

CORRIGENDUM

Department of Animal Husbandry , Livestock Complex , Sector 68 , SAS Nagar has extended the schedule date of e-Tender/Notice 1/ 2017-18 from 27-06-2017 to 10-07-2017 .This e-tenders can now be submitted online till 10-07-2017 upto 5:00 pm and the same shall be opened on 11-07-2017 at 11:00 am. Hard copies of the said tenders can be submitted at the office of Director Animal Husbandry Punjab , Livestock Complex ,Sector 68 , SAS Nagar till 10-07-2017 upto 5:00 pm.

NOTICE INVITING e-TENDERS

etender.punjabgovt.gov.in

Directorate, Animal Husbandry, Punjab, Livestock Complex , Sector-68, SAS Nagar

e-Tender/Notice-1/ 2017-18

The Department of Animal Husbandry, Punjab , Livestock Complex , Sector-68, SAS Nagar, invites e-tender on double bid system for the following items at Punjab Veterinary Vaccine Ludhiana, Punjab.

- (i) WFI -MULTI-COLUMN DISTILLATION PLANTCAPACITY: 200 LPH Along with Storage 1500L and Distribution system
- (ii) Supply, Installation, Commissioning & validation of GMP standard water purification system having 750 LPH generation capacity with all accessories, 2000lt storage tank & distribution system at Formulation Block.
- (iii) Pure Steam Generator Capacity: 200 Kgs/Hr .
- (iv) Tangential Flow Filtration system with Hold Vessel.
- v) Liquid filling and Bottling line havin1g following components
 - a) Linear Bottle Filling & Stoppering Machine ----- One
 - b) Bottle Cap Sealing Machine ----- One.
 - c) Manual Inspection Table----- One
- vi) Chiller----- One

For additional details such as detailed specifications, important dates etc visit the website: etender.punjabgovt.gov.in. Tender form, specifications, terms and condition can be obtained from this website on payment of Rs. 20/-(online payment) as per e-tendering procedure. Other details/brief description of the work can be seen in the office of the Deputy Director, Animal Husbandry, I/c Punjab Veterinary Vaccine Institute, PAU Campus, Ludhiana The tender will be in double bid system i.e. Technical/Pre-qualification Bids and Financial/Commercial Bids.

1. Tender shall be accepted only from manufacturers/authorized dealers.
2. Complete profile of the Authorized /Registered firm along with organizational structure, Key personnel employed along with their educational qualification and experience.
3. Tenderers should submit complete details on the organization, experience of work, man power with financial details.
4. The bidder must enclose attested copies/proof of consisting, Pan Card, TIN No., Service Tax No., CST, EPE, Registration/Authorisation of the firm etc.
5. The bidder firm should not be black listed/debarred by any department/ organization.
6. Bidder must submit undertaking in the shape of affidavit regarding providing all the information/documentations in the bid to be true and correct.
7. The e-tender should be submitted online till 27-06-2017 upto 5.00 pm and shall be opened on 28-06-2017 at 11. 00 am
8. Tenderers are also required to submit a hard copy of the technical bids of this tender on or before the closing date 27-06-2017 upto 5:00 pm at the office of Directorate, Animal Husbandry, Punjab, Livestock Complex , Sector-68, SAS Nagar.
9. The e-tender must be accompanied with earnest money amounting Rs 500/- (online payment) as per e-tendering procedure.
10. The undersigned reserves the right to accept or reject one or all offers/tenders and holds the discretion to increase/decrease the quantity of any or all the items. The undersigned also hold the discretion to place the order for any or none of the items qualifying in the tender and may increase/decrease the quantity of any or all the items as per requirement of the Department.
11. Successful tenders will have to submit a security deposit of 10% of the ordered value within the stipulated period of time after issuance of orders.
12. For participating in the above e-tender, the bidders shall have to get themselves registered with <http://etender.punjabgovt.gov.in> and get user ID & password. The bidders who have not registered with e-procurement portal need to get registered by paying the requisite registration fee for e-tender participation and obtain Class 3 Digital Signature Certificate (DSC) which are mandatory to participate in the e-tendering process. For any clarification/difficulty regarding e-tendering process, please contact on helpdesk numbers 09257209340, 08054628821, 0172-3934667.
13. The contractors/tenderers/bidders are also required to pay tender processing charges of Rs. 2,280/- or an estimated amount as per tender which are to be deposited online. (This tender processing fee/charges are other than the firm registration amount for Digital Signature Certificate (DSC).
14. e-Tender details can also be obtained from the Departmental website www.husbandrypunjab.org.

FAX No: 0172-2217084

Telephone No. 0172-2217083

Website www.husbandrypunjab.org

Director Animal Husbandry,
Punjab

Tendering Procedure.

It will be a two stage tendering. The technical tenders and financial/commercial tenders will have to be submitted AS PER E -TENDERING PROCEDURE.

The Technical Bids should contained detail information on the following: -

- Nature of Ownership.
- Composition of the Firm.
- Bankers Name & Address.
- C.S.T/S.T No./Vat No.
- PAN/TAN No.
- Tax clearance.
- Whether Manufacturer/Sole Selling Agent/Distributor/Authorized Dealer.
- Experience in line.
- Capability/Capacity to service the requirement.
- Details of relevant infrastructure.
- Arrangements of after sale service.
- List of Clients.
- Quality Assurance/Monitoring system followed.

Certificates where needed should be attached duly attested.

Financial/Commercial Bids.

Financial Bid should contain the price quoted per unit. The following information should be clearly given in the Financial Bid:-

- Price per Unit.
- Place of Delivery.
- Status of Taxation/Duties etc.
- Lead time/Delivery Period.
- Packing & forwarding.
- Mode of Transportation.
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- Payment condition.
- Warranty/Guarantee.
- Validity of Offer.
- Acceptance of Terms of N.I.T.
- Details of Earnest money attached.

Financial Bids will be opened only of those tenderers, who qualify and are found suitable during the processing of Technical Bids.

TERMS AND CONDITIONS

1. Rates should be quoted in Indian Rupees only, FOR anywhere in Punjab/Chandigarh.
2. All applicable taxes should be included in the quote.
3. Brochure/leaflets/catalogues should be submitted alongwith tender.
4. Tender shall be accepted only from manufacturers/authorized dealers.
5. Trouble free performance of the complete equipment for a minimum period of two years from date of commissioning should be guaranteed . Any defect intimated should be attended to and rectified within 15 days of receipt of such communication within guarantee period. The guarantee shall include cost of spares and labour.
6. The supplier should give an undertaking that they will be responsible to carry out the preventive maintenance and to repair the equipment during guarantee and post guarantee period.
7. The product offered should be supported with AMC for next three years on expiry of the guarantee period. Full details of after sale service offered during the post guarantee period should be furnished alongwith tender specified.
8. Tenderers should submit complete details on the organization, experience of work, man power with financial details.
9. The supplier shall train to the satisfaction of the purchaser one or two technicians at site/factory for operating, servicing and undertaking minor repairs without extra cost.
10. Complete profile of registered firm along with organizational structure should be submitted.
11. Supplier will have to deposit 10% value of the total price of the items in the form of Demand Draft/FDR payable at Chandigarh in the name of Director, Animal Husbandry, Punjab, Chandigarh within 10 days of receipt of supply order as security money.

Detailed specifications of e-Tender/Notice-1/ 2017-18

(i). WFI -MULTI-COLUMN DISTILLATION PLANT

(Pharmalab, Indo-German Pharma Engineers, CN Water, Nilson Nishotech Systems, Evoqua Water Technologies, Siemens, US Filters, Millipore)

CAPACITY: 200 LPH along with Storage 1500L and Distribution System at Punjab Veterinary Vaccine Institute, Ludhiana

SCOPE OF WORKS

The scope of specification covers design, fabrication, assembly, testing and inspection of Multi-Column Distillation Plant in compliance with cGMP, packing, transportation, unloading at site, erection, commissioning including transit & erection insurance & hand over of the system including preparation of validation document DQ, IQ & OQ and provide necessary support to client for PQ validation. WFI along with distribution system facility for 800lt. fermentor having 600lt. working volume along with 80lt. seed fermentor, 800lt. blending vessel and inactivation vessels and CIP system.

SCOPE OF SUPPLY

- To produce Sterile and pyrogen free water for injection complying with latest IP standards.
- The system shall comprise the multiple falling film evaporator & annulus centrifugal separation system & Cooling condenser.

The system should be compact in design with all process contact parts in SS 316L and all non-process contact parts in SS 304.

- All components shall be mounted on a single skid of SS 304 material.
- All pressure parts shall be designed as per ASME Sec. VIII, Div.1. Evaporators & pre-heaters shall be designed as per ASME Sec. VIII, Div.1 and TEMA Class 'C'.
- Double tube sheet design shall be employed in all Heat exchanger where fluids on either side are of different specifications viz. PW/WFI v/s. Plant steam /Condensate, Cooling Water v/s. PW / WFI.

- Quality acceptance of Plant includes complying to physical, chemical, microbiological and pyrogen limits.
- Scope of supply shall include the following but not necessarily limited to the following:
 - 2 Nos. SS pump (One for Feed Water and One for Cooling Water)
 - Pre-heaters
 - Multi effect Evaporators with three/ four stage separation
 - 2 Nos. Condensers shell & tube for cooling with purified water & cooling water separately.
 - Sampling arrangement
 - Interconnecting piping including drain header
 - PLC based control Panel with HMI 10" Allen Bradley /Siemens
 - SS304 skid

- Equipment with hot surface shall be pre-insulated and clad with SS 304, 14 SWG sheet. (Cladding shall be fully welded type and with externally matt finished to better than 180°

grit).

- All gaskets shall food grade Class VI quality of PTFE or Viton.
- Contractor will specify with quotation the terms for equipment delivery and the detailed schedule for engineering, manufacturing, and assistance to qualification of the systems.
- The Manufacturer/supplier should indicate the required utilities and consumptions.
- Manufacturer/supplier will be responsible for job, materials and/or equipments and documentation supplied by his sub-supplier.
- Supply will have to be in compliance with this document and with all standards and codes applicable. This does not subtract the Manufacturer/supplier to supply equipment, materials and accessories designed and built properly and perfectly suitable for the specified use and operational conditions.
- Scope includes a collection tank of 1500 lts and distribution piping with approximately 10 takes off points.
- Piping should be quoted separately on unit basis per mt. with unit cost for components such as elbows, bends, steam traps, manual diaphragm valves etc.
- The Storage and distribution tank should have distribution pumps with facility to sterilize them.

TECHNICAL REQUIRMENTS

Utilities: Electricity Power: 380V \pm 10%, 50Hz \pm 3%, 3Phase, 4 wires, combined voltage and frequency variation \pm 10% Control Voltage:230 V AC, 50Hz, 1 Ph. To be derived by manufacturer/supplier from 380 v, by powering suitable control transformer.
Feed Purified Water Quality.

Conductivity	:	<1.3 μ s/cm @ 25oC.
Microbial count	:	<10 cfu/ml.
TOC	:	< 500 ppb.
pH	:	5 – 7
Temperature	:	Ambient

MATERIAL OF CONSTRUCTION

All Parts in Contact with Feed Water, Product Water and Product Vapors should be in SS 316L & Non Contact part in SS 304 Quality

COOLER (SHELL & TUBE TYPE) FOR FEED WATER & COOLING WATER

Specially Designed Cooler With 0 % Pressure	
Drop. MOC	: SS 316 L Quality
Quantity	: 1 No.
Nozzle End Connections	: Triclover, 3/4" OC
Connection Gaskets	: Teflon

W.F. I STORAGE SYSTEM AND LOOP SYSTEM WITH S.S.304 SKID

WFI STORAGE VESSEL 1500 LTRS Material of Construction:

Shell	S.S. 316L
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Jacket	SS 304
Top & Bottom	Dish End
Insulation Cladding	SS 304 (2 mm Thk)
Nozzle	S.S. 316L
Gasket Material	Silicone Food Grade
Surface Finish : Internal External	0.5 Ra Mirror polished 0.8 Ra matt mech. Finish

Performance of Close circulation Loop System

PARAMETER	AT THE OUTLET
Conductivity	<1.3 μ S / Cm
Endotoxins	<0.25 EU/ml
Temp of WFI Loop System	Not Less Than 80 Deg C.
Bacteria	< 10 cfu / 100 ml
TOC	< 500 PPB

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pipe from the WFI room to other rooms where fermentor and other instruments are installed, which requires WFI, Pure Steam and dirty steam, minimum piping required approximately 2500 ft, it should include the quote. However for additional piping separate rate for supply line could be quoted per ft., so that in the event of increase or decrease, payment on actual is given .

2. Utility equipment supplier of WFI to provide utility piping with insulation wherever required with terminal valve up to 1 (One) meter. near the equipment location. Equipment supplier will connect the last 1 (One) meter. connection to the equipment. The rates for supply line should be quoted per ft. and the actual will be paid or measurement.
3. Pendent need to be provided for each vessel required by the manufacturer.

GENERAL

Client's Scope

- A. All civil work such as foundations for equipment, housing for the equipment, drains etc.
- B. Power Supply cable, 380 V, 3 Phase, 50 Hz, 3 phase, 3 core and neutral to the Control Panels.
- C. Provision of ventilation in the plant room.
- D. Power and water for erection, testing and commissioning of the plant.
- E. Piping beyond the specified battery limits.

Inspection and testing

- A. The system shall be offered for visual performance trials & hydrotest at the manufacturer's premises for inspection by client /authorized representative.
- B. Client /authorized representative shall at all times have an access to supplier's / suppliers sub contractor's workshop to witness fabrication stages.
- C. Internal inspection record shall be maintained by supplier / suppliers sub-contractor at all times, if any stages are found lacking by way of proper records, client reserves the right to ask supplier to modify / amend the fabrication stage at no extra cost.
- D. All material test certificates shall be reviewed by client during FAT

- E. Performance trial shall be done at manufacturers premises with qualified water and shall be performed at site after installation.
- F. Testing of the components (column, condenser, pre heater etc.) shall be done as per ASME Sec VIII, Div 1.
- G. All weld joints on PW service shall be Orbital welded with proper weld parameters record (voltage, current drawn & rpm of welding head). All internal welds shall be video graphed & recorded by Boroscope.

Guarantee

- A. The system supplied shall be guaranteed for trouble free operation for the period of two years from the date of handing over. All defects due to faulty design, material and workmanship and also the performance deficiencies which may come up during guarantee period shall be rectified by the manufacturer/supplier at his cost to the purchaser's satisfaction.
- B. All guarantees from equipment suppliers will be vested in the client.
- C. Where damage is caused to any other item by any failure of the item guaranteed, then the guarantee shall also include the costs incurred in rectifying that damage.

Documentation:

- A. P&ID clearly demarcating Battery limit terminations.
- B. GA Drawing.
- C. Equipment Layout.
- D. Foundation Drawings.
- E. Quality Assurance Plan.
- F. SLD for electrical circuit.
- G. GA & wiring diagram of control panel.
- H. PLC control logic, OIU Screens. Operators guide & Ladder logic.
- I. Piping drawing within battery limit.
- J. Design Qualification Document

During commissioning activities:

- K. Operation & maintenance manual for all mechanical, electrical & instrumentation items.
- L. Characteristic performance curves for all pumps, blowers.
- M. Calibration certificates for all instruments.
- N. Operation & ladder logic details for PLC.
- O. Internal inspections & acceptance reports.
- P. Test & Guarantee certificates.
- Q. Operation Manual for programming software of PLC & OIU.
- R. As built drawings as listed in item B.
- S. D.Q, I.Q, O.Q, & P.Q documents of items system being supplied by tenderer.

Tenderer QUALIFICATION.

- Trouble free performance of the project for a minimum period of two years from date of commissioning should be guaranteed. Any defect intimated should be attended to and rectified within 15 days of receipt of such communication within guarantee period. The guarantee shall include cost of spares and labor.
- At least one site visit by client to the manufacturer establishment .

ii) Supply, Installation, Commissioning & validation of WHO GMP standard water purification system having 750 LPH generation capacity with all accessories, 2000lt storage tank & distribution system at Formulation Block.

(Pharmalab, Indo-German Pharma Engineers, CN Water, Nilson Nishotech Systems, Evoqua Water Technologies, Siemens, US Filters, Millipore)

The specification covers design, fabrication, assembly, testing and inspection Purified water Plant in compliance with cGMP, packing, transportation, unloading at site, erection, commissioning including transit & erection insurance & hand over of the system including preparation of validation document DQ, IQ & OQ and provide necessary support to client for PQ validation. Purified water along with distribution system facility for 800lt. fermentor having 600lt. working volume along with 80lt. seed fermentor, 800lt. blending vessel and inactivation vessels and CIP system .

PURIFIED WATER GENERATION SYSTEM

This specification is intended to cover the minimum requirements to be met by the Manufacturer/supplier in the design, manufacture and supply Purified Water Generation System. The System should be designed for treatment of the BORE well Water. The PW should have quality as per latest USP Guidelines.

Specification required for the Purified Water according to USP	
pH	5 to 7
TOC	< 500 ppb
Bacteria	< 100 CFU/ml
Conductivity (µs/cm)	
Stage 1	< 0.5 µs/cm online; T > 25 ⁰ C

MAJOR PARAMETERS OF THE PROPOSED WATER PURIFICATION SYSTEM: _

Sr. No.	PARAMETERS	REQUIRED
1.	Capacity of the Water Purification System(Generation)	750 LPH ± 10 %
2.	Maximum peak load requirement at a time	800 LPH
3	Purified water Storage Cap .	2000 Lit
3.	Daily consumption of purified water-	4000 lits / day
4.	Quality of water required	Purified Water IP
5.	Operating Temperature	25 to30 °C(In Storage Tank)
6.	No. of user points (Tentative and may vary)	7 (Seven)
7.	Length of distribution pipe	250 mtrs (Tentative)
8.	Flow rate of water available at source for purification	

The following elements should be included in the system to produce purified water system:

Pre-treatment Unit :

Sodium Hypochlorite Dosing

- Multi Grade Filter
- Softener

- Soft Water Storage Tank

Generation System (750 LPH)

- Reverse Osmosis Unit (2 RO vessels)
- EDI

Technical Description

Sodium Hypochlorite Dosing

In line administer sodium hypochlorite for oxidizing all organic material present in the raw water and bacterial growing control inside the dual media filter. System should comprise.

- Supply Dosing Pump
- Chemical Storage Tank

Multi Grade Filter

Suitable Multi granular media filters to be supplied for efficiently and economically treat feed water to reverse osmosis. These filters to utilize a top layer of silica sand. Combination of media to be provided for coarse filtration, followed by fine filtration as water flows through the media. Coarse inert gravel to be used to support the media bed and provide superior flow distribution over the entire bed surface area.

Multi Grade Filter to be provided to remove suspended materials from raw water before further purification by softening, reverse osmosis, or deionization. It should be equipped with an arrangement for regularly scheduled backwashing to maintain the filter bed in peak operating condition.

The following characteristics should be accomplished:

- Tanks shall be designed with ample freeboard to accommodate high backwash rate needed for properly clean filter media.
- Tanks shall be constructed of FRP.
- Inert UPVC plastic piping interconnection.
- Skid mounted for easy positioning and installation.
- Air vent and water drain for filling and draining the tank.
- Pressure Gauges indicate pressure drop and back wash needs.
- Flow meter displays service and backwash rates.

Softener

Water Softeners should use high-capacity cation resin to exchange sodium for hardness (Calcium and Magnesium) ions in the water. Softener to use NaCl for regeneration.

Other Characteristics of this should be:

The Water Softener tank shall be for 2000 L .

- All piping MOC to be specified by the manufacturer/supplier.
- The Water Softeners should be supplied with manual control for all operations.
- The resin shall be a FDA approved high capacity ion exchange resin with uniform and stable beads to assure long life, high salt efficiency and maximum hardness removal.
- A bottom stack or hub and lateral distributor system to be provided for maximum service flow and minimal pressure loss.

Reverse Osmosis

The capacity of the reverse osmosis unit after second pass should be approximately 900 LPH of permeates water required for EDI feed.

The reverse osmosis (RO) machine should be high capacity units designed to economically produce high purity water. The RO should be designed horizontally mounted, stainless steel housing and with a quiet multi-stage centrifugal pump mounted on a freestanding frame.

Other Characteristics are:

- The system shall comprise of basic components like multi-stage centrifugal pump, cartridge pre-filters, housings and electrical package etc. The RO systems should be manufactured in accordance with GMP.
- The membrane configuration or other specifications(Manufacturer to specify)

- The membrane shall be of Polyamide Thin film composite.
- The pump/motor should be mounted on a base to enhance stability and to simplify service.
- All stainless steel welding should be tungsten inert gas (TIG) type.
- Automatic inlets shut-off valve to prevent flow through them a chine when it is shut down.
- Checkvalve in permeate line to prevent backflow or siphoning into the permeate side of the machine.
- The RO cleaning system should include a cleaning tank, centrifugal pump, heaters and required Interconnections.

Reverse Osmosis Monitoring

The following parameters should be mounted during operation:

- Feed Water Pressure
- Reject Pressure
- Feed Water Flow Rate
- Permeate / Reject water flow rate
- Product Water conductivity

Twin Stage Electro Deionization

The capacity of the Electro deionization unit (EDI) should be 750 liters per hour of Purified water at the output or as per the design of RO output.

The following elements should be considered:

- Conductivity meter with alarm set point.
- Digital DC volt and amp meter.
- Dilute plumbing.
- Concentrated and dilute flow meter.

RO EDI Piping

Items	Description
Piping Material	0.065" wall thickness, 316L stainless steel ASTM A270 Ra≤0.5 μm inside (180 grit); Ra≤0.8 μm outside (240 grit) finishing.
Valves	Diaphragm sanitary type, with tri-clamp connections. Body AISI 316L diaphragm EPDM.
Fittings	0.065" wall, 316L stainless steel A270 Ra≤0.5 μm inside (180 grit); Ra≤0.8 μm outside (240 grit) finishing.
Pumps	ASI 316L stainless steel sanitary. Simple mechanical seals carbide / silicon carbide.

Electrical Features

- Power: 400 volts 3-Phase; 50 Hz; 230 V single
- The electrical system of the equipment shall comply with the requirement established by the following standard of the International Electro Technical Commission: IEC 204

COMPLIMENTARY ASPECTS

Training

Training of Customer's operators. The Manufacturer/supplier shall supply all available information for the adequate exploitation of equipment. For the compliance of this purpose at the job site and/or at the Manufacturer/supplier's shop. Manufacturer/supplier's technical staff Customer's personnel. The scope of the training will be agreed during the contract signature.

Pre Delivery Qualification (PDO)

- Pre-Installation at the manufacturers shop. The system or its parts as provided for in the scope of supply shall be pre-installed at the Manufacturer/supplier's shop prior to delivery to Customer's site. Installation will be completed and documented including mechanical parts as well as electrical connections of all parts to facilitate taking-over tests at manufacturers shop prior to delivery.
- After the installation of the equipment at the manufacturers shop, Factory Acceptance Tests (FAT) shall be performed and accurately documented.

General Tests to be performed during FAT

- Visual inspection for compliance with the cGMP, in accordance with approved drawings.
- Alarms checkout.
- I/O Checks
- Functional tests for all control loops(where applicable)

Supplier Technical Documentation Requirements

In addition to providing the system specifications, the supplier must deliver the following documentation.

Drawings

Drawings should be sufficient in detail to indicate all critical installation, operation and performance parameters.

- Layout plans in scale 1:25
Process Flow Diagrams(PFDs)
- Piping & Instrumentation Diagrams(P&IDs)
- Pressure vessel drawings
- Engineering drawings for mechanical equipment/systems
- Isometric piping/ducts diagrams
- Control panel (internal & external) layout, wiring and installation
- Mechanical assembly drawings

Lists

- Equipment and instrument a list with component descriptions
- Input/output lists for computer related systems
- Documentation list
- Spare parts list
- List of all possible alarms and failures

Technical Manuals

Manufacturer's operation and maintenance manuals for all equipment, sub-system and components must be provided by the supplier. This includes also manuals of computer systems (PCs and PLCs). The manuals will be supplied in English language. Technical manuals should include:

- Operating Manual
- Trouble Shooting Guide
- Equipment Description
- Equipment Specification
- Process Description
- Process Flow Chart

Supplier Certification and Procedures

Certification with supporting documentation is required to verify all materials of construction for product contact surfaces. This should include:

- Certificate of analysis

- Traceability of materials certificates including lot numbers and heat numbers.
- Verification and documentation of surface finishes.

System which will be welded as part of the manufacturing and/or installation process require the following documentation, at minimum:

- 100% visual inspection of all welds fully documented
- 10% boroscopy of orbital welds
- Document evidence of Sanitization
- Supplier procedures for orbital welding, passivation, material handling, etc.

Computer Control System Documentation

Manufacturer's specifications and manuals for major components of the computer control system such as:

- PLC CPU
- Power supply modules
- Digital and analog I/O Modules
- Operator interface modules
- Remote I/O modules
- Communication Modules

Specification for computer hardware components (If applicable) should include:

- Manufacturer
- Catalog Numbers
- Component Type
- PLC Software version number (no application software)
- Hardware configuration information (Switch and jumper settings....)
- Power requirements

Description of alarm conditions, including:

- Alarm Messages
- Alarm Set points
- Machine responses to alarm inputs

Critical instruments (sensors) must be supplied with the following documentation, at minimum:

- Calibration certification for each instrument with the certificate of the instrument used as reference of calibration
- Instrument manufacturer's specifications (range, increments, accuracy, hysteresis, etc.)
- Instrument model number
- Instrument service/usage
- Info construction including installation connection to the system

CLEANING, MAINTAINENCE AND SERVICE

- In accordance with cGMP guidelines the unit(s) must be easy to clean, to disinfect, and where necessary, to sterilize.
- The Supplier should guarantee that, if required, a service team can be on site within one working day.
- The design should be such as to allow mechanical cleaning of the surfaces and that the cleanliness of the surfaces can be checked easily.
- All machine parts, in particular instrumentation, should be constructed so that they can be easily removed and calibrated.
- All special tools required for running and maintenance must be included in the offer.
- A spare parts delivery guarantee of at least one (manufacturers to specify) years is required.

1. RULES AND REGULATIONS

1. General

- The supplied equipment must confirm to all the relevant current GMP, EU, and FDA requirements.
- In the event of conflict between standards and specifications, the governing order of priority shall be:
 - This specification
 - Referenced Standards and codes
 - All lines should correspond to ISO-standard.
 - Contract is based upon codes, standards and regulations, which are validate the time the contract is signed.
 - All relevant changes in standard so regulations must be complied with even if they are changed after the placement of the order. The Supplier must inform the Customer immediately should this occur. Temporary regulations do not have to be complied with.
 - Anything, which meets not the codes, standards and regulations above, has to be listed and has to be added to the offer.
 - The unit will be inspected at the site of the manufacture. The function, performance and conformity with all relevant safety regulations will be inspected and assessed.
 - On installation, before any formal acceptance the supplied equipment will be tested according to the function and performance.

1. SCOPE OF DELIVERY

The scope of the delivery includes:

- Units described in the specific system requirements including all necessary controls and instrumentation.
- The complete mechanical and electrical installation.
- The connections to all the necessary utilities, exhaust, and waste lines necessary for its operation (**manufacturers** to specify)
- All piping and cabling of the units(s) itself.
- Wiring and cable run: all wiring and cable run is part of the supply. **manufacturers** will supply the main power switches to be located in correspondence to the electrical and control cabinets delivered by the equipment supplier (**manufacturers** to specify)
- Pneumatic system: the supplier is to foresee the pneumatic system from the take-off point placed in the proximity of the machine. The supplier is asked to indicate the number and location of the machines to be connected to the main pneumatic system and the fore seen consumption.
- All internal contacts of the supplied equipment for the required utilities.
- Unload on site of the equipment: the supplier is required to define all the necessary handling devices required to the unloading operation. The supplier will inform at least 4 weeks in advance the day of delivery and the list of required handling devices.
- Assembly operation: the required consumable, the internal transportation, the assembling tools and the required personnel are part of the supply.
- A complete set of commissioning spare parts.
- All special tools necessary for use and maintenance of the supplied equipment.
- A complete set of two years spare parts should be listed, quoted and offered as option.
- All test activities as specified in this document.
- Training in the use and maintenance of the equipment.

- A complete set of documentation as specified in his document.

1.INSTALLATION, COMMISSIONING AND TESTS

General

- The contractor must specify for each piece of equipment the guaranteed performance and the guaranteed system performance. These values will be tested during the acceptance tests.
- In addition the functionality described in the user requirements and detailed in the system specifications will be tested.

Factory Acceptance Test(FAT)

- The contractor will perform a Factory Acceptance Test (FAT), which will be fully documented and witnessed jointly by manufacturers & Representative.
- The FAT includes a full check-up of the complete system (control system, change of parts, instruments, etc.).
- The Supplier must submit a detailed description and time schedule for the FAT to the Customer for approval.
- The FAT can only start once all the foreseen documents have been produced by the manufacturers to representative.
- If additional test should be necessary because of major function failures, the Customer expenses (travel and lodging) must be carried out by the Supplier.
- Shipment will only be accepted after successful test approval.

Installation and Commissioning

- By manufacturers/suppliers

Site Acceptance Test (SAT)

- This test will be carried out once the commissioning will be completed. The scope will be to verify the performance and the functionality of the system integrated with the other factory systems.
- The test will be carried out to verify the system response with the expected productivity of the system.

System Acceptance Criteria

The system acceptance will be reached if:

- During SAT and FAT the required functionality, performances and system reliability are met.
- The functionality described in the User Requirement Specifications and in the System Specifications is verified and met
- All the documentation agreed has been delivered

1. QUALIFICATION/ VALIDATION

The system installation must be accepted by the Indian, European and American authorities.

The supplier should demonstrate:

- To be ISO-9001 certified or its equivalent
- To have experience in FDA qualified projects
- A strong Quality Assurance capability in software development, according to GMP.
- Capability and organization to follow the project according to a quality plan
Major attention must be given to the documentation to be developed in the different project phases (design, realization, installation, commissioning, testing).
- The complete list of the documentation required is to be in accordance with the FDA

qualification requirements.

- The qualification plan of the system will be handed out to the supplier according to an agreed time schedule.
- On this time schedule, there will be indications, when IQ and OQ protocol will be ready.
- The offer has to include the cost for a qualification according to FDA-requirements.
- Time schedule for IQ/OQ execution will be developed by manufacturer/supplier together with the supplier.
- Suppliers personnel used for IQ/OQ must be well trained and experienced. This should be documented.
- The on-site test run performed by the Supplier might become part of the Installation Qualification.
- Main IQ/OQ steps such as calibration must be performed and documented in accordance to a
- SOP approved by PVVI
- OQ can only start after IQ approved by PVVI
- Installation qualification (IQ) will be carried out by PVVI with manufacturer/supplier during FAT and installation phase.
- Part of the operational qualification (OQ) will be carried out by PVVI with manufacturer/supplier during commissioning, and SAT phase.

1. TRAINING

The supplier is to include the personnel training activities as under.

- Operator/supervisor training
- Managers training
- Electrical maintenance training
- Mechanical maintenance training
- Electronic and software maintenance training

The contract or is to specify the personnel background needed for each of the operators maintenance.

1. GUARANTEE

- The System must be guaranteed including all the sub-systems and components for a period of 2 years.

2. DOCUMENTS TO BE DELIVERED BY THE MANUFACTURER/SUPPLIER

Two copies , in the English language, of the following documents must be provided

- P&ID diagrams.
- Operating Instructions Manual(s), including operating panel and safety operation warnings.
- Maintenance Instructions Manual(s).
- Assembly and Installation Manual(s).
- Instrumentation and Calibration Manual(s).
- Troubleshooting list.
- Component list.
- Calibration certificate for each instrument installed in the equipment.
- Certificate of materials used for constructing those parts in contact with the product stream(s).
- Official approval document and manufacturing inspection protocol.
- Welding procedures and welding certificates: boroscopic examination and X rays. Interior of

pipng will be purged with 99.996% pure argon before and during welding work. Submit argon purity certified.

- Qualification certificates of the technical staffs who have worked in welding and assembling the equipment shall be available on request.
- Biological compatibility certificates of all non-metallic materials in contact with process streams (such as diaphragms, gaskets, O-rings, seals, couplings, etc.).
- Safety. The Manufacturer/supplier should provide the Customer with all legal documents related with safety issues regulated by the official agencies of the country where the equipment is built.
- PLC communication protocol.
- Control panel documentation, identifying instrument connections.
- PLC basic programming software.
- Programming interface for configuration.

The scope of these documents will be clearly defined during the negotiation of the contract.

3. VALIDATION

- All specified documents should be delivered at the Customer's site at least two months before the installation of the equipment so that they can be used in preparing the Validation Protocols.
- After installation of the equipment at Customer's site, complementary Installation and Operational Qualification (IQ, OQ) tests would be performed by manufacturers technical staff and Customer will supervised.

4. SPARE PARTS

The manufacturers should provide as part of the quotation is to proposed spare parts for at least two years' operation.

Manufacturer's /suppliers qualification

- Trouble free performance of the project for a minimum period of two years from date of commissioning should be guaranteed. Any defect intimated should be attended to and rectified within 15 days of receipt of such communication within guarantee period. The guarantee shall include cost of spares and labor.
- User reference list of clients complying with GMP
- At least one site visit by client to the manufacturer establishment

iii) PURE STEAM GENERATOR CAPACITY: 200 Kgs/Hr.

(Pharmalab, Indo German Pharma Engineers, CN Waters, Nilson Nishotech Systems, Evoqua Water Technologies, Siemens, US Filters, Millipore)

The scope of specification covers design, fabrication, assembly, testing and inspection of Pure Steam Generator Plant in compliance with cGMP, packing, transportation, unloading at site, erection, commissioning including transit & erection insurance & hand over of the system including preparation of validation document DQ, IQ & OQ and provide necessary support to client for PQ validation. Scope includes distribution piping and Pressure regulator at the outlet of the Generator to give a consistent pressure of 3 bar g.for facility for 800lt. fermentor having 600lt. working volume along with 80lt. seed fermentor,800lt. blending vessel and inactivation vessels and CIP system

- To produce Sterile and pyrogen free Pure Steam complying with latest EU & USP standards.
- The system shall comprise Non-condensable gas removal arrangement, evaporator & Pre-heaters etc.
- PSG water shall comply as per USP 36.parameters.

- Plant mechanical design shall be based on plant steam @ 6.0 Kg/cm² (g) pressure.
 - The system should be compact in design with all process contact parts in SS 316L and all non-process contact parts in SS 304.
 - All components shall be mounted on a single skid construction of SS304 material.
 - All pressure parts shall be designed as per ASME Sec. VIII, Div.1. Evaporators & pre-heaters shall be designed as per ASME Sec. VIII, Div.1
 - Double tube sheet design shall be employed in all exchangers where fluids on either side are of different specifications viz. PW v/s. Plant steam / Condensate.
 - All purified water / Clean Steam contact surfaces should be electro polished to <0.5 Ra and all external surface shall be matt finished to better than 180 grit.
 - All fittings should be sanitary triclover fittings for quick and easy operation and maintenance.

 - Quality acceptance of Plant includes complying to physical, chemical, microbiological and pyrogen limits.
 - Scope of supply shall include the following but not necessarily limited to the following:
 - No. Feed water pump
 - Non-condensable gas removal arrangement
 - Pre-heaters
 - Evaporators, with separation
 - Sampling arrangement
 - Interconnecting piping including drain header
 - MCC cum PLC based control Panel
 - SS304 skid
 - Equipment with hot surface shall be pre-insulated and clad with SS 304, 14 SWG sheet. (Cladding shall be fully welded type and with externally matt finished to better than 180° grit).
 - All gaskets shall food grade of PTFE or Viton.
 - Manufacturer/supplier will specify with quotation the terms for equipment delivery and the detailed schedule for engineering, manufacturing, and assistance to qualification of the systems.
 - The Manufacturer/supplier should indicate the required utilities and consumptions.
 - Manufacturer/supplier will be responsible for job, materials and/or equipment and documentation supplied by his sub-supplier.
 - Supply will have to be in compliance with this document and with all standards and codes applicable. This does not subtract the Manufacturer/supplier to supply equipment, materials and accessories designed and built properly and perfectly suitable for the specified use and operational conditions.
- Manufacturer/supplier can suggest alternatives to improve supply; this will be highlighted as option in the offer.

TECHNICAL SPECIFICATIONS

UTILITIES

Electricity Power: 400 V ± 10%, 50Hz ± 3%, 3Phase, 4 wires, combined voltage and frequency variation ±10%

Control Voltage: 230 V AC, 50Hz, 1 Ph. To be derived by manufacturer/supplier from 400 V, by powering suitable control transformer.

Feed water - Purified Water Quality.

Conductivity	:	<1.0 µs/cm @ 25°C.
Microbial count	:	<100 cfu/ml.
TOC	:	< 500 ppb.
pH	:	5 – 7
Temperature	:	Ambient

Material of Construction

All Parts in Contact with Feed Water, Product Water and Product Vapours should be in SS 316 & Non Contact part in SS 304 Quality in the plant feed . Pharma Grade Material will be used for non-metallic parts.

Parameter

<u>Plant Steam Temperature</u>	165° C
<u>Plant Steam Consumption</u>	230 Kg/hr
<u>Feed Water Pressure</u>	6.5 Kg/Cm2.
Feed Water Flow Rate (L/Hr)	240

Parameter at the Outlet of PSG

- Steam Pressure Output Pure Steam 200kg/hr
- Conductivity : Less than 1.0 Micro Siemens/CM
- TOC : Less than 500 PPB
- Endotoxin : Less than 0.25 EU/ml
- Microbiological Limit : Less than 10 CFU/100 MI
- Non Condensable Gases : Less than 3.5%
- Dryness fraction : It should not less than 0.9
- Degree of Superheat : Degree of super heat measured in free steam

Atmospheric pressure should not exceed 25 Degree C

- BRV : By Manufacturer/supplier
- FAT and SAT
- IQ (Installation Qualification)
- DQ (Design qualification)
- OQ (Operational Qualification)

GENERAL

Client's Scope

- F. All civil work such as foundations for equipment, housing for the equipment, drains etc.
- G. Power 3% Hz, 3 phase, 3 core and neutral to □Supply cable, 400V ±10%V, 3 Phase, 50 the Control Panels.
- H. Provision of ventilation in the plant room.
- I. Power and water for erection, testing and commissioning of the plant.
- J. Piping beyond the specified battery limits.

Inspection and testing

- A. The system shall be offered for visual performance trials & hydrotest at the manufacturer's premises for inspection by client / authorised representative.
- B. Client / authorised representative shall at all times have an access to supplier's / suppliers sub contractor's workshop to witness fabrication stages.
- C. Internal inspection record shall be maintained by supplier / suppliers sub contractor at all times, if any stages are found lacking by way of proper records, client reserves the right to ask supplier to modify / amend the fabrication stage at no extra cost.
- D. All material test certificates shall be reviewed by client during FAT
- E. Performance trial shall be done at Manufacturer/suppliers premises with qualified water and shall be performed at site after installation.
- F. Testing of the components (column, condenser, pre heater etc.) shall be done as per ASME Sec VIII, Div 1.
- G.** All weld joints on PWservice shall be Orbital welded with proper weld parameters record (voltage, current drawn & rpm of welding head). All internal welds shall be video graphed & recorded by Boroscope.

Guarantee A The system supplied shall be guaranteed for trouble free operation for the period of 12 months from the date of handing over. All defects due to faulty design, material and workmanship and also the performance deficiencies which may come up during guarantee period shall be rectified by the manufacturer/supplier at this cost to the purchaser's satisfaction.

B Performance guarantee runs shall be conducted after one month of continuous trouble free operations.

4. All guarantees from equipment suppliers will be vested in the client. Where damage is caused to any other item by any failure of the item guaranteed, then the guarantee shall also include the costs incurred in rectifying that damage.

Documentation:

- i) P&ID clearly demarcating Battery limit terminations.
- ii) GA Drawing.
- iii) Equipment Layout.
- iv) Foundation Drawings.
- v) Quality Assurance Plan.
- vi) SLD for electrical circuit.
- vii) GA & wiring diagram of control panel.
- viii) PLC control logic, OIU Screens. Operators guide & Ladder logic.
- ix) Piping drawing within battery limit.
- x) Design Qualification Document

During commissioning activities:

- xi) Operation & maintenance manual for all mechanical, electrical & instrumentation items.
- xii) Characteristic performance curves for all pumps, blowers.
- xiii) Calibration certificates for all instruments.
- xiv) Operation & ladder logic details for PLC.
- xv) Internal inspections & acceptance reports.
- xvi) Test & Guarantee certificates.
- xvii) Operation Manual for programming software of PLC & OIU.
- xviii) As built drawings as listed in item B.
- xix) D.Q, I.Q, O.Q, & P.Q documents of items system being supplied by Manufacturer/supplier
- xx) Pure-Steam Qualification: The Manufacturer/supplier to qualify the Steam Quality with respect to the Dryness fraction, its temp and the micro- content, after commissioning of the pure steam generator, at site.

MANUFACTURER/SUPPLIER QUALIFICATION---Trouble free performance of the project for a minimum period of two years from date of commissioning should be guaranteed. Any defect intimated should be attended to and rectified within 15 days of receipt of such communication within guarantee period. The guarantee shall include cost of spares and labor.

- User reference list of clients complying with GMP
- At least one site visit by client to the manufacturer establishment

iv) TFF SYSTEMS WITH HOLD VESSEL

TFF (Tangential Flow Filtration system) system with hold vessel should be of following makes :- (Biozeen , Sartorius, Millipore , Pall and Biotree)

Sl.No.	Description	Quantity (Nos)
1	Tangential Flow Filtration system for Concentration of Inactivated	01

	Bacterial antigens with a 100 L Vessel and membrane area of approx. 6 SQM. 0.2 Micron PESU membrane.	
2	<u>There should be one set fitted with cassette membrane in the instrument for clarification and concentration . Membrane should be of either of PAL OR SARTORIUS OR MILLIPORE COMPANY only with minimum one year warranty . Addition there should be one extra set of clarification and concentration membrane (in brief one fitted in the instrument and one extra)</u>	

-Cassettes must fit into universal Cassattes holder of Tangential Flow Filtration System.

-It should have warranty of 1yr

It includes-

- The vessels and system as per specifications
- Mixer components
- Instruments as mentioned,
- Insulation for the vessels
- Software integration and interconnecting piping

The TFF systems shall be designed along with a feed tank, all necessary piping, components and instruments. These systems shall be designed for concentration & diafiltration applications. The equipment shall be designed considering easy accessibility and maintainability. The TFF systems shall be designed to have minimum product hold up and maximum product recovery. The system should be designed as a manual system .

The systems shall be designed for the following activities:

- Cleaning in place (CIP)
- Empty vessel Sterilization (Vessel Only)
- Concentration
- Diafiltration
- Product recovery/ Harvest
- Cassette Cleaning/ Flushing
- Storage of Cassette in NaOH

Detailed Specification:

Features	System TFF-
Effective filtration shall be	6 SQM
Rotary lobe pump capacity shall be	4 m ³ /hr- r

Material of Construction:

Part	MOC
Process Piping	SS 316L
Non-contact parts	SS 304
Skid / Supports	SS 304

Surface Finish:

Internal finish shall be: $Ra \leq 0.6 \mu\text{m}$, Electro polished

External finish shall be: $Ra \leq 1.2 \mu\text{m}$ or better, mechanically polished.

Feed Tank

The system shall be supplied along with fixed feed tank. Capacity. The volume in the tank shall be measured using Capacitance type level sensor.

Features	TFF system
Working Volume	100 L
Geometric Volume	125L
H/D Ratio Approximate	1:1
Quantity	1

Following accessories shall be provided for the vessel;

- Static spray ball
- Light glass/Sight glass
- Product/Buffer inlet, Retentate, Recirculation port
- Level sensor port
- Rupture Disc
- Pressure sensor shall be provided on the Feed line, Retentate line, Permeate line
- Diaphragm pressure gauge should be provided on the top lid of the vessel.
- The vessels shall be designed with jacket for recirculation of chilled water.

FEED LINE

The following components & Instruments shall be provided in feed line:

- 1) Rotary Lobe Pump: A rotary lobe pump of 4 cu mt / hr. shall be provided to feed the cassettes with process stream at appropriate pressure. The pump shall be equipped with a variable frequency drive to control the speed of the pump. The pump shall be mounted vertically to ensure complete drainage as per drain ability requirements.
- 2) A Pressure Guager shall be provided in the feed line to monitor the pressure and control the Trans membrane pressure (TMP).
- 3) Diaphragm Valves: All valves used in the feed line shall be diaphragm valves.

RETENTATE LINE

The following components & Instruments shall be provided in the retentate line:

- 1) Retentate Return Line: A retentate return line in the system for routing the solution back into vessel during stabilization & TMP maintenance phase.
- 2) Provision for sampling should be provided
- 3) A Pressure Guage shall be provided in the retentate line to monitor the pressure in the feed line and control the Trans membrane pressure (TMP).
- 4) Diaphragm Valves: All valves used in the retentate line shall be diaphragm valves.

PERMEATE LINE

The following components & Instruments shall be provided in permeate line:

- 1) A pressure Gauge shall be provided in the Permeate line to monitor the pressure in the feed line and control the Trans membrane pressure (TMP) manually.
- 2) Diaphragm Valves: All valves used in the permeate line shall be diaphragm valves.
- 3) Cassette Holder

A suitable cassette holder shall be provided for placing cassettes to achieve effective filtration area.

4) A cassette drain tray shall be provided below the cassette holder. The cassette drain tray shall be provided with a drain line.

The tanks attached to the TFF systems shall be designed for semi-automatic operation. The pneumatically actuated valves provided in the clean steam line for empty sterilization & level control in the vessel during concentration/dia-filtration and also valves in the jacket line should be controlled in actuated mode.

Instrumentation Accuracy:

Description / Type	Calibrated Process Range	Accuracy	Product Contact MOCs
Vessel Pressure Gauge, Sanitary	0 to 5 bar (g)	Class 1.6	SS 316L
Level- Capacitance type	0-110 %	± 0.5%	PTFE
Temperature sensor & Transmitter (Simplex RTD with 4-20mA O/P) (Pipe)	0 C to 150	±0.1 % of measurement range	Not in product contact
Pressure sensor	-1 to 5 bar (g)	0.25 %	

Automation control strategy:

The TFF system shall be operated manually.

The system shall be designed for measurement of the following parameters:

- Temperature : 0 -150 °C
- Flow rate : 600 LMH
- Pressure : P1, P2 and P3 Manual – Diaphragm Pressure Guage.
- Level : 10 to 110% in vessel
- Flow Meter : Flow meter and totalizer.

A control panel for display of level, temperature and Motor Speed should be provided.

GENERAL SPECIFICATIONS

Materials & Surface Finishes.

All surfaces in contact with the process solution including the top lid shall be fabricated of SS 316L. All internal and external vessel welds shall be ground smooth, and mechanically polished to match the surrounding finish. Welds shall be free of ripples, pits, undercutting and other surface defects.

Surfaces in contact with product shall be free from pits, burrs, flash, folds, inclusions, crevices, and nicks. All interior surfaces shall be first mechanically polished to a finish of 0.6 micron Ra or better and then electro polished. The interiors shall be then passivated. The vessel exterior shall be mechanically polished to 1.2 micron Ra. All valves used in product contact surfaces shall be 0.6 micron Ra finish.

Drainability Test

Process piping shall be fully drainable. A drainability test shall be performed. The test results shall be documented on the Vessel Inspection Report. Slopes shall be verified after final assembly. Verification shall be documented in the FAT inspection report.

Pneumatic / Hydrostatic Testing

The vessel shall be hydrostatically tested. Hydrostatic testing of the vessel shall be performed and shall be documented in the Vessel Report.

The process lines on the skid and those attached to the vessel shall be pressurized with air and checked. Following installation on site, the process lines shall be checked again to ensure that they are leak proof.

SAFETY REQUIREMENTS

Following features must be provided to protect personnel, product and equipment:

- Emergency stop function on accessible areas
- Adequate and appropriate earthing connections.
- Safety relief valve for utilities such as steam and air.

QUALIFICATION REQUIREMENTS

Equipment shall be qualified for design phase (DQ), installation phase (IQ), Operational phase (OQ) by manufacturer/supplier. Manufacturer/supplier shall support client in execution of DQ, IQ & the OQ qualification phases.

FACTORY ACCEPTANCE TEST (FAT) AS APPLICABLE

The FAT shall be performed. A minimum of steam, chilled water, and compressed air and Purified water should be available for testing the equipment. All testing shall be performed with filtered steam and R.O.purified water.

Following shall be the tests / checks / activities that take place during FAT

Installation Qualification

- Mechanical components Installation checks
- Documentation Checks
- Operation Qualification
- Mechanical components operation check

INSTALLATION / ONSITE TESTS AS APPLICABLE.

After FAT the system shall be disassembled for shipment. The equipment shall be in housed under suppliers' supervision.

Onsite tests:

After installation, the following tests shall be performed by the supplier.

- Installation Qualification Checks (repeated)
- Operational Qualification (repeated)

DOCUMENTATION – AS APPLICABLE.

Following documents are expected from the manufacturer/supplier as part of the supply package as hard copy (One set). Manufacturer/supplier shall supply the document package in phases throughout the life cycle of the project as follows:

Phase 1: Preordering of the equipment

- Equipment layout drawing fitted in the room layout block

Phase 2: Post ordering and prefabrication stage of the equipment

Functional design specification and technical specification that should contain the following:

- P&ID
- BOM with tags and specifications
- System layout

- List of interlocks (if applicable)
- List of input/outputs (I/O List)
- Control Panel GA drawings
- List of media contact surface and its MOC
- Based on the above documents, equipment design shall be evaluated and approved by the User/representative for the fabrication

Phase 3: Fabrication stage of the equipment

Manufacturer/supplier shall provide the FAT protocol at least 1 month in advance of the date of FAT, for the approval by the user/consultant.

Phase 4: Delivery of the equipment

Manufacturer/supplier shall provide the following documents in the delivery package in minimum 2 sets

- Operation and maintenance manuals and preventive maintenance schedule.
- Manuals for components for the bought out items.
- Final as-built drawing for equipment (P&ID and system layout).
- Detailed drawing marking clearly all the necessary dimensions and locations of utilities along with requirement of utilities.
- Spare parts list.
- MOC certificates for all product contact surfaces.
- Weld log and welding verification reports of pipelines.
- Recommended SOPs for operation, cleaning and maintenance of each equipment
- Warranty certificates of equipment.
- Software installation CD with 2 back-ups, wherever applicable.
- Packing List
- IQ and OQ protocols
- I/O Test report

UTILITIES AVAILABLE AT SITE

The following utilizes will be made available prior to installation

UTILITY	TEMPERATURE	PRESSURE	OTHERS
Process Air	Ambient	6-8 bar(g)	
Purified Water		2 bar (g)	
WFI		2 bar (g)	
Clean Steam		2 bar (g)	
Plant Steam	Approx 150 °C	3 bar (g)	
Chilled water Supply	5- 8°C	3 bar (g)	
Cooling Water Supply	25 – 30 °C	3 bar (g)	
Nitrogen		3 bar (g)	
Compressed Air (Oil free) for instruments	Ambient	6 bar(g)	
Electrical			Power Supply 3ph 400V/1ph 230V, 50Hz

manufacturer/supplier qualification

- Trouble free performance of the project for a minimum period of two years from date of commissioning should be guaranteed. Any defect intimated should be attended to and rectified within 15 days of receipt of such communication within guarantee period. The guarantee shall include cost of spares and labor.
- The supplier should give an undertaking that they will be responsible to carry out the preventive maintenance and to repair the equipment during guarantee and post guarantee period.
- The product offered should be supported with AMC for next three years on expiry of the guarantee period. Full details of after sale service offered during the post guarantee period should be furnished along with tender specified.
- Tenderers should submit complete power point presentation on the organization, experience of work, man power with financial details.
- The supplier shall train to the satisfaction of the purchaser one or two technicians at site/factory for operating, servicing and undertaking minor repairs without extra cost.

V) Liquid filling and Bottling line

- a) Linear Bottle Filling & Stoppering Machine ----- One
- b) Bottle Cap Sealing Machine ----- One.
- c) Manual Inspection Table-----One

the above must be of following manufacturers of GMP standards

(Romaco Macofar, Income group and Snowbell machines, Bausch + Strobel, Ambica pvt. Ltd.)

1. Linear Bottle Filling & Stoppering Machine Capacity of 100 ml with 20 mm rubber stopper

Body Diameter	46mm - 66 mm
Height	68mm - 140mm
Output	360 Bottles/hr. (100ml.Bottles)
No. of filling heads	2 Nos.
bottle and stopper	100ml bottle and 20mm rubber stopper

The bottle filling and stoppering station is as monoblock machine to do the combined operation of filling and stoppering in controlled area.

Machines should meet the GMP requirements and the site plan where machines are to be installed can be obtained from the office of Deputy Director Animal Husbandry, Veterinary Vaccine Institute, Ludhiana.

Office Phone no. 0161-2401499, M. No- 092161-46627

Machine construction consists of the following units:

- Bottles moving unit composed of rotary unscrambler.
- Bottles stopping unit at the dosing station.
- Dosing nozzles support unit.(including pre & post gassing)
- Dosing unit composed of a support frame for Filling Syringes/Peristaltic Pumps.
- Stoppering unit composed of vibrator bowl, chute & rocker arm assembly.
- Infeed turntable
- Nitrogen gassing chamber
- Laminar flow

Infeed Turntable

- Integrated Infeed turntable, covered with SS 304 panels independently driven by a AC motor of 0.25HP speed control by variable frequency drive
- From this accumulating table, the bottles should be transferred to the Filling & Stoppering machine
- capable of complete self- emptying.
- No dead spots where Bottles may stand for extended periods of time.

Nitrogen gassing system is required before filling operation and after filling operation.

Dosing Unit

- Filling of product by Filling syringes, Peristaltic Pumps & autoclavable silicon tubes.
- Filling needle up/down movement with synchronism systems.
- Pre and post purging pulsed with flow control, flow meter.

Conveying system for the bottle should be compatible

Stoppering unit:

- Stoppering unit comprised of vibrating bowl feed chute and starwheel.
- Stopper placing unit consists of rocker arm to pick and place the stopper on to the bottles.
- Fork type sensor to monitor the machine in case of lesser no. of stoppers in feed chute
- Vertical manual adjustment provided to match the height of the bottles.
- Further pressing of stoppers on bottles are done by additional rocker arm for full stoppering.

- Suitable for half as well as full stoppering.

Control panels should be compatible with the system:

Technical data

Accuracy of fill	
+/-1% (subject to liquid characteristics)	
Materials	
Machine frame	: SS 304
Exposed metal surfaces	: SS 304
Parts with contact with product	: SS 316 L
Parts with contact with Bottle	: SS 304, UHMWPE
Finishes	
Exposed surfaces	: Matt finished.
Contact surfaces	: Mirror finished (internal electro-polishing available on request)

Alarms and interlocks required as per GMP standard

Change parts required:

- One set of change of parts for 50ml Bottles
- One set of syringes for 50 ml fill volume

On and off switch for
 -Main machine
 -Vibrator
 -Voltage meter
 -Rotary turn table

There should be light indication when machine is on.

INCH Switch

Electrical Installations

- Programmable logic controller (PLC), for monitoring and control of all machine functions thus providing quick access to the machine parameters with password protection.
- Control panel integrated with machine located in machine body.
- Operator console with MMI in SS304 located in front side of the machine.
- Display to show faults, speed of machine and quantity of bottle processed..

- 1) Touch screen color play 5.7” with English language
- 2) UPS System
- 3) Machine start after manual instructions
- 4) Provision of Jog button

UTILITIES:

Electrical energy:-

Total power consumption : Should be specified

Nitrogen pressure: Should be specified by the vendor

Vacuum: Should be specified by the vendor

Documents required

- Design Qualification (DQ)
- GA Drawing
- P & I Diagram
- Schedule with Certificates
- MOC Certificates
- Electrical Diagram & Component list
- Factory Acceptance Test (FAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Instruction & Operational Manual
- Manual for Bought out items

Containment system for Filling Machine:

Verticle laminar flow for cleanroom contamination control cabinet required

Linear Laminar Air flow constructed with SS make AISI 304 for bottle filling & stoppering machine as per GMP standard

Contamination control cabinet

- Contamination Control Cabinet for the machine with Toughened glass supported by SS Frame.
- Equipped with Door interlock sensors.
-

2) **Bottle Cap Sealing Machine** **One**

(100 ml capacity) having following specifications

Body Diameter	46mm - 66 mm
Height	68mm - 140mm
Output	360 Bottles/min. (100ml.Bottles)
seal size	20mm aluminium seal size

With machine materials of SS 304 of matt finish

Basic supply scope

- Infeed turntable
- Sealing station should be made of rotating Bottle base rests, caps sealing rollers and seal holding turrets.
- Vibratory orientor for aluminum plain & flip off seals.
- AC variable drive for the machine.
- Sealing height should be adjustable.
- The seal bowl should be removed & installed without the use of any tool or knobs, it should be provided with automatic locking system.
- Counter for sealed Bottles.
- Transfer system to transfer the sealed bottles to the Inspection table.

Control panel compatible for the system

Safety & Alarms as per GMP standard

Electrical Installations:

- Programmable logic controller (PLC), for monitoring and control of all machine functions thus providing quick access to the machine parameters.
- Control panel integrated with machine located in machine body.
- Operator console with MMI in SS304 located in front side of the machine.
- Display to show faults, speed of machine and quantity of bottle processed.

UTILITIES:

Electrical energy: -

Feeding voltage: 415 V (3 Phase)

Frequency : 50 Hz, 6kW

Power consumption:

Total power consumption: To be specified by the vendor.

Change parts required

- One set of change of parts for 100ml Bottles
- One set of change of parts for 50ml Bottles
- One set of change parts for 20mm plain stopper Aluminium seals
- One set of syringes for 50 ml and 100ml fill volume
- Change in stopper size (vibrating bowl and chute) for 20mm stopper size

Validation Master Plan (VMP):

- Design Qualification (DQ)
- GA Drawing
- P & I Diagram
- Schedule with Certificates
- MOC Certificates
- Electrical Diagram & Component list
- Factory Acceptance Test (FAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Instruction & Operational Manual
- Manual for Bought out items.

Containment system for Cap Sealing machine:

1. **Laminar Air Flow for bottle cap sealing machine a per GMP standard made of AISI 304**
2. **Contamination control cabinet**
 - Contamination Control Cabinet for the machine with Toughened glass supported by SS Frame.
 - Equipped with Door interlock sensors.

3) Manual visual Inspection Table

One

Requirements:

- Illumination tube light for inspection of bottles against black & white background.
- Inline transfer of bottles from the cap sealing machine
- Variable speed of conveyor.
- Easy access for cleaning and maintenance.
- Inspection belt with Black & White Board.
- Mechanical drive element and main motors are covered with removable SS304 panel.
- Uniform surface finish on all covers & guards.

MOC

- MS structure Machine frame with cladding :SS304
- Infeed Turntable: 304
- Conveyor: SS304

1. Controls

- Control panel located below the turntable.
- ON/OFF switch for conveyor on the machine table.
- Illumination tube lights for the Bottles.

2. Make of Components used in Electrical System

Sr. No.	Electrical Components	Make
1.	Motor	Rotomotive / Bonfiglioli
2.	Contactors	Siemens
3.	Transformer	AE
4.	MCB	Siemens

3. Documents required:

- Design Qualification (DQ)
- GA Drawing
- P & I Diagram
- Schedule with Certificates
- MOC Certificates
- Electrical Diagram & Component list
- Factory Acceptance Test (FAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

- Instruction & Operational Manual
- Manual for Bought out items

NOTE :

1. The company has to submit reference list of ten reputed organization along with three completion certificate of national / international organization
2. Company should have a turnover of average at least 10 crores per year and in the last three years the total turnover should be 30 crores
3. Company will be responsible to demonstrate one of the functioning machines in vaccines manufacturing unit and will organize the visit of TWO technical experts if required to the manufacturing unit or in installed unit

(VI) Chiller

One

the above must be of following manufacturers of GMP standards

(Reynold india pvt ltd, Freezotech , blue star, Thermo Scientific)

- Unit should be used for cooling 800 Lit and 80 Lt fermenter and inactivation vessel between -5 to 10 C
- Temperature Range of the chiller should be from -5° to 50° C
- Cooling capacity at 20°C 230V 50 Hz should be 8,500 Watts
- Heating Capacity should be 6 kW @ 460 V or better
- Temperature Stability required is +/- 0.1° C
- The condenser should preferably be Air cooled; water cooling option should also be available.
- The unit should have a suitable reservoir made of SS316 with heating and cooling partitions.
- The unit should have a centrifugal pump made of 316 SS which operates at 50 Hz with the below specifications;
10 gpm @ 20 psid (37.9 lpm @ 1.4 bar
- The unit should contain a flow control with flow read out that allows adjusting the flow to meet the application requirements & monitor the flow rate to application and set flow alarms via controller.
- The controller should house an LCD multi line alphanumeric display.
- The controller should also have an LCD level indicator to identify the level of internal fluid.
- Anti Drain back feature should be available that prevents fluid from flowing back to the reservoir when the chiller is installed.

- Auto Refill feature should be available that ensures automatic refilling from a facility-supplied water source to ensure that the proper fluid level is maintained.
- Analog and digital communications option should be available for remote operation, monitoring and data logging. It should include sensor port which allows for remote temperature control of an application when used with a remote sensor (optional accessory)
- Should include a Full flow filter to ensure clean fluid to protect the application and maximize recirculation system life
- Should have an easily removable condenser grill and air filter allow for quick and simple cleaning to optimize chiller performance and maximize component life.
- Should house an integrated funnel fill for easy filling.
- A Drain port should be located at the back of the unit for operator convenience.
- Design should allow two sides of the unit to be blocked, allowing placement in a corner while maintaining full refrigeration performance.
- Noise level of the unit should be less than <58dBA
- The unit should come with standard lockable casters.
- There should be external piping and fittings from chiller to external reservoir to process and back, top up line for reservoir and drain line from the reservoir, non return valve, solenoid valve, pressure gauges etc. And piping to the all the vessels of use along with the return piping.
- Civil/structural work included in the installation and commissioning .
- Compliance - CE
- 2 years warranty.