



**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES  
WASHING, DRYING & SELF ADHESIVE  
LABELING MACHINE**

<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



PHARMA DEVILS

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**PROTOCOL CONTENTS**

<b>S.No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
1.0	PROTOCOL PRE-APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	PROJECT REQUIREMENT	4
5.0	RESPONSIBILITY	5
6.0	BRIEF EQUIPMENT DESCRIPTION	6-7
7.0	EQUIPMENT SPECIFICATION	8
8.0	CRITICAL VARIABLES TO BE MET	9
8.1	PROCESS / PRODUCT PARAMETERS	9
8.2	UTILITY REQUIREMENT / LOCATION SUITABILITY	9
8.3	TECHNICAL SPECIFICATION /KEY DESIGN FEATURES	10-12
8.4	SAFETY FEATURES, ALARM & INTERLOCKING	13
8.5	MATERIAL OF CONSTRUCTION	15
8.6	VENDOR SELECTION	15
9.0	DOCUMENTS TO BE ATTACHED	16
10.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)	16
11.0	ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS	16
12.0	RECOMMENDATION	17
13.0	ABBREVIATIONS	18
14.0	REVIEWED BY	19



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**1.0 PROTOCOL PRE – APPROVAL:**

**INITIATED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**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 of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine (**Make:** M/s Aseptic Technology inc.) to be installed in Packing Hall, Ampoules Line.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.

**4.0 PROJECT REQUIREMENTS:**

To confirm that safe delivery of the equipment from the supplier site. To ensure that no un-authorized 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.



**DESIGN QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 AUTOMATIC EXTERNAL AMPOULES WASHING,  
 DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

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



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**6.0 BRIEF EQUIPMENT DESCRIPTION:**

**INFEED TRAY**

This machine is equipped with In-feed Tray system for loading of Ampoules. The Ampoules are loaded into the SS Tray and from this tray the Ampoules are passed to the In-feed Feed worm.

**STAR WHEEL ASSEMBLY**

A star wheel is made of Aluminum casting material. Star wheel is transfer the Ampoule one by one for washing and drying.

**TANK ASSEMBLY**

This machine is equipped with of SS304 Tank for Re- Circulated Water. And one for Purified water According to the washing cycle the piping are provided. Along with the Tanks Grundfoss Pumps & Require Heating arrangement are provided.

Purified water received from Loop is used for Final washing and this water collected into Re cycle Tank. This re cycle water is filtered through suitable Filtration system and again used for washing at First station and finally washed water goes to Drain

**AIR KNIFE ASSEMBLY**

Air knife is made of Aluminum material with black anodizing. Air Knife is blowing the dry air on Ampoule for Drying the Ampoule. Also the machine is equipped with Blower. This is connected at the out-feed end after the washing is over. This ensures that proper drying takes place as the machine is running at the high speed.

**OUT FEED FEEDWORM ASSEMBLY**

Out feed worm is made of Delrin material. Feed worm is feed the Ampoule One by one in collection tray.

**LABEL DISPENSING DEVICE**

It works on the basic principle of to apply sticker label on Ampoule, which is previously sensed by the Ampoule sensor, after getting the signal from the Ampoule sensor, it allows the label to come out from



**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

the label roll up to the label length which is feed in the HMI Unit of the machine. And label sensor sense the gap between the two labels and allows only single label to come out. The control of label dispensing device is on Servo Motor, Servo Drive, Ampoule Sensor and label Sensor.

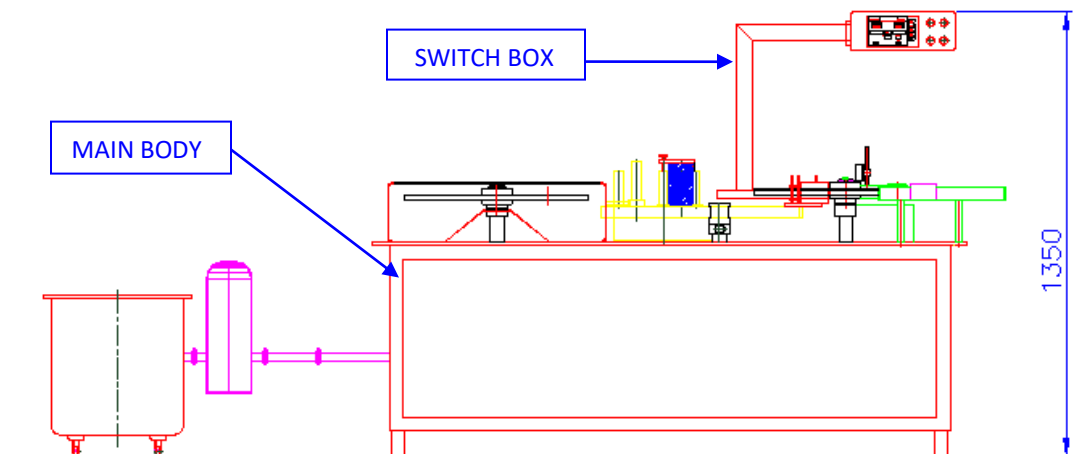
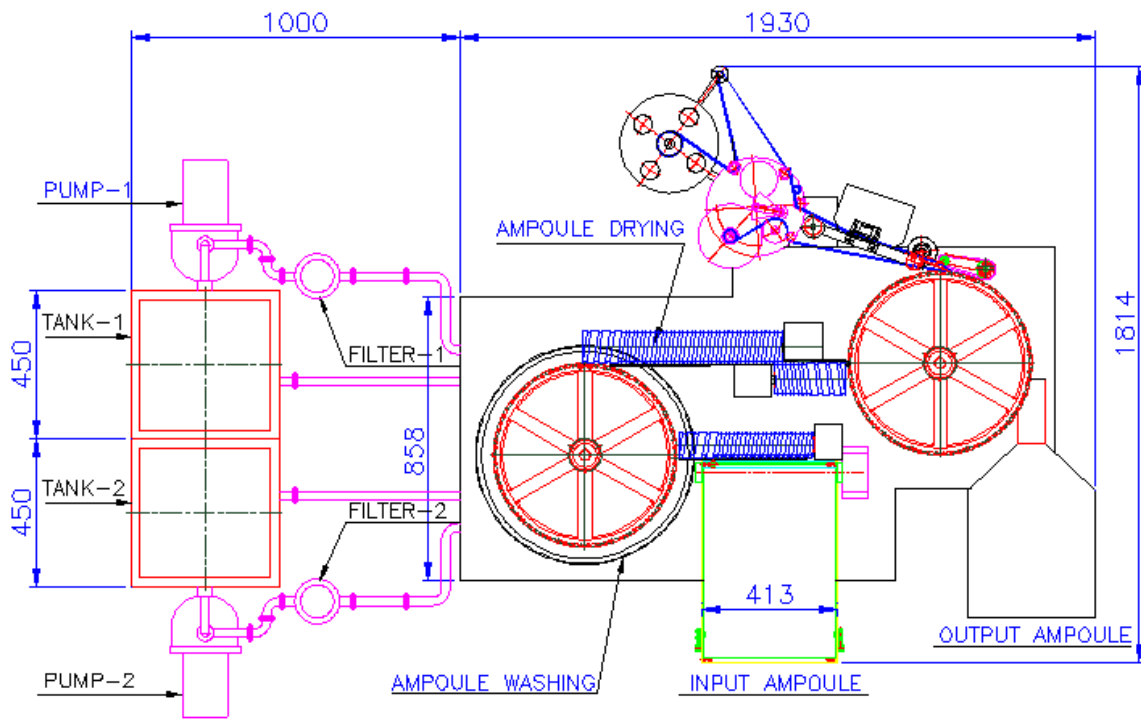
**PRESSING DEVICE**

It works on the basic Principle to press the sticker label on the Ampoule, which is previously applied by the label dispensing device. When sticker label is applied the applicator simultaneously Ampoule enters in to the pressing belt assembly and it will start move in rotary motion between the pressing belt and pressing pad. This allows the label to stick firmly on Ampoule and resulting wrinkle free Labeling.



**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**



**GA of Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine:**





**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**7.0 EQUIPMENT SPECIFICATION:**

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

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 PROCESS/PRODUCT PARAMETERS:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Application:</b> Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine is designed to Label the Round Objects for different size with over printing in single straight line operation	Should be able to Automatic External Ampoules Washing, Drying & Self Adhesive Labeling.	Process Requirement
<b>Working:</b> The machine product sensor sense the presence of container and dispense the label	Adhesive of label should be immediately done as product container reaches, and should stop as there is no container	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement

**8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Electrical Supply</b>	Voltage : 415 V( $\pm 10$ %) Phase : 3 Phase Frequency : 50 HZ	Process Requirement
<b>Compressed Air</b>	5 To 7 CFM at 6 Kg/Cm <sup>2</sup>	Process Requirement
<b>Water Requirement</b>	250 Liter/ Hr.	Process Requirement



**DESIGN QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 AUTOMATIC EXTERNAL AMPOULES WASHING,  
 DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<b>Basic Machine</b>		
Equipment Name	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine	Design Requirement
Machine No	EW-501/04/15-16	Design Requirement
Model No.	EWL-400	Design Requirement
Basic Unit	Machine with change part of 1ml Ampoules & Label	Design Requirement
Model	EWL-400	Design Requirement
Machine Capacity	350 Ampoules /min. for 1 ml ampoules .(Machine Speed Depend on Ampoules Size)	Process Requirement
Washing ,Drying & Labeling Operation	Single Track	Design Requirement
<b>Process</b>		
Washing & Drying Process	First Wash through Re-circulated Water through tank.	Process Requirement
	Second Wash Fresh Purified Water through Purified Water tank.	Process Requirement
	Air blow to dry unit through blower.	Process Requirement
	Air knife to complete drying of unit	Process Requirement
<b>Water Storage Tank</b>		
SS jacketed tank ( for Re-circulated Water)	MOC : SS316 Pump : (Make : Grundfoss) Filter Housing & Cartridge Drain Valve SS Piping Solenoid Valve Heater	Design Requirement



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
SS jacketed tank ( for Purified Water)	MOC : SS316 Pump : (Make : Grundfoss) Filter Housing & Cartridge Drain Valve SS Piping Solenoid Valve Heater	Design Requirement
<b>Height Adjustment</b>		
Height Adjustment	Manual	Design Requirement
<b>PLC</b>		
Type	PLC with color HMI touch Screen	Design Requirement
Make	Allen Bradley	Design Requirement
Sr.No.	1766-L32 BXB	Design Requirement
Volt	24VDC.	Design Requirement
<b>HMI</b>		
Make	Allen Bradley	Design Requirement
Power Supply	24VDC.	Design Requirement
Sr.No	2711P-T6C20D8	Design Requirement
<b>Other Feature</b>		
Fault Indication System	Fault is indicated in HMI screen.	Design Requirement
Gear Box	Make Bonfiglioli gear box with motor for machine.	Design Requirement
Drying System	Blower Provided For Ampoule Drying.	Design Requirement
User Friendly	Machine can be easily set for other size of Ampoule.	Design Requirement
<b>Motor (Main)</b>		
Make	Bonfigolioli	Design Requirement
Capacity	0.37 KW	Design Requirement
RPM	1370 RPM	Design Requirement
Sr.No.	BN71B4	Design Requirement
<b>Gear Box</b>		



**DESIGN QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 AUTOMATIC EXTERNAL AMPOULES WASHING,  
 DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Make	Bonfigolioli	Design Requirement
Ratio	RATIO-14:1	Design Requirement
Sr.No.	VF44F1 14 P71B5B3	Design Requirement
<b>AC Drive Main</b>		
Make	Allen Bradley	Design Requirement
Capacity	0.5HP.1Phase to 3Phase.	Design Requirement
Sr.No.	22F-A2P5N103	Design Requirement
<b>Servo Motor</b>		
Make	Allen Bradley	Design Requirement
Sr.No.	TL-A2540P-BJ32AA	Design Requirement
Capacity	0.86KW,	Design Requirement
RPM	5000RPM	Design Requirement
<b>Servo Gear Box</b>		
Make	Shimpo	Design Requirement
Ratio	RATIO-5:1	Design Requirement
Sr.No.	VRSF-5C-19DB19	Design Requirement
<b>Servo Drive</b>		
Make	Allen Bradley	Design Requirement
Capacity	800WATT.	Design Requirement
Sr.No.	2071-AP8	Design Requirement
<b>PUMP (PW)</b>		
Make	GRUNDFOS	Design Requirement
Sr.No.	CM3-3 A-R-G-V-AQQVF-A-A-N	Design Requirement
Capacity	0.46KW,0.62HP	Design Requirement
<b>PUMP (RE.CIR)</b>		
Make	GRUNDFOS	Design Requirement
Capacity	0.46KW,0.62HP	Design Requirement
Sr.No.	CM3-3 A-R-G-V-AQQVF-A-A-N	Design Requirement
<b>Blower</b>		
Make	AMBICA	Design Requirement
Sr.No	90L	Design Requirement
Capacity	3HP, 2.2KW	Design Requirement



PHARMA DEVILS

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
RPM	2910RPM,	Design Requirement
<b>Modbus Module With 485</b>		
Make	Allen Bradley	Design Requirement
Power Supply	24VDC.	Design Requirement
Sr.No.	1763-NC01	Design Requirement
<b>Out Put Module</b>		
Make	Allen Bradley	Design Requirement
Sr.No.	1762-OW8	Design Requirement
Volt	24 volt	Design Requirement
<b>Temperature Module</b>		
Make	Allen Bradley	Design Requirement
Sr.No.	1762-IT4	Design Requirement
Volt	24 volt	Design Requirement
<b>Temperature Sensor</b>		
Make	EMTECH CONTROLS	Design Requirement
Type	RTD	Design Requirement
<b>Water Level Sensor</b>		
Make	MTS ENGINEERING	Design Requirement
Model	SMT-16S	Design Requirement
Volt	24VDC	Design Requirement
<b>Heater</b>		
Make	TRILOK	Design Requirement
Capacity	2000 WATT	Design Requirement
<b>Proximity (Door Open)</b>		
Make	OMRON	Design Requirement
Sr.No.	E2B-M12KN05-WP-B1	Design Requirement
<b>Ampoule Sensor</b>		
Make	PANASONIC	Design Requirement
Model	FX-301-P	Design Requirement
<b>Label Sensor</b>		
Make	LEUZE	Design Requirement
Model	GS 61/6.3	Design Requirement
<b>Transformer</b>		
Make	CAMO CARE	Design Requirement
Model	1500VA	Design Requirement
Capacity	230/200VAC,	Design Requirement
<b>Pressure Switch (Pw Water)</b>		
Make	DANFOSS	Design Requirement
Model	KP35	Design Requirement
Range	0.2 TO 7.5BAR.	Design Requirement
<b>Pressure Switch (Re.Cir Water)</b>		
Model	KP35	Design Requirement
Range	0.2 TO 7.5BAR.	Design Requirement



**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<b>Pressure Switch (Air)</b>		
Make	DANFOSS	Design Requirement
Model	KP35	Design Requirement
Range	0.2 TO 7.5BAR.	Design Requirement
<b>Solenoid Valve (Pw Water)</b>		
Make	ROTEX	Design Requirement
Sr.No.	24103-12-4G-B13	Design Requirement
<b>Solenoid Valve (Re.Cir Water)</b>		
Make	ROTEX	Design Requirement
Sr.No.	24101-12-4G-B12	Design Requirement
<b>Solenoid Coil (Pw &amp; Re.Cir Water)</b>		
Make	ROTEX	Design Requirement
Sr.No.	I-24V-DC-22	Design Requirement
<b>Valve (Air)</b>		
Make	SMC	Design Requirement
Sr.No.	VXD232AA	Design Requirement
Range	0.5MPA	Design Requirement
<b>Solenoid Coil (Air)</b>		
Make	SMC	Design Requirement
Volt	24 VDC	Design Requirement

**8.4 Safety Features, Alarms & Interlock:** The equipment shall be provided with safety features as listed below.

S.No.	FEATURE	ACCEPTANCE CRITERIA	REFERENCE
1.	No Ampoule No Labeling.	No Ampoule No Labeling System is provided while machine is running in ideal condition and Ampoule is not present on Star Wheel.	Safety Requirement
2.	Emergency Stop	Machine stop	Safety Requirement
3.	Re. Cir. Temperature Low	Machine Stop	Safety Requirement
4.	Re. Cir. Water Pressure Low	Machine Stop	Safety Requirement
5.	Re. Cir. Tank Water Level Low	Machine Stop	Safety Requirement
6.	P.W. Temperature Low	Machine Stop	Safety Requirement
7.	P.W. Water Pressure Low	Machine Stop	Safety Requirement
8.	P.W. Tank Water Level Low	Machine Stop	Safety Requirement
9.	Guard Open (Washing Zone)	Machine Stop	Safety Requirement
10.	Pump Trip	Machine Stop	Safety Requirement



**DESIGN QUALIFICATION  
 PROTOCOL CUM REPORT  
 FOR  
 AUTOMATIC EXTERNAL AMPOULES WASHING,  
 DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

S.No.	FEATURE	ACCEPTANCE CRITERIA	REFERENCE
11.	Blower Trip	Machine Stop	Safety Requirement
12.	Main Star wheel Drive Trip	Machine Stop	Safety Requirement
13.	Air Pressure Low	Machine Stop	Safety Requirement
14.	Servo Drive Fault	Machine Stop	Safety Requirement

**8.5 MATERIAL OF CONSTRUCTION:**

S.No.	COMPONENT	MOC	REFERENCE
01.	Machine frame structure	M.S. Angle Duly Cladded with S.S.304 Sheet	Design Requirement
02.	External cladding	S.S 304, (No Painted Surface)	Design Requirement
03.	Star Wheel	Aluminum Casting	Design Requirement
04.	In Feed & Out worm	Delrin	Design Requirement
05.	In Feed Tray	S.S.304	Design Requirement
06.	Out Feed Tray	S.S.304	Design Requirement
07.	Water Tank	S.S.316	Design Requirement

**8.6 VENDOR SELECTION:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Automatic External Ampoules Washing, Drying & Self Adhesive Labeling .	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include 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) Specifications and Requirements as specified in PO and URS.  
 (2) Operating and service manual

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







**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**13.0 ABBREVIATIONS:**

ALM	:	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling
cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
CI.	:	Cast Iron
DQ	:	Design Qualification
HP	:	Horse Power
Hr	:	Hour
Hz	:	Hertz
IB	:	Injection Block
Kg	:	Kilogram
KW	:	Kilo Watt
MCB	:	Miniature circuit breaker
mm	:	Millimeter
MMI	:	Man Machine Interface
MOC	:	Material of Construction
MS	:	Mild Steel
No	:	Number
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RPM	:	Revolution per minute
SS	:	Stainless steel
URS	:	User requirement specification
VFD	:	Variable Frequency Drive



**PHARMA DEVILS**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC EXTERNAL AMPOULES WASHING,  
DRYING & SELF ADHESIVE LABELING MACHINE**

**PROTOCOL No.:**

**14.0 REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (ENGINEERING)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			