User Requirement Specifications

Filter Integrity Testing Machine

D-FIT 01
P-FIT 01
T-FIT 01
F-FIT 01

nne pharmaplan	User Requirement Specifications				
	Equipment/System	Filter Integrity Testing Machine			
	Identification	D-FIT 01 P-FIT 01 T-FIT 01 F-FIT 01	**Document**	URS/FIT 01	
	Effective Date	2014.02.13	**Revision#**	00	

URS Annexure List

URS Annex No.	Detail
1.	Layout showing location of the Filter Integrity testing machine in the Diphtheria and Pertussis Block
	Layout showing location of the Filter Integrity testing machine in the Tetanus Block
	Layout showing location of the Filter Integrity testing machine in the Formulation Block
2.	Drawing of the machine along with the housing arrangement.

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1.0 APPROVAL SIGNATURES

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Revival of DPT Vaccines manufacturing Facility" (**Project number:-110831**) of Pasteur Institute of India, Coonoor under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of Pasteur Institute of India, 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 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.

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) 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	
b) It should include the SS housing and other necessary fittings for carrying out the Code-7 filter and as well as for Capsule filter.	
c) SS filter housing should compatible for filter sizes ranging from 5” to 20”.	
d) SS filter housing shall be autoclavable.	
e) Pneumatic connections:	

i. Compressed air inlet: Staubli nipple

ii. Compressed air outlet: Staubli coupling

iii. Vent: Hose connection 8 mm outer dia (Vendor to specify if greater than 8 mm)

f) Communication ports:
   i. USB
   ii. RS 232 C
   iii. Ethernet

g) Internal printer:
   Thermal printer to be provided and specifications of printer to be provided by vendor.

h) External printer with:
   USB option, network option, virtual printing to PDF or XMF file format

i) 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

j) Fault detection:
   i. The system shall be able to give the screen messages to locate the leakage problem

k) 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

l) Vendor shall provide FRL with moisture removal filter at the compressed air inlet for regulating the pressure.

m) Audio Visual alarm system for critical alarms.

n) Vendor shall provide all the necessary fittings, valves wherever required for easy operation.

o) <u>Preffered makes:</u> 1. Pall 2. Sartorius 3. Millipore	
5.0 OPERATING PARAMETERS	
a) Maximum inlet pressure: 10 bar(g)	
b) Operating temperature : 1 to 50 deg C	
c) Relative humidity: 5-95%	
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: ±3% of measurement or ±0.05mL/min, whichever is greater	
l) Water intrusion test: ±3% of measurement or ±0.02mL/min, whichever is greater	
Resolution:	
m) Diffusion test: 0.1 mL/min (0.01 mL/min for flows below 10 mL/min)	
n) Bubble point test: 0.05 bar	
o) Water intrusion test: 0.01 ml/min	
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.	

7.0 CONSTRAINTS

Equipment location and available space:

A) This equipment will be installed in the Diphtheria and Pertussis block of the as follows.

Equipment Location: Diphtheria - Bulk
Room name: Washing + Preparation and Sterilization
Room no: B1G077
Room dimension: 7030 mm x 5340 mm
4900 mm x 3100 mm
False ceiling height: 3000 m

Physical condition of the room:

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

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

B) This equipment will be installed in the Diphtheria and Pertussis block of the as follows.

Equipment Location: Pertussis - Bulk
Room name: Washing + Preparation and Sterilization
Room no: B1G035
Room dimension: 7030 mm x 5340 mm
4900 mm x 3100 mm
False ceiling height: 3000 m

Physical condition of the room:

1. Room will be non-hazardous
2. Classification :Class 'D'
3. Differential pressure: '5' pa
4. Room Temperature: 22±2ºC

C) This equipment will be installed in the Tetanus block of the as follows.

Equipment Location: Tetanus - Bulk

Room name: Washing +Loading
Room no: B2G054
Room dimension: 7400 mm x 4915 mm
4300 mm x 3585 mm
False ceiling height: 3000 m

Physical condition of the room:

1. Room will be non-hazardous
2. Classification :Class 'D'
3. Differential pressure: '10' pa
4. Room Temperature: 22±2ºC

D) This equipment will be installed in the Formulation block of the as follows.

Equipment Location: Formulation

Room name: Washing
Room no: F1G032
Room dimension: 41 m^2
False ceiling height: 3000 m

Physical condition of the Wash room:

1. Room will be non-hazardous
2. Classification :Class 'D'
3. Differential pressure: '15' pa
4. Room Temperature: 22±2ºC

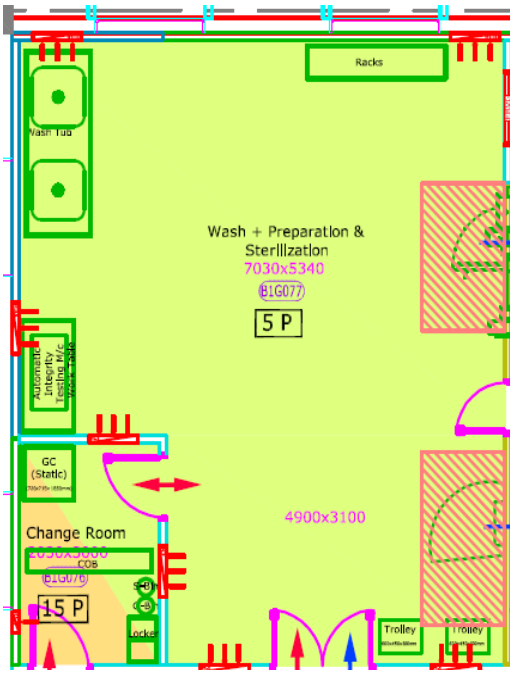
8.0 ABBREVIATION

Abbreviation	Definition
PII	Pasteur Institute of India
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

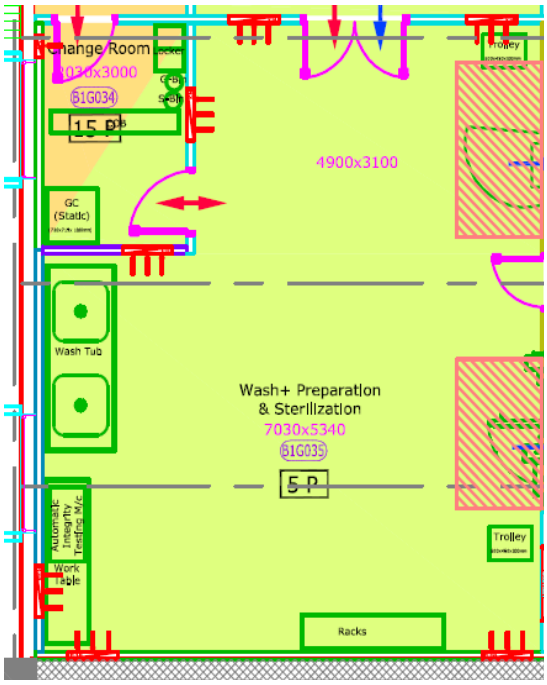
Revision index

Revision	Date	Reason for Revision
00	2014.02.13	First Draft for Client's approval

URS Annexure 1: Layout A



URS Annexure 1: Layout B



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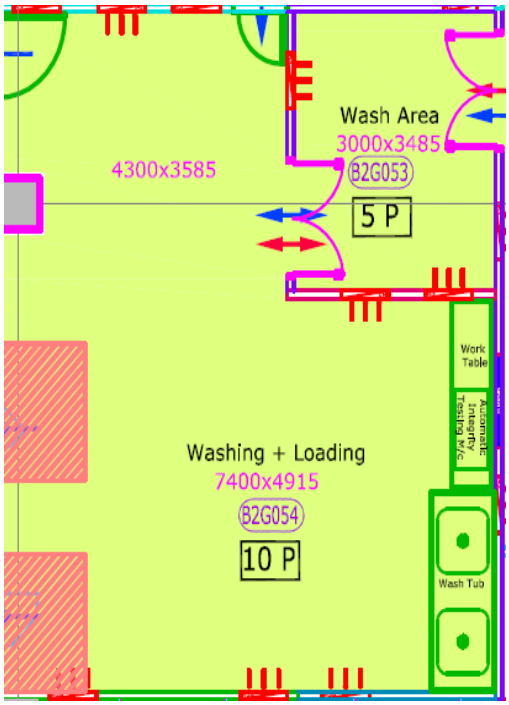
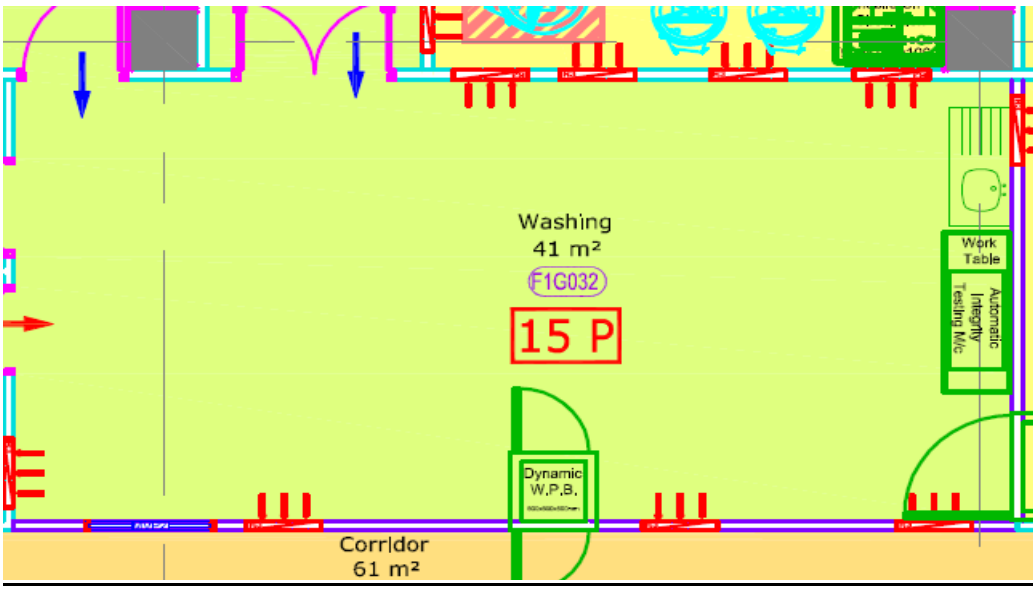
URS Annexure 1: Layout C



URS Annexure 1: Layout D



URS Annexure 2: Drawing