User Requirement Specifications
Vial Labeling Machine

Block Code	Block	Identification #	Capacity	Qty [Nos]
P1	Secondary packing	P1-VLM 01	200 vials/ min	1
P1	Secondary packing	P1-VLM 02	200 vials/ min	1

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URS Annexure List

URS Annex No.	Detail
1.	Specifications of customized 15 ml vial

1. APPROVAL SIGNATURE

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccines Complex, Chengalpattu, Chennai" (project number: 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective should be reviewed by HBL user/s and project/ engineering team, approved by team lead of user department and QA and authorized by the appropriate Project Authority.

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2. EQUIPMENT DESCRIPTION

Equipment operation requirements:

S. No.	Identification no.	Capacity	Vial Size	Label Sizes (LXW) mm	Remarks
1.	P1-VLM 01	200vials/ min	2R, 4R	50 x 18	
2.	P1-VLM 02	200vials/ min	6R & customised 15 ml	45 x 30, 50 x 22 & 62 x 26	

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 along with infeed system and conveyor
2.	Buffer table	To hold the vials.
3.	Label infeed unit	To feed the label for labeling of the Vials.
4.	In feed sensor / eye mark sensor	To read the eye mark of label.
5.	Label coding unit	For coding the labels with the batch details and inspecting the labeling and coding quality with the camera.
6.	Labeled Vial out feed unit	For discharging the labeled Vials at the out feed tray.
7.	Conveying unit	For conveying the vials from the vial in feed to the Vial out feed.
8.	Elephant chute	For collecting labeled vials at the out feed tray and to avoid the braking of vials.
9.	Labelling sensors	Optical character recognition(OCR)/ Optical character verification (OCR), 2D codes & RSS codes
10.	Servo Motor	For ease of driving the operation.
11.	Control panel	To regulate the desired parameters.
12.	Rejection Station	For missing of labels, overprinting details

Vials are fed from the vial infeed unit, which are directed towards the labelling unit. The Labels should be released intermittently and subsequently coded with the help of printer with the batch details. Coded labels are then pasted onto the vials and collected through the vial out feed. However, if there is **No Vial then there should be No label, No Label – No Printing**. This has to be controlled through Proximity Sensor and Camera system. Operations are controlled by the control panel.

Note:

I.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
II.	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.
III.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options becomes necessary the item must be clearly stated.
IV.	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.
V.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
VI.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
VII.	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.
VIII.	Special Instruction a. If no comments against any specification should be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it should be treated as unresponsive / technically non-compliant and rejected.
IX.	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 HBL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI-120310-IRS-S1-01
XII.	Refer Tender document with URS; NPI-120310-EQP-S1-TD-12

Specifications	Remarks
3. PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 Batch details are loaded in the system which is to be printed on the label.	
3.1.2 Printed label roll is loaded onto the dispenser of the labelling machine.	
3.1.3 Filled and sealed vials are loaded onto the infeed turn table with the help of tray loading system.	
3.2 Brief Process Steps	
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.	
3.2.2 Intermittent flow of the Reel Roll consisting of Labels.	
3.2.3 OCROCV, 2D codes, RSS codes, Pharma codes sensing and with rejection mechanism shall be done.	
3.2.4 Labelling of vials i.e. Batch number, Manufacturing date, MRP & expiry date has to be performed by the machine and later the machine should be able to stick the label on to the outer surface of the vial.	
3.2.5 Following interlocks shall be considered No Vial-No Label, No label - No Print, No vial in feeder – Machine stop	
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 to reject the vials). Lockable Rejection device is available for collection of rejected vials.	
3.3 Output & Discharging method	
3.3.1 There will be tray station at the Out feed for collecting all labelled vials.	
4. PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
The Vial labelling machine with below mentioned outputs:	
4.1.1 For P1-VLM 01: 200 Vials per minute on ISO 2R. (Set point will be 80-200 vials per minute) ***Format: Ø16mm, Height: 35mm***	
4.1.2 For P1-VLM 01: 200 Vials per minute on ISO 4R. (Set point will be 80-200 vials per minute) ***Format: Ø16mm, Height: 45mm***	
4.1.3 For P1-VLM 02: 200 Vials per minute on ISO 6R. (Set point will be 80-200 vials per minute) ***Format: Ø22mm, Height: 40mm***	

Specifications	Remarks
4.1.4 For P1-VLM 02: 200 Vials per minute on Customised 15ml vial. (Set point will be 80-200 vials per minute) ***Refer the URS annexure-2 for the specifications of customised 15 ml vial***	
Vendor should also suggest the best possible maximum output since labelled vials shall be collected manually at the out feed of labelling machine which will be a standalone Machine.	
4.2 Standard batch size / process time	

Identification #	Batch size vials/ batch
P1-VLM 01	Max. 1,00,000
P1-VLM 02	Max. 1,00,000

4.3 Change Over Time (if applicable)	
4.3.1 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.	
4.3.2 To fix the right position of the format parts, they should be marked that is not erasable.	
4.4 Other Productivity Requirement	
4.4.1 The equipment shall be able to operate for 24 hours	
5. CONTAINMENT	
Not applicable	
6. GMP REQUIREMENTS	
6.1 Process Control	
6.1.1 The vial labelling machine should essentially have the necessary provision for adjustment / control of the following critical process parameters:	
6.1.1.1 Labelling speed. (Speed should be synchronized with the conveyor)	
6.1.1.2 Label dispensing onto the Vial.	
6.1.1.3 Inspection with the help of camera for batch detail, printing quality.	
6.1.1.4 Rejection of faulty vials.	
6.1.1.5 Physical counter at the out feed of the machine.	
6.2 Failure mode detection	
6.2.1 Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
6.2.1.1 Emergency stop activated.	
6.2.1.2 In feed overload alarm to stop the Machine.	

Specifications	Remarks
6.2.1.3 Out feed overload alarm to stop the Machine.	
6.2.1.4 Low level of label alarm and machine should stop.	
6.2.1.5 Interlocks: No Vial-No Label No label - No Print No vial in feeder – Machine stop	
6.3 In –Process control	
6.3.1 Manual sampling as well to check the quality of printing batch detail	
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
Labelling Speed (Batch labels)	To synchronize the labelling speed with conveyor	Variable frequency drive
Batch overprinting, printing quality	To online checking of batch overprinting and printing quality	Camera
No Vial- No label No label - No Print No vial in feeder – Machine stop	If there is No Vial then there should be no Label dispensed and no printing will take place. (Interlocking required)	Proximity Sensor
Overload Control	To avoid Jamming of Vials at the In feed and Out feed	Proximity Sensor
Uniform Flow of Reel Roll	To have Intermittent Flow of Reel Roll for accurate and precise cutting of Label	Servo Motor
Uniform Cutting of Label	To have Eye Mark to Eye Mark cutting of label	Eye Mark sensor.
Counter	To count labelled vials at the out feed station, infeed vials and rejected vials	Proximity sensor
Rejection station	To collect rejected vials	Diverter, collection tray
Conveyor system	To vary the speed	Variable frequency drive

6.5 Batch data display and record

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, labelled vials quantity, alarm details, operator name.

	Specifications	Remarks
6.6	**GMP requirements (Others)**	
6.6.1	Refer IRS (Installation requirement specification and Specific Instructions)	
6.7	**Specific requirements**	
6.7.1	**Label properties:** 1. Pre-printed labels 2. Roll label cartridge type 3. Self-adhesive label	
6.7.2	**Batch details to be printed on the label:** 1. Batch No 2. Manufacturing Date 3. Expiry Date 4. Price (MRP)	
6.7.3	Infeed turntable should be able to hold minimum of 4000 vials.	
6.7.4	Buffer table to be provided in front of the infeed turn table to hold 2000 vials during the operation.	
6.7.5	HP ink type cartridge printer for printing the batch detail.	
6.7.6	Properties of ink need for labelling should be quickly dried and water proof.	
6.7.7	**Gap Between two labels = ~1 to 2 mm.** **Roll core Diameter = TBD mm (Vendor to specify)** **Label Roll diameter = TBD mm (Vendor to specify)**	
6.7.8	Variable frequency drives (Speed control).	
6.7.9	Printer required for printing the batch detail **(Vendor to specify the character size possible)**	
6.7.10	An automatic rejection system shall be included into the system **(Arm deviator rejection system is recommended)**	
6.7.11	Camera System: On-line inspection by camera for batch overprinting, printing quality. If deviation, send signals to pneumatic rejection system to reject the vials.	
6.7.12	Elephant chute to be provided to avoid vials braking after the outfeed.	
6.7.13	Out feed table height should be between 900-1100 mm **(Vendor to specify)**	
6.7.14	Out feed turn table should be able to hold 3500 to 4000 vials **(Vendor to confirm)**	
6.7.15	Height of the conveyor should be adjustable between 850 mm to 1100 mm **(Vendor to specify)**	
6.7.16	All the software backups shall be provided, which are installed in the PLC interfaced with labelling machine, Software with separate license key should be provided by the vendor	
6.7.17	HMI (10 inches at least) to be provided.	
6.7.18	Make of PLC shall be Allen Bradley / Siemens.	

Specifications	Remarks
6.7.19 Make of servo based mechanism shall be Allen Bradley / Siemens.	
6.7.20 Make of sensors shall be SICK / P&F.	
6.7.21 The construction of the complete system should be described in the documentation in detail.	
6.7.22 Cables, top (industrial plug), air tubes, etc. required from the point (single utility point) to equipment are in scope of vendor.	
6.7.23 Vendor shall provide tools for maintenance of the equipment.	
6.7.24 Space below the equipment shall be six inches for the accessibility of cleaning.	
Other Requirement	
6.7.25 All metallic surfaces should be constructed of SS 304	
6.7.26 The conveyor should be constructed of SS-304 or Polyethylene.	
6.7.27 In feed worm should be constructed of Delrin / USFDA material.	
6.7.28 Vial labelling machine should be compliance with 21 CFR Part 11	

7. CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the **Viral Vaccine Formulation Block** of **Integrated Vaccines Complex,** Chengalpattu.

i. **P1- VLM 01**

Equipment Location:

Block: **Secondary packaging Block**

Floor: **Ground floor**

Room No.: **P1G008**

Room Dimension : **223.38 sq. m**

Available room dimensions for equipment: **29200mm x 7650mm**

Fall Ceiling: **3.0 m**

The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1.**

Physical condition of the rooms:

Secondary Packaging Hall – 4 (Viral)

1) Room No.: P1G008
2) Clean room Classification: Grade "CNC"
3) Temperature maintained: Not more than 25 °C
4) Relative Humidity: Not more than 60%

ii. **P1- VLM 02**

Equipment Location:

Block: **Secondary packaging Block**

Floor: **Ground floor**

Room No.: **P1G010**

Specifications	Remarks
Room Dimension : **230.68 sq.m** Available room dimensions for equipment: **29200mm x 7900mm** Fall Ceiling: **3.0 m** The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1.** **Physical condition of the rooms:** **<u>Secondary Packaging Hall – 2 (Viral)</u>** 1) Room No.: P1G010 2) Clean room Classification: Grade "CNC" 3) Temperature maintained: Not more than 25 °C 4) Relative Humidity: Not more than 60%	

7.2 Available utility		
7.2.1 Electricity	- Single (220 V) & 3 phase (420 - 440 V)	
7.2.2 Compressed Air	- 6 bar(Report Requirement)	
Note:		
Vendor to provide the PRV and other associated equipment as per equipment utility requirement.		

8. ABBREVIATION

Abbreviation	Definition
ANSI	American National Standards Institute
CFR	Code of Federal Regulation
EU	European Union
FAT	Factory Acceptance Test
GA	General Assembly
GAMP	Good Automated Manufacturing Practice
GMP	Good Manufacturing Practice
HBL	HLL Biotech Limited
I/O	Input / Output
IRS	Installation Requirement Specifications
ISO	International Standards Organization
MOC	Material of Construction
NPI	NNE Pharmaplan India
OCR	Optical Character Recognition
OCV	Optical Character Verification
OS	Operating System
P&ID	Piping and Instrumentation Diagram
PLC	Programmable Logic Controller

PRV	Pressure reducing valve
QA	Quality Assurance
Ra	Roughness Average
SS	Stainless Steel
USFDA	United States Food and Drug Administration
VLM	Vial Labeling Machine

9. REVISION INDEX

Revision	Date	Reason for revision
00	12-03-2015	First Draft for Client's Review
01	23-06-2015	Updated as per comments received by HBL dated 19-06-2015

Annexure - 1

Specifications of 15 ml Customized vials

15 ml glass vials (for use with 20 mm stoppers)		
S.No.	Tests	Specifications
1	Overflow capacity	15.50 ± 0.50 mL
2	Mouth internal diameter	12.60 ± 0.20 mm
3	Mouth external diameter	19.60 to 20.10 mm
4	Body outer diameter	24.0 ± 0.2 mm
5	Body wall thickness	1.00 ± 0.04 mm
6	Total height	49.7 ± 0.5 mm
7	Neck height	9.0 ± 0.5 mm
8	Collar height	3.9 ± 0.2 mm
9	Total weight	10.0 ± 1.0 g