



**PHARMA DEVILS**

PRODUCTION DEPARTMENT

**USER REQUIREMENT SPECIFICATION**

**NAME OF ITEM:** URS for Deduster

**PROTOCOL No.....**

**FUNCTIONAL AREA:** Production

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**USER REQUIREMENTS SPECIFICATION  
FOR  
[VIBRO DEDUSTER]**



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### 1.0 General Information

<b>Name of Equipment/Instrument/System/Model/Make</b>	Vibro Deduster/GMP model/Rimek Karnavati Engg.Ltd.
<b>Brief description about the configuration of equipment/instrument/system</b>	<ul style="list-style-type: none"><li>➤ Dedusting units are used for effective dedusting by using vibratory effect.</li><li>➤ Geometrically designed tablet conveying route to ensure easy removal of burrs.</li><li>➤ Dedusting unit shall be compatible with all types of tablet presses and dust extractors.</li><li>➤ Height adjustment assembly to adjust the height w.r.t tablet press output discharge.</li><li>➤ Height of deduster shall be confirmed while raising the Purchase order.</li><li>➤ Provision for collection of dedusted powder shall be provided.</li><li>➤ Design of dedusting plates channel having smooth finish and shall not damage to the product during travel through channel.</li><li>➤ Gaskets shall be of silicone food grade quality.</li><li>➤ Main assembly shall be mounted on PU wheels for easy movement with wheel locking arrangement.</li><li>➤ Control panel shall contain ON/OFF switch.</li><li>➤ Provision to increase or decrease the vibrations as per product requirement.</li></ul>
<b>Numbers</b>	06 Nos
<b>Purpose of the equipment (Specific application)</b>	For removal of fine surface dust & edges without damaging the tablets after compression.

### 2.0 User Requirements

Sr. No	Parameters	Requirements Specification
2.1	Material of construction of components / accessories	All product contact parts in SS 316L. All other non-contact parts in SS 304.



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Sr. No	Parameters	Requirements Specification
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>	NA NA
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 5.31 m X 4.70 m
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 3Phase / 415V / 50Hz
	<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 Hygiene class D - 1,00,000
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>	25°c±2°c 40 ±10% NA NMT 80 DB



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Sr. No	Parameters	Requirements Specification
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>	<p>NA</p> <p>NA</p> <p>Manual</p>
2.8	<b>Capacity and use</b> <ul style="list-style-type: none"> <li>➤ Max. Operating capacity</li> </ul>	<p>Vendor has to conform the maximum operating capacity.</p> <p>8000 to 200,000 Tablets/Hour (Depending upon size &amp; speed)</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>NA</p> <p>NA</p>
2.11	<b>Nature of products to be handled</b>	<p>Materials used is non-corrosive, may be weak acidic / alkaline in nature.</p>
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>	<p>NA</p> <p>All contact parts shall be easily accessible for washing. Manual cleaning using water.</p> <p>Cleaning procedure shall be provided.</p> <p>Wing nuts shall be provided for easy dismantling &amp; assembling.</p>
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>	<p>NA</p> <p>NA</p>



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Sr. No	Parameters	Requirements Specification
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
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



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Sr. No	Parameters	Requirements Specification
2.22	<p><b>User License Requirement</b></p> <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	<p><b>Commissioning and Documentation</b></p> <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>➤ DQ/IQ/OQ to be completed by the supplier (as per Protocol) along with representatives.</li> <li>➤ Test certificate for major bought outs.</li> <li>➤ Factory – In house test certificate.</li> <li>➤ Instruction, operation and maintenance manual.</li> <li>➤ As built drawings.</li> <li>➤ Equipment electrical drawings.</li> <li>➤ Material of Construction certificate (MOC).</li> <li>➤ Motor details and ratings.</li> <li>➤ Mechanical drawing.</li> <li>➤ Electrical wiring diagram</li> </ul> <p>All the certificate shall be collected from vendor.</p>
3.0	<p><b>Training</b></p> <ul style="list-style-type: none"> <li>➤ Consent for training as and when required to user dept.</li> </ul>	Supplier to train the respective technical associates of ..... on Operation, Maintenance and Cleaning of the equipment, wherever applicable
4.0	<p><b>Reference documents</b></p> <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.

### 5.0 Abbreviations

Acronym	Definition
IQ	Installation qualification
OQ	Operational qualification
DQ	Design qualification
RPM	Rotation per minute.



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HVAC	Heating Ventilation & Air Conditioning
RH	Relative Humidity
DB	Descibals

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)