

 <b>HLL Biotech Limited</b> <small>(Subsidiary of HLL Lifecare Limited)  (A Government of India Enterprise)</small>	<b>USER REQUIREMENT SPECIFICATIONS</b>	
	<b>Equipment/ System/ Utility</b>	<b>BLISTER PACKING MACHINE</b>
	<b>Document No</b>	<b>HBL/URS/19-006</b>

**USER REQUIREMENT SPECIFICATION**

**FOR**

**BLISTER PACKING MACHINE**

<b>Block Code</b>	<b>Area</b>	<b>Equipment ID</b>	<b>Quantity</b>	<b>Capacity</b>
P1	Secondary packaging	-	1 no	Min 200 vials /ampoules per min or Min 40 Blister packs with 5 Vials/Ampoules in each pack

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## 1. APPROVALS

Department	Name	Designation	Signature	Date
<b>Prepared By</b>				
Process Engineering	HARIPRASAD.M.S	Deputy Manager-Process Engineering		15-05-2019
<b>Reviewed By</b>				
PROCESS ENGINEERING	J. PANNEERSELVAM	DM - PROCESS ENGINEERING		16-05-2019
PRODUCTION	B.SATHESH	SM - PRODUCTION		17-05-2019
PRODUCTION	G. NARASIMHA REDDY	DGM - PRODUCTION		17-05-2019
Quality Assurance	Vinothkumar.K	DM - QA		18-05-2019
		NA 		18-05-2019
<b>Approved By</b>				
Quality Assurance	R. Jaya Kandan	Sr. Manager		18-05-2019

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## 2. USER REQUIREMENT SPECIFICATIONS

S.NO	PARAMETERS
<b>1.0</b>	<b>Equipment Description</b>
	<p>The blister packing machine suitable for the packing of vials/ Vials/ ampoules. This machine model should be CE certified and is designed according to cGMP guidelines.</p> <p>Machine can handle Forming material like PVC, PVC/PVDC, PVC/PE/PVDC, ACLAR, PP, COC (Cyclic Olefin Copolymer) and Sealing material-ALU, Paper foil laminate, CR Materials, PP. The blister packaging machine shall be equipped with appropriate feeding device, viz conveyor followed by a turntable for smooth movement and to provide positive pressure to the vials/ampoule.</p> <p>The machine shall be equipped with misfeed device to divert the path of those blisters, which are not filled/packed as per the preset condition. The machine shall be equipped with safety guards for avoiding human injury. The blister machine shall be designed for easy manual cleaning &amp; material movement The unit must belong to standard GMP design. The unit shall be designed for fail-safe condition.</p>
<b>1.1</b>	<b>Preferable Stations:</b>
	<ul style="list-style-type: none"> <li>a) Unwinding film station</li> <li>b) Base foil splicing station</li> <li>c) Heating station</li> <li>d) Forming (Web) station</li> <li>e) Feeding machine</li> <li>f) Inspection station</li> <li>g) Sealing/ cooling Station</li> <li>h) Over printing (Batch details) station</li> <li>i) Web pulling station</li> <li>j) Bar and QR code Application and Reader (optional)</li> <li>k) Punching &amp; perforation station</li> <li>l) Pick Up station</li> </ul>
<b>2.0</b>	<b>Process / Operational Requirement</b>
	<ul style="list-style-type: none"> <li>a) Forming Material: PVC, PVC/PVDC, PVC/PE/PVDC, Polypropylene, PETG, Aclar &amp; COC.</li> <li>b) No of Tracks: Single track</li> <li>c) Forming cycles &amp; Speed: Thermoforming</li> <li>d) Output: Min 200 vials / minute (40 blister packs per min, each pack contains 5 vials/Ampoules)</li> <li>e) Fill area (from the machine front): 800mm</li> <li>f) Noise level: below 70db at a distance of 1m from the equipment</li> </ul>

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S.NO	PARAMETERS
<b>2.1</b>	<b>Purpose of the equipment</b>
	Blister packing machine is used for pack the Vials/ ampoules.
<b>2.2</b>	<b>Process Description</b>
	<p>The Vials/ ampoules which are in trays, to be loaded into the inlet chute of blister packaging machine. The films will be un-winded from the reel lock &amp; made to pass through the heating plate followed by forming (Heat and Vacuum) as per the desired pattern the blister to form grooves, where the Vials/ ampoules shall be placed. There shall be continuous blowers to take away the heat from the forming area.</p> <p>The Vials/ ampoule in inlet chute shall pass through orientor &amp; retainer (auto feeding device), which shall arrange to retain the Vials/ ampoules in the preset pattern, before being placed in the formed blisters. The Vials/ ampoules shall be placed in the grooves of the blisters, followed by sealing by lidding foil from blister pack.</p> <p>The entire web of blister packs shall be coded. (Batch No., mfg date &amp; exp date etc.) The indexing &amp; trimming mechanism then cuts each blister from the web, followed by trimming of the blister edges. The misfiled mechanism shall check crack/Pinhole in blister for preset number &amp; placement arrangement of Vials/ ampoules. In case of deviation the misfiled mechanism shall divert the path of such blister to rejects. The discharge from the blister packaging machine shall be fed to an inclined conveyor and table.</p>
2.2.1	<b>Effluent/Drainage:</b> The chilled water will be circulated for cooling of heating mechanism in the forming tool.
2.2.2	<b>Machine Description :</b>
	<p>2.2.1.1 Base Reel Holder: - The reel to be mounted on a shaft which shall have two guide rings fixed by knob</p> <p>2.2.1.2 Base Material Draw: - The function of drawing material from the base film reel during each machine cycle, so that the indexing of film through the machine is without any mechanical tension at the reel end Assembly.</p> <p>2.2.1.3 Splicing Table Assembly: -This facilitates the splicing of the base film, which conveniently grips and maintains the alignment of the two ends of the films to be joined. A knife or cutter can be used to cut the web manually &amp; a slot to facilitate slitting is provided in the unit along with splice detection sensor.</p> <p>2.2.1.4 Base Film Detection Sensor: -This sensor detects the presence of base film, and will stop the machine in normal mode if the base film is absent or over.</p> <p>2.2.1.5 Pre-Heater Platen Assembly: - This consists of Upper &amp; Lower preheating platen &amp; lifting is done by the pneumatic cylinder arrangement for top pre-heating platen assembly, the upper and lower assembly shall be made of Non-sticky material (Preferably Teflon).</p>

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S.NO	PARAMETERS
2.2.1.6	Web lock assembly: - To lock the film and to maintain tension on the film by means of mechanical braking system.
2.2.1.7	Forming Station: -This is CAM Operated Station, Forming will take place using plug assist. The lower forming die is cooled by placing it on top of a cooling plate with chilled water circulation through it.
2.2.1.8	Inspection system: Inspection system is capable of detecting missing product/broken or crushed product
2.2.1.9	Blister Guide Support: - After forming (i.e. web coming out of the forming die is perfectly supported vertically, and also guided sideways) i.e., it is necessary to guide the web perfectly as otherwise it can come out wavy, affecting the sealing and punching operations.
2.2.1.10	Grip & Pull Forming: - This is driven by a servo motor. This group is to index the web by required advance.
2.2.1.11	Solid guide track support: - It provides basic support to all the change parts required in the filling zone of the machine, the MOC of track shall be preferably Delrin and the side track shall be adjustable to accommodate all the vial/Ampoule sizes.
2.2.1.12	No Form No Fill: - If cavities are not being well-formed, sensor to be available to sense and reject those blisters
2.2.1.13	Safety Flap (For product out of Pocket: - Safety flap is mounted on the machine after Product Feeding Zone. It shall be made up of S.S.304.This flap is continuously sensed by a safety magnetic sensor. If product does not seat correctly in to the Blister Cavity, then machine will stop with alarm.
2.2.1.14	Feeding of Vials/ Ampoule: This is assembly which feeds Vials/ ampoule from an infeed conveyor into the formed cavities
2.2.1.15	Lidding Foil Reel Holder: This assembly fixed on the machine vertical plate and supports the lidding foil reel.
2.2.1.16	Sealing + cooling station: Sealing station is CAM Operated station where web and the lidding foil to be brought together at entry to the sealing station (heat and pressure) with Cooling Plate Unit
2.2.1.17	Lidding Foil Splice Detection: This sensor to detects the splice in the lidding foil. Packs with Splice will be rejected at exit of machine.
2.2.1.18	Print Registration Control (Eye mark): -This centres the printing matter on Blister by stretching foil to correct length of cutting advance.
2.2.1.19	Batch details Printing: - To print batch Number on the foil with the help rubber/metal stereo. printing station capable of embossing 1.57 mm or 2mm characters must be incorporated. Minimum of 5 rows with minimum of 10 characters and stereos must be explained and be readily mountable if required in the future or during routine changeovers.
2.2.1.20	Perforation Station: - This is CAM operated station. Alternately, a perforation tool can be attached in the station (Single unit perforation).

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	<p>2.2.1.21 Camera inspection system (Optional): Inspection system to be available for monitoring the QR/Bar code/ Text matter in the Blisters</p> <p>2.2.1.22 Punching station: This is a cam-operated station. Punching tool (Change Part) can be slided into these plates.</p> <p>2.2.1.23 Inline Conveyor Packs after punching to be dropped to Inline conveyor, rejected packs to be diverted to rejection bin. control measures to be in place for mix up of good and rejected blisters packs, Rejection confirmation sensors are equipped which senses the rejected/good packs.</p>
<b>2.3</b>	<b>Type of material handled</b>
	Vials / Ampoules
<b>2.4</b>	<b>Desired outcome from the Equipment.</b>
	The minimum output should be 200 vials /min. There should be 40 blister pack per min in which each blister should contain 5 vials.
<b>2.5</b>	<b>Expected Operational Hours per day/Shift.</b>
	Continuous operation
<b>2.6</b>	<b>Operational Control Requirements.</b>
	<p>The following minimum options available in the Machine but not limited to,</p> <p>2.6.1 On/Off button</p> <p>2.6.2 Form bottom plate temperature – Set and actual</p> <p>2.6.3 Form top plate temperature – Set and actual</p> <p>2.6.4 Sealing heater temperature – Set and actual</p> <p>2.6.5 Perforation heater temperature – Set and actual</p> <p>2.6.6 Chiller temperature – Set and actual</p> <p>2.6.7 Machine speed strokes per minute – Set and actual</p> <p>2.6.8 Cutting station delay timer</p> <p>2.6.9 Display the number of good blister packed on the machine</p> <p>2.6.10 Display the number of rejected blister packed and its reasons on the machine.</p> <p>2.6.11 Display the total time for which the machine has run up to till time</p>
<b>2.7</b>	<b>Batch data display and record printing</b>
	<p>The batch data display/report shall consist of minimum following information's,</p> <p>2.7.1 Batch details (Batch No, Date, start time, end time, running hours)</p> <p>2.7.2 Counts (Infeed/Good/rejection units)</p> <p>2.7.3 Alarm/Events</p>

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<b>3.0</b>	<b>Equipment Requirement</b>
<b>3.1</b>	<b>Specification for the Material of Construction.</b>
	3.1.1 Surface finish –SS 304 3.1.2 Control panels / installations located in service areas 3.1.3 Suitable MOC to comply with EHS requirements. 3.1.4 Material and surface finish of parts not in contact with the product 3.1.5 Outer surface finish of stainless materials in classified rooms shall be mirror polished. 3.1.6 The outer surface finish shall be of easily cleaning type
<b>3.2</b>	<b>Type of finish</b>
	The contact surface finish shall be electro polish, Scotch brite finish.
<b>3.3</b>	<b>Integration of the equipment</b>
	Stand alone
<b>3.4</b>	<b>Functional Specific Requirements.</b>
	<p>The following minimum options available in the Machine but not limited to,</p> 3.4.1 Vacuum – Enable and disable key 3.4.2 Heater – Enable and disable key 3.4.3 Seal – Enable and disable key 3.4.4 Blister – Enable and disable key 3.4.5 Blister Reject – Enable and disable key 3.4.6 Blister conveyor – Enable and disable key 3.4.7 Camera – Enable and disable key 3.4.8 Perforation/Embossing – Enable and disable key 3.4.9 Foil break – Enable and disable key 3.4.10 Suitable controls for the camera inspection system shall be part of the same HMI or will be provided in a separate HMI.
<b>3.5</b>	<b>Required Utilities / Available Utilities.</b>
	3.5.1 Electrical supply: Single Phase (220 V) & 3 Phase (420 – 440 V) 3.5.2 Chilled water: 6-7 °C (Supply) ,11-12 °C (return) 3.5.3 Cooling water: 30 – 35 °C @ 26 m <sup>3</sup> / hr 3.5.4 Compressed air: 8 to 10 bar ,10CFM 3.5.5 Ideal working temperature: 22- 25 °C 3.5.6 RH: not more than 55%
<b>3.6</b>	<b>Regulatory and GMP requirement</b>
	The equipment shall be built, certified in accordance with all applicable EU directives, The equipment shall be validated and used in accordance with cGEP requirements.

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<b>3.7</b>	<b>Safety Requirements.</b>
	<p><b><u>Safety features interlock &amp; alarms</u></b></p> <p>3.7.1 Base foil end sensor</p> <p>3.7.2 Lidding foil end</p> <p>3.7.3 Sensor for base foil low level</p> <p>3.7.4 Loop sensor for base foil unwinding</p> <p>3.7.5 Sensor for base foil joint &amp; lidding foil joint</p> <p>3.7.6 Safety alarms</p> <p>3.7.7 Operating air pressure low</p> <p>3.7.8 Emergency stop</p> <p>3.7.9 Eye mark</p> <p>3.7.10 Door guards open/close</p> <p>3.7.11 Low chilled water flow rate/ Pressure</p> <p>3.7.12 Machine over speed alarm</p> <p>3.7.13 Camera inspection alarms</p> <p>3.7.14 Pharmacode /OCR/barcode related error (Optional)</p> <p>3.7.15 Pinhole</p> <p>3.7.16 Motor overload</p> <p>3.7.17 Utility Low water flow, Heaters OFF</p> <p>3.7.18 Web slipping at punching/ Cutting station</p> <p>3.7.19 Low temperature - Forming top plate / Forming bottom plate / sealing / Cooling water / Perforation blade</p> <p>3.7.20 High temperature - Forming top plate/ Forming bottom plate / sealing/ Cooling water/ Perforation blade</p> <p>3.7.21 Vacuum pump On/Off</p>
<b>3.8</b>	<b>Sanitary Requirements.</b>
	<p>The blister packaging machine shall be designed with an accent on cleanliness &amp; easy accessibility to all parts to ensure easy maintenance and cleaning for changeover. The equipment shall be easily accessible for manual cleaning of the outside surfaces.</p>
<b>4.0</b>	<b>Documentation requirements</b>
	<p>4.1 Two sets of operation and maintenance manuals</p> <p>4.2 Design qualification and functional specifications confirming compliance with requirements specified in the URS.</p> <p>4.3 Detailed drawings, specifications for Blister formats</p> <p>4.4 Manufacturer component certificates</p>

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	4.5 Material Test certificates for components 4.6 List of sensors, measuring devices that require calibration along with calibration procedure and calibration records during first supply. 4.7 Complete set of cGMP qualification documentation –DQ, FAT, IQ, OQ and PQ protocol preparation and execution in supplier scope. 4.8 Software CD/DVDs to be provided 4.9 Training material and certificates for operators, maintenance engineers.																																				
<b>5.0</b>	<b>List of Annexures</b>																																				
<b>5.1</b>	<b>Material Dimensions and Pack layout</b>																																				
	<p><b>a. Vials</b></p> <table border="1"> <thead> <tr> <th>S.No</th> <th>Description</th> <th>2R- ISO 8362-1 (in mm)</th> <th>4R - ISO 8362-1 (in mm)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Body Diameter - d1</td> <td>15.80 to 16.20</td> <td>15.80 to 16.20</td> </tr> <tr> <td>2</td> <td>Neck Diameter -d2</td> <td>12.70 to 13.20</td> <td>12.70 to 13.20</td> </tr> <tr> <td>3</td> <td>Neck inner diameter -d4</td> <td>06.80 to 07.20</td> <td>06.80 to 7.20</td> </tr> <tr> <td>4</td> <td>Total height -h1</td> <td>34.5 to 35.50</td> <td>44.50 to 45.50</td> </tr> </tbody> </table> <p><b>b. Ampoule size: ISO 1ml,2ml and 5ml</b></p> <p>Form- B type, Circular break ring type, Standardized quality level according to ISO</p> <table border="1"> <thead> <tr> <th>Nominal Volume (ml)</th> <th>Dia (mm)</th> <th>Length (form b, flame cut) mm</th> <th>Wall thickness (mm)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>10.60 -10.90</td> <td>59-61</td> <td>0.50 ± 0.3</td> </tr> <tr> <td>2</td> <td>10.60 -10.90</td> <td>70-73</td> <td>0.50 ± 0.3</td> </tr> <tr> <td>5</td> <td>12.50 -13.00</td> <td>80-85</td> <td>0.55 ± 0.3</td> </tr> </tbody> </table> <div style="text-align: center;">  </div> <p align="center"><b>IMAGES FOR REPRESENTATION PURPOSE ONLY</b></p>	S.No	Description	2R- ISO 8362-1 (in mm)	4R - ISO 8362-1 (in mm)	1	Body Diameter - d1	15.80 to 16.20	15.80 to 16.20	2	Neck Diameter -d2	12.70 to 13.20	12.70 to 13.20	3	Neck inner diameter -d4	06.80 to 07.20	06.80 to 7.20	4	Total height -h1	34.5 to 35.50	44.50 to 45.50	Nominal Volume (ml)	Dia (mm)	Length (form b, flame cut) mm	Wall thickness (mm)	1	10.60 -10.90	59-61	0.50 ± 0.3	2	10.60 -10.90	70-73	0.50 ± 0.3	5	12.50 -13.00	80-85	0.55 ± 0.3
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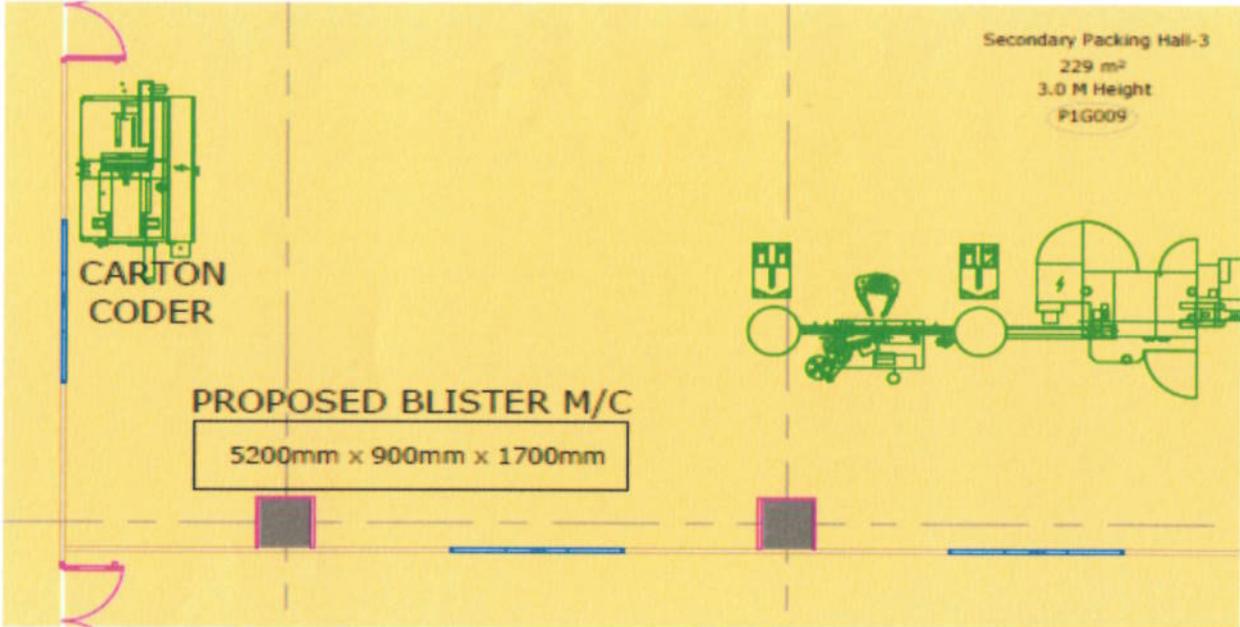
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5.2	<p><b>Room layout</b></p>  <p style="text-align: right;">Secondary Packing Hall-3 229 m<sup>2</sup> 3.0 M Height P1G009</p> <p style="text-align: center;"><b>CARTON CODER</b></p> <p style="text-align: center;"><b>PROPOSED BLISTER M/C</b> 5200mm x 900mm x 1700mm</p> <p style="text-align: center;"><b>Block name : Secondary Packaging</b> <span style="float: right;"><b>Block Code : P1</b></span></p>																																																			
5.3	<p><b>List of Preferred makes</b></p> <table border="1"> <thead> <tr> <th>S.No</th> <th>Description</th> <th>Make</th> </tr> </thead> <tbody> <tr> <td><b>A</b></td> <td><b>INSTRUMENTATION</b></td> <td></td> </tr> <tr> <td>1.</td> <td>PLC / HMI</td> <td>Allen Bradley / Siemens</td> </tr> <tr> <td>2.</td> <td>Operational Interface</td> <td>Allen Bradley / Siemens</td> </tr> <tr> <td>3.</td> <td>Temperature transmitter / controller</td> <td>Radix / Yokagawa / Emerson / Waree</td> </tr> <tr> <td>4.</td> <td>Pressure transmitter</td> <td>Siemens / Wika</td> </tr> <tr> <td>5.</td> <td>Photocell sensor</td> <td>Optex / Metler / Panasonic /</td> </tr> <tr> <td>6.</td> <td>DC Source</td> <td>Shavison / Yokagava / Emerson</td> </tr> <tr> <td>7.</td> <td>Printer</td> <td>Epson / HP / Canon</td> </tr> <tr> <td>8.</td> <td>MCB</td> <td>Siemens / ABB</td> </tr> <tr> <td><b>B</b></td> <td><b>MECHANICAL</b></td> <td></td> </tr> <tr> <td>1.</td> <td>Air filter regulator-L</td> <td>Festo / Janitics</td> </tr> <tr> <td>2.</td> <td>Manual ball valve</td> <td>President / Modentic / L &amp; T</td> </tr> <tr> <td>3.</td> <td>Pressure Gauge</td> <td>Wika / Forbes marshall / Waree</td> </tr> <tr> <td>4.</td> <td>Non return valve</td> <td>Alfa laval /Modentic</td> </tr> <tr> <td>5.</td> <td>Pneumatic valves / Angle seat valve</td> <td>Gemu / Emerson / Rotex</td> </tr> <tr> <td>6.</td> <td>Solenoid Valve</td> <td>Burkett / Festo /</td> </tr> </tbody> </table>	S.No	Description	Make	<b>A</b>	<b>INSTRUMENTATION</b>		1.	PLC / HMI	Allen Bradley / Siemens	2.	Operational Interface	Allen Bradley / Siemens	3.	Temperature transmitter / controller	Radix / Yokagawa / Emerson / Waree	4.	Pressure transmitter	Siemens / Wika	5.	Photocell sensor	Optex / Metler / Panasonic /	6.	DC Source	Shavison / Yokagava / Emerson	7.	Printer	Epson / HP / Canon	8.	MCB	Siemens / ABB	<b>B</b>	<b>MECHANICAL</b>		1.	Air filter regulator-L	Festo / Janitics	2.	Manual ball valve	President / Modentic / L & T	3.	Pressure Gauge	Wika / Forbes marshall / Waree	4.	Non return valve	Alfa laval /Modentic	5.	Pneumatic valves / Angle seat valve	Gemu / Emerson / Rotex	6.	Solenoid Valve	Burkett / Festo /
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2.	Manual ball valve	President / Modentic / L & T																																																		
3.	Pressure Gauge	Wika / Forbes marshall / Waree																																																		
4.	Non return valve	Alfa laval /Modentic																																																		
5.	Pneumatic valves / Angle seat valve	Gemu / Emerson / Rotex																																																		
6.	Solenoid Valve	Burkett / Festo /																																																		