

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

# TENDER NOTIFICATION FOR THE END TO END PERFORMANCE QUALIFICATION OF FULLY AUTOMATED FILLING LINE

### BID REF.NO.PIIC/TENDER/001/2025-26 DATED 09/07/2025

# **INTRODUCTION OF THE COMPANY**

Pasteur Institute of India started functioning as Pasteur Institute of Southern India, on 6<sup>th</sup> April 1907 and took a new birth as The Pasteur Institute of India (registered as a society under the societies Act 1860). It started functioning as an autonomous body under the Ministry of Health and Family Welfare, Government of India, New Delhi since the 10<sup>th</sup> of February, 1977. A governing body headed by Secretary of Health, Govt. of India as Chairman manages the affairs of the Institute.

Pasteur Institute of India (PIIC), Coonoor is one of the leading organization involving in the production of DTP group of Vaccines for the UIP programmed of Govt. of India.

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

### **SCOPE OF WORK**

The scope of work is "End to End Performance Qualification of the Fully Automated Filling Line" installed at PII, Coonoor" as in Annexure I:-

S.No.	Scope of the Work
01.	End to End Performance Qualification of the Fully Automated Filling Line
	Make: Romaco, Italy

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

S.No.	Description	Schedule
i.	Closing date & time for receipt of Tender	04/08/2025, 15.00 Hrs
ii.	Time and date of opening of Technical Bids	04/08/2025, 15:30 Hrs
iii.	Pre-Bid meeting Details:	<b>Date and Time: 18/07/2025</b> , 11:00 hrs
		VENUE: PASTEUR INSTITUTE OF
		INDIA, COONOOR
iv.	Duration of the project	45 Days from the date of Issuance of
		confirmed order

The bids are invited for the "End to End Performance Qualification of the Fully Automated Filling Line" installed at PII, Coonoor" as per scope of work mentioned in Annexure I 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.



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

The bids are invited as **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 "End to End Performance Qualification of the Fully Automated Filling Line" installed at PII, Coonoor" due on 04/08/2025 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 09/07/2025. The financial bid of the technically qualified parties will only be opened for financial evaluation.

- 1.1 Pre Bid Meeting will be held on 18/07/2025 at Pasteur Institute of India, Coonoor at 11.00 AM
- 1.2 If any changes are suggested in the Pre Bid Meeting in respect of Scope of Work Corrigendum will be published.
- 1.3 Bidders may raise their queries and clarification that may be required pertinent to this project in the Pre Bid Meeting scheduled on 18/07/2025.
- 1.4 Bids shall be addressed by designation only to:
  The Director
  Pasteur Institute of India,
  Coonoor 643 103
  Nilgiris, Tamilnadu
- 1.5 Due date of submission of the bid will be on 04/08/2025, **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 specified in this tender will be opened. The date & time of financial bid opening will be intimated separately to the technically qualified parties.
- 1.6 The tenders once submitted shall remain valid upto 120 days and the tender will not be entitled to withdraw or to suggest any change within the said period.
- 1.7 The details of Bidder Qualification Criteria (BQC) are given in the Annexure I. Bidders are advised to refer to the same. If required, bidders should get clarification for their doubts during understanding the tender documents with PIIC assigned OIC(Officer-In-Charge) Formulation and Filling, Controlling Officer/Officer-In-Charge, QA and subsequently submit their quotes/tenders to PIIC. In order to familiarize with nature and quantum of job; it is suggested to all Bidders/Tenderers to visit the location of operations before submission of their quotes and should get clarified all their doubts in contact with OIC (Officer-in-Charge) Formulation and Filling, CO-QA and OIC Engineering and Purchase.



- 1.8 All pages of the tender should be duly signed by the authorized signatory with company seal.
- 1.9 Non compliance of terms and conditions by successful tenderer will lead black listing and suspension of the tenderer for a minimum of 2 years.
- 1.10 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.
- 1.11 The bidder should not be under liquidation, court receivership or similar proceedings should not be bankrupt. Bidder shall upload undertaking to this effect with bid.
- 1.12 The bidder should have carried out atleast Minimum of 3 work order pertinent to end to end performance qualification of the Fully Automated Filling line including computer system validation (CVS) in any Pharma/Vaccine company. Bidders shall furnish copies of work order and completion certificate duly signed by authorized signatory of tenderer.
- 1.13 The bidder shall not sub-contract the contract in whole or part to any entity without obtaining the prior written consent of PIIC.
- 1.14 The bidders who are blacklisted by PIIC/Central Government/State Government/Public sector undertaking are ineligible to participate in this tender. Bidder should attach declaration to confirm his eligibility to this effect.
- 1.15 Bidders are suggested to visit PIIC on the Pre Bid Date (i.e.) 18/07/2025, 11.00 AM to inspect the filling line of the facility before submitting the tenders.
- 1.16 Tenders through email/fax will not be accepted.
- 1.17 The bidders or their representatives with necessary authorization letter shall present during the technical Pre bid conference/ bid opening.
- 1.18 PIIC reserves the right to accept or reject in part or whole, any or all the tenders received without assigning any reason, whatsoever. PIIC is not bound to accept the lowest tender and also reserves the right to split the tender if deemed fit. The decision of PIIC in this regard shall be final and binding on all bidders.
- 1.19 PIIC shall be entitled at all reasonable times to inspect the services/work or any part thereof under this contract. The Successful bidder shall provide all necessary assistance to PIIC in this regard. The successful bidder shall make all necessary corrections in quality of services/work under this contract to the satisfaction of PIIC.



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- 1.20 The successful bidder shall deploy adequate staff of the requisite competency that may be required for meeting the scope of work called for in this tender document. It is hereby specifically agreed that the responsibility for the employment of staff and their salary, wages remuneration, etc, shall be the sole responsibility of the successful bidder and that PIIC shall both be responsible in any manner directly or indirectly for such employment or expenses so incurred by the successful bidder. The successful bidder shall give a declaration to this effect.
- 1.21 The successful bidder shall enter into an agreement.

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

- a. Tender Cost/Tender fee: NIL
- **b. EMD:** EMD (Earnest Money Deposit) amount of **Rs.1,00,000.00 (Rupees One Lakh only)** shall be submitted in the form of Demand Draft in favour of "The Director, Pasteur Institute of India" payable at Coonoor or by Bank guarantee.
- c. Performance Security: As per terms and conditions clause '4'

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

- a. Compliance of Work Matrix (Scope of work) for End to End PQ of Filling Line as per Annexure I.
- b. Bid Security Declaration Form as per Annexure IV.
- c. Latest IT return statement.
- d. Undertaking that the bidder is not under liquidation, court receivership or similar proceedings, nor bankrupt.
- e. Pre contract Agreement for Integrity Pact as per Annexure V should be enclosed without fail.
- f. EMD (Earnest Money Deposit) amount of Rs.1,00,000.00 (Rupees One Lakh only) shall be submitted in the form of Account Payee Demand Draft, Fixed Deposit Receipt, Banker's Cheque or Bank Guarantee in favour of "The Director, Pasteur Institute of India" payable at Coonoor or by Bank guarantee from any of the commercial banks or payment online.
- g. Copies of 3 work order pertinent to End to End Performance Qualification of the Fully Automated filling machines including Computer System Validation (CVS) in any Pharma/Vaccine company

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

- a. Financial bid.
- b. Format of submission of bid as per Annexure II.
- c. Bid form as per the format enclosed in Annexure III.

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# 3. Minimum Eligibility Criteria

- 3.1 The Bidder shall have completed minimum 3 work order pertinent to End to End Performance Qualification of the Fully Automated filling machines including Computer System Validation (CVS) in any Pharma/Vaccine company. Bidders shall furnish copies of work orders and completion certificate issued by respective organization to this effect duly signed by the authorized signatory.
- 3.2 Buyer organization specific Integrity Pact shall have to be submitted by the BIDDERS without fail. BIDDERS have to submit the duly signed Pre contract Integrity Pact along with the Bid Documents.

### 4. **Bid Evaluation**

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.

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

a. The bidder shall quote strictly in **Indian Rupee** only

### 6. <u>EMD(EARNEST MONEY DEPOSIT)</u>

- 6.1 EMD (Earnest Money Deposit) amount of Rs.1,00,000.00 (Rupees One Lakh only) shall be submitted in the form of Account Payee Demand Draft, Fixed Deposit Receipt, Banker's Cheque or Bank Guarantee in favour of "The Director, Pasteur Institute of India" payable at Coonoor or by Bank guarantee from any of the commercial banks or payment online.
- 6.2 In Case of online payment the EMD amount shall be credited to our bank A/c as detailed below:-

Name: Director, Pasteur Institute of India, Coonoor

Bank Name: Bank of Baroda

**Branch: Coonoor** 

IFSC Code: BARB0COONOO (Fifth Character is Zero)

SB Account No: 10490100001689

- 6.3 The EMD shall remain valid for a period of 45 days beyond the final validity period.
- 6.4 EMD of the unsuccessful bidders will be returned after expiry of the final bid validity and latest on or before the 30<sup>th</sup> day after the award of contract.
- 6.5 Bid Security Declaration Form as per Annexure IV without fail.



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# 7. <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.

# 8. <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.

### 9. NOTIFICATION OF AWARD

- 9.1 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.
- 9.2 Upon selection of the successful bidder (technically qualified L1 party) PIIC will promptly notify the same to successful Bidder through a Purchase Order.



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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. PAYMENT SCHEDULE:

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

S. No.	Stage	Percentage (%)
1.	After completion of end to end performance	
	qualification of our fully automated filling line and submission of all documents and approved by authorized PIIC's Representative	100% of the order value

# 3. TAXES AND OTHER LEVIES

The quoted price shall be inclusive of all applicable taxes and duties. TDS @ 2% and GSTR 7 @ 2% will be deducted from your Invoice for the services.

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

- 4.1 Successful tenderer will have to furnish Performance Security within issuance of LOI/Work order by PIIC and before commencement of work. The amount of Performance Security shall be 10% of the work order value in the form of Account payee Demand Draft, Fixed Deposit Receipt, Banker's Cheque or Bank Guarantee from any of the commercial banks favouring "The Director, Pasteur Institute of India, Coonoor" or through NEFT to the Institute account.
- 4.2 Failure of the successful Bidder to furnish the required Performance Security shall constitute sufficient grounds for the annulment of the award of Contract and to black list the bidder to participate any tender to PIIC in future.



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4.3 Forfeiture of Performance Security:

In case, the Contractor/ Bidder fails to complete the work, PIIC, without prejudice to rights and remedies available under the contract, shall forfeit and en-cash the Performance Security.

### 5. ADDITIONS/DELETIONS

- 5.1 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.
- 5.2 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.

### 6 TIME SCHEDULE

- 6.1 Period of completion of work will be 45 Days from the date of Issuance of confirmed order.
- 6.2 The Final Acceptance Certificate shall be issued on completion of the entire scope of work by the vendor.
- 6.3 The Scope of work shall be carried out with all due diligence and as per the time schedule specified above. 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 5% (Five 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 (Bidder/Contractor) risk and cost.

# 7 EXTENSION OF TIME

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



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

- 8.1 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.
- 8.2 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.

# 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:
- 9.2 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.
- 9.3 This amount would be in addition to the recovery of liquidated damages.

### 10. FORCE MAJEURE CLAUSE

If, at any item during the continuance of the contract the performance in whole or partly either party off any obligation under the contract shall be prevented or delayed by reasons of war, hostility acts of public enemy, civil commotion, sabotage, fire, flood, explosions, epidemics, quarantine restricts, strikes, lockouts or acts of God (hereinafter referred to as events) then provided notice of the happenings of any such events if given by either party or the other within twenty one days from the date of occurrence thereof, neither party shall by reasons of such event, be entitled to terminate the contract nor shall either party have any claim for damage against the other whether in respect of such non-contract shall be resumed as soon as practicable after such event has come to an end or ceased to exist and the decision of PIIC as to whether the deliveries or acceptance of deliveries have to be so resumed or not shall be final and conclusive provided further if the performance in whole or part or any obligation under the contract is prevented or delayed by reasons of any such event for period exceeding 45 days either part may at its option terminate the contract.



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# 11. **GENERAL**

- 11.1 The Contractor/ Bidder shall be fully responsible to ensure that this scope of work is carried out as per the work matrix mentioned in the tender.
- 11.2 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.
- 11.3 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.
- 11.4 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.

# 12 INTEGRITY PACT

- 12.1 The Integrity Pact (IP) will be one of the conditions in this tender enquiry. It will be considered to be a material deviation resulting into ignoring and rejecting the tender if the tenderers do not agree to accept it.
- Pre Contract Integrity Pact has to be signed and submitted by the Tenderer along with the filled up tenders as enclosed in Annexure V.
- 12.3 The Pre Contract Integrity Pact should only be signed by the CEO/ Proprietor/ Partner/Director as the case may be.
- 12.4 If the Bidder is a partnership of a consortium, the Integrity Pact shall be signed by all the partners of consortium members.
- In case of a joint venture, all the partners of the joint venture should sign the Integrity Pact. In case of sub-contracting, the Principal contractor shall take responsibility of the adoption of IP by the sub-contractor. It is to be ensured that all sub-contractors also sign the IP. In case of sub-contractors, the IP will be tri-partite arrangement to be signed by the Organization, the contractor, and the sub-contractor.
- 12.6 Indian Bidder shall submit the Integrity Pact on a non-judicial stamp paper of ₹100/-duly signed by the persons signing the bid. Foreign Bidder may submit the Integrity Pact on its company's Letter head, duly signed by the persons signing the bid.
- 12.7 The non-judicial stamp papers are to be purchased in the name of the BIDDER and the date of purchase should not be earlier than six months of date of execution.
- 12.8 All the pages of the Integrity Pact are to be signed by the Bidder.
- Bidders are required to clearly indicate the name and designation of the signatory (i.e.,) as well as the name and address of the witnesses.
- 12.10 The person signing IP shall not approach the courts while representing the matters to IEMs and he/she will await their decision in the matter.
- 12.11 The Bidder shall not change the contents of the Integrity Pact.
- 12.12 Bidder may note that Bidder's failure to submit the Integrity Pact duly signed along with the Bid shall lead to outright rejection of the Bid/Tender.



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# 13 **ARBITRATION**

- 13.1 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 IEMs, appointed by PIIC and the award made in pursuance thereof shall be binding on the parties.
- 13.2 The place of arbitration shall be at **Udhagamandalam**, **Nilgiris**, **Tamilnadu**

### 14 <u>FALL CLAUSE</u>

The prices charged for this particular work 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.

# 15 <u>STATUTORY VARIATIONS</u>

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**

Work Matrix (Scope of Work) For End-To-End PQ of Filling Line				
S.No.	Key Deliverables	Respons		REMARKS
		Vendor	PIIC	
GENE	RAL		'	
01.	Preparation of PQ protocol and reports. The protocol shall include the following parameters but not limited to: VIAL WASHING MACHINE 01. PH, Conductivity, TOC 02. Sodium Chloride Test (Liquid Particle counter) 03. Flourescence test (Riboflavin solution UV light) 04. Product quality visual check particulate matter test 05. Machine production capacity DEPYROGENATION TUNNEL 01. Machine production capacity 02. Heat Distribution study (12 to 16 temp probes) 03. Heat penetration study (12-16 temp probes and minimum 09 Endotoxin vials shall be used and minimum 3 log reduction shall be observed) Vials Dehydrogenation (LAL-limulus Amoebocyte lysate test, CSE- Control Standard Endotoxin) 04. Calculation of Fd value shall be performed 05. Belt speed for tunnel 06. Cooling capacity (set of 8 temperature probes) 07. Air flow test for all zones 08. Air velocity (for HEPA filters) 10. Non Viable Particle count 11. Interlock verification (e.g. overshoot, blower check, conveyor speed, alarm check, power failure) VIAL FILLING MACHINE 01. Machine production capacity 02. Product quality visual check 03. Product dosing accuracy 04. Weight Test		X	The vendor has to prepare the PQ protocol and reports as per the format given by PIIC and in compliance with Schedule M, ISO, WHO GMP requirements and other guide lines like PIIC & PDA. PII will review and approve the protocol and reports



S.No.	Key Deliverables Responsibility		sibility	REMARKS		
		Vendor	PIIC	-		
GENE	GENERAL					
	<ul> <li>05. Bunging quality check</li> <li>06. Particle Count test(Viable and non viable)</li> <li>07. Interlock verification</li> <li>08. Vial temperature check at in feed</li> <li>09. Speed of filling machine and machine output verification</li> <li>SEALING MACHINE</li> <li>10. Machine production capacity</li> <li>11. Product quality visual check</li> <li>12. Particle Count test(Viable and non viable)</li> <li>13. Proper sealing check test (RSF- Seal force test)</li> <li>14. Interlock verification</li> <li>Pre-Verification</li> <li>01. Centering of needles</li> <li>02. Holding of vials in the gripper</li> <li>03. Breakage of vial</li> <li>04. DP-Hot to cooling, cooling to filling chamber</li> <li>05. Alarm challenge test: <ul> <li>(i) Safety Door</li> <li>(ii) Fault in compressed air</li> <li>Vial in feed below minimum load</li> <li>(iii) Stopper feed below minimum load</li> <li>(iv) Rejected continuously</li> <li>(v) Air velocity low</li> <li>(vi) Liquid level low</li> <li>(vii) No vial no filling</li> <li>(viii) No vial no stoppering</li> </ul> </li> </ul>			The vendor has to prepare the PQ protocol and reports as per the format given by PIIC and in compliance with Schedule M, ISO, WHO GMP requirements and other guidelines like PIIC & PDA. PII will review and approve the protocol and reports		
2.	External cleaning of all equipment and room cleaning	X	V	Nil		
3.	Training of applicable SOP's and log books	X	V	PIIC will impart training on relevant SOPs to the vendor's work force		
4.	Providing applicable utilities	X	√	Nil		
5.	Calibration and its maintenance	X	<b>V</b>	Nil		
6.	Consumables related to PQ activities (Vials, Stoppers, Seals etc.,)	V	V	Vendor is responsible for other consumables related to his scope of work		



7.	Sampling and tests during PQ or otherwise as per the approved protocols of QA dept of PIIC	V	V	Nil
8.	Manpower of operation	V	√ 	Vendor, Process, QA, Engineering & QC people of PIIC will involve in this activity in the applicable areas
9.	Provision of PC and with internet connection, Printer and telephone connection	X	$\sqrt{}$	PIIC will provide if it is requested by the vendor
10.	Spares related to PQ equipment	<b>√</b>	X	Nil
11.	Spares related to filling line	X	√ V	Nil
12.	Data loggers and other related equipment for PQ Note: All the equipment used shall be calibrated and the certificate shall be provided by the vendor along with traceability certificates of Masters	V	X	Nil
13.	Videography of PQ	<b>√</b>	X	Nil
14.	Office space to be provided	<b>'</b>	$\sqrt{\frac{\Lambda}{}}$	Nil
15.	Third party services required for PQ and Testing	V	X	Nil
16.	Shipment of samples for testing to the outsourced lab	V	X	Nil
17.	Computer system validation		X	Nil
18.	PQ contractor shall carry out the PQ activities as per GMP practices, Indian national standards and International best practices with support of his fully trained staff. The PQ contractor shall submit list of Officers/Staff deployed at the PII, Coonoor along with their qualifications and experiences etc. In case of change of manpower during contract, the PQ Contractor will obtain permission from PIIC with a request letter giving the reasons for the change of staff			
19.	The PQ contractor shall comply all applic regulations applicable to the law of land and			uirements, byelaws or
20.	The PQ Contractor shall be responsible to inform PIIC about applicable regulatory guidelines, statutory requirements and by-laws amendment applicable in relation to PIIC project			
21.	The PQ contractor shall support/assist minim	num 3 suc	cessful r	uns of media fill



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

# ANNEXURE – II

S.No.	Description	Details
01.	Your Tender Quotation No. and date	
02.	PIIC Tender reference number	BID Ref. No. PIIC/TENDER/001/2025- 26 dated 09/07/2025
03.	Due date for submission	04/08/2025 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/Public Sector/Govt. Institutes/Autonomous Bodies
07.	Contact Phone-Office	
08.	Mobile Phone No.	
09.	Email	
10.	PAN Number	
11.	GST Number	
12.	Contact person name	
13.	Rate	
14.	GST (No concessional certificate will be issued by PIIC)	@
15.	Payment terms	100% after completion of work and submission of all documents
16.	Copy of MOA/Partnership deed/ Registration	Attached/Not Attached
17.	Copy of PAN of Directors/Partners	Attached/Not Attached
18.	Latest IT return statement	Attached/Not Attached



19.	Past three years P & L, Balance Sheet	Attached/Not Attached
20.	All pages of bid document duly sealed and signed by the authorized person	YES/NO
21.	Manufacturer's authorization letter	Attached/Not Attached
22.	EMD submitted	YES/NO
23.	Bid Declaration Form	Attached/Not Attached/NA
24.	Undertaking that the bidder is not under liquidation, court receivership or similar proceeding nor bankrupt	Attached/Not Attached
25.	Whether the vendor is associated with PIIC in any other contract in the past	YES/NO
26.	Are you currently having any contract with PIIC	YES/NO
27.	Confirm that you have qualified/trained/ experienced staff on your payroll to handle this job	YES/NO
28.	Whether the bidder is put on holiday list of any of the PSU (If sought later, an affidavit to be produced later to PIIC)	Attached/Not Attached



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

# <u>ANNEXURE – III</u>

### BID Ref. No. PIIC/TENDER/001/2025-26 dated 09/07/2025

### **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

your written acceptan	ee of the old and your notification of award shall constitute a omaing
Contract between us. you may receive.	We understand that you are not bound to accept the lowest or any bid
Dated:	

In the capacity of

Signed by:



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

### **ANNEXURE –IV**

# **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



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# **ANNEXURE V**

# (TO BE SUBMITTED IN THE NON-JUDICIAL STAMP PAPER OF Rs.100/-)

# (Format of Integrity Pact) PRE CONTRACT INTEGRITY PACT

#### **AND**

Whereas the BUYER proposes for the End to End Performance Qualification of Fully Automated Filling Line as per Annexure I and the BIDDER/Seller is willing to offer/has offered the stores and

WHEREAS the BIDDER is a private company/public company/Government undertaking/partnership/Firm/joint venture/Individual/Consortium (Status of the copy), constituted in accordance with the relevant law in the matter and the BUYER is a Autonomous body under the Ministry of Health Family Welfare, Government of India, New Delhi.

### NOW, THEREFORE

To avoid all forms of corruption by following a system that is fair, transparent and free from any influence/prejudiced dealings prior to, during and subsequent to the currency of the contract to be entered into with a view to:-

Enabling the BUYER to obtain the desired said stores/equipment at a competitive price in conformity with the defined specifications by avoiding the high cost and the distortionary impact of corruption on public procurement and



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Enabling BIDDERs to abstain from bribing or indulging in any corrupt practice in order to secure the contract by providing assurance to them that their competitors will also abtain from bribing and other corrupt practices and the BUYER will commit to prevent corruption, in any form, by its officials by following transparent procedures.

The parties hereto hereby agree to enter into this Integrity Pact and agree as follows:

# 1 <u>COMMITMENTS OF THE BUYER</u>

- 1.1 The BUYER undertakes that no official of the BUYER, connected directly or indirectly with the contract, will demand, take a promise for or accept, directly or through intermediaries, any bribe, consideration, gift, reward, favour or any materials or immaterial benefit or any other advantage from the BIDDER, either for themselves or for any person, organization or third part related to the contract in exchange for an advantage in the bidding process, bid evaluation, contracting or implementation process related to the contract.
- 1.2 The BUYER will, during the pre-contract stage, treat all BIDDERs alike, and will provide to all BIDDERs the same information and will not provide any such information to any particular BIDDER which could afford an advantage to that particular BIDDER in comparison to other BIDDERs.
- 1.3 All the officials of the BUYER will report to the Vigilance Officer any attempted or completed breaches of the above commitments as well as any substantial suspicion of such a breach.
- 2 In case any such preceding misconduct on the part of such Official(s) is reported by the BIDDER to the BUYER with full and verifiable facts and the same in prima facie found to be correct by the BUYER, necessary disciplinary proceedings, or any other action as deemed fit, including criminal proceedings may be initiated by the BUYER and such a person shall be debarred from further dealings related to the contract process. In such a case while an enquiry is being conducted by the BUYER the proceedings under the contract would not be stalled.

### 3 COMMITMENTS OF BIDDERS

- The BIDDER commits itself to take all measures necessary to prevent corrupt practices, unfair means and illegal activities during any stage of its bid or during any pre-contract or post-contract stage in order to secure the contract or in furtherance to secure it and in particular commit itself to the following:
- 3.1 The BIDDER will not offer, directly or through intermediaries, any bribe, gift, consideration, reward, favour, any material or immaterial benefit or other advantage, commission, fees, brokerage or inducement to any official of the BUYER, connected directly or indirectly with the bidding process, or to any person, organization or third party related to the contract in exchange for any advantage in the bidding, evaluation, contracting and implementation/completion of the contract.



- 3.2 The BIDDER further undertakes that it has not given, offered or promised to give, directly or indirectly any bribe, gift, consideration, reward, favour, any material or immaterial benefit or other advantage, commission, fees, brokerage or inducement to any official of the BUYER or otherwise in procuring/awarding the Contract or forbearing to do or having done any act in relation to the obtaining or execution of the contract or any other contract with The Pasteur Institute of India, Coonoor for showing or forbearing to show favour or disfavor to any person in relation to the contract or any other contract with The Pasteur Institute of India, Coonoor.
- 3.3 BIDDERs shall disclose the name and address of agents and representatives including their their foreign principals or associates.
- 3.4 BIDDERs shall disclose the payments to be made by them to agents/brokers or any other intermediary, in connection with this bid/contract.
- 3.5 The BIDDER either while presenting the bid or during pre-contract negotiations or before signing the contract, shall disclose any payments he has made, is committed to or intends to make to Officials of the BUYER or their family members, agents, brokers or any other intermediaries in connection with the contract and the details of services agreed upon for such payments.
- 3.6 The BIDDER shall not collude with other parties interested in the contract to impair the transparency, fairness and progress of the bidding process, bid evaluation, contracting and implementation of the contract.
- 3.7 The BIDDER will not accept any advantage in exchange for any corrupt practice, unfair means and illegal activities.
- 3.8 The BIDDER shall not use improperly, for purposes of competition or personal gain, or pass on to others regarding any information provided by the BUYER as part of the business relationship, regarding plans, technical proposals and business details, including information contained in any electronic data carrier. The BIDDER also undertakes to exercise due and adequate care lest any such information is divulged.
- 3.9 The BIDDER commits to refrain from giving any compliant directly or through any other manner without supporting it with full and verifiable facts.
- 3.10 The BIDDER shall not instigate or cause to instigate any third person to commit any of the actions mentioned above.
- 3.11 If the BIDDER or any employee of the BIDDER or any person acting on behalf of the BIDDER, either directly or indirectly, is a relative of any of the Officers of the BUYER, or alternatively, if any relative of an Officer of the BUYER has financial interest/stake in the BIDDER's firm, the same shall be disclosed by the BIDDER at the time of filing of tender. The term relative for this purpose would be as defined in Section 2(77) of the Companies Act 2013.
- 3.12 The BIDDER(s) shall not lend to or borrow any money from or enter into any monetary dealings or transactions, directly or indirectly, with any employee of the Bidder.
- 3.13 The representative of the Bidder(s) signing Integrity Pact shall not approach the Courts while representing the matters to IEMs and he/she will wait their decision of IEM in the matter.



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3.14 In case of sub contracting, the bidder shall take the responsibility of the adoption of IP by the sub-contractor.

### 4. PREVIOUS TRANSGRESSION

- 4.1 The BIDDERS/CONTRACTORS declares that no previous transgression occurred in the last three years immediately before signing of the Integrity Pact, with any other company in any country in respect of any corrupt practices envisaged hereunder or with any Public Sector Enterprise in India or any Government Department in India that could justify BIDDER's exclusion from the tender process.
- 4.2 The Bidder agrees that if it makes incorrect statement in this subject, Bidder can be disqualified from the tender process or the contract, if already awarded, can be terminated for such reason.

# 5. <u>EARNEST MONEY /SECURITY DEPOSIT</u>

- 5.1 The provision regarding Earnest Money/Security Deposit as detailed in the Tender of the BID Document is to be referred.
- No interest shall be payable by the BUYER to the BIDDER on Earnest Money/Security Deposit for the period of its currency.

# 6. SANCTIONS FOR VIOLATIONS

- 6.1 Any breach of the aforesaid provisions by the Bidder or any one employed by it or acting on its behalf shall entitle by the Buyer to take all or any action of the following actions, wherever required:
  - (i) To immediately call of the pre contract negotiations without assigning any reason or giving any compensation to the Bidder/Contractor. However, the proceedings with the other Bidder would continue.
  - (ii) The Earnest Money Deposit (in pre-contract stage) and/or Security Deposit/Performance Security (after the contract is signed) shall stand forfeited either fully or partially, as decided by the BUYER and the BUYER shall not be required to assign any reason thereof
  - (iii) To immediately cancel the contract, if already signed, without giving any compensation to the Contractor. The Bidder/Contractor shall be liable to pay compensation for any loss or damage to the Bidder resulting from such cancellation/rescission and the BUYER shall be entitled to deduct the amount so payable from the moneys due to the Bidder/Contractor
  - (iv) To encash the Bank guarantee, in order to recover the dues if any by the Bidder, along with interest as per the provision of contract.
  - (v) To debar the Bidder from participating in future bidding processes of Pasteur Institute of India, Coonoor for a minimum period of 2 years, which may be further extended at the discretion of the Buyer



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- (vi) To recover all sums paid in violation of this Pact by Bidder/Contractor to any middleman or agent or broker with a view to securing the contract.
- (vii)In cases where irrevocable letters of credit have been received in respect of any contract signed by the BUYER with the Bidder/Contractor, the same shall not be opened/operated.
- (viii) Forfeiture of Performance Security in case of a decision by the BUYER to forfeit the same without assigning any reason for imposing sanction for violation of this Pact.
- 6.2 The BUYER will be entitled to take all or any of the actions mentioned at para 6.1 (i) to (viii) of this Pact also on the commission by the Bidder/Contractor or any one employed by it or acting on its behalf (whether with or without the knowledge of the Bidder/Contractor), of an offence as defined in Chapter IX of the Indian Penal Code, 1860 or Prevention of Corruption Act, 1988 or any other statute enacted for prevention of corruption
- 6.3 The decision of the BUYER to the effect that a breach of the provisions of this Pact has been committed by the Bidder/Contractor shall be final and conclusive on the Bidder/Contractor. However, the Bidder/Contractor can approach the Independent External Monitors appointed for the purposes of this Pact.

# 7 INDEPENDENT EXTERNAL MONITORS

- O The BUYER has appointed Independent External Monitors (hereinafter referred to as monitors) for this pact in consultation with the Central Vigilance Commission as detailed below:
  - 1) Shri Vijay Sharma, Flat No. 9112, Parx Laureate, Sector 108, Noida, UP- 201304 (Mob.No.95990 08865, Email Id: VIJAYEDTM@GMAIL.COM)
  - 2) Ms. Melattur Vishwanathan Bhanumathi, 29A, Laxmi Estate, Verma Nagar, Azad Road, Andheri East, Mumbai 400 069 (Mob.No. 97113 22828,Email Id: bhanumathimv@gmail.com)
- O The task of the Monitors shall be to review independently and objectively, whether and to what extent the parties comply with the obligations under this Pact.
- O The Monitors shall not be subject to instructions by the representatives of the parties and perform their functions neutrally and independently.
- O Both the parties accept that the Monitors have the right to access all the documents relating the procurement, including minutes of meetings. The right to access should only be limited to the extent absolutely necessary to investigate the issue related to the subject tender/contract.
- As soon as the Monitor notices, or has reason to believe, a violation of this Pact, he will so inform The Director, Pasteur Institute of India, Coonoor to discontinue or take corrective action, or to take other relevant action. The Monitor can in this regard submit recommendations, these recommendations would be in the nature of advice would not be legally binding. Beyond this the Monitor has no right to demand from the parties that they act in a specific manner, refrain from action or tolerate action.



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- O The Bidder/Contractor accepts that the Monitor has the right to access without restriction, to all Project documentation of the BUYER including that provided by the Bidder/Contractor. The Bidder/Contractor will also grant the Monitor, upon his request and demonstration of a valid interest, unrestricted and unconditional access to his project documentation. The same is applicable to Subcontractors. The Monitor shall be under contractual obligations to treat the information and documents of the Bidder/Contractor with confidentially.
- O The BUYER will provide to the Monitor sufficient information about all meetings among the parties related to the project provided such meetings could have an impact on the contractual relations between the parties. The parties will offer to the Monitor the option to participate in such meetings as and when required.
- O The Monitor will submit a written report to the Director, Pasteur Institute of India, Coonoor within 8 to 10 weeks from the date of reference or intimation to him by the Bidder/Bidder and should the occasion arise, submit proposals for correcting problematic situations.
- o The word "Monitor" would include both singular and plural.

# **8** FACILITATION OF INVESTIGATION

In case of any allegation of violation of any provisions of this Pact or payment of commission, the BUYER or its agencies shall be entitled to examine all the documents including the Books of Accounts of the Bidder/Contractor and the Bidder/Contractor shall provide necessary information and documents in English and shall extend all possible help for the purpose of such examination.

### 9 <u>LAW AND PLACE OF JURISDICTION</u>

This Pact is subject to India law. The place of performance and jurisdiction is the Registered Office of the BUYER, i.e Coonoor (Tamil Nadu). The arbitration clause provided in the tender document/contract shall not be applicable to any issue/dispute arising under Integrity Pact.

# 10. OTHER LEGAL ACTIONS

- 10.1 The actions stipulated in this Integrity Pact are without prejudice to any other legal action that may follow in accordance with the provisions of the extant law in force relating to any civil or criminal proceedings.
- 10.2 Changes and supplements as well as termination notice need to be made in writing.
- 10.3 If the Contractor is a partnership or a consortium or a joint venture, this pact must be signed by all partners of the consortium/joint venture.



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### 11. VALIDITY

- a. The validity of this Integrity Pact shall be from date of its signing and extend upto 6 months or the complete execution of the supply/contract as mentioned in the tender to the satisfaction of both the BUYER and the Bidder/Contractor/Seller, including warranty period and Defect Liability period as the case may be, whichever is later, In case Bidder is unsuccessful, this Integrity Pact shall expire after six months from the date of the signing of the contract.
- b. Should one or several provisions of this Pact turn out to be invalid, the remainder of this Pact shall remain valid. In this case, the parties will strive to come to an agreement to their original intention
- c. The Parties hereby sign this Integrity Pact as part of the contract at ------on ------ and parties concerned are bound by it provisions.

BUYER	Bidder/Contractor
Name of the Officer	(Authorized Person)
Designation	(Name of the Person)
	Designation
Place	Place
Date	Date
Witness 1	Witness 1
Name and Address	Name and Address
2.	2.
Name and Address	Name and Address