



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION  
FOR  
BLISTER PACKING MACHINE**

**PROTOCOL No.:**

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**1.0 PROTOCOL APPROVAL:**

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following signatories.

This Installation Qualification protocol of Blister pack machine has been reviewed and approved by the following signatories:

<b>FUNCTION</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		



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**2.0 OVERVIEW:**

**2.1 OBJECTIVE:**

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Blister pack machine and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the Blister pack machine was installed as required in Soft gel Blister packing area.

The Qualification of Blister pack machine performed in view of Soft gel Blister packing area of manufacturing facility.

**2.2 PURPOSE:**

The purpose of this protocol is to establish documentary evidence to ensure that the Blister pack machine received matches the Design specification and also to ensure that it is properly and safely installed.

**2.3 SCOPE:**

The installation qualification protocol shall be followed for installation qualification of Blister pack machine. This protocol defines the methods and documentation that shall be used to evaluate the system installation in accordance with the specifications and intended use. Successful implementation of this protocol shall verify that the systems installed meet the requirements specified.

**2.4 RESPONSIBILITY:**

In accordance with protocol, following functions shall be responsible for the qualification of system.

**Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:**

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures



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on system Qualification.

- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

**Head – Production/ Engineering:**

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

**Head – Operation and Quality Assurance:**

- Review and approval of protocol, the completed qualification data package, and the final report.

**2.5 EXECUTION TEAM:**

The satisfactory installation of the Blister packing machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Blister packing machine is installed satisfactorily.

Execution team is responsible for the execution of installation qualification of Blister packing machine and Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE



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**3.0 ACCEPTANCE CRITERIA:**

- 3.1 The Blister pack machine shall meet the system description given in design specification.
- 3.2 The Blister pack machine shall meet with the acceptance criteria mentioned under the topic "Identification of major components".
- 3.3 All material of constructions of the contact parts to be checked as per the specifications.
- 3.4 Safety feature, Utility & calibration shall be identified.

**4.0 REVALIDATION CRITERIA:**

The machine has to be revalidated if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown, maintenance is carried out.
- As per revalidation date and schedule.

**5.0 INSTALLATION QUALIFICATION PROCEDURE**

**5.1 EQUIPMENT DESCRIPTION:**

Equipment Name	:	Blister packing machine
Supplier / Manufacturer	:	Elmach Packages (India) Pvt. Ltd.
Dimension (LXWXH)	:	3480 mm X 1100 mm X 2180 mm
Model	:	EPI 2500
Serial no.	:	2608
Base film	:	Thermo-formable, bi-axially oriented, non- toxic pvc, pvc with pvdc coating.
Lidding material	:	Hard tempered Aluminium foil with heat sealable coating
PVC base film width	:	212 mm (Max)
PVC film thickness	:	0.25 mm to 0.30 mm
PVC reel diameter	:	440 mm (Max)
Aluminium foil width	:	208 mm (Max)
Aluminium foil thickness	:	0.02 mm to 0.03 mm
Aluminium reel diameter	:	220 mm (Max)
Format area	:	Min 25 MM X 196 MM Max 102 MM X 196 MM
Advance length	:	110 mm (Max)
Punched out pack length	:	204 mm (Max)



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Punched out pack width	:	110 mm (Max)
Output	:	Max 140 strokes / min (Depend on the Product).
Air Pressure Required	:	Minimum 6 bar (Kg/cm <sup>2</sup> )
Cooling water Flow Rate	:	2 lit / min. at 13 °C to 16 °C
Location	:	Blister packing area II

**Blister packing machine comprises of following components.**

- Hopper
- Vibrator
- Forming Roller (Assembly )
- Feeding Box
- Web guide track
- Sealing Roller (Assembly)
- Guide roller
- Machine panel & cover
- Trim chute
- Embossing Unit
- Perforation Unit
- Pack pick and place assembly
- Batch Code printing unit
- Punching station
- Conveyer belt
- Emergency switch

The Blister packing machine EPI –2500 is an automatic blister packing machine utilized for packing of tablets/capsules in blister packs. The EPI 2500 machine draws PVC base film from a reel feed assembly in to the forming station, where blister are continuously formed. The formed web moves over the guide track to the feeding station. Here using a suitable feeding attachment, product is automatically filled in the blister cavities. Filled web moves to the sealing station. Lidding material, drawn from the reel stock, is feed to the sealing station. Lidding material gets sealed with the filled web enclosing the product hermetically (airtight closure protecting the product from outside contaminates). The filled and sealed web is fed by an indexing mechanism into the pack punching station. Here, the web gets punched into the packs as per layout. The blister pack are either collected in bins or transferred on a conveyer belt and conveyed for further handling. The trim waste is sheared off into small pieces for easy handling and disposal.

All the operational controls and sequences of the machine are arranged by Man-Machine Interface mounted conveniently located in front of the machine and mechanical cams, which determines the positional accuracy of the machine with the feed pack.



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**5.2 INSTRUCTION FOR FILLING THE CHECKLIST:**

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.



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**5.3 INSTALLATION CHECKLIST:**

Installation checklist is as follows:

S.No.	Statement	Method of Verification	Actual observation	Checked By Sign/Date
1.	Verify the purchase order copy and PO no. Shall be written in observation column	Physically		
2.	Verify that the "As Built" drawing is complete and represents the design concept.	Physically		
3.	Verify that major components are securely anchored and shock proof.	Physically		
4.	Verify that there is sufficient room provided for servicing.	Physically		
5.	Verify that all piping and electrical connections are done according to the drawings.	Physically		
6.	All access ports are examined and cleared of any debris.	Physically		
7.	Safe electrical connections.	Physically		
8.	Sufficient room provided for maintenance.	Physically		
9.	Equipment identification nameplate visible.	Physically		
10.	Units installed on foundation are secure in place as per manufacturer's recommendations.	Physically		
11.	Verify that there is no observable physical damage	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**





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**5.4 IDENTIFICATION OF MAJOR COMPONENTS:**

Describe each critical component and check them and fill the inspection checklist.

System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
<b>Main motor</b>	Type	ATDC 90S-4	Physically / Visually		
	Make	Rotomotive	Physically / Visually		
	Sr. No.	M09142081	Physically / Visually		
	Tech. Specification	415 V, 1.5 HP, 1.1 KW, 50 Hz, 1390 RPM	Physically / Visually		
<b>Infeed motor</b>	Type	RU-56-3G	Physically / Visually		
	Sr. No.	J HUG-24471	Physically / Visually		
	Make	Remi	Physically / Visually		
	HP	1/8	Physically / Visually		
	Voltage	220 to 230V	Physically / Visually		
	RPM	75	Physically / Visually		
<b>Aluminium foil draw motor</b>	Type	2-63	Physically / Visually		
	Sr. No.	D-525	Physically / Visually		
	Make	Sudarshan Gears	Physically / Visually		
	Tech Specification	0.25 HP, 60 RPM	Physically / Visually		
<b>VFD for Main motor</b>	Model	ATV312HU15N4	Physically / Visually		
	Sr. No.	8B 1425194179	Physically / Visually		
	Make	Schneider	Physically / Visually		
	HP	2 HP	Physically / Visually		
<b>VFD for Aluminium foil motor</b>	Model	ATV12H037M2	Physically / Visually		
	Sr. No	8B 1419849094	Physically / Visually		
	Make	Schneider	Physically / Visually		
	HP	0.5	Physically / Visually		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
<b>Gear box</b>	Type	Box 063	Physically / Visually		
	Sr. No.	G09140969	Physically / Visually		
	Make	Rotomotive	Physically / Visually		
<b>Control Panel</b>	Make	Elmach	Physically / Visually		
<b>Ammeter</b>	Make	Automatic Electric Ltd.	Physically / Visually		
	Size	98 mm X 98 mm	Physically / Technical Specification		
	Current Range	0 to 20 Amp	Physically / Visually		
	Quantity	02	Physically / Visually		
<b>Potentiometer</b>	Make	Bourns, Mexico	Physically / Visually		
	Resistance	10 k Ohm (±5%)	Physically / Visually		
<b>Forming temperature controller</b>	Make	Datalogic	Physically / Visually		
	Type	QD-10	Physically / Visually		
	Range	0° to 450° C	Physically / Visually		
<b>Sealing temperature controller</b>	Make	Datalogic	Physically / Visually		
	Type	QD-10	Physically / Visually		
	Range	0° to 450° C	Physically / Visually		
<b>Perforation temperature controller</b>	Make	Datalogic	Physically / Visually		
	Type	QD-10	Physically / Visually		
	Range	0° to 450° C	Physically / Visually		
<b>Temperature sensor used in preheating roller and in sealing roller</b>	Type	Thermocouple type 'J'	Physically / Technical Specification		
	Metals used in thermo couple	Fe-con	Physically / Technical Specification		
	Make	Shabari	Physically / Technical Specification		
<b>Temperature sensor used in</b>	Type	PT-100	Physically / Visually		



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<b>System Components</b>	<b>Design Specification</b>		<b>Method of Verification</b>	<b>Actual Observation</b>	<b>Checked By Sign/Date</b>
<b>Perforation tool</b>	Make	Shabari	Physically / Visually		
<b>Heater used in Heating roller</b>	Type	Cartridge	Physically / Visually		
	Length & Diameter	225 mm, 15.8 mm (Ø)	Physically / Technical Specification		
	Wattage & Voltage	300 WATTS & 220 VOLTS	Physically / Technical Specification		
	Quantity	8 No's	Physically / Visually		
<b>Heater used in Sealing heater</b>	Type	Cartridge	Physically / Visually		
	Length & Diameter	225 mm, 15.8 mm (Ø)	Physically / Technical Specification		
	Wattage & Voltage	300 watts & 220 V	Physically / Technical Specification		
	Quantity	8 No's	Physically / Visually		
<b>SMPS</b>	Make	Shavison	Physically / Visually		
<b>PLC</b>	Type	FX3U-48M	Physically / Visually		
	Make	Mitsubishi	Physically / Visually		
	Sr. No.	1490124	Physically / Visually		
<b>PLC EXTN.</b>	Type	FX 2N - 16EX	Physically / Visually		
	Make	Mitsubishi	Physically / Visually		
	Sr. No.	14X0683	Physically / Visually		
<b>MMI</b>	Model	E1022	Physically / Visually		
	Type	06871	Physically / Visually		
	Make	Mitsubishi (Beijer)	Physically / Visually		
	Sr. No	1344-532	Physically / Visually		
<b>Limit Switch used for 'No PVC'</b>	Make	Kaycee	Physically / Visually		
<b>Solenoid coils</b>	Type	MSFG-24/42-50/60	Physically / Visually		



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<b>System Components</b>	<b>Design Specification</b>		<b>Method of Verification</b>	<b>Actual Observation</b>	<b>Checked By Sign/Date</b>
	Make	Festo	Physically / Visually		
	Tech Spec	24Vdc	Physically / Visually		
<b>Dimmer for feeding unit</b>	Type	0.750- IF	Physically / Visually		
	Make	Automatic electric	Physically / Visually		
	Capacity	202 KVA	Physically / Visually		
<b>Photocell for product level</b>	Make	P & F	Physically / Visually		
<b>Vibrator</b>	Make	Vibro Mex	Physically / Technical Specification		
<b>Pneumatic cylinder for PSR</b>	Type	DNC-80-40-PPV-A	Physically / Visually		
	Make	FESTO	Physically / Visually		
<b>Pneumatic cylinder for Forming</b>	Type	C0211025	Physically / Visually		
	Make	SCHRADER DUNCAN	Physically / Visually		
<b>Flow regulator for PRC</b>	Type	DNC-32-40-PPV-A	Physically / Visually		
	Make	FESTO	Physically / Visually		
<b>Filter regulator</b>	Make	SHAVO NORGREN	Physically / Visually		
	Type	SBO2-221-M2 KB	Physically / Visually		
<b>Lubricator</b>	Make	Shavo Norgren	Physically / Visually		
	Type	SL10M-2GQ	Physically / Visually		
<b>Airfilter</b>	Make	Shavo Norgren	Physically / Visually		
	Type	SF10G-2G-M2T-N	Physically / Visually		
<b>Vacuum Gauge</b>	Make	Manometer	Physically / Visually		
	Range	-760 mm to 0 mm of mercury column	Physically / Visually		
<b>Pressure gauge</b>	Make	Manometer, Shavo	Physically / Visually		
	Range	0 -10 (kg/Cm <sup>2</sup> ), 0-7 (kg/Cm <sup>2</sup> )	Physically / Visually		
<b>Vacuum Pump</b>	Make	Bharat vacuum pump	Physically / Visually		



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<b>System Components</b>	<b>Design Specification</b>		<b>Method of Verification</b>	<b>Actual Observation</b>	<b>Checked By Sign/Date</b>
	Capacity	150 LPM	Physically / Visually		
	Sr. No.	21806299	Physically / Visually		
<b>Vacuum pump motor</b>	Type	MDERAXX071-22	Physically / Visually		
	Make	Lenze	Physically / Visually		
	Sr. No	14010093	Physically / Visually		
	Capacity	0.5 HP/0.37 KW	Physically / Visually		
<b>Eye mark sensor</b>	Type	TLu-011	Physically / Visually		
	Make	Data logic	Physically / Visually		
<b>Encoder</b>	Type	8.5000.B152.0360	Physically / Visually		
	Sr. No.	91430800244	Physically / Visually		
	Make	Kubler	Physically / Visually		
<b>Front door safety limit switch</b>	Make	Kaycee	Physically / Visually		
<b>Lid foil Splice sensor</b>	Make	P & F	Physically / Visually		
	Type	DK-12-11/124/136	Physically / Visually		
<b>Base foil Splice sensor</b>	Make	P & F	Physically / Visually		
	Type	DK-12-11/124/136	Physically / Visually		
<b>Cooling water temperature controller</b>	Type	E5CWL-R1P	Physically / Visually		
	Range	4°C to 30°C	Physically / Visually		
	Make	Omron	Physically / Visually		
<b>Pneumatic Pressure Switch</b>	Type	IPS-100	Physically / Visually		
	Range	0 TO 7 BAR	Physically / Visually		



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<b>System Components</b>	<b>Design Specification</b>		<b>Method of Verification</b>	<b>Actual Observation</b>	<b>Checked By Sign/Date</b>
	Make	INDFOS	Physically / Visually		
<b>*Camera System</b>	Make	Jekson Vision	Physically / Visually		
<b>*Pin Hole Detector</b>	Make	Jekson Vision	Physically / Visually		

**Remark:** -----

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**Reviewed by (Sign/Date)**



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**5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:** Should be verified by test certificates of respective material apart from that SS material should be verified by molybdenum kit in absence of test certificate.

Name of Components	Material of Construction	Method of Verification	Observation	Checked By Sign/Date
Hopper with lid	SS 316	Molybdenum Kit		
Bowl dish / Vibrator	SS 316	Molybdenum Kit		
Feeding channel	Aluminum alloy (self anodized )	Physically		

\* Test certificate to be verify and attached to protocol.

**Remark:** -----  
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**Reviewed by (Sign/Date)**

**5.6 IDENTIFICATION OF SUPPORTING UTILITIES:**

Utility	Method of verification	Observation	Checked by Sign/ Date
<b>Electricity:</b> 3 phase, 415V AC, 50Hz supply with neutral and proper earthing.	Physically and with clamp meter		
<b>Chilled water:</b> 2 lit / min. at 14 <sup>0</sup> C to 16 °C.	Physically		
<b>Compressed air:</b> Minimum pressure 6 Kg/Cm <sup>2</sup>	Physically		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.7 IDENTIFICATION OF SAFETY FEATURES:** Identify and record the safety features (if any) and their function in following tables:

Safety Features Description	Function	Method Of Verification	Observation	Checked By Sign/ Date
Earthing	To avoid electrical shocks due to leakage current.	Physically		
Emergency stop button	To stop machine immediately in case of emergency	Physically		
Micro switch for PVC film	Machine will not operate if PVC roll is finished.	Physically		
Limit switch	If door open during operation the machine should be stop.	Physically		

**Remark:** -----  
-----  
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**Reviewed by (Sign/Date)**

**5.8 IDENTIFICATION OF COMPONENT (S) TO BE CALIBRATED**

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

**Remark:** -----  
-----  
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**Reviewed by (Sign/Date)**





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**5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)**

The following Standard Operating Procedures were identified as important for effective performance of Blister pack machine.

<b>S.No.</b>	<b>SOP TITLE</b>	<b>IDENTIFIED BY(Sing/ Date)</b>

**Remark:** -----  
-----  
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**Reviewed by (Sign/Date)**



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**5.10 VERIFICATION OF DRAWING AND DOCUMENTS:**

Following documents are reviewed and attached as listed below:

S.No.	DRAWING AND DOCUMENT DETAIL	CHECKED BY (SIGN)	DATE

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.11 LIST OF ANNEXURES:**

Annexure No.	Document Title

**Remarks (if any):**

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**Done By & Date:**

**Verified By & Date:**



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**DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):**

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

**Description of deficiency:**

**Corrective action(s) taken:**

**Deviation accepted by  
(Sign/Date)**

**Deviation Approved by  
(Sign/Date)**



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**5.13 ABBREVIATION(S)**

PLC: Programmable Logic Controller

MMI: Man Machine Interface

SMPS: Single Mode Power Supply

PRC: Printing Registration Control

PSR: Printing Register Scanner

VFD: Variable Frequency Drive

SOP: Standard Operating Procedure



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**6.0 INSTALLATION QUALIFICATION FINAL REPORT:**

**6.1 SUMMARY:**

**6.2 CONCLUSION:**

**Prepared By  
Sign/ Date**

**Checked By  
Sign/ Date**



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**6.3 FINAL REPORT APPROVAL**

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol. If applicable signature in the block below indicates that all items in this qualification report of Blister pack machine have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

<b>FUNCTION</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>REVIEWED BY</b>			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
<b>APPROVED BY</b>			HEAD OPERATION		
			QUALITY ASSURANCE		