# USER REQUIREMENT SPECIFICATIONS

## DUST EXTRACTION UNIT

## CONTENTS

**Continued...**

## 1.0 Approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution.

| Functional area | Name | Designation | Signature | Date |
|---|---|---|---|---|
| **PREPARED BY** | | | | |
| **User Department** | | | | |
| **REVIEWED BY** | | | | |
| **User Dept. Head** | | | | |
| **Engineering Dept. Head** | | | | |
| **Environment, health and safety** | | | | |
| **Quality Control (if applicable)** | | | | |
| **Quality Assurance** | | | | |
| **APPROVED BY** | | | | |
| **QA Head** | | | | |
| **Plant Head** | | | | |

**2.0 OBJECTIVE:** The objective of this document is to provide the requirement and appropriate design to support the prospective supplier to identify company needs, price quote for the subject equipment and performance requirements for procurement of equipment including major ancillary component or fabrication of the area so as to meet the in-house requirements as well as compliance with cGMP and cGEP.

The supplier shall abide by the information and conditions set forth by this document as well as the standard purchasing terms and conditions of company.

**3.0 Scope:** This user requirement specification (URS) is applicable for the procurement of Dust extractor unit.

**4.0 Reason for URS:** To procure Dust extractor unit for installation in Block-1 for extraction of dust from the tablet press during production and to keep the compression zone of tablet press clean.

**The reason for preparing this document is:**

Please tick any one (or multiple) option(s) from the following (☑):

| | | | |
|---|---|---|---|
| Refurbished premises/equipment | ☐ | | |
| Purchase of Utility Systems | | | ☐ |
| Purchase of Process Equipment | ☑ | | |
| Purchase of Laboratory Equipment | | | ☐ |
| Bespoke or user configured computer systems | ☐ | | |
| In-Use Systems that don't have a URS | ☐ | | |
| Others (Specify) | | | ☐ |

**5.0 Responsibility:** Personnel involved in qualification activity.

| Department | Name | Activity |
|---|---|---|
| **User** | | To provide the User Requirement Specification (URS) |
| **Engineering** | | To provide requirements with respect to utilities, components, based on the location of use and desired equipment parameters |
| **Health Safety and Environment** | | To provide the safety requirements of equipment and facility |
| **Quality Assurance** | | To be a part of qualification team |
| **QA Head** | | To review and approve the requirement and Qualification document |
| **Plant Head** | | To review and approve the requirement and Qualification document |

**6.0 Equipment Description:**

Dust Extractor deals with the process to extract the dust from the tablet press during production and keep the compression zone of tablet press clean.

Dust laden air is sucked by a Vortex pump and enters in the filter housing through a suction adaptor, where dust laden air is deflected around filter bag by deflector. Deflected air is sucked by pressure and pass through fine filter bag. The dust particles stuck to the inner wall of the filter housing and outer face of the filter bag. The Dust laden air passes upward through filter bag. The Top of filter cage with filter bag is mounted with highly effective spring action shaking mechanism, operated by a shaking knob on top of the filter housing assembly. On operating the shaking mechanism, the dust deposited on the outer wall of the filter bag is dropped into filter housing. The high level vortex pump is suck the dust laden air through filter bag, then cleaned discharge air in atmosphere after filtered by exhaust filter. Castor wheels are fitted at bottom side of the machine to give complete manoeuvrability.

**7.0 Information of Input Material:** The input material will be dust/ powder from the tablet press during compression of tablets.

**8.0 Information of Output Material:** The output material will be extracted dust/ powder.

**9.0 Environment:** This section gives a brief summary of the layout and physical condition of the proposed site of the equipment. This includes (but not limited to), the data sheet of the room where proposed equipment is to be placed with proposed placement drawing showing room dimensions, door/window locations and dimensions, etc.

| S.No. | Parameter | Specifications/Dimension |
|---|---|---|
| **1.** | **Available area** | ➢ Area (4.6 m Length x 4.5 m Breadth x 4.5 m Height)<br>➢ Area grade/class: ISO 8<br>➢ As Built Area Layout attached as attachment No._____<br>➢ Should be able to accommodate in compression area<br>➢ Should be installed at the suitable area for ease in cleaning. |
| **2.** | **Maximum Expected size of equipment (approx.)** | ➢ NMT 80 mm Width x 110 mm dia. x 155 mm Height |

**10.0 Equipment Design and Principle of Working:** NA

**11.0 Process Description:**

Pump of the dust extractor sucks the dust from the tablet press. The dust laden air enters in the filter housing through a suction adaptor. The dust laden air is deflected around the filter bag by deflector. Deflected air is sucked by pressure and pass through fine filter bag. The duct particles stuck in the inner and outer wall of the filter bag. The cleaned air is discharged in to the atmosphere after filtered by exhaust filter.

**12.0 Functional Requirements of Equipment:**

**12.1 Functionality of the Equipment:** The desired functional requirements and how it operates are listed under this section.

**USER REQUIREMENT SPECIFICATION**

| | |
|---|---|
| **NAME OF ITEM:** DUST EXTRACTION UNIT | **PROTOCOL No.:**..... |
| **FUNCTIONAL AREA:** PRODUCTION | **Page No.:** 8 of 13 |

| S.No. | Parameter | Specifications |
|---|---|---|
| 1. | Use/Purpose | The equipment should be able for extraction of dust particles generated during the compression of granules. |
| 2. | Capacity/Working Capacity | 180 CFM |
| 3. | Model | cGMP |
| 4. | Dust storage capacity | ➢ Suitable capacity shall be provided. |
| 5. | Vacuum pump | ➢ Shall be provided. |
| 6. | Vacuum suction nozzle | ➢ Shall be provided. |
| 7. | Filter housing | ➢ Shall be provided. |
| 8. | Filter bags | ➢ Shall be provided. |
| 9. | Shaking knob assembly | ➢ Shall be provided. |
| 10. | Cover on filter housing | ➢ Shall be provided. |
| 11. | Inlet adaptor | ➢ Shall be provided. |
| 12. | Deflector | ➢ Shall be provided. |
| 13. | Cage for filter bag | ➢ Shall be provided. |
| 14. | Silicone ring | ➢ Shall be provided. |

**12.2 Instrumentation Requirements:** This section mentions in brief the minimum requirement for measuring instrumentation for controlling and monitoring of process parameters. e.g. RPM indicator, printer etc.

| S.No. | Parameter | Specifications |
|---|---|---|
| NA | | |

**12.3 Data Collection and Reporting:** This section mentions in brief the data that is expected from the equipment with the respective unit of measurement. Need for printouts are also mentioned, if applicable e.g. RPM, Time duration.

| S.No. | Parameter | Specifications |
|---|---|---|
| NA | | |

**12.4 Recipe Provision/Data saving/Data Back-up/Data Security:** This section specifies the requirements (as applicable) for recipe provision, data saving facility, data back-up facility, data security facilities, etc.

| S.No. | Parameter | Specifications |
|---|---|---|
| NA | | |

**13.0 Performance Features:** The parameters that are planned to be evaluated during performance qualification and process validation activities are mentioned.

| S.No. | Parameter | Specifications |
|---|---|---|
| 1. | Performance of the machine according to operation. | The machine is intended to be operated regularly: 24 hours, 7 days per week with cleaning in between batch/ product changeover. |
| 2. | Change over time | A minimum change part to reduce the product change over time is required. |
| 3. | Cleaning Requirements | Easy accessible for cleaning.<br>Parts which are required for cleaning should be provided with quick fixing arrangement. |

**14.0 Capacity/Speed:** The desired capacity/speed with the UOM is specified in this section.

| S.No. | Parameter | Specifications |
|---|---|---|
| 1. | Capacity | 180 CFM |

**15.0 Automation and Safety Features:** Adequate safety feature for men and material shall be provided along with the equipment. The minimum required as well as desired automation and safety features (alarms, interlocking, etc.) are listed in this section. e.g. for loading/ unloading/material handling/ Blending activities, etc.

| S.No. | Parameter | Specifications |
|---|---|---|
| NA | | |

**16.0 System Boundaries :** NA

**17.0 Material of Construction:** Specifications for material of construction of contact parts, non-contact parts, etc. are listed here.

| S.No. | Parameter | Specifications |
|---|---|---|
| 1. | Filter housing | ➢ SS 316L |
| 2. | Cover on Filter housing | ➢ SS 316L |
| 3. | Inlet adaptor | ➢ SS 316L |
| 4. | Deflector | ➢ SS 316L |
| 5. | Cage for filter bag | ➢ SS 316L |
| 6. | Non contact parts | ➢ SS 304 |
| 7. | Filter | ➢ SS 316 |

**18.0 Surface Finish:** Specifications for surface finish of contact parts, non-contact parts, etc. are listed here.

| S.No. | Parameter | Specifications |
|---|---|---|
| 1. | Internal Surface finish (Product contact parts) | Smooth and Mirror polished inside surface with no welding burrs and crevices. Corners shall be rounded |
| 2. | Outer Surface finish | Dull polished. |

**19.0 Electrical and Control Equipment Philosophy:** A brief detail of the control requirements and whether the equipment is to be controlled using electrical system/ microprocessor/ PLC/ computers or a combination of these are mentioned in this section. The electrical system of the equipment shall be housed as per the cGMP and cGEP.

| S.No. | Parameter | Specifications |
|---|---|---|
| NA | | |

**20.0 cGxP Considerations:** The requirements for electronic compliance of the equipment.

| S.No. | Parameter | Specifications |
|---|---|---|
| NA | | |

**21.0 Expected Documents and Drawings:** Requirement of documents to be delivered by the suppliers during the procurement life cycle. A suggestive list (but not limited to), is as listed below:

| S.No. | Document details | Required (✓/×) |
|---|---|---|
| 1. | Design Specifications | ☑ |
| 2. | Functional Specifications | ☒ |
| 3. | PLC Alarm/Interlock/Safety/ communication/power failure test procedures | ☒ |
| 4. | Piping and Instrumentation Diagram (P&ID) | ☒ |
| 5. | Instrument Listing | ☒ |

| S.No. | Document details | Required (✓/×) |
|---|---|---|
| 6. | Control Schematics | ☒ |
| 7. | Control Panel Assembly Drawings | ☒ |
| 8. | Machine Assembly Drawings | ☒ |
| 9. | Bill of Materials | ☒ |
| 10. | Operator, Maintenance and Service Manuals | ☑ |
| 11. | Spare Parts List | ☑ |
| 12. | MOC certificates | ☑ |
| 13. | Calibration certificates of instruments | ☒ |
| 14. | Test certificates of components/test devices | ☒ |
| 15. | Weld certificates (if any) | ☒ |
| 16. | 'As-built' P&ID | ☒ |
| 17. | GA drawing | ☑ |
| 18. | Isometric drawing (if any) | ☒ |
| 19. | Electrical drawings | ☑ |
| 20. | Component Cut Sheets (optional) | ☒ |
| 21. | PLC Program Printouts and Disk File (optional) | ☒ |
| 22. | HMI Configuration Printout and Disk File (optional) | ☒ |
| 23. | Other (Specify) | ☒ |

✓: Applicable & required  × : Not applicable

**22.0 Available Utilities:**

| S.No. | Parameter | Specifications/Dimension |
|---|---|---|
| 1. | Electricity | ➢ Electrical supply three Phase<br>➢ Frequency: 50 Hz<br>➢ Voltage: 415 volts |

**23.0 Maintenance Requirements:** Maintenance related requirements like accessibility for easy maintenance, required spares, etc. are listed here.

| S.No. | Parameter | Specifications |
|---|---|---|
| 1. | Maintenance | Easy accessibility for maintenance |
| 2. | Spare parts | List of spare parts and spare parts should be provided |

**24.0 Delivery, Installation and Commissioning Requirements :**

**24.1** Should be delivered in disassembled condition and to be assembled at the site by the manufacturer/ supplier service engineer.

**24.2** Manufacturer should provide support in case of problems, which may not be able to rectify at the user end.

**24.3** FAT if any required by the customer then, same to be performed jointly by the nominated persons from both the side at the manufacturer's site.

**24.4** The manufacturer should install, qualify and commission the equipment at the user site and provide the necessary training to the user for operation and cleaning. Training to be provided by the manufacturer for the necessary critical steps involved in the operation, cleaning, maintenance, safety and handling of equipment.

**25.0 Other Specific Requirements:** To provide the necessary servicing at the site at defined intervals. Language requirements in manual should be in English.

**26.0 Reference Documents:** Nil.

**27.0 Abbreviations:** Full forms of all abbreviations are listed here.

| **Abbreviation** | | **Full form** |
|---|---|---|
| cGMP | : | Current Good Manufacturing Practice |
| GEP | : | Good electrical practices |
| ISO | : | International Standard Organization |
| L | : | Litre |
| MOC | : | Material of Construction |
| L x B x H | : | Length x Breadth x Height |
| Sr. No. | : | Serial Number |
| SS | : | Stainless Steel |
| URS | : | User Requirement Specification |
| dia. | : | Diameter |
| FAT | : | Factory acceptance test |
| DQ | : | Design Qualification |

**28.0 Attachments:** This section contains a list of all attachments referenced in the protocol.

| S.No. | Attachment Details | Attachment No. |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |