User Requirement Specifications Vial Washing Machine With Depyrogenating Tunnel

Process Code	Area	Equipment ID	Quantity	Capacity
F2	Bacterial vaccine formulation area	F2-VWD 01	1	200 Vials/Minute

nne pharmaplan	USER REQUIREMENT SPECIFICATIONS				HLL BIOTECH LIMITED
	EQUIPMENT/SYSTEM	Vial Washing Machine with Depyrogenating Tunnel			
	IDENTIFICATION No:	F2-VWD 01	**DOCUMENT No:**	URS/ F2-VWD 01	
	EFFECTIVE DATE	28-02-2014	**REVISION No:**	05	

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the installation of the Vial washing machine and Depyrogenating Tunnel
2	List of components and make
3	Specifications of customized vials

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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 Vaccine Complex, Chengalpattu, Chennai" (**project number:** 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective shall be reviewed by the QA team of HBL, approved by Team lead and authorized by the appropriate Project authority.

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2.0 EQUIPMENT DESCRIPTION

The vial washing machine and the depyrogenating tunnel shall be made in combination with proper synchronization to each other. The vial washing machine shall have a speed of 200 vials/min (In feed to filling machine should not be less than 200 vials /minute for ISO 2R & 6R vials and minimum of 100 vials/min for customized vials).

The machine shall consist of following parts in order to run operation smoothly.

S. No.	Description	Purpose
Vial Washing Machine		
1	In feed turntable	Feeding the vials to the turntable with tray. The vials will be unscrambled and singled to the washing station.
2	Transport system	Transporting the pre washed vials to the washing unit
3	Recirculation unit	Recirculating the WFI drained from final rinse of vials to be used for initial rinsing of vials
4	Washing Cycle	Washing the vials with WFI / Recirculated WFI.
5	Vapor Exhaust unit	Vapor Exhaust from the washing unit.
6	Out feed	Feeding the vials into the Tunnel
Depyrogenating tunnel		
1	Conveyor	Vials to be transported through appropriate transport system.
2	Drying zone with HEPA	For drying the washed vials with HEPA filtered air
3	Depyrogenating zone with HEPA	For depyrogenating the vials with circulation of HEPA filtered air (hot air)
4	Cooling /stabilization zone with HEPA	For cooling the vials with circulation of HEPA filtered air to bring the temperature to ambient

Machine shall have all operation in automatic mode. All the regulatory requirements shall be followed. The loading of the vials to the infeed bay shall be done by conveyor. The vial shall be transferred to the washing unit in a group by the transport system. The vials in the washing unit shall be washed from the inside as well as from outside. The washing cycle shall include washing with recirculated WFI and WFI with intermediate sterile compressed air drying. The equipment shall reduce contaminations and particulate matter. It shall help to reduce the amount of endotoxins by the use of WFI at the last rinse. A combination of at least six washing and drying cycle shall take place in the washing zone. The washed vials shall be transferred to the tunnel by the conveyor system.

The Tunnel shall be designed to produce the depyrogenating condition by achieving a temperature in the range of 300-3500C.The process shall be capable of doing a 6 log reduction for viable germs and ≥ 3 log reduction for endotoxins.

The temperature of vial at the outlet of cooling zone should be 22ºC (±2ºC). The system shall maintain a uniform temperature inside the tunnel. The wire mesh conveyor shall transport the vials from the in feed to the filling area through the drying, depyrogenating and cooling zone.

The following points from the IRS is not applicable for this equipment:

- 4.1.10, 4.1.11, 4.1.13, 4.1.17
- ANSI/NSF 49-2008,

Note:

I.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
II.	The vendor is asked to state in "REMARKS" column with "yes" if the described requirement will be completely fulfilled and with "no" in case the requirement will not or cannot be fulfilled with the proposed equipment. In case of a deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
III.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options becomes necessary the item must be clearly stated.
IV.	In case that the requirement includes a question or request or information from the vendor, the answer / information should be stated in the "REMARKS" column.
V.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
VI.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
VII.	The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design.
VIII.	Special Instruction a. If no comments against any specification shall be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it shall be treated as unresponsive / technically non compliant and rejected.
IX.	All the instruments and controls mentioned in the URS(s) are expected to be standard supply and part of your standard equipment model. In case of any deviation or redundancy or additional scope of supply is noticed, vendor is required to obtain clarification from HBL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
XI.	Refer Installation Requirement Specification and Specific Instruction with URS NPI-120310-IRS-S1-02
XII.	Refer Tender document with URS NPI-120310-EQP-S1-TD-02

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
Unwashed vials: Vials shall be loaded through tray onto the turntable (unscramble), and the vials will be singled to the washing station.	
3.2 Brief Process Steps	
3.2.1 Vial Washing Machine	
The rotary washing machines shall be capable to accommodate multiple cleaning stations • Station 1: Purified water 1 x interior / 1 x exterior • Station 2: Compressed air 1 x interior • Station 3: Recirculated WFI 1 x interior • Station 4: Compressed air 1 x interior • Station 5: Fresh WFI 1 x interior • Station 6: Compressed air 2 x interior / 1 x exterior	
a) Purified water: Purified water is used in the initial rinsing of vials (Station 1) (internal and external). This purified shall pass through 0.22 micron filter before entering into washing station and after washing, 100% of the rinse water (PW) should go to drain.	
b) Re-circulated WFI: Re-circulated WFI is used for rinsing of vials (Station 3) (internal). The vial washing machine shall have all arrangement for recirculation of water. The recirculated water shall pass through a pre-filter 5-micron filter. The vendor shall inform the exact arrangement of recirculation system in its technical offer. Fresh WFI to be considered as makeup of the tank.	
c) Filtered Compressed air: Filtered (0.22 micron) compressed air shall be used to blow out water from the vial between different washing steps. Compressed air shall also be used for removing water from the washed vials after final rinse to make it dry. *Filter housing with staubli connection (suitable for connection with integrity test apparatus) shall be vendor scope.*	
d) Fresh WFI: WFI shall be used as washing media in the vial washing machine. The vial washing machine shall be suitable to collect WFI directly from the room supply valve of WFI distribution loop and it will be passed to the machine. WFI shall be used for final rinse of vials. The interface location of connecting WFI line to the washing machine will be in the scope of the vendor. *Filter housing with staubli connection (suitable for connection with integrity test apparatus) shall be vendor scope.*	
e) Transport System: Appropriate system for holding of vials to provided during transportation of vials to the washing station in upside down position for easy cleaning and after washing the vials will be re-inverted to their original position and transferred it to the depyrogenation tunnel.	
f) Exhaust Module: The Machine shall have exhaust module to extract water vapour generated during washing cycle from the washing machine / room. The module shall consist of: Filter flange and flap to connect the blower which shall be in the technical area. *The SS duct with drain and filter will be in user scope and suction motor will be in equipment supplier scope.*	

Specifications	Remarks
3.2.2 Depyrogenating Tunnel	
Performance requirements: • No decoloration of the vial • No breakage of vial • ≥ 3 log reduction in endotoxin to be achieved. • No change in the vial property.	
a) Washed vials from the washing machine: The washed vials shall be transported automatically to the infeed zone of the tunnel by a conveyor from washing machine.	
b) Air: The room air shall be sucked, supplied and recirculated by the air handling unit of the tunnel. Final filtration is done by H 13 HEPA filter for hot zone and H 14 HEPA filter for drying and cooling zone respectively. The air shall be delivered as unidirectional airflow from the laminar flow unit of the equipment. Vendor shall inform the quantity of air intake from room.	
c) **Infeed Zone:** Glass vials enters the tunnel belt and is spread to the width of the tunnel belt.	
I. **Temperature:** Limited amount of heated air from the heat zone passes into the infeed zone to rise the temperature of the glass vials, prior to their entry in to the heat zone. Heat zone should have suitable temperature monitoring, recording and display system in place.	
II. **Air Flow:** The glass is subjected to unidirectional air flow consistent across the width of the zone. Air velocity is maintained +/-20% of the average airflow, and is delivered from the HEPA air filter at a rate of min 0.7 m/sec. Fresh air is provided to the inlet of the HEPA filter. Air is not recirculated (once through). A differential pressure device with display and alarming capabilities will monitor the differential pressure between the internal zone and the outside room pressure. Exhaust air exits the Infeed Zone through a duct to the outside of the washer and sterilisation room.	
d) **Heat Zone:** The glass is transferred into the heat zone where the temperature is controlled to a level capable of providing the required thermal activation factor (FH). The FH provides the necessary temperature and time to ensure the required 6 log reduction for viable germs and ≥3 log reductions for endotoxins.	
I. **Temperature:** The temperature within the heat zone must be adjustable in 5°C increments from ambient to a maximum of 350°C. The temperature uniformity / distribution measured above the conveyor in the empty tunnel should be within the range of +/- 5°C of the average, as measured in line across the belt. The temperature uniformity / distribution measured inside of the vial should be within the range of +/- 5°C for tubular glass, as measured in line across the belt. A suitable temperature monitoring, recording and display system in place.	
II. **Air Flow:** The glass is subjected to laminar air flow consistent across the width of the zone. Air velocity is maintained to +/-20% of the average airflow, and is recirculated through the HEPA air filter at a rate of 0.7 meters/sec. Fresh air is provided to the inlet side of the HEPA filter. There is no exhaust in the heat zone. Fresh air is used to make-up air that is lost to the adjacent zones through the gates. A differential pressure device with display and alarming capabilities will monitor the differential pressure between the internal zone and the washer/tunnel room pressure.	
e) **Cool Down Zone:** The glass is transferred to the cool down zone where the glass is cooled down gradually to near ambient temperatures to prevent cracking of the glass, or damage to the outfeed guides due to high temperatures.	

	Specifications	Remarks
I.	**Temperature Control:** The temperature of the glass must be cooled down to a maximum of 22 ± 2°C at the exit of the tunnel. Cooling of the vials is accomplished using fresh HEPA filtered air. A suitable temperature monitoring, recording and display system in place.	
II.	**Air Flow:** The glass is subjected to unidirectional air flow consistent across the width of the zone. Air velocity is maintained to +/-20% of the average airflow and passes through the HEPA air filter at a rate of 0.7 meters/sec. Fresh air is provided to the inlet side of the HEPA filter through a roughing filter. Air/ Chilled water through the heat exchanger is recirculated with cooling battery. A differential pressure device with display, recording and alarming capabilities will monitor the differential pressure between the internal zone and the outside room pressure.	
3.3	**Output & Discharging method**	
	The depyrogenated vials are transferred from the cooling zone to the filling machine turn table by the conveyor movement.	
4.0	**PRODUCTIVITY REQUIREMENT**	
4.1	**Desired/ suggested capacity**	
	Capacity: The washing machine shall be suitable to produce washed and sterilized vials at the rate of 200 vials per minute, based on the vial size of 2R and 6R and minimum of 100 vials/minute for customized vials. **Vendor shall consider DIN/ISO 8362-1 – 6R, 2R & customized vials as per URS annexure-3.** ***(Refer URS annexure-3 for specifications of customized vials)*** ***Efficiency:*** • Washing machine: Must be greater than 98% with respect to quality aspects. • Depyrogenation: 100% with respect to quality aspects.	
4.2	**Standard batch size**	
	The machine should be capable to wash and sterilize the 40000 to 90000 vials/batch and should be capable of running on a continuous basis.	
4.3	**Change Over Time (if applicable)**	
	Change part replacement should not take more than 30 minutes.	
4.4	**Other Productivity Requirement**	
4.4.1	Vendor to give information on change over time from one product to another product with the suitable output.	
4.4.2	The equipment shall be able to run for 24 hours.	
5.0	**CONTAINMENT**	
	Not Applicable	

Specifications	Remarks
6.0 GMP REQUIREMENTS	
6.1 Process control	
6.1.1 **Washing Machine**	
Equipment to have suitable control system to verify and control the process.	
6.1.2 **Depyrogenating Tunnel**	
Equipment to have suitable control system to verify and control the process.	
6.2 Failure mode detection and Alarms	
6.2.1 **Washing Machine**	
A. Equipment shall be provided with audio visual alarms and the equipment must restart with manual intervention.	
a) Main drive motor overload, Turntable motor overload, Pump overload	
b) In feed/ out feed empty	
c) In feed jamming and Maximum out feed condition reached at the inlet of tunnel	
d) Toppled vials, machine should stop with alarm	
e) Emergency stop activated	
f) Safety covering of washing machine open	
g) Malfunctioning of vapour exhaust system / Vapour exhaust blower overload	
B. Interlock	
a) Washing machine stop – WATER STOP.	
b) Water injection start – when nozzle enters in the vials.	
c) Pressure of clean utilities- high & low	
6.2.2 **Depyrogenation Tunnel**	
A. Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
a) Emergency stop activated	
b) In feed empty	
c) In feed/ out feed jamming	
d) Motor overload	
e) Alarm on, when belt operation stops and resumes with difference in alarm.	

Specifications	Remarks
f) Maximum out feed reached in the in feed turntable of filling machine	
g) The differential air pressure in the Depyrogenation zone must always be higher with respect to the drying zone and the cooling zone.	
B. Interlock for depyrogenation tunnel	
a. Pressure differentials of pre-hot zone, sterilization zone, cooling zone out of set limit – Machine shall interlock	
b. Temperature of pre-hot zone, sterilization zone, cooling zone out of set limit – Machine shall interlock	
c. Fan of the heating zone stops working- Machine shall interlock	
6.3 In –Process control	
6.3.1 Sampling valve for washing media (WFI) and compressed air to be provided at relevant location.	
6.3.2 In case re-circulated water, suitable sampling provision is required.	
6.4 Level of instrumentation	

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Parameter	Purpose	Type of control and Instrumentation	Failure Mode Detection	Alarm
Vial Washing Machine				
Infeed/ Outfeed sensor	Vial counting	Sensor	NA	___
Temperature	For monitoring, indicating the temperature of WFI supply	Temperature probe with transmitter, and indicator	Low or High	Yes
Level	For monitoring, indicating and controlling the level of WFI in re-circulating tank.	Level sensor, indicator with controller	Low or High	Yes
Pressure	For all clean utility inputs	Feedback for the machine to hold	Low or high	Yes
Speed	To adjust the vials speed	VFD	Low or High	Yes

Specifications					Remarks
Depyrogenating Tunnel					
Temperature	To monitor, control and record the temperature of drying zone	Temperature Transmitter	Low or High	Yes	
Temperature	To monitor, control and record the temperature of depyrogenation zone (beginning)	Temperature Transmitter	Low or High	Yes	
Temperature	To monitor, control and record the temperature of depyrogenation zone (end)	Temperature Transmitter	Low or High	Yes	
Temperature	To monitor, control and record the temperature of cooling zone	Temperature Transmitter	Low or High	Yes	
Air velocity	To measure air velocity of the tunnel laminar flow in all zones	Anemometer connected to PLC	-	Yes	
Speed	To determine the conveyor speed	VFD	Low or High	Yes	
Differential pressure	To monitor, control and record the differential pressure across HEPA filter	Pressure transducer (indicator)	-	-	
Differential pressure with respect to adjoining room	To monitor, and record the pressure cascade from filling room to washing and sterilization room between each zone.	Pressure transducer	-	-	
Vial sensor	Vial overload in in-feed turntable of filling machine	Sensor	NA	Yes	

6.5 Batch record display and printing

Basic / standard data acquisition to be done in HMI. This shall be mainly to collect the data by using external device.

Online printing using dot matrix printer along with strip chart recorder to be provided

	Specifications	Remarks
6.6	**GMP requirements (Others)**	
6.6.1	All parts of the machine exposed clean room area (Class D/C/B) must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.	
6.6.2	All Contact parts with the product and cleaning solution shall be SS316L	
6.6.3	The machine has to be designed in such way, that air turbulence is minimized.	
6.6.4	All sensoric, controls, PLC, HMI, all LAF, Differential cascades, ventilators, exhaust fans shall have provision to connect to the UPS.	
6.6.5	Two power supply entry shall be provided, the wiring of all mentioned above components shall separate than the other components wiring i.e. one for UPS and one for main power supply.	
6.6.6	Required support services, like cable tray/SS conduits/pendants outside the complete machine will be in client's scope.	
6.6.7	Vendor shall demonstrate 6 log reduction for viable germs and ≥3 log for endotoxins.	
6.6.8	All product contact parts should be made with SS 316L	
6.6.9	All non-product contact parts should be made with SS 304	
6.6.10	All Gaskets should be made of food grade silicone /EPDM and should be non-toxic.	
6.6.11	Equipment should be fitted with SS 316 L filter housing for all the utilities required.	
6.6.12	**Vial washing**	
a)	Manual hood lifting system shall be provided.	
b)	Machine should not have any hold up water in the machine. Slopes should be designed for complete draining of any hold-up water.	
c)	Machine should have manual intervention to start-up the cycle for flushing of hold water at intermediate washing steps if machine is stopped for sufficiently long interval.	
d)	The water collection tub shall be completely drainable with drain valve for draining the water. The sloping inside the tub shall be towards the drain point.	
e)	When vial washing machine stops the machine shall have suitable outputs to close the WFI and purified water user points valves to avoid dead lags.	
f)	After vial washing, vials should not be exposed to outer environment before entering to tunnel area.	
g)	Inching provision to be provided both front end and back end side.	
h)	Manual override system to be provided for maintenance of the machine.	
6.6.13	**Depyrogenating tunnel**	
a)	All LAFs should have provision for UPS	
b)	The tunnel shall be provided with a strip chart recorder for continuous graph of temperature of all zone, differential pressures between different zones & adjoining rooms and to record	

Specifications	Remarks
conveyor speed & power failure (if any). Recording time intervals should be adjustable on time to time basis.	
c) The connections of DEHS test in the side cladding of the tunnel have to be Tri-clover connections.	
d) The tunnel will have a night mode that will allow an energy-efficient mode of operation to hold temperature and sterility of the tunnel between batches. It has to be possible to reduce the temperature at night and at weekend with a programmable clock or manually. When temperature is below 100℃ the fan of the heating zone is turned off.	
e) During IQ, Following validations (not limited to the points mentioned below) to be done by vendor i. Demonstrate more than 3 log reduction of endotoxin. ii. Heat distribution study- empty load iii. Heat penetration study- with load iv. Non viable particle count v. Air velocity measurement vi. Integrity of HEPA filters	
f) If temperature decreased below minimum set value, the conveyor should stop automatically.	
g) Validation document to give precise information on the time and minimum temperature exposure of vials inside the tunnel during depyrogenation at maximum vials output.	
h) Data Input requirements to be provided: 1) Batch No 2) Vial size 3) Sterilization temperature (Minimum and Maximum values) 4) Conveyor-off temperature	
6.7 Specific requirements	
6.7.1 Operating height: must be 900 mm ± 30 mm (to be finally decided during mock-up test of filling machine). The height of the machine has to be adjustable by means of adjustable legs.	
6.7.2 Size of the opening of the tunnel (outfeed) at the filling room shall be provided.	
6.7.3 Physical separation between washing area and out feed area is required, to avoid glass splinters from spreading into open area.	
6.7.4 In feed turntable shall be designed to provide 3 minutes buffer to the machine speed.	
6.7.5 All setting shall be user adjustable and through the control panel whichever is possible.	
6.7.6 All supply fans should be provided with variable frequency drives.	
6.7.7 The complete machine and its components have to be designed and constructed to avoid stagnation of water (slope of atleast 1%)	
6.7.8 Cable between the single machines/units and the control cabinets inside the clean rooms are within the scope of delivery.	
6.7.9 Control panel for the vial washing/tunnel shall be in the vial washing/tunnel room.	

Specifications	Remarks
6.7.10 Vendor to provide the provision for removal of broken vials in vial washing machine.	
6.7.11 This equipment should be compatible for integration with in-feed turntable of the filling and stoppering machine.	
6.7.12 Vendor has to supply all the change-over parts, if any for the different vials sizes (2R, 6R and customized vial).	
6.7.13 GMP toolbox shall be provided as per requirement for changing the change-over parts and for general maintenance, which should include all the tools for the said machine maintenance.	

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the **Bacterial Vaccine Formulation Block** of **Integrated Vaccine Complex, Chengalpattu**

Equipment Location:
Floor: **Ground Floor,**
Room dimensions (L x W): 6600mm x 6300mm
Room No:**F2G043**
False Ceiling height: **3000 mm**
The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1.** The equipment must be positioned as per the generic layout provided below.

Physical condition of the rooms:

Vial Washing and Sterilization Room:

1. Room will be non-hazardous
2. Class: EU Class “C”
3. Differential Pressure: 45 Pa Absolute
4. Temperature maintained: 22 ^{0}C ±2^{o}C
5. Relative Humidity: NMT 55%

7.2 Available Utility

Vial Washing & Depyrogenation machine

a) Electricity: Single (220 V) & 3 phase (420 - 440 V) (Report Requirement)
b) Compressed air 6-8 bar, 21 CFM (Report Requirement)
c) Purified water @ 3 to 3.5 bar, 900 LPH (Report Requirement)
d) Chilled water @ 7 to 12 ^{o}C, 2 to 3 bar and 5 m^{3}/hr (Report Requirement)
e) WFI @ 3-5 bar at 80 deg C and 200 LPH (Report Requirement)

Note:

- Vendor to confirm on the above utilities provided for the equipment.
- Vendor to provide Pressure reducing valves and Pressure gauges along with the equipment as per equipment utility requirements.
- Vendor to provide the all utility consumptions in details for the equipment during pre-bid.

8.0 ABBREVIATION

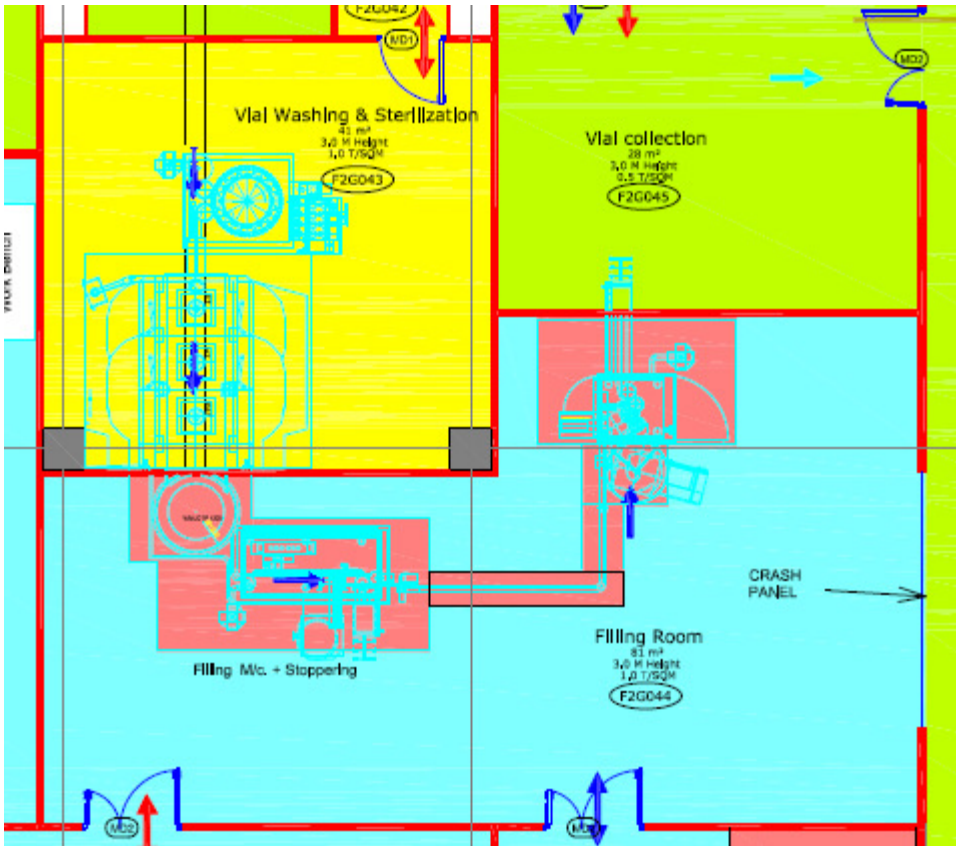
Abbreviation	Definition
DQ	Design Qualification
DEHS	*Di-Ethyl-Hexyl-Sebacat*
FAT	*Factory Acceptance Test*
GA	General Arrangement
HEPA	High Efficiency Particulate Air
HMI	Human Machine Interphase
MOC	Material Of Construction
NA	Not applicable
O-RABS	Open-Restricted Access Barrier System
PLC	Programmable Logic Controller
PID	Piping and Instrumentation Diagrams
QA	Quality Assurance
Ra	Roughness average
RPM	Revolutions Per Minute
RTP	Rapid Transfer Port
SS	Stainless steel
UPS	Uninterrupted Power Supply
VFD	Variable Frequency Drive
VWD	Vial Washing Machine with Depyrogenating Tunnel
WFI	Water For Injection

REVISION INDEX

Revision	Date	Reason for revision	
00	25-07-2012	First Draft for Client's Review	
01	27-05-2013	As per comments given by HBL on 27-05-2013 by email.	
02	07-11-2013	As per comments given by HBL on 28-10-2013 by email.	
03	03-02-2014	Updated with respect to change in vial size.	
04	13-02-2014	Updated as per comments given by HBL on 13-02-2014 by email	
05	28-02-2014	Updated as per comments given by HBL on 18.02.2014 and 27.02.2014 by email	
		Section	**Revision**
		Approved Signatures	Checked by and Approved by Changed
		3.2.2 (e) (i)	The temperature of the glass must

			be cooled down to a maximum of 22±2°C at the exit of the tunnel. Cooling of the vials is accomplished using fresh HEPA filtered air. A suitable temperature monitoring, recording and display system in place.
		3.2.2 (e) (ii)	Air/ Chilled water through the heat exchanger is recirculated with cooling battery. A differential pressure device with display, recording and alarming capabilities will monitor the differential pressure between the internal zone and the outside room pressure.
		4.1	***Efficiency:*** Washing machine: Must be greater than 98% with respect to quality aspects. Depyrogenation: 100% with respect to quality aspects.
		6.2.2 (B) c.	Fan of the heating zone stops working- Machine shall interlock
		6.5	Basic / standard data acquisition to be done in HMI. This shall be mainly to collect the data by using external device. Online printing using dot matrix printer along with strip chart recorder to be provided
		6.6.12 (b)	The tunnel shall be provided with a strip chart recorder for continuous graph of temperature of all zone, differential pressures between different zones & adjoining rooms and to record conveyor speed & power failure (if any).Recording time intervals should be adjustable on time to time basis.
		Annexure 3	Format Revised

URS Annexure 1: LAYOUT POSITION
Room No: F2G043, Room Area: 41 m²



Annexure - 2

List of components and make for Vial Washing & Depyrogenating Tunnel

S.No	Description	Preferred List
1.	Mobile guide position transmitter	Pepperl Fuchs / Novotechnik
2.	Pressure transmitter	Bourdon Haenni / Dwyer / Wika / Testo
3.	Main Drive Gear Motor	Bonfiglioli/Seimens
4.	Frequency Inverter	Allen-Bradley/ Siemens
5.	Gear Box	Bonfiglioli/Bauer
6.	Proximity Switch	Contrinex/Rockwell/Omron
7.	Proximity Sensor	Contrinex/Rockwell/Omron
8.	Pressure Transmitter	Rosemount / Dwyer / Wika
9.	Recirculatory Water Pump	Grundfos/Alfa Laval
10.	Peristatlic pump	Masterflex / Watson Marlow
11.	Pressure Gauge	Rosemount / Dwyer / Wika
12.	Solenoid Valve	Gemu / Burkert
13.	Filters & Filter Housing	Pall/Millipore/Sartorius
14.	Air Connection	Festo / SMC/Sweglok
15.	Temperature Sensors (PT-100)	E & H / Negele/Rosemount
16.	Pressure sensors	E & H / Negele/Rosemount
17.	PLC	Allen-Bradley/Honeywell/Siemens
18.	HMI	Allen-Bradley/Siemens
19.	Inlet shutter position sensor	Novotechnik / Pepperl Fuchs
20.	Transmitter for inlet gate position	Novotechnik / Pepperl Fuchs