

**PRE-BID MEETING TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND
VALIDATION OF PACKAGING EQUIPMENT
AT PII, COONOR**

Document No.: : NPI/110831/EQP/TD/09

Venue: : HLL Biotech Ltd,

Date: : 6th Jan 2016

Project: : Revival of DPT group of Vaccine Manufacturing Facility PII,
Coonor

Attendees: : See attached list of attendees

Issued By: : CEO HBL

Issued On: : 10th Mar 2016

Agenda	
1.	Pre bid Meeting Tender for Supply, Installation, Commissioning and Validation of Packaging Equipment at PII, Coonor

S. No.	Clarifications on queries	
	Pre bid Meeting Tender for Supply, Installation, Commissioning and Validation of Packaging Equipment at PII, Coonoor Doc No: NPI-110831-EQP-TD-09	
A	Discussion on Tender Enquiry Document: NPI/110831/EQP/TD/09	
	General Discussion Points	
1.	The EMD should be furnished in the name of “HLL Biotech Limited, payable at Chennai” for the amount mentioned in Section-I, NIT. The EMD has to be submitted separately as per schedule wise. For, Schedule V:- EMD=Rs. 5000/- Schedule VI:- EMD=Rs.5000/-	
2.	Closing date & time for receipt of Tender has been revised as 30-Mar-2016 at 15:30Hrs. instead of 20-Jan-2016 at 15:30Hrs	
3.	Time and date of opening of Technical Bids has been revised as 30-Mar-2016 at 16:00Hrs. instead of 20-Jan-2016 at 16:00Hrs	
	B. Clarifications on URSS	
	Schedule-II Label Counter Rewinder with VVM dot applicator	
	General discussion point for Schedule –II	
	Schedule II- Label Counter Rewinder with VVM dot applicator	
4.	4.4 Automatic reset to zero in the length mode for winding repetitive length shall be possible.	4.4 Manual reset to zero after desired VVM count
5.	4.5 It should be having retain the data during power off.	4.5 It should be having retain the data during power off. Vendor should provide 1.5 kw capacity of UPS along with machine.
6.	4.6 It should have preset option, to stop after desire count of labels.	Point deleted
	Schedule III - Vial Labelling Machine	
7.	2.0 Equipment Description 1. Vial infeed unit - Infeed tray and turn table along with infeed system and conveyor 5. Labeled Vial out feed unit - For discharging the labeled Vials at the out feed tray. 11. Rejection Station - For missing of labels, overprinting details	1. Vial infeed unit - Infeed tray and turn table along with infeed conveyor 5. Labeled Vial out feed unit - For discharging the labeled Vials at the out feed tray.(300mm x 400mm) 11. Rejection Station - For missing of labels, overprinting details and missing VVM label rejection option with camera
8.	3.2.1 Vials shall be loaded manually to the infeed turn table of vial labelling machine. Vials are transferred with the help of infeed worm and conveyor system	3.2.1 Vials shall be loaded manually to the infeed turn table of vial labelling machine. Vials are transferred with the help of conveyor system

S. No.	Clarifications on queries																				
9.	3.2.3 OCR,OCV, Pharma codes sensing and with rejection mechanism shall be done.	3.2.3 OCR,OCV, Pharma codes sensing and with rejection mechanism shall be done and also machine shall be capable to upgrade for 2D barcode application by changing the printer.																			
10.	3.2.6 Faulty/ printed labelled vials shall be rejected in rejection tray for appropriate further action. It will reject by camera system and collected in to lockable rejection bin. For Missing label - Label presence/absence sensor and for over printing or OCR (Optical character Recognition) rejection - camera system is there (If any batch overprinting or printing quality is not good, camera will inspect it and send signals to pneumatic rejection system	3.2.6 Faulty/ printed labelled/Missing VVM vials shall be rejected in rejection tray for appropriate further action. It will reject by camera system and collected in to lockable rejection bin. For Missing label/Missing VVM - Label presence/absence sensor and for over printing or OCR (Optical character Recognition) rejection - camera system is there (If any batch overprinting or printing quality is not good, camera will inspect it and send signals to pneumatic rejection system																			
11.	3.3.1 There will be tray station at the Out feed for collecting all labelled vials.	3.3.1 There will be tray station at the Out feed for collecting all labelled vials.(Tray size will be provided on DQ phase of the project)																			
12.	<p>6.4 Level of instrumentation</p> <table border="1" data-bbox="188 1093 818 1469"> <thead> <tr> <th>Type of control</th> <th>Purpose</th> <th>Instrumentation</th> </tr> </thead> <tbody> <tr> <td>Batch overprinting, printing quality</td> <td>To online checking of batch overprinting and printing quality</td> <td>Camera</td> </tr> <tr> <td>Rejection station</td> <td>To collect rejected vials</td> <td>Diverter, collection tray</td> </tr> </tbody> </table>	Type of control	Purpose	Instrumentation	Batch overprinting, printing quality	To online checking of batch overprinting and printing quality	Camera	Rejection station	To collect rejected vials	Diverter, collection tray	<table border="1" data-bbox="842 1093 1505 1469"> <thead> <tr> <th>Type of control</th> <th>Purpose</th> <th>Instrumentation</th> </tr> </thead> <tbody> <tr> <td>Batch overprinting, printing quality and VVM presence</td> <td>To online checking of batch overprinting and printing quality and missing VVM</td> <td>Camera</td> </tr> <tr> <td>Rejection station</td> <td>To collect rejected vials</td> <td>Lockable rejection bin</td> </tr> </tbody> </table>		Type of control	Purpose	Instrumentation	Batch overprinting, printing quality and VVM presence	To online checking of batch overprinting and printing quality and missing VVM	Camera	Rejection station	To collect rejected vials	Lockable rejection bin
Type of control	Purpose	Instrumentation																			
Batch overprinting, printing quality	To online checking of batch overprinting and printing quality	Camera																			
Rejection station	To collect rejected vials	Diverter, collection tray																			
Type of control	Purpose	Instrumentation																			
Batch overprinting, printing quality and VVM presence	To online checking of batch overprinting and printing quality and missing VVM	Camera																			
Rejection station	To collect rejected vials	Lockable rejection bin																			
13.	6.7.2 Batch details to be printed on the label: 1. Batch No 2. Manufacturing Date 3. Expiry Date 4. Price (MRP)	6.7.2 Batch details to be printed on the label (12.5 mm height): 1. Batch No 2. Manufacturing Date 3. Expiry Date 4. Price (MRP)																			
14.	6.7.4 HP ink type cartridge printer for printing the batch detail	Deleted																			
15.	6.7.7 Printer required for printing the batch detail (Vendor to specify the character size possible)	6.7.7 Printer required for printing the batch detail (four lines to be printed between 12.5 mm height)																			
16.	6.7.9 Camera System: On-line inspection by camera for batch overprinting, printing quality. If deviation, send signals to pneumatic rejection system to reject the vials.	6.7.9 Camera System: On-line inspection by first camera for batch overprinting, printing quality. If Deviation, send signals to pneumatic rejection system to reject the vials. Second camera will detect the absence of VVM dot label on brand labels.																			

S. No.	Clarifications on queries	
17.	6.7.10 Elephant chute to be provided to avoid vials braking after the outfeed	6.7.10 Out feed collection system /Elephant chute /Tray collection bin shall be decided during the detailed design
18.	6.7.12 Out feed turn table should be able to hold 3500 to 4000 vials (Vendor to confirm)	Deleted
19.	6.7.13 Height of the conveyor should be adjustable between 850 mm to 1100 mm (Vendor to specify)	Deleted
20.	6.7.16 Make of PLC shall be Allen Bradley / Siemens.	6.7.16 Make of PLC shall be Allen Bradley / Siemens/Fatek
21.	6.7.17 Make of servo based mechanism shall be Allen Bradley / Siemens. Make of sensors shall be SICK / P&F/Omron.	6.7.17 Make of servo based mechanism shall be Allen Bradley / Siemens/Panasonic Make of sensors shall be SICK / P&F/Omron/Leuze
22.	6.7.24 The conveyor should be constructed of SS-304 or Polyethylene.	6.7.24 The conveyor should be constructed of Polyethylene, Delrin / USFDA material.
23.	6.7.25 In feed worm should be constructed of Delrin / USFDA material.	Deleted
Schedule III – Semi-Automatic Vial Optical Inspection Machine		
24.	Revised URS for Semi-Automatic Vial Optical Inspection Machine is attached as Annexure I of these Pre-Bid minutes. Vendor to consider the same for the tender.	
Schedule V - BOPP Tapping Machine (Added as a new schedule)		
25.	DS for BOPP Tapping Machine is attached as Annexure II of these Pre-Bid minutes. Vendor to consider the same for the tender.	
Schedule VI – Continuous Inkjet Printing with Conveyer (Added as a new schedule)		
26.	DS for Continuous Inkjet Printing with Conveyer Machine is attached as Annexure III of these Pre-Bid minutes. Vendor to consider the same for the tender.	

For HLL Biotech Limited




CEO

ANNEXURE I

HLL BIOTECH LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor


nne pharmaplan	User Requirement Specifications				
	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification	--	Document		URS/VIM 01
	Effective Date	2015-02-02	Revision		02

User Requirement Specifications Semi-Automatic Vial Optical Inspection Machine

Process Code	Area	Equipment ID	Qty(Nos)	Capacity (W.V)
F	Formulation	F-VIM 01	3	120 vials/ min
		F-VIM 02		
		F-VIM 03		

HLL BIOTECH LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

HLL pharmaparr	User Requirement Specifications				 HLL BIOTECH LIMITED (A Government of India Company)
	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification	--	Document	URS/VIM 01	
	Effective Date	2015-02-02	Revision	02	

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the in the block

HLL BIOTECH LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor



HLL pharmaplan	User Requirement Specifications				
	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification	--	Document		URS/VIM 01
	Effective Date	2015-02-02	Revision		02

Table of Contents

1.0	APPROVAL SIGNATURE	4
2.0	EQUIPMENT DESCRIPTION	5
3.0	PROCESS DESCRIPTION	6
3.1	INPUT & CHARGING METHOD	6
3.2	BRIEF PROCESS STEPS	7
3.3	OUTPUT & DISCHARGING METHOD.....	7
4.0	PRODUCTIVITY REQUIREMENT	7
4.1	DESIRED/ SUGGESTED CAPACITY	7
4.2	STANDARD BATCH SIZE	7
4.3	CHANGE OVER TIME	7
4.4	OTHERS(IF ANY)	7
5.0	CONTAINMENT	7
6.0	GMP REQUIREMENTS	8
6.1	PROCESS CONTROL	8
6.2	FAILURE MODE DETECTION	8
6.3	IN – PROCESS CONTROL	8
6.4	LEVEL OF INSTRUMENTATION.....	8
6.5	BATCH DATA DISPLAY AND RECORD PRINTING	8
6.6	GMP REQUIREMENTS (OTHERS)	9
6.7	SPECIFIC REQUIREMENTS.....	9
7.0	CONSTRAINTS	10
7.1	EQUIPMENT LOCATION AND AVAILABLE SPACE	10
7.2	AVAILABLE UTILITY.....	10
8.0	ABBREVIATION	10

HLL BIOTECH LIMITED, CHENNAI

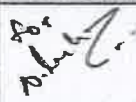
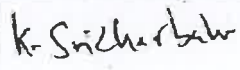




Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

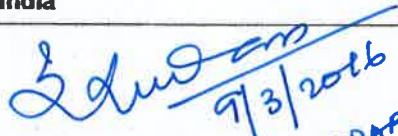
User Requirement Specifications			
	Equipment/System	Semi-Automatic Visual Optical Inspection Machine	
	Identification	Document	URS/VIM 01
	Effective Date	2015-02-02	Revision 02

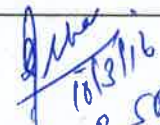


1.0 APPROVAL SIGNATURE

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Revival of DPT Vaccines 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 of Pasteur Institute of India, and authorized by the appropriate Project Authority.


Prepared by		
Name/ Designation	Signature	Date
Mr. Tushar Process Engineer-Process Engineering NNE Pharmaplan India Ltd.		05-03-2016
Checked by		
Name/ Designation	Signature	Date
Mr. Sridhar Babu Sr. Process Engineer-Process Engineering NNE Pharmaplan India Ltd.		06-03-2016
VIGNESH KARANJ HLL Biotech Limited		06-03-2016
Approved by		
Name/ Designation	Signature	Date
Dr. Harshad Mali Lead Process Engineer-Process Engineering NNE Pharmaplan India Ltd.		06-03-2016
HLL Biotech Limited		09-03-2016
Pasteur Institute of India		
Authorized by		
Name/ Designation	Signature	Date
Project Authority Pasteur Institute of India	 R. MOHAN	09-03-2016


7/3/2016
(Dr. B. SUNDAR
AD)


10/3/16
Dr. B. SEKAR
Director

HLL BIOTECH LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

HLL BIOTECH LIMITED CHENNAI	User Requirement Specifications				
	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification	--	Document		URS/VIM 01
	Effective Date	2015-02-02	Revision		02

2.0 EQUIPMENT DESCRIPTION

The semi-automatic vial inspection machine for filled vials. This machine will be used for vial inspection with the help of white & black board. The machine shall be of intermittent motion as operator intervention is required. The machine shall have two conveyors which are driven by motor.


The machine should consist of following parts in order to run operation smoothly

S. No.	Description	Purpose
1.	Vial infeed unit	Infeed tray and turn table with conveyor to unscramble the vials in two line feed to inspection hood
2.	No of operators	6 nos. [3 on each side] with minimum 1 meter distance.
3.	Conveyor system	Two line conveyor system
4.	Inspection Unit	Inspection hood with magnifying glass, illumination light (2000lux) and white & black board background
5.	Elephant chute	For collecting inspected vials at the out feed tray with low slop to avoid the breaking of vials.
6.	Rejected vials collection bin	To collect rejected vials with min. capacity 50 nos.6R vials for each operator
7.	No.of Rejection bin per person	Five, Each bin should accommodated 50 no's rejected vials
8.	Counters	Infeed counter, outfeed counter and over load sensor in the vial track is required along with batch data printing
9.	Conveyor speed	60-120 VPM
10.	Quantity	3 nos.

Note:

HLL BIOTECH LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor


nne pharmaplan	User Requirement Specifications				
	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification	--	Document	URS/VIM 01	
	Effective Date	2015-02-02	Revision	02	

1.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
2.	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 any deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
3.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options become necessary the item must be clearly stated.
4.	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.
5.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
6.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
7.	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.
8.	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.
9.	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.
10.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.
11.	Refer document "Installation Requirement Specifications and Specific Instructions" with URS NPI/110831/EQP/IRS01
12.	Refer tender document NPI/110831/EQP/TED/09

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 Filled vials shall be loaded on the Infeed Tray of Turn Table. Where vials will be divided in	
File Name	NPI_110831_EQP_URS_VIM 01
Page No.	Page 6 of 11

HLL BIOTECH LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

HLL Pharmaplan	User Requirement Specifications				
	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification		Document	URS/VIM 01	
	Effective Date	2015-02-02	Revision	02	

Specifications	Remarks
----------------	---------

two rows, further vials will be fed to inspection rollers.

3.2 Brief Process Steps

- | | | |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 3.2.1 | The vial passes to the inspection hood through the conveyer where the lights, Black/ White surrounding area with minimum 2000 lux along with magnifying glass should be placed for each person. | |
| 3.2.2 | The machine should be suitable for six operators, three on the right side and three on the left side. | |
| 3.2.3 | The operators should have the choice to reject the vials having faults /defects i.e. the operator has to manually pick and drop the faulty vial, therefore 5 no's rejection bin required for each person. | |

3.3 Output & Discharging method

- | | | |
|-------|----------------------------------------------------------------------------------------------------------------------|--|
| 3.3.1 | The rejected vial gets collected in the collection box with a cloth bag with a holding capacity of 50 no's 6R vials. | |
| 3.3.2 | Good vials shall be collected through elephant chute, must be of low slope to avoid vial breakage. | |

4.0 PRODUCTIVITY REQUIREMENT

4.1 Desired/ suggested capacity

60-120 vials per minute

Vendor should also suggest the best possible maximum output since inspected vials shall be collected manually at the out feed of inspected machine which will be a standalone Machine.

4.2 Standard batch size

Identification #	Batch size vials/ batch
F-VIM 01	Max. 1,00,000
F-VIM 02	Max. 1,00,000
F-VIM 03	Max. 1,00,000

4.3 Change Over Time

Operation without machine changeover is preferred, if changeover to be done, this must be possible in not longer than 30 minutes by a single operator with minimum tool usage. The number of format parts should be minimized and stated in the quotation.

- | | | |
|-------|--------------------------------------------------------------------------------------------|--|
| 4.3.1 | To fix the right position of the format parts, they should be marked that is not erasable. | |
|-------|--------------------------------------------------------------------------------------------|--|

4.4 Others(if any)


- | | | |
|-------|-----------------------------------------------------|--|
| 4.4.1 | The equipment shall be able to operate for 24 hours | |
|-------|-----------------------------------------------------|--|

5.0 CONTAINMENT

Not Applicable

HLL BIOTECH LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

HLL Pharmaplan	User Requirement Specifications				
	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification	--	Document	URS/VIM 01	
	Effective Date	2015-02-02	Revision	02	

Specifications	Remarks
----------------	---------

6.0 GMP REQUIREMENTS

6.1 Process control

The inspection machine should essentially have the necessary provision for adjustment / control of the following critical process parameters:

6.1.1.1 Inspection	
6.1.1.2 Rejection of faulty vials (manually)	
6.1.1.3 Infeed counter and outfeed counter ,over load sensor in the vial track is required along with batch data printing	

6.2 Failure mode detection

Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:

6.2.1 Emergency stop activated.	
---------------------------------	--

6.3 In – Process control

NA	
----	--

6.4 Level of instrumentation

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:


Type of control	Purpose	Instrumentation
Speed (infeed)	To synchronize the speed with conveyor	Variable frequency drive
Counter	To count filled vials at the out feed station, infeed vials	Proximity sensor
Rejection station	To collect rejected vials	collection bin
Conveyor system	To vary the speed	Variable frequency drive
Vial Overload	To stop conveyor during overload	Proximity Sensor
Lux level	The one lux meter required to verify the lux level before commencing the work on each machine.	Lux meter

6.5 Batch data display and record printing

Batch report to be printed at the end of the batch. It should mention the requirement of batch report, batch id, start time, end time, rejected vials quantity, accepted vials quantity,

HLL BIOTECH LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

one pharmaplan	User Requirement Specifications				
	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification	--	Document		URS/VIM 01
	Effective Date	2015-02-02	Revision		02

alarm details, operator name along with checked by and verified by at the bottom.
Vendor should consider a printer for the same.

6.6 GMP requirements (Others)

6.6.1 Refer IRS (Installation requirement specification and Specific Instructions)

6.7 Specific requirements

6.7.1 Variable frequency drives (Speed control) should be provided.

6.7.2 The Optical inspection machine shall be easy to clean.

6.7.3 Partitions to be provided in the table for each operator/station with minimum 1 meter distance.

6.7.4 Elephant chute to be provided to avoid vials braking after the out feed.

6.7.5 Out feed table height should be between 900-1100 mm

6.7.6 The MOC of body shall be SS 304

6.7.7 Height of the conveyor should be adjustable between 900 mm to 1100 mm

6.7.8 All the software backups shall be provided, which are installed in the PLC interfaced with the machine, Software with separate license key should be provided by the vendor

6.7.9 HMI (10 inches at least) to be provided.

6.7.10 Make of servo based mechanism shall be Allen Bradley / Siemens/Panasonic/

6.7.11 Make of sensor for counter shall be SICK / P&F/Omron /Leuze

6.7.12 Make of PLC shall be Allen Bradley / Siemens/Fatek

6.7.13 The construction of the complete system should be described in the documentation in detail.

6.7.14 Cables, top (industrial plug), air tubes, etc. required from the point (single utility point) to equipment are in scope of vendor.

6.7.15 Vendor shall provide tools for maintenance of the equipment.

6.7.16 Space below the equipment shall be six inches for the accessibility of cleaning.

Other Requirement

6.7.17 All metallic surfaces should be constructed of SS 304.

6.7.18 The conveyor should be constructed of Derline or Polyethylene/ USFDA material

6.7.19 Single track operation must be possible.

6.7.20 Minimum 6 nos people per machine at any point of time is required with seating arrangement.

HLL BIOTECH LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

ne pharmaplan®

User Requirement Specifications

Equipment/System Semi-Automatic Vial Optical Inspection Machine

Identification -- **Document** URS/VIM 01

Effective Date 2015-02-02 **Revision** 02



7.0 CONSTRAINTS

7.1 Equipment location and available space

- a) This equipment will be installed in the **Formulation block** of Revival of DPT vaccine manufacturing facility at PII, Coonoor as follows:

Floor: Formulation Block – Ground Floor

Room Name : Inspection room

Room no.: F1G023

Room dimension : 45 m² (5 m x 9.5 m)

False ceiling height: 4 m

Physical condition of the room:

1. Class: CNC
2. Differential Pressure: 05 Pa
3. Temperature maintained: 23 °C
4. Relative Humidity: NMT 60% RH

7.2 Available Utility

7.2.1 Compressed Air@ 6- 8 bar

7.2.2 Electricity : _____ kW

8.0 ABBREVIATION


Abbreviation	Definition
PII	Pasteur Institute Of India
GMP	Good Manufacturing Practices
HLL	HLL Life care Limited
NPI	NNE Pharmaplan India Ltd

REVISION INDEX

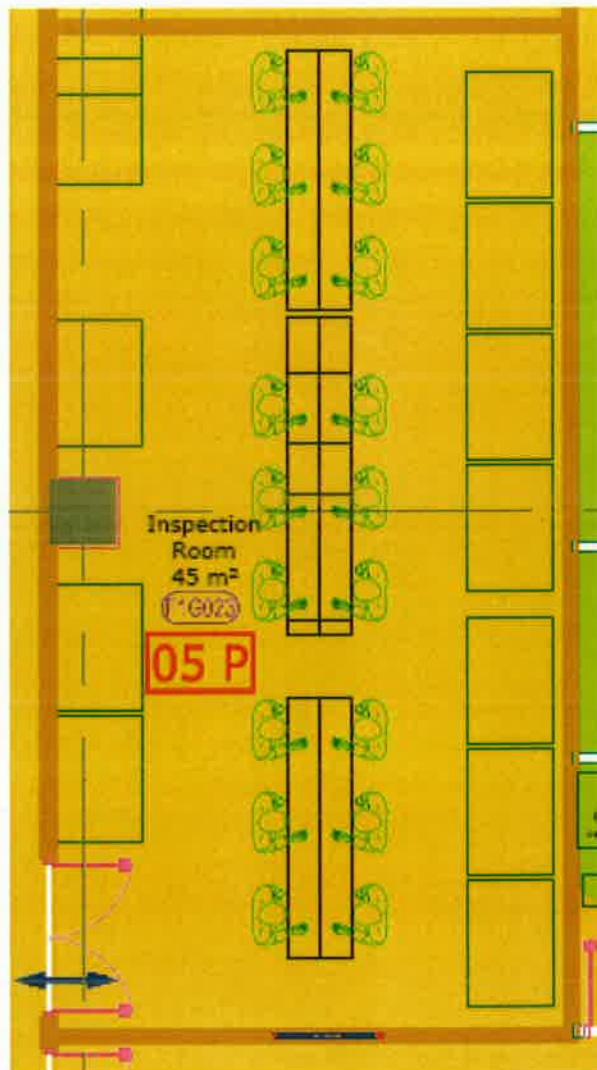
Revision	Date	Reason for Revision
00	2015-08-17	First Draft for Client's Review
01	2015-09-30	Updated as per client comments
02	2016-02-02	Update as per client comments

HLL BIOTECH LIMITED, CHENNAI



Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor


nne pharmapian	User Requirement Specifications				
	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification	--	Document		URSVIM 01
	Effective Date	2015-02-02	Revision		02

URS Annexure 1: LAYOUT C FORMULATION BLOCK





ANNEXURE II

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PILCOONOOR		
	BOPP Taping Machine [Carton sealing machine]		
	Project No	110831	
	Document No	DS-BTM 01	
1	Process requirements		
1.1	This equipment shall be used to pack the carton box / shipper in packaging area		
2	Equipment ID		
2.1	P-BTM 01		
3	Technical Specification		
3.1	Model	cGMP (Industrial) Complies	
3.2	Type	BOPP Taping Machine[Carton sealing machine]	
3.3	Belt Orientation	Vendor to specify	
3.4	Carton sealing range	Vendor to specify	
3.5	Tape Head	Standard 2 inch and 3 inch	
3.6	Bed Hight	Adjustable	
3.7	Uniform sealing	Required	
3.8	Sealer Type	Vendor to specify	
3.9	Operating temperature	(+10-45°C)	
3.10	Operating Humidity	RH:0-85%	
3.11	Motor	1-1/4 HP Motors	
3.12	Weight	Vendor to specify	
3.13	Sealing speed	30- 40 Cartons/ minute	
3.14	Operational accessories	Vendor to specify	
3.15	Power requirement	110V/ 5.4A/ 60Hz	
3.16	Capacity	30- 40 Cartons/ minute	
3.17	Quantity	1 Nos	
4	Material of Construction		
4.1	Body Construction	cGMP compliant	
5	Specific Equipment requirment		
5.1	The conveyor hight of the BOPP tape machine shall be adjustable.		
5.2	The packaging of carton box shall be fast and easy to change box size .		
5.4	The machine conveyor hight shall be adjustable for flexible operation.		
5.5	The equipment should be plug in operation.		
5.6	The equipment shall control following 1) Speed of taping 2) Overlapping distance of tape 3) width of tape 4) Hight table		
6	Other requirement		
6.1	Training/demonstration to be provided to users		
7	Regulatory guidelines / standards		
7.1	Certification		

Equipment Specification Data Sheet						
HLL Biotech Limited, Chennai						
nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PILCOONOOR					 <small>HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>
	BOPP Taping Machine [Carton sealing machine]					
	Project No		110831			
	Document No		DS-BTM 01			
8	Safety requirements					
8.1	Appropriate closure of all parts.					
8.2	No sharp edges/Corners stripettor.					
8.3	Noise level should be below <75 dB.					
9	Documents					
9.1	IOQ document.					
9.2	Operation and maintenance manuals shall be provided along with IOQ documents.					
9.3	List of standard spare parts with ordering information					
9.4	Warranty Letter for minimum 1 year from the date of completion.					
9.5	Vendor should provide list of standard spare parts with ordering information.					
10	Timelines					
10.1	Not Applicable					
NOTE: Accurate size and technical specification need to be mentioned by the vendor						
	AFI Approved for Enquiry			AFO Approved for Ordering		
1		TUSS	SDBB			
REV	Date	Completed	Checked By	AFI	AFO	

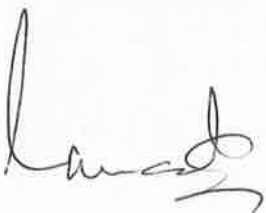
ANNEXURE III

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PILCOONOOR	
	Continuous Inkjet Printing with Conveyer	
	Project No	110831
	Document No	DS-CIP 01
		
1	Process requirements	
1.1	In-line Carton code printers are designed for printing materials as they pass by on a conveyor line. The printers use the friction of the passing items to trigger printing. As the print wheel rotates, ink is applied to the printing dies with an ink roller for clear and even printing.	
2	Equipment ID	
2.1	P-CIP 01	
3	Technical Specification	
3.1	Model	GMP model
3.2	Type	Continuous Inkjet Printing with Conveyer
3.3	Details to be printed on mono carton	Product, Net weight, Gross Weight, Quantity, Batch Number, Date of Manufacturing, Date of Expiry and M.R.P
3.4	Operation Temperature	5 to 45 degree celsius
3.5	No Carton-No Printing	This Interlocking should be incorporated
3.6	Selection of Fonts	It should be Automatic
3.7	Humidity	10 to 90 percent Non Condensing
3.8	Quantity	1 nos
3.9	Shipping Weight	Vendor to specify
3.10	Power Consumption, KW	Vendor to specify
3.11	Dimension (H x W x L) in mm	Vendor to specify(External Dimension)
3.12	Capacity	Vender to specify
3.13	Conveyer type	Vendor to specify
4	Material of Construction	
4.1	Body	SS304
5	Specific Equipment requirement	
5.1	The Machine shall have character width adjustment	
5.2	The Machine shall be capable for adjustable Drop size, Inverse, Reverse and Bold characters.	
5.4	No Carton-No Printing should be done.	
5.5	Vender to specify the maximum print height per printhead	
5.6	Printer shall be support various colours of ink	
5.7	Vender to specify the print speed	
6	Other requirement	
6.1	The Machine shall be equipped with RS 232 as standard.	
7	Regulatory guidelines / standards	
7.1	Not Applicable	

Equipment Specification Data Sheet						
HLL Biotech Limited, Chennai						
nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PILCOONOOR			 HLL BIOTECH LIMITED <small>(Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>		
	Continuous Inkjet Printing with Conveyer					
	Project No	110831				
	Document No	DS-CIP 01				
8	Safety requirements					
8.1	Noise level should be below <75 dB.					
8.2	Heat given out of the equipment should be stated.					
9	Documents					
9.1	Operation and maintenance manual.					
9.2	Warrantee certificate for 2 year.					
9.3	list of make with certificate.					
9.4	IQ Protocol to be provided by Vendor					
9.5	MOC certificates.					
10	Timelines					
10.1	Not Applicable					
NOTE: Accurate size and technical specification need to be mentioned by the vendor						
	AFI Approved for Enquiry			AFO Approved for Ordering		
1	19-01-2016	TUSS	SDBB			
REV	Date	Completed	Checked By	AFI	AFO	

S. No.	Clarifications on queries	
17.	6.7.10 Elephant chute to be provided to avoid vials braking after the outfeed	6.7.10 Out feed collection system /Elephant chute /Tray collection bin shall be decided during the detailed design
18.	6.7.12 Out feed turn table should be able to hold 3500 to 4000 vials (Vendor to confirm)	Deleted
19.	6.7.13 Height of the conveyor should be adjustable between 850 mm to 1100 mm (Vendor to specify)	Deleted
20.	6.7.16 Make of PLC shall be Allen Bradley / Siemens.	6.7.16 Make of PLC shall be Allen Bradley / Siemens/Fatek
21.	6.7.17 Make of servo based mechanism shall be Allen Bradley / Siemens. Make of sensors shall be SICK / P&F/Omron.	6.7.17 Make of servo based mechanism shall be Allen Bradley / Siemens/Panasonic Make of sensors shall be SICK / P&F/Omron/Leuze
22.	6.7.24 The conveyor should be constructed of SS-304 or Polyethylene.	6.7.24 The conveyor should be constructed of Polyethylene, Delrin / USFDA material.
23.	6.7.25 In feed worm should be constructed of Delrin / USFDA material.	Deleted
Schedule III – Semi-Automatic Vial Optical Inspection Machine		
24.	Revised URS for Semi-Automatic Vial Optical Inspection Machine is attached as Annexure I of these Pre-Bid minutes. Vendor to consider the same for the tender.	
Schedule V - BOPP Tapping Machine (Added as a new schedule)		
25.	DS for BOPP Tapping Machine is attached as Annexure II of these Pre-Bid minutes. Vendor to consider the same for the tender.	
Schedule VI – Continuous Inkjet Printing with Conveyer (Added as a new schedule)		
26.	DS for Continuous Inkjet Printing with Conveyer Machine is attached as Annexure III of these Pre-Bid minutes. Vendor to consider the same for the tender.	

For HLL Biotech Limited



CEO

