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		

URS Annexure List

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

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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.

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2.0 EQUIPMENT DESCRIPTION

The semi-automatic vial inspection machine for lyophilised 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.

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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	On one table 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.	Pause and Pass buttons	Pause- To stop the conveyor moment while inspecting the vials Pass- To start the conveyor moment
6.	Elephant chute	For collecting inspected vials at the out feed tray with low slop to avoid the breaking of vials.
7.	Rejected vials collection bin	To collect rejected vials with min. capacity 50 nos.6R vials between two operator
8.	No. of Rejection bin per Table	Four
9.	Counters	Infeed counter, outfeed counter and over load sensor in the vial track is required along with batch data printing
10.	Conveyor speed	60-120 VPM
11.	Quantity	3 nos.

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	Equipment/System	Semi-Automatic Vial Optical Inspection Machine			
	Identification	--	**Document**	URS/VIM 01	
	Effective Date	2015-02-02	**Revision**	02	

Note:

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

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	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 two rows, further vials will be fed to inspection rollers.	
3.1.2	Vials in vertical position are then passed through the Nylon invertors to the rollers in for proper inspection of the vials where operator can inspect black particle, and crack on vials, seal defect.	
3.2	**Brief Process Steps**	
3.2.1	The rollers passes the vials to the inspection hood 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 1 rejection bin required between two people.	
3.3	**Output & Discharging method**	
3.3.1	The rejected vial gets collected in the collection box with a cloth bag/ Self-sealing poly bag with a holding capacity of 50 no's 6R vials.	
3.3.2	Each rejection station should have capacity to hold 50 no's vials of 6R vials	
3.3.3	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**	
	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.	

Specifications	Remarks
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	
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 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
Vial Overload	To stop conveyor during overload	Proximity Sensor

Specifications			Remarks
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, alarm details, operator name. 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 Space 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 **(Vendor to specify)**	
6.7.6 The MOC of body shall be SS 304	
6.7.7 Height of the conveyor should be adjustable between 850 mm to 1100 mm **(Vendor to specify)**	
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.	
6.7.11 Make of sensor for counter shall be SICK / P&F/Omron	
6.7.12 The construction of the complete system should be described in the documentation in detail.	
6.7.13 Cables, top (industrial plug), air tubes, etc. required from the point (single utility point) to equipment are in scope of vendor.	
6.7.14 Vendor shall provide tools for maintenance of the equipment.	
6.7.15 Space below the equipment shall be six inches for the accessibility of cleaning.	
Other Requirement	

6.7.16 All metallic surfaces should be constructed of SS 304.	
6.7.17 The conveyor should be constructed of Derline or Polyethylene/ USFDA material	
6.7.18 Single track operation must be possible.	
6.7.19 Minimum 18 nos people seating arrangement required with respect to three table.	
6.7.20 Infeed turntable is required and it is suggested to have a common turn table to reduce the foot print.	

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 m^2 (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

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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

URS Annexure 1: LAYOUT C
FORMULATION BLOCK