



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
FOR
DYNAMIC GARMENT CABINET**

URS No.:

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FOR
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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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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 Dynamic garment cabinet 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 Dynamic garment cabinet.
- 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.

2.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of Dynamic garment cabinet 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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3.0 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.
User Department	<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.• Assist in preparation of User Requirement Specification.



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4.0 GMP/REGULATORY REQUIREMENTS:

The Purpose of procuring Dynamic garment cabinet is to provide a system should meet the requirement to provide a clean environment for Garments in the injection Block.

Dynamic Garment Cabinet 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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5.0 SYSTEM OVERVIEW:

- The Dynamic garment cabinet shall contain cabinet consisting of Pre Filter, Motor Blower Assembly and HEPA Filter with efficiency of 99.99 % down to 0.3µm. Outer surface of the Dynamic garment cabinet shall be made of SS 304 with smooth finish.
- Dynamic Garment Cabinet is devices that facilitate to provide a clean environment for Garments, maintain controlled environmental conditions of designated area.

➤ **. 5.1 TECHNICAL SPECIFICATION:**

S.No.	Name of the Component	MOC	Technical Specification
01.	Dynamic garment cabinet		
	Capacity (Inner Dimensions.) (W) x (D) x (HT)	----	3' x 1.5' x 6' (01 No.) 3' x 1.5' x 7' (02 No)
	Supply HEPA Filter		
	Efficiency	---	99.99% down to 0.3 micron Grade : EU -13
	Type		Minipleat
	Media	---	Micro Glass Fiber Paper
	Make/size:	--	As per your specification.
	Velocity		90 ± 20% FPM at working height
	Pre Filter		
	Efficiency	---	99% down to 5 micron
	Size	---	As per your specification
	Media	---	Non Woven Synthetic Media Sandwiched between 2 Layer of HDPE Mesh
	Qty.		02 nos.
	Type		As per your specification
	Return Air Filter		
	Efficiency	---	90 % down to 5 micron
	Size	---	As per your specification
	Media	---	Non Woven Synthetic Media Sandwiched between 2 Layer of HDPE Mesh



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S.No.	Name of the Component	MOC	Technical Specification
	Separator	---	Aluminum
	Type		As per your specification
	Pre-filter Grill	SS304	. As per your cGMP requirement
	Doors	SS304	Stainless Steel Having Glass View panel. (Both Doors Should not be Open at a Time)
	Outside		
	Velocity	---	90 ± 20 percent FPM at Working Height
	Flow		Vertical
	Blower Assembly	---	Should be Provided as per your Specification and Finalized Purchase Order.
	Fluorescent Tube Light	---	01 Nos.
	Ultra Violet Light	---	Should be Provided as per your Specification and Finalized Purchase Order.
	DOP port	SS304	Qty.-01 Nos.
	Magnehelic Gauge	---	0 to 50 mm of Pascal -01 No.
	Display	----	Digital Display Should be provided.
	Digital UV Burning Hour Meter	---	Hour Meter should be provided.
	Electrical Motor	---	As per your specification
	Solenoid Lock-For Interlocking	---	Qty.-01 Nos. , Should Be Provided.
	Hanging hook	---	As per your specification
02.	Safety Feature		Adequate safety features should be provided.
03	Noise Level		Less than 85 db.
04.	Utilities		
	Electrical configuration & cabling		
	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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6.0 OTHER REQUIREMENTS AND CONSTRAINTS:

6.1 FUNCTIONAL REQUIREMENTS:

- Dynamic garment cabinet shall comply as per ISPE, cGMP, cGEP Guidelines.

6.2 RELIABILITY AND AVAILABILITY:

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

6.3 MAINTENANCE:

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- Recommended spare parts list shall be provided.
- 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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7.0 LIFE CYCLE:

7.1 DEVELOPMENT:

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

7.2 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.

7.3 SUPPORT:

- Supplier shall provide support for Preventive maintenance plan development, Operation & cleaning procedure for Dynamic garment cabinet, Assembly and Operator training.

7.4 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.

8.0 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.
- Instrument list with manufacturer's calibration certificate.
- G.A Drawing.
- Operating & Service Manual
- Spare Part List.
- Warranty Certificate of machine



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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.

9.0 REVIEW COMMENTS:

- For any changes in the design/make of the Dynamic garment cabinet 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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10.0 ABBREVIATIONS:

URS	:	User Requirement Specification
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
cGMP	:	Current Good Manufacturing Practices
SSG	:	Sterile storage cabinet
SS	:	Stainless Steel
db	:	Decibel
Qty.	:	Quantity
P & ID	:	Piping and instrumentation design
GA	:	General arrangement
GMP	:	Good Manufacturing Practices
Sr.	:	Senior
mm	:	millimeter
SS	:	Stainless steel
HEPA	:	High efficiency particulate air
EU	:	European union
%	:	percent
FPM	:	Feet Per Minute
DOP	:	Diocetyl phthalate
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
AC	:	Alternate current