MINUTES OF THE MEETING

PRE BID MEETING OF TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF SEED FERMENTORS AT PASTEUR INSTITUTE OF INDIA,COONOOR

Document No.	:	**NPI/110831/EQP/TD/01**
Venue	:	**HLL Lifecare Limited, Chennai**
Date	:	**30.07.2014**
Project	:	**Revival Of DPT group of Vaccine Manufacturing Facility-PII,Coonoor**
Attendees	:	**See attached list of attendees**
Issued by	:	**CEO HBL**
Issued on	:	**4th Aug 2014**
Issued from	:	**NNE Pharmaplan India Limited, Bangalore**

Agenda	
1.	Pre-bid Meeting for supply, installation, commissioning and validation of Seed Fermentors at PII,Coonoor

S. No.	Clarifications on queries	
	Tender for supply, installation, commissioning and validation of Seed Fermentors at PII,Coonoor - TE Doc No: NPI-110831-EQP-TD-01	
A	**Discussion Tender Enquiry Document: NPI-110831--EQP-TD-01**	
	General Discussion Points	
1.	**There is no changes in terms & conditions of this Tender Enquiry Document: NPI-110831-EQP-TD-01**	
2.	**Last date for the tender submission is extended up to 20th Aug,2014@15:30hrs as per the vendor request.**	
S. No.	**Clarifications on URSs**	
B	**URS: – D-SFR 01, P-SFR 01 _02**	
1.	Peristaltic pump specifications. • 1 No. for the addition of inoculum – flow rate 300 ml/min • 1 No. for the addition of antifoam – flow rate 30ml/min	
2.	Agitator specification • Top driven- Dry run single mechanical seal • Agitation range: 20-600 rpm	
3.	Removable type baffles to be provided	
4.	Aeration Supply System(Overlay): Rotameter for Overlay-with data logging (4 to 20 mA output) to be provided	
	URS Point number and excerpt* / description of the specification *	**Point modified as/Comment**
5.	**g. Temperature Control:** The temperature during fermentation shall be controlled via circulation of utilities (plant steam, Cooling water, Chilled water, etc) in the jacket with electric heater or steam and a circulation pump. Temperature control during cultivation 35-37 °C (tolerance limit: ±0.1 °C) & during sterilization (tolerance limit: ±0.1 °C) • The system consists of closed loop pressurized thermostat system with recirculation pump 2 heat exchangers for heating and cooling alternatively which provides a high flow through the hollow vessel jacket and ensures fast temperature control at high accuracy with PT 100 probe (sterilizable). • Electrical heater ,Heat exchanger and steam for cooling water & chilled water for operation temperature • Safety relief valve for jacket • Bourdon type pressure gauge for jacket utility • Pneumatically operated valves for steam and cooling water/ chilled water	**g. Temperature Control:** The temperature during fermentation shall be controlled via circulation of utilities (plant steam, Cooling water, Chilled water, etc) in the jacket with electric heater and a circulation pump. Temperature control during cultivation 35-37 °C (tolerance limit: ±0.1 °C) & during sterilization (tolerance limit: ±1 °C) • The system consists of closed loop pressurized thermostat system with recirculation pump , heat exchangers for heating and cooling alternatively which provides a high flow through the vessel jacket and ensures fast temperature control at high accuracy with PT 100 probe (sterilizable). • Safety relief valve for jacket • Bourdon type pressure gauge for jacket utility • Pneumatically operated valves for steam and cooling water/ chilled water

<table>
<tr><th>S. No.</th><th>Clarifications on queries</th></tr>
<tr><td>6.</td><td>2.0.4. Nozzle schedule :
1. Top Lid:
19 mm spare port with septum-1 No
2.Upper wall side:
Vertical view Glass –Bolted with gasket-1 No
Port for sparger -1 No
Port for overlay air -1 No
3.Lower wall side:
25 mm Spare port-1 No</td><td>2.0.4. Nozzle schedule :
1. Top Lid:
19 mm spare port with septum-1 No-Deleted
2.Upper wall side:
Vertical view Glass –Bolted with gasket-1 No-Deleted
Port for sparger -1 No-Deleted
Port for overlay with spray ball -1 No
3. Lower wall side:
25 mm Spare port-1 No-Deleted</td></tr>
<tr><td>7.</td><td>6.1 Process control
vi) Rate of flow of process Air (Overlay and Sparger)
vii) Duration of CIP and temperature ,pressure during CIP</td><td>6.1 Process control
vi) Rate of flow of process Air (Overlay)
vii) Duration of CIP and temperature</td></tr>
<tr><td>8.</td><td>6.4 Level of instrumentation
<table><tr><th>Parameter</th><th>Purpose</th><th>Type of control and Instrumentation</th></tr><tr><td>Process Air for Sparger and Overlay</td><td>To monitor, control and indicate Air flow</td><td>Rotameter</td></tr><tr><td>Dosing</td><td>To dose Media , inoculum and Antifoam</td><td>Peristaltic pump(2 Nos)</td></tr></table></td><td>6.4 Level of instrumentation
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<tr><td>9.</td><td>6.7.10 Performance Criteria Required for FAT/SAT</td><td>6.7.10 Performance Criteria Required for FAT/SAT-Points included[Only for D-SFR 01]]
• Media hold with process simulation during SAT
• Thermal mapping during FAT
• All control system simulation and tuning of control loops
• All FAT/SAT,IQ,OQ as per IRS</td></tr>
<tr><td>10.</td><td>URS Annexure 2: List of Preferred Make of components
<table><tr><th>S.NO</th><th>DESCRIPTION</th><th>MAKE</th></tr><tr><td>5</td><td>Temperature sensor</td><td>NEGELE</td></tr><tr><td>10</td><td>Steam trap</td><td>STERIFLOW/ITT</td></tr><tr><td>17</td><td>Spray ball</td><td>HAKE</td></tr><tr><td>18</td><td>Diaphragm valve(Manual)</td><td>GEMU</td></tr><tr><td>21</td><td>Sampling valve</td><td>Novaseptic/GEMU</td></tr><tr><td>22</td><td>Flush bottom valve</td><td>Novaseptic/GEMU</td></tr><tr><td>29</td><td>Diaphragm valve(Automatic)</td><td>GEMU / ITT</td></tr><tr><td>30</td><td>Angle seat valve(Automatic)</td><td>GEMU / ITT</td></tr><tr><td>32</td><td>Heater</td><td>Common wealth</td></tr></table></td><td><table><tr><th>S.NO</th><th>DESCRIPTION</th><th>MAKE</th></tr><tr><td>5</td><td>Temperature sensor</td><td>NEGELE/RADIX</td></tr><tr><td>10</td><td>Steam trap</td><td>STERIFLOW/ITT/THERMAX</td></tr><tr><td>17</td><td>Spray ball</td><td>HAKE/ALFA LAVAL</td></tr><tr><td>18</td><td>Diaphragm valve(Manual)</td><td>GEMU/SED/ITT</td></tr><tr><td>21</td><td>Sampling valve</td><td>Novaseptic / Aerre inox</td></tr><tr><td>22</td><td>Flush bottom valve</td><td>Novaseptic/GEMU</td></tr><tr><td>29</td><td>Diaphragm valve(Automatic)</td><td>GEMU / ITT/SED</td></tr><tr><td>30</td><td>Angle seat valve(Automatic)</td><td>GEMU / SED</td></tr><tr><td>32</td><td>Heater</td><td>Common wealth / Hot Watt / Next Thermal</td></tr></table></td></tr>
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C	URS/ D-SFR 01	
11.	**2.0EQUIPMENT DESCRIPTION** **2.0.2. TABLE 2-** **point no.** 4.Min mixing volume- 3.5L **2.0.3. e.** Aeration Supply System(Sparger)	**2.0EQUIPMENT DESCRIPTION** **2.0.2. TABLE 2-** point no. 4.Min operating volume- 3.5L 2.0.3. e. deleted
D	URS/ P-SFR 01_02	
12.	**2.0EQUIPMENT DESCRIPTION** **2.0.2. TABLE 2- point no.** 1.GV-22L 4.Min mixing volume- 5.5L **2.0.3. e.** Aeration Supply System(Sparger)	**2.0EQUIPMENT DESCRIPTION** 2.0.2. TABLE 2-point no. 1. GV-25L 4.Min operating volume- 7L 2.0.3. e. deleted

For HLL Lifecare Limited

Chief Executive Officer

nne pharmaplan

NNE Pharmaplan India Limited, #12, Achiah Shetty Layout, RMV extn, Bangalore – 80, INDIA

List of Attendees

Date: 30 July 2014

Client: M/s. HLL Lifecare Limited, Chennai

Venue: M/s. HLL Lifecare Limited, Chennai

Project: Revival of DPT Vaccine Manufacturing Facility

Subject: Pre Bid Meeting For Supply, Installation, Commissioning And Validation Of Seed Fermentors

Name	Company	Signature
K. SRIDHAR BABU	NNE pharmaplan	K.Sridharbabu
Shilpa Rao	NNE Pharmaplan	ShilpaRao K.V
Dr. B. Sundaran	Pasteur Institute of India Coonoor	[signature] 30/7/14
R. Srinivasan	SCIGENICS INDIA LTD Chennai	[signature]
S. Muthuswamy	Scigenics (I) Pvt Ltd. Chennai	[signature]
Rohit Kumar	PRAJ HIPURITY SYSTEM	Rohit Kumar
Himesh Mehta	Praj Hipurity System	[signature]
Renjith. M.C	HLL	[signature]
A.C. Subhash.	Biozeen, Blore	[signature]
Sankhajeet Kole	BIOZEEN	[signature]
K. Anil Kumar	HBC	[signature]
Gireesh. S.M	HBL	[signature]
Polina Sreenath	HLL	Polina

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Name	Company	Signature
T. VIGNESHWARAN	HLL	
A. ANTO FELIX	HLL	