

HLL LIFECARE LIMITED, CHENNAI

Revival of BCG Vaccine Laboratory, BCGVL, Guindy, Chennai

nne pharmaplan®	User Requirement Specifications				
	Equipment/System	Vial Filling and Stoppering Machine			
	Identification	FG-VFS 01	Document		URS/FG-VFS 01
	Effective Date	2013-04-08	Revision		07

User Requirement Specifications Vial Filling and Stoppering Machine Equipment ID: FG-VFS 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

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URS Annexure List

URS Annex No.	Detail
1.	Layout showing location of the installation of Vial filling and Stoppering Machine
2.	List of components and make
3.	Process Flow Diagram (To understand transfer philosophy of the Bulk bottle and recirculation of the product)
4.	Typical PFD for the arrangement of box+ cassetting station + mobile trolley

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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 machine should consist of following parts in order to run operation smoothly.

S. No.	Description	Purpose
1.	In feed Turn Table	To feed vials for filling machine integrated /synchronised with depyrogenation tunnel
2.	In feed starwheel, turret/screw	For uniform spacing
3.	Filling Machine	Filling of product in vials
4.	Rubber Stoppering Machine	Rubber stopper placement
5.	Hopper with vibration unit	Used for feeding the rubber stoppers to the stoppering unit.
6.	Star wheel	This indexes the vial into and out of the pocket on the conveyor belt
7.	Collection of vials	product filled half stoppered vials should be collected for cassetting station

Machine should have all operation automatic with minimum manual intervention with specified accuracy of $\pm 1\%$ of fill volume. The turn-table should have provision for attachment with out-feed system of tunnel so that smooth transfer of vials takes place from tunnel to turn table with interlocking.

Stoppering should takes place automatically with the help of vacuum release system. All operation should take place in aseptic condition under laminar air-flow (class A zone) i.e **Open RABS (active)** with background of class B.

This equipment is a part of an integrated line.

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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 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.	<p>Special Instruction</p> <p>a. If no comments against any specification shall be considered as "NO" and</p> <p>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.</p>
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

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3.0 Process Description

3.1 Input & Charging method

a) **Sterilized and Depyrogenated vials from depyrogenating tunnel:** The depyrogenated vials (**2R size according DIN ISO standard 8362-1**) after cooling cycle in the tunnel shall enter into filling room. The vial shall be collected in a turntable. From the turn table vials should be singled on to a positive transport to-reach filling station and this operation should conform to GMP guidelines.

Format: Ø16mm, Height: 35mm

b) **Steam sterilized rubber stoppers (siliconized / non-siliconized) (according DIN ISO 8362-5 for freeze dried vials)** The rubber stopper will be sterilized in Tyvek bag. From Tyvek bag stoppers will be charged within hopper manually under RABS with the help of glove arrangement. The machine shall be have the capability to operate with siliconized / non siliconized

Format : 13mm Nominal Size

c) **Bulk SS Vessel (WV 10L) with flat bottom:** The product (BCG vaccine) shall be filled in sealed vessel, having sterile filter (0.22µm), flexible hose, one spare port. The product is transported from the bulk area under mobile LAF with provision with S2S connection. The bulk vessel has provision for magnetic stirring during transfer of bulk to transfer vessel to prevent the product sedimentation.

Preferable transfer from bulk vessel to buffer vessel shall be by gravity.

Vendor should include the space for the Bulk SS Vessel within the RABS system and aseptic connection (S2S connection) to be made under LAF with Buffer Vessel (1.5 L volume). Additionally electrical socket needs to be provided to connect magnetic agitator. Also, vendor to provide detailed GA drawing along with bulk vessel design as per Annexure 3 during DQ stage.

d) **Buffer Vessel:** The capacity of the buffer vessel to be 1.5L (WV) which will be placed on the manifold. This will be connected to the bulk vessel aseptically (S2S connection). The product will be re-circulated between manifold and buffer vessel as the product has the tendency of sedimentation.

e) **Outfeed System:** Turntable shall be provided to singularise the vials before the starwheel. The filled and half stoppered vials from the collection table / conveyor shall be collected in frames (Cassetting operation) for transfer to Lyophilizer. The transfer of frames shall be facilitated by means of closed LAF Trolley system (Class Ä).

Note: for detailed technical requirement refer section 7.0

3.2 Brief Process Steps

Filling and stoppering machine is to perform following process steps:

- Transportation of depyrogenated vials synchronized with turntable with dead plate in between to provide buffer time.
- Transportation of singularise vial from turntable to infeed starwheel.
- Transportation of vials from starwheel to infeed turret/ screw will transport the vial on

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<p>filling station.</p> <p>d) Dosing of product liquid within vial of 2R with the help of rotary piston pump with a filling of 0.2 ml with an minimum accuracy of $\pm 2\%$ within a 3 sigma range.</p> <p>e) There shall be provision of rejecting unstoppered vials.</p> <p>f) The outfeed of the vial is attached with cassetting station where arrangement of the vial will take place according to the frame size.</p> <p>g) Cassetting station will be docked with mobile trolley which will pull the frames on the platform and transport it to the lyophiliser.</p> <p>Note: No vial rejection (like breakage) shall occur during the process (maximum 0.5 %). No vials shall be scratched by the machine during processing</p>	
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3.3 Output & Discharging method

<p>a) The machine shall enable the collection of half stoppered vials at the cassetting station at predefined arrangements and then be transferred through conveyor to the lyophilizer via mobile cart/ trolley with semiautomatic loading-unloading arrangement for lyophilization process under LAF.</p>	
<p>b) Lyophiliser vendor will provide the frame size (atleast 330 vials per frame) and according to frame size cassetting station and vial arrangement to be designed by the filling line vendor. The filling line vendor has to describe in detail the process flow. The cassetting operation has to fulfill the following requirements:</p> <ul style="list-style-type: none"> Best row loading of the frames to achieve best utilization. Counting of the vials before frame loading to achieve a pre determined amount of vials per frame. 	

4.0 Productivity Requirement

4.1 Desired/ suggested capacity

<p>The filling line should be suitable to produce filled and stoppered or half stoppered vials at the rate of:</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">2R</td> <td style="padding: 5px;">200 vials/ min</td> </tr> </table> <p>Vendor shall consider ISO 2R vial.</p> <p>Efficiency: Overall line efficiency of the filling & stoppering machine shall be 99%.</p>	2R	200 vials/ min	
2R	200 vials/ min		

4.2 Standard batch size

<p>A) Product 1</p> <ul style="list-style-type: none"> 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). <p>B) Product 2</p> <ul style="list-style-type: none"> Vial size – 2R Vial filled volume – 1.0 ml (before freeze drying) 	
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4.3 Change Over Time	
Not applicable	
4.4 Other Productivity Requirement	
4.4.1 Hold-up volume should be less than the 1% of the bulk batch volume.	
4.4.2 All change parts shall be less than 5 kg.	
5.0 Containment	
Vial filling & stoppering machine to be executed with active O-RABS with a provision to accommodate LAF.	
6.0 GMP requirements	
6.1 Process control	
6.1.1 The equipment control system should be suitable to adjust and maintain the rate of filling (number of vials/ minute)	
6.1.2 Stoppering heights shall be adjustable and to be controlled.	
6.2 Failure mode detection	
A. Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
a) Emergency stop activated	
b) Opening of the RABS door of filling unit & stoppering unit, stop the machine.	
c) Alarm notification and process trip in case of infeed is empty	
d) Maximum infeed condition in turn table should notify the operator with alarm and stops the tunnel out feed. Note: integration between filling, depyrogenation tunnel and washing machine is required.	
e) Maximum out feed condition reached	
f) Any toppled vial on transport conveyor	
g) Very low level of product in buffer vessel	
h) Continuous detection of missing vial on filling station	
i) Rotary piston pump not working	
j) The vibrating bowl runs only on machine stopper request. Bowl stops when machine is not working.	
k) Continuous detection of missing stoppers on stoppering station	

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B. Following condition (not limited to the mentioned below) need only notification to operator for procedural control	
a) Compressed air pressure low	
b) Vacuum pressure low	
c) Toppled vial on transport conveyor	
d) Rejection of vial, notify the operator with alarm.	
C. Following interlocks with alarm for procedural control	
a) No Vial no fill	
b) No vials no stoppering	
c) Jamming of the stoppers in the transport chute	

6.3 In – Process control

6.3.1 Continuous monitoring of particulate is required in different locations over filling and stoppering machine and conveying system to demonstrate Class A condition. Therefore machine table should have proper sampling nozzle connection to connect the air sampling system for both viable and nonviable particulate. The exact position and number shall be decided on receipt of the GA drawing of the equipment and in a direct meeting with vendor.	
6.3.2 Isokinetic sampling system ports for plate exposure and for particle count of Class A condition. Ports for the following environmental monitoring system have to be supplied and integrated within the filling machine: - 3 x particle count isokinetic funnel - 3 x viable microbiological air sampling - 3 x holders for settle plates (surface germs)	

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
Filling machine		
Speed	To monitor and control filling speed with recording	Variable frequency drive
Quantity of vials	To count, indicate and record the number of vials (filled / rejected)	Digital counter

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Infeed/ outfeed sensor	To monitor the jamming or accumulation of the vials.	Optical sensor		
Pumps	To fill the product into the vials	Rotary Piston pump with PLC control		
Sensors	<ul style="list-style-type: none"> No vial no fill No vial no stoppering No stoppering reject Jamming of the stoppers in the transport chute 	Optical sensor		
Differential pressure	To monitor and indicate differential pressure across the HEPA filter	Magnehelic / Photohelic gauges		
Stoppering Machine				
Vacuum	To monitor the vacuum for stopper placement.	Vacuum indicator and controller		
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.		

6.5 Batch data display and record printing (Specific to filling and stoppering)

a) Sensoric details	
b) Level/weight of the product with in buffer vessel	
c) Number of vials filled.	

6.6 GMP requirements (Others)

6.6.1 All parts of the filling machine exposed in A/B area must be resistant to standard disinfectants or vendor should provide the name of specific disinfectants.	
6.6.2 The internal vibration of the equipment should be considered in installation of the equipment.	
6.6.3 After every stoppage of the filling machine "Home positioning" of the filling with the centering of the filling needle into the vials to be provided.	
6.6.4 The vial filling line has to be controlled via the PLC. Data collecting of critical parameters shall be done by the paperless recorder.	
6.6.5 All sensoric, controls, PLC, HMI, all LAF, RABS, Differential cascades, shall be have provision for UPS connection.	

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6.6.6 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 which will be backed by DG set.	
6.6.7 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.	
6.6.8 GMP Requirements for RABS	
a) Machine shall be equipped with RAB system and all the operation should be through glove ports. All doors made of security glass (toughened and shatter proof)	
b) RAB system shall have three sections for in feed table, filling station and capping station separated by partitions (security glass) with a mouse hole for movement of vials	
c) The Mock up test shall be done jointly by the vendor and client for the proper positioning of gloves.	
d) Pressure across the HEPA filters shall be recorded, Vendor to provide provision for the pressure measurement.	
e) Machine shall have provisions in RAB system for facilitating utilities and product connections	
f) Illumination within the RABS to be min 500 lux	
g) Suitable provisions for transfer chutes to be made to ensure the movement of material inside (example: bulk bottle, bags with sterilized filling arrangement, bags with sterilized stoppers) and outside the RABs.	
h) Equipment parts requiring aseptic cleaning shall be designed suitably for handling them inside the RAB system using glove port. Handles of appropriate size to be provided wherever necessary with door interlocking.	
6.7 Specific requirements	
6.7.1 In general the equipment has to be designed in a way to be maintenance friendly e. g. pumps, motors, filters, etc.	
6.7.2 All open doors should be under LAF, so vendor shall provide the provision for extended LAF till that point.	
6.7.3 Turntable	
a) Turntable should have a barrier plate between filling and tunnel to maintain positive pressure between filling and tunnel.	
b) The bio seal between the turn table and the tunnel should be designed suitably to transfer depyrogenated vials onto turn table of filling machine.	
c) Turntable shall be integrated within the RABS with ergonomic glove port.	
6.7.4 Transport Belt/ turret/ screw	
a) Frictionless, continuous motion shall be provided and driven by programmable servo motor drive.	
6.7.5 Filling Station	

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<p>a) Bulk Bottle (W.V 10L)</p> <ul style="list-style-type: none"> – Placement of the bulk bottle shall be considered within the RABS. – Placement of the bottle at the back side of filling machine should be considered. – Transfer of the bottle aseptically under RABS shall be provided with S2S connectors (sterile to sterile connections). – Slightly Inclined platform shall be provided to use the product completely. – Magnetic stirring arrangement shall be provided on the platform for continuous stirring. – Ergonomic glove port shall be provided to transport the bottle and make the connection to the buffer vessel. – The transfer of product from bulk vessel to buffer vessel would through gravity. In case of any other method considered, vendor to specify. 	
<p>b) Buffer Vessel, manifold</p> <ul style="list-style-type: none"> – Capacity of the vessel shall be 1.5 L. – Level control using Load cell (platform with Asymmetric positioning slot for buffer vessel) with high accuracy connected to PLC of the machine. – Buffer vessel to be placed on the top of the manifold. – Manifold should be slightly inclined at one end with recirculation provision in between buffer vessel and manifold. 	
<p>c) Dosing Nozzle</p> <ul style="list-style-type: none"> – Movement of nozzle shall be programmable. – Nozzle shall be dripping proof (suck back mechanism) to avoid wastage of the product and spilling of the product. – All parts and components shall be sterilizable by autoclaving at 121°C. – Proper transfer of buffer vessel, manifold, nozzles to be provided for cleaning and after sterilisation under LAF in to the filling machine. – 2 sets of nozzles shall be provided along with the filling machine. 	
<p>d) Rotary Piston Pump</p> <ul style="list-style-type: none"> – Individual rotary piston pump to every nozzle shall be provided – Servo driven rotary piston pump to be provided and controlled by PLC – Suck back function to be provided to avoid dripping of the nozzle. – Size of the rotary piston pump shall be small and easy installation of tubings from glove port shall be achievable 	

6.7.6 Stoppering Machine

a) Loading of stoppers area shall be provided under integrated extended LAF of the machine at the back side of the filling machine.	
b) Chute shall be provided under RABS to load the stoppers.	
c) Half stoppering of the vial shall take place.	
d) Vibrating hopper shall be provided.	

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e) Hopper guiding rail shall be provided.	
f) Vendor to provide the diameter or the size of the chute to load the stoppers and number of stoppers which can be loaded in one go. (minimum capacity should be 3000 bungs/load).	
g) Pick and place system shall be provided or vendor shall provide alternate option.	

6.7.7 Reject Station

a) Rejection station shall be provided to collect faulty vials. (i.e. empty vials, unstoppered vials).	
b) Vendor to provide proper rejection system.	
c) Rejection station shall have tray to collect the vials in front of the machine 90 degree to good vials collection .	

6.7.8 Cassetting Station (semi-automatic)

<p>a) Procedure:</p> <ul style="list-style-type: none"> - The singularize line output of the filling line is attached to the cassetting station. - Arrangement of vials on the cassetting station (predefined number of vials) according to the frame size should take place. - The arrangement of vials shall be row wise. - Predefined number of vials per frame according to frame size (provided by lyophiliser vendor). So vial counter is required at the infeed of the cassetting station to have same number of vials. Filling line vendor shall design cassetting station synchronizing with frame size. - The cassetting station will be docked with the container having sterilized frames placed in the shelf of the container - Manually frames will be picked with the help of glove port from the shelf of the container and place it around vial arrangement. - At the other end lyophiliser loading and unloading cart shall be docked. - After making the frame arrangement, frame shall be pulled onto the lyophiliser loading and unloading cart. - Lyophiliser cart shall be taken to lyophiliser loading area to load the frames into the lyophiliser chamber. - Relevant space to be provided in the cassetting station so as to accommodate 12 buffer frames (in addition to the standard). <p>Note: Refer URS Annex 3 (Typical PFD for the arrangement of box+ cassetting station + mobile LAF trolley)</p>	
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<p>b) Technical Specification</p> <ul style="list-style-type: none"> - Guided side arms are required to form the vial arrangement. - Optical sensor shall be provided. - Station shall be closed system along with interlock doors. - The provision to made to have independent LAF with HEPA filter to maintain the sterility . - Working Platform height shall be mentioned clearly within the quote so that it 	
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<p>can be synchronized with outfeed of the filling line, container of frames and lyophiliser cart.</p> <ul style="list-style-type: none"> The station shall be mobile provided with height adjustable castor wheels. 	
6.7.9 Operating height: must be 900± 30 mm (to be finally decided during mock-up of filling machine). The height of the machine has to be adjustable by means of adjustable legs and clearance from the bottom shall be 200mm.	
6.7.10 Mock up test shall be conducted for the filling accuracy during FAT.	
6.7.11 All RAB doors have to be supervised by security switches. In case of opening the machine must stop immediately	
6.7.12 Complete filling line to be CE certified.	
6.7.13 Product contact parts shall be easily dismantle-able and cleanable e.g. buffer vessel, manifold, nozzle heads.	
6.7.14 The dosing nozzles should be constructed of SS 316L with Ra = 0.38	
6.7.15 The conveyor should be constructed with material which will be easy to clean, resistant to disinfectants and low particle emitting comply to class A and shall be designed for minimum friction	
6.7.16 The MOC of safety cabinet and safety glass shall be compatible with the different disinfectants used.	
6.7.17 The RAB should be constructed of SS 304 frame with transparent safety glass (antistatic type)	

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:FG034

Floor: Ground floor-Formulation

Plant: Revival of BCG Vaccine Laboratory

Room dimension : 7895 mm x 7695 mm (The equipment to be positioned as per the layout provided below).

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:

1. Room will be non-hazardous
2. Class: EU Class "B"
3. Differential Pressure: 55Pa Absolute
4. Temperature maintained: 22°C ±2°C
5. Relative Humidity: <55% RH

HLL LIFECARE LIMITED, CHENNAI

Revival of BCG Vaccine Laboratory, BCGVL, Guindy, Chennai

nne pharmaplan®	User Requirement Specifications				
	Equipment/System	Vial Filling and Stoppering Machine			
	Identification	FG-VFS 01	Document		URS/FG-VFS 01
	Effective Date	2013-04-08	Revision		07

Specifications	Remarks
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7.2 Utility

a) Electricity: Single (220 V) & 3 phase (420 - 440 V) (Report Requirement) b) Compressed air 6-8 bar (Report Requirement)	
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	Effective Date	2013-04-08	Revision		07

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 Frequency Drive
VFS	Vial Filling Stoppering Machine
WFI	Water For Injection

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User Requirement Specifications

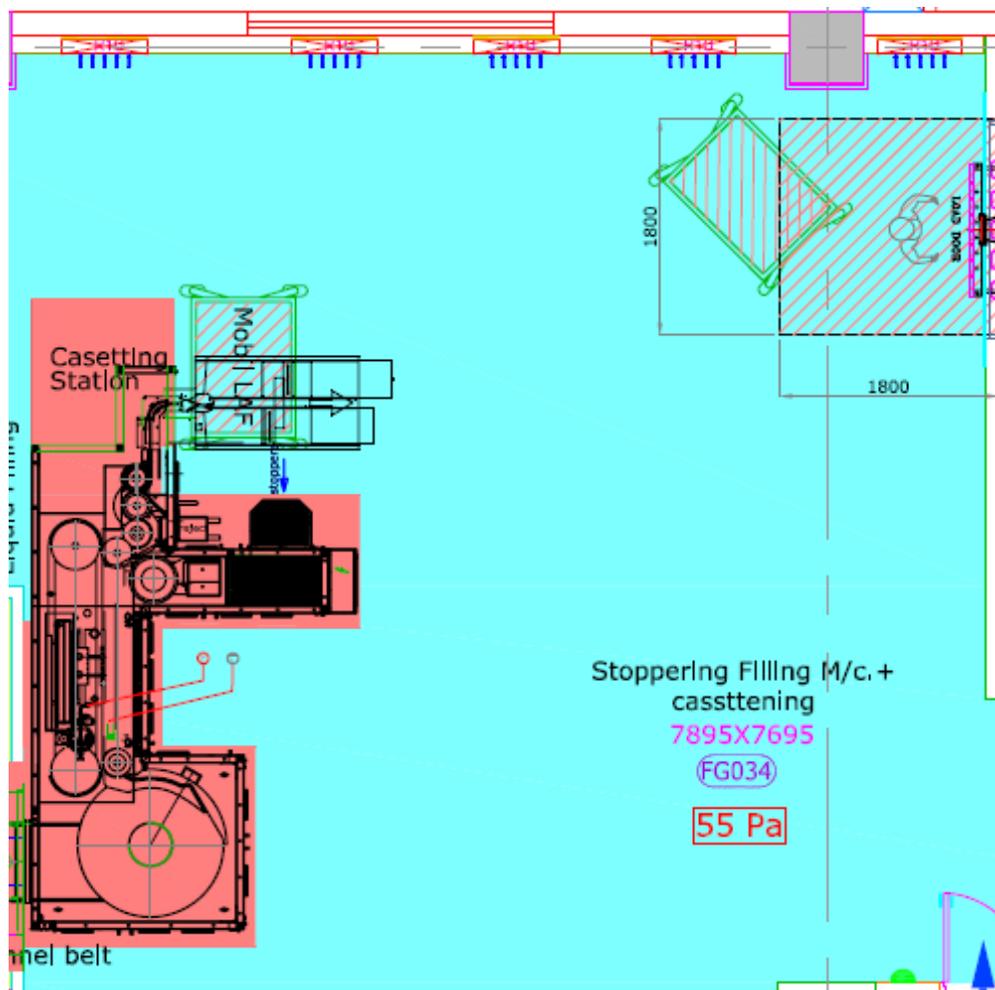
Equipment/System	Vial Filling and Stoppering Machine		
Identification	FG-VFS 01	Document	URS/FG-VFS 01
Effective Date	2013-04-08	Revision	07



URS Annexure 1: LAYOUT POSITION

Room No: FG034:

Room Name: Filling Machine



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User Requirement Specifications

Equipment/System	Vial Filling and Stoppering Machine		
Identification	FG-VFS 01	Document	URS/FG-VFS 01
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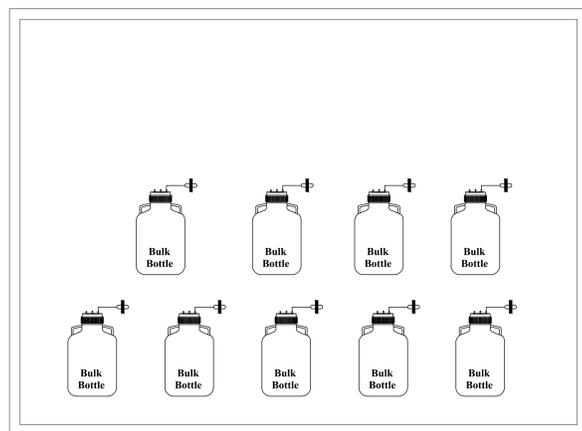


URS Annexure - 2

List of components and make for Vial Filling & Stoppering Machine

S.No	Description	Preferred List
1.	Load Cell	SARTORIUS / E&H / Mettler
2.	Vacuum Pump	Becker/Bosch
3.	Vacuum Gauge	Wika/E&H/Rosemount
4.	Pressure Transmitter	Rosemount / Dwyer / Wika
5.	Main Drive Gear Motor	Bonfiglioli / Siemens/ABB
6.	Frequency Inverter	Allen-Bradley/Mitsubishi/Siemens
7.	Gear Box	Bonfiglioli/Bauer
8.	Proximity Switch	Contrinex/Rockwell/Omron/
9.	Proximity Sensor	Contrinex/Rockwell/Omron
10.	Peristaltic pump	Masterflex / Watson Marlow
11.	Pressure Gauge	Rosemount / Dwyer / Wika
12.	Solenoid Valve	Gemu / Burkert
13.	Air Connection	Festo / SMC / Sweglok
14.	Temperature Sensors (PT-100)	E & H / Negele / Rosemount
15.	Pressure sensors	E & H / Negele / Rosemount
16.	PLC	Allen-Bradley / Mitsubishi / Siemens
17.	HMI	Allen-Bradley / Mitsubishi / Siemens
18.	Optical sensor	Contrinex / Pepperl Fuchs

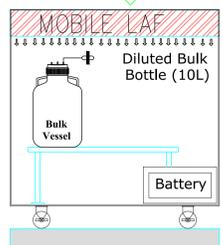
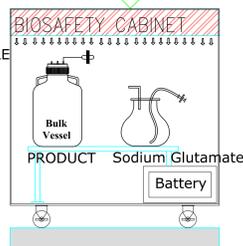
BULK AREA - FIRST FLOOR



2L Intermediate Bulk bottle



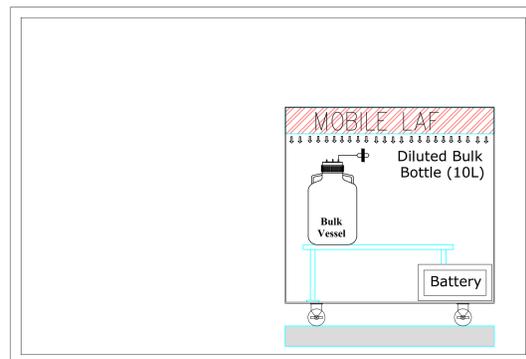
DILUTION PROCEDURE



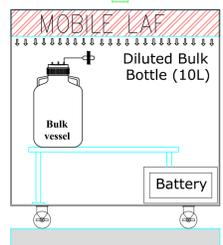
MOBILE LAF

Transfer via LIFT

FILLING-FORMULATION AREA-GROUND FLOOR

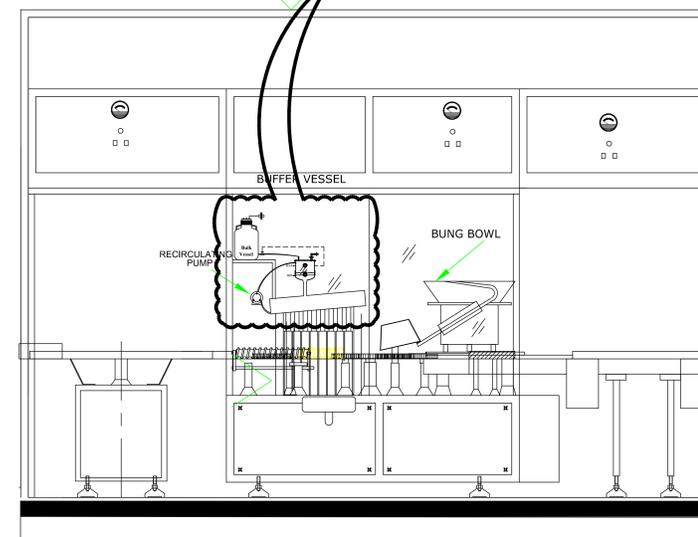
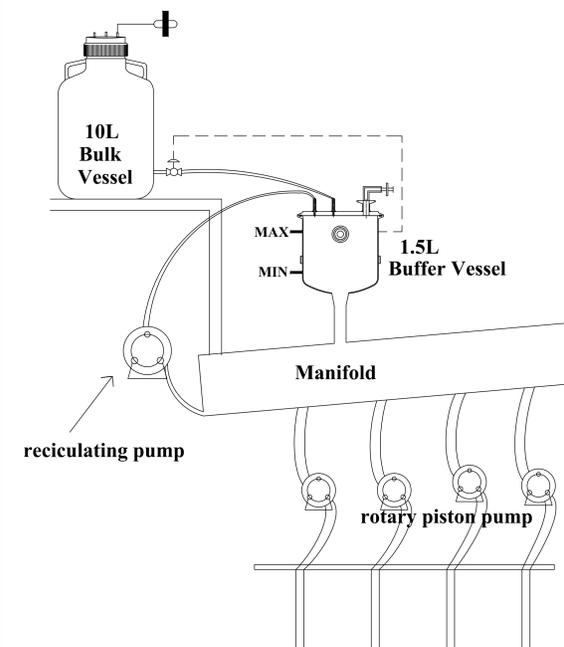


INTERMEDIATE COLD ROOM



MOBILE LAF

Recirculation from Manifold to Buffer Vessel



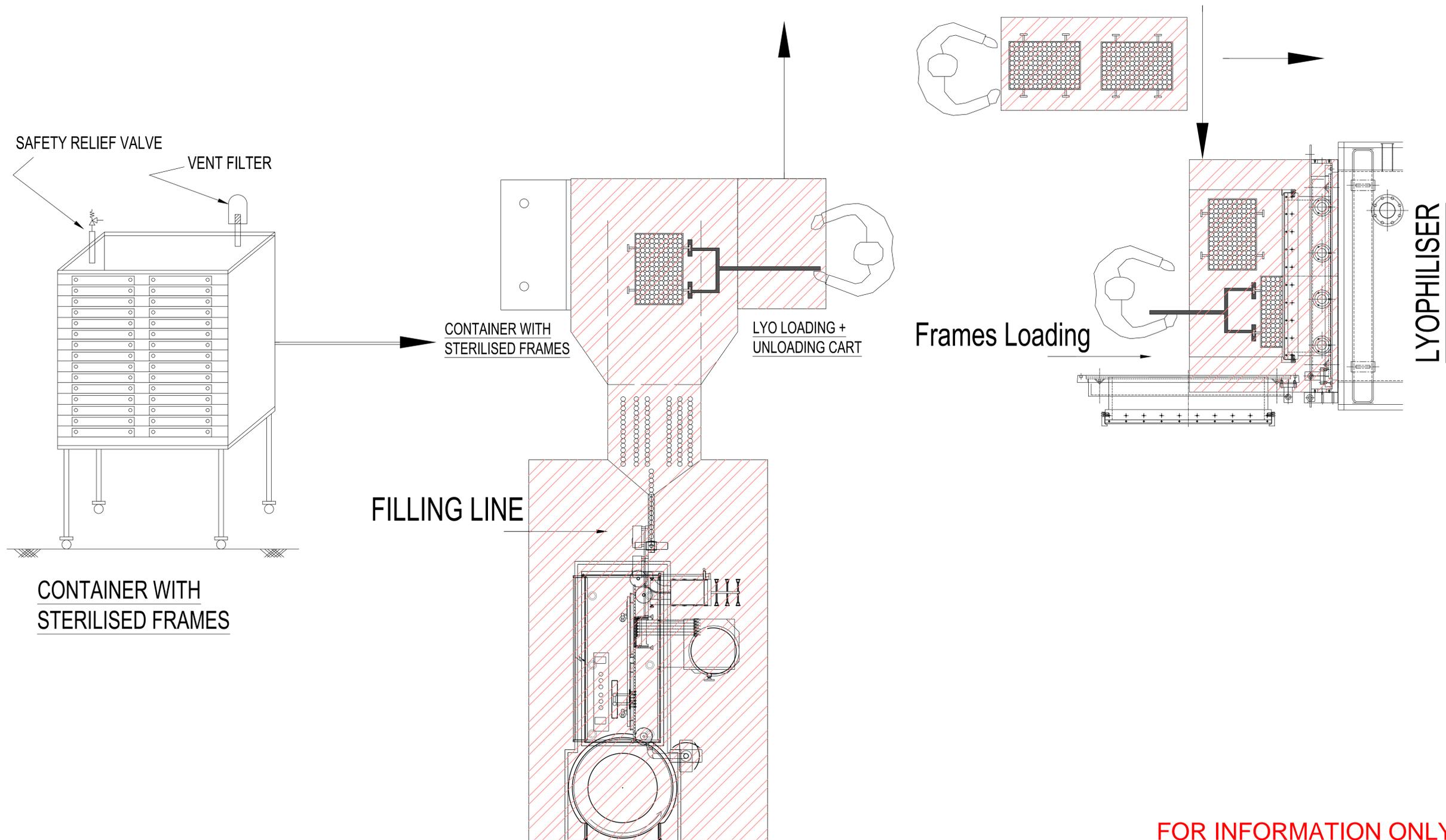
Vial Filling & Stoppering M/C

FOR INFORMATION ONLY

Rev.	Date	Changed	Checked	Kind of revision	No. Of Prints	Date	Issued To
02	01.04.2013	NHSG	NVNG	Change in transfer philosophy from bulk vessel to buffer vessel			
01	13.07.2012	NHSG	NVNG	Transfer of bulk from bulk bottle to buffer vessel via peristaltic pump instead of nitrogen pressure	--	--	--

File name :		Originated From Drg. No : NPI/110729/...../...../.....-Rev 00 [Option -00] Dt. 00.00.00													
Project: REVIVAL OF BCG VACCINES LABORATORY GUINDY, CHENNAI HLL LIFECARE LIMITED		Project No.: 110729 Location CHENNAI													
Description:		<table border="1"> <thead> <tr> <th>Drawn</th> <th>Date</th> <th>Name</th> </tr> </thead> <tbody> <tr> <td></td> <td>13.07.2012</td> <td>PJNJ</td> </tr> <tr> <td>Checked</td> <td>13.07.2012</td> <td>NHSG</td> </tr> <tr> <td>Approved</td> <td>16.07.2012</td> <td>NVNG</td> </tr> </tbody> </table>		Drawn	Date	Name		13.07.2012	PJNJ	Checked	13.07.2012	NHSG	Approved	16.07.2012	NVNG
Drawn	Date	Name													
	13.07.2012	PJNJ													
Checked	13.07.2012	NHSG													
Approved	16.07.2012	NVNG													
URS ANNEXURE 3 PROCESS FLOW DIAGRAM OF TRANSFERING BULK BOTTLE TO FILLING FORMULATION AREA GROUND FLOOR		Scale-NTS Units : mm Size : A4 Drawing no: NPI/110729/PFD(SCH)/02													
		Rev. 02													

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Bangalore - 560 080., INDIA.



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01	13.07.2012	NHSG	NVNG	Transfer trolley will have inbuilt LAF instead of Ceiling suspended LAF which will eliminate the ceiling suspended LAF from the path.	--	--	--
Rev.	Date	Changed	Checked	Kind of revision	No. Of Prints	Date	Issued To
File name :							
Originated From Drg. No :							
Project: REVIVAL OF BCG VACCINES LABORATORY GUINDY, CHENNAI HLL LIFECARE LIMITED				Project No.: 110729		nne pharmaplan® NNE Pharmaplan India Limited # 14, Achiah Shetty Layout, Bangalore - 560 080., INDIA.	
				Location CHENNAI			
Description:					Date	Name	
URS ANNEXURE 4 PROCESS FLOW DIAGRAM FOR TRANSFER OF LYO LOADING+UNLOADING CART					Drawn	13.07.2012	SRTR
					Checked	13.07.2012	NHSG
					Approved	16.07.2012	NVNG
					Scale-NTS	Units : mm	Size : A4
Drawing no:					Rev.		
NPI/110729/PFD(SCH)/03							01