# Haffkine Bio Pharmaceutical Corporation Limited

(A Govt. of Maharashtra Undertaking)

Acharya Donde Marg Parel, Mumbai 400 012

Tel: 24129320-22 ext 232 / Direct 24147564 10. 24129320-22 CA 2527 DICCL 24147504

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COST OF TENDER FORM: Rs. 3900/- only (Non-refundable) through online Netbanking

**TENDER NO. : M-103/Semi Automatic Vial Inspection Machine/2024-25** DATE: 28/03/2025

To,

#### Subject: Tender No. : M-103/Semi Automatic Vial Inspection Machine/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. 65,000/- 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. 3,900/- (Non-refundable)
  - b. EMD of Rs. 65,000/-
  - 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	

# <u>Annexure – "B"</u> TECHNICAL SPECIFICATIONS FOR SEMIAUTOMATIC VISUAL INSPECTION MACHINE

Specification	Yes/No
Minimum output required is NLT 48 vials / min for 3 ml vial. (moulded/tubular) with variable	
speed against white and / or black background.	
Change part required for 3 ml vial Inspection.	
Machine should be suitable for 2 ml to 5 ml (molded/tubular) filling range with minimum change parts.	
Operation should be through high quality HMI with three level password system	
All parts should be of SS 304/HDPE/ or suitable material as per GMP	
Rigid vibration free construction for trouble free performance	
SS 304 elegantly matt finish body	
Self-Iubricating UHMW-PE (Ultra High Molecular weight- polyethylene) guide profile for S.S. Slat chain provide low friction wear surface, smooth and noiseless conveying.	
Separate A/C drive for main motor/ servo motor drive and / or steppar motor. Machine should run with CAM free mechanism	
Inbuilt protection against over current, voltage fluctuation, short circuit in A/C/D.C.Drive.	
Direction of movement from Left to Right	
Machine should inspect four vials in inspection station using light illumination method	
Machine should have provision to swirl each vial in vertical position against (one background) black and / or white background without any modification	
The suitable inspection magnification shall synchronized with the container for better object	
Machine should inspect presence of white and black particles, glass particles, and any other foreign particles, cracks on vials, molded, improper volume	
Machine should have provision to inspect with the light illumination method to detect if any heavy nonmoving particle in vials which is at the bottom	_
Light intensity should be 2000-3750 Lux	
The design to be made for use in vaccine manufacturing plant & in compliance with cGMP, WHO guidelines and in special accordance with the requirements of the pharmaceutical and biotech industry	
Digital & HMI base counter for counting production output	
Machine should be easily accessible for the convenience of cleaning for critical and non- critical parts.	
Machine should be in compact form and should fit in the present inspection area. Size of the room should be verified by the vendor	
Vendor should provide all document (DQ, IQ, OQ, PQ) & SOP for operation and maintenance, in HBPCL and Vendors formats with soft copy. Software validation, as per WHO Guideline & norms FAT/SAT	
Vendor should provide list of all essential spares / accessories for their Machine	
All-inclusive onsite warrantees i.e. 1 Year Comprehensive and 2 years Non-comprehen	
sive which includes Electrical, Electronic and Mechanical items	
Vendor should give training to our staff till their satisfaction for operation & Maintenance at our site with training certificate	
Vendor to do all required validation at site and provide its reports also provide MOC certificates, Manual as per guidelines	
Machine should have Manual rejection system and separate collection trays for rejects	
Machine should have less noise during operation	
Machine should have auto infeed & outfeed channels	

#### **Control panel :**

- 2.1.1 ON and OFF Switch for main machine
- 2.1.2 PLC / HMI system.
- 2.1.3 Inch switch for machine
- 2.1.4 Repeat switch for machine
- 2.1.5 Emergency Stop
- 2.1.6 Lamp indication for Machine ON.
- 2.1.7 Speed indicator for machine.
- 2.1.8 Counter for filled vials, inspected vials and rejected vials.

#### Alarm Interlock :

- 2.1.9 Alarm for rejections
- 2.1.10 Minimum accumulation at in feed.
- 2.1.11 Motor overload

#### Controls:

- Operation should be on PLC/HMI Basis with three levels pass word system facility and with number of vials inspected, number of vials rejected and report should be in PDF format.
- > Electric control panel made of SS304.
- > Machine, Turn table should be control by HMI/ PLC system
- > Machine should have counter for number of inspected vials, rejected vials.

#### **Process/Operational requirements:**

1 Glass Vial

PARAMETER	Specification
Vial Dimension	3 ml
Туре	USP Type 1 (Moulded)
Overall Height	29.5 to 30.5 mm
Outer neck diameter	19.7 to 20.2 mm
Inner neck diameter	12.5 to 12.9 mm
Neck collar height	3.2 to 3.6 mm
External body diameter	21 to 22 mm
Overflow capacity	5.00 to 6.00 ml
Weight of the vial	9.5 to 12.0 gm

#### 2 Rubber Stopper:

Physical PARAMETER	Specification	
Diameter of the top ring	18.6 to 19.00 mm	
Rubber stopper diameter below NP ring	12.9 to13.1 mm	
Plunger diameter at notch	13.1 to 13.5 mm	
Total height	8.5 to 9.1 mm	
Height of collar	3.05 to 3.55 mm	
Weight of Rubber stopper	NLT 1.4 gm.	

#### 3 Aluminium Seal

PARAMETER	Specification
Outer Diameter	20.45 mm to 20.75 mm
Inner Diameter	20.0 mm to 20.2 mm
Thickness	0.19 mm to 0.21 mm
Height of Cap	7.5 mm to 8.1 mm
Trimming	Duly evenly trimmed

#### **GMP REQUIREMENTS:**

- Vial Inspection machine with the latest technology as per WHO cGMP and USFDA guideline and should comply with the 21 CFR part 11.
- Parts coming in contact with the vial / aluminium cap / exposed to the atmosphere are made out of stainless steel for good house keeping & GMP accordance.

#### Utility Available / Requirement:

#### 1 Electric Power Supply

- 1. 230-240 V, AC, 50 Hz frequency.
- 2. Phase motor with suitable earthing for safety.

#### Safety requirements:

1 Emergency Stop Buttons.

#### **Documentation/Validation Requirements**

Following are the general Documentation / Validation requirements:

- 1) Design qualification documents should be provided before the actual construction of the machine starts and on approval of the same construction should commence
- 2) Installation to be done by the vendor.
- 3) Training to the operator after installation with certification by vendor.
- 4) Design Qualification (DQ) / Installation Qualification (IQ) / Operational Qualification (OQ) protocols and execution.
- 5) Electrical wiring diagramalongwith GA drawing.
- 6) Control and Instrumentation drawings.
- 7) Instruction manual in English (02 copies)
- 8) Material of Constructions Certificates for all parts.
- 9) PLC Qualification.
- 10) Test Certificates for all bought out component parts.
- 11) Calibration certificates for critical instruments associated with the equipment.
- 12) SOP for operation.
- 13) List of machine components
- 14) Factory acceptance test protocol(FAT)
- 15) Onsite Validation.

### **ANNEXURE 'C'**

#### COMMERCIAL INFORMATION

1. Name			
2. Address			
<b>3.</b> Communication details:-	Factory	Office	
<ol> <li>Tel. No.</li> <li>Mobile No.</li> <li>Official Email ID</li> </ol>			
<b>4.</b> Status: Manu	facturer / Agent	/ Other	
<b>5.</b> a) GST No.			
b) PAN No			
6. Subsidiary Co. and its par	ticulars if any		
a) b) c)			
7. Turnover of the Company	& Experience		
1) 2022 - 2023 :			
2) 2023 - 2024 :			
3) Total Experience of th	e Company :	Year	rs
<b>8.</b> In case manufacturer or at	uthorized dealer	, details in brie	ef about manufacturing un

- 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.)