User Requirement Specifications
Vial Sealing Machine

Process Code	Area	Equipment ID	Quantity	Capacity
F1	Viral vaccine formulation area (Measles)	F1-VSM 02	1	200 Vials/Minute

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 "Integrated Vaccine Complex, Chengalpattu, Chennai" (**project number:** 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective shall be reviewed by the QA team of HBL, approved by Team lead and authorized by the appropriate Project authority.

NNE Pharmaplan		
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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 are received from Lyophiliser and transferred through mobile LAF cart and fed onto the turn table of sealing machine.
2.	In feed starwheel, turret/screw	For uniform spacing
3.	Seal Hopper	Pre-sterilized seals shall be loaded through O-RABS
4.	Chute	Used for feeding the flip-off seals to the sealing unit
5.	Multi head Sealing Unit	For sealing the vials
6.	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.

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 conveyor belt. The Vials shall be unloaded from the Lyophiliser in Frames and shall be transferred onto the Mobile LAF Transfer Trolley. The same trolley shall then be manually brought and docked to the feed turntable of the Vial Sealing Machine. The transfer of Vials shall be mechanized by means of pushing the Frames transfer trolley onto the in-feed transfer table and lifting the frames manually.

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 flip-off seal in chute, machine will stop with alarm.
4. If doors are open, the sealing machine shall stop with alarm and recording
5. Vibrator overload, the sealing machine shall stop with alarm

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
- ANSI/NSF 49-2008

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 become necessary the item must be clearly stated.
IV.	In case that the requirement includes a question or request or an 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-120310-IRS-S1-02
XII.	Refer Tender document with URS; NPI-120310-EQP-S1-TD-02

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 **Vial Sealing Machine**	
a) Fully Stoppered Vials: The fully stoppered vials in frames from the lyophiliser will be loaded on the trolley which will be transferred to the cassetting station of the vial sealing machine using mechanized transfer system and from cassetting station frames will be removed and transferred to the infeed turn table.	
b) Sterilized flip-off 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 : 13mm Nominal Size***	
3.2 Brief Process Steps	
The vial sealing machine shall follow the process as below a) Transportation of stoppered vials from Lyophilizer using Lyophilizer loading and unloading cart. b) Charging of the sterile flips off 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 between vial sealing to vial collection station.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
The sealing line should have the line output of 200 vials/min for standard ISO 4R vials ***Efficiency: Overall line efficiency of the Vial sealing machine is 100%***	
4.2 Standard batch size	
Standard batch size shall vary ranging from 40,000 to 80,000 vials / shift of 8hrs based on the given vials size. Equipment shall be able to run for 24 hours.	
4.3 Change Over Time	
Not applicable	
4.4 Other Productivity Requirement	
a) The vial sealing machine should have vial counter and reject vial counter.	
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 manually 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 from the cassetting station.

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 flip-off seals on sealing station

h) Alarm notification and process trips in case of reaching very low level of seals in hopper

i) Rejection of vial, notify the operator with alarm.

j) Cycle finish

B. **Following condition (not limited to the mentioned below) need only notification to operator for procedural control**

a) Toppled vial in turn table.

C. **Following Interlocks with alarm for procedural control**

a) No Vial no seal

b) No stopper 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 frequency drive	
Quantity of vials	To count and indicate the number of vials at the in-feed	Digital counter	
Quantity of vials	To count and indicate the number of reject 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 bung no sealing	Optical sensor	

6.5 Batch data display and record printing

Basic / standard data acquisition to be done in HMI. This shall be mainly to collect and store the data by using external device.

Online printing using dot matrix printer along with strip chart recorder to be provided

6.6 GMP requirements (Others)

6.6.1 General

a)	All 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.	
c)	All process relevant wiring has to be executed in fail safe manner.	
d)	Manual operation idling with tip switch must be possible for all applicable machines of the sealing line to be used during setup.	
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, HMI and LAF 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	Equipment shall be able to run for 24 hours.	
6.7.11	Appropriate loading and transport mechanism to be given for seals vibrating hopper in sealing machine.	
6.7.12	Tool box shall be provided for general maintenance, which should include all the tools for the said machine maintenance.	
6.7.13	**Turntable**	
a)	Vendor to specify the diameter of the turntable.	
b)	Turntable should have own frame, isolated installation and integration with tunnel and sealing machine	
c)	The dead plate with side guides between tunnel and turn table shall be provide to create buffer.	
d)	Stability of vials to be considered for given vials size.	
e)	Integration of star-wheel to be considered.	
f)	Turntable shall be integrated with ergonomic glove port.	
6.7.14	**Sealing Machine**	
a)	The equipment control system shall be suitable to adjust and maintain the rate of sealing (number of vials/ minute).	
b)	Vendor to specify the mechanism of loading of the sealing into the machine.	
c)	Sealing pressure has to be adjustable and to be controlled.	
d)	Specification of the sorting bowel/ hopper for stoppers shall be provided.	
e)	Vibrating hopper shall be provided.	
f)	Hopper guiding rail shall be provided.	
g)	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.	
h)	Vendor to provide the diameter of the vibrating hopper and the finish of the bowl so that seals movement shall be smooth.	
i)	Pick and place system shall be provided or vendor shall provide better option.	
j)	The conveyor belt shall be designed with minimum friction and have a possibility of height and width adjustment.	

k)	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.	
6.7.15	**Reject Station**	
a)	Rejection station shall be provided to collect faulty vials. (Unsealed vials).	
b)	Vendor to specify proper rejection system shall be provided to reject the rejected vials.	
c)	Rejection station shall have tray to collect the vials in front of the machine 90 degree to good vials collection.	
d)	Optical sensor shall be provided at the rejection tray to notify the operator if the tray is filled.	
e)	Total count of the vial should be displayed and recorded	
f)	Total no of reject vials should be displayed and recorded	
6.7.16	Comprehensive warranty will commence after completion certificate and shall be valid for 1 year	

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipments will be installed in the **Viral Vaccine Formulation Block (Measles section)** of **Integrated Vaccines Complex**, Chengalpattu.

Room No.: **F1G086**

Floor: **Ground floor**

Room Dimensions (L x W) : **10900mm x 6200mm, 4900mm x 4353mm**

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:

Liquid Filling:

1. Room will be non-hazardous
2. Class: EU Class “B”
3. Differential Pressure: 65 Pa Absolute
4. Temperature maintained: 22^{o}C ±2^{o}C
5. Relative Humidity: Not more than 55%

7.2 Available Utility

a) Electricity: Single (220 V) & 3 phase (420 - 440 V) (Report Requirement)

b) Compressed air 6-8 bar (Report Requirement)

Note: Vendor to provide Pressure reducing valves and Pressure gauges along with the equipment as per equipment utility requirements.

Vendor to provide the all utility consumptions in details for the equipment during pre-bid.

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
RTP	Rapid Transfer Port
SAT	Site Acceptance Test
SOP	Standard Operating Procedure
SS	Stainless steel
VSM	Vial Sealing Machine

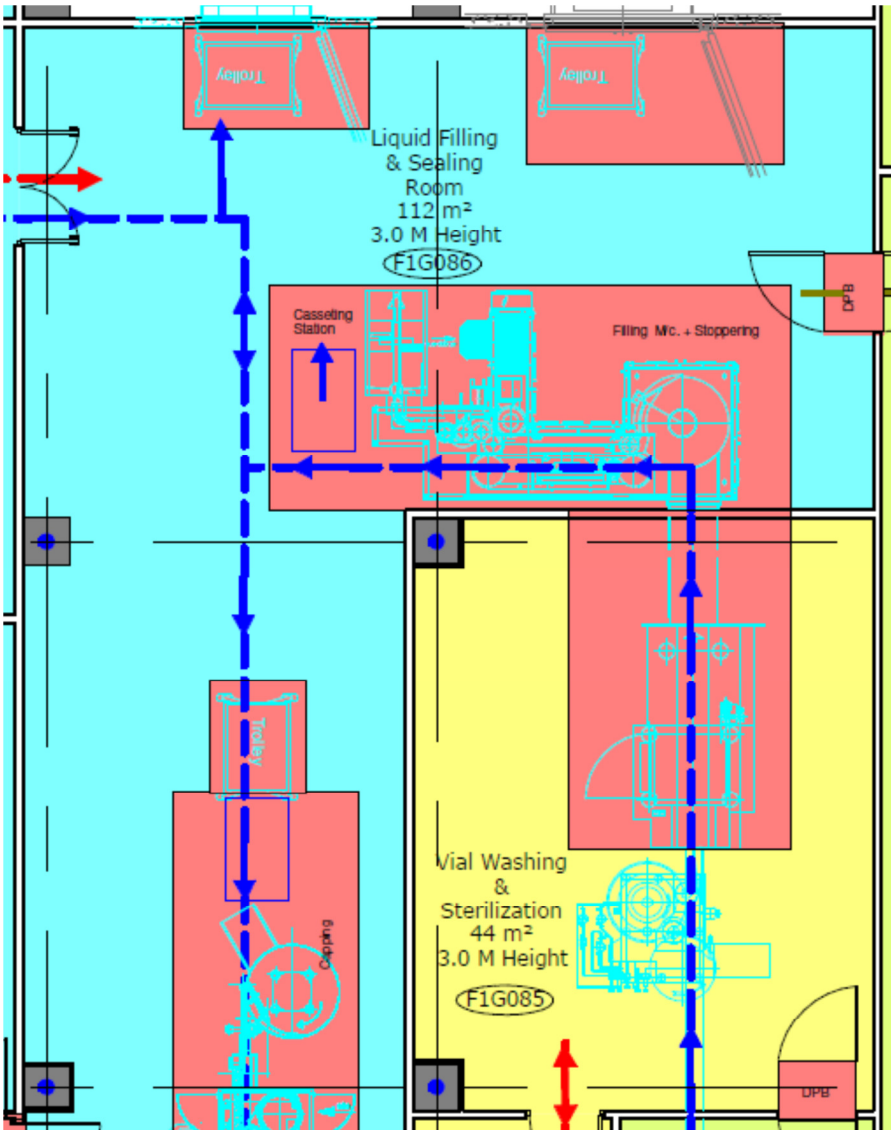
REVISION INDEX

Revision	Date	Reason for revision	
00	19-07-2013	First Draft for Client's Review	
01	27-05-2013	As per comments sent by HBL on 27-05-2013 by email	
02	03-02-2014	Updated as per change in vial size	
03	13-02-2014	Updated as per comments given by HBL on 13-02-2014 by email	
04	28-02-2014	Updated as per comments given by HBL on 18.02.2014 and 27.02.2014 by email	
		Section	Revision
		1.0	Approval Signature Sheet updated
		4.1	Overall line efficiency of the Vial sealing machine is 100%
		6.5	Basic / standard data acquisition to be done in HMI. This shall be mainly to collect and store the data by using external device. Online printing using dot matrix printer along with strip chart recorder to be provided
		6.7.10	Equipment shall be able to run for 24 hours.
		6.7.15 (e)	Total count of the vial should be displayed and recorded
		6.7.15 (f)	Total no of reject vials should be displayed and recorded
		6.7.16	Comprehensive warrantee will commence after completion certificate and shall be valid for 1 year

URS Annexure 1: LAYOUT POSITION

Room No. : F1G086

Room Name: Liquid filling



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