



# **OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Packing Area</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE**

**PROTOCOL CONTENTS**

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# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

### 1.0 PROTOCOL 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)			



## **OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE**

### **2.0 OBJECTIVE:**

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of FLOW WRAP Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

### **3.0 SCOPE:**

- The scope of this operational qualification protocol cum report is limited to qualification of **FLOW WRAP Machine (Make: Uflex Limited-Engineering Division FLOW WRAP)** Installed in Packing Area.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of FLOW WRAP Machine.
- Successful completion of this Protocol will verify that FLOW WRAP Machine meet all acceptance criteria and ready for Performance Qualification.



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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 cum Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and compilation of the operational Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Operational Qualification.</li><li>• Monitoring of Operation Process.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Operational Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Operational Qualification Protocol cum Report.</li><li>• To co-ordinate and support Operational Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE**

**5.0 EQUIPMENT DETAILS:**

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

**6.0 EQUIPEMENT 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.



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**7.0 PRE - QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Flow Wrap Machine.

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

**7.1.2 Acceptance Criteria:**

All the documents should be available, complete and approved by respective authorities.



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### 8.0 CRITICAL VARIABLES TO BE MET:

#### 8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	DOCUMENT /SOP No.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	DQ Protocol cum Report			
2.	IQ Protocol cum Report			
3.	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:** .....





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### 8.2 Operational and Functional Checks:

Operate the Flow Wrap Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

ITEM	OPERATION	ACCEPTANCE CRITERIA	OBSERVATION (Satisfactory/Non Satisfactory)
<b>Power supply</b>	Connect 3Phase, 415V, AC supply to the panel through proper isolation.	Machine will be ready for operation.	
<b>Motor &amp; drive</b>	Check the direction of motor shows on machine by direction arrow.	Motor should not run in opposite direction as arrow shows.	
<b>Conveyer Speed Adjustor</b>	Run the Conveyer at different speed.	Motor can be allowed to run at adjustable speed.	
<b>Earthing</b>	Earthing will secure from shocks to operator of machine.	Proper earthing should be provided to machine.	
<b>Temperature Controller</b>	PID Type Temperature Controller. Provided on panel to see the actual temperature.	Temperature can be allowed to adjust as per the requirement.	
<b>Filling System</b>	Manual	Machine is Operated by the manual feeding system	
<b>Type of Pouches</b>	Centre Seal	Pouches should be seal from center.	
<b>Speed</b>	70-100 Pouches/Min	Machine speed should be within the specified range	
<b>Eye Mark Registration</b>	By Photocell	The cutting of Shrink wrap should be accurate	
<b>Continuous Film Pulling</b>	-----	Film pulling should be maintained according to the size of bottle	



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ITEM	OPERATION	ACCEPTANCE CRITERIA	OBSERVATION (Satisfactory/Non Satisfactory)
Centralized Film Pulling	-----	Film pulling should be exact in the center of the conveyer.	
Proximity Switches	-----	Gap adjusted between pouches should be accurate	

**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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**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE**

**8.3 Power Failure Verification:**

<b>ITEM</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( Satisfactory/Non Satisfactory )</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Main Power Shut Down</b>	Equipment stops in a safe and secure condition.		
<b>Main Power Restored</b>	Equipment can be restarted with no problems or adverse conditions.		

**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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### 8.4 Emergency Operation Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION (Satisfactory/Non Satisfactory)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
ON/OFF button <ul style="list-style-type: none"><li>• Press ON Button</li><li>• Press OFF Button</li></ul>	<ul style="list-style-type: none"><li>• Equipment should Start</li><li>• Equipment should Stop</li></ul>		
With the Press OFF Button pressed, try to cause movement of an operating function.	The Equipment will be inoperative.		

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

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

**Inference:**

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.....

**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE**

**9.0 REFERENCES:**

**The Principle Reference is the following:**

- Validation Master Plan.
- Schedule - M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.

**10.0 DOCUMENTS TO BE ATTACHED:**

- Operation and Maintenance Manual.
- Any other Relevant Documents.

**11.0 DEVIATION FROM PREDEFINED 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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**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE**

**16.0 ABBREVIATIONS:**

AC	:	Alternating Current
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
HP	:	Horse Power
ID.	:	Identification
IQ	:	Installation Qualification
KW	:	Kilo Watt
MCB	:	Miniature Circuit Break
mm	:	Millimetre
MOC	:	Material of Construction
NLT	:	Not Less Than
No.	:	Number
OQ	:	Operational Qualification
SS	:	Stainless Steel
SWM	:	Flow Wrap Machine
V	:	Volt
WHO	:	World Health Organization



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## OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

### 17.0 PROTOCOL 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)			