



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

S.No.	ITEM DESCRIPTION	PAGE No.
1.0	REPORT APPROVAL	3
2.0	OVERVIEW	4
2.1	Objective	4
2.2	Purpose	4
2.3	Scope	4
2.4	Responsibility	5
2.5	Execution Team	6
3.0	GENERAL CONSIDERATION/PREREQUISITE	7
4.0	REVALIDATION CRITERIA	7
5.0	PERFORMANCE QUALIFICATION PROCEDURE	8
5.1	Brief Description of Equipment	8-9
5.2	Risk Analysis	9
5.3	Methodology	10
5.3.1	Qualification/ Validation Sampling Plan	11-12
5.4	Product Details	12-13
5.5	Process Flow Diagram With Qualification Parameters of Blister Packing Machine (EPI 2500)	13
5.6	Set Parameters	14
5.7	Acceptance Criteria	14
5.8	Recording of Sampling	15-17
5.9	Observations And Results of Challenge Tests	18-65
5.10	Environmental Monitoring During Primary Packing	66-67
6.0	DEFICIENCY AND CORRECTIVE ACTION(S) REPORT(S)	68
7.0	PERFORMANCE QUALIFICATION FINAL REPORT	69
7.1	Summary	69
7.2	Conclusion	69
7.3	Final Report Approval	70



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

1.0 REPORT 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 performance qualification protocol of Blister Packing Machine EPI-2500 has been reviewed and approved by the following persons:

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



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to

- Document the verification of all aspects of the equipment that can affect product quality.
- To establish, check and document the performance of equipment in the established/predetermined operating ranges.

2.2 PURPOSE:

The purpose of this protocol is to verify that the equipment produces the desired output. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

The equipment working capacity is recommended by manufacturer challenged by charging the tablets with the maximum and minimum capacity of the pan.

2.3 SCOPE:

The protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the performance of the equipment shall meet the predetermined acceptance criteria.

The Scope of this protocol is limited to the performance qualification of Blister Packing Machine EPI-2500 installed in Soft gel Blister Packing area of manufacturing facility.

Once the performance qualification of Blister Packing Machine EPI-2500 has been completed successfully, the equipment shall be released for the production purposes.



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

2.4 RESPONSIBILITY:

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

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

- Prepares the performance qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures 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 analysis of sample shall be carried out by quality control department.
- Engineering department shall support for execution.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Quality control / 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 Packing Machine EPI-2500 shall be verified by executing the performance qualification studies described in this protocol. The successfully executed protocol documents that the Blister Packing Machine EPI-2500 is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Blister Packing Machine EPI-2500. Execution team comprises of:



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

3.0 GENERAL CONSIDERATION/ PREREQUISITE

- Approved Standard operating procedure of Blister Packing Machine.
- The impact analysis of the equipments shall be recorded in the summary sheet.
- The installation and operational qualification of Blister Packing Machine shall be successfully completed before the execution of the performance qualification.
- All the deficiencies and discrepancies related to Blister Packing Machine which may affects the product quality and corrective action taken shall be recorded in the appropriate section of the report.
- After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

4.0 REVALIDATION CRITERIA:

The machine shall be requalified 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.



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

5.0 PERFORMANCE QUALIFICATION PROCEDURE:

5.1 EQUIPMENT DESCRIPTION:

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
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.



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

5.2 RISK ANALYSIS:

- Machine is designed to operate on high speed & high temperature.
- Base film presence sensor is attached to the guide roller. It acts as a limit switch. If the roll of the base film is not mounted or the base film roll is not drawn or has exhausted, the sensor senses and activates the control panel to stop the machine.
- Chute is meant for emptying out the flooding box and a level sensor for intermittent stopping and starting the inflow of capsules into the flooding box.

S.No.	Risk identified	Control measures
1.	If the roll of the base film is not mounted or the base film roll is not drawn or has exhausted.	The sensor senses and activates the control panel to stop the machine.
2.	If case of machine overload.	MCB immediately trips and machine stops.
3.	Interrupted flow of capsules into the flood box.	Chute is meant for emptying out the flooding box and a level sensor for intermittent stopping and starting the inflow of capsules into the flooding box.

EVALUATION AND CONCLUSION:

All the risks associated with Blister Packing Machine (EPI 2500) have been evaluated and control/preventive Measures has been taken.

5.3 METHODOLOGY:

- The dummy batches manufactured shall be packed with different change parts which are available and shall be used in packing of different products.
- Details of the change parts shall be mentioned under the heading of challenge run.
- All the challenge run mentioned in the qualification/validation sampling plan shall be done separately with all available change part (lay out).
- The Performance Qualification of the Blister Packing Machine shall be done on PQ Batch packed under BPR No. _____ & BPR No. _____ for minimum and maximum batch sizes respectively.
- Transfer the approved capsules from the capsules quarantine area to primary packaging area along with the BMR and shall be checked by the production officer.
- Start the packing activity as per mentioned in the BPR.
- Start up test shall be done before continue the primary packing.
- Load the capsules according to the serial number of the containers.



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

Note: Never leave the capsules in chute, channel and in hopper during lunch and tea breaks and always close the hopper when the machine is running.

At the end of shift if balance capsules are left in the hopper or in the drum the same should be unloaded into a HDPE drum lined with double poly bags; tie inner poly bag, then second poly bag is to be tied. Finally the drum has to be closed with lid.

In primary packaging area during blister packaging, temperature $23^{\circ}\pm 4^{\circ}\text{C}$ and Relative Humidity between $50 \pm 5\%$ is to be maintained.



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

5.3.1 QUALIFICATION/ VALIDATION SAMPLING PLAN:

The qualification/ validation sampling plan is as following, the challenge run shall be perform for each change part (Lay Out) individually:

S.No.	Speed	Forming Temperature	Sealing Temperature	Sample Quantity	Test Required		
1.	Minimum	High forming temp.* (140°C)	High sealing temp.* (205°C)	As per complete blister formed / rotation	Appearance of Blister, Horizontal Cutting & Vertical Cutting, Knurling, Coding Details on Blister, Leak test, Pocket Formation & Assay.		
2.		Low forming temp. (120°C)	High sealing temp. (205°C)				
3.		High forming temp. (140°C)	Low sealing temp. (185°C)				
4.		Low forming temp. (120°C)	Low sealing temp. (185°C)				
5.	Maximum	High forming temp.* (140°C)	High sealing temp.* (205°C)	As per complete blister formed / rotation		Appearance of Blister, Horizontal Cutting & Vertical Cutting, Knurling, Coding Details on Blister, Leak test, Pocket Formation & Assay.	
6.		Low forming temp. (120°C)	High sealing temp. (205°C)				
7.		High forming temp. (140°C)	Low sealing temp. (185°C)				
8.		Low forming temp. (120°C)	Low sealing temp. (185°C)				
9.	Optimum	High forming temp.* (140°C)	High sealing temp.* (205°C)	As per complete blister formed / rotation			Appearance of Blister, Horizontal Cutting & Vertical Cutting, Knurling, Coding Details on Blister, Leak test, Pocket Formation & Assay.
10.		Low forming temp. (120°C)	High sealing temp. (205°C)				
11.		High forming temp. (140°C)	Low sealing temp. (185°C)				
12.		Low forming temp. (120°C)	Low sealing temp. (185°C)				

***Sample shall be sent to QC for Assay analysis at this stage.**



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

5.4 PRODUCT DETAILS:

Product details of the dummy batches and over printing shall be verified from the BPR of the product and record in the following section:

Product Details

- A) **Product Name :** _____
Product Code : _____
Batch Number : _____
Batch Size : _____
Mfg. Date : _____
Exp. Date : _____
BPR Number : _____
- B) **Product Name :** _____
Product Code : _____
Batch Number : _____
Batch Size : _____
Mfg. Date : _____
Exp. Date : _____
BPR Number : _____



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

Overprinting Details:

A) **Batch No.** : _____
Mfg. Date : _____
Exp. Date : _____

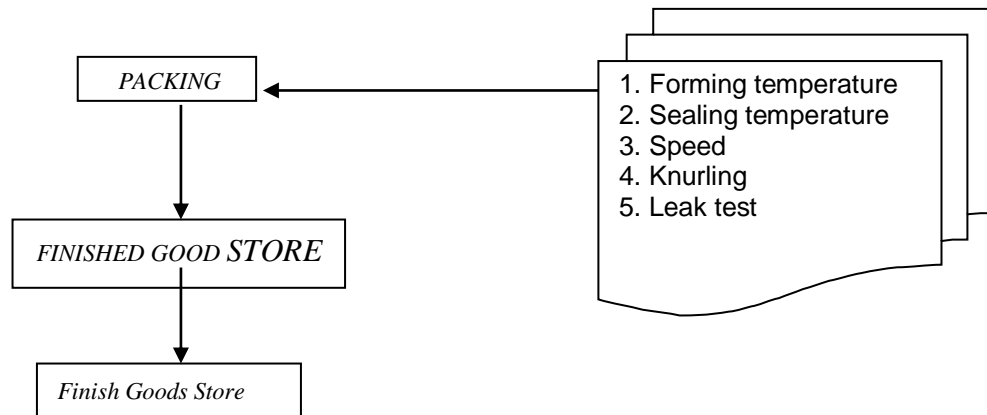
M.R.P. PER BLISTER OF **15** CAPSULES RS. **XX.XX** (INCL. OF ALL TAXES)

B) **Batch No.** : _____
Mfg. Date : _____
Exp. Date : _____

M.R.P. PER BLISTER OF **10** CAPSULES RS. **XX.XX** (INCL. OF ALL TAXES)

5.5 PROCESS FLOW DIAGRAM WITH QUALIFICATION PARAMETERS OF BLISTER PACKING MACHINE (EPI 2500):

Process flow diagram of Blister Packing Machine (EPI 2000) is mentioned below:





PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

5.6 SET PARAMETERS:

S.No.	Test	Specification
1.	Forming Temperature	130 ± 10°C
2.	Sealing Temperature	195 ± 10°C
3.	Horizontal Cutting	Should be proper
4.	Vertical Cutting	Should be proper
5.	Knurling	Should be legible
6.	Leak test	Should pass
7.	Coding Details on Blister	Should be proper
8.	Number of Stereo on drum	08 Nos.
9.	Air Pressure	NLT 6 Kg/cm ²
10.	Speed of Machine	45 ± 10 cuts/ minute

5.7 ACCEPTANCE CRITERIA:

The test will be considered failed if the actual test results do not correspond to the expected results as following:

- Horizontal Cutting should be proper.
- Vertical Cutting should be proper.
- Knurling should be proper.
- Coding Details on Blister should be proper.
- Leak Test should be pass.



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

5.8 RECORDING OF SAMPLING:

Date	Batch Number	Sampling Details			Quantity	Sampled By (Sign. & Date)
		Lay out No.	Speed	Parameters		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

Date	Batch Number	Sampling Details			Quantity	Sampled By (Sign. & Date)
		Lay out No.	Speed	Parameters		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		
				High forming & High Sealing Temperature		



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

Date	Batch Number	Sampling Details			Quantity	Sampled By (Sign. & Date)
		Lay out No.	Speed	Parameters		
				Low forming & High Sealing Temperature		
				High forming & Low Sealing Temperature		
				Low forming & Low Sealing Temperature		

Remark: -----

Reviewed by (Sign/Date)

5.9 OBSERVATIONS AND RESULTS OF CHALLENGE TESTS:

OBSERVATION				
MINIMUM BATCH SIZE				
Batch Number:		Change Part (Lay Out) Number:		
Speed	Minimum			
	Set:		Observed:	
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should				



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

be satisfactory)		
Knurling (Knurling should be satisfactory by visual inspection)		
Vertical Cutting (Cutting should be satisfactory by visual cuts)		
Horizontal Cutting (Cutting should be satisfactory by visual cuts)		
Assay		

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MINIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Minimum		
	Set:	Observed:	
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION				
MINIMUM BATCH SIZE				
Batch Number:		Change Part (Lay Out) Number:		
Speed	Maximum			
	Set:		Observed:	
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should be satisfactory)				
Knurling (Knurling should be satisfactory by visual inspection)				
Vertical Cutting (Cutting should be satisfactory by visual cuts)				
Horizontal Cutting (Cutting should be satisfactory by visual cuts)				
Assay				

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MINIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Maximum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MINIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Optimum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			
Assay			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MINIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Optimum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION				
MAXIMUM BATCH SIZE				
Batch Number:		Change Part (Lay Out) Number:		
Speed	Minimum			
	Set:		Observed:	
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should be satisfactory)				
Knurling (Knurling should be satisfactory by visual inspection)				
Vertical Cutting (Cutting should be satisfactory by visual cuts)				
Horizontal Cutting (Cutting should be satisfactory by visual cuts)				
Assay				

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Minimum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION				
MAXIMUM BATCH SIZE				
Batch Number:		Change Part (Lay Out) Number:		
Speed	Maximum			
	Set:		Observed:	
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should be satisfactory)				
Knurling (Knurling should be satisfactory by visual inspection)				
Vertical Cutting (Cutting should be satisfactory by visual cuts)				
Horizontal Cutting (Cutting should be satisfactory by visual cuts)				
Assay				

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Maximum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:		
Speed	Optimum			
	Set:	Observed:		
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should be satisfactory)				
Knurling (Knurling should be satisfactory by visual inspection)				
Vertical Cutting (Cutting should be satisfactory by visual cuts)				
Horizontal Cutting (Cutting should be satisfactory by visual cuts)				
Assay				

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Optimum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Minimum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)
	Set	Observed	Set
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			
Assay			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Minimum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)
	Set	Observed	Set
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Maximum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			
Assay			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Maximum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Optimum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			
Assay			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION				
MAXIMUM BATCH SIZE				
Batch Number:		Change Part (Lay Out) Number:		
Speed	Optimum			
	Set:		Observed:	
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should be satisfactory)				
Knurling (Knurling should be satisfactory by visual inspection)				
Vertical Cutting (Cutting should be satisfactory by visual cuts)				
Horizontal Cutting (Cutting should be satisfactory by visual cuts)				

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Minimum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual cuts)			
Horizontal Cutting (Cutting should be satisfactory by visual cuts)			
Assay			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:		
Speed	Minimum			
	Set:	Observed:		
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should be satisfactory)				
Knurling (Knurling should be satisfactory by visual inspection)				
Vertical Cutting (Cutting should be satisfactory by visual cuts)				
Horizontal Cutting (Cutting should be satisfactory by visual cuts)				

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION				
MAXIMUM BATCH SIZE				
Batch Number:		Change Part (Lay Out) Number:		
Speed	Maximum			
	Set:		Observed:	
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should be satisfactory)				
Knurling (Knurling should be satisfactory by visual inspection)				
Vertical Cutting (Cutting should be satisfactory by visual inspection)				
Horizontal Cutting (Cutting should be satisfactory by visual inspection)				
Assay				

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:		
Speed	Maximum			
	Set:	Observed:		
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should be satisfactory)				
Knurling (Knurling should be satisfactory by visual inspection)				
Vertical Cutting (Cutting should be satisfactory by visual inspection)				
Horizontal Cutting (Cutting should be satisfactory by visual inspection)				

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION				
MAXIMUM BATCH SIZE				
Batch Number:		Change Part (Lay Out) Number:		
Speed	Optimum			
	Set:		Observed:	
Parameters (Acceptance Criteria)	High forming temp. (140°C) & High sealing temp. (205°C)		Low forming temp. (120°C) & High sealing temp. (205°C)	
	Set	Observed	Set	Observed
Forming Temperature (130° ± 10°C)				
Sealing Temperature (195° ± 10°C)				
Physical Appearance (It should be satisfactory by visual appearance)				
Pocket Formation (should be satisfactory)				
Leak Test (There should be no any leakage)				
Coding Detail (Quality of overprinting / Embossing should be satisfactory)				
Knurling (Knurling should be satisfactory by visual inspection)				
Vertical Cutting (Cutting should be satisfactory by visual inspection)				
Horizontal Cutting (Cutting should be satisfactory by visual inspection)				
Assay				

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

OBSERVATION

MAXIMUM BATCH SIZE

Batch Number:		Change Part (Lay Out) Number:	
Speed	Optimum		
	Set:		Observed:
Parameters (Acceptance Criteria)	High forming temp. (140°C) & Low sealing temp. (185°C)		Low forming temp. (120°C) & Low sealing temp. (185°C)
	Set	Observed	Set Observed
Forming Temperature (130° ± 10°C)			
Sealing Temperature (195° ± 10°C)			
Physical Appearance (It should be satisfactory by visual appearance)			
Pocket Formation (should be satisfactory)			
Leak Test (There should be no any leakage)			
Coding Detail (Quality of overprinting / Embossing should be satisfactory)			
Knurling (Knurling should be satisfactory by visual inspection)			
Vertical Cutting (Cutting should be satisfactory by visual inspection)			
Horizontal Cutting (Cutting should be satisfactory by visual inspection)			

Note: Write satisfactory if parameters are complies with the acceptance criteria and not satisfactory if parameters do not comply the acceptance criteria.

Done By: _____

Date: _____

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

6.0 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)



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

7.0 PERFORMANCE QUALIFICATION FINAL REPORT:

7.1 SUMMARY:

7.2 CONCLUSION:

**Prepared By
Sign/ Date**

**Checked By
Sign/ Date**



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
BLISTER PACKING MACHINE (EPI-2500)**

PROTOCOL No.:

7.3 FINAL REPORT APPROVAL

The final report shall be signed after verifying that all the tests required in the qualification report of Blister Packing Machine (EPI 2500) are completed, reconciled and attached to the Qualification report or included in the qualification summary report and also verified that all amendments and discrepancies are documented, approved and attached to respective report (If applicable) Signature in the block below indicate that all items in the qualification report of Blister Packing Machine (EPI 2500) have been reviewed and found to be acceptable and that all variations or discrepancies (if any) have been satisfactorily resolved.

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