

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

I- Supply, Installation and Commissioning of Cyclotron Synthesizer.

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 BIOS.
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:

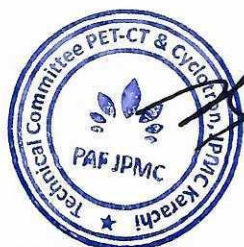
i. M/s Allmed Solutions	Technically approved
ii. M/s BIOS.	Technically Approved

Technical Compliance Sheet

S.No	1. Synthesizer for production of 18F based multiple radiopharmaceuticals	M/s Allmed Solutions	M/s BIOS
	Brand	ORA- Neptis	ORA- Neptis
	Country of Origin	Belgium	Belgium
1.1	Should be Compatible with ABT BG-75 Dose on Demand Biomarker Radioisotope Generator.	Yes	Yes
1.2	Should be capable of synthesizing following 18F based Radiopharmaceuticals with commercial consumables: - 18F- FDG - 18F- FDG (Dual Run) - 18F- PSMA-1007	Yes	Yes



	<ul style="list-style-type: none"> - 18F- FMISO - 18F- FLT - 18F- FES - 18F- L-Dopa - 18F- Choline - 18F- Acetate - 18F-FDGal - 18F-FET - 18F-NaF 		
1.3	Should be capable of producing all the 18F based Radiopharmaceuticals via nucleophilic synthesis.	Yes	Yes
1.4	The synthesizer must have a high and reproducible yields of > 65% for 18F-FDG and >30% for 18F-FPSMA-1007	Yes	Yes
1.5	Synthesizer should be able to produce dual 18F-FDG batches with single set of consumables.	Yes	Yes
1.6	Waste produced by synthesis unit should be less than 100mL/ FDG synthesis.	Yes	Yes
1.7	18F-FDG consumables compatible with the synthesizer must be available from 3 different suppliers.	Yes	Yes
1.9	The synthesizer electronics must be located outside of the to minimize radiation effect.	Yes	Yes
1.10	Communication between electronic devices should be by LAN.	Yes	Yes
1.11	Should have atleast 3 radiation detectors to visualize location of radioactivity.	Yes	Yes
1.12	Operating software must be LINUX based.	Yes	Yes
1.13	Laptop/PC & tablet must be provided as interface, to assist operator to assist the operator for visualization of processes, to view and print the reports & perform maintenance tests. Laptop/ Tablet must support wireless connection.	Yes	Yes
1.14	User interface must have password protection as defined by level of user access.	Yes	Yes
1.15	Software must be open for process sequence design of new compounds with straightforward execution in production mode.	Yes	Yes
1.16	User interface must be remotely accessible by operator and Factory for remote assistance and maintenance.	Yes	Yes
1.17	Software must comply with 21CFR part 11.	Yes	Yes
1.18	Should offer Data storage and retrieval as per cGMP guidelines.	Yes	Yes
1.19	<p>The synthesis unit must be able to perform following automated functions:</p> <ul style="list-style-type: none"> - Hardware test - Consumables test - Cartridge Conditioning & Cleaning - Dissolving of precursors - Heating solutions in reactor - Purification of the product 	Yes	Yes



	<ul style="list-style-type: none"> - Final formulation - Extensive rinsing the end of synthesis 		
1.20	<p>The unit must have the capacity to detect and indicate for the following conditions:</p> <ul style="list-style-type: none"> - Usage of incorrect cassette - Detection of faulty cassette - Unstable test values - Faulty environmental conditions 	Yes	Yes
1.21	The synthesis unit shall have an operating life span of upto 15 years in radiation environment with support.	Yes	Yes
1.22	Must provide Technical publications & application notes and software maintenance & operations document.	Yes	Yes
1.23	Factory Acceptance Test (FAT) certificate should be provided.	Yes	Yes
1.24	The supplier shall comply with the ISO 13485 and provide a valid ISO certificate. Country of origin shall be USA/UK/Europe/Japan.	Yes	Yes
1.25	Warranty should be 01 year inclusive of preventive maintenance kits.	Yes	Yes
1.26	Bidder shall possess distribution/agency certificate from the manufacturer.	Yes (Offered Through Third party Best ABT)	Yes (Offered through OEM, Agency Certificate provided)
1.26	Bidder shall have atleast 01 factory trained installation & service engineer.	No (Undertaking submitted of scheduled factory training in Q4-2023)	Yes (Travel History & Training Certificate provided)
1.27	Onsite training of the operator by factory trained installation & service engineer.	Yes	Yes
1.28	Bidder shall submit complete profile of manufacturer, and provide details of existing locally/internationally installed units.	Yes	Yes

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