PERFORMANCE QUALIFICATION PROTOCOL FOR FLOW WRAP MACHINE

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

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR FLOW WRAP MACHINE

PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR FLOW WRAP MACHINE

1.0 PROTOCOL 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 Protocol covers all aspects of Performance Qualification for the Flow Wrap Machine (Make: Uflex Limited-Engineering Division) installed in LVP Line Packing Area.
- This Protocol will define the methods and documentation used to qualify the Flow Wrap Machine.

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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.

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

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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

6.0 EQUIPMENT DESCRIPTION:

- Uflex Limited-Engineering Division provides Flow Wrap 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. Flow Wrap Machine is equipped with high quality heating. Independent regulate system controls temperature and conveyer speed. The efficient heating system on machine reduces the amount of electricity needed to run the machine consequently reducing the operating costs. Machine can be attached with any other packing machine or operation to give online application. Uflex Limited-Engineering Division Flow Wrap Machine provides protection to the product and enhances its aesthetic value. Single set of products can be packed. 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.
- The flow wrap Machine is a standalone unit with plug in type electrical connections for operation and is on castor wheel. Hence, may be moved as per requirement to other area of operation which shall not change the performance of equipment.

7.0 REASON FOR QUALIFICATION:

- New equipment in Packing Area.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

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8.0 SITE OF STUDY:

Packing Area, LVP Line

9.0 FREQUENCY OF QUALIFICATION:

- Once in a two year ± 01 month
- After any major breakdown or after major modification.

10.0 PRE - QUALIFICATION REQUIREMENTS:

10.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Flow Wrap Machine.

10.2 Training Record of Validation Team:

- All the persons involved in the execution of qualification activity must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working.

10.3 Calibration of Test Instruments:

- Calibration of all the instruments used for qualification should be mentioned along with Calibration Certificates.

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11.0 TESTS AND CHECKS:

11.1 Evaluation of Performance by Using Drug Product:

11.1.1 Objective:

The Objective of this evaluation is ensure following;

- To verify that shrink packs are uniform in appearance, free from any visual defects.
- To ensure that sealing quality of wrap pack and set temperature during the flow wrap process.

11.1.2 Machine Setting

- Set the pre- heater temperature at 80-120°C.
- Set die roll heater temperature at 180-220°C.
- Set sealer heater temperature at 180-200°C.
- Adjustment of proxy sensor is to be done carefully to avoid bottle cutting between the sealing heaters.
- Initial adjust the machine speed at 50-60 bottles/min.
- After adjusting all parameter increase the machine speed at 80 bottles/min.

11.1.3 Method:

- Load the approved wrapping material on Rolls.
- Run the machine as per respective SOP.
- Check the temperature set parameters.
- Record the test data and any observations throughout the process.
- Special attention shall be paid to monitor and record temperature.
- Samples shall be verified for uniform wrapping without holes as visually seen.
- Record the temperature in performance requalification report.
- Repeat the same procedure three times.
- Three consecutive batches must be tested as described before, in order to demonstrate consistent performance.

11.1.4 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.

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12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of performance by Using Three Batch.

13.0 REFERENCES:

The Principle References are as following:

- Validation Master Plan.
- Design Qualification cum report for flow wrap machine.
- Installation Qualification cum report for flow wrap machine.
- Operational Qualification cum report for flow wrap machine.
- SOP "Operation and Cleaning of Flow Wrapping Machine".

14.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

15.0 NON COMPLIANCE:

In case of any Non-compliance observed during PQ, same shall be handled through SOP for Handling of Non-Compliance.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

In case of any deviation observed during PQ, same shall be handled through SOP for Handling of Deviation.

17.0 CHANGE CONTROL, IF ANY:

If any change is required during PQ, same shall be handled through SOP for Change Management.

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18.0 ABBREVIATIONS:

DQ	:	Design Qualification
ID	:	Identification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
PPQ	:	Performance Qualification Protocol
SOP	:	Standard Operating Procedure
QA	:	Quality Assurance
BMR	:	Batch Manufacturing Record
LVP	:	Large Volume Parenteral
Min	:	Minute
CH	:	Channel