User Requirement Specifications
Semi-Automatic Vial Inspection Machine
Equipment ID: FG-VIM 01

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the Semi-automatic vial Inspection machine.
2	List of preferred MAKE of components

Table of Contents

nne pharmaplan	User Requirement Specifications			
	Equipment/System	Semi-automatic Vial Inspection Machine		
	Identification	FG-VIM 01	**Document**	URS/ FG-VIM 01
	Effective Date	2015-01-07	**Revision**	06

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. Manohar M S **Process Engineer - COC Vaccines** **NNE Pharmaplan India Ltd.**		

Checked by		
Name/ Designation	**Signature**	**Date**
Mr. Sridhar Babu **Sr. Process Engineer COC Vaccines** NNE Pharmaplan **India Ltd**		
HLL Lifecare Ltd		

Approved by		
Name/ Designation	**Signature**	**Date**
Mr. Vikas Katial **GM – Head COC Vaccines** NNE Pharmaplan India Ltd.		
QA-BCGVL		

Authorized by		
Name/ Designation	**Signature**	**Date**
Project Authority **BCG Vaccine Laboratory**		

2.0 Equipment description

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

S. No.	Description	Purpose
1.	Vial infeed unit	Infeed tray to feed turn table
2.	Turn table	To unscramble the vials in two line feed
3.	Inspection hood	Inspection hood with magnifying glass, illumination light and white board.
4.	Pause, Reject and Pass buttons	Rejection bin will be provided for each operator. Pause and Pass button option are deleted.
5.	Reject chute	Manual reject chute shall be provided with collection bin to avoid faulty vials in good vials
6.	Out feed tray	To collect the vials
7.	Digital Counter	Digital counter shall be provided to count the vials at the in- feed and out-feed area

The machine shall be used for vial inspection of vials to check following defects:

- Particles, air bubbles in the glass body
- Cracks in the glass body
- Particles in the product
- Crimping fault
- Cake pattern

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

nne pharmaplan	User Requirement Specifications			
	Equipment/System	Semi-automatic Vial Inspection Machine		
	Identification	FG-VIM 01	**Document**	URS/ FG-VIM 01
	Effective Date	2015-01-07	**Revision**	06

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 vendors' 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/13

Specifications	Remarks
3.0 Process Description	
3.1 Input & Charging method	
3.1.1 There will be manual loading of vials at the infeed tray of the Semi-automatic Inspection Machine**.**	
3.2 Brief Process Steps	
3.2.1 Vials will be fed on infeed tray to turntable which will singularise the vials and transport.	
3.2.2 Vials will be transported further on inspection hood with particular space intervals (minimum 60 mm with spacer / suitable arrangement)	
3.2.3 The operator will check the following defects ➢ Particles, air bubbles in the glass body ➢ Cracks in the glass body ➢ Particles in the product ➢ Crimping fault ➢ Cake pattern **Note:** Double track conveyor will be provided and it should ensure their will be no mix-up with the inspected vials and non-inspected vials. 3-4 visual inspection hood to be provided on their side.	
3.2.4 Good vials will be transported further to out feed tray.	
3.2.5 Operator will manually pick the defected vials and collect it separately in rejection bin	
3.3 Output & Discharging method	
3.3.1 The output is collected on the out feed Tray	
4.0 Productivity Requirement	
4.1 Desired/ suggested capacity	
The machine is with the below mentioned outputs:- • 120 Vials per minute on ISO 2R (Set point will be 60-120 vials per minute) ***Format: Ø16mm, Height: 35mm*** ***Vendor should also suggest the best possible maximum output since vials shall be collected manually at the out feed of machine which will be a standalone Machine.***	
4.2 Standard batch size	
The Batch production is required of ISO 2R vial size. 40,000 vials/ batch	
4.3 Change Over Time	
Not Applicable	

Specifications	Remarks
4.4 Other Productivity Requirement	
The equipment shall be able to operate for 24 hours	
5.0 Containment	
Not Applicable	
6.0 GMP requirements	
6.1 Process control	
Not Applicable	
6.2 Failure mode detection	
The vial Inspection machine should essentially have the necessary provision for adjustment / control of the following critical process parameters:	
6.2.1 Emergency switch shall be provided	
6.2.2 In case, out feed tray is full, notification shall be provided	
6.2.3 In case, in feed tray is empty, notification shall be provided	
6.3 In – Process control	
Not Applicable	
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
Counter	To count vials at the in-feed station	Proximity sensor
Counter	To count vials at the out feed station	Proximity sensor (Provision to collect rejected vials)
Conveyor speed	To control the conveyor speed	Variable frequency drive

6.5 Batch data display and record printing	
Not Applicable	
6.6 GMP requirements (Others)	
6.6.1 Space below the equipment shall be sufficient for the accessibility of cleaning	

	Specifications	Remarks
6.7	**Specific requirements**	
6.7.1	Main machine frame and turn table shall be of SS 304	
6.7.2	In feed turn table shall be provided with in feed provision. Turn table shall be provided with Variable frequency drive.	
6.7.3	Vendor shall provide the dimension of the turn table and capacity of the turntable as per capacity mentioned	
6.7.4	Machine shall be provided with two conveyors which are driven by motor connected with a VFD rating 20 vials/min or 60 vials/min (or more)	
6.7.5	Intermittent motion ergonomic switch shall be provided to stop-start the conveyor. It can be of foot paddle type	
6.7.6	Inspection hood shall be provided with the following requirements: ➢ High quality magnifying lens with scratch proof and the flexibility of adjustment according to the operator ➢ Background (top, bottom) illumination - CFL ➢ White board with scratch proof coating ➢ The vials should be in inclined position and it should rotate 360° within in the viewable area. ➢ The angle of tilting and speed of rotation of vial should be variable. ➢ The lyophilized cake should not be disturbed by speed of rotation of vials.	
6.7.7	Lockable rejection bin shall be provided.	
6.7.8	Control panel shall be provided with emergency switch along with intermittent ergonomic switch.	
6.7.9	Digital counter shall be provided to count the vials at the in-feed of the machine along with visual indication on control panel.	
6.7.10	Digital counter shall be provided to count the good vials at the out feed of the machine along with visual indication on control panel.	
6.7.11	Working height of the machine shall be 900±30mm.	
6.7.12	Easy access for cleaning and maintenance.	
6.7.13	Equipment design must realize no breakage of glass vials.	
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: Inspection room Room No. FG019 Room dimension:9905 mm x 4465 mm Room height: 5500 m	

Specifications	Remarks
False ceiling height: 2400 mm **Physical condition of the rooms:** Coding & Labelling 1. Class: EU Class "D" 2. Differential Pressure: 25 Pa 3. Temperature maintained: 22°C ±2°C 4. Relative Humidity: <55% RH The equipment location is indicated in the relevant block of the layout enclosed as URS Annex-1.	
7.2 Utility	
➢ Electricity: _____(Report Requirement)	

8.0 Abbreviation

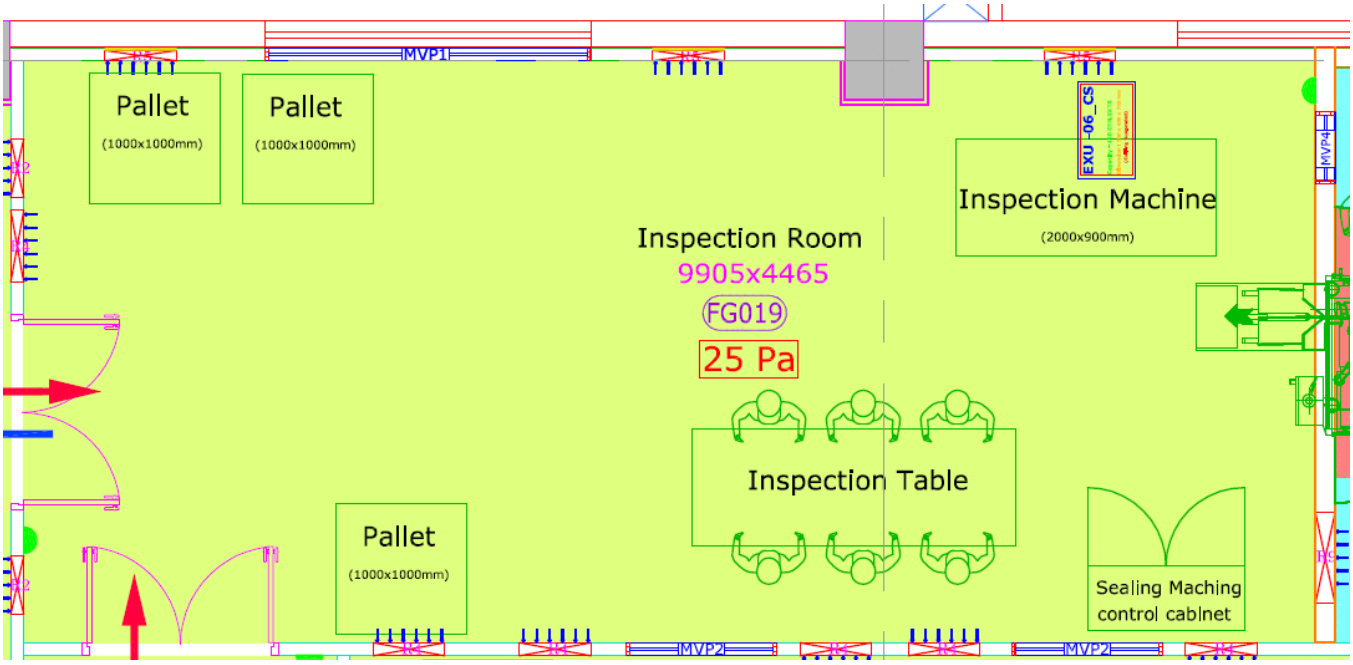
Abbreviation	Definition
IPM	Semiautomatic inspection machine
VIM	Vial Inspection machine
GMP	Good Manufacturing Practices
HLL	HLL Lifecare Limited
NPI	NNE Pharmaplan India Ltd

Revision index:

Revision	Date	Reason for Revision
00	2013-02-22	First Draft for Client's Review
01	2013-06-25	As per MOM dated 20th June 2013
02	2013-07-26	As per Client's comments dated 23rd July 2013
03	2013-09-25	As per Client's comments dated 25th September 2013
04	2013-10-03	As per Client's comments dated 3rd October 2013
05	2013-12-18	As per Client's comments dated 9th December 2013
06	2015-01-07	As per Pre-Bid MoM dated 26th August 2014

URS Annexure 1: LAYOUT

Room No. FG019



URS Annexure 2: List of preferred make of components

S. No	Description	Make
1.	Proximity sensors	Leuze/Rockwell/Omron
2.	Variable Frequency Drive	Delta/Allen Bradley/ABB
3.	Main Drive Gear Motor	Bonfiglioli / Siemens/ABB
4.	Control panel	Allen-Bradley / Honey well / Siemens
5.	Gear Box	Bonfiglioli/Bauer