User Requirement Specifications
Vial Sealing Machine
Equipment ID: F-VSM 01

nne pharmaplan	User Requirement Specifications			
	Equipment/System	Vial Sealing Machine		
	Identification #	F-VSM 01	**Document#**	URS/F-VSM 01
	Effective Date	2013-06-06	**Revision#**	04

URS Annexure List:

URS Annex No.	Detail
1	Layout showing location of the installation of the Vial sealing machine
2	List of components and make

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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 Vaccine 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 and authorized by the appropriate Project Authority.

Prepared by		
Name/ Designation	**Signature**	**Date**
Mr. Nihit Singhal **Sr. Engineer – Projects (Biotech)** **NNE Pharmaplan India Ltd.**		

Checked by		
Name/ Designation	**Signature**	**Date**
Dr. Naveen Nagaraj **Sr. Project Manager - Head Biotech Division** **NNE Pharmaplan India Ltd.**		
Mr. Vikas Katial **GM –Head COC Vaccines** **NNE Pharmaplan India Ltd.**		

Approved by		
Name/ Designation	**Signature**	**Date**
Mr.Narendra Prasad **Director-Technical** **NNE Pharmaplan India Ltd.**		
Mr. Hartmut Schaz **Senior Technology Partner, Experts I** **NNE Pharmaplan, Germany**		
HLL Lifecare Limited		

Authorized by		
Name/ Designation	**Signature**	**Date**
Project Authority **Pasteur Institute of India**		

2.0 Equipment description

The vial sealing machine shall consist of following parts in order to run operation smoothly.

S. No.	Description	Purpose
1. Sealing Machine		
1.	In feed Turn Table	Full stoppered vials received from Filling machine and fed onto the turn table .
2.	Multi head Sealing Unit	To seal the vials
3.	In feed starwheel, turret/screw	For uniform spacing
4.	Vibrating Hopper	Used for feeding the Aluminum seals to the sealing unit.
5.	Out feed Turn table	To accumulate the vials from the sealing unit and feed the vials for further activity. Alternately, the vials shall be collected in the tray manually from the out feed of sealing unit.
6.	Seal Hopper	Pre-Sterilized seals shall be loaded using manual type transfer port.

Machine shall have all operation in automatic mode. All the regulatory requirements shall be followed. The vial shall be transferred to the sealing unit in a group by the transport system.

The machine shall be provided with the following interlocking.

1. The in feed to turn table over load, the turntable shall stop with alarm.
2. The infeed/ out feed to sealing unit over load, the sealing machine shall stop with alarm
3. No aluminum seal in chute, machine will stop with alarm.
4. If doors are open, the sealing machine shall stop with alarm
5. Vibrator overload, the sealing machine shall stop with alarm

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

- 4.1.11, 4.1.13, 4.1.17
- FDA Guidance for industry- Documentation for sterilization Process Validation
- Current GMP regulation 21 CFR Part 11, ANSI/NSF 49-2008
- 5.6
-

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 HLL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.

XI.	Refer Installation Requirement Specification and Specific Instruction with URS NPI_110831_IRS_PII_05
XII.	Refer Tender document with URS NPI/110831/EQP/TD/05

Specifications	Remarks
3.0 Process Description	
3.1 Input & Charging method	
3.1.1 Vial Sealing Machine	
• **Fully Stoppered Vials:** The fully stoppered vials will be transferred to the vial sealing machine from the transferred conveyor/ turret from vial filling and stoppering machine under LAF.	
• **Sterilized Aluminium Seals (according DIN ISO 8362-6):** External tyvek bag of seals shall be removed and transferred using Flap type transfer port where second tyvek bag will be removed and charged within chute manually. ***Format : 20mm Nominal Size***	
3.2 Brief Process Steps	
The vial sealing machine shall follow the process as below a) Transportation of stoppered vials from stoppering machine from the transferred conveyor/ turret from vial filling and stoppering machine under LAF. b) Charging of the sterile aluminum seals to the chute of the vibrating hopper. c) Transportation of the seals from the hopper to the vials. d) Sealing of the vials by the sealing unit with the help of sealing rollers	
3.3 Output & Discharging method	
a) Transportation of the sealed vials by the conveyor through mouse hole and collection in the vial collection area	
b) Independent conveyor belt to be considered across the two hygiene zones with the dead plate in between to ensure smooth movement	
4.0 Productivity Requirement	
4.1 Desired/ suggested capacity	
The filling line should be suitable to produce filled and stoppered vials at the rate of: 6R — 200 vials/ min ***Vendor shall consider ISO 6R vial..*** ***Efficiency: Overall line efficiency of the Vial sealing machine is 98%***	
4.2 Standard batch size	
A)Product 1,Product 2,Product 3 – 13 Million vials per annum	

Specifications	Remarks
• Vial size – 6R • Vial filled volume –5.8 ml • Vial filling time – 9 hrs • Standard batch size should be 90,000 vials/ batch (6R).	
4.3 Change Over Time	
Not applicable	
4.4 Other Productivity Requirement	
a) The vial sealing machine shall have one working hours counter, object counter and reject counter at the vial sealing machine.	
b) Any single change part should be not more than 5 kg.	
5.0 Containment	
Not applicable	
6.0 GMP requirements	
6.1 Process control	
6.1.1 **Sealing Machine**	
a) The equipment control system shall be suitable to adjust and maintain the rate of sealing (number of vials/ minute).	
6.2 Failure mode detection	
6.2.1 **Sealing Machine**	
A. **Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:**	
a) Emergency stop activated	
b) Alarm notification and process trip in case of infeed is empty	
c) Maximum infeed condition in turn table should notify the operator with alarm and stops the infeed .	
d) Maximum out feed condition reached	
e) Any toppled vial on transport conveyor	
f) The vibrating bowl runs only on machine request. Hopper stops when machine is not working.	
g) Continuous detection of missing aluminium seals on sealing station	
h) Alarm notification and process trips in case of reaching very low level of seals in hopper	
i) Cycle finish	

Specifications	Remarks
B. **Following condition (not limited to the mentioned below) need only notification to operator for procedural control**	
a) Toppled vial in conveyor system	
C. **Following Interlocks with alarm for procedural control**	
a) No Vial no seal	
b) No bung no seal	

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:

Parameter	Purpose	Type of control and Instrumentation
Speed	To monitor and control the sealing speed with recording	Variable speed drive
Quantity of vials	To count and indicate the number of vials	Digital counter
Hopper Vibration	To monitor, indicate and control the vibration speed.	Vibration indicator with controller.
Infeed/ outfeed sensor	To monitor the jamming or accumulation of the vials.	Optical sensor
Sensors	No vial no sealing	Optical sensor

6.5 Batch record display

Basic / standard data acquisition system to be provided. This shall be mainly to collect and store the data in industrial PC. Data output should be in non-editable format with print out option .PC and printer in vendors scope.

6.6 GMP requirements (Others)

6.6.1 **General**

a) Vials with failures have to be rejected at the machine in a reject magazine.	
b) The internal vibration of the equipment should be considered in installation of the equipment.	

Specifications		Remarks
c)	All process relevant wiring has to be executed in fail safe manner.	
d)	Manual operation for idling with tip switch must be possible for all applicable machines of the sealing line.	
e)	All parts of the machine exposed in A/B area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.	
f)	All sensoric, controls, PLC, LAF,HMI should have provision for UPS connection.	
g)	Two power supply entry shall be provided, the wiring of all mentioned above components shall separate than the other components wiring i.e. one for UPS and one for main power supply.	
h)	Required support services, like cable tray /SS conduits /pendants outside the complete machine will be in client's scope.	
6.7	**Specific requirements**	
6.7.1	The Vial Sealing Machine shall have open RABS and shall have provision for installation of LAF.	
6.7.2	The complete cabling from the electrical cabinets to the single machines and to the further equipment is in the scope of delivery. Ladder rack cable supports will be provided within the building.	
6.7.3	Operating height: must be 900mm ± 30 mm (to be finally decided during mock-up of Sealing machine). The height of the machine has to be adjustable by means of adjustable legs and clearance from the bottom shall be 200mm.	
6.7.4	In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points e. g. pumps, motors, filters, etc.	
6.7.5	As a special requirement the machine must allow set up by tip switches with cable	
6.7.6	The conveyor shall be designed with minimum friction and have a possibility of height and width adjustment.	
6.7.7	Vendor has to consider the monitoring of particles and microbiological sampling ports, monitoring system and necessary connection as per ISO 14644	
6.7.8	The equipment control system shall be suitable to adjust and maintain the rate of sealing (number of vials/ minute).	
6.7.9	The design should ensure exchange of bulbs without cladding removal.	
6.7.10	CE certification for the Vial sealing machine is mandatory and would be part of User requirements.	
6.7.11	**Turntable**	
a)	Vendor to specify the diameter of the turntable.	
b)	Turntable should have own frame, isolated installation and integration with tunnel and filling machine	
c)	The dead plate with side guides between tunnel and turn table shall be provide to create buffer	

Specifications	Remarks
d) Stability of vials to be considered as vials size is 6R.	
e) Integration of star-wheel to be considered.	
f) Turntable shall be integrated with egronomic glove port.	
6.7.12 **Sealing Machine**	
• Vendor to specify the mechanism of loading of the sealing into the machine.	
• The equipment control system shall be suitable to adjust and maintain the rate of sealing (number of vials/ minute).	
• Sealing head pressure has to be adjustable and to be controlled.	
• Specification of the sorting hopper for stoppers shall be provided.	
• Vibrating hopper shall be provided.	
• Hopper guiding rail shall be provided.	
• Vendor to provide the diameter or the size of the chute to load the seals and number of seals which can be loaded in one go.	
• Vendor to provide the diameter of the vibrating hopper and the finish of the bowl so that seals movement shall be smooth.	
• Pick and place system shall be provided or vendor shall provide better option.	
• The conveyor shall be designed with minimum friction and have a possibility of height and width adjustment.	
• Inspection sensor shall be provided at the sealing station to check for the no stoppered vials, not fully stoppered vials and the faulty vial will be rejected.	
6.7.13 **Reject Station**	
• Rejection station shall be provided to collect faulty vials. (unsealed vials).	
• Vendor to specify proper rejection system shall be provided to reject the rejected vials.	
• Rejection station shall have tray to collect the vials in front of the machine 90 degree to good vials collection.	
• Optical sensor shall be provided at the rejection tray to notify the operator if the tray is filled.	
7.0 Constraints	
7.1 Equipment location and available space	
This equipment will be installed in the Formulation block of **Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor.** **Equipment Location: F1G055** Floor: Ground floor-Formulation Room no: **F1G055**	

Specifications	Remarks
Room Area : 44 m²	
False ceiling height: 3000 mm	
The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1.**	
Physical condition of the rooms Vial Filling, Stoppering & Sealing Room (F1G055):	
1. Room will be non-hazardous	
2. Class: EU Class "B"	
3. Differential Pressure: 55 Pa	
4. Temperature maintained: 22°C ±2°C	
5. Relative Humidity:< 55 % RH	
7.2 Utility	
a) Electricity: Single (220 V) & 3 phase (420 - 440 V) (Report Requirement)	
b) Compressed air 6-8 bar (Report Requirement)	

8.0 Abbreviation

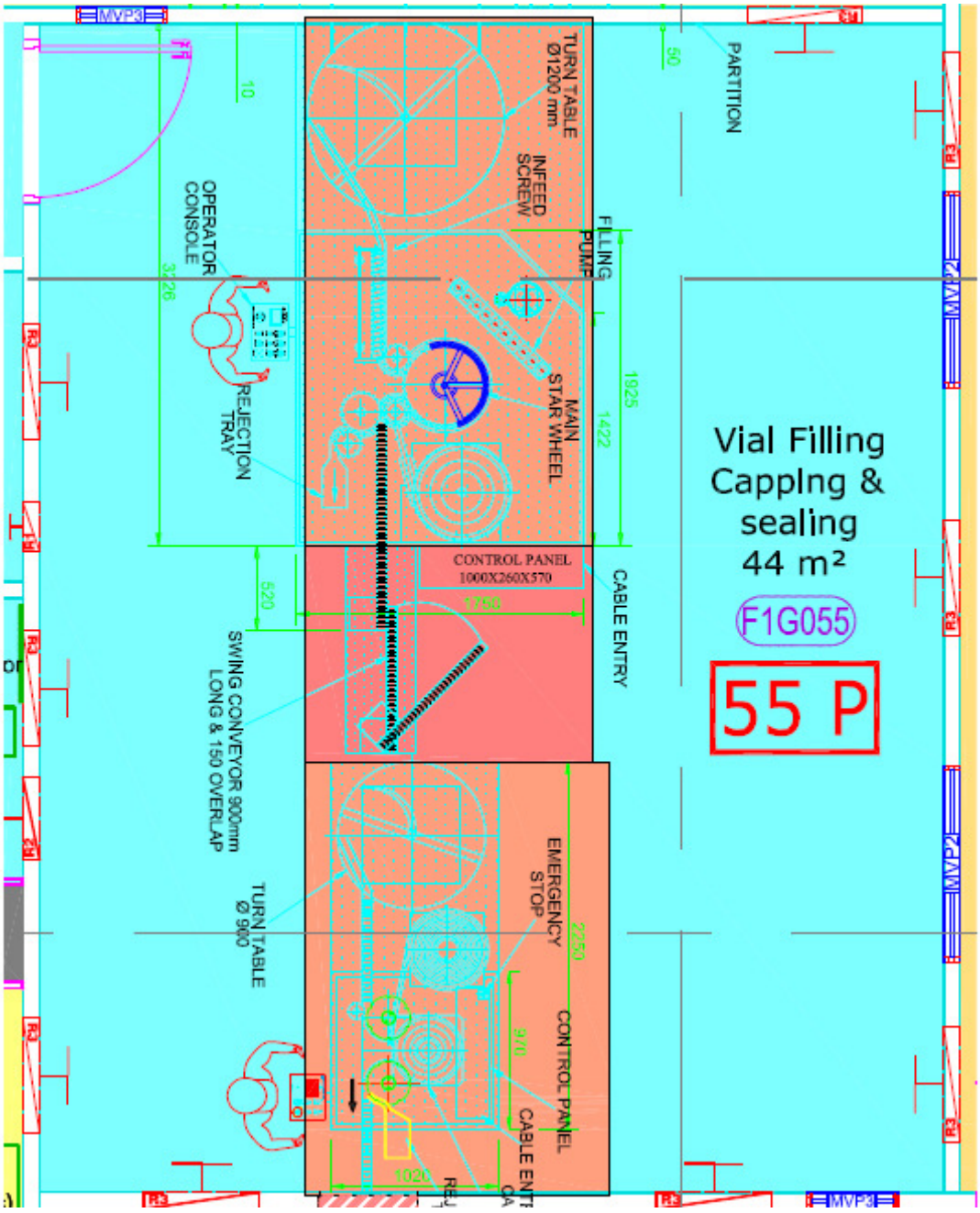
Abbreviation	Definition
FAT	Factory Acceptance Test
GA	General Arrangement
GMP	Good Manufacturing Practice
HMI	Human Machine Interface
ISO	International Standards Organization
LAF	Laminar Air Flow
MOC	Material Of Construction
NPI	NNE PHARMAPLAN INDIA LTD
O-RABS	Open- Restricted Access Barrier System
PID	Proportional Integral Derivative
PLC	Programmable Logic Controller
QA	Quality Assurance
Ra	Roughness Average
SAT	Site Acceptance Test
SOP	Standard Operating Procedure
SS	Stainless steel
VSM	Vial Sealing Machine

Revision index

Revision	Date	Reason for revision
00	18.05.2012	First Draft for Client's Review
01	2012-12-20	Format changed as per HLL requirement
02	2013-04-15	As per technical discussions had with HLL during BCGVL URS preparation
03	2013-04-25	As per BCGVL pre-bid meeting MOM dated on 12.04.2013
04	2013-06-06	As per discussion had with PIIC team on 2013-05-28

URS Annexure 1: LAYOUT POSITION

Room No: F1G055, Room Area: 44 m²



URS Annexure 2

List of components and make for Vial Sealing Machine

S.No	Description	Preferred List
1.	Pressure Switch	Contrinex / Rockwell / Omron
2.	Electro pneumatic Regulator	Festo / Wika / Siemens
3.	Main Drive Gear Motor	Bonfiglioli / Seimens
4.	Conveyor Gear Motor	Bonfiglioli / Seimens
5.	Optical Sensor	Contrinex / Pepperl Fuchs
6.	PLC	Allen-Bradley / Honeywell/ Siemens
7.	HMI	Allen-Bradley / Siemens
8.	Frequency Inverter	Allen-Bradley / Siemens