

User Requirement Specifications				
HLL pharmaplan	Equipment/System:	Filter Integrity Testing Machine		
	Identification No:	-	Document No:	URS/FIT 01
	Effective Date:	18-04-2016	Revision No:	02

User Requirement Specifications

Filter Integrity Testing Machine

Block Code	Area	Identification #	Qty (Nos)	Capacity
F1	Viral Vaccine Formulation - Rabies	F1-FIT 01	1	-
F1	Viral Vaccine Formulation - Measles	F1-FIT 02	1	-
F2	Bacterial Vaccine Formulation	F2-FIT 01-02	2	-
B4	Rabies Bulk Block	B4-FIT 01-02	2	-
F4	BCG Bulk and Formulation block	F4-FIT 01	1	-
B1	MBB Block – Hep B	B1-FIT 01-03	3	-
B1	MBB Block – Hib	B1-FIT 04-05	2	-
Q1	Quality Control block	Q1-FIT 01	1	-
R1	Measles and Rubella bulk block	R1-FIT 01	1	-

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INTEGRATED VACCINES COMPLEX, CHENGALPATTU

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URS Annexure List

URS Annex No.	Detail
1.	Diagrammatic Representation of the machine along with the housing arrangement.

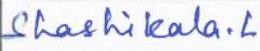
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1.0 APPROVAL SIGNATURE

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccines Complex, Chengalpattu, Chennai" (project number: 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective should be reviewed by HBL user/s and project/ engineering team, approved by team lead of user department and QA and authorized by the appropriate Project Authority.

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HLL Biotech Limited

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2.0 EQUIPMENT DESCRIPTION

The Equipment shall be a cGMP compliant, fully automatic, microprocessor-controlled filter integrity tester. The Equipment shall be used to check the integrity of membrane filter systems, both hydrophilic & hydrophobic type. The Equipment should be capable of checking integrity of systems such as

- a. Normal Flow Filters (NFF)
- b. Tangential Flow Filters (TFF)
- c. Hydrophilic and Hydrophobic Filters
- d. Pressure hold test for Tanks/Systems

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. Combination Test (Bubble point and Diffusion test)
- 4. Multipoint diffusion test
- 5. Pressure decay test / Pressure hold test
- 6. Water intrusion test

3.0 BATCH DATA DISPLAY AND RECORD PRINTING

a) Non editable data shall be available or transferred to USB drive / SD card reader / equivalent for printing the batch report, alarm log.	
b) The progress of all tests and results should be viewable as both bar charts and line graphs.	
c) The test results should be transferrable to a PC via an Ethernet port for secure archiving and records for comprehensive documentation control and traceability.	
d) Real time online printing should be provided.	

4.0 SPECIFIC REQUIREMENT

a) The equipment should be easily accessible for cleaning and sanitisation with standard disinfectants as the equipment will be used in a GMP facility.	
b) MOC of the equipment should be GMP Compliant.	
c) The equipment should be 21 CFR part 11 compliant.	
d) Login based supervisory access control should be provided.	
e) The equipment should be compact design with quick-connect parts for easy steps.	
f) The equipment should be GAMP compliant.	
g) The system should include following:	

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<p>i. All the test relevant data and parameter should be printed on the hard copy, including;</p> <ul style="list-style-type: none"> • 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 air inlet.	
iii. Tubing for compressed air outlet.	
iv. NRV should be fitted on air inlet and outlet.	
h) Pneumatic connections:	
i. Compressed air inlet: Staubli nipple	
ii. Compressed air outlet: Staubli coupling	
i) Internal printer: Printer and specifications of printer to be provided by vendor.	
j) USB / SD card / equivalent option, network option, virtual printing to PDF or XMF file format	
k) Environmental conditions:	
i. Operating system: shall be based on Windows, Linux or equivalent operating system.	
ii. HMI: shall be 10" colour display touch screen.	
l) Fault detection:	
i. The system shall be able to give the screen messages to locate the leakage problem	
m) Checks:	
i. Inlet gas pressure	
ii. Function of the internal valves	
iii. Function and signal of the internal pressure sensors	
iv. Function of the internal pressure regulator	
v. Internal communication	
vi. Integrity of the operating system and its software	
vii. Data integrity of user lists, test programs and test results	
n) Vendor shall provide FRL with moisture removal filter at the compressed air inlet for regulating the pressure.	
o) Audio Visual alarm system for critical alarms.	
p) Vendor shall provide all the necessary fittings, valves wherever required for easy operation.	

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5.0 OPERATING PARAMETERS

a) Maximum inlet pressure: 8 bar(g)
b) Operating temperature : 15 to 35 deg C
c) Relative humidity: 10-80%
d) Internal limit pressure :2.4 bar
e) Pressure drop: 0.001 bar to 2 bar
f) Power- <i>Vendor to specify with the UPS supply</i>
Measuring range:
g) Diffusion test: 1 – 600 mL/min
h) Water intrusion test: 0.03 - 50 mL/min
i) Bubble point test: 0.4 - 6.0 bar
j) Pressure decay test: 0.05 - 6.5 bar
Accuracy:
k) Diffusion test: ±5% of measurement or ±1 mL/min, whichever is greater
l) Water intrusion test: ±5% of measurement or ±0.02mL/min, whichever is greater

6.0 OTHER REQUIREMENTS

a) The manufacturer should provide training on Operation and maintenance of the equipment.
b) Operation and Maintenance manual to be provided.
c) IOQ protocols should be provided.
d) The instruments should be calibrated and have a traceability to National standards.
e) All test and Calibration certificate should be provided (Should be minimum 1 year at the time of completion).

7.0 CONSTRAINTS

7.1 Equipment location

This equipment will be installed in the different blocks of HLL Biotech Limited, Chengalpattu as specified below

Sl.no	Identification #	Area	Qty (Nos)	Room Name
1.	F1-FIT 01	Viral Vaccine Formulation - Rabies	1	Buffer Prep.& solution preparation
2.	F1-FIT 02	Viral Vaccine Formulation - Measles	1	Washing Area
3.	F2-FIT 01	Bacterial Vaccine Formulation	1	Buffer & solution Preparation
4.	F2-FIT 02	Bacterial Vaccine Formulation	1	Blending
5.	B4-FIT 01	Rabies Bulk Block	1	Purification

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Sl.no	Identification #	Area	Qty (Nos)	Room Name
6.	B4-FIT 02	Rabies Bulk Block	1	Media & Buffer preparation
7.	F4-FIT 01	BCG Bulk and Formulation block	1	Wash Area
8.	B1-FIT 01	MBB Block – Hep B	1	Fermentation
9.	B1-FIT 02	MBB Block – Hep B	1	Adsorption & Desorption
10.	B1-FIT 03	MBB Block – Hep B	1	Media preparation
11.	B1-FIT 04	MBB Block – Hib	1	Media preparation
12.	B1-FIT 05	MBB Block – Hib	1	Fermentation
13.	Q1-FIT 01	Quality control block	1	Media preparation
14.	R1-FIT 01	Measles and Rubella Bulk block	1	Washing

8.0 ABBREVIATION

Abbreviation	Definition
GMP	Good Manufacturing Practices
CFR	Code for federal Regulations
HBL	HLL Biotech Limited
HMI	Human Machine Interface
IQ	Installation Qualification
OQ	Operational Qualification
NPI	NNE Pharmaplan India Ltd
NRV	Non-Return Valve
ISO	International Standards Organization
FIM	Filter Integrity testing Machine
FRL	Filter Regulator Lubricator
UPS	Un-interrupted Power Supply

9.0 REVISION INDEX

Revision	Date	Reason for Revision
00	04-01-2016	First Draft for Client's approval
01	02-02-2016	Equipment ID's, location details are updated as discussed with HBL dated 02-02-2016
02	29-02-2016	Updated as per the comments received by HBL dated 17-02-2016

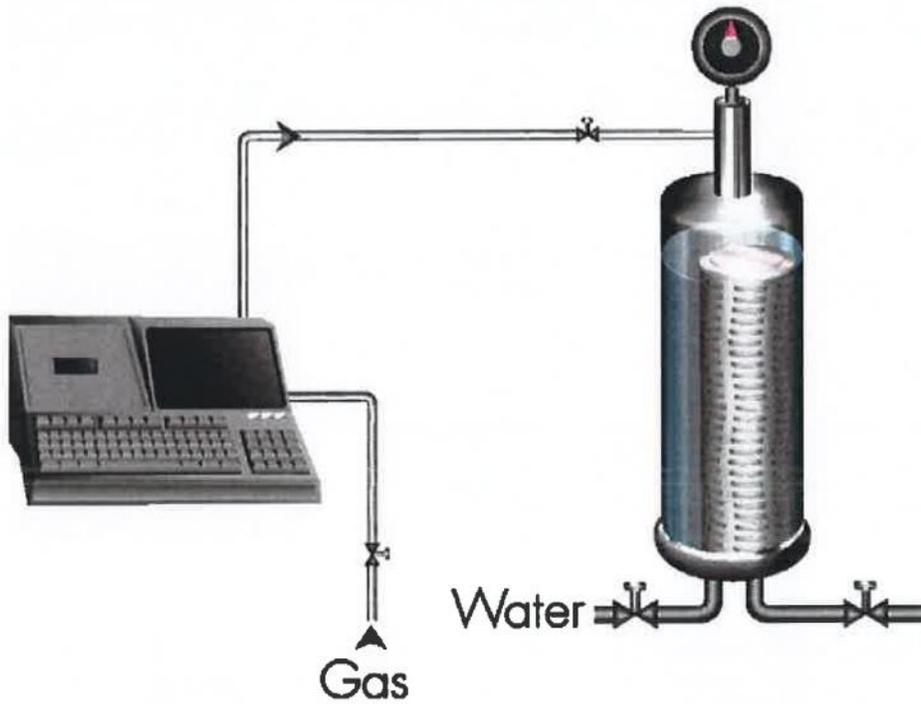
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URS Annexure 1: Drawing



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User Requirement Specifications

Equipment/System	SS Filtration Housing Unit		
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User Requirement Specifications SS Filtration Housing Unit

Block Code	Area	Identification #	Description	Quantity
R1	Measles and Rubella Bulk block	R1-SFU 01-04	1 x 10"; SS filter housing to suit Code 7 type filter cartridge	4
		R1-SFU 05-14	1 x 6"; SS filter housing to suit Code 7 type filter cartridge	10