BRIHANMUMBAI MUNICIPAL CORPORATION OF GREATER MUMBAI

King Edward VII Memorial Hospital,

CSR Wing, Social Service Department,

Parel, Mumbai 400012

CSR-KEMH/EoI/1004 **Date: 20/02/2024**

Expression of Interest

Subject- To invite Expression of Interest from Original Equipment Manufacturer /Vendor / Distributor to supply of High Performance Liquid Chromatography System at Clinical Pharmacology Dept of KEM Hospital through CSR Fund received in PBCF Dept of KEM Hospital.

King Edward Memorial Hospital is one of the leading tertiary care, public hospitals in the metropolis of Mumbai that provides basic as well as specialized services to needy patients from all over the country. With a glorious legacy of 96 years and currently catering to over 1.8 million out-patients and 85,000 in-patients annually, the institute is among the top ranked medical institutes in India. The CSR Wing of the Social Service Department has been working hard to raise funds to procure advanced medical equipment for various medical and surgical specialty and super specialty departments of KEM, with the objective of providing state of the art facilities to the underprivileged sections of our society.

Through CSR funds raised by the CSR Wing of the Social service department, we wish to purchase of **High Performance Liquid Chromatography System at Clinical Pharmacology Dept of KEM Hospital.**

For purchase of the above equipment, it is proposed to invite "Expression of Interest" from Original Equipment Manufacturer /vendors / Distributor, to supply the same to KEM Hospital. To supply of Original Equipment Manufacturer /vendors / Distributor should purchase a form Poor Box Charity Fund, KEM Hospital from **21.02.2024 to 29.02.2024** in working hours and all proposals with the required documents should be submitted on or before **29.02.2024 (by 1.00 pm) in the CSR office, Room No. 65, Social Service Department, KEM Hospital, Parel, Mumbai 400012**. With Two packet System (i.e. Packet A is a Administrative & Technical Documents & Packet B is a commercial) do not disclosed the price other than commercial packet. The packet will be open in front of CSR Committee as per schedule decided by committee.

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Specifications For High Performance Liquid Chromatography System use in Clinical Pharmacology Dept of KEM Hospital

	Description
Name of Equipment	**High Performance Liquid Chromatography System use in Clinical Pharmacology Dept of KEM Hospital**
Specification of Equipment	**1. Quaternary HPLC Pump** • Solvent Delivery - Quaternary solvent delivery system with low pressure gradient mode • Flow Rate Range: 0.000 – 10.000 ml/min or more • Effective Delay volume should be ≤ 1000 µL independent of backpressure • Flow rate accuracy ±1% or 10 µL/min whatever us greater • Flow rate precision ±0.05% RSD or higher precision. • Operating Pressure: Approximate high range 400 bar or better • Number of channels – 4 • Integrated degassing unit – minimum 4 channel or more • Safety measures - Leak Sensor and safe leak handling • Composition accuracy – approx.. ±0.8% or better (independent of back pressure) • The pump should be supplied with online vacuum degasser of 4 independent channel with the flow rate of approx.. 0.2 – 5.0 mL/min or higher **2. Thermostatauto sampler** • Should be able to accommodate 100 vials or more • Sample injection volume should be variable between 0.1 µl to 100 µl. • Inbuilt Injector needle wash should be integral, active, and programmable • Near Zero carryover performance (Less than or equal to 0.002%) with caffeine or chlorohexidine • Injection volume setting minimum should be 0.1 µl • Injection volume accuracy must be below ±1%. • The injection precision should be less than ±0.25% RSD. • Injection loop: 50ul standard and spare loop up to 100ul • Automated IQ/OQ/PQ • Injector linearity should be > 0.999 • Sample thermos tatting - 4 to 35˚C or better • Pressure upto 5000psi

- Safety measures - leakage sensors
- Provision of repeat injections and needles rinsing should be available
- All the operations should be controlled to the parent software

3. Column Oven:

- Temperature range: Ambient + 4˚C to 65˚C in steps of 1˚C.
- Temperature accuracy: ±1˚C.
- The Oven Compartment: Should have provision for housing one or more columns of 30 cm length.
- Safety measures – liquid leakage sensors

4. In-built Vacuum Degasser

- Online Degassing Unit.
- Number of channel: 4 Channels.

5. UV/Visible Detector:

- Optical system – Double beam ratio photometric system
- Light source – D2 lamp and tungsten lamp. Hg lamp for checking wavelength
- Wavelength range: 190 - 900 nm.
- Wavelength Accuracy: ± 1 nm
- Flow cell Volume: 10uLor better (optical path length 10mm)
- Pressure Limit: 950 psi or better
- Spectral bandwidth – 8nm
- Noise – $\leq 0.7 \times 10^{-5AU}$ AU at 250nm, under a specified condition
- Drift – 1.0×10^{-3}AU/h at 250nm under specified condition
- 2-wavelengh measurement – 2 wavelength is wavelength region 190 to 350 nm and 355 to 900 nm respectively (minimum wavelength 5nm, max wavelength internal 160nm with data sampling period set at 400 nm)
- Response - should have selectable response time
- Materials of wetted parts – Quartz glass, fluorosis, SUS etc.
- Thermostatically flow cell – Optional, thermostatic temperature 40˚C
- Power supply and power consumption – DC24 V, 2.5 A (Maximum) / 60W

6. Fluorescence Detector:

	• Light source: Xenon lamp, Hg lamp for checking wavelength • Wavelength range - EX- 200 to 850 nm, EM – 250 to 900 nm (Change photomultiplier at 731 nm or more) • Wavelength Accuracy: ± 1 nm • Response - should have selectable response time • Spectral bandwidth – EX- 20 nm, EM – 20nm (Variable) • Sensitivity - >900 S/N ratio of water raman (Bandwidth 30nm, EX = 350nm. TC = 2s. Baseline method – standard cell) • Materials of wetted parts – Quartz glass, PEEK, SUS • Flow cell irradiation volume – 12 µL • Thermostat flow cell – optional, Thermostatic temp. 40˚C • Power supply and power consumption – AC100 V to 240V (50/60 Hz) / 30VA **7. Chromatography Manager Software:** • Updated and licensed copy of the master software with compatible software controlling individual modules compatible with Windows 11 operating system. • Software should fully support of all compliance requirement mandatory by USFDA-21 CFP part 1 • Compliance21 CFR part 11 ensures: ➢ Accurate and complete copies of records ➢ Versioning of all relevant records for traceability ➢ Preservation of records between their creation and their automatic ➢ Transfer immediately after acquisition, reprocessing or interactive modifications ➢ Controlled copies of the data ➢ Mandatory login of the data ➢ Records of changes captured in user – independent time – stamped audit trials • Software should provide the necessary controls for managing systems access, management, data transfer handling and audit trail functionality. • Single point control of the entire HPLC customizable data reports, online help wizards. • Report publisher/ Reports can be stored at PDF format **8. Other Requirement**

	• Complete installation of electrical switches and power supply extension for HPLC System with PC. • Tool kit along with calibration kit (Flow meter, Restriction Capillary, union temperature measuring thermostat) for routine maintenance of HPLC Sufficient quantities of silicon connecting tubes and ferrules for fitting (1sets) • Sampling vials of insert Glass material(1000 numbers)of 200µL capacity with septa, Solvent bottle‟s (minimum 5 units of varying volume :500ml to 2000 ml) spare deuterium Tungsten and xenon lamps (1numbers each) • 2 sets of each of following consumables- Piston, Injection Port seal, Pump seal, injection seal valve, flow cell in and flow cell Out. • Online UPS 5 KVA which stabilized current at 230V with external maintenance free battery for minimum back up 60 min of the instruments in power failure. • Computer and printer- should have branded computer compactable to the system (with i5 or above latest processor, 4 USB Port 8GB Ram, ITB Hard Disk, DVD Writer,19”LCD monitor)with Licensed software for data reduction and analysis and parallel laser Colour Wi-Fi Printer(HP model) **9.** System should be supplied with following Columns from Merk –Supelco: • C-18 250 x4.6 mm, 5µm particle size(1- number) • C-18 150 x 4.6 mm, 5µm particle size (1-number) **10.** 2 sets of following Finn pipette F3 micro pipettes • 100-100 µL(1- number) • 20-200 µL(1- number) **11.** Prices of all individual item/components must be quoted. **12.** Vendor should provide the list of users (minimum 3) with their telephone numbers complete address. **13.** Instruments must be attended within 48 hours in case of breakdown. Down time of instruments will be less than 5% of the warranty period per year .in the event of longer downtime the vendor shall increase the comprehensive maintenance period by five time of the down time. **14.** Vendor should provide onsite abs offsite training at accredited laboratory as well as application support for optimum use of equipment. **15.** Documentation: All the manual like operation service and maintenance with all electronics circuit di comprehensive diagram to be provided.

	16. Installation qualification, Performance qualification and operation qualification (IQ/PQ/OQ)documents are necessary **17. Terms and condition** • Three year"s comprehensive warranty to be followed by 5 years CMC. The list of spare parts and the rate of which valid for 8 years(warranty 3 years and CMC 5 years) irrespective of whether those are treated a. s consumables or otherwise Technical support, required spares and consumables should be assured for two Years after contact period (3+5 years) is over During the period of warranty and CMC the number of preventive maintenance should be 4 times per year and break down maintenance should be unlimited. • In warranty and CMC period, the uptime should be minimum 96% • It should be CE Certified along with Declaration of conformity or US FDA approved • Users list with address and contract numbers and past performance certificate for the quoted model should be provided. • Demonstration of offered model is compulsory. • All the equipment, instrument offered should be supplied by the same manufactures principal • Power supply- 230 V± 15%,50 Hz ±3% • Service Training to MEC Engineer and Operational training to user department should be provided. • Operating and detail service manual with circuit diagram should be provided. • Topicalizations: Operation Temperature : 40˚C Storage Temperature : 60˚C Relative Humidity : Up to 90% non -Condensing

General Conditions :

Warranty period	Comprehensive warranty on equipment and all spares shall be three years. Inclusion and exclusion of Warranty documents should be clearly stipulated.
CMC	**<u>Comprehensive Maintenance Contract (CMC)</u>** 1) After the warranty period is over, five years Comprehensive Maintenance Contract (CMC) will have to be entered into with the

	terms and conditions mentioned in the documents as per BMC norms. List of spare parts / consumables will be submit by supplier with cost freeze in advance for the warranty and CMC period. 2) The successful supplier must ensure that all the required spares/consumables and services are available during warranty and CMC period and 2 years after that, duly backed by the principal.
GENERAL REQUIREMENTS:	1) All items Price should include GST charges & any other charges. (Supplier needs to submit basic cost of equipment and GST rate in prescribed format). 2) The above equipment shall be new and manufactured from virgin materials. 3) It is mandatory to provide free installation & training for use of equipment. 4) The equipment should have warranty of three years as described in the terms and condition document. The warranty and CMC shall cover the list of spare parts and the rate of which shall be valid for total 8 years (warranty 3 years and CMC 5 years) irrespective of whether those are treated as consumables or otherwise. (Mentioned as per Technical Specification) 5) After the warranty period is over, five years Comprehensive Maintenance contract (CMC) will have to entered into with the terms and conditions mentioned in the documents as per BMC norms. List of spare parts / consumables will be submitted by supplier with cost freeze in advance for the warranty and CMC period 6) Training to Medical Electronics Cell Engineers from servicing point of view and to user department from operating point of view is compulsory. 7) Supplier should submit all technical details in the form of technical brochures / leaflets for all the equipment proposed for supply and mentioned in the technical offer.

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Procedure for the opening of EOI:	Packet-„1" (Administrative & Technical) will be opened in front of CSR Committee as per schedule decided by committee. Packet- „2"(Commercial Packet) will be opened only if the administrative & technical offer is acceptable. In case the administrative and technical offer in Packet „1" is found not acceptable or found incomplete, then Packet -„2" (Commercial Packet) will not be opened and offer will be kept out of consideration. The date and time of the opening of Commercial Packet will be intimated to the responsive bidder via mail. No complaint for non receipt of such intimation will be entertained.
Delivery & Installation Period	1) Supplier should give free delivery at user department of KEM Hospital within 60 days from the date of receipt of purchase order. 2) Installation and commissioning of equipment shall be done within 15 days from the delivery of the equipment.
Payment Conditions	1) 80% payment will be made after the satisfactory supply & Installation of the equipment, submission of bills and submission of all required documents as per BMC norms. 2) The balance 20 % payment will be released after satisfactory installation commissioning of the equipment. The Performance Certificate of equipment shall be issued by competent authority/ Concerned HOD of User department. Also user department shall obtain satisfactory inspection report from EE (MEC).
All the above conditions should be strictly adhered to failing which the tender will be treated as non-responsive and no correspondence will be entertained in the matter.	
Necessary structural strengthening of site of installation shall be done through registered structural engineer appointed by bidder. Certificate to this effect shall be submitted after completion of work.	

The supplier should be submit documents mention in chek list attached herewith.

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If any doubts or any query about above mentioned work, you can contact CSR Wing of the Social Service Department / Dept of Clinical Pharmacology, KEM Hospital, Parel, Mumbai - 400012.

Sd (20/02/2024)
CSR Head
GSMC & KEMH

Sd (20/02/2024)
HoD, Social Service Dept
GSMC & KEMH

Sd (20/02/2024)
HOD, Dept of
Clinical Pharmacology
K.E.M. Hospital

Sd (20/02/2024)
Dean
GSMC & KEMH

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Check list of Documents to be submit with EOI form as per the order given below.

Sr No	Administrative Documents	Sr. No.	Technical Documents
1	EOI Form	1	Technical Offer
2	Tri party agreement	2	List of Consumables (Applicable in Warrenty & CMC Period)
3	EOI Form Fee Receipt	3	Comparison of EOI specification v/s Quoted equipment specification
4	Authorization Certificate.	4	Experience Certificate
5	Undertaking about CMC for 5 year after 3 year warranty period is over will be follows as per BMC norms	5	Past Performance Certificate of Quoted Equipment.
6	Signed copy of Terms & Condition of EOI Document	6	Copy of valid CE certificate OR copy of valid USFDA approval as mentioned in General Conditions (Technical specifications).
7	Firm/Company/ Sanstha Registration Certificates	7	Technical brochure of quoted model
8	Partnership deed (If applicable)		
9	Pan Card with Photograph.(Only for Indian Bidder)		
10	GST Registration Certificate as applicable		
11	Import / Export license issued by competent authority(if applicable)		
12	Power of Attorney to sign the tender		
13	Irrevocable Undertaking		
14	Special Annexure for GST		