User Requirement Specifications
Vial Filling and Stoppering Machine

Process Code	Area	Equipment ID	Quantity	Capacity
F1	Viral vaccine formulation area (Rabies)	F1-VFS 01	1	200 Vials/Minute

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 from blending vessel to filling line.
4.	Typical PFD for the arrangement of box+ cassetting station + mobile trolley
5.	Data sheet for the buffer vessel of filling machine.

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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 approved by the QA team of HLL BIOTECH LIMITED, and authorized by the appropriate Project Authority

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2.0 EQUIPMENT DESCRIPTION

Equipment operation requirements:

Product No.	**Vial size**	**Fill volume** (excluding overages)	**Capacity**	**Stoppering**
Product - 1	2R	1.0 ml	200 Vials/min	Half stoppering
Product - 2	2R	0.5 ml	200 Vials/min	Full stoppering
	4R	2.5 ml	200 Vials/min	

Vendor to consider 10% overage for all fill volumes.

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 /synchronized with depyrogenation tunnel
2.	In feed star wheel, 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 in cassetting station

Machine should have all operation automatic with minimum manual intervention with specified accuracy of ± 1% for all 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) with **Open RABS** and background of class B.

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

- 4.1.11
- FDA Guidance for industry, 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 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 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-S1-01
XII.	Refer Tender document with URS; NPI-120310-EQP-S1-TD-01

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
a) **Sterilized and depyrogenated vials from depyrogenating tunnel**: The depyrogenated vials **(2R and 4R 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.	
b) **Sterilized rubber stoppers (siliconized / non-siliconized) (according DIN ISO 8362-5 for freeze dried vials):** Sterilised rubber stoppers in the tyvek bag 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 rubber stoppers. ***Format : 13 mm size (For 2R -7 mm ,nubbed-2leg and 4R -type-B stoppers)***	
c) **Bulk Single Use Bag (WV 40L) / Mobile pressure vessel (WV 40L):** Vendor should provide the extended LAF for the single use bag / mobile pressure vessel and aseptic connection (Sterile connector (Male & Female)) to be made under same LAF with buffer vessel (intermediate transfer vessel – 10 L working volume).Space to be provided for holding the buffer vessel inside the RABS. The peristaltic pump for transfer of bulk from single use bag / mobile pressure vessel to buffer vessel will be under the scope of filing line vendor. Preferable transfer from single use bag to buffer vessel shall be by gravity. Vendor should include the space for the single use bag within the RABS system and aseptic connection (Sterile connector (Male & Female)) to be made under LAF with buffer vessel (10 L working volume). Additionally electrical socket needs to be provided to connect magnetic stirrer. Also, vendor to provide detailed GA drawing along with buffer vessel design as per Annexure 3 during DQ stage.	
d) **Buffer Vessel:** The capacity of the buffer vessel to be 10 L (WV) which will be kept outside the O-RABS with dedicated skid arrangement under LAF. This will be connected to the bulk single use bag / mobile pressure vessel aseptically. The product will be recirculated between manifold and buffer vessel as the product has the tendency of sedimentation. **Note:** Vendor shall provide buffer vessel with load cell and recirculation pump. Load cell shall have interlock for the controlled flow and transfer of bulk from single use bag / mobile pressure vessel to buffer vessel (sanitary port). ***Refer URS Annexure-5 for detailed technical specifications of buffer vessel.***	
e) **Outfeed System:** i. Turntable shall be provided to singularise the vials before the star wheel. 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).	
3.2 Brief Process Steps	
Filling and stoppering machine is to perform following process steps: a) Transportation of depyrogenated vials synchronized with turntable with dead plate in between to provide buffer time. b) Transportation of singularise vial from turntable to infeed starwheel. c) Transportation of vials from starwheel to infeed turret/ screw will transport the vial on filling station. d) Dosing of product liquid within vial of 2R or 4R with the help of rotary piston pump with a minimum accuracy of ± 1% for all fill volume within a 3 sigma range.	

Specifications	Remarks
e) There shall be provision of rejecting unstopperred vials. f) The equipment should have both the options for full stoppering and half stoppering of the vials. g) The outfeed of the vial is attached with cassetting station where arrangement of the vial will take place according to the frame size. h) Cassetting station will be docked with mobile trolley which will pull the frames on the platform and transport it to the lyophilizer. ***Note: No vial rejection (like breakage) shall occur during the process (maximum 0.2 %). No vials shall be scratched by the machine during processing***	
3.3 Output & Discharging method	
a) The machine shall enable the collection of half stoppered vials at the cassetting station at predefined arrangements and then be transferred to the lyophilizer via mobile cart/ trolley with manual loading-unloading arrangement for lyophilisation process under LAF.	
b) Lyophilser vendor will provide the frame size 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 fulfil the following requirements: • 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	
The filling line should be suitable for line output of 200vial/min for both 2R &4R vials with half stoppering and full stoppering options. ***Vendor shall consider ISO 4R and 2R vials.*** ***<u>Efficiency:</u> Overall line efficiency of the filling & stoppering machine shall be 99%.***	
4.2 Standard batch size	
Standard batch size shall vary ranging from 10,000 to 40,000 vials / shift of 8hrs based on the 4R & 2R vials.	
4.3 Change over time	
Change part replacement should not take more than 30 minutes.	
4.4 Other Productivity Requirement	
a) Hold-up volume should be less than the 1% of the 10 L buffer vessel.	
b) Any single change part should be not more than 5kg.	
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	
6.6.1 The equipment control system should be able to adjust and maintain the rate of filling (number of vials/ minute).	

Specifications	Remarks
6.6.2 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 will 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, depyrogentaion tunnel and washing machine is required.***	
e) Maximum out feed condition reached.	
f) Less than 1% volume of product in buffer vessel.	
g) Continuous detection of missing vial on filling station.	
h) Rotary piston pump not working.	
i) The rubber stopper bowl runs only on machine stopper request. Bowl stops when machine is not working.	
j) Continuous detection of missing stoppers on stoppering station.	
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) Rejection of vial, notify the operator with alarm.	
d) Any toppled vial on transport conveyor.	
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. 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	

Specifications	Remarks
- 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
Infeed/ outfeed sensor	To monitor the jamming or accumulation of the vials.	Optical sensor
Volume of product in buffer vessel	To maintain level in the buffer vessel	Load cell
Pumps	To fill the product into the vials	Rotary piston pump with PLC control
Sensors	• 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

Batch data printing shall be provided for basic / standard data acquisition. This shall be

Specifications	Remarks
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 vendor scope.	
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 and 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.	
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.	
6.6.7 Required support services, like cable tray/SS conduits/pendants outside the complete machine will be in client’s scope.	
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. (HEPA not under supplier scope).	
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. Note: Vendor to provide dimensions of the LAF in the technical bid with top view. At DQ	

Specifications	Remarks
stage the vendor to provide accurate drawings with dimensions. The supply of LAF is not under the scope of the vendor.	
6.7.3 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.	
6.7.4 Mock up test shall be conducted for the filling accuracy & line output during FAT.	
6.7.5 Support during initial product runs during SAT.	
6.7.6 All RAB doors have to be supervised by security switches. In case of opening the machine must stop immediately.	
6.7.7 CE certification for the filling line is mandatory and would be part of user requirements.	
6.7.8 Product contact parts should be easily dismantle able and cleanable e.g. buffer vessel, manifold, nozzle heads.	
6.7.9 The dosing nozzles should be constructed of SS 316L with Ra = 0.38	
6.7.10 Conveyor belt should be constructed with material which will be easy to clean, the resistant to disinfectants and low particle emitting comply to Grade A and shall be designed for minimum friction and also ensure that the conveyor belt shall be cleaned automatically towards the end/bottom of the conveyor.	
6.7.11 The MOC of safety cabinet and safety glass shall be compatible with the different disinfectants used.	
6.7.12 The RAB should be constructed of SS 304 frame with transparent safety glass (antistatic type)	
6.7.13 The equipment should be accessible from front side.	
6.7.14 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.	
6.7.15 **Transport Belt/ turret/ screw**	
a) Frictionless, continuous motion shall be provided and driven by programmable servo motor drive.	
6.7.16 **Filling Station**	
a) **Bulk Single Use Bag (W.V 40L) / Mobile pressure vessel (W.V 40L)** – Slightly Inclined platform shall be provided to use the product completely. – Stirring arrangement shall be provided on the platform for continuous stirring. – Vendor should provide peristaltic pump to transfer product from bulk single use bag to the buffer vessel. ***(with interlocks with load cell of the buffer vessel)***	
b) **Buffer Vessel, manifold** – Capacity of the vessel shall be 10 L. – Level control using load cell with high accuracy connected by PLC of the machine. – Buffer vessel to be placed on the top of the manifold.	

Specifications	Remarks
– Manifold should be slightly inclined at one end with recirculation provision in between buffer vessel and manifold.	
c) **Dosing Nozzle** – 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℃. – Proper transfer of buffer vessel, manifold, nozzles to be provided for cleaning and after sterilisation under LAF in to the filling machine. – 1 set each for 4R and 2R nozzles shall be provided along with the filling machine.	
d) **Rotary Piston Pump** – Individual rotary piston pump to every nozzle shall be provided – Sterilizable grade SS316 L – 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 (gloves used should be of sanitable grade)	
6.7.17 **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) The equipment control system shall be suitable to adjust and maintain the rate of stoppering (number of vials/ minute).	
d) Equipment shall be adjustable for half stoppering as well as full stoppering of the vials.	
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 stoppers and number of stoppers which can be loaded in one go. (Minimum capacity should be 3000 bungs/load).	
h) Pick and place system shall be provided or vendor shall provide alternate option.	
i) Vacuum system shall be provided for stoppering of the vials.	
6.7.18 **Reject Station**	
• Rejection station shall be provided to collect faulty vials. (i.e. empty vials, unstoppered vials).	
• Vendor to provide proper rejection system.	
• Rejection station shall have tray to collect the vials in front of the machine 90 degree to good vials collection.	
6.7.19 Software ladder logic shall be provided.	
6.7.20 Change parts to be provided for 2R and 4R vial sizes.	
6.7.21 **Cassetting Station (For lyophilised vaccine)**	
a) Procedure:	

Specifications	Remarks
– 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). 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 casseting 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 2 buffer frames (in addition to the standard). ***Note: Refer URS Annex 4 (Typical PFD for the arrangement of box+ cassetting station + mobile LAF trolley)***	
b) Technical Specification – 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 be 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 can be synchronized with outfeed of the filling line, container of frames and lyophiliser cart. – The station shall be mobile, provided with height adjustable castor wheels.	
7.0 CONSTRAINTS	
7.1 Equipment location and available space	
This equipment will be installed in the **Viral Vaccine Formulation Block (rabies section)** of **Integrated Vaccines Complex**, Chengalpattu. **Equipment Location: F1-VFS-01** Room No.: **F1G043** Floor: **Ground floor** Room Dimensions (L x W) : **10900mm x 6200mm, 5200mm x 7000mm** False ceiling height: **3000 mm** The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1.** The equipment must be positioned as per the generic layout provided below. **Physical condition of the rooms:** Liquid Filling:	

Specifications	Remarks
1. Room will be non-hazardous 2. Class: EU Class "B" 3. Differential Pressure: 65 Pa Absolute 4. Temperature maintained: 22°C ±2°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

Abbrevation	Definition
ANSI	American National Standards Institute
CE	European conformity
FAT	Factory Acceptance Test
FDA	Food and Drug Administration
GA	General Arrangement
GMP	Good Manufacturing Practice
HMI	Human Machine Interface
ISO	International Standards Organization
IRS	Installation requirement specifications
LAF	Laminar Air Flow
MOC	Material Of Construction
NPI	NNE PHARMAPLAN INDIA LTD
O-RABS	Open- Restricted Access Barrier System
PLC	Programmable Logic Controller
QA	Quality Assurance
Ra	Roughness Average
SAT	Site Acceptance Test
SOP	Standard Operating Procedure
SS	Stainless steel
VFS	Vial Filling and Stoppering Machine
WV	Working Volume

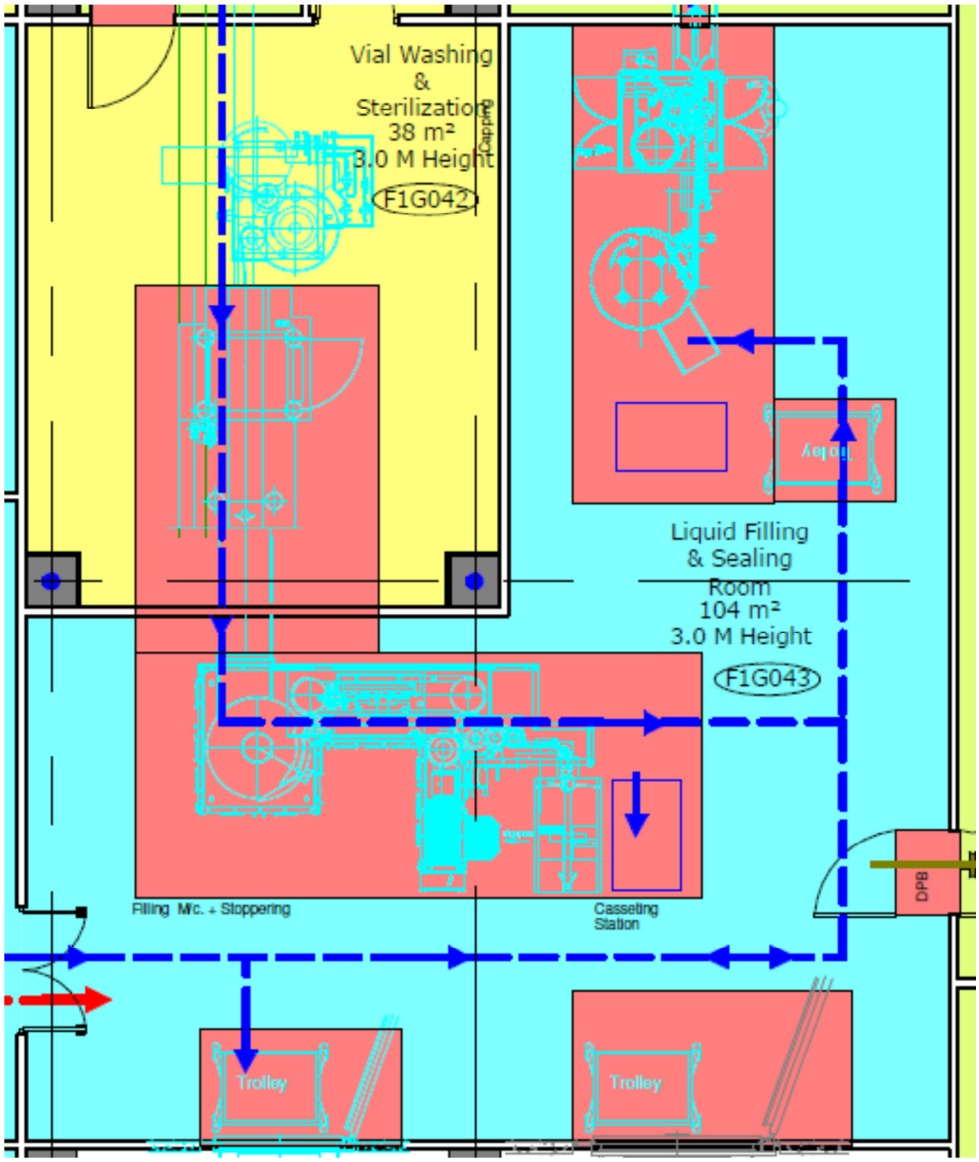
REVISION INDEX

Revision	Date	Reason for revision
00	19-07-2012	First Draft for Client's Review
01	27-05-2013	As per comments given by HBL on 27-05-2013 by email
02	18-10-2013	As per comments given by HBL on 10-10-2013 by email
03	28-11-2013	Updated as per MOM dated 26-11-2013
04	10-12-2013	As per comments given by HBL on 07-12-2013 by email.

URS Annexure 1: LAYOUT POSITION

Room No. : F1G043

Room Name: Liquid filling



URS Annexure - 2

List of components and make for Vial Filling & Stoppering Machine

S.No	Description	Preferred List
1.	Load cell	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/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 / Honeywel / Siemens
17.	HMI	Allen-Bradley / Siemens
18.	Optical sensor	Contrinex / Pepperl Fuchs

Note: - Vendor shall follow the similar make for all the instrument.