BHARAT IMMUNOLOGICALS & BIOLOGICALS CORPORATION LIMITED (BIBCOL)
(A Govt. of India Undertaking)
OPV SITE, CHOLA, BULANDSHAHR(U.P.)

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Last Date of submission of tender: 18.12.2019 at 02.00 P.M.
Date of opening of Technical Bid: 18.12.2019 at 3.00 P.M.

1. INTRODUCTION:

Bharat Immunologicals & Biologicals Corp. Ltd. (BIBCOL), A Govt. of India Undertaking, under administrative control of Ministry of Science and Technology, located at Village-Chola, Distt- Bulandshahr (UP), about 70Km away from Delhi at Old G.T. Road connecting Sikandrabad to Khurja, has been engaged in manufacturing Vaccine for the last twenty five years with contributing significantly in National Immunization Programme.

2. OBJECTIVE:

BIBCOL invites sealed tenders **from reputed & experienced Manufacturers/Suppliers only** for the supply of **Fermenter as per Annexure 'A'** .

3. INSTRUCTION TO TENDERERS:

Tenders should be submitted in two parts separately in two sealed envelopes super scribed as Techno Commercial Bid and Price Bid respectively & two envelops should be kept in large envelop duly super scribed as Bid for the "**Supply of Fermenter - not to be opened before 18.12.2019 at 3.00 P.M.** on the left of top side of envelope addressed to **Associate Vice President (P), Bharat Immunologicals & Biologicals Corporation Limited, (A Govt. of India Undertaking), Oral Polio Vaccine Plant, Village-Chola, Bulandshahr - 203203 (UP). If you wish to send your offer through courier, please prefer only DTDC and write PIN Code 203 001.**

4. TECHNICAL BID:

Techno Commercial bid should essentially consists of Name of firm, address, type of establishment along with certificates, contact person name, list of clients, GST registration details, PAN, Production capacity, Annual Turnover along with detail technical specifications of the product with catalogue, etc**.**

5. PRICE BID:

Price Bid will essentially consist of item wise basic cost, duties, taxes and packing and forwarding charges, freight charges, insurance charges and other terms and conditions etc. Techno-Commercial bid will be opened on the due date and price bid will be opened after evaluation of Techno Commercial Bid by the committee constituted by competent authority. The date of opening of price bid will be separately communicated to successful bidders and the price bid of technically rejected party will not be opened but will be returned to unsuccessful bidders.

6. EMD:

Bidder has to submit EMD in the form of DD for rupees 50,000/- (Rupees Fifty thousand only) in favour of BIBCOL at Bulandshahr (UP) **alongwith Technical bid**. **(Firms registered under Micro Scale Industry & Small Scale Industry are exempted from EMD).**

Terms and conditions

1. The quantity mentioned is tentative and it may be increased or decreased.

2. There is no prescribed form for submitting the quotation in this case and the bidder may use his own letter head or quotation form for this purpose.

3. **The prices are to be quoted for delivery F.O.R. OPV Site, Village Chola, Bulandshahr-203001 (UP)**. Taxes, other Govt. levies and packaging forwarding transit insurance etc. must be clearly indicated. Your quotation will be treated as firm offer and must remain open for the period of at least three months. No revision, amendment or withdrawal will be permissible during this period.

4. BIBCOL may visit at your plant to see the facility before issuing the actual order.

5. No figures or words should be overwritten. Incorrect figures or words should be scored out and rewritten under your signatures.

6. Supplies must be of first class quality and in accordance with our specifications only.

7. You are at liberty to be present or authorize a representative to be present at the opening of the bids at the specified time and date.

8. BIBCOL reserves the right not to accept the lowest or any tender or part there of without assigning any reason.

9. Quotations received after the due date and time will not be accepted.

10. Incase of any dispute, the decision of the Managing Director, BIBCOL shall be final and binding on both the parties.

11. No post-tender communications will be entertained unless it is solicited in writing.

12. The Court of Jurisdiction will be at Buland Shahr(UP)

Read and accepted the terms and condition:

Name: Designation:
Company name:
Address:
Telephone No: Mobile No.
E-mail:

Annexure 'A'

1.0 NAME OF EQUIPMENT:

Fermenter – 13 - 15L (GV) Quantity-01 No.

2.0 PURPOSE:

This equipment is used for bacterial fermentation.

3.0 PROCESS DESCRIPTION

A. CIP/SIP of the Fermenter will be done and it is kept under sterile air pressure till further use.
B. Culture is inoculated into pre-sterilized media (*in-situ* steam-sterilized) and grown at appropriate temperature, pH, DO and other specific conditions to get optimum growth.
C. The Fermenter content is transferred to downstream processing.
D. CIP and SIP is carried out after harvesting.

4.0 TYPE OF MATERIAL HANDLED:

The material handled is live culture grown in appropriate media.

5.0 DESIRED OUTCOME:

The Fermenter shall be hermitically sealed to maintain sterility during the fermentation.

6.0 OPERATIONAL DUTY

Continuous duty.

7.0 PROCESS AND OPERATIONAL CONTROL REQUIRMENT

A. There shall be provision for auto CIP / SIP of the system after each use.
B. Temperature control to be provided for ESIP, FSIP, Fermentation temperature controls.
C. Foam level detection and auto addition of antifoam during fermentation shall be available.
D. Necessary pH controls, *i.e.* alkali/acid auto additions to be provided.
E. MFC shall be provided for controlling air and O_2.
F. Vents filter assembly with condenser and heater.
G. Automation control shall have following controls at minimum –
   - pH and DO controls using with selectable cascades of following wherever applicable.
   - Airflow
   - Oxygen
   - RPM
   - Feed
   - Acid
   - Alkali
H. Pressure transmitter shall be available to measure pressure and the system shall to have Back Pressure Control valve for Pressure control.
I. Five number of peristaltic pumps (variable flow rates with digital display) required for dosing of Acid / Alkali, Inoculum of seed, Antifoam feed, Nutrient.
J. Continuous level measurement shall be provided.
K. Detachable baffles to be provided.

8.0 SPECIFICATION OF MATERIAL OF CONSTRUCTION OF MAIN EQUIPMENT AND PARTS

Manufacturing compliance	ASME/BPE protocols
Design	1 vessel on one skid
Direct Product Contact Surface	SS 316 L
Non-Contact Surface	SS 304
Jacket Design Pressure	4.1 bar g. and full vacuum
Shell Design Pressure	6.2 bar g. and full vacuum
Jacket	SS 304
Insulation	Hot and cold insulation shall be provided. Thickness to ensure skin temperature of NMT 55° C while heating (with an ambient temperature of 30°C) and to avoid condensation during cooling temperatures of 2 to 8°C.
Insulation cladding	SS 304 – 2 mm thick, Welded with sand blasted finish
Seals, Elastomers / Diaphragms / Gaskets, etc.	Teflon lined EPDM / Equivalent (USP Class VI), which can withstand for operating conditions for continuous duty
Working Volume	10 Lts.
Gross Volume	13 - 15 Lts.
H/D Ratio	2.5:1
Agitation Requirement	1. Top-driven agitator to be provided with variable frequency drive with encoder feedback (Vendor shall design the agitator considering the process requirement) 2. Magnetic Coupling 3. Ruston type impeller 3 Nos. 4. Agitator speed: 100-1200 RPM with ±5% variation. 5. Minimum Stirring volume: 3 Lts. 6. Double-mechanical seal, steam sterilizable with sterile condensate circulation for lubrication and cooling or Magnetic Coupling.

Piping Interior	All Stainless-Steel process piping in contact with process material must have an interior finish of Ra <0.6 Microns after electro polishing
Pumps	1. A Total of 5 Pumps need to be included. 2. Dosing pumps programmable – 3 Nos. 3. 2 Additional Spare Variable speed pumps – 0–10 volts / 4–20 mA, 220 Volts 4. Computer control for addition of feed using a weight-based feed control system. 5. And the second for profile / program-based glucose addition.
Liquid Addition Bottles	Liquid addition bottles – 1 L x 3 Nos. (for acid / alkali, antifoam) and 5 Liter X 1 No. (for nutrients), Autoclavable bottles with necessary filters and outputs.
Illumination	Fixed integrated in head plate
Pressure gauge	Required for vessel and Jacket
External	Mechanical polish to ≤0.8 Ra
View glass	Rectangular Vertically mounted with upper level close to maximum working volume
Harvest line	CIP-able and SIP-able
Sampling port	CIP-able and SIP-able
Membrane valves	ITT / Burkert / Gemu valves

9.0 INTEGRATION OF EQUIPMENT

Suitable to integrate CIP skid	
CIP	
Design	CIP-ready with spray balls
Automation	Automated; Recipe-based
CIP system	An independent skid mounted CIP system, to be interfaced with the controller of the fermenter and used as required, might be added by user
SIP	
Source	Via Steam and Electrical heating with minimal steam requirement for sterilization of addition ports, sampling port and harvest port.
Automation	Automated; recipe-based
Sterilization temperature	121°C

10.0 REQUIREMENT OF COMPONENTS

Nozzles / Ports requirement on Vessel (With Components)	
Top Dish (Tori spherical)	1. Vent Filter with single cartridge in housing (TC) 2. Port for Diaphragm Pressure Gauge. (TC) 3. Manhole with swing arm & lifting action for lid. 4. Sanitary safety valve with piping routed to safe location (TC) 5. Port for Pressure Transmitter (TC) 6. Lifting lugs for vessel 7. Antifoam probe port 8. Antifoam addition port 9. CIP & SIP port with spray ball – 2 nos. 10. No. of Lines (ports) 6 Nos. • Media / Inoculum, • Nutrient, • Acid / Base • Anti-foam • Spare • Fully resterilizable (contained) line – 2 Nos., 1 for Inoculum / Nutrient-1 and second for Nutrient 2. 11. Push Valve based addition lines – 4 Nos. for acid, alkali, anti-foam and 1 spare line. 12. Baffles 4 Nos., removable
Side (On Vertical portion of shell)	1. pH Sensor, DO Sensor & Temperature Sensors - inclined Position (*in situ* sterilizable) with blind sockets 2. Temperature sensors to measure jacket, inlet, outlet and drain temperatures 3. Sampling valve (*in situ* sterilizable) of Novaseptic 4. Jacket Inlet and Outlet. 5. Air inlets with sparger & without sparger
Spare ports	For Probes -1 No. On Lid – 2 Nos.
Bottom Dish (Tori Spherical)	1. Flush bottom valve. 2. Level transmitter (Differential pressure based)
Sparger	
Type	Ring Sparger with holes at bottom
CIP/SIP of Sparger Line	automated; CIP/SIP
MFCs	Separate MFCs for all gases required with bypass lines to rotameters
Rotameters	Required for all the gases below

MFC - Air	Flow rate – Minimum 2.0 vvm, desirable 3 vvm. (min. process flow rate = 0.1 vvm)
MFC - O_2	Flow rate - Up to 0.5vvm (min. process flow rate =0.1 vvm)
N2 Rotameter with valve	Needed only for calibration purposes.
Exhaust	
CIP/SIP	automated
Condenser	Spiral Condenser, Required
Heater for Condenser filter	Required Filter heater with heating blanket

11.0 SPECIFIC REQUIREMENT

1. Vent filter housing with ONLY one single filter cartridge required.
2. The Sterilization setting range shall be considered between 80 & 150^{o}C.
3. Inoculation to be done by using 1–2 litre glass bottle. Necessary aseptic connection with provision for sterilization to be provided.
4. Sampling valve shall have aseptic connection for *in-situ* sterilization along with Aseptic Sampling bottle & kit.
5. Provision for individual port CIP & sterilization in auto mode.
6. Weep hole to be provided for insulation.
7. Guards to be provided for all the motors.
8. All hot & cold insulation for interconnecting piping within the skid and in between vessel & skid to include in the scope.
9. Vessels to be designed & made as per ASME / BPV Section VIII Div I.
10. All Seals, Elastomers / Diaphragms / Gaskets, etc. to comply with USP Class VI or equivalent (*e.g.* EPDM).
11. Piping and Pipe fittings shall be designed & made as per ASME BPE -2007.
12. Motors / Drives should be Energy Efficient EFF-1 only.
13. Separate Control Transformer in the panels for UPS connectivity.
14. All electronic components / hardware should be designed for operation at 40°C, RH – NMT 65%.
15. In the skid panel, electrical and operation control shall be provided.
16. There shall be a provisions to test the integrity of vent filter in position, valve test, pressure-hold test, ESIP, FSIP, harvesting & sampling.
17. The fermenter and skid piping shall be designed to perform CIP/SIP in position. Accessories required for the same shall be provided along with the Fermenter with necessary controls.
18. All electronic monitoring devices and HMI mounted on the control panel shall comply with IP-65 code.
19. The Vendor's quote shall include commissioning spares required during commissioning & qualification.
20. The vendor shall quote maintenance spares requirement for **two years** with a separate BOM. Commissioning spares shall be identified and delivered along with the equipment for installation & commissioning free of cost. In case of any component failure during IC the same shall be used for saving on time. Post qualification the balance commissioning spares shall be taken back.

12.0 AUTOMATION AND CONTROL REQUIREMENT

Panel & Controls:

- Fermenter Control – PLC based, Completely Automatic System with HMI at Control Panel and SCADA for remote operation & data logging.
- Primary operation shall be done from SCADA with HMI being parallel redundant system.
- The SCADA shall be connected to a printer.
- PLCs & Software used for SCADA & HMI shall be as per cGMP practices.
- The operation screen at both HMI & SCADA shall be same for ease in operation.
- Provision for SCADA installation & operation from out of Fermenter (remoter operating terminals) room/office to be considered.
- Provision for running individual sequences in Auto from SCADA & HMI.
- SCADA & HMI shall be provided with display of all running step information / messages for operator to respond.
- SCADA software shall to have the provision for comparing batch to batch parameters (minimum of 3 batches at a time)

Transmitter	Dedicated transmitter for DO and pH sensor, with RAW signal transfer.
pH	With acid / alkali addition, Feed. User defined sequence and limits
DO	Cascaded with Sparger Air, O_2, agitation and feed along with User defined sequence and limits.
Back pressure	Controlled through control valve at exhaust line
Temperature	Electrical heating (No steam requirement to be there for regular running of the fermenter)
Foam	Controlled using Foam Sensor and Peristaltic pump.
PLC /Control	Industry standard HARD PLC Controller
	Industry standard WAGO I/O Modules
	Individual control panel with HMI (Touch screen) shall be considered for each Fermenter
	One Controller (& Utility Console) needed per fermenter system
	A suitable UPS to be included for the controller.
	System standard equipped for Redundancy on pH, DO and Temp.
Other controls	
Weight based feed control system	The system must have the necessary I/O's, interface, control loop and load Cells.
CASCADE	All pH / DO Cascade loops are user definable / selectable based on the time to time requirement.
Data management	
SCADA	Licensed SCADA Software
Online	Required for all parameters (user selectable)

Data export	Required (preferably in Excel and PDF formats)
Data archival	Required
Event log	Required
Alarm log	Required
User login	Multiple user logins with access levels
Programming	Programs writing and editing for various parameters
Edit	Editing of programs / recipes in control

	Display	Control	Record	Print	Alarm
Agitator RPM	Y	Y	Y	Y	Y
Process Temp (Vessel)	Y	Y	Y	Y	Y
Sterilization Temp. exhaust, inlet, drain temperatures)	Y	Y	Y	Y	Y
Process pH	Y	Y	Y	Y	Y
Process DO	Y	Y	Y	Y	Y
Pressure	Y	Y	Y	Y	Y
MFC & Mass flow PV and % opening	Y	Y	Y	Y	Y
BPC valve feed back	Y	Y	Y	Y	Y
Foam	Y	Y	Y	Y	Y
Level	Y	Y	Y	Y	Y
All set points, user & parameter relevant that batch detail as relevant to particular cycle.	Y	Y	Y	Y	NA

13.0 UTILITIES AVAILABILITY

Following utilities are available at site:-

A. Compressed Air @ 4.0–6.0 kg/cm^2 g
B. Chilled Water at 6.0-8.0 ^{0}C & 2.0 kg/cm^2 g
C. Purified water/WFI – in Containers
D. Pure Steam @ 2.5–3.0 kg/cm^2 g
E. Power Supply – 3 Ph, 415 V; 50 Hz (±5 %) & 1 Ph, 230 V AC, 50 Hz (±5%)

14.0 GMP REQUIREMENT

1. Proper slopes shall be maintained in all the pipelines to ensure complete drainability. Minimum of 1:100 slopes to be maintained.
2. All connections shall be of sanitary type triclover fittings. No screwed or flanged fittings are acceptable in the process pipelines.
3. All components shall be easily accessible for maintenance purpose.
4. Sanitary Steam Traps shall be provided at appropriate locations for SIP purpose.
5. Dead legs shall be avoided in the equipment & pipelines. Maximum of 2D is allowed wherever unavoidable.
6. Multiport block valves shall be provided wherever applicable. (Process feed, bottom discharge).

15.0 SAFETY REQUIREMENT

Product safety
1. An emergency button shall be provided to stop / hold the process, in case of an emergency. 2. No asbestos products shall be used /exposed anywhere in the equipment.
Personnel safety
1. All hot surfaces shall be insulated so that the temperature of external body is maintained not more than 55°C (With an ambient temperature of 30°C). 2. Rupture Disc / Safety valves shall be provided at appropriate locations with alarming facility. 3. No component of the equipment shall generate noise in excess of 80 dBA measured at 1 metre distance from the component.

16.0 MAINTENANCE

All components shall be easily accessible for maintenance.

17.0 DOCUMENTATION REQUIREMENT

All types of documents required with the equipment as operational and maintenance manual, DQ,IQ, PQ, Equipment data sheet, MOC certificates, Vendor test certificates, FAT protocol, Instrument and electrical drawings, Software validation document, service support agreement, etc.

18.0 PREFERABLE MAKES

High Efficiency Motors	Siemens / ABB
PLC / HMI / SCADA	Allen Bradley / Siemens / Emerson
VFDs	Allen Bradley / ABB / Siemens
Temperature Sensors	E&H / Rosemount / Negele
pH / Conductivity Sensor	Mettler Toledo / E&H / Rosemount / Equivalent
DO Sensor	Mettler Toledo / E&H / Rosemount / Equivalent
L T Switch Gear / Contactors / Relays etc.	L & T / Siemens / Telemechanique / Equivalent
Sampling Valves	Novaseptic
Product Contact Valves (Transfer Lines)	Novaseptic / ITT / Gemu / Burkett
Services - Valves	Saunders / Avcon

19.0 COMPLIANCES

ASME/BPE protocols

20.0 OTHER REQUIREMENT

The manufacturer/supplier of the equipment shall train the operators for operation and maintenance crew for maintenance.

ANNEXURE 'B'

COMPULSORY TO BE FILLED BY MANUFACTURER

Sl. No.	Industry registered under	Please tick whichever is applicable (Copy of certificate may also be attached with offer)	Caste of entrepreneurship (SC/ST/OBC/GEN)	Whether entrepreneurship is belongs to Male/Female
1.	Micro Scale Industry			
2.	Small Scale Industry			
3.	Medium Scale Industry			
4	Heavy Industry			