

DATASHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan®

REVIVAL OF BCG VACCINE LABORATORY GUINDY,
CHENNAI

Dry Fog Generator

PROJECT #: 110729

EQUIPMENT ID #: FG-DFG 01

DOCUMENT #: DS/FG-DFG 01



1 Process requirements

1.1 This equipment shall be used in clean rooms to reduce the bio-burden by creating the vapours / aerosols of suitable disinfectant solution.

2 Technical Specification

2.1 Model cGMP for clean room application

2.2 Type Mobile (portable)

2.3 Max. Room volume coverage required, m³ Refer annexure-1 for total room volume

2.4 Disinfectant solution Tank capacity Shall be suitable for one complete cycle of room decontamination mentioned in annexure-1

2.5 Aerosols generation type Using compressed air or evaporator (electricity)

2.6 Droplet size 5 to 10 µm

2.7 Power connection requirement To be compatible to standard Indian power supply socket

2.8 Power consumption, kW Vendor to specify

2.9 Compressed air pressure requirement, bar Vendor to specify

2.10 Compressed air consumption, CFM Vendor to specify

2.11 Complete coverage of the room Required

2.12 Operating temperature 15 to 40 deg.C

2.13 Operating Relative humidity < 75% RH

2.14 Disinfectant type Oil / Water based liquid

2.15 Disinfectant solution discharge rate vendor to specify

2.16 External Dimensions vendor to specify

2.17 Quantity One

2.18 No. of spray nozzles Minimum 4

2.19 Type of control system Vendor to specify

2.20 Remote control of the equipment Optional

2.21 Preferred disinfectant solution Hydrogen Peroxide

2.22 Concentration of Hydrogen peroxide Vendor to specify

3 Material Of Construction

3.1 Spray Nozzle SS 304 or Clean room Compliant (Vendor to specify)

3.2 Disinfectant solution tank SS 304

3.3 Tank gasket FDA approved

3.4 External surfaces Poly Propylene or Clean room Compliant (Vendor to specify)

3.5 Wheels Lockable castor wheels

4 Specific Requirements

4.1 The equipment should be effective in decontaminating the rooms and equipment surfaces.

4.2 The equipment shall have flow rate adjustable knob.

4.3 The fog generated by equipment should not be condensed in the room.

4.4 Fogger should provide maximum thrust, deeper penetration and wide spread of aerosols ensuring effective and uniform treatment of chemical being fogged.

4.5 Vendor to demonstrate and validate the six log reduction of microbial with suitable indicators.

4.6 Portable hydrogen peroxide sensors to be provided inside the room.

4.7 It should provide control on droplet size and is capable of generating ultrafine droplets as application demands.

4.8 Fogger should produce greater aerosol volume and fine diffusion of chemical being fogged in to space, obstructed surface ensuring uniform treatment of entire space.

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4.9	There should not be leakage of disinfectants on the floor / surface.					
4.10	It should be compatible with wide range of disinfectants (vendor to suggest the range of compatible disinfectants)					
4.11	The equipment must have detachable solution tank for easy filling and cleaning.					
4.12	Chocking of nozzles during the injection should be prevented.					
4.13	The system should be equipped with fixed lockable castor wheels for easy movement of equipment from one place to other place.					
4.14	Special Note: Equipment should be able to pass through pass box of 900 mm x 900 mm x 1200 mm (W x D x H)					
5	Other requirements					
5.1	The equipment must have rugged design and made from corrosion resistant material.					
5.2	It should be light weight, portable and extremely user friendly.					
5.3	It should be designed for easy cleaning					
6	Regulatory aspects					
	Not applicable					
7	Safety requirements					
7.1	Equipment should not contain any sharp edges.					
7.2	In the event of equipment / system malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment / system and the article remain in a safe condition.					
7.3	Proper earthing of the equipment (if applicable)					
8	Documents					
8.1	DQ Document					
8.2	IOQ Protocol					
8.3	Operational and maintenance manual					
8.4	MOC certificates					
8.5	List of MAKE with certificate					
9	Timelines					
	NA					
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.					
	AFI Approved for Enquiry			AFO Approved for Ordering		
00	2015-06-17	MGGP	MJY	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	

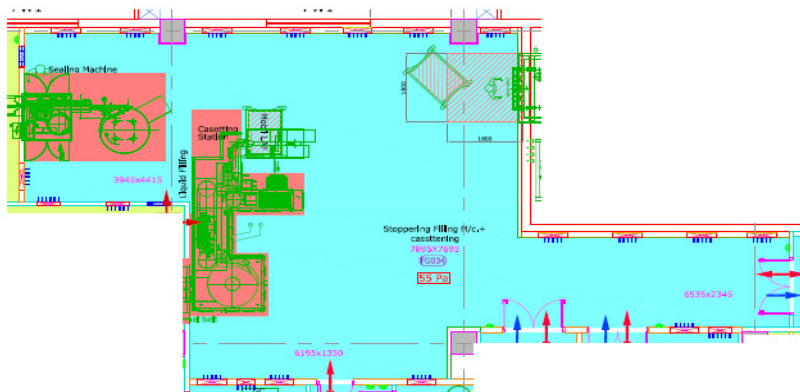
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Annexure-1: Table showing the volume of rooms for each cycle

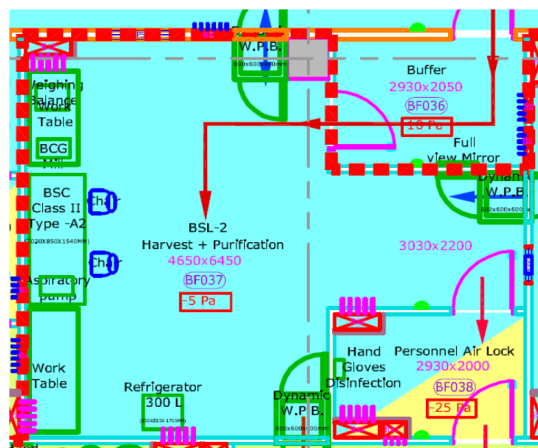
Cycle no.	ROOM NO.	ROOM TITLE	HYGIENE CLASS	Area m ²	ROOM DIMENSION		
					Slab Height m	False Ceiling Height, m	Room Volume m ³
BCGVL ground floor							
1	FG034	STOPPERING FILLING M/C+ CASSETTING	Grade B	102.0	5.5	3	306.0
BCGVL first floor							
2	BF037	BSL 2_HARVEST+PURIFICATI ON	Grade B	37.0	5.5	3.0	111.0
3	BF040	BSL 2_SEED	Grade B	62.0	5.5	3	186.0
4	BF041	BSL 2-INCUBATOR	Grade B	31.6	5.5	3	94.8
5	BF042	BSC SEED STORE	Grade B	9.0	5.5	3	27.0

Annexure-2: Layout showing the shape of the rooms

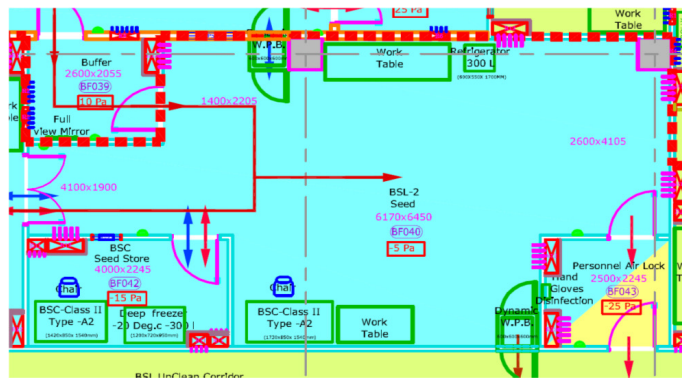
STOPPERING FILLING M/C+ CASSETTING



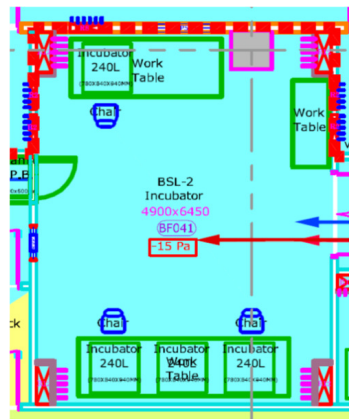
BSL 2_HARVEST+PURIFICATION



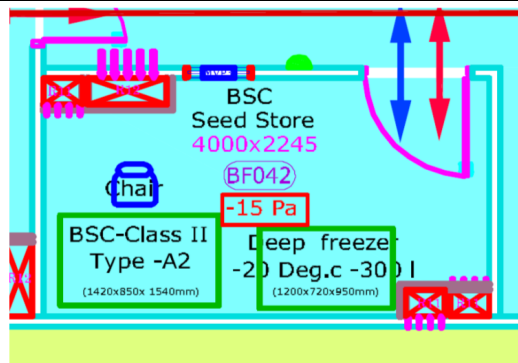
BSL 2_SEED



BSL 2-INCUBATOR



BSC SEED STORE



	AFI Approved for Enquiry			AFO Approved for Ordering		
00	2015-06-17	MGGP	MJY	<input type="checkbox"/>	<input type="checkbox"/>	
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