



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
ALU-ALU BLISTER PACKING MACHINE**

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
ALU-ALU BLISTER PACKING
MACHINE**

EQUIPMENT ID No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL CUM REPORT No.	NIL



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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
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1.0 PRE – 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 a documented evidence for the Installation Qualification of Alu–Alu Blister Packing Machine.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- To verify the critical dimensions of the unit and record Serial Numbers / Model Number of critical components.
- To verify that the correct hardware has been installed, system initializes correctly.
- To record the as-built drawing numbers of equipment drawing, P & ID and circuit diagram.
- To Calibrate Temperature and Pressure Measurements of Control System, Recorder, Gauges and displays.



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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 cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Initiation, Authorization, Approval and Compilation of the IQ Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• Co-ordination, Execution and technical support in Alu–Alu Blister Packing Machine Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Qualification Protocol cum Report after Execution



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5.0 EQUIPMENT DETAILS:

Equipment Name	Alu–Alu Blister Packing Machine
Equipment	
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 roll mount

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 cleaning 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 to start and stop unwinding of the foil, which is driven by an induction motor. When dancing lever



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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.

Forming station-cold forming

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

- Parts for Forming



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- 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

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.



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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 lidding 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 sealing 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

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



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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.

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



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



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Piping and instrumentation diagram (P& ID)
- Electrical circuits diagram
- Technical specification of equipment
- Calibration certificate of components
- Certificate of material of construction of components

7.1.1 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. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

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



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 VERIFICATION OF MAJOR COMPONENTS:

S. No.	Name of The Component	Technical Specification		Observation	Observed by Sign & Date
1.	Servo Motor for Main cam	Make Model	Mitsubishi Electric HG — SR1524B		
2.	Gear Box for Main cam	Make Model	Nidec Shimpo Corp VRL-12OB-45-K5-28HF24		
3.	Servo Motor Drum feeding	Make Model	Mitsubishi Electric HG — KR23		
4.	Gear box for Drum feeding	Make Model	Nidec Shimpo Corp VRSF-45C-14BK14		
5.	Motor for Base foil unwinding	Make Model	Panasonic M91X4OG4GGA		
6.	Gear box for base foil unwinding	Make Model	Panasonic MX9G20B		
7.	Motor for Wiper Brush	Make Model	Panasonic M91X4OG4GGA		
8.	Gear box for Wiper Brush	Make Model	Panasonic MX9G7.5B		
9.	Power Pack	Make S.No.	Zeon Enterprises U -758		
10.	Power Pack motor	Make Model	Hindustan Electrical Motors Type: 2KA2-123-0405		
11.	Servo Motor for Punching	Make Model	Mitsubishi Electric HG-SR1524		
12.	Gear Box for Punching	Make Model	Nidec Shimpo Corp NEVSH-9E-1500		
13.	Servo Motor for Printing	Make Model	Mitsubishi Electric HG — KR23		
14.	Gear box for Printing	Stake Type	Bonfiglioli VF44 P1 28 HS BE		
15.	Servo Motor for Pulling	Make Model	Mitsubishi Electric HG - KR2S		
16.	Gear Box for Pulling	Make Model	Nidec Shimpo Corp VRSF — 81C - 14BK14		
17.	Motor for Lidding foil unwinding	Make Model	Hindustan Electrical Motors Type: 2KA2 O63-O405		



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18.	Geared box for Lidding foil unwinding	Make Model	Bonfiglioli VF 30 P1 20 P63 BS B3		
19.	Pin Hole Detection System	Make Model	ACG Inspection PHD		
20.	Blister Inspection System	Make Model	ACG Inspection Qualishield BS10		

8.2 ELECTRONIC COMPONENTS:-

S. No.	Name of The Component	Technical Specification		Observation	Observed by Sign & Date
1.0	HMI	Make Model	Weintek Labs MT80 71iE		
2.0	PLC	Make Model	Mitsubishi Electric Q series		
3.0	Power supply for PLC	Make Model	Omron S8VK — C48024		
4.0	Power Supply for HMI	Make Model	Omron S8VK-C12024		
5.0	Linear vibrator controller	Make Model	CUH SDVC21-S		
6.0	Rotary vibrator controller	Make Model	CUH SDVC21-S		
7.0	Single Phase Preventer	Make Model	Omron K8AK — PM		
8.0	Servo Drive for Main cam Motor	Make Model	Mitsubishi Electric MR - J4 — 200B4		
9.0	Servo Drive for Punching Motor	Make Model	Mitsubishi Electric MR - J4 - 200B4		
10.0	Servo Drive for Pulling Motor	Make Model	Mitsubishi Electric MR - J4 — 20B		
11.0	Servo Drive for Printing Motor	Make Model	Mitsubishi Electric MR — J4 - 20B		
12.0	Servo Drive for Drum feeding motor	Make Model	Mitsubishi Electric MR - J4 - 20B		
13.0	Drive for Lidding foil unwinding motor	Make Model	Danfoss VLT		
14.0	Drives for Brush Box motors (02 Nos.)	Make Model	Danfoss VLT		



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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15.0	Transformer for Machine	Make	Chaitanya 415V, 50Hz		
16.0	Transformer for Vibrator	Make	Chaitanya 415V, 50Hz		
17.0	Perforation temperature Controller	Make Model	Electroquip DTC - 72 SR NO:		
18.0	Energy Meter	Make Model	RISH Delta Delta VAF SR NO: 1911066771		
19.0	Tower Lamp	Make Model	Schneider XVGB3S		
20.0	PLC Software	GX Works 2 Version 1.77F			
21.0	HMI Software Details	Easy Builder Pro VS.05			

8.3 IDENTIFICATION OF COMPONENTS OF CONTROL SYSTEM:

To identify the various components of the control system installed on the machine.

S. No.	Name of Components	Function of Components	Observation	Observed By Sign & Date
1.	Main Switch	To switch ON and OFF the power supply		
2.	HMI	To operate the machine		
3.	PLC	To operate the function through HMI		
4.	Pressure Regulators	To supply required air by regulators		
5.	Pressure Switch	To indicate low air pressure		
6.	Lidding foil motor controller	To control the speed of lidding foil motor		
7.	Linear vibrator controller potentiometer knob on operating panel	To control the vibration of linear vibrator assembly for better product flow		
8.	Rotary vibrator controller potentiometer knob on operating panel	To control the vibration of rotary vibrator assembly for better product flow		
9.	Brush box motor speed control potentiometer knob on operating panel.	To control the speed of motor to achieve feeding efficiency as per BF drawing		



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8.4 GENERAL CHECKS AND LOCATION SUITABILITY:

Installation Checks	Acceptance Criteria	Observation	Observed By Sign & Date
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Packing-01		
Room Condition	General working condition		
Illumination in area	Above 200 Lux inside the cubicle		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Verified By
Sign & Date:

8.5 EQUIPMENT VERIFICATION:

Installation Checks	Acceptance Criteria	Observation	Observed By Sign & Date
Equipment	Alu-Alu Blister Packing Machine		
Model	BQS		

ELECTRICAL INSTALLATION:

Electrical Supply	AC, 3 Phase + N + E Voltage- 380 V (\pm 6%) Frequency- 50 Hz		
Compressed Air	Pressure : 6 kg/cm ² (Bar) Flow rate : 200 Liter/min Velocity : 30 CFM		
Cooling Water Requirement	Temperature: Approx 8 to 22°C Flow Rate: 15 to 20 Liters/min.		

Verified By
Sign & Date:



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8.6 INSTALLATION CHECKS:

S. No.	Specification	Observation	Observed By Sign & Date
1.	Check the proper mechanical installation of Alu – Alu Blister Packing Machine.		
2.	Check the proper electrical installation of Alu – Alu Blister Packing Machine.		
3.	Check the parts are working properly.		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of product contact parts.		
6.	Check that all parts are properly lubricated.		

Verified By

Sign & Date:

8.7 MOC VERIFICATION LIST:

S. No	Component	MOC	Observation	Observed By Sign & Date
1.	Product hopper	SS 316 L		
2.	Linear vibrator tray	SS 316 L		
3.	Distributor plate	SS 316 L		
4.	Guide Block for Drum Feeding	Alloy Temper 63400 (HE9) WP		
5.	Perforated Sheet	SS 316 L		
6.	Stiffener Plate	Alloy 6082 T6		
7.	Rubber for Hopper	Silicon		
8.	Wiper Brush	Nylon		

Verified By

Sign & Date:



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8.8 VERIFICATION OF SENSORS AND ALARM SYSTEMS:

Description of test	Message displayed on HMI	Result of test	Observation
An Emergency stop activated on control panel	Emergency stop	The machine will stop immediately	
An Emergency stop activated at Indexing	Emergency stop	The machine will stop immediately	
Manually disable Vacuum key from HMI	Vacuum Key Off	The machine will stop at cycle end / will not start	
Disturb the Web on indexing	Indexing fault	The machine will stop at cycle end.	
Manually disable Heater key from HMI	Heater Key Off	The machine will stop at cycle end / will not start	
Reduce the main air pressure less than 4 bar (Switch off main air supply)	Low Air Pressure	The machine will stop at cycle end.	
Low temperature of forming Top plate (15 ⁰ C less than set temperature)	Forming Top Low Temperature	The machine will stop at cycle end / will not start	
High temperature of forming top plate (15 ⁰ C more than set temperature)	Forming Top High Temperature	The machine will stop at cycle end / will not start	
Manually open the Thermocouple connector of forming top plate	Forming top thermocouple open	The machine will stop at cycle end / will not start	
Low temperature of forming Bottom plate (15 ⁰ C less than set temperature)	Forming Bottom low Temperature	The machine will stop at cycle end / will not start	
High temperature of forming bottom plate (15 ⁰ C more than set temperature)	Forming bottom high temperature	The machine will stop at cycle end / will not start	
Manually open the Thermocouple connector of forming bottom plate	Forming bottom thermocouple open	The machine will stop at cycle end / will not start	
Low temperature of Sealing Top plate (15 ⁰ C less than set temperature)	Sealing Low Temperature	The machine will stop at cycle end / will not start	
High temperature of sealing top plate (15 ⁰ C more than set temperature)	Sealing High Temperature	The machine will stop at cycle end / will not start	
Manually open the thermocouple connector of sealing top plate	Sealing thermocouple open	The machine will stop at cycle end as per time	
High temperature of chiller water (less than set temperature in the machine setting, basic cam-water chiller)	Chiller High Temperature	The machine will stop at cycle end.	
Manually of the water chiller supply while machine is running	Low Water Flow	The machine will stop at cycle end.	



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Manually open machine guard while machine is in RUN mode	Guard Open	The machine will stop at cycle end.	
Manually trip MCB (7,8,9,17,22) inside control cabinet	Heater MCB	Machine should not start/ Should stop	
Machine homing not done	Homing Not Done	Machine will not start	
Start the machine & Block the pneumatic connection to Sealing station side lock. Stop the machine by pressing 'Machine OFF ' push button	Sealing Top unlock SW 1 Fail Sealing Left unlock SW 3 Fail	Sealing station does not go to the home position	
Block the pneumatic connection and Start the machine	Sealing Side Lock (L) SW 4 Fail	Sealing station not ready & Machine will not start	
Block the pneumatic connection and Start the machine	Sealing Side Lock (R) SW 6 Fail	Sealing station not ready & Machine will not start	
Start the machine & Block the pneumatic connection to Sealing station side lock. Stop the machine by pressing 'I machine OFF push button	Sealing Top Unlock SW1 Fail Seating Side unlock (R) SW 5 Fail	Sealing station does not go to the home position	
Start the machine & Block the pneumatic connection to Sealing station Top lock. Stop the machine by pressing 'Machine OFF ' gush button	Sealing Top Unlock SW1 fail	Sealing station does not go to the home position	
Block the pneumatic connection and Start the machine	Sealing Top lock SW2 fail	Sealing station not ready & Machine will not start	
Manually disturb the eye mark on the foil	Print Mark Out of Band	Machine wilt stop at cycle end	
Continuous print mark missing	Print Mark Missing	Machine will stop at cycle end. after 5 cycles	
Base foil end (No web) (manually take out foil)	Base foil end	Machine will stop at cycle end.	
Lidding foil end (No Foil) (Manually take out the Foil }	Lidding foil end	Machine will stop at cycle end.	
Loop sensor ON tog & bottom in running	Web Loop Sensor	Machine will stop at cycle end.	
Manually enable Camera key from HMI when camera system is not ready	Camera System Not Ready	Machine will stop / will not start	
Manually enable Pin hole key from HMI when Pin Hole system not ready	Pin Hole System Not Ready	Machine will stop / will not start	

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**Verified By
Sign & Date:**



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Inference:

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Reviewed By
Sign & Date:

9.0 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC
- Calibration Certificates

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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.....

12.0 CHANGE CONTROL, IF ANY:

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
ALU-ALU BLISTER PACKING MACHINE**

13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
ALU-ALU BLISTER PACKING MACHINE**

16.0 ABBREVIATIONS:

Sr.	:	Senior
No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
cGEP	:	Current Good Engineering Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
Amp.	:	Ampere
MOC	:	Material of Construction
NLT	:	Not less than
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
PLC	:	Programmable logical control
ID	:	Identification
Kg	:	Kilo gram
Ltrs	:	Liters
mm	:	Millimeter
MCB	:	Miniature Circuit Breaker
MMI	:	Man Machine Interface
PVC	:	Poly Vinyl Chloride
BLM	:	Blister Packing Machine
LPM	:	Liter Per Minute
SNPS	:	Switch Mode Power Supply



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ALU-ALU BLISTER PACKING MACHINE**

17.0 POST- APPROVAL:

PREPARED 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)			