HLL LIFECARE LIMITED, CHENNAI

Revival of BCG Vaccine Laboratory, Guindy, Chennai

nne pharmaplan	**User Requirement Specifications**			
	Equipment/System	Vial Labeling Machine		
	Identification #	FG-VLM 01	Document#	URS/ FG-VLM 01
	Effective Date	2014-02-05	Revision#	06

User Requirement Specifications
Vial Labeling Machine
Equipment ID: FG-VLM 01

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URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the equipment
2	List of preferred MAKE of components

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1.0 APPROVAL SIGNATURE

This document is prepared by the Process and Validation and GMP compliance team of "NNE Pharmaplan India" to satisfy the customer requirement for the project "Revival of BCG Vaccine Manufacturing Facility" (**Project number:-110729**) of BCG Vaccine Laboratory, Guindy, Chennai under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team and authorized by the appropriate Project Authority.

Prepared by

Name/ Designation	Signature	Date
Mr. Shivaraj B K **Technical Assistant (Biotech)** NNE Pharmaplan India Ltd.		05-02-2014

Checked by

Name/ Designation	Signature	Date
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HLL Lifecare Limited A. ANTO FELIX		14/2/4

Approved by

Name/ Designation	Signature	Date
Mr. Narendra Prasad **Director- Technical** NNE Pharmaplan India Ltd.		10-02-2014
QA-BCGVL / ENGG DEPT		18/3/14

Authorized by

Name/ Designation	Signature	Date
Project Authority **BCG vaccine Laboratory**		

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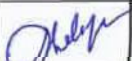
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2.0   EQUIPMENT DESCRIPTION

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 worm 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.	Servo Motor	For ease of driving the operation.
10.	Control panel	To regulate the desired parameters.
11.	Rejection Station	For missing of labels, overprinting details

Vials are fed from the vial infeed unit, which are directed towards the labeling 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.

All points of the IRS except the below mentioned would be applicable for the equipment

- 4.1.11

- 4.1.17

- ASME-BPE

- ANSI / NSF 49-2008, ISO 14664

- 5.4 - Material of constructions –Please refer the section: Specific requirement.

- 5.1 - Table 2, point 2,6 and 8

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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. I n case of an 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 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.
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_110729_IRS_BCG_01
XII.	Refer Tender document with URS; NPI/110729/EQP/TD/xx

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Specifications	**Remarks**
3.0 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 labeling 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 labeling machine. And then 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 Eye Mark Sensing of the labels to ensure proper cutting of Labels.	
3.2.4 Labeling of vials i.e. Batch number, Manufacturing date and 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 No Vial-No Label, No label - No Print, No vial in feeder – Machine stop	
3.2.6 Faulty/ printed labeled 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 Recognisation) 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	
There will be tray station at the Out feed for collecting all labeled vials.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
The Vial labeling machine with below mentioned outputs:- • 200 Vials per minute on ISO 2R. (Set point will be 80-200 vials per minute) *Format: Ø16mm, Height: 35mm* *Vendor should also suggest the best possible maximum output since labeled vials shall be collected manually at the out feed of labeling machine which will be a standalone Machine.*	
4.2 Standard batch size	
The Batch production is required of ISO 2R vial size. 40000 vials/ batch	

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Specifications	Remarks

4.3 Change Over Time

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

5.0 CONTAINMENT

Not Applicable

6.0 GMP REQUIREMENTS

6.1 Process control

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

6.1.1 Labeling speed. (Speed should be synchronized with the conveyor)

6.1.2 Label dispensing onto the Vial.

6.1.3 Inspection with the help of camera for batch detail, printing quality.

6.1.4 Rejection of faulty vials.

6.1.5 Physical counter at the out feed of the machine.

6.2 In –Process control

Manual sampling as well to check the quality of printing batch detail

6.3 Failure mode detection

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

6.3.1 Emergency stop activated.

6.3.2 In feed overload alarm to stop the Machine.

6.3.3 Out feed overload alarm to stop the Machine.

6.3.4 Low level of label alarm and machine should stop.

6.3.5 No Vial-No Label
No label - No Print
No vial in feeder – Machine stop

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Specifications	Remarks

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
Labeling Speed (Batch labels)	To synchronize the labeling 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 labeled vials at the out feed station	Proximity sensor
Rejection station	To collect rejected vials	Diverter, collection tray
Conveyor system	50-200 rpm	Variable frequency drive

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, reject vials quantity, labeled vials quantity, alarm details, operator name.

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Specifications	Remarks

6.6 GMP requirements (Others)

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

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 labeling should be quickly dried and water proof.

6.7.7 Label height approximate 10mm to 25mm. (Vendor should provide the exact dimension of label)

6.7.8 Variable frequency drives (Speed control).

6.7.9 Printer required printing the batch detail. Vendor to specify the character size possible on ISO 2R vial.

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 from 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 labeling 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.

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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.	

7.0   CONSTRAINTS

7.1   Equipment location and available space

This equipment will be installed in the Fill-Formulation Area of Revival of BCG Vaccine Laboratory, Guindy, Chennai.

Equipment Location: Ground floor-Formulation

Room name: Coding and labeling

Room No. FG016

Room dimension: 4850 mm x 5960 mm

Room height: 5500 mm

False ceiling height: 2400 mm

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

Physical condition of the rooms:

Coding & Labeling

1. Class: EU Class "D"
2. Differential Pressure: 5 Pa Absolute
3. Temperature maintained: $22°C \pm 2°C$
4. Relative Humidity: < 55% RH

7.2   Utility

7.2.1 Electricity: _____(Report Requirement)	
7.2.2 Power consumption: _____(Report Requirement)	

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8.0 ABBREVIATION

Abbrevation	Definition
MOC	Material Of Construction
NPI	NNE Pharmaplan India Ltd
OCR	Optical character Recognisation
P&ID	Piping and Instrumentation Drawing
Ph	Phase
QA	Quality Assurance
Ra	Roughness Average
SS	Stainless Steel
VLM	Vial Labeling Machine

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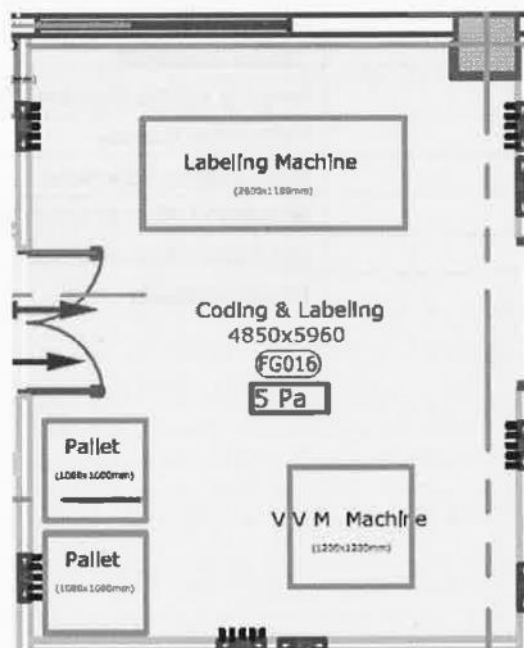| Revision	Date	Reason for revision
00	2011-12-09	First Draft for Client's Review
01	2012-11-16	Format changed as per HLL requirement
02	2013-01-01	Comments received on 2012-12-31 by HLL
03	2013-06-25	As per MOM dated 20th June 2013
04	2013-07-26	As per client's comments dated 23rd July 2013
05	2013-12-18	As per Client's comments dated 9th December 2013
06	2014-02-05	As per Client's comments dated 4th January 2014

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URS Annexure 1: LAYOUT POSITION
Room No. FG016

Labeling Machine
(2600x1189mm)

Coding & Labeling
4850x5960
FG016
5 Pa

Pallet
(1080x1000mm)

Pallet
(1080x1000mm)

V V M Machine
(1200x1200mm)

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URS Annexure 2: List of preferred make of components

S. No	Description	Make
1.	Proximity sensors	Contrinex/Rockwell/Omron
2.	Eye Mark sensor	Vendor to specify
3.	Camera	Imaging source-Germany/ Baumer-Germany
4.	Variable Frequency Drive	Delta/Allen Bradley
5.	Servo motor	Allen Bradley / Siemens
6.	PLC + touch screen HMI	Mitsubishi/ Allen Bradley/ Siemens
7.	Main Drive Gear Motor	Bonfiglioli / Siemens/ABB
8.	Gear Box	Bonfiglioli/Bauer