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USER REQUIREMENT SPECIFICATION FOR GRAMENT WASHING MACHINE

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LOCATION	THREE PIECE LINE
SUPERSEDES URS No.	NIL



URS No.:

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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, 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 Garment washing 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 Garment Washing 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	
	Initiation and Approval of User Requirement Specification.	
Quality Assurance	• Co-ordination with User Department to prepare User Requirement Specification.	
	To check the completeness and Technical Accuracy of the URS.	
User Department	Review of User Requirement Specification for compliance with the Product	
Oser Department	Requirement.	



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5.0	GMP/REGULATORY REQUIREMENTS:
	The Purpose of procuring garment Washing machine is to clean & dry sterile area garment in injection
	Block.
>	Schedule-M "Good Laboratory Practices and Requirements of Premises, Plant & Equipments for
	Pharmaceuticals Products".



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6.0 SYSTEM OVERVIEW:

Garment Washing Machine is designed to wash the used garments by 3- Step Washing (Rubbing, shaking and disentangling). Machine should be able to eliminate the dirty particles, grease, and oil from used garments

6.1 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name		Garment washing machine
2.0	Capacity		8.0 Kg (Turbo Drum)
3.0	Overall Size of the Machine		As per your specification
4.0	Color		As per your specification
5.0	Program		Fuzzy / Wool / Quick Wash
6.0	Washing Type		3- Step Washing (Rubbing, rubbing & shaking,
7.0	Temperature Selection		Hot / Warm / Cold
8.0	Hot/ Cold Water inlet		Hot / Cold
9.0	Window (Glass Type)		Transparent (Glass)
10.0	Other Features		Auto Balance System, Child Lock, Digital
11.0	Inner Tube	SS	As per your specification
12.0	Powder Detergent Box		Process requirement
13.0	Function Selector		Process requirement
14.0	Drain Hose		Process requirement
15.0	Adjustable Legs		Process requirement
16.0	Water Supply Hose		Process requirement
17.0	Castors		Process requirement
18.0	Tub	SS	Process requirement
19.0	Start/ Pause Button		Process requirement



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7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

> FUNCTIONAL REQUIREMENTS:

• Washing machine shall comply as, industrial purpose.

> 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.



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8.0 LIFE CYCLE:

8.1 DEVELOPMENT:

• The supplier shall follow industrial purpose 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 garment washing 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:

- Operating & Service Manual
- Spare Part List.
- 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 machine if not as per the URS, prior intimation/approval
	should be taken by the supplier from the Site.

•	All parts should ha	ave MOC	certificates,	test	certificates,	Calibration	certificates	for	traceability	and
	authenticity.									

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



URS No.:

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

SS : Stainless Steel

QA : Quality Assurance

DWM : Dress washing machine