



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 1 of 2

**USER REQUIREMENT
SPECIFICATIONS**

DEDUSTER CUM METAL DETECTOR

Document Reference: Nil

Issue Date: Nil



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 2 of 2



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 3 of 16

CONTENTS

Sr. No.	Title of sections	Page No.
1.0	Approval	
2.0	Objective	
3.0	Scope	
4.0	Reason for URS	
5.0	Responsibility	
6.0	Equipment Description	
7.0	Information of Input Material	
8.0	Information of Output Material	
9.0	Environment	
10.0	Equipment Design and Principle of Working	
11.0	Process Description	
12.0	Functional Requirements of Equipment	
12.1	Functionality of the Equipment	
12.2	Instrumentation Requirements	
12.3	Data Collection and Reporting	
12.4	Recipe Provision/ Data Saving/ Data Back-up/ Data Security	
13.0	Performance Features	
14.0	Capacity / Speed	
15.0	Automation and Safety Features	
16.0	System Boundaries	



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 4 of 16

Continued...

S. No.	Title of sections	Page No.
17.0	Material of Construction	
18.0	Surface Finish	
19.0	Electrical and Control Equipment Philosophy	
20.0	cGxP Considerations	
21.0	Expected Documents and Drawings	
22.0	Available Utilities	
23.0	Maintenance Requirements	
24.0	Delivery, Installation and Commissioning Requirements	
25.0	Other Specific Requirements	
26.0	Reference Documents	
27.0	Abbreviations	
28.0	Attachments	



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 5 of 16

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				



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 6 of 16

- 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.

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 de-duster cum metal detector.

- 4.0 Reason for URS:** To procure de-duster cum metal detector for installation in Block-1 to remove the surface dust, burred edges from tablets and metal contaminated tablets.

The reason for preparing this document is:

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

- | | |
|---|-------------------------------------|
| Refurbished premises/equipment | <input type="checkbox"/> |
| Purchase of Utility Systems | <input type="checkbox"/> |
| Purchase of Process Equipment | <input checked="" type="checkbox"/> |
| Purchase of Laboratory Equipment | <input type="checkbox"/> |
| Bespoke or user configured computer systems | <input type="checkbox"/> |
| In-Use Systems that don't have a URS | <input type="checkbox"/> |
| Others (Specify) | <input type="checkbox"/> |



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 7 of 16

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



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 8 of 16

6.0 Equipment Description:

De-duster:

It is vertically round shaped consisting spiral tray with outlet chute covered by inlet drum which is mounted on base structure with lockable wheel. The spiral tray is constructed from SS 316. Dust collection through tube provided vertically down wards .The core tablets from compression machine conveying from lower side to upward of dedusting system with help of vibration and dust collected through the dust collecting tube.

Metal detector:

Metal detector consists of inlet chute, test Coil Aperture with rejection mechanism and rejection box outlet chute. Control panel of metal detector having Indicator lamp, key pad and display. All product non contact part should be made of SS 304 grade and product contact part of test coil should be made of food grade material.

Outlet of de-duster is connected through the inlet of metal detector. The tablets comes from de-duster to metal detector and run through the test Coil Aperture where perform the detection of metal contamination in tablets .Detected metal contaminated tables rejected through rejection flap and contaminated tables collected in the rejection box along with Buzzer of alarm and indicator light.

7.0 Information of Input Material: The input material will be compressed tablets directly coming from compression machine.

8.0 Information of Output Material: The output material will be dust free tablets and metal contamination free tablets.

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,HVAC supply/return grill locations, utility point locations, etc.



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 9 of 16

Sr. No.	Parameter	Specifications/Dimension
9.1	Available area	<ul style="list-style-type: none">➤ Area (L x B x H)➤ Area grade/class: ISO 8➤ As Built Area Layout attached as attachment No._____.➤ Should be able to accommodate in compression area and should be easily linked between compression machine and product container. Inlet of dedusting unit connected with outlet of compression machine and outlet of dedusting unit connected with inlet of metal detector, the outlet of metal detector should be connected through the product container.➤ Should be installed at the suitable area for ease in cleaning.
9.2	Maximum Expected size of equipment (approx.)	<p>De-duster:</p> <ul style="list-style-type: none">➤ Total Height: Between 980 mm to 1170 mm➤ Charging height: Between 755 mm to 945 mm➤ Discharge Height: Between 850 mm to 1040 mm <p>Metal detector:</p> <ul style="list-style-type: none">➤ Total Height: NMT 960 mm➤ Charging height: Between 500 mm to 1000 mm➤ Discharge Height: Between 300 mm to 800 mm

10.0 Equipment Design and Principle of Working:

De-duster: The core tablets pass through the spiral tray of de-duster. The core tablets run in the dedusting unit from lower side to upward on the working principle of vibration with the use of magnetic coil. This vibration helps for dedusting of tablets. The dust is collected through the dust collecting tube which mounted vertically down ward.

Metal Detector: The metal detector work on Eddy current principle. The Excitation i.e. Primary coil carries high frequency sinusoidal voltage which generates steady electromagnetic field in side metal detector test coil aperture.

The pick-up i.e. Secondary Coil which are electronically balanced, sense the change in the electromagnetic field by the moving metal, With the help of phase sensitive detection and dual



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 10 of 16

channel detection technique. Good detection sensitivity is achieved for both types of metals i.e. ferrous and non ferrous.

Once the metal contaminated tablets detected rejection mechanism activated and Flap is open/Air flow / pusses and contaminated tablets rejected which is collected in the attached rejection box and only good tablets pass to the product container.

11.0 Process Description: This section mentions in brief the details of the process to be handled by the equipment.

De-duster: The core tablets come from outlet of compression machine in to the de-duster through its inlet. The de-duster convey this core tablets from lower side to upper side with the help of vibration .Tablets dedusted throughout the Spiral tray and dust is collected by the dust collecting tube which is mounted vertically down ward.

Metal Detector: The de-dusted tablets further pass through the metal detector. Inlet of metal detector connected with outlet of de-duster. When the metal contaminated tablets pass through the test coil of aperture, change occurs in already generated magnetic filed. The change in electromagnetic field by the moving metal contaminated tablets detected and metal contaminated tablets rejected through the rejection actuator by mean of flap/ air/ pusher along with buzzer alarm and light indicator. The flap / air /pusher re positioned after the collection rejection in rejection box only good tablets pass in to the product container.

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.

Sr. No.	Parameter	Specifications
DEDUSTER		
12.1.1	Use/Purpose	➤ The equipment should be able for De-dusting of compressed tablets.
12.1.2	Capacity/Working Capacity	➤ Between 220000 to 230000 tablets/ hr
12.1.3	Model	➤ cGMP Model
12.1.4	Change parts	➤ Inlet and outlet drum, Spiral tray,



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 11 of 16

		Springs, Bushes, Vibrator mounting plate, Dust collection box, Silicon rubber gasket.
12.1.5	Castor wheels	➤ PU wheels / fibre wheels of suitable size should be provided.
12.1.6	Power Failure and Recovery	➤ The equipment should not function in case of power failure and start only after operator intervention.
METAL DETECTOR		
Sr. No.	Parameter	Specifications
12.1.7	Use / Purpose	➤ The equipment should be able to detect the metal contamination and reject the metal contaminated tablets.
12.1.8	Capacity / Working Capacity	➤ Between 600000 to 800000 tabs./Hr.
12.1.9	Model	➤ cGMP Model
12.1.10	Change parts	➤ Inlet chute, Outlet chute along with rejection (Flap Type) mechanism for rejection, Reject Actuator, Rejection box.
12.1.11	Control panel	➤ Should be provided having liquid crystal display and soft touch key pad.
12.1.12	Electrical connection	➤ Should have connections through socket with PVC cable.
12.1.13	Indicators /Alarm	➤ Should have Buzzer and LED indication on detection of metal contamination.
12.1.14	Power Failure and Recovery	➤ Set parameters shall retain on loss of power.
12.1.15	Reject Actuator	<ul style="list-style-type: none"> ➤ Should be provided ➤ Machine shall have high detection sensitivity.

12.2 Instrumentation Requirements: This section mentions in brief the minimum requirement for measuring instrumentation for controlling and monitoring of process parameters etc.

Sr. No.	Parameter	Specifications
NA		



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 12 of 16

12.3 Data Collection and Reporting: NA

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

METAL DETECTOR SYSTEM		
Sr. No.	Parameter	Specifications
12.4.1	Data saving facility	➤ Data should be get auto saved.
12.4.2	Data security	➤ Access should be controlled through password protection. ➤ Three Security level passwords shall be provided.

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

Sr. No.	Parameter	Specifications
13.1	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.
13.2	Change over time	Minimum change parts to reduce the product change over time are required.
13.3	Cleaning Requirements	Easy accessible for cleaning. 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.

Sr. No.	Parameter	Specifications
DEDUSTER		
14.1	Capacity	➤ Between 220000 to 230000 tabs./hr.
Sr. No.	Parameter	Specifications
METAL DETECTOR		



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 13 of 16

14.2	Capacity	➤ Between 600000 to 800000 tabs./ hr.
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15.0 Automation and Safety Features: The minimum required as well as desired automation and safety features (Alarms, Locking, etc.) are listed in this section.

Sr. No.	Parameter	Specifications
15.1	Moving parts	➤ All the moving parts should be covered.
15.2	Noise level	➤ Should not be more than 80 dB at a distance of NMT 1.0 meter
15.3	Electrical connection & System design	➤ Should Ensured Earthing & total enclosure for all electrical & electronic parts & constructed as per GEP. ➤ All Electrical connections should made through Sockets & shielded cables, no exposure to surroundings. ➤ Should be Flame proof.
15.4	Locking	➤ Should be provided locking lever for permanent locking of deduster and metal detector.
15.5	No Sharp Edges	➤ Should be free of Sharp Edges.
15.6	External Contamination	➤ All Materials used in Construction shall be of Stainless steel, Food Grade Polycarbonate.

16.0 System Boundaries:

Description of the attached components and accessories to the main machine.

Sr. No.	Parameter	Specifications
NA		

17.0 Material of Construction: Specifications for material of construction of contact parts, non-contact parts of Metal detector with de-duster are listed here.

DEDUSTER		
Sr. No.	Parameter	Specifications
17.1	Stand	➤ Should be SS 304 Grade.



USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 14 of 16

17.2	Spiral tray	➤ Should be SS 316 Grade.
17.3	Vibrator mounting plate	➤ Should be SS 304 Grade
17.4	Bushes	➤ Anti vibration pads
METAL DETECTOR		
17.5	Stand	➤ Should be SS 304 Grade.
17.6	Base Shell	➤ Should be SS 304 Grade.
17.7	Detector holding shaft	➤ Should be SS 304 Grade.
17.8	Inlet chute	➤ Should be SS 316 Grade.
17.9	Outlet chute	➤ Should be SS 316 Grade.
17.10	Product Non-Contact Parts	➤ Should be SS 304 Grade.
17.11	Non-Metallic parts which come into product contact	➤ Non - toxic Food Grade Polycarbonate. ➤ Shall be non-additive, non-absorptive and non-reactive.

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

Sr. No.	Parameter	Specifications
18.1	Internal Surface finish (Product contact parts)	➤ Smooth and Mirror finish inside surface with no welding burrs and crevices.
18.2	Outer Surface finish (Product Non contact parts)	➤ Smooth and Matt finish outer surface with no welding burrs and Crevices.
18.3	No Sharp Edges	➤ Should be free of Sharp Edges.

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.

DE DUSTER SYSTEM		
Sr. No.	Parameter	Specifications
NA		



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 15 of 16

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

Sr. No.	Parameter	Specifications
20.1	Security Levels	<ul style="list-style-type: none">➤ Three Level Security should be provided (Operator, Officer and Admin).➤ Operation Control for operator➤ For password at least 4 characters required to enforce their use.➤ System should be able to display unauthorized access attempts.➤ When password entry fields are shown on the screen, password entries must be obscured (e.g. "*****").➤ Software if any should be 21 CFR part 11 compliance

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:

DE DUSTER SYSTEM & METAL DETECTOR SYSTEM		
Sr. No.	Document details	Required (✓ / ✗)
21.1	Design Specifications	<input checked="" type="checkbox"/>
21.2	Functional Specifications	<input type="checkbox"/>
21.3	PLC Alarm/Interlock/Safety/ communication/power failure test procedures	<input type="checkbox"/>
21.4	Piping and Instrumentation Diagram (P&ID)	<input type="checkbox"/>
21.5	Instrument Listing	<input type="checkbox"/>
21.6	Control Schematics	<input type="checkbox"/>
21.7	Control Panel Assembly Drawings	<input type="checkbox"/>
21.8	Machine Assembly Drawings	<input checked="" type="checkbox"/>
21.9	Bill of Materials	<input checked="" type="checkbox"/>



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 16 of 16

DE DUSTER SYSTEM & METAL DETECTOR SYSTEM		
Sr. No.	Document details	Required (✓ / ✗)
21.10	Operator, Maintenance and Service Manuals	✓
21.11	Spare Parts List	✓
21.12	MOC certificates	✓
21.13	Calibration certificates of instruments	✗
21.14	Test certificates of components/test devices	✓
21.15	Weld certificates (if any)	✗
21.16	'As-built' P&ID	✗
21.17	GA drawing	✓
21.18	Isometric drawing (if any)	✗
21.19	Electrical drawings	✓
21.20	Component Cut Sheets (optional)	✗
21.21	PLC Program Printouts and Disk File (optional)	✗
21.22	HMI Configuration Printout and Disk File (optional)	✗
21.23	Other (Specify)	✗

✓: Applicable & required ✗ : Not applicable

22.0 Available Utilities:

Sr. No.	Parameter	Specifications
22.1	Electricity	➤ Single Phase/ 230 Volt

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



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 17 of 16

DE DUSTER SYSTEM & METAL DETECTOR SYSTEM		
Sr. No.	Parameter	Specifications
23.1	Maintenance	➤ Easy accessibility for maintenance
23.2	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.

<u>Abbreviation</u>	<u>Full form</u>
cGMP	: Current Good Manufacturing Practice
dB	: Decibel
GEP	: Good electrical practices
HZ	: Hertz
ISO	: International Standard Organization



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Deduster Cum Metal Detector

PROTOCOL No.....

FUNCTIONAL AREA: Production

Page No.: 18 of 16

MOC : Material of Construction
Nos : Number
L x B x H : Length x Breadth x Height
Sr. No. : Serial Number
SS : Stainless Steel
URS : User Requirement Specification
mm : Millimetre

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

Sr. No.	Attachment Details	Attachment No.