



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

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

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	PROTOCOL PRE-APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	RESPONSIBILITY	5
5.0	PROJECT REQUIRMENTS	5
6.0	BRIEF PROCESS DESCRIPTION	6
7.0	EQUIPMENT SPECIFICATION	6
8.0	CRITICAL VARIABLES TO BE MET	7
8.1	PROCESS/PRODUCT PARAMETERS	8
8.2	UTILITY REQUIREMENT/LOCATION SUITABILITY	8
8.3	TECHNICAL SPECIFICATION /KEY DESIGN FEATURES	8
8.4	MATERIAL OF CONSTRUCTION	9
8.5	SAFETY	10
8.6	VENDOR SELECTION	10
9.0	DOCUMENTS TO BE ATTACHED	12
10.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)	12
11.0	ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS	12
12.0	RECOMMENDATION	12
13.0	ABBREVIATIONS	12
14.0	REVIEWED BY	13



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN 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)			



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for **Flow Wrap Machine (Make: Uflex Limited-Engineering Division)** at
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by vendor shall be verified during Design Qualification.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review, Authorization and Compilation of the Qualification Protocol cum Report• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Design Qualification Protocol cum Report• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing.➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures.➤ Details of utilities Required.➤ Identification of components for calibration.➤ Material of construction of Product Contact Parts.➤ Brief Process Description.➤ Safety Features and Alarms.• Review of Design Qualification Protocol cum Report after Execution.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

5.0 PROJECT REQUIRMENTS:

To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and/or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.

6.0 BRIEF PROCESS 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.

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared by The manufacturer of equipment ensures complies with User Requirement Specification.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The Flow Wrap Machine should be able to seal a single bottle of 100 ml.	Flow Wrap Machine should meet the requirement for sealing of a single bottle of 100ml.	Process Requirement
Working: Working of Flow Wrap Machine.	Flow Wrap Machine should be able to seal a single bottle of 100ml.	Process Requirement

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Electrical Supply:	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in service area.	GMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Critical Variables	Acceptance Criteria
1.	Equipment	Flow Wrap Machine
2.	Overall Dimensions	756 (L) mm x 565 (W) mm x 335 (H) mm
3.	Temperature Controllers	a) Quantity : 06 b) Range: 0-800 ° C. c) Make : Omron d) Type: J Type
4.	Motor detail	a) Quantity: 01 b) Capacity :1 H.P., 1440 rpm, 230 V AC c) Make : Crompton Greaves d) Type: AC Motor
5.	Heaters	a) For Die Roller Heaters: Length- 190 mm, Dia-15.5 mm; Watt: 500; Quantity: 06 b) For Sealer Heaters: Length-150 mm, Dia-10 mm; Watt: 350; Quantity: 02
6.	PLC detail	a) Quantity : 01 b) Make : Omron c) Model : CP1E-N30DR-D
7.	Drive	a) Make : Omron b) Capacity : 1 hp c) Quantity: 01 Nos.
8.	Photocell	a) Make : Datalogic b) Capacity : 24 V D.C c) Quantity :1



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

8.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction	Reference
1.	Basic Structure	MS	Process Requirement
2.	Former	SS 304	Process Requirement
3.	Die roller	E N 9	Process Requirement
4.	Sealer	E N 9	Process Requirement
5.	Electrical Panel	MS	Process Requirement
6.	Shafts	SS 304	Process Requirement
7.	Sprockets (Gears)	E N 353	Process Requirement
8.	Chain	M S	Process Requirement
9.	Cutter	HSS	Process Requirement
10.	Unwinding Shaft	Al with Powder coating	Process Requirement
11.	Cladding	SS 304	Process Requirement
12.	Reel Bob	AL	Process Requirement



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

8.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
Electrical Wiring and Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine panel and motors and operator should be provided.	Safety Requirement
Noise Level	Below 80 db	Safety Requirement

8.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Flow Wrap Machine	Selection of Vendor is done on the basis of review of vendor. Criteria for review were vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment).	Process Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement.
(2) Operating and service manual for Flow Wrap Machine.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Purchase Order Copy.

10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

13.0 ABBREVIATIONS:

AMP	:	Ampere
cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
db	:	Decibel
DQ	:	Design Qualification
GA	:	General Arrangement
HP	:	Horse Power
QB	:	Quality Block
Kg	:	Kilogram
MCB	:	Miniature Circuit Breaker
mm	:	Millimeter
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RPM	:	Revolution per Minute
SS	:	Stainless Steel
STD	:	Standard
FWM	:	Flow Wrap Machine
URS	:	User Requirement Specification
V	:	Volt



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FLOW WRAP MACHINE

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			