

(Autonomous Institute under the Ministry of Health & Family Welfare, Govt. of India, New Delhi) Ph.0423 2231852, Fax - 0423-2231655, Email: purchasepiic@gmail.com

#### ADVERTISEMENT TENDER NOTIFICATION FOR THE SUPPLY, INSTALLATION & COMMISSIONING OF STABILITY CHAMBERS

#### BID REF.NO.PIIC/ADVT/001/2023-24 DATED 14/08/2023

#### **INTRODUCTION OF THE COMPANY**

The Institute started functioning as Pasteur Institute of Southern India, on 6th April 1907 and the Institute took a new birth as The Pasteur Institute of India (registered as a society under the societies Act 1860) and started functioning as an autonomous body under the Ministry of Health and Family Welfare, Government of India, New Delhi since the 10th of February, 1977. A governing body manages the affairs of the Institute. The Institute is a charitable organization working on a no profit-no loss basis.

Pasteur Institute of India (PIIC), Coonoor is one of the leading organization which are into the production of Antirabies Vaccine and DPT group of Vaccines for the EPI programme of Govt. of India.

The scope of supply involved is detailed in the subsequent paragraphs and is precise to the extent possible.

#### **SCOPE OF SUPPLY**

The scope of supply is Supply, Installation and Commissioning of Stability Chambers as per User Requirement Specification mentioned in Annexure I as detailed below:-

S.No	Equipment Stability Chamber	Facility Requirements (LXBXH)	Temperature & RH Requirements	Quantity
01.	Cold Room	3350 mm x 3350 mm x 3050 mm	5°C±3°C	01 No
02.	Ambient Room	2440 mm x 3350 mm x 3050 mm	$\frac{22^{\circ}C \pm 3^{\circ}C}{(60\% \text{ RH} \pm 2\% \text{ RH})}$	01 No
03.	Hot Room	2440 mm x 3350 mm x 3050 mm	$37^{\circ}C \pm 1^{\circ}C$ (60% RH ± 2%RH)	01 No

#### **DETAILS REGARDING IMPORTANT DATES ARE AS FOLLOWS:**

S.No.	Description	Schedule
i.	Closing date & time for receipt of Tender	15/09/2023, 15.00 Hrs
ii.	Time and date of opening of Technical Bids	15/09/2023, 15:30 Hrs
iii.	Pre-Bid meeting Details:	<b>Date and Time: 25/08/2023</b> , 11:00 hrs VENUE: PASTEUR INSTITUTE OF
		INDIA, COONOOR
iv.	Venue of opening of Tender	PASTEUR INSTITUTE OF INDIA, COONOOR.



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The bids are invited for the **Supply, Installation and Commissioning of Stability Chambers** as per specification and other details given in the bid document. All bidders who qualify the eligibility conditions as detailed in the bid document are eligible to participate except in the case of firms who are blacklisted / barred by competent agencies in participation and award of such contracts.

#### 1. <u>Instruction to Bidders</u>

The bids are invited on **two bid system**. The bid will constitute a Technical bid and Financial bid. Technical bid and financial bid to be submitted in separate sealed envelope. Technical bid cover along with EMD cover & financial bid cover should be kept in a separate single cover. Both the covers should be put in a single cover which should be superscribed as **"Tender for the Supply, Installation and Commissioning of Stability Chambers" due on 15/09/2023 by 15.00 Hrs."** without fail. **The Tender Reference Number should also be mentioned on the cover without fail.** The covers containing the tenders should be sent to us on or before the due date. The tenders must reach the "**Director, Pasteur Institute of India, Coonoor**" not later than 15.00 Hrs on 15/09/2023. The financial bid of the technically qualified parties will only be opened for financial evaluation.

- 1.1 Pre Bid Meeting will be held on 25/08/2023 at Pasteur Institute of India, Coonoor at 11.00 AM
- 1.2 Bidders can send their queries and clarifications to the address given in clause 1.2 or by email purchasepiic@gmail.com, up to three days prior to the due date of bid submission.
- Bids shall be addressed by designation only to: The Director Pasteur Institute of India, Coonoor – 643 103 Nilgiris, Tamilnadu
- 1.4 Due date of submission of the bid will be on 15/09/2023, upto 15:00 Hrs. The technical bid will be opened on the same day at 15:30 hrs. The financial bid of only those bidders who are qualifying the minimum eligibility criteria & technical specification will be opened. The date & time of financial bid opening shall be intimated separately to the technically qualified parties.
- 1.5 The tenders once submitted shall remain valid upto 120 days and the tender will not be entitled to withdraw the tenders or to suggest any change therein within the said period.
- 1.6 Tenders should be strictly sent in a sealed manner. Tender sent through Email/Fax will not be accepted.
- 1.7 Technical specification of three products should be submitted separately for easy evaluation.



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- 1.8 List of clients with contact address, phone no, email id to whom similar Stability Chambers supplied and installed by the tenderer in the previous two years should be sent as per Annexure VIII along with the Technical bid without fail.
- 1.9 All pages of the tender should be duly signed by the authorized signatory with company seal.
- 1.10 Non compliance of terms and conditions by successful tenderer will lead black listing and suspension of the tenderer.
- 1.11 PIIC reserves the right to award the contract to deserving parties either in full or in parts. The decision of PIIC is final and unquestionable.
- 1.12 In case of imported products, OEM or Authorized Seller of OEM should have a registered office in India to provide after sales service support in India. The certificate to this effect should be submitted.
- 1.13 The bidder should not be under liquidation, court receivership or similar proceedings should not be bankrupt. Bidder to upload undertaking to this effect with bid.
- 1.14 Bidders shall quote only those products in the bid which are not obsolete in the market and has at least 3 years residual market life i.e., the offered product shall not be declared end-of-life by the OEM before this period
- 1.15 Data Sheet of the product offered in the bid should be submitted along with the bid documents to verify the Data Sheet with the product specifications offered. In case of any unexplained mismatch of technical parameters, the bid is liable for rejection.
- 1.16 Details of service after sales to render services for equipment to be furnished with complete address, telephonic numbers, emails etc. It shall be the responsibility of seller to ensure that service centers are available to cater to the areas where supplies are made within reasonable distance from where the service calls can be handled. Details of toll free numbers, mobile number for service call and online registration of service requested also to be provided.

#### 2. Mode of submission of Tenders:

- a. Tender Cost/Tender fee: NIL
- **b. EMD:** NIL
- c. Performance Security: As per terms and conditions class '3'



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#### 2.1 DOCUMENTS TO BE SUBMITTED ALONG WITH THE TECHNICAL BID

- a. User Requirement specification as per Annexure I
- b. Bid Data Sheet as per Annexure II
- c. Detailed specifications, along with Make, Model No. etc
- d. Specifications Compliance/Data Sheet as per Annexure V
- e. Manufacturer Authorization Form as per Annexure VII
- f. List of companies and cGMP companies to whom similar type of Stability Chambers were supplied, installed during the previous Five years as per Annexure VIII (Purchase order copies and satisfactory completion certificates should be enclosed without fail)
- g. Bid Security Declaration Form as per Annexure IX
- h. Past three years Profit and Loss account and balance sheet certified by a Chartered accountant (only main pages should be enclosed).
- i. Latest IT return statement
- j. Undertaking that the bidder is not under liquidation, court receivership or similar proceedings, nor bankrupt.
- k. After sales service details as per 1.17 of the tender.

#### **2.2 DOCUMENTS TO BE SUBMITTED ALONG WITH THE FINANCIAL BID**

- a. Financial bid
- b. Schedule of Requirement as per the format enclosed in Annexure III
- c. Format of submission of bid as per Annexure IV
- d. Bid form as per the format enclosed in Annexure VI

#### 3. Minimum Eligibility Criteria

- 3.1 The Tenderer has to be a manufacturer or authorized dealer of the Schedule equipment (OR) has to be an authorized Indian representative / agent of the original equipment manufacturer/s of the Scheduled equipment. In case of authorized dealer / agent, the Manufacturer's Authorization certificate/Form (as shown in Annexure VII of the tender document) from the Manufacturer to be attached.
- 3.2 The bidder must have proven and demonstrable experience in supply of scheduled equipment.
- 3.3 The bidder must have supplied, installed and commissioned similar to the type as specified in the schedule during the last five financial years as per the schedules mentioned above. Completion certificates / Handing over report/ Proof to be provided.
- 3.4 Net worth of the company shall be positive during the last three financial years. The balance sheet, profit and loss account for last three financial years certified by a Chartered Accountant shall be submitted.
- 3.5 The Average Annual Turnover of the tenderer for the last three financial years certified by a Chartered Accountant shall be submitted.



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### 4. <u>COUNTRY OF ORIGIN</u>

- 4.1 All goods and services to be supplied and provided for the contract shall have the origin in India or in the countries with which the Government of India has trade relations.
- 4.2 The word "origin" incorporated in this clause means the place from where the goods are manufactured, produced or processed or from where the services are arranged.
- 4.3 The country of origin may be specified in the Price Schedule

#### 5. <u>Bid Evaluation</u>

Bid determined to be substantially responsive will be checked by PIIC for any arithmetic errors and the same will be corrected as follows:

- a. Where there is a discrepancy between the rates in figures and in words, the rates in words will prevail.
- b. Where there is a discrepancy between the unit price and the total price resulting from the multiplying the unit price by the quantity, the unit price as quoted shall prevail.
- c. The tenderer supplying indigenous goods or already imported goods shall quote only in Indian Rupees.

#### 6. <u>Tender Price & Documents</u>

- a. The price of the goods should be quoted strictly in **Indian Rupee** on **FOR PII COONOOR basis** with the detailed breakup of ex-factory/ex-showroom/exwarehouse/off-the-shelf, as applicable, including all taxes and duties like GST, Custom Duty etc. already paid or payable on the components and raw material used in the manufacture or assembly of the goods quoted ex-factory etc. or on the previously imported goods of foreign origin quoted ex-showroom etc;
- b. Any sales or other taxes and any duties, which will be payable on the goods in India, if the contract is awarded to the tenderer.
- c. Charges towards Packing & Forwarding, Inland Transportation, Insurance (local transportation and storage) would be borne by the Supplier from their warehouse to the PIIC for a period, including 3 months beyond date of delivery, Loading/Unloading and other local costs incidental to delivery of the goods to their final destination as specified in the List of Requirements and Price Schedule.
- d. The charges for Insurance (local transportation and storage) would be extended and borne by the Supplier from warehouse to the PIIC for a period including 3 months beyond date of delivery

#### 7. <u>DISTRIBUTION OF DISPATCH DOCUMENTS FOR CLEARANCE/ RECEIPT</u> <u>OF GOODS</u>

7.1 The supplier shall send all the relevant dispatch documents well in time to the Purchaser/Consignee, to enable the Purchaser/Consignee receive the goods in terms of the contract.



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- 7.2 The usual documents involved and the drill to be followed in general for this purpose are as follows.
- 7.3 Within 24 hours of dispatch, the supplier shall notify PIIC, and others concerned if mentioned in the contract, the complete details of dispatch and also submit the following documents as per the instruction of purchaser:
  - a. Three copies of supplier's invoice showing contract/PO number, goods description, quantity, unit price and total amount.
  - b. Two copies of packing list identifying contents of each package, if any
  - c. Inspection certificate issued by the nominated Inspection agency, if any.
  - d. Certificate of origin, if any
  - e. Insurance Certificate, if any
  - f. Manufacturers/Supplier's warranty certificate & In-house inspection certificate.

#### 8. <u>EXEMPTIONS/FORMS</u>

- a) PIIC will not be giving any duty exemption, GST Concession form.
- b) The tenderers who are currently registered with National Small Industries Corporation (NSIC) MSME shall be eligible for exemption from EMD. In case the tenderer falls in these categories, they should furnish copy of the valid registration details as the case may be.

#### 9. <u>REJECTION OF BIDS</u>

Notwithstanding the above conditions, PIIC reserves the right to accept or reject any offer, and to annul the tender process and reject all offers, at any time prior to award of Contract without thereby incurring any liability to the affected Bidder or Bidders or any obligations to inform the affected Bidder or Bidders of the grounds for PIIC action.

#### 10. NOTIFICATION OF AWARD

- 10.1 Prior to the expiry of the period of offer validity prescribed by PIIC, PIIC will notify the successful Bidder by email, registered post/ courier, that his offer has been accepted. The purchase order will be issued to the successful bidder. No correspondence will be entertained by PIIC from the unsuccessful Bidders.
- 10.2 Upon selection of the successful bidder (technically qualified L1 party) PIIC will promptly notify the same to successful Bidder through a Purchase Order.
- 10.3 EMD's of unsuccessful bidders will be returned only after finalizing the L1 Party and EMDs of technically non-qualified bidders will be returned after financial bid opening.



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#### **TERMS AND CONDITIONS**

#### 1. **DEFINITION:**

- 1.1 For the purpose of this contract, the following words and expressions shall have the meaning hereby assigned to them except where the context otherwise requires:
  - a. "PIIC" means Pasteur Institute of India, Coonoor, which expression shall unless excluded by or repugnant to the context include PIIC's representative.
  - b. "Contractor/ Bidder" Means successful lowest bidder.
  - c. "Earnest Money Deposit" (EMD) means Bid Security/ monetary or financial guarantee to be furnished by a tenderer along with its tender.
  - d. "Performance Security" means monetary or financial guarantee to be furnished by the successful tenderer for due performance of the contract placed on it. Performance Security is also known as Security Deposit.
  - e. "Consignee" means the organization/person to whom the goods are required to be delivered as specified in the Contract. If the goods are required to be delivered to a person as an interim consignee for the purpose of dispatch to another person as provided in the Contract then that "another" person is the consignee, also known as ultimate consignee.

### 2. <u>PAYMENT SCHEDULE:</u>

Payment shall be made as specified in the contract in the following manner:

Sl.No	Stage	Percentage (%)
<b>SI.No</b> 1.	Stage After supply, successful Installation and commissioning of submission of all documents such as DQ,IQ, OQ & PQ protocol including MKT calculation, soft and hard copies, Instrument calibration certificate traceable to NABL with Master calibration certificate, Third part validation certificate and validation document along with the used instruments calibration and master traceability certificate. Warranty Card &	<b>U</b> · · ·
	Final Acceptance approved by authorized PIIC's	
	Representative	

#### 3. <u>PERFORMANCE SECURITY</u>

- 3.1 Successful tenderer will have to furnish Performance Security @ 3% of the total contract value in the form of a Demand Draft drawn in favour of "The Director, Pasteur Institute of India" payable at any Nationalized Bank in Coonoor or by NEFT to our bank account directly.
- 3.2 Failure of the successful Bidder to furnish the required Performance Security shall constitute sufficient grounds for considering not issuing contract on their behalf and the next L2 vendor will be considered for awarding contract.



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- 3.3 Forfeiture of Performance Security: In case, the Contractor/ Bidder fails to complete the work, as per the commitment in the tender, PIIC, without prejudice to rights and remedies available under the contract, shall forfeit and en-cash the Performance Security submitted by the tenderer.
- 3.4 Non compliance of terms and conditions by successful tenderer will lead to suspension for participation of any tenderer for a period of one year.
- 3.5 The Performance security will be refunded to you only after 3 months from the date of satisfactory completion of installation and submission of documents.

#### 4. <u>ADDITIONS/DELETIONS</u>

- 4.1 PIIC shall have the right to direct in writing for changes, additions, modifications or deletions in the items shown in Annexure I or any part of the work and to request in writing additional work in connection therewith and the Contractor/ Bidder shall comply with such directions.
- 4.2 The Contractor/ Bidder shall not make any deviations, alterations, additions, to or omissions from the work shown/described and awarded to the Contractor/ Bidder except through and with proper approval of PIIC.

#### 5. <u>TIME SCHEDULE</u>

- 5.1 The day of commencement of delivery period will be reckoned from the date of issue of Purchase order.
- 5.2 The material shall be delivered and installed at site within 3-4 weeks from the date of issue of purchase order or as per delivery terms mentioned in the Purchase Order.
- 5.3 The Final Acceptance Certificate shall be issued on completion of the entire scope of supply by the vendor.
- 5.4 The supply and installation shall be carried out with all due diligence and as per the time schedule specified above. In case of any delay/default, of the Contractor/ Bidder to adhere to the agreed time schedule, PIIC shall recover the liquidated damages from the Contractor/ Bidder at the rate of 0.5% (Zero point Five percent) of the total amount of fee per week of delay of any activity subject to a maximum of 3% (Three percent) of the total order value. However, if there is a purposeful delay by the Contractor/ Bidder, PIIC reserves all rights to terminate the contract and get the full work executed at his risk and cost.

#### 6. EXTENSION OF TIME

6.1 To adhere to the above mentioned time schedule the Contractor/ Bidder shall provide on demand necessary documents, information and certificates/ undertakings to PIIC.



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Any delay in supplying the requisite documents and delay due to any other cause beyond the control of the Contractor/ Bidder shall be considered for grant of extension of time. If the Contractor/ Bidder require extension of time, they shall intimate in writing to PIIC within 3 days of the occurrence of such hindrance/delay, along with proper documents. PIIC after satisfying itself about the reasonableness of grounds may grant extension of time, if it is justified and communicated the same in writing. Whenever such extension of time is granted, it would be without prejudice to the rights of PIIC for any penal action to the extent of the delay attributable to the Contractor/ Bidder. Any extension of time granted as stated above shall neither entitle the Contractor/ Bidder to any claim for increase in their fees nor shall it release him from any of the obligations under the said agreement.

#### 7. <u>ABANDONMENT OF WORK</u>

- 7.1 If the Contractor/ Bidder/ supplier abandons the work for any reason whatsoever or becomes incapacitated as aforesaid, PIIC shall forfeit/en-cash the Performance Guarantee. PIIC shall be at liberty to make full use of all or any of material supplied by the Contractor/ Bidder/ supplier. The Contractor/ Bidder/ supplier shall also be liable to refund all the charges paid to him up to date plus such damages as may be assessed by PIIC including the recovery of liquidated damages.
- 7.2 Provided, however, that in the event of the termination of the agreement under proper notice as provided in the clause hereinafter, the Contractor/ Bidder shall be liable to refund any excess payment made to him over and above which is due to him in accordance with the terms of this agreement, for the work executed by him till the date of termination of agreement.

#### 8. WARRANTY

8.1 The bidder shall give warranty for a minimum period of one year of the equipment from the date of final acceptance certificate from PIIC.

#### 9. DETERMINATION AND RESCISSION OF TERMS & CONDITIONS

- 9.1 When the Contractor/ Bidder have made himself liable for action under any of the clauses aforesaid, PIIC shall have powers. To rescind the agreement to engage another Contractor/ Bidder to carry out the balance work debiting the Contractor/ Bidder the extra amount, if any, so spent for getting the balance work done. In such case, the Performance Security submitted by the tenderer will also be forfeited.
- 9.2 This amount would be in addition to the recovery of liquidated damages.



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#### 10. <u>GENERAL</u>

- 10.1 The Contractor/ Bidder shall be fully responsible for the technical soundness of the material and also ensure that the material is supplied as per the specifications.
- 10.2 The Contractor/ Bidder hereby agrees that the charges to be paid as provided herein will be in full discharge of functions to be performed by him and no claim whatsoever shall be made against PIIC in respect of any proprietary rights or copy right on the part of any other party relating to plans, models and drawings.
- 10.3 The Contractor/ Bidder shall indemnify and keep indemnified Pasteur Institute of India against any such claims and all costs and expenses paid by PIIC in defending such claims to be borne by the Contractor/ Bidder.
- 10.4 The Contractor/ Bidder hereby agrees that PIIC shall have the right to take out any of the activities, which in the opinion of PIIC is not being performed by the Contractor/ Bidder with due diligence, and within the agreed time schedule, and which can be performed independently. The fees or the expenses incurred shall be debited to the Contractor/Bidder.

#### 11. ARBIRATION

- 11.1 All disputes or differences whatsoever arising between the parties out of or relating to the Contractor/ Bidder services, meaning and operations or effect of this contract or the breach thereof shall be settled by arbitration. Matters to be arbitrated upon shall be referred to a sole Arbitrator, to be appointed by PIIC and the award made in pursuance thereof shall be binding on the parties. Such arbitration shall be governed by the Indian Arbitration and Conciliation Act 1996.
- 11.2 The place of arbitration shall be at **Udhagamandalam**.

#### 12. FALL CLAUSE

The prices charged for this particular service/supply under the Contract by the supplier/service provider shall in no event exceed the lowest price at which the supplier/service provider sells the service/supply of identical description to any person(s)/organization (s) including the Purchaser or any Department of the Central Government or any Department of a State Government or any statutory undertaking of the Central or a State Government, as the case may be, during the period till performance of all Supply Orders placed during the currency of Rate Contract is completed



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## 13. STATUTORY VARIATIONS

In case of statutory variation in regard to taxes/levies, within the stipulated date of completion of individual agreement, the same shall be paid or recovered as per the actual against documentary proof. However beyond this period PIIC will take advantage of any reduction in taxes/levies but will not pay extra on account of increase in taxes/levies.

---sd/----DIRECTOR



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# ANNEXURE - I

USER REQUIREMENT SPECIFICATION			
	STABILITY CHAMBER – Cold Room (L x B x H) ( 3350 mm x 3350mm x 3050 mm)		
Facility Requirements	STABILITY CHAMBER – Ambient Room (L x B x H) (2440 mm x 3350mm x 3050 mm)		
	STABILITY CHAMBER – Hot Room (L x B x H) (2440 mm x 3350mm x 3050 mm)		
Temperature & RH Requirements	Cold Room (Temperature: $5^{\circ}C \pm 3^{\circ}C$ ) - 01 Unit Ambient Room (Temperature: $22^{\circ}C \pm 3^{\circ}C$ ) -01 Unit (60% RH $\pm 2\%$ RH) Hot Room (Temperature: $37^{\circ}C \pm 1^{\circ}C$ ) -01 Unit (60% RH $\pm 2\%$ RH)		

#### 1. PROCESS REQUIREMENT:

There is a need of Stability chambers with controlled temperature for stability testing of Drug intermediates, Drug substance, Final Bulk vaccines and Drug product i.e., BPDT, BPTT, BPP, Td, DTP and TT varies with the time under the influence of variety of environmental factors such as temperature and light and enables recommended storage conditions.

#### 2. EQUIPMENT REQUIREMENT:

- 2.1 Cold room Refrigeration unit contains indoor, outdoor working unit and stand by unit to maintain the temperature of 5°C±3°C by eco-friendly gas 134a/404 a.
  Ambient room- Refrigeration unit contains indoor, outdoor working unit and stand by unit with humidification, dehumidification unit and heating unit to maintain the temperature of 22°C±3°C (60% RH±2%RH) by eco-friendly gas 134a/404a
- 2.2 Evaporator shall be designed forced air circulation to maintain uniform air flow with required temperature
- 2.3 **Hot room** Heating unit contains working unit and stand by unit with humidification and dehumidification unit to maintain the temperature of 37°C±1°C(60%RH±2%RH)



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N		Internal Measurements		
Name of the rooms	Length	Breadth	Height	
Cold Room	3350 mm	3350mm	3050mm	
Ambient Room	2440mm	3350mm	3050mm	
Hot Room	2440mm	3350mm	3050mm	

#### 3.1 **Specification of the Material of Construction**

- 3.2 Double walled, PUF insulated, leak proof modular panels with arrangements for easy assembly at on-site.
- 3.3 Modular vertical panel thickness PUF shall be 80 mm (Inside stainless steel (SS304) and outside powder coated GI
- 3.4 Ceiling panel thickness PUF shall be 100 mm (Inside stainless steel (SS304) and outside powder coated GI
- 3.5 Floor panel thickness PUF shall be 100 mm with Aluminium Chequered sheet
- 3.6 Door panel thickness PUF shall be 100 mm with double flush view glass (B x H) 350mm x 650mm (Inside stainless steel (SS 304) and outside powder coated GI.
- 3.7 Handle and hinges for positive sealing with lock and key arrangement
- 3.8 Heavy duty door hinges and latches to maintain a secure and uniform seal
- 3.9 SS304 ceiling, wall and floor coving shall be provided.
- 3.10 Controlling System: The equipment shall operate at 380v to 44pv AC 50Hz and suitable MCB to be provided for individual control system.
- The equipments such as cold room, ambient room, hot room suitable HMI/PLC to control all 3.11 the parameters such as operation time delay temperature set point High alarm, low alarm, humidification control, PID and all safety provisions to be incorporated.
- 3.12 LED lights shall be provided with required lumens.

#### 3.13 **Door Access System:**

- 3.14 The door access system shall be provided with password-based control &restricts access of the chamber to unauthorized persons.
- 3.15 Alarms: Audio-visual alarms to Temperature deviations (Both High and Low), door open, component Circuit error & Mains failure, communication failure, Equipment failure, test push button, Individual alarm acknowledge button.
- 3.16 Software Requirements: Software shall not become obsolete up to five years from the date of installation. 21 CFR part 11 Compliance window based communication software of data management.
- 3.17 Password protection authentication shall be provided multi level for setting parameter, audit electronic trails, event logging report, door access report, Auto backup and restore facility.
- 3.18 Software compatible with extension of additional equipment.
- 3.19 Validation Requirements: 55-65 mm port hole with rubber seal to insert sensors for validation purpose. 8-10 point temperature and 8-10 point relative humidity monitoring sensors for on line mapping. Sensors shall be High quality PT-100. The accuracy shall be ±0.25%



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- 3.20 Temperature mapping shall be done as per the regulatory guidelines i.e., cGMP (Mapping at rest & Mapping at dynamic)
- **3.2 Personnel Computer:** Compactable with above all equipments
- 3.2.1 Processor: Intel core i7-8700-cpu @ 3.20Hz 3.19Ghz
- 3.2.2 Operating system: Windows 10 Pro
- 3.2.3 I/O port: Front side mic/ head set port to front-side to back.
- 3.2.4 HDMI port, stereo Line-in.
- 3.2.5 Networking: Integrated Gigabyte Ethernet Intel
- 3.2.6 RAM memory: DDR4-16 GB RAM.
- 3.2.7 Upgradable RAM port.
- 3.2.8 CD/DVD drives
- 3.2.9 System type 64 Bit.
- 3.2.10 Monitor -LED.
- 3.2.11 Monitor resolution: 1920 x1080
- 3.2.12 Monitor Size: 21.5 inch.
- 3.2.13 Storage : 1 TB (hard drives capacity)
- 3.2.14 Keyboard: USB enhanced
- 3.2.15 Mouse: USB optical 2 button scroll.
- 3.2.16 Speaker : Built in speaker integrated sound speaker
- 3.2.17 Printing on local or network printer.
- 3.2.18 Ethernet communication compatible with PLC

#### 3.3 Printer

- **3.3.1** Black and white laser printer
- **3.3.2** Network provision

**4.0 cGMP REQUIREMENTS:** All components shall be easily accessible for cleaning Maintenance purpose.

#### **5. SAFETY REQUIREMENTS:**

#### 5.1 Temperature Safety:

- **5.1.1** Safety devices for Temperature overshoot & undershoot, Delay, timer & overload Protection circuit to safeguard the compressor.
- **5.1.2** High temperature safety relay and thermostat which cut off supply of heaters in case of temperature undershoot, when error is rectified, safety device is reset automatically.
- **5.1.3** Low Temperature safety relay and thermostat which cut off supply of cooling system in case of temperature undershoot. When error is rectified safety device is reset automatically.



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#### 5.2 Personnel Safety:

- 5.2.1 The door can be opened from inside without key even if it is locked outside.
- 5.2.2 An Emergency hooter switch (Bell) is provided inside the chamber to draw attention incase of emergency.

#### 5.3 Component Safety:

- 5.3.1 MCB to cut off over current supply.
- 5.3.2 Surge arrester to filter electrical noise.

#### 5.4 Warranty:

**5.4.1** The warranty period shall be minimum one year and Warranty card should be provided with duration.

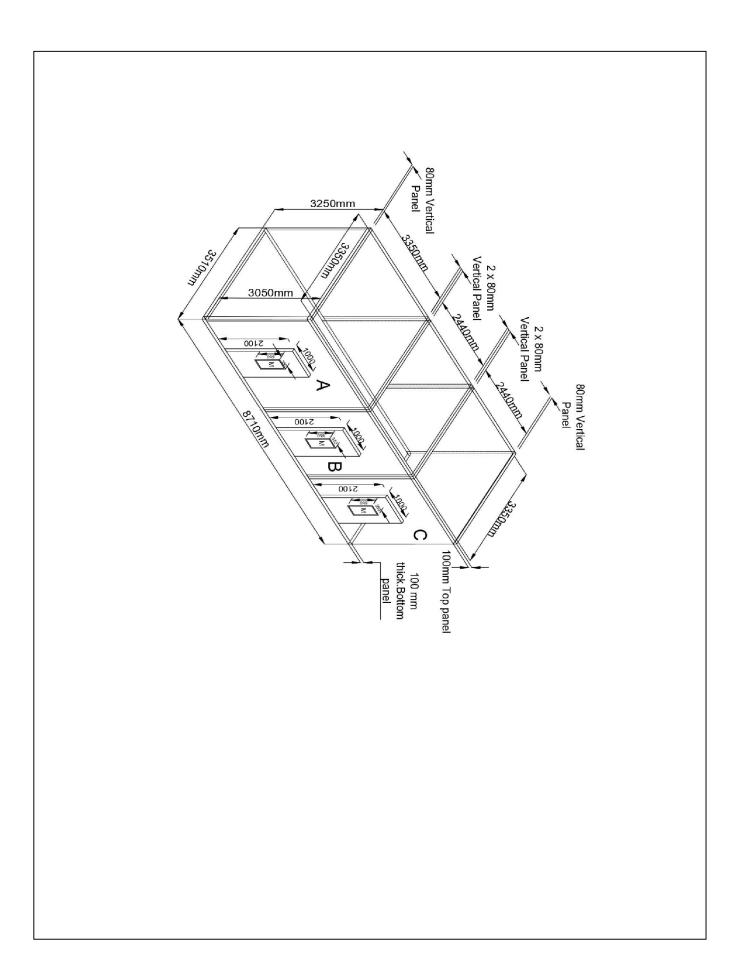
#### **6 DOCUMENT REQUIREMENTS:**

- 6.1 Operation & Maintenance Manual 2 Sets
- 6.2 DQ, IQ, OQ & PQ protocol including MKT calculation, soft and hard copies to be provided.
- 6.3 Instrument calibration certificate traceable to NABL with Master calibration certificate
- 6.4 List of spare parts: All Bought out components test certificates shall be provided
- 6.5 Application Notes: Third party Validation certificate and validation document should be provided along with the used instruments calibration and master traceability certificate.



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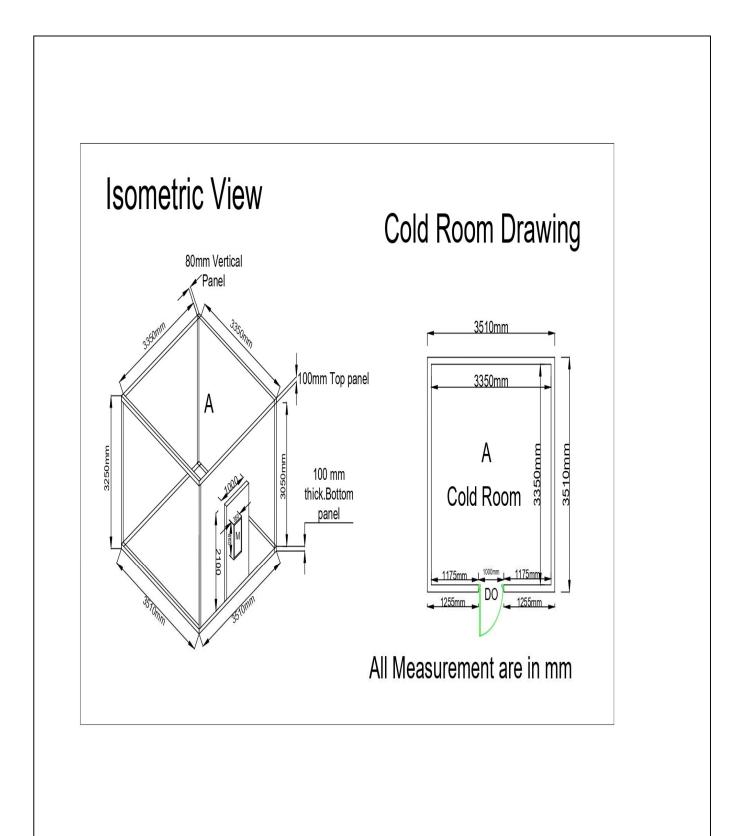
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S.No.	. Description Internal Rooms Measure			ements
		L	В	Н
1	Room – A (Cold Room)	3350 mm	3350 mm	3050 mm
2	Room – B (Ambient Room)	2440 mm	3350 mm	3050 mm
3	Room – C (Hot Room)	2440 mm	3350 mm	3050 mm
4	Door With View Panel	1000 mm	100 mm Thickness	2100 mm
5	Double flush glass panel	350 mm	12 mm Thick toughened glass	650 mm
6	Vertical panel	Modular <sub>J</sub>	panel board	80 mm (Thickness)
7	Top & Bottom Panel	Modular <sub>j</sub>	panel board	100 mm (Thickness)
8		ision on bottom modular panel d top portion		03 mm (Thickness)

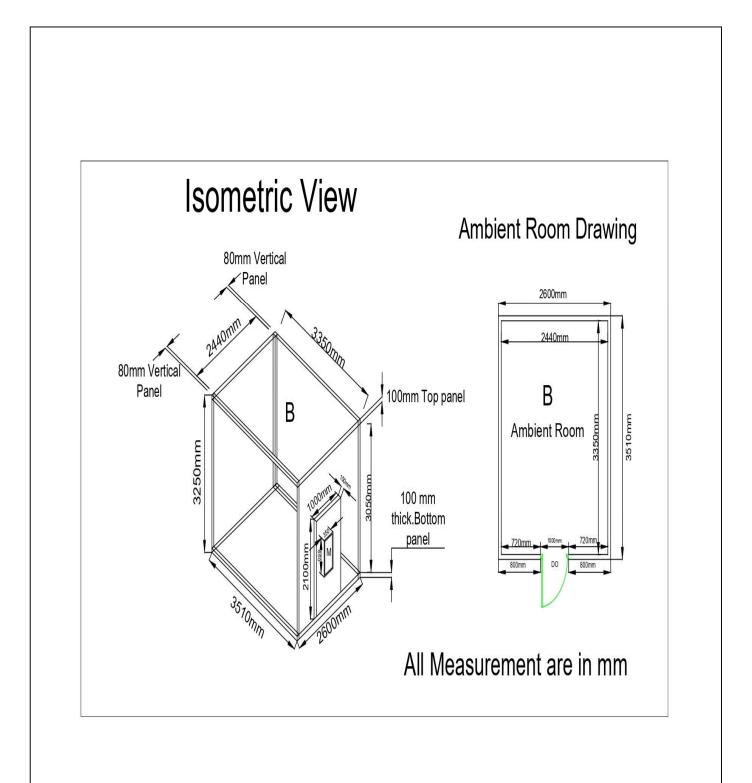


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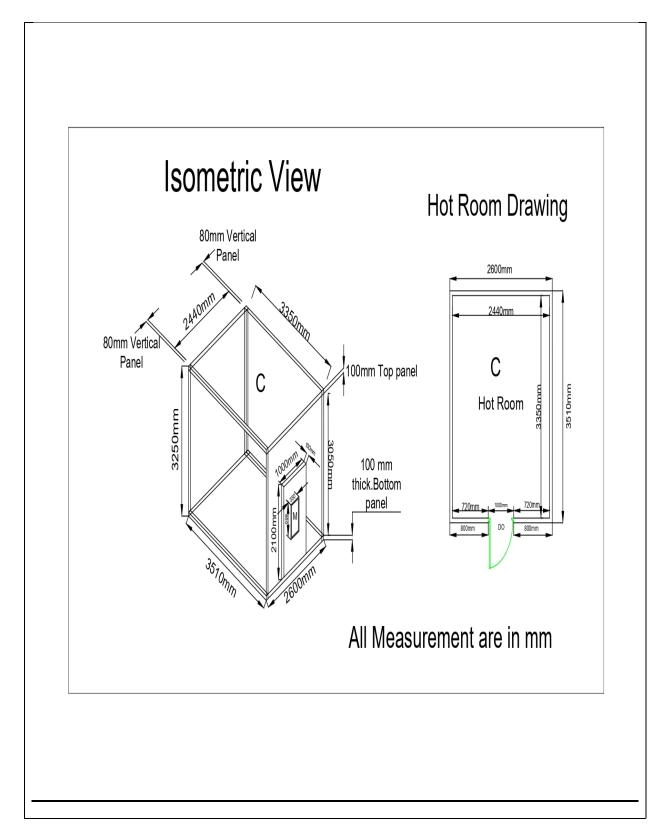


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## <u>ANNEXURE – II</u>

#### (to be submitted in the supplier's letter head) BID DATA SHEET

S.No	Description	Details
01.	Tenderer Quotation No. and date	
02.	PIIC Tender reference number	BID Ref. No. PIIC/ADVT/001/2023-24 dated 14/08/2023
03.	Due date for submission	15/09/2023 UPTO 15:00 HRS
04.	Name & Address of the bidder	
05.	Year of establishment	
06.	Type of the firm	Public Ltd/Pvt Ltd./Partnership/Regd. firm
07.	Contact Phone-Office	
08.	Mobile Phone No.	
09.	Email	
10.	PAN Number	
11.	GST Number	
12.	Contact person name	
13.	Delivery Period	
14.	Warranty	
12.	Copy of PAN of Directors/Partners	Attached/Not Attached
13.	Latest IT return statement	Attached/Not Attached
14.	Past three years P & L, Balance Sheet	Attached/Not Attached
15.	All pages of bid document duly sealed and signed by the authorized person	Attached/Not Attached
16.	Power of Attorney/Authorization to sign the bid	Attached/Not Attached
17.	Manufacturer's authorization letter	Attached/Not Attached
18.	EMD Declaration Form	Attached/Not Attached
19.	List of Pharmaceutical companies and cGMP companies to whom the stability chambers	Attached/Not Attached
	supplied & installed in the last two years	



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#### (to be submitted in the supplier's letter head along with Financial Bid)

### ANNEXURE –III

#### PART A

#### SCHEDULE OF REQUIREMENT

Sl.No.	Description of the item	Unit Rate (Rs)	GST	Total Amount with GST (Rs)
01.	Stability Chamber – Cold Room			
02.	Stability Chamber – Ambient Room			
03.	Stability Chamber- Hot Room			
	Total Amount in (Rs)			

NB: Unit price shall be written in figures and words

Total Tender price in Rupees:

In Words:

#### Note:

If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.

Name: \_\_\_\_\_

Business Address:

Place: \_\_\_\_\_\_ Signature of Tenderer \_\_\_\_\_

Date: \_\_\_\_\_ Seal of the Tenderer \_\_\_\_\_



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#### (to be submitted in your letter head along with Financial Bid)

### ANNEXURE – IV

S.No.	Description	Details
01.	Tenderer Quotation No. and date	
02.	PIIC Tender reference number	BID Ref. No. PIIC/ADVT/001/2023-24 dated 14/08/2023
03.	Due date for submission	15/09/2023 UPTO 15:00 HRS
04.	Name & Address of the bidder	
05.	Year of establishment	
06.	Type of the firm	Public Ltd/Pvt Ltd./Partnership/Regd. firm
07.	Contact Phone-Office	
08.	Mobile Phone No.	
09.	Email	
10.	PAN Number	
11.	GST Number	
12.	Contact person name	
13.	Unit rate	
14.	GST (No concessional certificate will be issued by PIIC)	@
15.	Packing & Forwarding if applicable	
16.	FOR Institute	YES / NO
17.	If not quoted for FOR Institute freight charges applicable	
18.	Delivery period	



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19.	Warranty	
20.	Payment terms	100% after supplying of items through NEFT to your bank A/c
21.	Copy of MOA/Partnership deed/ Registration	Attached/Not Attached
22.	Copy of PAN of Directors/Partners	Attached/Not Attached
23.	Latest IT return statement	Attached/Not Attached
24.	Past three years P & L, Balance Sheet	Attached/Not Attached
25.	All pages of bid document duly sealed and signed by the authorized person	YES/NO
26.	Power of Attorney/Authorization to sign the bid	Attached/Not Attached
27.	Manufacturer's authorization letter	Attached/Not Attached
28.	Bid Declaration Form	Attached/Not Attached/NA



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(to be submitted in the supplier's letter head and to be enclosed with Technical Bid)

#### SPECIFICATION/COMPLIANCE – STABILITY CHAMBER

#### S.No. Details Description Cold room- Refrigeration unit contains indoor, outdoor working unit YES/NO 01. and stand by unit to maintain the temperature of 5°C±3°C by ecofriendly gas 134 a /404 a Ambient room – Refrigeration unit contains indoor, outdoor working 02. YES/NO unit and stand by unit with humidification, dehumidification unit and heating unit to maintain the temperature of 22oC±3oC (60% RH $\pm 2\%$ RH) by eco-friendly gas 134 a /404 a Evaporator shall be designed forced air circulation to maintain 03. YES/NO uniform air flow with required temperature Hot room - Heating unit contains working unit and stand by unit 04. YES/NO with humidification and dehumidification unit to maintain the temperature of $37^{\circ}C \pm 1^{\circ}C$ (60% RH±2% RH) Double walled, PUF insulated, leak proof modular panels with 05. YES/NO arrangements for easy assembly at on-site. Modular vertical panel thickness PUF shall be 80 mm (Inside 06. YES/NO stainless steel (SS 304) and outside powder coated GI 07. Ceiling panel thickness PUF shall be 100 mm (Inside stainless steel YES/NO (SS 304) and outside powder coated GI Floor panel thickness PUF shall be 100 mm with Aluminium 08. YES/NO Chequered sheet 09. Door panel thickness PUF shall be 100 mm with double flush view YES/NO glass (B x H) 350mm x 650mm (Inside stainless steel (SS 304) and outside powder coated GI 10. Handle and hinges for positive sealing with lock and key YES/NO arrangement 11. Heavy duty door hinges and latches to maintain a secure and uniform YES/NO seal 12. SS 304 ceiling, wall and floor coving is provided YES/NO 13. Controlling System: The equipment shall operate at 380v to 440 v YES/NO AC 50Hz and suitable MCB should be provided for individual control system 14. The equipments such as cold room, ambient room, hot room suitable YES/NO HMI/PLC to control all the parameter such as operation time delay temperature set point High alarm, low alarm, humidification control, PID and all safety provision to be incorporated LED lights to be provided with required lumens. YES/NO 15.

#### ANNEXURE –V



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16		MEGNIO
16.	The door access system shall be provided with password-based control & restricts access of the chamber to unauthorized persons	YES/NO
17.	Alarms: Audio-visual alarms for temperature deviations (Both High	YES/NO
17.	and Low), door open, component Circuit error & Mains failure,	I ES/INO
	communication failure, Equipment failure, test push button,	
	Individual alarm acknowledge button	
18.	Software Requirements: Software shall not become obsolete up to	YES/NO
10.	five years from the date of installation. 21 CFR part 11 Compliance	I LS/INO
	window based communication software for data management	
19.	Password protection authentication shall be provided multi level for	YES/NO
17.	setting parameter, audit electronic trials, event logging report, door	I LO/I (O
	access report, Auto backup and restore facility	
20.	Software compatible with extension of additional equipment	YES/NO
21.	Validation Requirements: 55-65 mm port hole with rubber seal to	YES/NO
	insert sensors for validation purpose. 8-10 point temperature and 8-	
	10 point relative humidity monitoring sensors for on line mapping.	
	Services shall be high quality PT-100. The accuracy shall be $\pm 0.25\%$	
22.	Temperature mapping shall be done as per the regulatory guidelines	YES/NO
	i.e. cGMP (Mapping at rest & Mapping at dynamic)	
23.	Personnel Computer: Compactable with above all equipments	
24.	Processor: Intel core i7-8700-cpu @ 3.20Hz 3.19Ghz	YES/NO
25.	Operating system: Windows 10 Pro	YES/NO
26.	I/O port: Front side mic/ head set port to front-side to back.	YES/NO
27.	HDMI port, stereo Line-in.	YES/NO
28.	Networking: Integrated Gigabyte Ethernet Intel	YES/NO
29.	RAM memory: DDR4-16 GB RAM.	YES/NO
30.	Upgradable RAM port.	YES/NO
31.	CD/DVD drives	YES/NO
32.	System type 64 Bit.	YES/NO
33.	Monitor –LED.	YES/NO
34.	Monitor resolution: 1920 x1080	YES/NO
35.	Monitor Size: 21.5 inch.	YES/NO
36.	Storage : 1 TB (hard drives capacity)	YES/NO
37.	Keyboard: USB enhanced	YES/NO
38.	Mouse: USB optical 2 button scroll.	YES/NO
39.	Speaker : Built in speaker integrated sound speaker	YES/NO
40.	Printing on local or network printer.	YES/NO
41.	Ethernet communication compatible with PLC	YES/NO
42.	Printer	YES/NO
	Black and white laser printer	
43.	Network provision	YES/NO



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44	cGMP REQUIREMENT: All components shall be easily accessible	YES/NO
	for cleaning maintenance purpose	
45.	Safety devices for Temperature overshoot & undershoot, Delay,	YES/NO
	timer & overload Protection circuit to safeguard the compressor	
46.	High temperature safety relay and thermostat which cut off supply of	YES/NO
	heaters in case of temperature overshoot. When error is rectified,	
	safety device is reset automatically.	
47.	Low temperature safety relay and thermostat which cut off supply of	YES/NO
	cooling system incase of temperature undershoot. When error is	
	rectified safety device is reset automatically	
48.	The door can be opened from inside without key even if it is locked	YES/NO
	outside	
49.	An Emergency hooter switch (Bell) is provided inside the chamber to	YES/NO
	draw attention incase of emergency.	
50.	MCB to cut off over current supply.	
51.	Surge arrester to filter electrical noise.	YES/NO
52.	The warranty period shall be minimum one year and Warranty card	YES/NO
	should be provided with duration.	
53.	Operation & Maintenance Manual – 2 Sets	YES/NO
54.	DQ, IQ, OQ & PQ protocol including MKT calculation, soft and	YES/NO
	hard copies to be provided.	
55.	Instrument calibration certificate traceable to NABL with Master	YES/NO
	calibration certificate	
56.	List of spare parts: All Bought out components test certificates shall	YES/NO
	be provided	
57.	Application Notes: Third party Validation certificate and validation	YES/NO
	document should be provided along with the used instruments	
	calibration and master traceability certificate	



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#### (to be submitted in the supplier's letter head)

#### <u>ANNEXURE – VI</u>

#### BID Ref. No. PIIC/ADVT/001/2023-24 dated 14/08/2023

#### **BID FORM**

#### Item:

Having examined the bidding documents, including amendments of which is hereby acknowledged, we the undersigned, offer to execute the contract including the supply and delivery of the goods (FOR PII Coonoor) in full conformity with the said bidding documents for the sum of:

#### In Fig:

#### In Words

(Hereinafter call: The Total Bid Price") or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Scheduled attached herewith and are made part of this bid.

We undertake, if our bid is accepted, to execute the contract in accordance with the delivery schedule specified in the schedule of requirements.

If our bid is accepted, we undertake to provide a performance security in the form, in the amounts, and within the times specified in the Bidding Documents.

We agree to abide by this bid, for the Bid Validity period specified in their Bid Data Sheet and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

Until the formal final Contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award shall constitute a binding Contract between us. We understand that you are not bound to accept the lowest or any bid you may receive.

Dated:

Signed by:

In the capacity of



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#### (to be submitted in the supplier's letter head)

#### **ANNEXURE-VII**

#### **MANUFACTURER'S AUTHORISATION FORM**

То

#### The Director Pasteur Institute of India Coonoor 643 103

Dear Sir,

Ref: Your Tender document No \_\_\_\_\_, dated \_\_\_\_\_

We,			who are proven and reputable manufacturers					
of			(name and description of the goods offered in the tender)					
having	factories	at	, hereby authorize					
Messrs_			(name and address of the agent) to submit a					
tender, process the same further and enter into a contract with you against your requirement as								
contained	l in the abov	ve refer	red TE documents for the above goods manufactured by us.					

We further confirm that no supplier or firm or individual other than Messrs. (*name and address of the above agent*) is authorized to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also hereby extend our full warranty, AMC/CMC as applicable for the goods and services offered for supply and installation by the above firm against this Tender Document.

Yours faithfully,

[Signature with date, name and designation] for and on behalf of Messrs [Name & address of the manufacturers]

#### NOTE:

This letter of authorization should be on the letter head of the manufacturing firm and should be signed by a person competent and having the power of attorney to legally bind the manufacturer



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# (to be submitted in the supplier's letter head)

#### ANNEXURE –VIII

#### Details of Companies to whom supplied & installed in the last TWO years

SI. No	Name, Address,	Project		
	Contact No, Email id, Contact person No	Details of the equipments supplied	Project Value Rs Lakhs	Completion Date
1				
2				
3				
4				
5				
6				

Satisfactory completion certificates from the clients should be attached.



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#### (to be submitted in the supplier's letter head)

#### ANNEXURE –IX

#### **BID SECURITY DECLARATION FORM**

I/We hereby declare that we will not withdraw or modify our Bids during the period of validity, or if we are awarded the contract and we fail to sign the contract, or to submit a performance security before the deadline defined in the request for bids document. I/We understand that we will be suspended for the period of time specified in the request for bids document from being eligible to submit Bids for contracts with the entity that invited the Bids.

Name & Signature of the Authorized Signatory with seal