



PHARMA DEVILS

**OPERATIONAL 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 authorities.

This Operation Qualification protocol of Blister pack machine has been reviewed and approved by the following Persons

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
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 machine and to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document, are the same at utmost transparency.

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 Scope of this protocol is limited to the operational Qualification of Blister pack machine in Soft gel Blister packing area of manufacturing.

Once the operational qualification of Blister pack machine has been completed successfully, the equipment shall be preceded for the performance qualification procedure.

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 on system Qualification.



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- 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 operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and production person.
- 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 operation of the Blister pack machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Blister pack machine is operational and is satisfactorily working.

Execution team is responsible for the execution of Operational Qualification of Blister pack machine.

Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The equipment shall be operational as per its specified operating instructions.
- 3.2 All SOPs for the equipment shall be verified and checked.
- 3.3 All material of constructions of the contact parts to be checked as per the specifications.
- 3.4 All the functionality of equipment components to be checked.
- 3.5 All the safety features of the equipment shall be verified and utilities shall be available near the equipment.
- 3.6 The validity of the calibration of tests instruments shall be checked and all the required calibration of the components of the equipment shall be performed.

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 OPERATIONAL 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.	:	2606
Base film	:	Thermo-formable, bi-axially oriented, non- toxic pvc,



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		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)
Punched out pack width	:	110 mm (Max)
Output	:	Max 140 strokes / min (Depend on the Product).
Air Pressure Required	:	Minimum 6 bar (Kg/cm ²)
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.

1. Hopper
2. Vibrator
3. Forming Roller (Assembly)
4. Feeding Box
5. Web guide track
6. Sealing Roller (Assembly)
7. Guide roller
8. Machine panel & cover



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9. Trim chute
10. Embossing Unit
11. Perforation Unit
12. Pack pick and place assembly
13. Batch Code printing unit
14. Punching station
15. Conveyer belt
16. Emergency switch

The Blister packing machine EPI –2500 is an automatic blister packing machine utilized for packing of tablets 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 conveyor 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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5.4 Test instrument calibration:

Review the calibration status for the test instrument to be utilized in operational qualification testing and record the calibration due dates in the table below. All equipment / instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilized.

S.No.	Test Instrument	ID	Calibration done Date	Calibration Due Date	Calibration Certificate No

Remarks:

Checked By/Date:

Verified By/Date:



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5.5 VERIFICATION OF FUNCTIONAL CHECKS:

Name of system component	Specified function	Method of verification	Observation	Checked By Sign/Date
Check correct working of the machine	The machine should be operational.	Physically by challenging		
Hopper	To charge the Tablet	Visually		
Vibrator	To produce vibration so that tablets come in the feeding channel easily	Visually		
Feeding channel	To collect the tablets	Visually		
Operating panel	To operate the machine through the switches	Visually		
Forming roller	Formation of pockets with the aid of vacuum	Visually		
Sealing roller	The seal the Aluminium foil with the base foil.	Visually		
Punching Station	For proper cutting of the packs from the web as per layout	Visually		



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Name of system component	Specified function	Method of verification	Observation	Checked By Sign/Date
<p>Uniformity of sealing of the formed web with the lidding material:</p> <ol style="list-style-type: none">1. Place a carbon paper in between two plain paper sheets & place them over the counter sealing roller.2. Stick them with an adhesive tape to the counter sealing roller. Press the start push button for pressing the papers between pressure sealing roller and counter sealing roller. Repeat the test using the web and the lidding material.	<p>Uniform impression of the counter sealing die and knurling of the pressure Sealing roller on the paper is observed.</p>	<p>Physically by challenging</p>		



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Name of system component	Specified function	Method of verification	Observation	Checked By Sign/Date
Base foil splice detection: 1. Splice the end of preceding base foil with the end of succeeding base foil an adhesive tape & start the machine	Filled and sealed web with spliced base foil is punched into blister packs & splice pack are rejected.	Physically by challenging		
Lid foil splice detection: 1. Splice the end of preceding lid foil with the end of succeeding lid foil an adhesive tape & start the machine	Filled and sealed web with spliced lid foil is punched into blister packs & splice packs are rejected.	Physically by challenging		



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Name of system component	Specified function	Method of verification	Observation	Checked By Sign/Date
Overprinting arrangement: 1. Mount Batch code printing drum. 2. Mount the stereo types over the drum. 3. Put a mixture of ink and thinner over inking roller and engage the roller against the drum. 4. Press the start push button.	Batch code printer stereos are on the roller, in the position as described Drum and inking roller are engaged. No smudging of ink and no shifting of printing are observed.	Physically by challenging		
Forming & Sealing & Perforation temperature controllers: 1. Switch on the temperature controller & set the temperature at between 145°C & 160°C. Run the machine	Temperature control is 'ON', temperature is set & remains within the set value	Physically by challenging		



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Name of system component	Specified function	Method of verification	Observation	Checked By Sign/Date
Cooling water temperature: Press the start push button & switch off the cooling of the water cooler.	Initially machine starts & when cooling water temperature exceeds the set value, the machine stops	Physically by challenging		

Remarks: _____

Done By & Date:

Verified By & Date:



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5.5.1 Verification of Operational Checks:

Test	Acceptance Criteria	Method of verification	Observation
Switch 'ON'	Power supply should be on	By Challenging	
Switch 'OFF'	Power supply should be off	By Challenging	
Speed control with rotating knob	Control the machine speed with knob	Physically by challenging	
Forming heater indicator	Indication shall glow when start the forming heater.	Physically by challenging	
Sealing heater indicator	Indication shall glow when start the sealing heater.	Physically by challenging	
Green start push button	Machine should start.	Physically by challenging	
Red stop push button	Machine should stop.	Physically by challenging	
Feeder motor Speed controller	Control the feeder motor speed	Physically by challenging	
Aluminum foil Speed controller	Control the aluminum foil motor speed	Physically by challenging	
Vibrator Switch for auto / manual	Vibrator should start in auto / manual mode	Physically by challenging	



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Name of system component	Specified function	Method of verification	Observation
Machine speed	Set the machine On various speed like 40 ,60,80 and 100 cuts / minute	On controller display	
Forming roller temperature indicator	To indicate the temperature of Forming roller .Set the roller temperature at various temperature like 120°C , 160 °C 180 °C and record the same	Display check	
Sealing roller temperature indicator	To indicate the temperature of Sealing roller .Set the roller temperature at various temperature like 180 °C , 200 °C, 220 °C and record the same	Display check	
Power failure test	Machine shall be set at different temperature of sealing and forming temperature and shut down for 3 minute and again restart the machine, The set parameter should not change.	Display check	

Remarks:

Done By & Date:

Verified By & Date:



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5.6 VERIFICATION OF SAFETY FEATURES:

Safety Features Description	Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
No PVC film	Remove the PVC and start the machine.	The machine should not start.		
Emergency stop	Run the machine & Press the emergency stop push button.	The machine should stop immediately.		
Earthing	Check whole body with multimeter for any current leakage.	No current leakage should be observed.		

Remark: -----

Reviewed by (Sign/Date)



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5.7 VERIFICATION OF SUPPORTING UTILITIES:

Utility	Method of Verification	Observation	Verified By Sign/Date
Electricity: 3 phase, 415V AC, 50Hz supply with neutral and proper earthing	By challenging with clamp meter		
Compressed air 6 kg/cm ²	Physically		
Chilled water line 13 to 16 °C	Physically		

Remark: -----

Reviewed by (Sign/Date)

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

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

S.No.	SOP Title	SOP Number	Verified By (Sign/Date)

Remark: -----

Reviewed by (Sign/Date)



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5.9 TRAINING RECORD OF PERSONNEL (S):

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

Remark: -----

Reviewed by (Sign/Date)

5.10 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any):

Done By & Date:

Verified By & Date:



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

Following deficiency was identified 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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6.0 OPERATIONAL 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 Operational qualification report of Blister pack machine have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		