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

Revision index

Revision	Date	Reason for revision
00	09.12.2011	First Draft for Client's Review
01	05.04.2012	NP expert and Client's inputs incorporated.
02	13.07.2012	Comments from BCGVL and HLL
03	2012-10-16	Format changed as per HLL requirement
04	2013.03.25 & 2013.03.28	As per technical discussion with HLL/BCGVL
05	2013.04.03	As per the client's inputs in the MOM dated 2013.03.28
06	2013.04.04	As per HLL's inputs dated 2013.04.04 by email
07	2013.04.08	As per HLL's inputs dated 2013.04.05 by email

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 Validation and GMP compliance team of "NNE Pharmaplan India for the project "Revival of BCG Vaccine Laboratory" (**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.

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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.	Multi head Sealing Unit	Sealing the vials
3.	In feed starwheel, turret/screw	For uniform spacing
4.	Vibrating Hopper	Used for feeding the ALU 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 Vials shall be unloaded from the Lyophilizer 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 aluminum 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

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User Requirement Specifications			
Equipment/System	Vial Sealing Machine		
Identification #	FG-VSM 01	**Document#**	URS/FG-VSM 01
Effective Date	2013-04-08	**Revision#**	07

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 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 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 document Installation Requirement Specification and Specific Instructions with URS; NPI_110729_IRS_BCG_01
XII.	Refer Tender document with URS; NPI/110729/EQP/TD/08.

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) Steam 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 : 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 aluminum seals to the chute of the vibrating hopper. c) Transportation of the seals from the hopper to the vials. ***Transportation of the sealed vials to the turntable via mouse hole.***	
Note: for detailed technical requirement refer section 7.0	
3.3 Output & Discharging method	
3.3.1 Transportation of the sealed vials by the conveyor to the turntable via mouse hole with a dead plate.	
3.3.2 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 be suitable to produce sealed vials at the rate of: 2R | 200 vials/ min ***Vendor shall consider ISO 2R vial.***	

Efficiency: ***Overall line efficiency of the Vial sealing machine is 98%***

4.2 Standard batch size

A) Product 1 –

- Vial size – 2R
- Vial filled volume – 0.2 ml (before freeze drying)
- Vial filling time – 4 hrs
- Standard batch size should be 40,000 vials/ batch (2R).

B) Product 2 –

- Vial size – 2R
- Vial filled volume – 1.0 ml (before freeze drying)

4.3 Change Over Time

4.3.1 Operation without machine change over 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 vial sealing machine shall have object counter and reject counter at the vial sealing machine.

4.4.2 All change parts shall be less than 5 kg.

4.4.3 The equipment shall be able to run for 24 hours.

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 aluminium seals on sealing station	
h) Alarm notification and process trips in case of reaching very low level of stoppers 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 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
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 • No stopper no sealing	Optical sensor

Quantity of vials	To count and indicate the number of vials.	Digital counter	
Hopper Vibration	To monitor and control the vibration speed.	Vibration indicator with controller.	

6.5 Batch data display and record printing

Refer IRS

6.6 GMP requirements (Others)

6.6.1 **Generals**

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 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, 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) The complete cabling from the electrical cabinets to the single machines and to the further equipment is in the scope of delivery including cable supports and trays.

i) The complete cabling from the electrical cabinets to the single machines and to the further equipment is in the scope of delivery including cable supports and trays.

6.7 Specific requirements

6.7.1 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.

6.7.2 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.

6.7.3 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.

6.7.4 As a special requirement the machine must allow set up by tip switches with cable

6.7.5 The conveyor shall be designed with minimum friction and have a possibility of height and width adjustment.

6.7.6 Vendor has to consider the monitoring of particles and microbiological sampling ports, monitoring system and necessary connection as per ISO 14644	
6.7.7 **Turntable**	
• Vendor to specify the diameter of the turntable.	
• Turntable should have own frame, isolated installation and integration with tunnel and sealing machine	
• The dead plate with side guides between tunnel and turn table shall be provide to create buffer	
• Stability of vials to be considered as vials size is 2R.	
• Integration of star-wheel to be considered.	
• Turntable shall be integrated with egronomic glove port.	
6.7.8 **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.	
6.7.9 **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.

6.7.10 The equipment control system shall be suitable to adjust and maintain the rate of sealing (number of vials/ minute).

6.7.11 The design should ensure exchange of bulbs without cladding removal.

6.7.12 Complete sealing line to be CE certified.

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 at BCGVL, Guindy, Chennai.

Equipment Location:

Floor: Ground floor-Formulation

Plant: Revival of BCG Vaccine Laboratory

Room no: FG034

Room dimension : 3912 mm x 4415 mm

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:

Filling and stoppering + lyo loading + capping**:**

1. Room will be non-hazardous
2. Class: EU Class “B”
3. Differential Pressure: 55Pa Absolute
4. Temperature maintained: 22^{o}C ±2^{o}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)

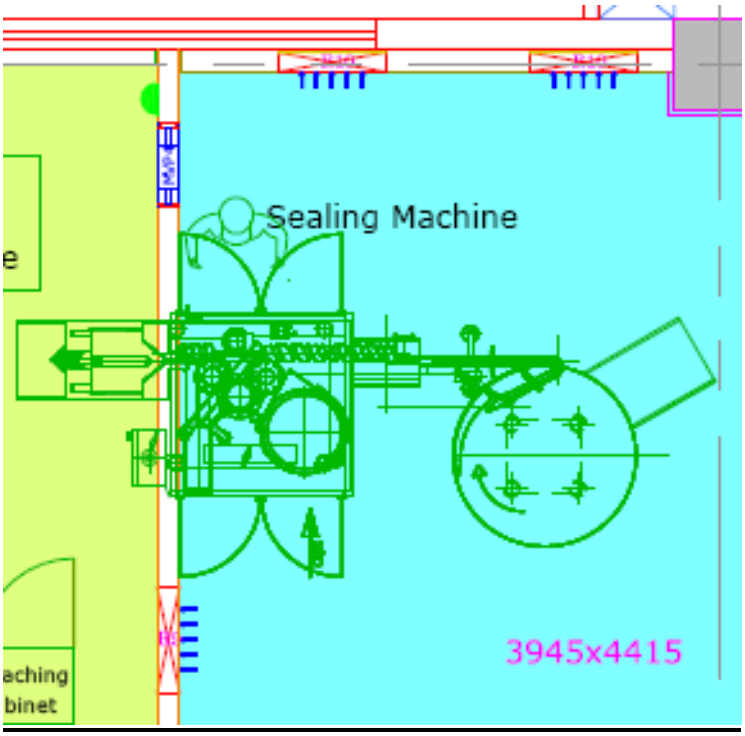
8.0 Abbreviation

Abbreviation	Definition
DQ	Design Qualification
DEHS	Di-Ethyl-Hexyl-Sebacat
GA	General Arrangement
HEPA	High Efficiency Particulate Air
HMI	Human Machine Interphase
MOC	Material Of Construction
NA	Not applicable
PLC	Programmable Logic Controller
PW	Purified Water
QA	Quality Assurance
Ra	Roughness average
RPM	Revolutions Per Minute
SS	Stainless steel
UPS	Uninterrupted Power Supply
VFD	Variable Frequncy Drive
VSM	Vial Sealing Machine
WFI	Water For Injection

URS Annexure 1: LAYOUT POSITION

Room No: FG034:

Room Name: Sealing Machine



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 / Mitsubishi / Siemens
7.	HMI	Allen-Bradley / Mitsubishi / Siemens
8.	Frequency Inverter	Allen-Bradley / Mitsubishi / Siemens