

MINUTES OF THE MEETING

**PRE BID MEETING OF TENDER FOR
SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF STERILIZATION EQUIPMENTS AT
IVC, CHENGALPATTU.**

Document No. : NPI-120310-EQP-S1-TD-05

Venue : HLL Biotech Limited, Chennai

Date : 24.07.2014

Project : Integrated Vaccines Complex, Chengalpattu

Attendees : See attached list of attendees

Issued by : CEO HBL

Issued on : 25th July 2014

Issued from : NNE Pharmaplan India Limited, Bangalore

Agenda

1.

Pre-bid Meeting for supply, installation, commissioning and validation of Sterilization equipment at IVC, Chengalpattu

S. No.	Clarifications on queries
	Tender for supply, installation, commissioning and validation of Sterilization equipments at IVC, Chengalpattu - TE Doc No: NPI-120310-EQP-S1-TD-05
A	Discussion Tender Enquiry Document: NPI-120310-EQP-S1-TD-05
	General Discussion Points
1.	<p>Vendor has requested for 20% advance , based on that HBL has confirmed that the followings,</p> <p>Pg.No.40 Point no. 21. Terms and Mode of Payment [Modified as]</p> <p>21.1 Payment Terms</p> <p>Payment shall be made subject to recoveries, if any, by way of liquidated damages or any other charges as per terms & conditions of contract in the following manner.</p> <p>A) Payment for Domestic Goods Or Foreign Origin Located Within India.</p> <p>Payment shall be made in Indian Rupees as specified in the contract in the following manner:</p> <p>a) Advance</p> <p>An advance of 20% of the contract value shall be released against Bank guarantee equivalent to 110% of the advance amount and submission of 5 % of the contract value as Security Deposit/ Performance Security in the form of Bank Guarantee from any scheduled commercial bank. The advance bank guarantee shall be valid for a period upto the completion of the contract.</p> <p>b) On delivery at site:</p> <p>60 % of the contract price shall be paid on receipt of goods in good condition and upon the submission of the following documents:</p> <p>(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;</p> <p>(ii) Consignee Receipt Certificate as per Section XVII in original issued by the authorized representative of the consignee;</p> <p>(iii) Two copies of packing list identifying contents of each package;</p> <p>(iv) Dispatch Clearance from Purchaser or authorized agent</p> <p>(v) Inspection certificate issued by the nominated Inspection agency, if any.</p> <p>(vi) Certificate of Country of origin.</p>
2.	<p>Tender Enquiry Document: NPI-120310-EQP-S1-TD-05</p> <p>Vendors had asked about to clarify on the Pg.No:- 56,57 point no.2 of (Schedule –I Steam Sterilizer, Schedule –II Dry Heat Sterilizer)</p> <p>HBL has clarified that the value of Rs.260Lakh & Rs. 18 lakh mentioned in (Schedule –I Steam Sterilizer, Schedule –II Dry Heat Sterilizer), it may be single order value or multiple order value.</p>
3.	There is no changes in terms & conditions of this Tender Enquiry Document: NPI-120310-EQP-S1-TD-0 Except the point no.1 & 2 mentioned above.
4.	TE doc: NPI-120310-EQP-S1-TD-05 , Pg No.4- Tender fee for schedule-I has been modified as Rs.3000/-
S. No.	Clarifications on URSs
B	URS: – URS/SAT 01 & URS/DAT 01
1.	Vacuum pump for Steam Sterilizers [Sterilization autoclave & Decontamination autoclave] should be placed in the service floor and vendor should provide necessary piping arrangement from vacuum pump to the equipment. Vacuum system should have a secondary cooling system for recirculating the soft water and chilled water as a coolant medium.
2.	HMI size should not be less than 5.5 inches and it should be colour display with touch screen.
3.	URS Annexure 3: List of critical items to be supplied for the equipments mentioned in URS/SAT01& URS/DAT 01
4.	Only For URS/DAT 01 :-The steam condensate received inside the chamber during initial pulsing of steam, before start-up of decontamination cycle should not get drained from the autoclave chamber without completion of decontamination cycle, provision should be provided to accommodate the condensate inside the chamber itself.

S. No. Clarifications on queries		
	URS Point number and excerpt* / description of the specification *	Point modified as/Comment
1.	6.5 Batch data display and record printing Batch report should be in the mode of dot matrix online printing and strip chart recording. HMI should be able to store minimum of 10 cycles & provision for connecting with PC.	6.5 Batch data display and record printing Batch report should be in the mode of dot matrix online printing and strip chart recording. HMI should be able to store minimum of 1 cycle & provision for connecting with PC to be provided.
2.	2.0 EQUIPMENT DESCRIPTION	2.0 EQUIPMENT DESCRIPTION The below mentioned points included, <ul style="list-style-type: none"> • One flexible probe to be provided to perform product cycle development and auto-sequence to be provided • Small valve for steam pulsing should be provided in the Stem Sterilizer design
3.	3.1.2 Chamber Carriages: The unit should be provided with 1 no loading carriage which should be made of SS 316L and it should be with removable / adjustable perforated shelves (4 no.s) of SS 316L, which can be positioned according to the height of the goods. The carriage should be provided with 4 wheels, which would withstand the high temperature inside the autoclave. It should be designed to slide easily from chamber to trolley.	3.1.2 Chamber Carriages: The unit should be provided with 1 no loading carriage which should be made of SS 316L and it should be with removable / adjustable perforated shelves (4 no.s) of SS 316L except W1 SAT-01, which can be positioned according to the height of the goods. The carriage should be provided with 4 wheels, which would withstand the high temperature inside the autoclave. It should be designed to slide easily from chamber to trolley. <u>Note:- For W1 SAT-01 - adjustable perforated shelves (2 no.s) of SS 316L.</u>
4.	6.6.5 Vacuum break filter: 0.22 µm hydrophobic type with arrangements for in place sterilization and provision for in-place integrity test. This filter should be provided on the unloading side for pressure equalization after vacuum creation	6.6.5 Vacuum break filter: 0.22 µm Code 7 type filter cartridges with arrangements for in-situ sterilization and provision for in-situ integrity connectors to be provided. This filter housing TC end to be extended till unloading side for pressure equalization after vacuum creation, provision for connecting disposable capsule filter to be provided at the unloading side. [Only for sterilization autoclave]
5.	6.6.11 Vendor to give code numbers for each component.	6.6.11 Vendor to give code numbers for each component. Name tag of the components, instruments should be of SS plates & it should be tied with SS rope.
6.	6.7.7 Analogue module with back up	6.7.7 - deleted
7.	6.7.15 FAT/SAT the following need to be demonstrated : a. All probes to reach 121 °C ±3 °C within 30 sec of the first probe for above 800L capacity chamber and 15 sec for below 800 L Chamber capacity. b. Temperature differences between any two probes should not be more than 1 °C during hold time.	6.7.15 FAT/SAT the following need to be demonstrated : a. All probes to reach 121 °C within 30 sec of the first probe for above 800L capacity chamber and 15 sec for below 800 L Chamber capacity. b. Temperature differences between any two probes should not be more than 1 °C during hold time.

S. No.		Clarifications on queries											
8.	<p>URS Annexure 3: List of Preferred Make of components</p> <ul style="list-style-type: none"> Automatic Angle Valve - Gemu / ITT Diaphragm Valve (Sterile side) - GEMU / ITT Solenoid valves for Gasket -Festo/ Danfos Pressure & Vacuum Switch-Orion/ Wika/ Emerson Pressure Gauges - Forbes Marshould/ Wika/ Waaree Instruments Pressure Reducing Valve-Klinger/ Forbes Marshould/ Armstrong International Level Switch - Mahalaxmi/ Endress & Hauser/ Emerson 	<p>URS Annexure 3: List of Preferred Make of components [Included/Modified]</p> <ul style="list-style-type: none"> Sanitary PRV –Jordon [<i>Included in Pre-Bid Meeting</i>] Automatic Angle Valve - Gemu / ITT /SED Diaphragm Valve (Sterile side) - GEMU / ITT /SED Solenoid valves for Gasket -Festo/ Danfos /Janatics Pressure & Vacuum Switch-Orion/ Wika/ Emerson/Danfoss Pressure Gauges - Forbes Marshall/ Wika/ Waaree Instruments Pressure Reducing Valve- Klinger/ Forbes Marshall/ Armstrong International Level Switch –[deleted] 											
C		URS: – URS/DHS 01											
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2.	URS Annexure 3: List of critical items to be supplied for the equipments mentioned in URS/DHS 01												
	URS Point number and excerpt* / description of the specification *	Point modified as/Comment											
1.	6.1.12 Cooling time (not more than 90 min), another 30 min extra in case of glass wares. 6.1.13 Cooling temperature (less than 55 °C). 6.1.14 Cooling time (not more than 45 min)	6.1.12- Total cycle should not exceed more than 5 hours including cooling set point of 55-60 °C 6.1.13,6.1.14- deleted											
2.	6.1.28 Equipment should have laminar airflow of 0.45 m/s ± 20%.	6.1.28 Equipment should provide airflow of 0.45 m/s ± 20%.											
3.	6.2.1.6 Door pre-condition fail	6.2.1.6- Deleted											
4.	6.4 Level of instrumentation		6.4 Level of instrumentation										
	<table border="1"> <thead> <tr> <th>Parameter</th> <th>Purpose</th> <th>Type of control and Instrumentation</th> </tr> </thead> <tbody> <tr> <td>Data logger and recorder</td> <td>Recording and display of temperature and time</td> <td>Data logger with digital display (DDMMYYYY/ HRS:MIN:SEC)</td> </tr> </tbody> </table>	Parameter	Purpose	Type of control and Instrumentation	Data logger and recorder	Recording and display of temperature and time	Data logger with digital display (DDMMYYYY/ HRS:MIN:SEC)	<table border="1"> <thead> <tr> <th>Parameter</th> <th>Purpose</th> <th>Type of control and Instrumentation</th> </tr> </thead> <tbody> <tr> <td>Strip chart recorder</td> <td>Recording and display of temperature and time</td> <td>Data logger with digital display (DDMMYYYY/ HRS:MIN:SEC)</td> </tr> </tbody> </table>	Parameter	Purpose	Type of control and Instrumentation	Strip chart recorder	Recording and display of temperature and time
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S. No.	Clarifications on queries	
6.	6.6.2 There Should be a sanitary Tri-clamp type port in the drain piping, immediately adjacent to the drain temperature monitor, for installation of validation monitoring probe(Size: 1" OD)	6.6.2 -deleted
7.	7.2 Available utility Note: Vendor to provide Pressure reducing valves and Pressure gauges along with the equipment as per equipment utility requirements.	7.3 Available utility Note: Vendor to provide FRL and Pressure gauges along with the equipment as per equipment utility requirements.
8.	URS Annexure 2: List of Preferred Make of components <ul style="list-style-type: none"> • Operator Interface/HMI - Mitsubishi/Allen Bradley/ Siemens 	URS Annexure 2: List of Preferred Make of components, Below components, Make[included/modified] <ul style="list-style-type: none"> • Operator Interface/HMI - Allen Bradley/ Siemens • High temperature HEPA filter TROX/Pharma tech/ Dyna filters



For HLL Biotech Limited

Chief Executive Officer

nne pharmaplan

NNE Pharmaplan India Limited, #12, Achiah Shetty Layout, RMV Extn, Bangalore - 80, INDIA

List of Attendees

Date: 24 July 2014
Client: M/s HLL Biotech Limited
Venue: M/s HLL Biotech Limited, Chennai
Project: Integrated Vaccine Complex, at Chengalpattu
Subject: Pre-bid Meeting of Sterilization Equipment Package

Name	Company	Signature
Sanjay Popat	Indo German	
VIGNESHWARAN.T	HBL	
Sanjeev Kumar R	HBL	
P. NAVIN KUMAR	HBL	
B. Satbosh	HBL	
K. YASINANTHA RAO	HBL	
Shankar Kunal	Klenzoids	
Santosh Kelkar	Klenzoids	
Ramesh Lata	Klenzoids	
T.S.S. Narayanaswami	Machine Fabrik	
Abhay Patel	Machine Fabrik/Indo German	
Ch. LAKSHMI PUNNARAO	HBL	
B. Amroliya	Metal Chem	
Dr. K. A. Arul Anand	HBL	
K. Anil Kumar	HBL	
Gireesh S.M	HBL	
R. Muthukrishnan	HBL	
S. Senthil Kumar	HBL	
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Name	Company	Signature
K. Sridhar babu	NNE Pharmaplan	K. Sridhar babu
Vijay kumar	NNE Pharmaplan	

