



**USER REQUIREMENT SPECIFICATION
FOR
CHECK WEIGHER MACHINE**

URS No.:

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LOCATION	THREE PIECE LINE
SUPERSEDES URS No.	NIL



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1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE :

- The User Requirements Specification (URS) is provided to aid the user through the critical aspects of Fabrication, Facility for Installation of Required Instruments, Cleaning / Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional Check Weigher Machine that meets the user's needs in the most cost-effective method possible.
- The URS is then provided to Vendor to submit a Price Quote for procurement of Check Weigher Machine.
- The URS shall help Vendor in understanding the end user requirement in details. This document shall help vendor for developing the Design Specification, which on approval by the Site, will become a Contractual Agreement between Vendor and the Site.
- This URS Shall be recognized as an integral part of the procurement agreement with the vendor. The vendor will abide by the information and conditions set forth by this document as well as the Standard Purchase Terms and Conditions of the Site.

3.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of **Check Weigher Machine** of the Site.
- The URS shall be used as a reference document for Design Qualification considering all aspects of Current Good Manufacturing Practices (cGMP) and Safety.

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4.0 RESPONSIBILITY:

The Team, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this URS.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none"> • Initiation and Approval of User Requirement Specification. • Co-ordination with User Department to prepare User Requirement Specification. • To check the completeness and Technical Accuracy of the URS.
Production	<ul style="list-style-type: none"> • Review of User Requirement Specification for compliance with the Product Requirement.
Engineering	<ul style="list-style-type: none"> • Review of User Requirement Specification for compliance with the Product Requirement.

5.0 GMP/REGULATORY REQUIREMENTS:

- The Purpose of procuring Check Weigher Machine is to provide a system to check the weight for filled Vial.
- Check Weigher Machine should complies with the “Current Good Manufacturing Practices”.
- Schedule–M “Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.



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6.0 SYSTEM OVERVIEW:

- Check weigher Machine is intended to be used for online weight checking of vials.
 - Check weighing after the filling and capping before labeling of vials.
 - To check the empty vials and missing dropper from the vials.
 - The product images can be uploaded from USB memory.
- Check Weigher Machine shall be provided with Magnehelic Gauge to show the pressure differential across the HEPA Filter.

6.1 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
1.0	Dynamic Pass Box		
	Capacity (Inner Dimensions.) (W)x(D)x(HT)	----	1) 610 x 610 x 610 mm Qty. 13 Nos. 2) 450 x 450 x 450 mm, Qty. 01 Nos. 3) 300 x 300 x 450 mm, Qty. 01 Nos.
	Outer Dimensions (W)x(D)x(HT)	---	1) 850 x 750 x 1400 mm Qty. 13 Nos. 2) 690 x 590 x 1235 mm, Qty. 01 Nos. 3) 540 x 300 x 450 mm, Qty. 01 Nos
	Machine Body	SS304	As per cGMP Requirements.
2.0	Supply HEPA Filter		
	Efficiency	---	99.99% down to 0.3 micron Grade : H – 14
	Media	---	Micro Glass Fibre Paper
	Make/size:	--	As per your specification.
	Velocity		90 – 110 FPM at working height
3.0	Pre Filter		
	Efficiency	---	99% down to 5 micron
	Size	---	As per your specification
	Grade	---	EU – 4
	Media	---	Non Woven Synthetic Media Sandwiched between 2 Layer of HDPE Mesh
	Separator	---	Aluminum



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S.No.	Name of the Component		MOC	Technical Specification
	Pre-filter Grill		SS304	Should be Equipped with quick assembling & disassembling for Easy Cleaning.
4.0	Return Air Filter			
	Efficiency		---	90 % down to 5 micron
	Size		---	As per your specification
	Grade		---	EU – 4
	Casing		---	As per cGMP Requirement.
	Media		---	Non Woven Synthetic Media Sandwiched between 2 Layer of HDPE Mesh
	Separator		---	Aluminum
5.0	Doors	Inside	SS304	Stainless Steel Having Glass View panel. (Both Doors Should not be Open at a Time)
		Outside		
6.0	Velocity		---	90 – 110 FPM at Working Height
7.0	Blower Assembly		---	Should be Provided as per your Specification and Finalized Purchase Order.
8.0	Fluorescent Tube Light		---	01 Nos.
9.0	Ultra Violet Light		---	Should be Provided as per your Specification and Finalized Purchase Order.
10.0	DOP port		SS304	Qty.-01 Nos.
11.0	Magnehelic Gauge		---	0 to 50 mm of Pascal -01 No.
12.0	Display		----	Digital Display Should be provided.
13.0	Digital UV Burning Hour Meter		---	Hour Meter should be provided.
14.0	Electrical Motor		---	As per your specification
15.0	Solenoid Lock-For Interlocking		---	Qty.-01 Nos. , Should Be Provided To the Pass Box.
16.0	Fluorescent Tube Light		----	01 Nos. Should be Provided as per your specification and Finalized Purchase order.
17.0	Safety Feature			Adequate safety features should be provided.
18.0	Noise Level			Less than 80 db.
19.0	Utilities			
	Electrical configuration & cabling			



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S.No.	Name of the Component	MOC	Technical Specification
	Power Supply	-----	As per your specification and Finalized Purchase order.
	Power cable	-----	
	Power / Inverter	-----	Should be Provided as per your specification and Finalized Purchase order.



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7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

➤ **FUNCTIONAL REQUIREMENTS:**

- Check Weigher Machine shall comply as per ISPE, cGMP, cGEP Guidelines.

➤ **RELIABILITY AND AVAILABILITY:**

- The system shall be available for continuous operation.
- Material of construction used shall be suitable for the intended service so as to withstand the working stress without frequent break down.

➤ **MAINTENANCE:**

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- The supplier shall replace the parts found to be damaged/ broken during Installation.
- The supplier shall be available at the site when asked in case of major breakdown.
- The supplier shall replace the parts found to be damaged/ broken during installation.



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8.0 LIFE CYCLE:

8.1 DEVELOPMENT:

- The supplier shall follow cGMP in design, development, construction and Installation of the Machine.

8.2 TESTING:

- The system shall be Factory tested by the supplier with approval witness.
- The system shall be commissioned and qualified at site for Installation and Operation by the supplier with approval witness.

8.3 SUPPORT:

- Supplier shall provide support for Preventive maintenance plan development, Operation & cleaning procedure for Check Weigher Machine, Assembly and Operator training.
- Supplier shall provide Safety Manuals during Installation, Operation & Calibration at the site.

8.4 DELIVERY:

- All parts of the system shall be sourced, delivered and installed by the Supplier.
- The supplier shall provide Functional design specification (MOC & Calibration Certificates) and Operation Manual in Soft as well as Hard Copy.



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9.0 DOCUMENTS TO BE PROVIDED:

- All MOC Certificates, Manual for Bought out items
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Electrical unit Diagram.
- P&ID Diagram / G.A Drawing.
- Operating & Service Manual
- Spare Part List.
- Load Cell Calibration Certificate
- Warranty Certificate of machine

Note: The whole URS is a tentative document. Manufacturer or Vendor will be solely responsible for performance of machine specified in the catalogue or during discussion at the time of finalization of purchase order. Specifications and details mentioned in the DQ, duly signed by Vendor/ Manufacturer and duly signed by Head QA will be treated as final specifications of the machine.

The said DQ will be treated as an integral part of purchase order.



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10.0 REVIEW COMMENTS:

- For any changes in the design/make of the Check Weigher Machine if not as per the URS, prior intimation/approval should be taken by the supplier from the Site.
- All parts should have MOC certificates, test certificates, Calibration certificates for traceability and authenticity.

Approved By: _____
(Head QA)
(Sign./Date)



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11.0 ABBREVIATIONS:

URS	:	User Requirement Specification
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
cGMP	:	Current Good Manufacturing Practices
CWM	:	Check Weigher machine