

KENYA MEDICAL SUPPLIES AUTHORITY

Commercial Street, Industrial Area
P.O. Box 47715, 00100 GPO,
Nairobi, Kenya



Tel: +254 20 3922000, Fax: +254 203922400
GSM +254 719 033000, +254 733 606600
Email: info@kemsaco.ke

All Correspondence should be addressed to Chief Executive Officer

When replying please quote our ref:

KEMSA/ GF ATM TB NFM/2023

Date: 20th March, 2023

ADDENDUM 2

Attn.: All Prospective Bidders

RE: RE: TENDER NO.: GF ATM TB (RSSH) NFM- 2022/2023 OIT - 05 SUPPLY, INSTALLATION, COMMISSIONING AND TRAINING OF RAMAN SPECTROSCOPY

Pursuant to ITT Clause 8, **At any time prior to the deadline for submission of Tenders, the Procuring Entity may amend the tendering document by issuing addenda.** Any addendum issued shall be part of the tendering document and shall be communicated in writing to all who have obtained the tendering document from the Procuring Entity in accordance with ITT 6.

In view of the above, the extension of tender closing date was necessitated by a query raised by one potential bidder regarding specifications. In response, find below revised specifications.

GENERAL DESCRIPTION

A rapid non-destructive analytical technique that is applied in identification of drug substances and drug products by frequency and quantification of the active pharmaceutical ingredient by intensity of the peaks. The equipment should provide capability to support monitoring of drug quality, drug product authentication and monitoring drug product shelf life.

The offer must be by a single vendor supplier for all components of the equipment. This vendor should have demonstrated local technical competence to service the equipment, train the end users and perform Installation Qualification, Operation Qualification and Performance Qualification (IQ/OQ/PQ).

Official brochures and information pamphlets, as published by the Manufacturer regarding all specifications shall be submitted with the offer, stating the Make, Model and Country of Origin of the equipment.

A handwritten signature in black ink, appearing to be 'B', is written over the page number '1'.

TECHNICAL SPECIFICATIONS FOR THE RAMAN SPECTROSCOPY

Feature	Technical Specification
Laser Excitation Wavelength	785nm
Laser power output	Adjustable up to 450 MW (Class 3B)
Spectral Range	Specific to the equipment
Spectral Resolution	On average 14cm^{-1} (measured according to ASTM E2529/EP 2.2.48)
Stability over 24 hours power supply	>4 hours operation time
Measurement Accessories	Holders for different drug formulations e.g., universal tablet holder, vial holder, cuvette holder
Operating temperature range	-5°C to +35°C
Relative Humidity	Up to 95% non-condensing at +30°C
Barcode scanner and supported barcodes	All barcodes
Connection	Wi-Fi (IEEE 802.11 WLAN) and Ethernet (IEEE 802.3/RJ-45 via Ethernet dongle)
Operating System	Windows 10 OS
Certification and compliance	Compliant for at least 10 years with internationally recognized certification e.g., Ph. Eur.8.7 or FDA 1040 OR 21 CFR Part 11
Warranty Period	Minimum 1 Year

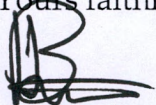


Mandatory support requirements

Mandatory Support Requirements		
1) Training & Warranty	Training & Warranty	<p>The vendor shall install the equipment at the quality control unit, 1st floor of the Pharmacy and Poisons Board headquarters, Lenana Road, Opposite Ministry of Defence, NAIROBI premises and provide on-site training in English language on system operation and application, as well as guidance on basic maintenance and troubleshooting.</p> <p>The equipment should be covered by a minimum 1 year warranty including spare parts and labour.</p>
2) Installation, Operational & Performance Qualification (IQ/OQ/PQ)	(IQ/OQ/PQ)	Supplier MUST undertake comprehensive and thoroughly documented IQ & OQ including PQ (System Suitability Test & Calibration) of the equipment at time of commissioning (receipt) in accordance with the manufacturer's guidelines.
3) After Sales Service	After Sales Service	Supplier must commit to undertake after sales service as and when required.

All other terms and conditions of the tender remain unchanged.

Yours faithfully,



Dr. Justus Kinoti (Ph.D)
Ag. DIRECTOR, PROCUREMENT
FOR: CHIEF EXECUTIVE OFFICER

