



**PHARMA DEVILS**

PRODUCTION DEPARTMENT

**USER REQUIREMENT SPECIFICATION**

**NAME OF ITEM:** PAD PRINTING MACHINE

**PROTOCOL No.**.....

**FUNCTIONAL AREA:** PRODUCTION

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**USER REQUIREMENTS SPECIFICATION  
FOR  
[PAD PRINTING MACHINE]**



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### 1.0 General Information

<b>Name of Equipment/Instrument/System/Model/Make</b>	Pad printing machine/ Tamprint-60/Parle global technologies.
<b>Brief description about the configuration of equipment/instrument/system</b>	<ul style="list-style-type: none"> <li>➤ Pad printing machine is used to print logo, name or symbol on sugar coated tablets.</li> <li>➤ Compact, robustly constructed, height adjustable operating handle with adjustable brush drive.</li> <li>➤ Wet scrubbing &amp; vacuuming.</li> <li>➤ Tanks shall be emptied quickly &amp; easily through outlet hose.</li> <li>➤ All operational switches shall be within direct view and easy reach of operator.</li> <li>➤ Clean &amp; dirty water tanks shall be leak proof.</li> </ul>
<b>Quantity Required</b>	01 No.
<b>Purpose of the equipment (Specific application)</b>	For effective cleaning of floors in production area.

### 2.0 User Requirements

S.No.	Parameters	Requirements Specification
2.1	<b>Material of construction of components/ accessories</b>	Vendor has to confirm the material of construction of components/accessories.
2.2	<b>Specification of equipment/instrument/ system at the installation site</b> <ul style="list-style-type: none"> <li>➤ Width</li> <li>➤ Length</li> <li>➤ Height</li> </ul>	Vendor has to confirm the Dimensions.
2.3	<b>Description of Accessories</b> <ul style="list-style-type: none"> <li>➤ List of Accessories</li> <li>➤ Dimensions</li> </ul>	Vendor has to confirm the list of accessories & dimensions.
2.4	<b>Location Suitability</b> <ul style="list-style-type: none"> <li>➤ Installation Space</li> <li>➤ Operational Space</li> </ul>	NA NA



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S.No.	Parameters	Requirements Specification
2.5	<b>Details of utilities required</b>	
	<ul style="list-style-type: none"> <li>➤ Air, Water, Nitrogen, Hydrogen etc.</li> <li>➤ Compressed air, steam</li> <li>➤ Electrical supply</li> </ul>	<p>NA</p> <p>NA</p> <p>230AC / 50Hz</p>
2.6	<ul style="list-style-type: none"> <li>➤ Spike guards</li> <li>➤ UPS back up system</li> <li>➤ Air conditioning / HVAC</li> <li>➤ Air grade of specific class</li> </ul>	<p>NA</p> <p>NA</p> <p>HVAC</p> <p>Hygiene class D - 1,00,000</p>
	<ul style="list-style-type: none"> <li>➤ Temperature</li> <li>➤ Humidity</li> <li>➤ LUX level at working place</li> <li>➤ Noise level in decibels</li> </ul>	<p>25°c±2°c</p> <p>40 ±10%</p> <p>NA</p> <p>Very low noise level</p>
	<ul style="list-style-type: none"> <li>➤ Fully Automatic (PLC based etc.)</li> <li>➤ Semi Automatic</li> <li>➤ Manual</li> </ul>	<p>NA</p> <p>Semi Automatic</p> <p>NA</p>
	<ul style="list-style-type: none"> <li>➤ Max. Operating capacity</li> </ul>	<p>Vendor has to conform the maximum operating capacity.</p>
2.9	<b>Safety</b>	
	<ul style="list-style-type: none"> <li>➤ Personnel safety</li> <li>➤ Environmental hazard if any</li> </ul>	<p>No person shall be allowed to work on the machine unless the person has been fully trained.</p> <p>NA</p>
2.10	<b>Speed</b>	
	<ul style="list-style-type: none"> <li>➤ RPM</li> <li>➤ Operational speed</li> </ul>	<p>Brush speed –Minimum 280 rpm</p> <p>Up to 4km/hr.</p>
2.11	<b>Nature of products to be handled</b>	NA



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S.No.	Parameters	Requirements Specification
2.12	<b>Cleaning process parameters to be controlled</b> <ul style="list-style-type: none"> <li>➤ Clean in Place</li> <li>➤ Manual Cleaning</li> <li>➤ Water, Detergents, Solvents</li> <li>➤ Cleaning procedure</li> </ul>	NA All parts shall be easily accessible for washing. Manual cleaning using water, detergents. Cleaning procedure shall be provided.
2.13	<b>Critical process parameters to be controlled</b> <ul style="list-style-type: none"> <li>➤ Critical process parameters</li> <li>➤ Control procedure</li> </ul>	NA NA
2.14	<b>Power failure and recovery</b> <ul style="list-style-type: none"> <li>➤ Probability</li> <li>➤ Recovery procedure</li> </ul>	NA NA
2.15	<b>Emergency stop</b> <ul style="list-style-type: none"> <li>➤ Provision for emergency stop</li> </ul>	Provision shall be provided.
2.16	<b>Alarm warning</b> <ul style="list-style-type: none"> <li>➤ Indication of abnormality in operation</li> </ul>	Equipment shall be normal in operation.
2.17	<b>Data security</b> <ul style="list-style-type: none"> <li>➤ Data storage</li> <li>➤ Data integrity</li> <li>➤ Data retrieval</li> </ul>	NA NA NA
2.18	<b>Constraints</b> <ul style="list-style-type: none"> <li>➤ Timelines</li> <li>➤ Delivery</li> </ul>	To be delivered at the following site of ....., within 4 to 6 weeks from the date of approved Purchase Order. .....
2.19	<b>Maintenance</b> <ul style="list-style-type: none"> <li>➤ Procedure</li> <li>➤ Frequency</li> </ul>	The preventive Maintenance schedule shall provides a guideline for periodic servicing
2.20	<b>Computer Configuration</b> <ul style="list-style-type: none"> <li>➤ Details of configuration through computer software</li> </ul>	N.A



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S.No.	Parameters	Requirements Specification
2.21	<b>Computer Hardware &amp; Software Requirement</b> <ul style="list-style-type: none"><li>➤ Hard disk storage capacity</li><li>➤ Compatible software with specific version</li><li>➤ 21 CFR part 11 compliant software</li></ul>	NA NA N.A
2.22	<b>User License Requirement</b> <ul style="list-style-type: none"><li>➤ Availability of sufficient licenses for used dept.</li></ul>	Sufficient licenses shall be available with user dept.
2.23	<b>Commissioning and Documentation</b> <ul style="list-style-type: none"><li>➤ Availability of the Engineer/s at the time of commissioning</li><li>➤ Availability of IQ, OQ, PQ protocols at the time of commissioning</li></ul>	<ul style="list-style-type: none"><li>➤ Factory – In house test certificate.</li><li>➤ Instruction, operation and maintenance manual.</li><li>➤ Material of construction certificate</li><li>➤ Motor details and ratings.</li><li>➤ Electrical wiring diagram</li></ul> <p>All the certificate shall be collected from vendor.</p>
3.0	<b>Training</b> <ul style="list-style-type: none"><li>➤ Consent for training as and when required to user dept.</li></ul>	Supplier to train the respective persons of ..... on Operation, Maintenance and Cleaning of the equipment, wherever applicable
4.0	<b>Reference documents</b> <ul style="list-style-type: none"><li>➤ Operating manual</li><li>➤ Technical manual</li><li>➤ Trouble shooting manual</li><li>➤ Test certificates</li><li>➤ Calibration certificates</li></ul>	Supplier shall provide all the Reference Documents.



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### 5.0 Abbreviations:

Acronym	Definition
RPM	Rotation per minute.
HVAC	Heating Ventilation & Air Conditioning
RH	Relative Humidity



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This document has been prepared by User department, reviewed by Engineering and safety, approved by Quality Assurance, Unit Head and authorized by Functional Head. This document shall be sent to supplier / vendor for his acceptance.

### APPROVALS

PREPARED BY: \_\_\_\_\_ DATE: \_\_\_\_\_  
(USER DEPARTMENT)

REVIEWED BY: \_\_\_\_\_ DATE: \_\_\_\_\_  
(ENGINEERING / SAFETY)

APPROVED BY: \_\_\_\_\_ DATE: \_\_\_\_\_  
(QUALITY ASSURANCE)

APPROVED BY: \_\_\_\_\_ DATE: \_\_\_\_\_  
(UNIT HEAD)

AUTHORIZED BY: \_\_\_\_\_ DATE: \_\_\_\_\_  
(FUNCTIONAL HEAD {CORPORATE})

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ACCEPTED BY: \_\_\_\_\_ DATE: \_\_\_\_\_  
(NAME, STAMP & SIGNATURE OF  
SUPPLIER / VENDOR)