



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Checkweigher

PROTOCOL No.....

FUNCTIONAL AREA: Production

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**USER REQUIREMENT
SPECIFICATIONS**

CHECKWEIGHER



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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				



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- 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 Checkweigher.

- 4.0 Reason for URS:** To procure Checkweigher for installation in Block-1 to get the product within the approved acceptance range of weight after passing the product through the Checkweigher.

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"/> |



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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



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6.0 Equipment Description:

The Checkweigher is a high precision dynamic weighing system designed to weigh conveyor fed product. It is designed to weigh products to a high degree of accuracy as they pass through a production line and reject products lying outside a predefined range of acceptable weight limits.

7.0 Information of Input Material: The input material will be conveyor fed product (i.e. cartons filled with blisters/strips).

8.0 Information of Output Material: The output material will be product (i.e. cartons filled with blisters/strips) within the approved acceptance range.

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.

S.No.	Parameter	Specifications/Dimension
9.1	Available area	<ul style="list-style-type: none">➤ Area in meter: (7.5 m Length x 5.0 m Breadth x 4.0 m Height)➤ Area grade/class: Unclassified➤ As Built Area Layout attached as attachment No._____.➤ Should be able to accommodate in Secondary packing line.➤ Should be installed at the suitable area for ease in cleaning.
9.2	Maximum Expected size of equipment (approx.)	<ul style="list-style-type: none">➤ Belt height from floor: NMT 820 mm➤ Entry platform size: NMT 350 mm (L) x 250 mm (W)➤ Weighing platform size: NMT 350 mm (L) x 250 mm (W)➤ Exit platform size: NMT 350 mm (L) x 250 mm (W)



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10.0 Equipment Design and Principle of Working:

The equipment consists of an infeed conveyor, weighing conveyor and exit conveyor. The rejection mechanism is located on the exit conveyor. Reject collection bin is also provided on the exit conveyor to collect the rejected products.

The Checkweigher works on the principle of pneumatically operated air blow type rejection mechanism. When the product with missing leaflets/ blister/ strip or with excess material gets passed through the Checkweigher by conveyor, the product gets rejected by a stream of air blow and the rejected product gets collected in the reject bin.

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

11.1 Set the product required parameters (e.g. target weight, upper limit, lower limit, product speed, product length etc.) in the HMI of the equipment.

11.2 Challenge the Checkweigher by passing lower and upper weight product through it and check if the product is getting rejected.

11.3 After satisfactory challenge test, pass the product through the Checkweigher by conveyor.

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
12.1.1	Use/Purpose	➤ The equipment should be able to pass the product within the acceptable range and reject the product outside the acceptable range.
12.1.2	Capacity/Working Capacity	➤ 2 gram to 1000 gram
12.1.3	Model	➤ cGMP Model
12.1.4	Direction of Flow of product	➤ Left to Right
12.1.5	Speed	➤ 120 PPM For pack size-100mm passing width
12.1.6	Least Count	➤ 0.1g



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Sr. No.	Parameter	Specifications
12.1.7	Accuracy	➤ ± 0.2 g
12.1.8	Pneumatic Requirement	➤ Shall be provided
12.1.9	Power Requirement	➤ Shall be provided
12.1.10	Conveyor belt	➤ Shall be provided
12.1.11	Reject type	➤ Under weight and over weight
12.1.12	Reject Mechanism	➤ Pneumatically Operated Air Blow type rejection mechanism
12.1.13	Weighing Device	➤ Load Cell
12.1.14	Direction of Flow	➤ Left to right
12.1.15	Rejection bin	➤ Shall be provided
12.1.16	Motor with VFD	➤ Shall be provided
12.1.17	Tower lamp	➤ Shall be provided
12.1.18	HMI	➤ Shall be provided
12.1.19	Computer & Printer connectivity	➤ Shall be provided
12.1.20	Over flaps for ports for Computer & Printer connectivity	➤ Shall be provided
12.1.21	Control panel	➤ Shall be provided
12.1.22	Platform mounted on four leg stand	➤ Shall be provided
12.1.23	Height adjusting screws	➤ Shall be provided
12.1.24	Anti vibration pads	➤ Shall be provided



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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
12.2.1	Photo sensors	Shall be provided at both the ends of weigh conveyer
12.2.2	Pressure switch	Shall be provided

12.3 Data Collection and Reporting:

Sr. No.	Parameter	Specifications
1.	Time	In Minutes/seconds.
2.	RPM	In Numbers

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

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.



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13.3	Cleaning Requirements	Easy accessible for cleaning. Parts which are required for cleaning should be provided with quick fixing arrangement.
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14.0 Capacity / Speed: The desired capacity/speed with the UOM is specified in this section.

Sr. No.	Parameter	Specifications
14.1	Capacity	➤ 2 gram to 1000 gram
14.2	Speed	➤ 120 PPM For pack size-100mm passing width

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	Top cover	➤ Should be provided to avoid any deviations due to any external factors like direct Fan air blow etc on weigh conveyor
15.2	Electrical connection	➤ Should be through PVC cable, all contacts enclosed & not exposed to surrounding ➤ Ensured earthing & total enclosure for all electrical & electronic parts
15.3	No Sharp Edges	➤ Should be free of Sharp Edges.
15.4	External Contamination	➤ All Materials used in Construction is of Stainless steel & Food Grade material belts.
15.5	Motor	➤ Motor Brackets provided to reduce risk of accidents.
15.6	Motor overloaded	➤ In case of overload of motor then machine should be stop motor
15.7	Door locking	➤ Rear door locking shall be provided
15.8	Emergency stop switch	➤ Shall be provided

16.0 System Boundaries:

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



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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 deduster are listed here.

Sr. No.	Parameter	Specifications
17.1	Product contact parts	➤ Should be food grade material
17.2	Product non contact parts	➤ Should be SS 304 Grade.
17.3	Conveyor	➤ Food Grade material

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

Sr. No.	Parameter	Specifications
18.1	Surface finish	➤ Smooth and Matt finish no welding burrs and Crevices.
18.2	No Sharp Edges	➤ Should be free of Sharp Edges and corners should be rounded.

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.

Sr. No.	Parameter	Specifications
19.1	HMI	On the operating panel for operating the machine and setting the programme in Auto/manual mode.

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

Sr. No.	Parameter	Specifications
20.1	Security Levels	➤ Three Level Security should be provided (Operator, Supervisor and Manager). ➤ Operation Control for operator



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		<ul style="list-style-type: none">➤ 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
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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:

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 checked="" type="checkbox"/>
21.4	Piping and Instrumentation Diagram (P&ID)	<input type="checkbox"/>
21.5	Instrument Listing	<input checked="" type="checkbox"/>
21.6	Control Schematics	<input checked="" type="checkbox"/>
21.7	Control Panel Assembly Drawings	<input checked="" type="checkbox"/>
21.8	Machine Assembly Drawings	<input checked="" type="checkbox"/>
21.9	Bill of Materials	<input checked="" type="checkbox"/>
21.10	Operator, Maintenance and Service Manuals	<input checked="" type="checkbox"/>
21.11	Spare Parts List	<input checked="" type="checkbox"/>
21.12	MOC certificates	<input checked="" type="checkbox"/>
21.13	Calibration certificates of instruments	<input checked="" type="checkbox"/>
21.14	Test certificates of components/test devices	<input checked="" type="checkbox"/>
21.15	Weld certificates (if any)	<input type="checkbox"/>



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Sr. No.	Document details	Required (✓ / ✗)
21.16	'As-built' P&ID	<input type="checkbox"/>
21.17	GA drawing	<input checked="" type="checkbox"/>
21.18	Isometric drawing (if any)	<input type="checkbox"/>
21.19	Electrical drawings	<input checked="" type="checkbox"/>
21.20	Component Cut Sheets (optional)	<input type="checkbox"/>
21.21	PLC Program Printouts and Disk File (optional)	<input type="checkbox"/>
21.22	HMI Configuration Printout and Disk File (optional)	<input type="checkbox"/>
21.23	Other (Specify)	<input type="checkbox"/>

✓ : Applicable & required ✗ : Not applicable

22.0 Available Utilities:

Sr. No.	Parameter	Specifications
22.1	Electricity	➤ 3 Phase/ 230 Volt

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

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.



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- 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
GEP	: Good electrical practices
ISO	: International Standard Organization
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.



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