User Requirement Specifications
Vial Washing Machine
With
Depyrogenating Tunnel
Equipment ID: F-VWD 01

nne pharmaplan	User Requirement Specifications			
	Equipment/System	Vial Washing Machine with Depyrogenating Tunnel		
	Identification #	F-VWD 01	**Document#**	URS/ F-VWD 01
	Effective Date	2013-06-06	**Revision#**	04

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the installation of the Vial washing and Depyrogenation Tunnel
2	List of components and make

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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 "Revival of DPT Vaccine 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 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 .This equipment is a part of an integrated line.

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 re-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, fresh WFI with intermediate sterile compressed air drying. The equipment shall reduce contaminations and particle matter. It shall help to reduce the amount of endotoxins by the use of WFI at the last rinse. A combination of 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 250-350^{0}C.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 23ºC (±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.

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User Requirement Specifications

Equipment/System	Vial Washing Machine with Depyrogenating Tunnel		
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Effective Date	2013-06-06	**Revision#**	04

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 HLL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.
XI.	Refer Installation Requirement Specification and Specific Instruction with URS NPI_110831_IRS_PII_05
XII.	Refer Tender document with URS NPI/110831/EQP/TD/05

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All points of the IRS except the below mentioned would be applicable for the equipment

- 4.1.11, 4.1.13, 4.1.17
- FDA Guidance for industry, GAMP- 21 Part CFR 11, ANSI/NSF 49-2008,
- 5.6

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 stations.	
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: Recirculated WFI 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) Re-circulated WFI: Re-circulated WFI is used in the initial rinsing of vials (internal and external). 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.	
b) 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.*	
c) 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) and user point valve shall be vendor scope..*	
d) 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.	

Specifications	Remarks
e) 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, suction motor, and filter will be in user scope.*	
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.	
III. **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 reduction for endotoxins.	
IV. **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.	
V. **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	

Specifications	Remarks
washer/tunnel room pressure.	
d) 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.	
I. **Temperature Control:** The temperature of the glass must be cooled down to a maximum of 23±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. *Vendor to provide the time of contact for vials.*	
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 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 & depyrogenation machine shall be suitable to produce washed and sterilized vials at the rate of 200 Vials per minute, based on the vial size of 6 R **(as per DIN: ISO 8362-1 standard)** **Efficiency :** • Washing machine and Depyrogenation : 95%	
4.2 Standard batch size	
Standard batch size should be 90,000 vials/ batch (@6R).	
4.3 Change Over Time (if applicable)	
Not Applicable	
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	

Specifications	Remarks
e) Depyrogenation tunnel belt stops	
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	
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	To monitor, indicate and control 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
Depyrogenating Tunnel				

Specifications					Remarks
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	-	-	
Differential pressure with respect to adjoining room	To monitor and record the pressure cascade from filling room to washing and sterilisation room between each zone.	Pressure transducer	-	-	

6.5 Batch record display and printing

Basic / standard data acquisition system to be provided. This shall be mainly to collect and store the data in industrial PC. Data output should be in non-editable format with print out option. The PC and the printer in vendor scope.

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 The machine has to be designed in such way, that air turbulence is minimized.	
6.6.3 All sensoric, controls, PLC, HMI, all LAF, Differential cascades, ventilators, exhaust fans shall have provision to connect to the UPS.	

Specifications	Remarks
6.6.4 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.	
6.6.5 Required support services, like cable tray/SS conduits/pendants outside the complete machine will be in client's scope.	
6.6.6 Vendor shall demonstrate 6 log reduction for viable germs and ≥ 3 log for endotoxins.	
6.6.7 **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 user points valves to avoid dead lags.	
6.6.8 **Depyrogenating tunnel**	
a) All LAFs should have provision for UPS	
b) The tunnel shall be provided with a minimum 6 point strip chart recorder for continuous graph of temperature of all zone and differential pressures between different zones and adjoining rooms	
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.	
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	

Specifications	Remarks
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.	
6.7.10 CE certification for the vial washing machine and depyrogenation tunnel is mandatory and would be part of user requirements.	

7.0 Constraints

7.1 Equipment location and available space

This equipment will be installed in the Formulation area of **Revival of D.P.T Vaccine Manufacturing Facility, PII, Coonoor.**

Equipment Location:
Floor: Ground Floor, Formulation Block
Room Area : 49 m²
False Ceiling height: 3 m
Room No : F1G042
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:

Washing and Sterilisation Room:

1. Room will be non-hazardous
2. Class: EU Class “D”
3. Differential Pressure: 5Pa Absolute
4. Temperature maintained: 22°C ±2°C
5. Relative Humidity: <55% RH

7.2 Utility

Vial Washing & Depyrogenation machine

a) Electricity: Single (220 V) & 3 phase (420 - 440 V) (Report Requirement)
b) Compressed air 6-8 bar (Report Requirement)
c) WFI @ 3-5 bar at 80 deg C (Report Requirement)

In the scope of the client, the supply will include the WFI and compressed air (with pressure relief valve).

8.0 Abbreviation

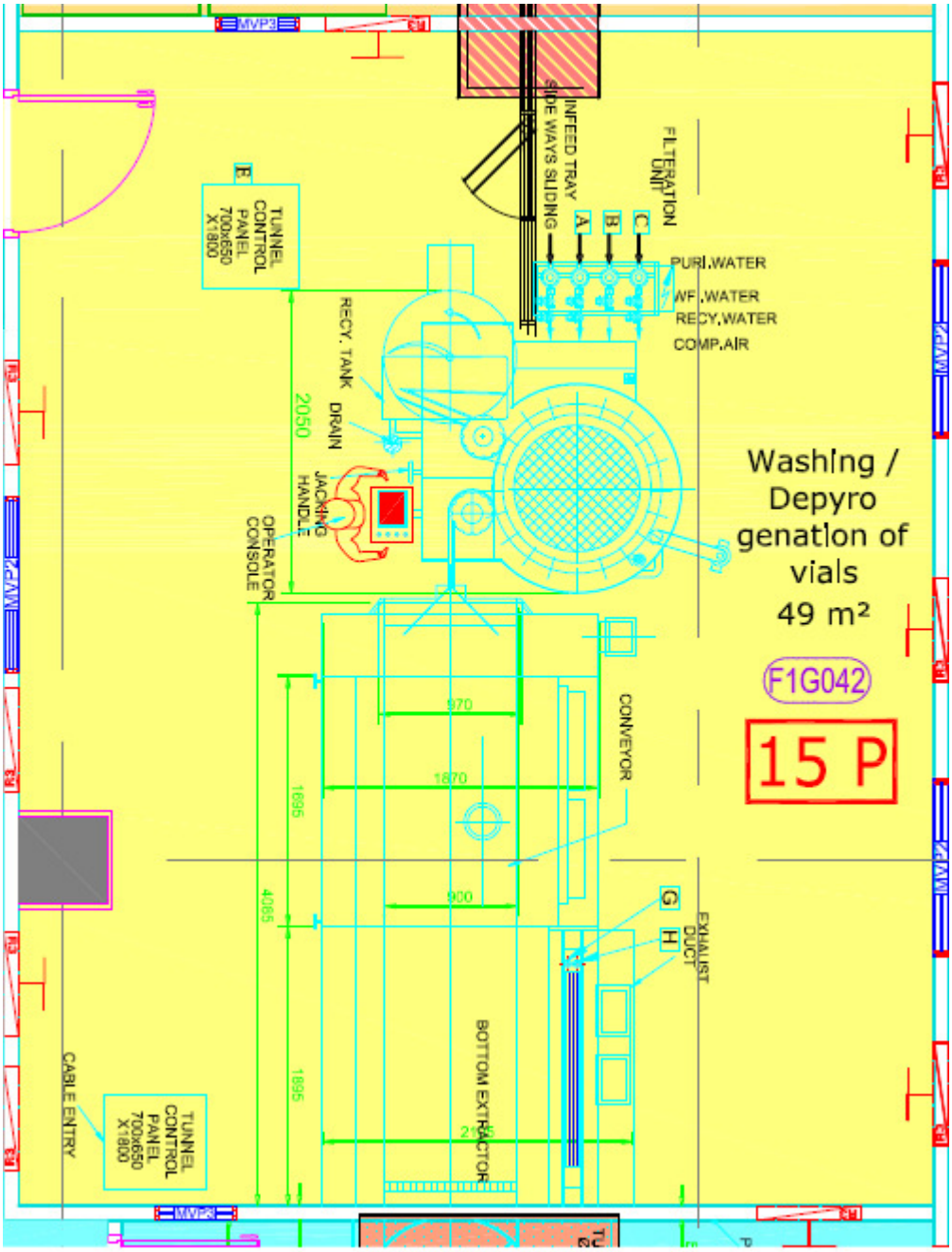
Abbreviation	Definition
DQ	Design Qualification
DEHS	Di-Ethyl-Hexyl-Sebacat
GA	General Arrangement
HEPA	High Efficiency Particulate Air
HMI	Human Machine Interphase
MOC	Material Of Construction
NA	Not applicable
PLC	Programmable Logic Controller
QA	Quality Assurance
Ra	Roughness average
RPM	Revolutions Per Minute
SS	Stainless steel
UPS	Uninterrupted Power Supply
VFD	Variable Frequncy Drive
VWD	Vial washing machine with Depyrogenating Tunnel
WFI	Water For Injection

Revision index

Revision	Date	Reason for revision
00	18.05.2012	First Draft for Client's Review
01	2012-11-23	Format changed as per HLL requirement
02	2013-04-15	As per technical discussions had with HLL during BCGVL URS preparation
03	2013-04-25	As per BCGVL pre-bid meeting MOM dated on 12.04.2013
04	2013-06-06	As per discussion had with PIIC team on 2013-05-28

URS Annexure 1: LAYOUT POSITION

Room No: F1G042, Room Area: 49 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.	Pressure Gauge	Rosemount / Dwyer / Wika
11.	Solenoid Valve	Gemu / Burkert
12.	Filters & Filer Housing	Pall/Millipore/Sartorius
13.	Air Connection	Festo / SMC/Sweglok
14.	Temperature Sensors (PT-100)	E & H / Negele/Rosemount
15.	Pressure sensors	E & H / Negele/Rosemount
16.	PLC	Allen-Bradley/Honeywell/Siemens
17.	HMI	Allen-Bradley/Siemens
18.	Inlet shutter position sensor	Novotechnik / Pepperl Fuchs
19.	Transmitter for inlet gate position	Novotechnik / Pepperl Fuchs