

MINUTES OF THE MEETING

**PRE BID MEETING OF TENDER FOR
SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF
VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINE AT
HLL BIOTECH LIMITED, CHENGALPATTU, CHENNAI**

Document No. : NPI-120310-EQP-S1-TD-02

Venue : HLL Biotech Limited, Chennai

Date : 20.03.2014

Project : Integrated Vaccines Complex, Chengalpattu

Attendees : See attached list of attendees

Issued by : CEO HBL

Issued on : 21st March 2014

Issued from : NNE Pharmaplan India Limited, Bangalore

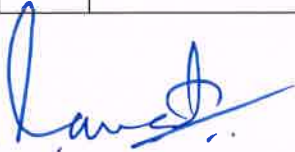
Agenda	
1.	Pre-bid Meeting for supply, installation, commissioning and validation of Vial Washing Machine with Depyrogenating Tunnel and Vial Sealing Machine for IVC, Chengalpattu

S. No.	Clarifications on queries																																																																												
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A	Discussion Tender Enquiry Document: NPI-120310-EQP-S1-TD-02																																																																												
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1.	Vendor requested for AutoCAD Format of the room layouts & the same is attached as annexure.																																																																												
2.	Tender fee of 500USD at an exchange of rate 1USD = 61.1248 INR as on 12-03-14 [Tender published date] Refer Pg No. 4/92 in TE doc																																																																												
3.	Purchaser shall provide 50 Nos. of 2R, 4R, 6R & customized vials and 5000 Nos. aluminium seals of 13mm, 20 mm for designing of the hopper.																																																																												
4.	Purchaser shall provide 20,000 Nos. of 2R, 4R, 6R & customized vials and 15000 Nos. aluminium seals of 13mm, 20mm of each type to the qualified vendor for conducting the FAT.																																																																												
5.	Consumables for 2years of continuous operation to be provided as a part of supply.[except ceiling suspended & expanded LAF-HEPA filters& utility filters]																																																																												
6.	Majority of spares [not limited to mentioned in URSs] for 1year of continuous operation to be provided as a part of supply																																																																												
7.	Conveyor system - 3No.s, dead-plate (Diaphragm) -3No.s for vial filling machine from outfeed of the depyrogenating tunnel to be provided as a part of supply. The length of the each conveyor belt should be considered at an approximate length of 1.5m ± 30% (as per site conditions)																																																																												
8.	<p>Infeed turntable- 3 nos. to be provided as a part of supply and the same should be quoted as a separate line item (Pg. No 4/92).</p> <table border="1"> <thead> <tr> <th>SI no</th> <th>Item (Package)</th> <th>Equipment ID</th> <th>Qty (Nos.)</th> <th>Capacity / Size</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Vial Washing Machine With Depyrogenating Tunnel</td> <td>F2-VWD 01,</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>2.</td> <td>Vial Washing Machine With Depyrogenating Tunnel</td> <td>F1-VWD 01</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>3.</td> <td>Vial Washing Machine With Depyrogenating Tunnel</td> <td>F1-VWD 02</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>4.</td> <td>Vial sealing machine</td> <td>F2-VSM 01</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>5.</td> <td>Vial sealing machine</td> <td>F1-VSM 01</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>6.</td> <td>Vial sealing machine</td> <td>F1-VSM 02</td> <td>1</td> <td>200 Vials per minute</td> </tr> </tbody> </table>	SI no	Item (Package)	Equipment ID	Qty (Nos.)	Capacity / Size	1.	Vial Washing Machine With Depyrogenating Tunnel	F2-VWD 01,	1	200 Vials per minute	2.	Vial Washing Machine With Depyrogenating Tunnel	F1-VWD 01	1	200 Vials per minute	3.	Vial Washing Machine With Depyrogenating Tunnel	F1-VWD 02	1	200 Vials per minute	4.	Vial sealing machine	F2-VSM 01	1	200 Vials per minute	5.	Vial sealing machine	F1-VSM 01	1	200 Vials per minute	6.	Vial sealing machine	F1-VSM 02	1	200 Vials per minute	<table border="1"> <thead> <tr> <th>SI no</th> <th>Item (Package)</th> <th>Equipment ID</th> <th>Qty (Nos.)</th> <th>Capacity / Size</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Vial Washing Machine With Depyrogenating Tunnel</td> <td>F2-VWD 01,</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>2.</td> <td>Vial Washing Machine With Depyrogenating Tunnel</td> <td>F1-VWD 01</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>3.</td> <td>Vial Washing Machine With Depyrogenating Tunnel</td> <td>F1-VWD 02</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>4.</td> <td>Vial sealing machine</td> <td>F2-VSM 01</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>5.</td> <td>Vial sealing machine</td> <td>F1-VSM 01</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>6.</td> <td>Vial sealing machine</td> <td>F1-VSM 02</td> <td>1</td> <td>200 Vials per minute</td> </tr> <tr> <td>7.</td> <td>infeed Turn table for Vial Filling Machine</td> <td>-</td> <td>3</td> <td>-</td> </tr> </tbody> </table>	SI no	Item (Package)	Equipment ID	Qty (Nos.)	Capacity / Size	1.	Vial Washing Machine With Depyrogenating Tunnel	F2-VWD 01,	1	200 Vials per minute	2.	Vial Washing Machine With Depyrogenating Tunnel	F1-VWD 01	1	200 Vials per minute	3.	Vial Washing Machine With Depyrogenating Tunnel	F1-VWD 02	1	200 Vials per minute	4.	Vial sealing machine	F2-VSM 01	1	200 Vials per minute	5.	Vial sealing machine	F1-VSM 01	1	200 Vials per minute	6.	Vial sealing machine	F1-VSM 02	1	200 Vials per minute	7.	infeed Turn table for Vial Filling Machine	-	3	-
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9.	The modular partition panel between the vial washing and vial filling room is of 150mm thickness																																																																												
10.	The last date (01.04.2014) of bid submission & bid opening was agreed upon by the attendees (vendors) and commercial & payment terms shall remain as described in TE doc. (4/92 and 92/ 92)																																																																												
11.	The supply of materials and tests for 6 log reduction and ≥ 3log reduction for endotoxins shall be carried out in Purchaser's lab in the presence of the vendor. The vendor shall be responsible for achieving the set benchmark.																																																																												
12.	All interface inputs and outputs between the Vial Filling Machine and the depyrogenation tunnel shall be provided upon award of the orders to vendors.																																																																												
13.	Mobile LAF trolley is not included in the scope of supply for Vial Sealing Machines.																																																																												
14.	For Vial Washing machines and Depyrogenation tunnels it was informed that the FAT shall be carried out without HEPA and SAT shall be carried out with HEPA																																																																												
15.	For all product contact parts of Depyrogenation Tunnel MOC should be of SS316L																																																																												

S. No.	Clarifications on URs													
B	URS: F1-VWD-01, F1-VWD 02 and F2- VWD-01													
	URS Point number and excerpt / description of the specification	Point modified as/Comment												
1.1	<p>2.0 EQUIPMENT DESCRIPTION:</p> <p>Vial Washing Machine</p> <table border="1" data-bbox="204 533 799 674"> <tr> <td data-bbox="204 533 260 674">1</td> <td data-bbox="264 533 405 674">In feed turntable</td> <td data-bbox="410 533 799 674">Feeding the vials to the turntable with tray. The vials will be unscrambled and singled to the washing station.</td> </tr> </table> <p>Depyrogenating tunnel</p> <table border="1" data-bbox="204 797 799 909"> <tr> <td data-bbox="204 797 260 909">1</td> <td data-bbox="264 797 405 909">Conveyor</td> <td data-bbox="410 797 799 909">Vials to be transported through appropriate transport system.</td> </tr> </table>	1	In feed turntable	Feeding the vials to the turntable with tray. The vials will be unscrambled and singled to the washing station.	1	Conveyor	Vials to be transported through appropriate transport system.	<p>2.0 EQUIPMENT DESCRIPTION</p> <p>Vial Washing Machine</p> <table border="1" data-bbox="863 533 1458 734"> <tr> <td data-bbox="863 533 919 734">1</td> <td data-bbox="924 533 1064 734">In feed turntable</td> <td data-bbox="1069 533 1458 734">Feeding the vials to the turntable with conveyor belt (scope of supply of vendor) from decartoning room. The vials will be unscrambled and singled to the washing station.</td> </tr> </table> <p>Depyrogenating tunnel</p> <table border="1" data-bbox="863 824 1458 1025"> <tr> <td data-bbox="863 824 919 1025">1</td> <td data-bbox="924 824 1064 1025">Conveyor</td> <td data-bbox="1069 824 1458 1025">Vials to be transported through appropriate transport system. [An auto pusher system to push the overload of vials in the tunnel shall be provided.]</td> </tr> </table>	1	In feed turntable	Feeding the vials to the turntable with conveyor belt (scope of supply of vendor) from decartoning room. The vials will be unscrambled and singled to the washing station.	1	Conveyor	Vials to be transported through appropriate transport system. [An auto pusher system to push the overload of vials in the tunnel shall be provided.]
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1.2	<p>Pg.No:- 5/19 2.0 Equipment description</p> <p>"The temperature of vial at the outlet of cooling zone should be 22°C (±2°C)."</p>	<p>Pg.No:- 5/19 2.0 Equipment description</p> <p>For F1-VWD 01 and F2-VWD 01- "The temperature of vial at the outlet of cooling zone should not more than 30°C." For F1-VWD 02- The temperature of vial at the outlet of cooling zone should be 22°C (±2°C).</p>												
1.3	<p>3.2.1 Vial Washing Machine</p> <p>The rotary washing machines shall be capable to accommodate multiple cleaning stations</p> <ul style="list-style-type: none"> • 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 	<p>3.2.1 Vial Washing Machine</p> <p>The rotary washing machines shall be capable to accommodate multiple cleaning stations</p> <ul style="list-style-type: none"> • Station 1: Recirculated WFI 1 x interior + 1 x exterior • Station 2: Compressed air 1 x interior • Station 3: Purified water 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 												
1.4	<p>3.2.1 Vial Washing Machine d. Fresh WFI: <i>Filter housing with staubli connection (suitable for connection with integrity test apparatus) shall be vendor scope</i></p>	<p>3.2.1 Vial Washing Machine d. Fresh WFI: <i>Filter housing with 0.22 um Code 7 filter TC end along with distance piece & staubli connection (suitable for connection with integrity test apparatus) shall be vendor scope</i></p>												

S. No.		Clarifications on queries													
1.5	<p>3.2.2 Depyrogenating Tunnel</p> <p>d) Heat zone</p> <p>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</p> <p>ii-Air flow</p> <p>Air velocity is maintained +/-20% of the average airflow, and is delivered from the HEPA air filter at a rate of 0.7 m/sec.</p> <p>e) Cool down zone</p> <p>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.</p>	<p>3.2.2 Depyrogenating Tunnel</p> <p>d) Heat zone</p> <p>The temperature uniformity / distribution measured above the conveyor in the empty tunnel should be within the range of +/- 15°C (for temperature set above 250 °C) of the average, as measured in line across the belt. (As per USP-29 Chapter 1211)</p> <p>ii-Air flow</p> <p>Air velocity is maintained +/-20% of the average airflow, and is delivered from the HEPA air filter at a rate of 0.45 m/sec. (for infeed zone and heat zone)</p> <p>e) Cool down zone</p> <p>i. The temperature of the glass must be cooled down to a temperature not more than 30°C at the exit of the tunnel (For F1-VWD 01 and F2-VWD 01).</p> <p>Temperature Control: The temperature of the glass must be cooled down to a maximum of 22±2°C at the exit of the tunnel (For F1-VWD 02).</p>													
	<p>Annexure - 3</p> <p>List of spares for Vial Washing & Depyrogenating Tunnel</p> <table border="1"> <tr> <td>4</td> <td>Heater bank</td> <td>1 complete set</td> </tr> </table>	4	Heater bank	1 complete set	<p>Annexure - 3</p> <p>List of spares for Vial Washing & Depyrogenating Tunnel</p> <table border="1"> <tr> <td>4</td> <td>Heater bank/ Heaters</td> <td>1 complete set</td> </tr> </table> <p>1 Complete set of heat resistant HEPA filters should also be provided</p>	4	Heater bank/ Heaters	1 complete set							
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1.8	Conveyor system - 3No.s, dead-plate (Diaphragm) -3No.s for vial sealing machine to be provided as a part of supply. The length of the each conveyor belt should be considered at an approximate length of 600 mm (as per site conditions)														
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1.9	<p>2.0 EQUIPMENT DESCRIPTION:</p> <table border="1"> <tr> <td>1</td> <td>In feed turntable</td> <td> <p>a. To receive the full stoppered vials from Lyophiliser, transferred through mobile LAF cart or</p> <p>b. To receive the full stoppered vials from the stoppering station transferred through conveyor belt (In sealing machine vendor scope)</p> </td> </tr> <tr> <td>6</td> <td>Out feed unit</td> <td>The vials shall be collected in the tray manually from the out feed of sealing unit.</td> </tr> </table>		1	In feed turntable	<p>a. To receive the full stoppered vials from Lyophiliser, transferred through mobile LAF cart or</p> <p>b. To receive the full stoppered vials from the stoppering station transferred through conveyor belt (In sealing machine vendor scope)</p>	6	Out feed unit	The vials shall be collected in the tray manually from the out feed of sealing unit.	<p>2.0 EQUIPMENT DESCRIPTION:</p> <table border="1"> <tr> <td>1</td> <td>In feed turntable</td> <td>a. To receive the full stoppered vials from Lyophiliser, transferred through mobile LAF cart.</td> </tr> <tr> <td>6</td> <td>Out feed unit</td> <td>The vials shall be collected in a buffer tray (450 mm x 600mm) manually from the out feed of sealing unit with a pushing device through a Dynamic Passbox (Vendor Scope).</td> </tr> </table>	1	In feed turntable	a. To receive the full stoppered vials from Lyophiliser, transferred through mobile LAF cart.	6	Out feed unit	The vials shall be collected in a buffer tray (450 mm x 600mm) manually from the out feed of sealing unit with a pushing device through a Dynamic Passbox (Vendor Scope).
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d		URS: F2- VSM 01							
1.11		The sealing machine shall be placed as close as the filling machine.							
1.12	2.0 EQUIPMENT DESCRIPTION: <table border="1"> <tr> <td>6</td> <td>Out feed unit</td> <td>To accumulate the vials from the sealing unit and feed the vials for further activity. Alternately, the vials shall be collected in the tray manually from the out feed of sealing unit.</td> </tr> </table>		6	Out feed unit	To accumulate the vials from the sealing unit and feed the vials for further activity. Alternately, the vials shall be collected in the tray manually from the out feed of sealing unit.	2.0 EQUIPMENT DESCRIPTION: <table border="1"> <tr> <td>6</td> <td>Out feed unit</td> <td>To accumulate the vials from the sealing unit and feed the vials for further activity. Alternately, the vials shall be transported through a half swing conveyor belt (Vendor's scope) and collected manually from the out feed of sealing unit with a pushing device through a Dynamic Passbox (Vendor Scope).</td> </tr> </table>	6	Out feed unit	To accumulate the vials from the sealing unit and feed the vials for further activity. Alternately, the vials shall be transported through a half swing conveyor belt (Vendor's scope) and collected manually from the out feed of sealing unit with a pushing device through a Dynamic Passbox (Vendor Scope).
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For HLL Biotech Limited
Chief Executive Officer



HLL BIOTECH LIMITED
(Subsidiary of HLL Lifecare Limited)
(A Government of India Enterprise)

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LIST OF ATTENDEES

Project : Integrated Vaccine complex-HBL,Chengalpattu
Date Of Meeting : 20th March2014
Venue : HLL Biotech Limited , Chennai
Subject : Pre Bid Meeting – Supply,Installation,Commissioningand
 Validation of Vial Washing with Depyrogenating and Vial
 Sealing machines at HBL.

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