	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To Execute Performance Qualification Activity.• Post Review of Performance Qualification Report after Execution.
Engineering	<ul style="list-style-type: none">• Review Performance Qualification report for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.• Post Review of Performance Qualification Report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Flow Wrap Machine
Equipment
Manufacturer's Name	Uflex Limited-Engineering Division
Model	FW-1001
Sr. No.
Supplier's Name	Uflex Limited-Engineering Division
Location of Installation	Packing Area



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6.0 PRE - QUALIFICATION REQUIREMENTS:

6.1 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 Flow Wrap Machine.			

**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

Inference:

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Reviewed By

(Manager QA)

Sign & Date:



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

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6.2 Training Record of Validation Team:

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

S.No.	Name of Trainee	Designation	Trainee (Sign./Date)	*Training Evaluation (Satisfactory/Not Satisfactory)
Training Given By: Sign & Date				

**Note: Training evaluation shall be done on the basis of oral assessment.*

Inference:

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



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6.3 Calibration of Test Instrument: Test Instrument Should be calibrated.

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

Inference:

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Reviewed By
(Manager QA)
Sign & Date:



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7.0 TESTS AND CHECKS:

7.1 Evaluation of Performance by Using First Batch:

Product Name		Batch No.	
Equipment ID		Frequency	Every 15 Minute

Items	Acceptance Criteria	Observation	Complies/not Complies
Pre-heater Temperature	80-120°C		
Roll Heater Inner 1	180-220°C		
Roll Heater Outer 1	180-220°C		
Roll Heater Inner 2	180-220°C		
Roll Heater Outer 2	180-220°C		
Sealer Lower	180-220°C		
Sealer Upper	180-220°C		

Date	Time Duration		Speed	Shrink Sealing Quality
	From	To		

Acceptance Criteria:

- Shrink packs should be uniform in appearance and should be free from any visual defects.
- Temperature remains within specified limits throughout the process.

Checked By
(Production)

Sign/Date:

Verified By
(Quality Assurance)

Sign/Date:

Inference:

.....
.....

Reviewed By
(Manager QA)

Sign & Date:



PERFORMANCE QUALIFICATION REPORT FOR FLOW WRAP MACHINE

7.2 Evaluation of Performance by Using Second Batch:

Product Name		Batch No.	
Equipment ID		Frequency	Every 15 Minute

Items	Acceptance Criteria	Observation	Complies/Not Complies
Pre-heater Temperature	80-120°C		
Roll Heater Inner 1	180-220°C		
Roll Heater Outer 1	180-220°C		
Roll Heater Inner 2	180-220°C		
Roll Heater Outer 2	180-220°C		
Sealer Lower	180-220°C		
Sealer Upper	180-220°C		

Date	Time Duration		Speed	Shrink Sealing Quality
	From	To		

Acceptance Criteria:

- Shrink packs should be uniform in appearance and should be free from any visual defects.
- Temperature remains within specified limits throughout the process.

Checked By
(Production)

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

Inference:

.....
.....

Reviewed By

(Manager QA)

Sign & Date:



PERFORMANCE QUALIFICATION REPORT FOR FLOW WRAP MACHINE

7.3 Evaluation of Performance by Using Third Batch:

Product Name		Batch No.	
Equipment ID		Frequency	Every 15 Minute

Items	Acceptance Criteria	Observation	Complies/Not Complies
Pre-heater Temperature	80-120°C		
Roll Heater Inner 1	180-220°C		
Roll Heater Outer 1	180-220°C		
Roll Heater Inner 2	180-220°C		
Roll Heater Outer 2	180-220°C		
Sealer Lower	180-220°C		
Sealer Upper	180-220°C		

Date	Time Duration		Speed	Shrink Sealing Quality
	From	To		

Acceptance Criteria:

- Shrink packs should be uniform in appearance and should be free from any visual defects.
- Temperature remains within specified limits throughout the process.

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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8.0 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 Three Batch		

**Checked By
(Production)**
Sign/Date:

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

Inference:

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



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9.0 DOCUMENTS ATTACHED:

- 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:

- DQ : Design Qualification
- IQ : Installation Qualification
- OQ : Operational Qualification
- PQ : Performance Qualification
- PPQ : Performance Qualification Protocol
- RPQ : Performance Qualification Report
- CH : Channel
- QA : Quality Assurance



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PERFORMANCE QUALIFICATION REPORT FOR FLOW WRAP MACHINE

17.0 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:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			