



**PHARMA DEVILS**

PRODUCTION DEPARTMENT

**USER REQUIREMENT SPECIFICATION**

**NAME OF ITEM:** Carton Printing Machine

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

**FUNCTIONAL AREA:** Production

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**USER REQUIREMENT SPECIFICATION  
FOR  
[CARTON CODING MACHINE]**



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### 1.0 General Information

Name of Equipment / Instrument / System / Model / Make	Carton coding machine.
Brief description about the configuration of equipment / instrument / system	<ul style="list-style-type: none"><li>➤ Carton coding machine is used to print uniform coding details on all types of cartons including lock bottom type &amp; catch covers.</li><li>➤ Design of the machine shall comply as per cGMP standards.</li><li>➤ Design of the machine shall include mechanisms like automatic carton feeding, accurate printing and ejection of printed cartons.</li><li>➤ Machine shall be provided with efficient carton feeding, legible printing system and use of rubber stereo letters for easy adjustment. .</li></ul>
Quantity Required	02 No.
Purpose of the equipment (Specific application)	For effective over printing of coding details like Batch No.Mfg.Dt, Exp.Dt, MRP etc on all types of cartons & catch covers.

### 2.0 User Requirements

Sr. No	Parameters	Requirements Specification
2.1	<b>Material of construction of components/ accessories</b>	Vendor has to confirm the material of construction of all 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.



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Sr. No	Parameters	Requirements Specification
2.4	<b>Location Suitability</b> <ul style="list-style-type: none"> <li>➤ Installation Space</li> <li>➤ Operational Space</li> </ul>	Length (L) X Width (W) X Height (H) = 5.00 m X 5.20 m X 3.00 m  NA
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>	NA NA 440V / 3 Phase
	<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>	NA NA HVAC Unclassified
2.6	<b>Environmental condition at installation site</b> <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>	NA NA NLT 300 LUX NMT 80 DB
2.7	<b>Level of Automation</b> <ul style="list-style-type: none"> <li>➤ Fully Automatic (PLC based etc.)</li> <li>➤ Semi Automatic</li> <li>➤ Manual</li> </ul>	Automatic NA NA
2.8	<b>Capacity and use</b> <ul style="list-style-type: none"> <li>➤ Max. Operating capacity</li> <li>➤ Output capacity</li> </ul>	250 cartons per minute.  Vendor has to confirm the maximum output capacity.
2.9	<b>Safety</b> <ul style="list-style-type: none"> <li>➤ Personnel safety</li> <li>➤ Environmental hazard if any</li> </ul>	The machine shall be designed to carry basic safety standards. Safety guards with interlock shall be provided.  NA



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Sr. No	Parameters	Requirements Specification
2.10	<b>Speed</b> <ul style="list-style-type: none"><li>➤ RPM</li><li>➤ Operational speed</li></ul>	NA Vendor has to confirm the min & max operational speed.
2.11	<b>Nature of products to be handled</b>	All types of cartons & catch covers.
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 the parts shall be easily accessible for cleaning. Manual cleaning using lint free cloth/solvent. 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>	Over printing shall be clear & legible. NA
2.14	<b>Power failure and recovery</b> <ul style="list-style-type: none"><li>➤ Probability</li><li>➤ Recovery procedure</li></ul>	NA Power backup by DG set.
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>	NA
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



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Sr. No	Parameters	Requirements Specification
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
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 NA
2.22	<b>User License Requirement</b> <ul style="list-style-type: none"> <li>➤ Availability of sufficient licenses for used dept.</li> </ul>	NA
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>	Required <ul style="list-style-type: none"> <li>➤ Factory – In house test certificate.</li> <li>➤ Instruction, operation and maintenance manual.</li> <li>➤ Material of construction certificates.</li> <li>➤ Motor details and ratings.</li> <li>➤ Electrical wiring diagram</li> <li>➤ IQ, OQ protocols.</li> </ul> Vendor shall provide required certificates.



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Sr. No	Parameters	Requirements Specification
3.0	<b>Training</b> <ul style="list-style-type: none"><li>➤ Consent for training as and when required to user dept.</li></ul>	Vendor shall train the respective persons of ULL 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>	Vendor shall provide all the required reference documents.

### 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)