



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

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

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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1.0 PROTOCOL PRE – 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)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification document for Alu-Alu Blister Packing Machine on the basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in the designing of equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Alu-Alu Blister Packing Machine (Make: ACG Pampac) .
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



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4.0 RESPONSIBILITY:

The Validation Group, comprising of representatives 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 and Approval of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Post Approval of Qualification Protocol cum Report after Execution
Engineering	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures.➤ Details of utilities required.➤ Identification of components for calibration➤ Material of construction of Product Contact Parts➤ Brief Process Description➤ Safety Features and Alarms• Review of Qualification Protocol cum Report after Execution.



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5.0 BRIEF EQUIPMENT 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. For 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.

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 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 plates. The Heating plates are Teflon coated to avoid sticking of Foil to the plates. Temperature required to heat these Foils are about 1000C to 1300C.

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



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➤ **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 plates 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 plates to cool the web after cavity formation. The temperature required to cool the web is about 8 to 160C 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
- 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:
 1. Continuous feeding channel: This system is required for flat tablet, capsules etc.
 2. Spring type feeding channel: This system is required for DS tablet.



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➤ **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.

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 plate, top 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 1800C to 2400C depending on format size, forming foil and lidding foil.

Note:



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The temperature of the sealing will vary UP TO 15 degrees more or less than the set limit when the machine starts and stop during the machine operation. Starts the function of the machine after temperature steady to its set limit. The temperature variation may vary for format part to format part based on the size, maximum temperature variation is up to 20 degree. 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 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.



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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 plate, 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:

- 45°: To reject the blisters and drop them in separate collection bin
- 90°: To accept and drop the blisters on the transfer conveyor
- 180°: 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



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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.

➤ **Print registration control (PRC) system:**

The print mark control system is designed to halt specially printed lidding foils in a fixed position relative to the formed web and blister cavities during production process. For this purpose, position of print mark and hence the position of lidding foil is sensed by colon sensor. The position of the lidding foil is corrected by cyclic adjustment of foil feed.

Print mark scanner is continuously monitoring the eye mark on the lidding foil. The Print registration mark is provided on the Aluminium foil between each adjacent blister format {indexing stroke}.

These marks are sensed by scanner while the lidding foil is moving towards the sealing station.

Whenever the pre-printed matter lags the formed cavities, the extra accumulated foil is pulled by additional speed given to a pulling roller. It is done by servo motor. The speed of motor can be increased/decreased for the adjustment of mark as per the requirement.



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6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

S.No.	Parameter	Specification
1.	Machine type	Flat Forming Flat Sealing Blister Packaging Machine
2.	Machine size	Refer Machine Layout (W0910003628Z-000)
3.	Machine weight (Net)	Approximately 3830 Kg
4.	Machine weight (Gross)	Approximately 4830 Kg
5.	Forming area	240 x 180 mm
6.	Forming depth	• Up to 12 mm for PVC forming foil (thermoforming) • Up to 9 mm for ALU forming foil (Cold forming)
7.	Forming speed	Up to 8.1 meters per minute
8.	Forming cycles	• Up to 45 Cycles per minute for thermoforming foils. • Up to 35 Cycles per minute for cold forming foils
9.	Roll diameter (PVC Foil)	Maximum: 400 mm
10.	Roll diameter (Lidding foil)	Maximum: 250 mm
11.	Ambient temperature range	18° to 30°C
12.	Noise level	80 dB (approx.) at 1 meter
13.	Suitable humidity range for the machine	45 to 60% RH
14.	Punching cycles	Max. 180 cycles per minute

6.1 FOIL SPECIFICATION:-

S. No.	Name of The Component	Technical Specification
Forming Foil		
1.0	Material	<ul style="list-style-type: none">• PVC• PVC /PVDC• ACLAR• PVC /PE /PVDC• Cold form base foil
2.0	Thickness	Maximum 350 micron, Minimum 250 micron
3.0	Width	Maximum 252 mm
4.0	Roll diameter	Maximum 400 mm
Lidding Foil		
5.0	Material	<ul style="list-style-type: none">• Push through (Alu)• Peelable (Paper)• Child Resistant (CR)



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6.0	Thickness	<ul style="list-style-type: none">• 20 to 30-micron aluminium foil• Standard paper & CR foils
7.0	Width	Maximum 246 mm
8.0	Roll Diameter	Maximum 250 mm

6.2 AUTOMATION & CONTROL SYSTEM:

6.2.1 USER INTERFACE (OPERATING PANEL):

6.2.1.1 HARDWARE FEATURES:

- 600Mhz Processor, 256MB memory
- 7-inch touch screen for screen access.
- Data history limited by memory.
- 24V DC isolated with or without UPS (optional).

6.2.1.2 SOFTWARE FEATURES:

Access Security

- Password-protected individual user accounts.
- System consist three user levels (Operator, Supervisor & Admin)
- System can store around 20 recipes
- Alarm log available limited as per memory.

6.2.2 AUTOMATION UNIT (PLC)

A PROGRAMMABLE LOGIC CONTROLLER (PLC) is an industrial computer control system that continuously monitors the state of input devices and makes decisions based upon a custom program to control the state of output devices. (Q170MSCPU)

- Motion Controller
- Build in 24VDC power supply
- CPU standard memory is 8K Bytes and multiple CPU high speed transmission area is 32K Bytes
- Program capacity 30K steps (120K Bytes)
- LD instruction processing speed is 0.02
- Flat surface mounting
- Password access protection
- Communication speed for SSCNET III is 50Mbps and for SSCNET III/H is 150Mbps
- Number of control axes is up to 16 axes.
- Servo program capacity 16k step
- ROM operation function provided



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- Total no. of instructions is 858
- Constant scan time is 0.5 to 2000ms (Setting available in 0.5ms unit)

6.2.3 USER MATRIX AND ACCESS LEVEL:

S.No.	Privileges Rights	Operator	Supervisor	Administrator
Home				
1.	Forming Bottom	No	Yes	Yes
2.	Forming Top	No	Yes	Yes
3.	Sealing	No	Yes	Yes
4.	Speed	Yes	Yes	Yes
Function Keys				
5.	Keys	Yes	Yes	Yes
6.	Blister Accept Blister Reject Camera	No	Yes	Yes
		No	Yes	Yes
		No	Yes	Yes
7.	Special Function • Default Parameter • Add NFD	No	Yes	Yes
		No	Yes	Yes
		No	Yes	Yes
8.	PRC	Yes	Yes	Yes
9.	Power Fail Correction	Yes	Yes	Yes
10.	Temperature Trend	Yes	Yes	Yes
Machine Setting				
11.	Basic Cams	No	Yes	Yes
12.	Cyclic Cams	No	Yes	Yes
13.	User Cams	No	Yes	Yes
14.	Universal Cams	No	Yes	Yes
15.	Timers	No	Yes	Yes
16.	Recipe	No	Yes	Yes
17.	Manual Mode	No	Yes	Yes
System Setting				
18.	Login	Yes	Yes	Yes
19.	Factor	No	No	Yes
20.	HMI Setting	No	No	Yes
21.	Change Password (option)	No	No	Yes



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Alarms / Events				
22.	Alarm	Yes	Yes	Yes
23.	Events	Yes	Yes	Yes
24.	Servo error	Yes	Yes	Yes
25.	Buzzer Ack	Yes	Yes	Yes
26.	Reset	Yes	Yes	Yes
Monitor				
27.	Shift Array	Yes	Yes	Yes
28.	PLC Input	Yes	Yes	Yes
29.	PLC Output	Yes	Yes	Yes
30.	Rejection Counter Reset	No	Yes	Yes
31.	Servo Status	Yes	Yes	Yes
32.	Rejection Status	Yes	Yes	Yes

6.2.4 ENERGY METER:

The energy meter is fitted on the rear side of the control cabinet. It measures electrical parameters like AC Voltage, AC current, Frequency, Active, Reactive, Apparent Power, Import and Export energy and more. This meter shows the voltage and current supplied readings to forming bottom heater, forming top heater and sealing heater which helps to calculate the power consumption of the heaters. If any of the heater trips, the values turn to zero and will be known by. The instrument stores minimum and maximum values for system voltage, system current, Run Hour, ON Hour and number of interrupts. Every 60 Sec stored values are updated. In case of power failure, the instrument memorizes the last energy count. Every 1 min, the instrument updates the energy counter in the non-volatile memory.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:



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Critical Variables	Acceptance Criteria	Reference
Application: The machine should be able to Pack the Tablets & Capsules in laminated materials PVC/PVDC, Aluminium Foil considering all aspects of packing process.	Blister packing should meet the requirement for Tablet & Capsules Packing.	Process Requirement
Working: Working of Blister Packing Machine	Blister Packing Machine should capable to pack the various sizes and shape of tablets and capsules in PVC/PVDC or Alu Alu Foil.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical supply	3 Phase ,415V + 5 % ,50Hz	Design Requirement
Power consumption	19 kW max	Design Requirement
Incoming cable	5 Core x 4 mm' Copper Cable	Design Requirement
Compressed air pressure	4-6 bar	Design Requirement
Compressed air consumption	30 CFM @ 4-6 bars with Air venture	Design Requirement
Water chiller capacity	9000 kcal/Hour Flow Rate: 15 to 20 Liters / minute	Design Requirement
Chilled water temperature range	<ul style="list-style-type: none">PVC: 14 to 20⁰CPVDC: 8 to 10⁰C	Design Requirement

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

7.3.1 MECHANICAL & ELECTROMECHANICAL COMPONENTS:-



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S. No.	Name of The Component	Technical Specification	
1.	Servo Motor for Main cam	Make Model / Specification	Mitsubishi Electric HG – SR1524B Input: 3AC, 236V, 4.7A Output: 1.5kW, 9.3Kg, 2000RPM
2.	Gear Box for Main cam	Make Model	Nidec Shimpo Corp VRL-120B-45-K5-28HF24
3.	Servo Motor Drum feeding	Make Model / Specification	Mitsubishi Electric HG – KR23 Input: 3AC, 119V, 1.3A Output: 200W, 0.91Kg, 3000RPM
4.	Gear box for Drum feeding	Make Model	Nidec Shimpo Corp VRSF-45C-14BK14
5.	Motor for Base foil unwinding	Make Model	Panasonic M91X40G4GGA
6.	Gear box for Base foil unwinding	Make Model	Panasonic MX9G20B
7.	Motor for Wiper Brush	Make Model	Panasonic M91X40G4GGA
8.	Gear box for Wiper Brush	Make Model	Panasonic MX9G7.5B
9.	Power Pack	Make Sr. No.	Zeon Enterprises U 788
10.	Power Pack motor	Make Model/ Specification	Hindustan Electrical Motors Type: 2KA2-123-0405 Rating: 3 Phase, 415V, 50Hz, 3.7kW, 5.0HP, 7.1A, 1445RPM
11.	Servo Motor for Punching	Make Model / Specification	Mitsubishi Electric HG – SR1524 Input: 3AC, 236V, 4.7A Output: 1.5kW, 7.3Kg, 2000RPM
12.	Gear Box for Punching	Make Model	Nidec Shimpo Corp NEVSH-9E-1500
13.	Servo Motor for Printing	Make Model / Specification	Mitsubishi Electric HG – KR23 Input: 3AC, 119V, 1.3A Output: 200W, 0.91Kg, 3000RPM
14.	Gear box for Printing	Make Type	Bonfiglioli VF44 P1 28 HS B3



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15.	Servo Motor for Pulling	Make Model / Specification	Mitsubishi Electric HG – KR23 Input: 3AC, 119V, 1.3A Output: 200W, 0.91Kg,3000RPM
16.	Gear Box for Pulling	Make Model	Nidec Shimpo Corp VRSF – 81C – 14BK14
17.	Motor for Lidding foil unwinding	Make Model / Specification	Hindustan Electrical Motors Type: 2KA2 063-0405 Rating: 415V, 50Hz, 0.18kW, 0.25HP, 0.57A, 1380 RPM
18.	Geared box for Lidding foil unwinding	Make Model	Bonfiglioli VF 30 P1 20 P63 B5 B3

7.3.2 ELECTRONIC COMPONENTS:-

S. No.	Name of The Component	Technical Specification	
1.0	HMI	Make Model	Weintek Labs MT8071iE
2.0	PLC	Make Model / Specification	Mitsubishi Electric Q series Q170MSCPU, Q61P, QX81, QY80, QY80, QY80, QY80, Q64TCTTN
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



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12.0	Servo Drive for Drum feeding motor	Make Model	Mitsubishi Electric MR – J4 – 20B
13.0	Drive for bidding foil unwinding motor	flake Model / Specification	Danfoss VLT (Micro Drive) Rating : 0.37 kW, 0.5 HP
14.0	Drives for Brush Box motors (02 Nos.)	Make Model / Specification	Danfoss VLT (Micro Drive) Rating : 0.37 kW, 0.5 HP
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	lectroquip DTC – 72 SR NO: 2007-0025
18.0	Energy Meter	Make Model	RISH Delta Delta VAF SR NO: 2006021077
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	

7.3.3 PNEUMATIC COMPONENTS:

S.No.	Name of The Component	Technical Specification	
1.0	Vacuum venturi for Blister pickup	Make Model	Festo VN-30-H-T6-PQ4-VQ5-R02-M
2.0	Air pressure switch	Make Model	Orion EX-7
3.0	Pneumatic cylinder for main cam	Make Model	Pneumax 1396.50.150.01 PNXSPP
4.0	Pneumatic cylinder for heating station top	Make Model	Pneumax 1581.32.25.01.1 PNXSPP
5.0	Pneumatic cylinder for heating station bottom	Make Model	Pneumax 1581.32.30.25.B PNXSPP
6.0	Pneumatic cylinder for sealing station side locks (02 Nos.)	Make Model	Festo ADVU-25-50-A-P-A
7.0	Pneumatic cylinder for sealing station top	Make Model	Festo ADVC 40-25 I-P-A
8.0	Pneumatic cylinder for cooling station	Make Model	Pneumax 1501.63.5 PNX SFM 10



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9.0	Pneumatic cylinder for foil brakes (03 Nos.)	Make Model	Festo AEVC-20-5-I-P
10.0	Pneumatic cylinder for Indexing Flap	Make Model	Pneumax 1280.25.50.M

7.3.4 LIST OF SENSOR:-

S. No.	Name of The Component	Technical Specification	
1.0	Switch for base foil end (Lever type)	Make Model	Telemecanique XCJI27
2.0	Sensor for Base foil dancing lever (02 Nos.)	Make Model	Pepperl + Fuchs NBB4-12GM50-E2
3.0	Sensors for Lidding foil dancing lever (02 Nos.)	Make Model	Pepperl + Fuchs NBB4-12GM50-E2
4.0	Scanner for Base foil joint	Make Model	Pepperl + Fuchs DK20-9,5/110/124
5.0	Sensor for Drum feeding motor homing	Make Model	Pegeerl + Fuchs NBB4-12GM50-E2
6.0	Water Flow Switch	Make Model	IFM SI-S000
7.0	Sensor for Main Cam motor homing	Make Model	Pepperl + Fuchs NBB5-18GM50-E2
8.0	Sensor for Product level on distributor plate	Make Model	IFM KB 5004
9.0	Sensor for Hopper low level check	Make Model	IFM KB S002
10.0	Scanner for bidding foil joint & PRC eye mark	Make Model	Pepperl + Fuchs DK20-9,5/JJO/J24
11.0	Sensor for bidding foil end	Make Model	IFM OJ 5148
12.0	Sensor for Indexing fault	Make Model	Pepperl + Fuchs NBB5-18GM50-E2
13.0	Loop sensor for sealed foil web bottom side	Make Model	IFM KG 5043
14.0	Loop sensor for sealed foil web tog side	Make Model	IFM KG 5043
15.0	Sensor for Punching motor homing	Make Model	Pepperl + Fuchs NBB5-18GM50-E2
16.0	Sensor for Printing motor homing	Make Model	Pepperl + Fuchs NBB5-18GM50-E2
17.0	Guard Switches (06 Nos. }	Make Model	Telemecanique XCJ-110



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18.0	Thermocouple sensor for forming top plate	Make Sr. No	Yog Electro Process 19111279
19.0	Thermocouple sensor for forming Bottom plate	Make Sr. No	Yog Electro Process 19111281
20.0	Thermocouple sensor for sealing tog plate	Make Sr. No	Yog Electro Process 19111272
21.0	Thermocouple sensor for embossing / perforation	Make Sr. No	Yog Electro Process 20020409
22.0	Thermocouple sensor for water chiller	Make Sr. No	Yog Electro Process 20030927

7.3.5 COMPONENTS FOR CALIBRATION:-

S. No.	Name of The Component	Make	Accuracy	Operating range
1.0	Vacuum gauge for vacuum Pump	Festo	±3 %	-30 to 0 In Hg
2.0	Pressure gauge for Blister Pickup	Pneumax	±3 %	0 to 10.6 Kg/cm ²
3.0	Pressure gauge for Flap on indexing roller	Pneumax	±3 %	0 to 10.6 Kg/cm ²
4.0	Pressure gauge for Cooling station bottom cylinder	Pneumax	±3 %	0 to 10.6 Kg/cm ²
5.0	Pressure gauge for Sealing station side lock cylinders	Pneumax	±3 %	0 to 10.6 Kg/cm ²
6.0	Pressure gauge for Sealing station top plate cylinder	Pneumax	±3 %	0 to 10.6 Kg/cm ²
7.0	Pressure gauge for Foil Brake vertical movement cylinder	Pneumax	±3 %	0 to 10.6 Kg/cm ²
8.0	Pressure gauge for Foil Brake horizontal movement cylinder	Pneumax	±3 %	0 to 10.6 Kg/cm ²
9.0	Pressure gauge for Main air supply	Pneumax	±3 %	0 to 12 Bar
10.0	Pressure gauge for Cooling plate	Pneumax	±3 %	0 to 12 Bar
11.0	Pressure gauge for Main cam cylinder	Pneumax	±3 %	0 to 10.6 Kg/cm ²
12.0	Pressure gauge for Product stopper for dedicated feeding	Pneumax	±3 %	0 to 10.6 Kg/cm ²
13.0	Pressure gauge for Heating plate short stroke cylinder	Pneumax	±3 %	0 to 10.6 Kg/cm ²
14.0	Pressure gauge for Heating station Top & Bottom plate cylinders	Pneumax	±3 %	0 to 10.6 Kg/cm ²
15.0	Pressure gauge for S. S. Feeding channel	Pneumax	±3 %	0 to 12 Bar
16.0	Pressure gauge for Air reservoir tank	Pneumax	±3 %	0 to 12 Bar
17.0	Pressure gauge for Power Pack Main Pressure	MASS	±1.6 %	0 to 280 Kg/cm ²
18.0	Pressure Gauge for Accumulator	MASS	±1.6 %	0 to 280 Kg/cm ²
19.0	Oil Temperature gauge	SHREEJI	±2 %	0 to 100 °C



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7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction	Area (CM ²)
1.	Product hopper	SS 316 L	6320
2.	Linear vibrator tray	SS 316 L	1414
3.	Distributor plate	SS 316 L	5310
4.	Guide Block for Drum Feeding	Alloy Temper 63400 (HE9) WP	443
5.	Perforated Sheet	SS 316 L	480
6.	Stiffener Plate	Alloy 6082 T6	902
7.	Rubber for Hopper	Silicon	60
8.	Wiper Brush	Nylon	668

7.5 SAFETY FEATURES:-

- Safety interlocks are provided for:
 - The Acrylic guards.
 - The safety switches are provided for protection from the moving parts. In case any of the above are opened in run mode the machine will immediately stop
- Emergency switches are provided at common working places of the machine viz. On the HMI box and on guarding above punching station.
- Safety interlocks have been provided for doors.
- All the electrical components. Which are having high voltage, are covered with proper cover.
- API the electrical / electronic components are mounted in a fully enclosed cabinet. This provides proper safety from live parts.
- API components are having proper earthing
- Operator accessible area i.e. HMI, console, safety interlocks, switches and sensors etc. Operating at 24 V DC supply.
- MCB's are provided to avoid over current situation.

7.5.1 SAFETY COMPONENTS:-

S. No.	Safety Components	Location
1.	Emergency Stop Switch (02 Nos.)	On HMI & Near Punching
2.	Power ON (Push Button)	On Control cabinet door
3.	Power OFF (Push Button)	On Control cabinet door
4.	Main Switch (Isolator)	On Control cabinet door



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5.	MACHINE ON (Push Button)	On Operating Panel
6.	MACHINE OFF (Push Button)	On Operating Panel
7.	Guard Switches (06 Nos.)	On safety guards

7.5.2 SAFETY FEATURES AND ALARM IN RUN MODE:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Tower Light	Mounted on top of machine for emergency operation. Yellow Light: Machine is made ON Green Light: Glow when machine is running Red Light: Emergency stop push button has been pressed.	Safety Requirement
PVC Film Limit switch Breaker	Limit switch provided to stop the operation at a time of PVC absence.	Safety Requirement
EMERGENCY STOP Push Button	EMERGENCY STOP Push Button provided at approachable distance for safety of machine and operator	Safety Requirement
Vacuum key OFF from HMI	Vacuum key OFF from HMI Push Button provided at approachable distance for safety of machine and operator	

7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Blister Packing Machine	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowledge, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) User Requirement Specifications (URS).

(2) Design & Functional Specifications provided by Vendor.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ALU-ALU BLISTER PACKING MACHINE

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ALU-ALU BLISTER PACKING MACHINE

12.0 ABBREVIATIONS:

URS	:	User Requirement Specification.
cGMP	:	Current Good Manufacturing Practice
Ltd.	:	Limited
QA	:	Quality Assurance
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
STD	:	Standard
VFD	:	Variable Frequency Drive
PLC	:	Programmable Logical Control
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo Watt
SS	:	Stainless Steel
HMI	:	Human Machine Interface
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



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR ALU-ALU BLISTER PACKING MACHINE

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			