

**MINUTES OF THE MEETING**

**PRE BID MEETING OF TENDER FOR  
SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION  
OF BLISTER PACKING MACHINE AT HLL BIOTECH LIMITED, CHENGALPATTU**

**Document No. :** HBL/IVC/LTE/BLISTER PACKING MACHINE/19-20 dtd 09.07.2019

**Venue :** HLL Biotech Limited, Chengalpattu

**Date :** 16-07-2019

**Project :** Integrated Vaccines Complex, Chengalpattu

**Attendees :** See attached list of attendees

**Issued by :** M/s. HLL Biotech Ltd

**Issued on :** 31-07-2019

**Issued from :** M/s. HLL Biotech Ltd

<b>Agenda</b>	
1.	Pre-bid Meeting for Blister Packing Machine for IVC, Chengalpattu

<b>Clarification on queries</b>										
A	Discussion Tender enquiry document									
<p>General discussion points</p> <ol style="list-style-type: none"> <li>Financial bid sheet has been revised. All the optional items are to be quoted in the second sheet of the bid sheet. HBL reserves the rights to choose any or all the optional items during the time of evaluation. The optional items should be inclusive of GST on FOR Chengalpattu basis.</li> <li>Vendor has asked for 20 % advance and remaining 80% as LC. Based on the request, HBL have considered to change the payment terms as below:</li> </ol> <p style="text-align: center;"><b>Payment schedule as per tender document ( Page 8 off 22):</b>            Payment shall be made as specified in the contract in the following manner:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">S.No</th> <th style="width: 60%;">Stage</th> <th style="width: 30%;">Percentage</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td>On Supply of material at site</td> <td style="text-align: center;">80% of the order value</td> </tr> <tr> <td style="text-align: center;">2</td> <td>After successful Installation, Commissioning, Validation &amp; Final Acceptance by HBL's Representative</td> <td style="text-align: center;">20% of the order value</td> </tr> </tbody> </table> <p style="text-align: center;"><b>Shall be read as:</b></p> <p>Payment shall be made in Indian Rupees as specified in the contract in the following manner:</p> <p><b>a) Advance</b>            An advance of 20% of the contract value shall be released against Bank guarantee equivalent to 110% of the advance amount and submission of 10 % 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>b) On delivery at site:</b></p> <p><b>60 % of the contract price shall be paid on receipt of goods in good condition and upon the submission of the following documents:</b></p> <ol style="list-style-type: none"> <li>(i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;</li> <li>(ii) Consignee Receipt Certificate as per Section XVII in original issued by the authorized representative of the consignee;</li> <li>(iii) Two copies of packing list identifying contents of each package;</li> <li>(iv) Dispatch Clearance from Purchaser or authorized agent</li> <li>(v) Inspection certificate issued by the nominated Inspection agency, if any.</li> <li>(vi) Certificate of Country of origin.</li> </ol> <p><b>c) On installation and Final Acceptance Certificate by Purchaser:</b>            Balance 20 % payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to be issued by the consignee/ purchaser subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.</p>		S.No	Stage	Percentage	1	On Supply of material at site	80% of the order value	2	After successful Installation, Commissioning, Validation & Final Acceptance by HBL's Representative	20% of the order value
S.No	Stage	Percentage								
1	On Supply of material at site	80% of the order value								
2	After successful Installation, Commissioning, Validation & Final Acceptance by HBL's Representative	20% of the order value								

**B** Clarifications on IRS queries:  
**Document No: NPI\_120310\_IRS\_S1\_01**  
**Date: 27-03-2014**  
**Rev.No : 01**

Vendor is requested to comment only on the below said points on the IRS document rest of the document need not be commented.

List of points to be commented:

Sl. No	Ref No.	Description	Applicability
1	4.1	General safety requirements	All points applicable
2	4.2	Power failure & recovery	All points applicable
3	5.2	Cleaning requirement	5.2.1 to 5.2.6 - Applicable
4	5.5	Use of Lubricants	All points applicable
5	5.7	Data Integrity	5.7.1 & 5.7.2 –Applicable
6	5.9	Desired documents	5.9.5- All points applicable
7	5.9.5	Fabrication stage of equipment & FAT	5.9.5.1 & 5.9.5.2 - Applicable
8	5.9.6	Delivery of equipment & SAT	5.9.6.23 – Applicable
9	5.11	GMP requirement	5.11.1 to 5.11.3, 5.11.9 & 5.11.10 – Applicable
10	6.0	Technical requirement	All points applicable
11	7.0	Transport, Packing & Storage	All points applicable
12	8.0	Good engineering Practice Requirements	8.1 to 8.3, 8.5 & 8.6 - Applicable

**C** Clarifications on URS queries:  
**Document No: HBL/URS/19-006**  
**Date: NA**  
**Rev.No:NA**

URS Point number and excerpt* / description of the specification *	Point modified as / Comment
Capacity - Vials / ampoules ( wherever applicable)	Vials & ampoules
<b>1.0-Equipment/System/ Utility Description</b>	<b>1.0-Equipment/System/ Utility Description</b>

<p>Machine can handle Forming material like PVC, PVC/PVDC, PVC/PE/PVDC, ACLAR, PP, COC (Cyclic Olefin Copolymer) and Sealing material-ALU, Paper foil laminate, CR Materials, PP. The blister-packaging machine shall be equipped with appropriate feeding device, viz conveyor with visual inspection lamps for detecting the cracks on vials followed by a turntable for smooth movement and to provide positive pressure to the vials/ampoule.</p>	<p>Machine can handle Forming material like PVC, PVC/PVDC, PVC/PE/PVDC. The blister-packaging machine shall be equipped with appropriate feeding device, separately for vials &amp; ampoules. <b>In feed &amp; outfeed operation should be suitable for both vials &amp; ampoules. First vial &amp; last vial should be transported from infeed to outfeed without any manual intervention. Vendor to provide ss trays ( 10 nos) for loading of vials &amp; ampoules in which one tray should accommodate minimum 250 nos. of 4R vials</b></p>
<p><b>2.0 -Process / Operational Requirement</b>  <b>a. Forming Material: PVC, PVC/PVDC, PVC/PE/PVDC, Polypropylene, PETG, Aclar &amp; COC.</b></p>	<p><b>2.0 -Process / Operational Requirement</b>  <b>a. Forming Material: PVC, PVC/PVDC, PVC/PE/PVDC.</b></p>
<p><b>2.2 Process Description</b>  The Vials/ ampoules / vials which are in trays, shall be loaded into the inlet chute of blister packaging machine. The films will be unwinded from the reel lock &amp; made to pass through the heating plate followed by forming (Heat and Vacuum) as per the desired pattern the blister to form grooves, where the Vials/ ampoules shall be placed. There shall be continuous blowers to take away the heat from the forming area.  The Vials/ ampoule in inlet chute shall pass through orientor &amp; retainer (auto feeding device), which shall arrange to retain the Vials/ ampoules in the preset pattern, before being placed in the formed blisters. The Vials/ ampoules shall be placed in the grooves of the blisters, followed by sealing by lidding foil from blister pack.  The entire web of blister packs shall be coded. (Batch No., mfg date &amp; exp date etc.) The indexing &amp; trimming mechanism then cuts each blister from the web, followed by trimming of the blister edges. The misfiled mechanism shall check crack/Pinhole in blister for preset number &amp; placement arrangement of Vials/ ampoules. In case of deviation the misfiled mechanism shall divert the path of such blister to rejects. The discharge from the</p>	<p><b>2.2 Process Description</b>  The Vials/ ampoules / vials which are in trays, shall be loaded into the inlet chute of blister packaging machine. The films will be unwinded from the reel lock &amp; made to pass through the heating plate followed by forming (Heat and Vacuum) as per the desired pattern the blister to form grooves, where the Vials/ ampoules shall be placed. <b>There shall be continuous blowers to take away the heat from the forming area or vendor should provide a alternative option to remove the excess heat dissipating out of the machine, so that room temperature should be not be altered beyond 25 degrees .</b>  The Vials/ ampoule in inlet chute shall pass through orientor &amp; retainer (auto feeding device , magazine ), which shall arrange to retain the Vials/ ampoules in the preset pattern, before being placed in the formed blisters. The Vials/ ampoules shall be placed in the grooves of the blisters, followed by sealing by lidding foil from blister pack.  The entire web of blister packs shall be coded. (Batch No., mfg date &amp; exp date etc.) The indexing &amp; trimming mechanism then cuts each blister from the web, followed by trimming of the blister edges. The misfiled mechanism shall check crack/Pinhole in blister for preset number &amp; placement arrangement</p>


<p>blister packaging machine shall be fed to an inclined conveyor and table.</p>	<p>of Vials/ ampoules. In case of deviation the misfiled mechanism shall divert the path of such blister to rejects. <b>The discharge from the blister packaging machine shall be fed to an planar conveyor with tray / suitable container ( 50 packs) to avoid any breakage of ampoules and vials .</b></p>
<p><b>2.2.1.21</b> Camera inspection system : This feature is also need to be available in the system</p>	<p><b>2.2.1.21</b> Camera inspection system : This feature is also need to be available in the system – <b>(handheld device optional)</b></p>
<p>2.2.1.23 -Inline Conveyor Packs after punching to be dropped to Inline conveyor, rejected packs to be diverted to rejection bin. control measures to be in place for mix up of good and rejected blisters packs. Rejection confirmation sensors are equipped which senses the rejected/good packs.</p>	<p>2.2.1.23 - Inline Conveyor Packs after punching to be dropped to Inline conveyor, rejected packs to be diverted to rejection bin. Control measures to be in place for mix up of good and rejected blisters packs. <b>Scales &amp; notches to be provided in guider to make it adjustable for each size of product.any adjustable guider/ holder shall provided with notches</b></p>
<p>2.6.8-Cutting station delay timer</p>	<p>2.6.8-Cutting station delay timer <b>or vendor to provide any other features</b></p>
<p>2.6.10 - Display the number of rejected blister packed and its reasons on the machine</p>	<p>2.6.10 - Display the number of rejected blister packed and <b>alarms</b></p>
<p>3.1.2 -Control panels / installations located in service areas</p>	<p>3.1.2 -Control panels <b>ip65 or higher /</b> installations located in service areas.</p>
<p>3.1.5 Outer surface finish of stainless materials in classified rooms shall be mirror polished.</p>	<p><b>Point removed</b></p>
<p>3.4.7 Camera – Enable and disable key</p>	<p>3.4.7 Camera – Enable and disable key – <b>optional</b></p>
<p>3.5.1 Electrical supply: Single Phase ( 220 V) &amp; 3 Phase ( 420 – 440 V)</p>	<p>3.5.1 Electrical supply: Single Phase ( 220 V) <b>ups for HMI</b> &amp; 3 Phase ( 420 – 440 V) <b>raw powr for machine operation</b></p>
<p>3.5.4 Compressed air: 8 to 10 bar ,10CFM</p>	<p>3.5.4 Compressed air: <b>6 bar-8 bar</b> ,10CFM</p>
<p>3.5.7 ADDITION OF POINT</p>	<p>3.5.7 <b>battery limit will be with manual ball valve which will be dropped at one corner in the room.vendor to fabricate the line accordingly to the requirements &amp; install the necessary saftey &amp; measing requirements.clean room insulation should also be considered</b></p>
<p><b>3.6 Regulatory and GMP requirement</b>  The equipment shall be built, certified in accordance with all applicable EU directives, The equipment shall be validated and used in accordance with cGEP requirements.</p>	<p><b>3.6 Regulatory and GMP requirement</b>  The equipment shall be validated and used in accordance with cGEP requirements.</p>

3.7 ADDITION OF POINT	3.7.22 <b>infeed &amp; outfeed overload,turntable overload,line jammer &amp;rejection bin full to be included in plc program</b>
3.7.13 Camera inspection alarms	3.7.13 Camera inspection alarms <b>(optional)</b>
<b>3.8 Sanitary Requirements.</b> The blister packaging machine shall be designed with an accent on cleanliness & easy accessibility to all parts to ensure easy maintenance and cleaning for changeover. The equipment shall be easily accessible for manual cleaning of the outside surfaces. The IPC bins/blister hopper shall be removable and manually cleaned in a separate washing room.	<b>3.8 Sanitary Requirements</b> The blister packaging machine shall be designed with an accent on cleanliness & easy accessibility to all parts to ensure easy maintenance and cleaning for changeover. The equipment shall be easily accessible for manual cleaning of the outside surfaces. The IPC bins/blister hopper shall be removable and manually cleaned in a separate washing room. <b>Air gun with suitable connections (extended length ) for cleaning of broken vials &amp; ampoules throughout the machine to be provided.</b>
4.0 Documentation requirements	4.0 Documenation requirements <b>All certificate ,documents,HMI should be in english language only</b>
4.9 Training material and certificates for operators, maintenance engineers.	<b>Point removed</b>
5.1. C ADDITION OF POINT	<b>5.1.C The machine should be inbuilt with ISO 2R change part &amp; tools ,tackles for preventive maintaianance &amp; changeover to be provided.</b>
5.1. D ADDITION OF POINT	<b>5.1.D vendor to provide all the necessary change parts in respective with the operation of 4r (vials), 1ml ,2ml &amp; 5ml (ampoules) along with required tools &amp; tackles</b>
5.1.E ADDITION OF POINT	<b>5.1.E NECESSARY LOADING &amp; UNLOADING TRAYS, ITEMS ETC SHALL BE PROVIDED BY THE VENDOR</b>
5.2 ADDITION OF POINT	<b>5.2 VENDOR TO DESGIN THE MACHINE ACCORDING TO THE ROOM SPACE ALLOCATED IN THE DRAWING ,IN SUCH A WAY THAT DURING OPERTIONAL CONDITIOIN IT SHOULD NOT CREATE DIFFCULTY FOR THE OPERATION &amp; TO END USER.</b>
5.3 Instrumentation 5 .Photocell sensor - Optex / Metler / Panasonic / 8. MCB – Simens / ABB	5.3 Instrumentation 5 .Photocell sensor & <b>other sensors-</b> Optex / Metler / Panasonic / 8. MCB & <b>drives</b> – Simens / ABB

Sl no.	Optional items to be quoted	Qty
1.	S tray dimension required to load vials/ampoules	12 nos.
2.	QR code scanner/reader	1 nos.
3.	Splicing station & no form no fill	1 nos.
4.	Eye mark (print reg control) optional	1 nos.
5.	Rejection Flap System	1 nos.
6.	Embossing digits	1 nos.
7.	Polycarbonate guarding of the machine on front side,with safety interlock switches.	1 nos.
8.	Chilled water flow interlock	1 nos.
9.	Chilled water temperature interlock	1 nos.
10.	Safety Interlock for front clear guards	1 nos.
11.	Camera at infeed for detecting breakage, colour change & cracks	1 nos.
12.	Low incoming air pressure switch	1 nos.
13.	Pin Hole Detector (for lid foil)	1 nos.
14.	Change parts, accessories & tool kit for 4R - ISO 8362-1 (in mm)	1 nos.
15.	Change parts, accessories & tool kits for Ampoule size : ISO- 1ml	1 nos.
16.	Change parts, accessories & tool kits for Ampoule size : ISO- 2ml	1 nos.
17.	Change parts, accessories & tool kits for Ampoule size : ISO- 5ml	1 nos.

**Note: Last date of submission of bids is on 08.08.2019, 15:30 hrs. Technical Bid opening is 08.08.2019,16:00 hrs.**

For HLL Biotech Limited

  
 31-07-2019.

Authorized Signatory

