



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION PROTOCOL
FOR
ALU-ALU BLISTER PACKING MACHINE**

**PERFORMANCE QUALIFICATION
PROTOCOL
FOR
ALU-ALU BLISTER PACKING
MACHINE**

EQUIPMENT ID. No.	
LOCATION	Packing
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the ALU-ALU Blister Packing Machine (Make - Pampac) installed in the 'Packing'.
- This Protocol will define the methods and documentation used to qualify the Blister Packing Machine for PQ.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Authorization, Approval and Compilation of the Performance Qualification.• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.
Production	<ul style="list-style-type: none">• Review of Protocol.• To co-ordinate and support Performance Qualification Activity.
Engineering	<ul style="list-style-type: none">• Reviewing of qualification protocol for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Alu–Alu Blister Packing Machine
Equipment ID No.	
Manufacturer’s Name	Pampac
Model	BQS
Location of Installation	Packing

6.0 SYSTEM DESCRIPTION:

Functional Description

The Blister Packaging Machine; model BQS is designed to produce blisters as per approved blister format drawing. For the PVC blisters, the forming foil is heated, and the cavities are formed using compressed air through blowing plate. F-or ALU-ALU blisters, the cavities are formed with the help of compressed air through cylinder and forming plugs. The product is fed into the formed cavities. An aluminium lidding foil at sealing station seals the formed web. Blisters of the required size are cut with the help of the cutting tool.

The machine consists of following major stations and functions:

Forming foil rollmount

The forming Foil reel is mounted on the spindle provided at the left bottom side of the machine. Two spindles are provided in the machine; one reel is in a process and another is a standby to minimize the machine downtime.

The reel is mounted on two cones, one is fixed and the other is adjustable.

The reel position with respect to the front plate of the machine can easily be set with the knob according to format parts. The center of the Foil reel should be at 185mm from the front plate.

Forming foil splicing unit

Splicing unit is provided on the machine:

- To properly cut the forming Foil.
- To join the finish foil end with subsequent foil, start and.
- To clean the Foil with c leaning mat (using air pressure).

The clamping of foil is done mechanical clamps, which has rubber pad to clamp forming foil.

Forming foil unwinding station

This station is provided to unwind the forming Foil. A dancing lever and two sensors are provided



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to start and stop unwinding of the foil, which is driven by an induction motor. When dancing lever comes in front of upper sensor, it senses the lever and motor starts unwinding the foil. When dancing lever goes down, a down sensor senses the lever and motor stops unwinding the foil.

Forming foil joint scanner

After the unwinding station, a scanner is provided to check Foil joint. This scanner checks the Foil joint and gives the input to a control system to reject the blister.

Heating station

The heating station is provided to heat the thermoforming Foils i.e., PVC, PVC/PVDC, and Triplex before forming of the cavity. It consists of top and bottom heating plates. A Foil is heated to its plastic state by holding the Foil between two heating grates. The Heating plates are Teflon coated to avoid sticking of Foil to the plates.

Temperature required to heat these Foils are about 100°C to 130°C .

The pneumatic cylinders are mounted at front side of the machine to operate the top and bottom plates.

Forming station - thermoforming

In this station cavities are formed in the forming Foil as per specified layout. The heated forming Foil comes to the forming station. The Foil is continuously moving forward, and station is intermittently moving forward and backward. This station consists of bottom plate, top plate, bottom forming plate. Blowing plate and other pneumatic parts.

A hydraulic cylinder moves the bottom forming plate upward and the forming Foil clamped between top and bottom forming plates. These elates are mounted on moving plates that are guided by four pillars and bearings

Cavity formation takes place; by blowing air in case of PVC Foil or by plugs in case of ALU Foil.

A special pneumatic cylinder is provided to drive plugs to form the cavities in Aluminium Foil.

In case of ALU-ALU forming; plugs operated with multistage pneumatic cylinder. To generate the required force for formation of cavities in Aluminium Foil, a separate reservoir is provided. In case of PVC-ALU forming; cavities formed by the compressed air of pressure approximately 6 bars.

Top and bottom cooling plates are provided in between Forming and Blowing / Plug guide elates to cool the web after cavity formation. The temperature required to cool the web is about 8 to 16°C depending on the forming Foil to be processed, circulated through the cooling plates.



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Forming station-cold forming

This attachment is required in case of cold (Aluminium) forming film. This includes:

- Parts for Forming
- Multistage Pneumatic Cylinder
- Air Reservoir

Above mentioned parts help to generate force required to form the cavities in Aluminium foil which require more force as compared to PVC film.

Standard feeding system Feeding system consists of:

- A hopper that stores the product and feed to a linear vibrator by gravity.
- A linear Vibrator that transfers the product to the distributor plate.
- A rotary vibrator that feeds the product further to the feeding channel. A feeding sector is a change part provided to feed the products from the distributor plate to the feeding channel.

This sector has a slot to remove dust. Powder and chips from the product.

The feeding channel from a rotary vibrator to a guide plate changes depending on the type of product to be packed. This channel is classified as:

- Continuous feeding channel: This system is required for flat tablet, capsules etc.
- Spring type feeding channel: This system is required for DS tablet.

Drum feeding system

Product feeding in Aluminium formed web is critical because of cavity shape. Drum feeding system is used to feed the product in such cavities. Tablets from the distributor plate/rotary vibrator are transferred to the drum either through continuous or spring channels depending on tablets. If spring channels are used, then feeding shoe is provided to transfer the tablets on the drum.

Product is transferred into cavities by rotating drum. Drum cavities are synchronized with web cavities. This unit is driven by servo motor and it linked with MMI. This is suitable only for ALU/ALU forming Foil

Wiper brush

The wiper brush is provided to remove an excess product from the formed web. It is mounted after the dedicated feeding system.

A universal motor drives the rotating brush and *speed* controller controls its speed.

Lidding foil roll mount



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The lidding foil reel is mounted on a collet. It is locked with a nut on its fixed position. A dancing lever and two sensors are provided to start and stop unwinding of the foil, which is driven by a motor. When dancing lever comes in front of upper sensor. It senses the lever and motor starts unwinding the foil. When dancing lever goes down, a sensor senses the lever and motor stops. Another sensor is provided to monitor the foil presence. If the sensor does not sense the foil, it gives signal to PLC and machine stops.

Lidding foil joint scanner/PRC Scanner

After the unwinding station, a scanner is provided to check Foil joint. This scanner checks the Foil joint and gives the input to a control system to reject the blister. This scanner also works to check “Print Mark” on the lidding foil for PRC system.

Sealing station

This station is provided to seal the formed web with a lidding foil. The bidding foil can be Aluminium, paper or child proof foil. This station consists of bottom grate, toe plate, and bottom sealing plate, top sealing plate, heater plate and pneumatic parts.

Sealing is done in between the top and bottom sealing plate with hydraulic pressure. The formed web with product and lidding foil comes to the sealing station. A guide piece guides the formed web and lidding foil aligned with each other. A hot Sealing plate exerts pressure on the web and lidding foil to seal the web. Hydraulic power pack develops the pressure as per requirement. Temperature required for the seating is about 180 °C to 240 °C depending on format size, forming foil and lidding foil.

Note:

The initial temperature of the sealing will may vary by 15 to 20 degrees more or less than the set limit when the machine starts the first time in the morning or after power off for long duration. Starts the function of the machine after temperature steady to its set limit. In machine running temperature variation will be +/- 5 degree.

Cooling station

The cooling station is provided to cool the sealed web immediately after sealing. This station consists of the top plate, bottom plate and the change part cooling plate. The web is guided in between top plate and the change part cooling plate. The bottom plate is operated in every cycle and the pneumatic cylinder, which is operated by PLC, controls the operation.

Pulling station



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The pulling station is provided to pull the sealed web in continuous motion. The web is pulled by pulling roller and the thrust roller. The pulling roller is driven by servo motor. Speed of the servo motor is controlled by PLC program and parameters entered for blister format.

Web loop detection system

Web guide is provided to hold and align the sealed web properly before embossing and perforation station.

Loop Setting: Round disc used to hold and position the web. Position of this disc is adjustable with the square rod laterally according to the cavities on the web. It is adjustable with knob to rotate the disc around the stud. Main purpose of the loop adjuster is to adjust loop for NFD count. Web guide: Guides provided to guide the sealed web before embossing and perforation station.

Perforation station

In this station, perforation is done on a sealed web according to the blister layout. Assembly of perforation blade does this function. It consists of blade holding block, which is spring loaded and mounted on a fixed plate. A counter plate is mounted on a moving plate. A slit on the counter plate is used to guide the blade during perforation.

Embossing station

This station is provided to facilitate coding of useful information on a sealed web. The sealed web passes through the embossing tool; an adjustable web guide aligns the web before embossing. A spring-loaded clamp exerts a continuous pressure on the web. A Letter holder is mounted in the upper side and a counter tool is mounted on the bottom side. A moving plate with the counter tool forces the web against letters and code on the web.

Number of letters in embossing tool depends on blister size or requirement. Maximum 40 letters can emboss on per blister.

Indexing station

Indexing station consists of indexing roller that indexes the web in punch tool for cutting the blister. Indexing roller is designed as per cavity shape. A servomotor drives this roller, which are mounted on backside of the roller.

A sensor is provided to sense the web when the web gets jammed in punching station and loop formed in between punching and indexing roller. The sensor senses the sealed web and stops the machine.



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Punching station

In this station, punching tool cuts the Blisters as per the Blister layout. It consists of a punch and a die (cutting plate) that decides the blister shape. The punch is moving, and the die is fixed with guide pillar. A support plate is fixed on the die plate to guide the web in contact with the die for precise cutting. After Blister punching, another cutter fitted on bottom side of the moving elate, and then cuts whatever wastage left.

Punch speed depends on the blister layout and is in multiple of machine cycles. If one cycle consists of one blister, then ratio is 1:1, If one cycle consists of two blisters, punching speed is double (Number of tacks are not important).

Blister pickup station

The Blister pickup unit picks up the blisters from punching tool and drops them at different angles as per the requirement:

- 45⁰ : To reject the blisters and drop them inseparate collection bin
- 90⁰ : To accept and drop the blisters on the transfer conveyor
- 180⁰: To accept and drop the blisters in separate collection bin when downstream machine is not ready.

Blisters are picked up with suction cups mounted on the sucker arms. An air venturi generates the vacuum and it is connected to the sucker arms through a channel.

Blister Accept or Reject signal to pick up system is given through either NFD or Camera. Based on this signal, pick up unit drops the blister at above mentioned position.

Tower lamp

Tower lamp is installed on the top of the machine which shows the status of the machine in terms of running, stop, and ready mode. These lights blow with the hooter installed in the machine. The yellow light blows ON when the machine is ready to RUN. Green light blows ON when the machine is in running state. Red light blows ON when the machine stops due to any fault or error in the system.

Over printing unit

The printing unit is provided to print information like batch, manufacturing information and so on. This unit is installed before the sealing station. The printing is done on lidding foil at a pitch distance (depending on blister layout) to have print on every blister. The lidding foil is passed through a stereo roller and a pressure roller. Stereos are stuck on the stereo roller. An ink from the ink cartridge is transferred to the stereos and then from the stereos to the lidding foil



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The pressure between stereo roller and pressure roller can be adjusted with the help of knob to get sharp and clear printing.

7.0 REASON FOR QUALIFICATION:

- New equipment in Packing.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Packing.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every five years time period.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of Alu-Alu Blister Packing Machine
- Preparation of SOP for Preventive Maintenance of Alu-Alu Blister Packing Machine.

11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.



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- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Alu–Alu Blister Packing Machine (BQS).
- SOP for Preventive Maintenance Alu–Alu Blister Packing Machine (BQS).

Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

11.2 Evaluation of Performance Using Drug Products:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish documented evidence that the Alu-Alu Blister Packing Machine is performing consistently and the result of all test parameters meet the pre - defined acceptance criteria of sifted products.

11.2.1 Checks:

- Knurling Uniformity
- Sealing Temperature
- Perforation
- Leak Test
- Wrinkles
- Pin Holes
- Coding Imprint
- Cutting Edges
- Localized Overheating



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- Discoloration of Blister Pack
- Defective Tablets and blister detection by Camera.
- Rejection mechanism for defective blister packs.

11.2.2 Method:

- Install product specific change parts and foil in the machine.
- Load the product in the hopper of machine
- After attaining the required temperature perform initial run of machine without product to verify formed Blister packs initially.
- Perform packing of product using machine as per the product specific parameters of the machine.
- Perform checks on the packed Blister Packs.
- Record the observations for all the checks in the report.

11.2.3 Acceptance Criteria:

S.No.	TEST PARAMETER	ACCEPTANCE CRITERIA
1.	Knurling Uniformity	Should be Uniform
2.	Sealing Temperature	Should be within the range specified in BPR
3.	Perforation	Should be Uniform
4.	Leak Test	No pocket of Blister pack should show sign of leakage in the test
5.	Wrinkles	Should be absent
6.	Pin Holes	Should be absent
7.	Coding Imprints	Should be clear & legible
8.	Cutting Edges	Should be Uniform
9.	Localized overheating	Should be absent
10.	Discoloration of Blister Packs	Should be absent
11.	Defective Tablets and blister detection by Camera	Machine should effectively identify the defective tablet and blister packs
12.	Rejection mechanism for defective blister packs	Machine should effectively reject the defective tablet and blister packs



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12.0 CHECKLIST OF ALL TESTS AND CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of performance using Drug product.

13.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan
- Schedule-M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

14.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Operation and Maintenance Manual.

15.0 NON COMPLIANCE:

- All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.



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17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
mm	:	Millimetre
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
BMR	:	Batch Manufacturing Record
SOP	:	Standard Operating Procedure
RSD	:	Relative Standard Deviation
Sr.	:	Senior
Asst.	:	Assistant
EU	:	European Union