

User Requirement Specifications

nne pharmaplan

Equipment/System

Filter Integrity Testing Machine

Identification

BF-FIM 01

Document

URS/BF/FIM 01

Effective Date

2014.02.04

Revision#

06



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HLL LIFECARE LIMITED, CHENNAI

Revival of BCG Vaccine Laboratory, Guindy, Chennai

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URS Annexure List

URS Annex No.	Detail
1.	Layout showing location of the Filter Integrity testing machine in the wash room of the Bulk area
2.	Drawing of the machine along with the housing arrangement.

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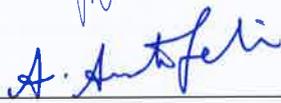
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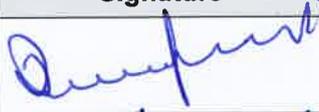
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1.0 APPROVAL SIGNATURES

This document is prepared by the Process and Validation and GMP compliance team of "NNE Pharmaplan India" for the project "Revival of BCG Vaccine Laboratory" (**Project number:-110729**) of BCG Vaccine Laboratory, Guindy, Chennai under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of BCG Vaccine Laboratory, and authorized by the appropriate Project Authority.

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2.0 EQUIPMENT USE

The Equipment must be a cGMP fully automatic, microprocessor-controlled integrity tester. The Equipment must shall be used to check the integrity of membrane filter systems, both hydrophilic & hydrophobic filter. The Integrity check must be by Non-destructive test since it is a sterilizing grade application. This Filter Integrity testing machine shall be used in the bulk block. It will be located in the wash room (BF048) of the BCG bulk preparation area.

The following types of Non-destructive tests shall be used to measure the following upstream integrity values:

1. Diffusion test
2. Bubble point test
3. Pressure decay test / Pressure hold test
4. Water intrusion test

3.0 BATCH DATA DISPLAY AND RECORD PRINTING

a) Non editable data shall be available or transferred to USB drive for printing the batch report, alarm log.

b) Real time online printing shall be available for batch report.

4.0 SPECIFIC REQUIREMENT

a) System should be designed for use in pharmaceutical production environments.

b) The system should include following:

- i. All the test relevant data and parameter should be printed on the hard copy, including;
 - Product, product lot, used filter cartridge(s)
 - Wetting agent
 - Test parameter (test pressure, time, limit values etc.)
 - Results, including actual test pressure, net volume, pressure drop, actual test value, evaluation)
 - Date and time
 - Test pass / Fail remark

ii. Tubing for compressed gas inlet.

iii. Tubing for compressed gas outlet.

iv. NRV should be fitted on each gas pipe.

v. Air volume chamber in the machine (Vendor to mention the chamber size)

vi. Interface cable

vii. Max distance between SC4 and multi-unit RS485 shall be 100 mm

c) It should include the SS housing and other necessary fittings for carrying out the Code-7 filter and as well as for Capsule filter.

d) SS filter housing should compatible for filter sizes ranging from 5" to 20".

e) SS filter housing shall be autoclavable.

f) Pneumatic connections:

i. Compressed air inlet: Staubli nipple

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ii. Compressed air outlet: Staubli coupling

iii. Vent: Hose connection 8 mm outer dia (or vendor to provide)

g) Communication ports:

- i. USB
- ii. RS 232 C
- iii. Ethernet

h) Internal printer:

Thermal printer to be provided and specifications of printer to be provided by vendor.

i) External printer with:

USB option, network option, virtual printing to PDF or XMF file format

j) Environmental conditions:

- i. Splash proof: IP54
- ii. Operating system: As GMP norms-Linux or equivalent
- iii. Screen: shall be 10" screen with colour, illuminated back ground, adjustable contrast, touch screen

k) Fault detection:

- i. The system shall be able to give the screen messages to locate the leakage problem

l) Self-test:

The system has to be automatically run an internal self-test once per day when it is switched on or when it is initiated by a user at any time. The test shall be saved and can be printed at any time. The following conditions shall be checked out during the self-test:

- i. Check for internal leaks
- ii. Inlet gas pressure
- iii. Function of the internal valves
- iv. Function and signal of the internal pressure sensors
- v. Function of the internal pressure regulator
- vi. Internal communication
- vii. Integrity of the operating system and its software
- viii. Data integrity of user lists, test programs and test results

m) Vendors are requested to provide FRL with moisture removal filter at the compressed air inlet for regulating the pressure.

n) Audio Visual alarm system for critical alarms.

o) Vendors are requested to provide all the necessary fittings, valves wherever required for easy operation.

p) Approved makes:

1. Pall
2. Sartorius
3. Millipore
4. mdi Membrane Technology

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5.0 OPERATING PARAMETERS

- a) Maximum operating pressure: 10 bar
- b) Operating temperature : 1 to 40 deg C
- c) Relative humidity: 5-90%
- d) Internal limit pressure :2.4 bar
- e) Pressure drop: 0.001 bar to 2 bar
- f) Power- *Vendor to specify with the UPS supply*

Measuring range:

- g) Diffusion test:0.1 – 1000 mL/min
- h) Water intrusion test:0.03-50 mL/min
- i) Bubble point test:0.4-6.5 bar
- j) Pressure decay test: 0.05-6.5 bar

Accuracy:

- k) Diffusion test: $\pm 3\%$ of measurement or ± 0.05 mL/min, whichever is greater
- l) Water intrusion test: $\pm 3\%$ of measurement or ± 0.02 mL/min, whichever is greater

6.0 OTHER REQUIREMENTS

- a) Pre-pressurisation test should be included in the program
- b) Installation and operation manual to be provided.
- c) IOQ protocols writing and execution.
- d) The instruments should be calibrated and have a traceability to National standards.
- e) Test certificate and Calibration certificate (Should be minimum 1 year at the time of completion)
- f) Maintenance manual.

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7.0 CONSTRAINTS

Equipment location and available space:

This equipment will be installed in the BCG bulk block of the BCG Vaccine Laboratory as follows.

Equipment Location: First floor - Bulk

Room name: Wash

Room no: BF048

Room dimension: 6450 mm x 5485 mm

Room height: 5500 mm

False ceiling height: 3000 m

Physical condition of the Wash room:

1. Room will be non-hazardous
2. Classification :Class 'D'
3. Differential pressure: '5' pa
4. Room Temperature: 22±2°C
5. Relative humidity: <55%

Note: The equipment location is indicated in the layout enclosed as URS Annex-1.

8.0 ABBREVIATION

Abbreviation	Definition
BCGVL	BCG Vaccines Laboratory
GMP	Good Manufacturing Practices
CFR	Code for federal Regulations
HLL	HLL Lifecare Limited
IQ	Installation Qualification
OQ	Operational Qualification
NPI	NNE Pharmaplan India Ltd
ISO	International Standards Organization
FIM	Filter Integrity testing Machine
UPS	Un-interrupted Power Supply

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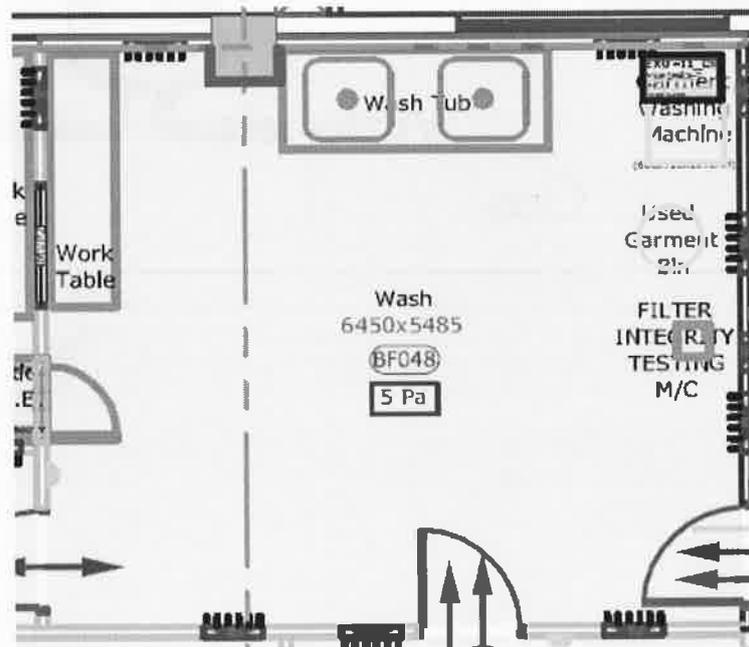
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Revision	Date	Reason for Revision
00	2012.11.16	First Draft for Client's approval
01	2013.01.03	After HLL comments
02	2013.06.25	As per MOM comments dated 20 th June 2013
03	2013.09.25	As per MOM comments dated 23 rd July 2013 and comments by mail dated. 2013.09.25
04	2013.12.18	As per client's comments on 2013.12.09
05	2014.01.28	As per client's comments on 2014.01.27
06	2014.02.04	As per client's comments on 2014.01.31

URS Annexure 1: Layout



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URS Annexure 2: Drawing

