



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Cadmill

PROTOCOL No.....

FUNCTIONAL AREA: Production

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**USER REQUIREMENTS SPECIFICATION
FOR
[CADMILL]**



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1.0 General Information

Name of Equipment /Instrument/System/Model/Make	Cadmill (Comminuting mill) /GMP model.
Brief description about the configuration of equipment/ instrument/system	<ul style="list-style-type: none"> ➤ Cadmill is used reduce the size of granules and at the same time obtain granules of uniform size. ➤ Easy dismantling facility for product contact parts. ➤ Gaskets shall be of silicone food grade quality. ➤ Water jacketed for processing of heat sensitive products. as per product requirement. ➤ Swinging type with knife and impact edge beater assembly. ➤ Main assembly shall be mounted on PU wheels for easy movement with wheel locking arrangement (Portable). ➤ Control panel shall contain ON/OFF switch. ➤ Provision to increase or decrease the speed of rotor as per product requirement.
Quantity Required	01 No.
Purpose of the equipment (Specific application)	Purpose of the equipment is to reduce the size of granules and at the same time obtain granules of uniform size.

2.0 User Requirements

Sr. No.	Parameters	Requirements Specification
2.1	Material of construction of components / accessories	<p>All product contact parts in AISI SS 316L quality with smooth & mirror finish.</p> <p>Beaters and shaft in AISI SS 410 quality and beaters shall be further hardened and chrome plated.</p> <p>All drive assembly components housed in the AISI SS 304 base frame.</p> <p>All other non-contact parts in AISI SS 304 quality.</p> <p>All other MS non-contact parts shall be painted.</p> <p>All non stainless steel parts shall be covered with AISI SS 304 quality material for assuring paintless exterior.</p>



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Sr. No.	Parameters	Requirements Specification
2.2	Specification of equipment / instrument / system at the installation site <ul style="list-style-type: none">➤ Width➤ Length➤ Height	Vendor has to confirm the dimensions.
2.3	Description of Accessories <ul style="list-style-type: none">➤ List of Accessories➤ Dimensions	Vendor has to confirm the list of accessories & dimensions.
2.4	Location Suitability <ul style="list-style-type: none">➤ Installation Space➤ Operational Space	Length (L) X Width (W) X Height (H) = 5.00 m X 5.31 m X 4.70 m
2.5	Details of utilities required <ul style="list-style-type: none">➤ Air, Water, Nitrogen, Hydrogen etc.➤ Compressed air, steam➤ Electrical supply➤ Spike guards➤ UPS backup system➤ Air conditioning / HVAC➤ Air grade of specific class	Water (if required) NA 415 V /3 Phase / 50Hz NA NA HVAC Hygiene class D - 1,00,000
2.6	Environmental condition at installation site <ul style="list-style-type: none">➤ Temperature➤ Humidity➤ LUX level at working place➤ Noise level in decibels	25°C±2°C 40 ±10% NLT 300 LUX NMT 80 DB



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Sr. No.	Parameters	Requirements Specification
2.7	Level of Automation <ul style="list-style-type: none"> ➤ Fully Automatic (PLC based etc.) ➤ Semi Automatic ➤ Manual 	<p>NA</p> <p>NA</p> <p>Manual</p>
2.8	Capacity and use <ul style="list-style-type: none"> ➤ Max. Operating capacity 	<p>Vendor has to confirm the maximum operating capacity.</p> <p>30 to 300 kgs per hour (Depending upon physical properties of materials)</p>
2.9	Safety <ul style="list-style-type: none"> ➤ Personnel safety ➤ Environmental hazard if any 	<p>No person shall be allowed to work on the machine unless the person has been fully trained.</p> <p>Emergency switch shall be provided to stop the equipment in case of emergency.</p> <p>NA</p>
2.10	Speed <ul style="list-style-type: none"> ➤ RPM ➤ Operational speed 	<p>Rotor speed: 1000-2250-4500 RPM.</p> <p>NA</p>
2.11	Nature of products to be handled	<p>Materials used is non-corrosive, may be weak acidic / alkaline in nature.</p>
2.12	Cleaning process parameters to be controlled <ul style="list-style-type: none"> ➤ Clean in Place ➤ Manual Cleaning ➤ Water, Detergents, Solvents ➤ Cleaning procedure 	<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 & assembling.</p>
2.13	Critical process parameters to be controlled <ul style="list-style-type: none"> ➤ Critical process parameters ➤ Control procedure 	<p>NA</p> <p>NA</p>



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Sr. No.	Parameters	Requirements Specification
2.14	Power failure and recovery <ul style="list-style-type: none">➤ Probability➤ Recovery procedure	NA To be backed by DG set.
2.15	Emergency stop <ul style="list-style-type: none">➤ Provision for emergency stop	Provision shall be provided.
2.16	Alarm warning <ul style="list-style-type: none">➤ Indication of abnormality in operation	NA
2.17	Data security <ul style="list-style-type: none">➤ Data storage➤ Data integrity➤ Data retrieval	NA NA NA
2.18	Constraints <ul style="list-style-type: none">➤ Timelines➤ Delivery	To be delivered at the following site of ULL, within 4 to 6 weeks from the date of approved Purchase Order.
2.19	Maintenance <ul style="list-style-type: none">➤ Procedure➤ Frequency	The preventive maintenance schedule shall provides a guideline for periodic servicing
2.20	Computer Configuration <ul style="list-style-type: none">➤ Details of configuration through computer software	NA
2.21	Computer Hardware & Software Requirement <ul style="list-style-type: none">➤ Hard disk storage capacity➤ Compatible software with specific version➤ 21 CFR part 11 compliant software	NA NA NA
2.22	User License Requirement <ul style="list-style-type: none">➤ Availability of sufficient licenses for used dept.	Sufficient licenses shall be available with user dept.



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2.23	<p>Commissioning and Documentation</p> <ul style="list-style-type: none"> ➤ Availability of the Engineer/s at the time of commissioning ➤ Availability of DQ IQ, OQ protocols at the time of commissioning 	<p>Required.</p> <ul style="list-style-type: none"> ➤ DQ/IQ/OQ to be completed by the supplier (as per ULL Protocol) along with ULL representatives. ➤ Test certificate for major bought outs. ➤ Factory – In house test certificate. ➤ Instruction, operation and maintenance manual. ➤ As built drawings. ➤ Equipment electrical drawings. ➤ Material of construction certificate (MOC). ➤ Motor details and ratings. ➤ Mechanical drawing. ➤ Electrical wiring diagram <p>Vendor shall provide required certificates.</p>
3.0	<p>Training</p> <ul style="list-style-type: none"> ➤ Consent for training as and when required to user dept. 	<p>Vendor shall train the respective persons of on Operation, Maintenance and Cleaning of the equipment, wherever applicable.</p>
4.0	<p>Reference documents</p> <ul style="list-style-type: none"> ➤ Operating manual ➤ Technical manual ➤ Trouble shooting manual ➤ Test certificates ➤ Calibration certificates 	<p>Vendor shall provide all the required reference documents.</p>

5.0 Abbreviations

Acronym	Definition
GMP	Good Manufacturing Practices.
PU	Polyurethane.
AISI	American Institute of Steel & Iron.
SS	Stainless Steel.



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Acronym	Definition
MS	Mild Steel.
PLC	Programmable Logic Control.
UPS	Uninterrupted power supply.
DQ	Design qualification
IQ	Installation qualification.
OQ	Operational qualification
RPM	Rotations per minute.
HVAC	Heating Ventilation & Air Conditioning
RH	Relative Humidity
DB	Decibel



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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})

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