



DESIGN QUALIFICATION PROTOCOL FOR GARMENT STORAGE CABINET

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Approved By				



DESIGN QUALIFICATION PROTOCOL FOR GARMENT STORAGE CABINET

1.0 Objective:

The purpose of Design Qualification of the Garment Storage cabinet is to ensure that all the critical aspects including safety, effective cleaning, maintenance, utility requirement, working space, have been considered while designing the equipment and they are properly documented.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	Garment storage Cabinet
ID Number
Location	Change Room

3.0 Equipment / System Description:

KlenzChange™ recirculatory Garment Storage cabinet is designed to provide controlled micro - environment for storage of sterile garments or other clean room for accessories.

This recirculatory unit is designed with a horizontal side to side air flow in the work area with pick up from the opposite side through the return plenum which has a fresh intake pre filter to replace any loss of air through opening of the cabinet door. The cabinet is suitable for storing & sets of sterilized packed garments.

The storage cabinet is equipped with:

- Single door with polycarbonate glass panel.
- Shelves for storage.

4.0 Checklist for design verification:

Design of Garment Storage cabinet shall be verified for the compliance with the critical parameters mentioned in the URS/ executed tender.



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Construction			
Cabinet	SS 304	SS 304	
Door	SS 304	SS 304	
HEPA filter Screen	SS 304	SS 304	
HEPA filters	Not Mentioned	EU – 13, 855x570x75 mm (Antimicrobial)	
Pre filters	Not Mentioned	EU – 6, 855x570x45 mm (Biocidal)	
	Not Mentioned	EU – 6, 180x180x25 mm (Biocidal)	
DOP Port	Should be provided	100 % DOP test port	
Electrical construction	a) 300 lux along with one number of 5/15 amp, each switch socket (combined) b) Independent controls for lighting, blowers & sockets.	a) Illumination : U.V light: 1.5'L ; 15Watts. b) Independent controls for lighting, blowers & Sockets.	
UV lamp	UV lamp with hour meter and interlocking arrange for put OFF UV light should be provided	UV lamp with hour meter and interlocking arrange for put OFF UV light	
IR Heater	IR Heater wither thermister controlled set point	Provided	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Acceptable Tolerance for Control Parameter			
Air velocity	Between 0.50 m/sec to 0.45 m/sec	0.45 ± 0.05 m/sec	
Noise (Decibels)	Less than 65	Not Mentioned	
Differential pressure	Should be between 7 to 12 mm WC	Not Mentioned	
Particle count	As per ISO 14644 - 1	Complies	
Type of Control System			
Relay / Switchgear	Should be provided	Provided	
Indicators	<ul style="list-style-type: none"> ➤ Power ON ➤ Blower ON ➤ UV ON ➤ Light switch 	Provided	
Differential pressure gauge	0 to 25 mm WC	0 to 25 mm WC	
Accuracy of gauge	± 3 %	± 3 %	
Electrical power supply	440 - 3 phase 50 Hz / 220 1 phase 50 Hz	230 V; AC; 50 Hz	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Special features	Not Mentioned	Soft touch ON – OFF switch	
	Not Mentioned	Adjustable floor aligner	
Safety			
Alarm	Audiovisual alarm for motor blower trip	Audiovisual alarm for motor blower trip	
MCB	Make Hager / Merlin gerlin / Legrand	Provided	
Motor	Not Mentioned	0.5 HP; 1440 RPM;	
Blower (Impeller)	Not Mentioned	235 x 117 mm	
Overall Dimensions (WxDxH)	Not Mentioned	960 x 640 x 1555 mm	
Work Space Dimensions (WxDxH)	24 x 24 x 24 inch (610 x 610 x 610 mm)	610 x 610 x 610 mm	



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5.0 Any Changes identified towards equipment design / lay out.

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6.0 Recommendations and Conclusions:

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7.0 References:

- User requirement specification.
- Copy of purchase order.
- Risk assessment.
- Document submitted by the supplier / vendor

8.0 Documents Attached

Document Title	Annexure No.
List of changes / deviation	I
User requirement specification.	II
Copy of purchase order	III
Risk assessment	IV
Document submitted by the supplier / vendor	V



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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9.0 Abbreviations:

URS	: User requirement specification
SS	: Stainless Steel
mm	: millimeter
WC	: water content
%	: Percentage
m/sec	: Meter per second
U.V.	: Ultra Violet



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Annexure - I

List of changes / Deviations

S.No.	Description of Change / Deviations	Justification

Verified By:

Approved By:



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Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Approved By				