

Patients' Aid Foundation (PAF)
Jinnah Postgraduate Medical Centre (JPMC)
Karachi.

TENDER FOR
Provision of Supply, Installation and Commissioning of Cyclotron
Synthesizer for production of 18F based multiple
Radiopharmaceutical for PET-CT facility at JPMC Karachi.

For The Financial Year 2023-2024
Due on 7th August 2023 at 11:00 am

IV- Quality Control Equipment.

Technical Evaluation Report:

1. Tender was advertised on 8th July 2023.
2. Following bidders participated in the tender:
 - a. M/s Allmed Solutions.
 - b. M/s Prime Scientific.
3. Technical opening of the tender was held on 7th August 2023.
4. Technical evaluation was initiated with mandatory documents check list in which both above stated bidders complied on required documents.
5. Hence, Bidders were technically evaluated by Committee as:

i. M/s Allmed Solutions	Technically Approved
ii. M/s Prime Scientific.	Technically Approved

Technical Compliance Sheet

S.No	IV. Quality Control Equipment	M/s Allmed Solutions	M/s Prime Scientific
a. High Performance Liquid Chromatography (HPLC)			
	Brand	Schimadzu	Thermofisher
	Model	Gradient LC-40 UV/VIS/RAD Detector Gabi Nova with G10	Vanquish Core UV/VIS/RAD Detector
	Country of Origin	Japan	USA
1	Pump: Isocratic Pump Flow Accuracy: $\pm 0.1\%$ Flow Precision: $< 0.05\%$ RSD or < 0.01 min SD, whichever is greater	Yes	Yes



	Gradient Formation: High-Pressure Gradient Proportioning Max. Flow Rate: 10 mL/min. Pressure Range: 2 to 70 Mpa Type: Serial Dual-Piston Isocratic Pump C Solvent Degassing: Optional, 1 channel		
2	Solvent Rack: Up to nine 1-L bottles or up to four 2.5-L bottles	Yes	Yes
3	Column Compartment: Column Capacity 2 x max. 300 mm w/ pre-heater or guard column, max. Column i.d.: 10 mm Column Identification Up to 4 column ID tags Temperature zones 1 per device Temperature accuracy ± 0.5 °C (up to 80 °C) Pre-Column heating 2 x max. 250 mm w/pre-heater and guard column, Max. ID: 10 mm Temperature range 5–85 °C in 0.1 °C increments (max 18 °C below ambient) Temperature Precision ± 0.05 °C.	Yes	Yes
4	UV Detector: Data Collection Rate: Up to 125 Hz (Single Channel) Detection Mode: UV-vis Detection (Up to 2 Channels) Detector Type: Variable Wavelength Type: Variable Wavelength Detector Wavelength Range: 190-750 nm Optical System: UV/VIS/NIR photometer (tunable Czerny-Turn monochromator) with additional internal reference beam PC Connection: USB 2.0; 3-port HUB to connect additional Modules	Yes	Yes
5	RI Detector: Detection Mode: Light Refraction Detector Type: Universal HPLC Detection Measuring Method: Deflection Type Type: Refractive Index Detector Flow Cell Volume: 8 μ L Linearity: 600 μ RIU Refractive Index Range: 1.00 to 1.75 RIU	Yes	Yes
6	Rad Probe: Detection Unit: State-of-the-art ultra-sensitive dual 2 "PMT detection system	Yes	Yes



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	<p>with random coincidence counting and luminescence subtraction.</p> <p>Display: Graphical touch screen with 320 x 240 pixel resolution.</p> <p>Communication: USB port (B-Type) RS-232 for pump control.</p> <p>Inputs: Start-, Stop- and Ready signal (TTL). 2 analog inputs (24 bit resolution) variable voltage (bipolar, max 2.5V).</p> <p>Outputs: Scintillator pump control (RS-232 and analog). 2 analog signal outputs 0-1V (2,5 times oversampling) with 16 bit resolution. Waste valve and fraction collector control output (open collector output).</p> <p>Software: Built-in software operated with touch screen or external control and evaluation via RadioStar software or Chromeleon™ driver.</p> <p>Temp. range Storage: 5–40°C Operation: 15–35°C</p> <p>Humidity: 10-90% non-condensing.</p>		
7	<p>Software: Software from same manufacturer that has both data processing and local instrument control capabilities (directly connected to an instrument).. Secure, administrator-controlled user access and permissions to ensure data integrity and enable compliance with GxP and 21 CFR Part 11 with 3-D data acquisition.</p>	Yes	Yes
8	<p>Columns: As per Application requirement.</p>	Yes	Yes
9	<p>Data Station: Branded 11th Generation Core i7 , 16 GB DDR, 1 TB harddisk, DVD RW, LCD 19 “ Keyboard Mouse & Mono Laserjet Printer</p>	Yes	Yes
10	<p>Training: The supplier must provide training for the users of the instruments at site, after installation and commissioning.</p>	Yes	Yes
11	<p>System Warranty & Technical Support: On-site installation, commissioning, training and IQ/OQ (one vendor support) by factory-trained Engineer is required. Comprehensive support for equipment for a period of 12 Months. Accessories shall also be included in the offer.</p>	Yes	



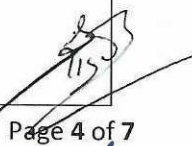
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12	Country of origin: USA/UK/ Europe/Japan.	Yes	Yes
b. High Performance Gas Chromatograph (GC)			
	Brand	Schimadzu & Elysia Raytest	Thermofisher
	Model	GC-2030-AF	Trace 1610
	Country of Origin	Japan & Germany	USA
1	<p>GC Mainframe: Cool-Down Time: 450°C to 50°C in less than 4 minutes Heat Up Time: Max. of 125°C/min Temperature Range: Ambient +3°C to 450°C (cryogenic option for sub-ambient operation) Voltage 230 V Certifications/Compliance: Conforms to safety standards according to Machinery Directive 2006/42/EC and Low Voltage Directive 2006/95/EC. Conforms to the regulations on Electromagnetic Compatibility (EMC) and Radio Frequency Interference (RFI) according to directive 2004/108/EC. Inlet Type: Up to 2: SSL, PTV, SSL-BKF, PTV-BKF, COC, GSV Detector Type: Up to 2: FID, TCD, ECD, NPD, FPD, PDD; plus MS</p>	Yes	Yes
2	<p>Split Splitless Injector: Type: Kit for SSL injector module Injection Mode: Split and Split less injection For Use With (Equipment): SSL injector on GC. Compatible with capillary columns from 50 µm to 320 µm inner diameter</p>	Yes	Yes
3	<p>FID Detector: Type: Flame Ionization Detector Detection Mode: Flame Ionization Dynamic Range: >107 (±10%) Sensitivity: >0.03 Coulombs/GC Temperature Range: 450°C in steps of 0.1°C Description: Flame Ionization Detector (FID) module For Use With (Equipment): Gas Chromatography Detector Type: FID</p>	Yes	Yes
4	<p>Software: Data storage in a relational database, and logon and role level security with hundreds of configurable privileges to adhere to GMP</p>	Yes	Yes

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	and 21 CFR Part 11 compliance requirements.		
5	Data Station: Branded 11th Generation Core i7, 16 GB DDR, 1 TB hard disk, DVD RW, LCD 19 " Keyboard Mouse & Mono Laserjet Printer	Yes	Yes
6	Gases: All gases required for smooth operations shall be included.	Yes	Yes
7	UPS: Compatible Online backup for 30 mins	Yes	Yes
8	Training: The supplier must provide training for the users of the instruments at site, after installation and commissioning.	Yes	Yes
9	System Warranty and Technical Support: On-site installation, commissioning, training and IQ/OQ (one vendor support) by factory-trained Engineer is required. Comprehensive support for equipment for a period of 12 Months.	Yes	Yes
10	Country of Origin: USA/UK/Europe/Japan	Yes	Yes

c. Radio Thin Layer Chromatography System for PET Isotopes with accessories.

	Brand	Elysia Raytest	Did Not Quoted
	Model	Minigita Single	-
	Country of Origin	Germany	-
1	Versatile state of the art radio TLC system, with motor technology to reduce running noise. Should be capable of basic spectrum scan, half life time confirmation and GXP features of PET radionuclides. Detectors must be gas free, and offer high sensitivity and fast analysis with an average scanning time of less than 1 minute or better.	Yes	-
2	Should be capable of testing radiochemical purity with thin layer chromatography and basic gamma spectrometry or better.	Yes	-
3	Shall meet GMP standards and documentation rules.	Yes	-
4	Capable of detecting system settings and configurations and store it in the electronic report.	Yes	-
5	Software must have atleast 03 measuring modes including, Chromatography, Spectrum analysis & half life time determination or better.	Yes	-

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6	PET detector probe shall be of scintillation material with digital detector technology or better.	Yes	-
7	The detector probe shall offer high resolution and sensitivity to positrons.	Yes	-
8	The detector probe shall offer high dynamic range.	Yes	-
9	The detector probe should be capable of ensuring very low background noise to gamma irradiation.	Yes	-
10	Collimators with detector probe if required should be quoted as optional.	Yes	-
11	System should be controlled with software in compliance with GMP/GLP standards or better.	Yes	-
12	Probe holder with automatic probe recognition.	Yes	-
13	Scan area 25x200 mm or better or better.	Yes	-
14	Probe/detector should be PET radionuclide compatible.	Yes	-
15	Energy range must be 450-550 KeV or as of PET radionuclides or better.	Yes	-
16	Count rate: 0-1,000,000 cps or better.	Yes	-
17	Linearity: 0-600,000 cps & r2 >= 0.99 or better.	Yes	-
18	Communication: USB 2.0, and ethernet 10/100 or higher.	Yes	-
19	PC 11 th generation, core i7, 8GB RAM, 1TB ROM, 21" LED, laser jet printer and accessories.	Yes	-

d. Osmometer.

	Brand	Knauer	Did Not Quoted
	Model	K-7400-S	-
	Country of Origin	Germany	-
1	Capable of measuring osmolality of various aqueous solutions.	Yes	-
2	Easy and fast to operate.	Yes	-
3	Capable of determining freezing point depression.	Yes	-
4	Device should be controlled via software and capable of storing data/ print on external printer.	Yes	-
5	Shall comply with European pharmacopeia.	Yes	-
6	Sample volume 50-150uL or better.	Yes	-
7	Osmolality range: 0-2000 mOsmol/kg or better.	Yes	-
8	Test time: upto 2mins or better.	Yes	-



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9	Linearity: +/- 1% (0-1500 mOsmol/kg) or better.	Yes	-
10	Calibration: upto 3 point or better.	Yes	-
11	Warranty: 01 year	Yes	-
12	On-site installation, commissioning, training and IQ/OQ (one vendor support) by factory-trained Engineer is required.	Yes	-
13	Should include all the accessories, calibration standards and consumables for 1,000 tests.	Yes	-
14	Country of Origin: USA/UK/Europe/Japan.	Yes	-
a. pH Meter.			
	Brand	Elysia Raytest	Did Not Quoted
	Model	Easy pH Meter	-
	Country of Origin	Germany	-
1	Automatic pH reading capability, capable of reducing radioactive sample volume, shall contain highest precision, and easy result administration.	Yes	-
2	Shall have a graphic touch screen display.	Yes	-
3	Shall have an onscreen keyboard & compatible with external keyboard.	Yes	-
4	Able to store upto 200 test results or better.	Yes	-
5	Both RS232 & USB options should be available.	Yes	-
6	On-site installation, commissioning, training and IQ/OQ (one vendor support) by factory-trained Engineer is required.	Yes	-
7	Offer shall be inclusive of all the accessories and consumables for 1,000 tests.	Yes	-
8	Warranty 01 year.	Yes	-
9	Country of Origin: USA/UK/Europe/Japan	Yes	-

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