Haffkine Bio Pharmaceutical Corporation Limited

(A Govt. of Maharashtra Undertaking)

Acharya Donde Marg Parel, Mumbai 400 012

Tel: 24129320-22 ext 232 / Direct 24147564 ГСС. 24129520-22 СК 2527 DICCC 24147504 Гах. 24106576

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COST OF TENDER FORM: Rs. 2600/- only (Non-refundable) through online Netbanking

TENDER NO. : M-104/Semi Automatic Glove Integrity Tester/2024-25 DATE: 28/03/2025

To,

Subject: Tender No. : M-104/Semi-Automatic Glove Integrity Tester/2024-25

Sir.

Thank you for your response to our E-Tender portal, enclosed are the Tender documents with detail Terms and Conditions.

This tender is two bid type meaning

1) Technical Bid for vendor/supplier/ manufacturer selection / Registration

2) Commercial bid, only those Tenderers who are technically gualified, (Technically gualified and accepted) their commercial bid will be considered for Commercial Bid opening.

Tender document contains following Annexure:-

- 1. Special Instructions
- 2. General Conditions
- 3. General Instruction and Terms & Conditions
- 5. Annexure 'A'- Declaration
- 6. Annexure 'B'- Technical Specification/Scope of Work
- 7. Annexure 'C'- Commercial Information
- 8. Annexure 'D'- Price Bid (BOQ)

Thanking You, For Haffkine Bio-Pharmaceutical Corporation Ltd.,

Material Manager

Note: 1) Rate should be quoted in the given format only.

2) Last date of submission : 03/04/2025

3) EMD of Rs. 13,000/- to be paid through online payment (Net Banking).

SPECIAL INSTRUCTIONS

Offer submitted should be Technical Bid and Commercial bid separately. Commercial bid of only technically qualified and accepted bidders will be opened.

Date of opening the Technical Bids.

Technical Bids will be open on <u>04/04/2025 at 12.00 P.M</u> at MM Dept Haffkine Bio-Pharmaceutical Corporation Ltd. (HBPCL), Acharya Donde Marg, Parel, Mumbai – 400 012. Technical bid will be opened in the presence of Tenderers. Tenderers may be present at the time of opening of tender. The Technical Bids will be evaluated to shortlist the eligible bidders by Technical Committee. The commercial bids of only the short listed bidders shall be considered for further processing, bidders whose technical offer is found acceptable and fulfilling the eligibility requirements as specified in this tender will be informed about the date and time of the opening of the commercial bid.

Technical Bid/offer

Note:- Only Technical details should be uploaded in Technical Envelope.

- 01. Detailed Technical specification of the machinery/equipment/System/ Job work being offered with all relevant details.
- 02. Company product manual and profile
- 03. Client list with company name & contact number :- Special mention of similar type the machinery/ equipment/System/ Job work supplied to companies engaged in Pharma/vaccines activities.
- 04. Income Tax Return for last 2 years.
- 05. Company Registration certificate.
- 06. 2 years Audited Balance sheet.
- 07. GST Registration Certificate
- 08. Copy of Company's PAN card
- 09. Delivery period/work completion schedule.
- 10. Authorized manufacturing distributor letter, if applicable.
- 11. Annexure A, B, C, D duly filled and signed with acceptance of all term and conditions.
- 12. Quantity mentioned in the estimated are approximate & vendor/supplier/ manufacturer (who are awarded) shall verify the quantities at site before start the work at site.
- 14. Any changes during execution on the work shall be carried out only with the consent of HBPCL
- 15. Vendor/supplier/ manufacturer shall give shop floor/equipment drawing before start the work and should adhere to Rules & also inform the utilities required.
- 16. Any faults repairs, during defects liability period to be rectified without any charges.
- 17. Vendor/supplier/ manufacturer having experience in Pharmaceutical/Bio-Pharmaceutical Industries will be given preference.
- 18. Vendor/supplier/ manufacturer should submit the technical architecture of system to be supplied, drawings and technical details of equipments & instruments with technical bid otherwise those bids will be disqualified required technical details are not submitted like architecture of system, drawing, specification.
- 19. Vendor/supplier/ manufacturer must visit the site prior to submitting the bid and get acquainted themselves fully about the work/equipment to be installed and understand the actual site dimensions, requirements.
- 20. Any accreditation for the company to be provided & will be taken into consideration.
- 21. Vendors having consistent turnover for last 3 years should be Rs. 1 crore and above.
- 22. HBPCL will consider the merits of Vender before taking a final decision.
- 23. Vendor should mention whether he is manufacturer/sole distributor.
- 24. Machine loading & unloading and transportation from factory to HBPCL is in the scope of vendor.
- 25. Machine placement at HBPCL site is in the scope of vendor.
- 26. HBPCL official visit the vendor site for FAT. (Approx. 4 to 5)

Commercial Bid

1. Lowest discounted offer – Annexure 'D' (Price bid) with Commercial terms and condition and acceptance letter of Payment Terms & Condition should be strictly as per tender document.

GENERAL CONDITIONS

- 01. The tenders received after the due date and time shall not be accepted under any circumstances whatsoever.
- 02. Any change in the specifications and suggestion in designs proposed, payment terms & if any other change to be brought to the notice of the HBPCL at the time of Pre-bid meeting only. Suggestions in prebid meeting shall be accepted / denied based on our technical team opinion.
- 03. HBPCL will open commercial bids of only technically qualified bidder. The Date and Time of opening the Commercial Bid will be intimated by HBPCL at a later date.
- 04. Pre-bid meeting would be conducted for technical queries.
- 05. The tender must accompany copy of latest Income Tax Certificate, Solvency Certificate, Annual Turn Over, details of similar works executed by vendor/supplier/manufacturer during last three years with names and addresses of clients, consultants and values of individual work and durations of individual project.
- 06. The tenders must be submitted by uploading on mahatenders.gov.in super scribing as below for tender:
 - a. Tender fee of Rs. 2,600/- (Non-refundable)
 - b. EMD of Rs. 13,000/-
 - c. Technical Bid
 - d. Financial Bid

Note the following :-

- Financial offer to be uploaded in the Price Bid / Financial bid should clearly mention 1) Basic price 2) Other heads of price associated with point no. 8 shall be mentioned clearly in other charges section.
- All other sheets to be signed and sealed & uploaded in .rar format in Technical Bid. (Without any commercial bid/offer details)
- 07. Earnest Money of unsuccessful bidders shall be returned after Award of Contract. Earnest Money of successful bidder shall be returned only after successful completion of job OR 90 days after delivery whichever is earlier. No interest shall be paid on the earnest money & security deposit.
- 08. The rate quoted by the tenderer shall be the Total landed cost of any item inclusive of royalties, rents, cost of labour, service tax, insurance, transportation, loading unloading, packing forwarding or any other duties/taxes/levies etc. (Refer as per Annexure 'D')
- 09. All agreement is subject to Mumbai jurisdiction.
- 10. The terms and conditions contained herein shall be considered to be binding to the successful tenderer.
- 11. Any conditional offer will not be accepted.
- 12. Any changes during execution on the work shall be carried out only with the consent of HBPCL.
- 13. Work commencement to be as per the negotiations between HBPCL and the bidder.
- 14. HBPCL reserves the right to accept & reject any tender without assigning any reason.
- 15. The Managing Director HBPCL reserves the right to accept the offer in full or in parts or reject summarily or partly.

GENERAL TERMS AND CONDITIONS

- 01. This tender is issued by the Material Manger on behalf of Managing Director Haffkine Bio-Pharmaceutical Corporation Ltd. (HBPCL), Acharya Donde Marg, Parel, Mumbai 400 012, herein referred to as 'TENDEREE'. The term tenderer means a firm, Partnership or individual who offers to supply goods/job work against the Company's requirements.
- 02. E-Tenders are invited for items mentioned in Annexure 'B' from reputed manufacturer/distributors only.
- 03. Tender document will be available from 28/03/2025.
- 04. All Annexure should be signed with Company's seal by Chief Executive / Directors of firm or his authorized representative or else tender will be treated as invalid.
- 05. Exact delivery schedule / Job work schedule will be given by HBPCL from time to time on confirmation of contract / PO awarded.
- 06. Tender Bid must be submitted online at http://mahatenders.gov.in in our prescribed form and will be rejected if submitted in any other form.
- 07. Rates submitted will remain firm during contract period and no revision in rates will be entertained except statutory charges such as Sales Tax, Service Tax etc.
- 08. Information sought as per Annexure 'A' and 'C' should be provided correctly and is a part of tender conditions.
- 09. Only Technical Bid (Annexure A, B, C and other relevant documents) will be opened first. Only technically qualified vendors will be informed for commercial bid opening; hence price bid should be enclosed separately.
- 10. Technical evaluation will be done by HBPCL. No report/reason will be given to the technically disqualified vendors.
- 11. Agreement is subject to Mumbai Jurisdiction.
- 12. Neither the tender form nor the contract, if granted, is transferable.
- 13. Equipment, machineries, Goods and services supplied will be accepted on subject to approval basis as per our specification.
- 14. Delivery challan must be printed with registered and branch office addresses, S.T., C.S.T., GST etc. Also details of Make, Purchase Order No. etc. must be mentioned on delivery challan and invoice pertaining to suppliers.
- 15. In case for any reason the vendor is unable to maintain the delivery schedule / work schedule, he should give written intimation along with reason about within time to enable the HBPCL to take the necessary steps in proper time. Non observance of this would be seriously viewed by the HBPCL.
- 16. The Tax Invoice must be submitted in triplicate by vendor to HBPCL, Parel, and Mumbai along with acknowledged delivery challan.
- 17. The Tax Invoice (Digital copy)sent through bank will not be accepted.
- 18. The terms and conditions herein contained shall be binding to the successful Tenderer.
- 19. All equipment and machineries supplied by the contractor shall be subject to warranty that no law regulation or ordinance of the Indian Republic or any state of any Govt. authorities or agency has been violated in the manufacturer, procurement or sale of the said item/materials.
- 20. Vendors should upload all the Annexure digitally signed.

21. Order Placement and Release of Payment

The Purchase Order and payment shall be processed by – Material Manager Haffkine Bio-Pharmaceutical Corporation Ltd. (HBPCL) Acharya Donde Marg, Parel, Mumbai – 400 012 Terms and Conditions for the Payment of the machines/equipment to be supplied by the vendor against the purchase order, as decided by Haffkine Bio-Pharmaceutical Corporation Ltd. are as follows:-

1. HBPCL shall pay 30% of the basic Purchase Order amount in advance upon submission of a Bank Guarantee of the same value.

OR:

HBPCL shall pay 30% of the basic Purchase Order amount as an advance immediately after delivery to HBPCL.

- 2. HBPCL shall release next 30% of amount after successful delivery to HBPCL, along with all applicable taxes as per the Tax Invoice.
- 3. Next 30% amount will be paid to vendor only after the machine has been successfully installation and commissioning, and submission of DQ, IQ, OQ, and O & M manual documents by the vendor & training to the operator of HBPCL.
- 4. HBPCL will retain 10% of the basic amount as a security deposit for the three-year warranty period.

OR

The vendor may opt to receive the 10% payment upon submission of a Performance Bank Guarantee valid for the entire warranty period.

5. HBPCL reserves the right to forfeit the Bank Guarantee at any time during its validity period if the vendor fails to perform as per the Purchase Order terms and conditions.

22. Delivery period within 4-6 weeks.

23. During FAT visit travelling meals & accommodation is in the scope of vendor/manufacturer (approx. 4 to 5 persons).

24. Warranty Clause

The vendor shall provide an all-inclusive on-site warranty for the first year and non-comprehensive warranty shall be provided for the second and third year.

- 25. The successful bidder, on award of contract / order, must send the contract / order Acceptance in writing, within 7 days of award of contract / order failing which the EMD will be forfeited.
- 26. The price quoted shall be considered firm and no price escalation will be permitted at any time. The price should be in Indian Rupees.

27. Indemnity

The vendor shall indemnify, protect and save HBPCL against all claims, losses, costs, damages, expenses, action suits and other proceeding, resulting from infringement of any law pertaining to patent, trademarks, copyrights etc. or such other statutory infringements in respect of all the services provided by him.

HBPCL reserves the right to forfeit whole or part of the security money towards any damage/lose caused due to the negligence on the part of the vendor.

28. Penalty for delayed Services

If the supplier fails to Supply & install as per specifications mentioned in the order within the due date, the Supplier is liable to pay liquidated damages of 1% of order value per week of delay subject to a maximum of 10% of order value beyond the due date. Such money will be deducted from any amount due or which may become due to the supplier.

HBPCL reserves the right to cancel the order in case the delay is more than 30 days without any written information from successful bidder. Penalties, if any, will be deducted from the EMD.

29. Security Deposit

The Successful bidder shall deposit 3% of the order value as security deposit within 15 days of the issuance of the Purchase Order (PO). If not paid, same amount will be deducted from first advance payment. This amount will be retained by HBPCL until the execution and completion of the work as per the PO.

30. Jurisdiction

The disputes, legal matters, court matters, if any, shall be subject to Mumbai Jurisdiction only.

31. The date of delivery in P.O. should be strictly adhered to. If the supplier fails to make the deliveries within the time specified. HBPCL may terminate this purchase order to such part as to which there has been delay, the purchaser in that event also reserves right to purchase the goods from open market and to charge the supplier with any loss incurred as a result thereof.

ANNEXURE 'A'

DECLARATION

Following declaration shall be made therein by the tenderers

I/We hereby declare that terms and conditions and specifications of this tender and the agreement forms have been read by me / us, translated and explained to me/us and I/We accept the same terms and conditions and specification of the Tender forms without reservation. It is also certified that all the terms and conditions of the tender document are fully acceptable to me/us and I/We will abide by the all the terms conditions.

Name and seal of the Tenderers	
Signature of the Tenderers	
Name of the Signatory (IN BLOCK LETTERS)	
Official Designation	
Date	
Address	

Annexure – "B"

TECHNICAL SPECIFICATIONS FOR SEMIAUTOMATIC GLOVE INTEGRITY TESTER

SN.	Description	Yes/No		
1	Single Glove Port – fitted with Gloves at provided Stand Trolley.			
2	Report generation in the system for view & print.			
3	The contact surface shall not be reactive, additive or absorptive.			
4	The equipment shall not contribute any particulate contamination or lubricant oil to the glove.			
5	The equipment shall have cleaning facility.			
6	There should not be dust accumulating location like crevices.			
7	All instruments used in the equipment should be calibrated with traceability complying with any national standard.			
8	The equipment design shall consider process, environment and operator safety & shall be user-friendly.			
	Process mapping of the system shall be included: 9.1 Test time			
	9.1 Test time 9.2 Test pressure			
	9.3 Excessive pressure			
9	9.4 Threshold pressure			
	9.5 Measuring and stabilization time			
	9.6 All spares available with MOC certificate.			
	9.7 Dimension of glove port stand: Glove port size 8"			
	9.8 Leak test start pressure min. requirement is equal & more than 800Pa			
10	Leak test mechanism must be pressure decay against ISO 14644 PART 7			
	Parameters shall be displayed on the screen			
	Inflate Pressure			
	Excessive Pressure			
11	Insufficient Pressure			
	Max. Pressure Drop			
	Inflate Time Out			
	Stabilization Time			
12	System shall display the results of the test: "Pass", "Fail", "Interrupt/Abort"			
13	Software should meet GAMP III, 21 CFR part 11 tamper proof results.			
14	System shall have caster wheels with locking system.			
15	Glove port tester must not have any flexible connection.			
16	Self-Stand Trolley shall have space to keep glove tester during non – working condition & during charging.			
17	Ethernet Communication in between PLC & HMI			
18	Printer Communication with suitable Port.			
19	Suitable printer for printing the reports			

20	Electric Supply – 230 V		
21	Compressor should be inbuilt to supply Compressed air		
22	Failure and alarm handling, Emergency Stop Buttons.		
23	All parts of the system shall be of non-corrosive, easily Cleanable.		
24	Phase motor with suitable earthing for safety.		
25	Describe Cleaning and sterilization requirement as applicable for contact part and non-contact part.		
26	Adequate access for maintenance and calibration should be provided.		
27	Operation and Maintenance manuals, GA drawing, electrical drawing should be provided.		
28	Calibration certificates of instruments.		
29	Vendor should provide spare part list, component list.		
30	HMI will display the system status and cycle status.		
31	All instrument should be easily accessible and removable where required for calibration purpose.		
32	All control and monitoring equipment shall be powered from BATTERY sources.		
33	All process parameters and alarms will be interfaced with HMI system.		
34	Shall have alarms to allow operates to trouble shoot to avoid overshooting a critical parameter.		
35	The HMI shall be color touch screen with 7" panel view, the HMI shall be compatible with clean room condition.		
36	User access function shall be provided consisting of at least Three levels (Operator, maintenance, admin)		
37	Each individual shall have unique user id and password based on access level. System should support password complexity		
38	Login shall be with Unique User ID and Password combination.		
39	Administrator can perform the activities like Create, Disable, the user account, Reset the user password and change the parameters.		
40	System shall have password expiry feature and notify the same to Users.		
41	Password shall contain minimum 7 characters including Alphanumeric & Special characters.		
42	Idle lockout time for the Application is 5 minutes (should be adjustable).		
43	Only Admin should be able to edit the date and Time and other quality parameters.		
44	Facility to create and store minimum FIVE cycles (set of sequential phases) with unique identifier to each cycle.		
45	Facility to store and print report in non-editable format.		
46	Equipment name and model number shall be printed.		
47	User name shall be printed on report.		
48	Gloves under test cycle number shall be printed on report.		
49	Glove port number which is used for testing should be printed on report.		

50	Activity Date and time should be printed on report.				
51	Test Start and End time and Date shall be print on report.				
52	Alarm should be printed, if occurred during cycle.				
53	Controls provided with data collection system for use in the manufacturing in the pharma product shall be complies.				
54	The system shall be designed and constructed cGMP guidelines.				
55	Internal material shall made up of SS material.				
56	In order to verify system performance, the vendor shall provide DQ, IQ, Operation Manual and documents along with execution.				
57	System is rated for acceptable sound levels (70 dBA)				
58	All labelling should be English. Name plate shall remain permanent attached to exterior of the unit.				
59	All requirements in this document shall be qualified in accordance with applicable WHO and ISO regulations and standards.				
60	The Semi – Automatic Glove Integrity Tester design shall be based on the prevailing cGMP norms.				
61	Required documentation for the Semi – Automatic Glove integrity tester, as specified must be included and filed in the engineering archive.				
62	 Typical document list required for Equipment / System Qualification, but not limited to,Is mentioned below: - Detailed Design Specification / Functional Design Specifications (including hardware & software specifications) 				
	Control Schematics document shall be provided by vendor.				
63	Input / Output List shall be provided by vendor.				
	Component Data Sheets / Catalogues shall be provided by vendor.				
	Factory Acceptance Test document shall be provided by vendor.				
	Guarantee and warranty certificate shall be provided by vendor.				
	Typical document list required for Software Qualification, but not limited to: System architecture diagram.				
64	Functional specification including hardware and software specification.				
	Control system address wise Input & output list shall be provided by vendor.				
	Software program details (PLC, HMI) like application program file name & its version.				
	System security (Access level Vs Assigned right/function) details.				
65	Design Qualification document shall be provided by vendor.				
66	Installation Qualification shall be performed by vendor.				
67	Operation Qualification shall be performed by vendor.				
68	All-inclusive onsite warrantees i.e. 1 Year Comprehensive and 2 years Non – comprehensive which includes Electrical, Electronic and Mechanical items.				
69	Software up- gradation shall be done by vendor in future.				
	1				

ANNEXURE 'C'

COMMERCIAL INFORMATION

1. Name			
2. Address			
3. Communication detai	s:- Factory	Office	Resi. of Partners
 Tel. No. Mobile No. Official Email ID 			
4. Status: N	anufacturer / Agei	nt / Other	
5. a) GST No.			
b) PAN No			
6. Subsidiary Co. and its			
a) b) c)			
7. Turnover of the Com	pany & Experience	e	
1) 2022 - 2023 :			
2) 2023 - 2024 :			
3) Total Experience	of the Company : _	Years	5

- 8. In case manufacturer or authorized dealer, details in brief about manufacturing unit.
 - 1) Location with Tel. No. /Fax No.
 - 2) No. of employees
 - 3) Manufacturing Licence No.
- 9. In case of authorized dealer please produced certificate of authorization from the manufacturer.

Seal & Signature of Tenderer

Important Notice :-

Bidders are requested to submit/upload the Technical documents in below <u>sequence</u> only for Technical document scrutiny.

- 1) EMD Paid Receipt (If exempted please provide MSME Certificate)
- 2) Company Profile (Not more than 2 page)
- 3) Company Registration Certificate / Incorporation / Partnership Registration Certificate
- 4) PAN Card copy
- 5) GST Registration Certificate
- 6) EPF & ESIC Registration if any
- 7) Experience Certificate if any / Client List (Not more than 2 page)
- 8) Entire Tender Document with company's seal & Sign (Including Filled Annexure A, B, C, D/ Price Bid)
- 9) GST paid receipt (2 latest receipt)
- 10) IT Return (Last 2 Years)
- 11) Balance sheet And Profit & Loss statement (Last 2 Years)

(Note : All the above documents are mandatory to upload, any missing documents will be treated as technical disqualification.)