



## **Open International Tender (OIT)**

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### **Tender Document**

**For the**

**Supply of Liquid Chromatography/Mass Spectroscopy System**

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**Invitation for Tender (IFT) Number:**

**GF ATM TB NFM - 21/22 - OIT - 003 For Supply of Liquid  
Chromatography/Mass Spectroscopy System**

**IFT No.: GF ATM TB NFM - 21/22 - OIT - 003**

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**Tender Closing date: 12<sup>th</sup> May, 2022**

**Time: -10.00 a.m. Local time**

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## INVITATION TO TENDER

PROCURING ENTITY: Kenya Medical Supplies Authority, 13 Commercial Street, Industrial Area, P.O Box 47715-00100, Nairobi. Tel No: +254 719033000/ +254 726618520/1 Email: [procurement.programs@kemsa.co.ke](mailto:procurement.programs@kemsa.co.ke)

### **TENDER NUMBER AND DESCRIPTION: GF ATM TB NFM - 21/22 - OIT - 003 SUPPLY OF LIQUID CHROMATOGRAPHY/MASS SPECTROSCOPY SYSTEM**

1. The Government of Kenya has received a grant from the Global Fund to fight AIDS, Tuberculosis and Malaria under New Funding Model (NFM 3) for the Year 2021/2022, which it intends to use part of the proceeds to fund payments under the contract(s) for the **Supply of Liquid Chromatography/Mass Spectroscopy System**.
2. The Kenya Medical Supplies Authority (KEMSA), on behalf of the Government of Kenya, Ministry of Health and Global Fund herewith invites sealed tender (s) for **Supply of Liquid Chromatography/Mass Spectroscopy System**.
3. Bidding will be conducted through the procedures specified in the Public Procurement and Asset Disposal Act (PPADA) 2015 and the Global Fund's Policies on Procurement and Supply Management, June 2021 and is open to all.
4. Interested eligible Bidders may obtain further information from Procurement office situated at:

Kenya Medical Supplies Authority,  
13 Commercial Street, Industrial Area  
P.O Box 47715-00100, Nairobi  
Tel No: +254 719033000/ +254 726618520/1

Email: [procurement.programs@kemsa.co.ke](mailto:procurement.programs@kemsa.co.ke)

On normal working days on Monday to Friday 09.00hrs and 16.00hrs except on Public Holidays or download at the PPIP Portal: [tenders.go.ke](http://tenders.go.ke) and KEMSA website. Documents downloaded are free of charge and bidders are advised to register their bid documents at the Procurement Office or via email at [procurement.programs@kemsa.co.ke](mailto:procurement.programs@kemsa.co.ke) (Refer to registration form in the tender document).

5. A complete set of bidding documents in English may be purchased by interested bidders on the submission of a written application on company letterhead to the address below and upon payment of a non-refundable/non-transferable fee of USD.13 or Kenya Shillings; 1,000/=. The method of payment is i) by Cash or by Bankers cheque payable to "Kenya Medical Supplies Authority" KEMSA and ii) By direct deposit to the following accounts;

Kenya shillings Account  
Account Name: Kenya Medical Supplies Authority

Bank Name & Branch: Co-operative Bank, Enterprise Road Branch  
Account Number: 01141217405100

United States Dollar Account

Account Name: Kenya Medical Supplies Authority

Bank Name & Branch: Co-operative Bank, Enterprise Road Branch

Account Number: 02120217405100

Swift Code: KCOOKENA

6. Completed serialized/paginated Bidding documents shall be submitted accompanied with a signed declaration of the number of pages. The documents will be One original and a copy in plain sealed envelopes clearly marked on top with the Tender Number and Description and accompanied by a Bid Security of **USD 5,000 or KES 575,000.00** or equivalent in a freely convertible currency from Commercial Banks or Insurance Companies Approved by The Insurance Regulatory Authority (IRA) and listed by The Public Procurement Regulatory Authority and should be addressed to:

The Chief Executive Officer  
Kenya Medical Supplies Authority  
13 Commercial Street, Industrial Area  
P.O B Box 47715-00100  
Nairobi, Kenya.

7. The bid documents must be deposited in the Tender Box No.2 marked Global Fund at the reception on the Ground floor KEMSA's Commercial Street Office in Nairobi on or before **12<sup>th</sup> May, 2022**
8. Bulky tenders can be handed over to KEMSA Procurement Director's office for registration and safekeeping till the tender opening date.
9. Bids will be opened promptly in public and in the presence of Bidders' and or representatives who choose to attend the opening of bids at KEMSA's Conference Hall on the dates indicated against each tender.
10. Late bids, portion of bids, Electronic bids shall NOT be accepted for evaluation irrespective of circumstances.

**There will be a Pre-bid conference at KEMSA Conference Hall, Commercial Street on 27<sup>th</sup> April 2022 at 9:00 a.m.**

**REGISTRATION FORM**

**Tender No. GF ATM TB NFM - 21/22 - OIT - 003 SUPPLY OF LIQUID CHROMATOGRAPHY/MASS SPECTROSCOPY SYSTEM**

**NOTE:** Bidders are required to provide their contact details as shown below.

Name of the firm:.....

Postal Address:.....

Telephone Contacts:.....

Company email address:.....

Contact Person:.....

Once completed please submit this form to the email address below;

**[procurement.programs@kemsa.co.ke](mailto:procurement.programs@kemsa.co.ke)**

## PART 1 - TENDERING PROCEDURES

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### SECTION I - INSTRUCTIONS TO TENDERERS

#### A General

##### 1 Scope of Tender

- 1.1 In connection with this Invitation to Tenderer (ITT), the Procuring Entity issues this tendering document for the supply of Health Products as specified in Section V, Schedule of Requirements. The name, identification and number of items or lots (contracts) of this ITT are specified **in the TDS**.

##### 2 Definitions

Throughout this tendering document:

- a) The term "in writing" means communicated in written form (e.g. by mail, e-mail, including if specified **in the TDS**, distributed or received through the electronic-procurement system used by the Procuring Entity) with proof of receipt;
- b) If the context so requires, "singular" means "plural" and vice versa; and "Day" mean scale day, unless otherwise specified as "Business Day." A Business Day is any day that is an official working day of the Procuring Entity. It excludes the Procuring Entity's official public holidays.

##### 3 Fraud and Corruption

- 3.1 The Procuring Entity requires compliance with the provisions of the Public Procurement and Asset Disposal Act, 2015, Section 62 "Declaration not to engage in corruption". The tender submitted by a person shall include a declaration that the person shall not engage in any corrupt or fraudulent practice and a declaration that the person or his or her sub-contractors are not debarred from participating in public procurement proceedings.
- 3.2 The Procuring Entity requires compliance with the provisions of the Competition Act 2010, regarding collusive practices in contracting. Any tenderer found to have engaged in collusive conduct shall be disqualified and criminal and/or civil sanctions may be imposed to this effect, Tenderer's shall be required to complete and sign the "Certificate of Independent Tender Determination" annexed to the Form of Tender.
- 3.3 Unfair Competitive Advantage-Fairness and transparency in the tender process require that the firms or their Affiliates competing for a specific assignment do not derive a competitive advantage from having provided consulting services related to the assignment in question. To that end, the Procuring Entity shall indicate in the **Data Sheet** and make available to all the firms together with this tender document all information that would in that respect give such firm any unfair competitive advantage over competing firms.
- 3.4 Tenderers shall permit and shall cause their agents (where declared or not), subcontractors, sub-consultants, service providers, suppliers, and their personnel, to permit the Procuring Entity to inspect all accounts, records and other documents relating to any initial selection process, prequalification process, tender submission, proposal submission, and contract performance (in the case of award),



and to have them audited by auditors appointed by the Procuring Entity.

#### **4 Eligible Tenderers**

- 4.1 A Tenderer may be a firm that is a private entity, a state-owned enterprise or institution subject to ITT4.6 or any combination of such entities in the form of a joint venture (JV) under an existing agreement or with the intent to enter in to such an agreement supported by a Form of intent. In the case of a joint venture, all members shall be jointly and severally liable for the execution of the entire Contract in accordance with the Contract terms. The JV shall nominate a Representative who shall have the authority to conduct all business for and on behalf of any and all the members of the JV during the Tendering process and, in the event the JV is awarded the Contract, during contract execution. Members of a joint venture may not also make an individual tender, be a subcontractor in a separate tender or be part of another joint venture for the purposes of the same Tender. The maximum number of JV members shall be specified in the **TDS**.
- 4.2 Public Officers of the Procuring Entity, their spouse, child, parent, brother, sister, child, parent or brother, sister of a spouse their business associates or agents and firms/organizations in which they have a substantial or controlling interest shall not be eligible to tender or be awarded a contract. Public Officers are also not allowed to participate in any procurement proceedings.
- 4.3 A Tenderer shall not have a conflict of interest. Any Tenderer found to have a conflict of interest shall be disqualified. A Tenderer may be considered to have a conflict of interest for the purpose of this Tendering process, if the Tenderer:
- a Directly or indirectly controls, is controlled by or is under common control with another Tenderer; or
  - b Receives or has received any direct or indirect subsidy from another Tenderer; or
  - c has the same legal representative as another Tenderer; or
  - d has a relationship with another Tenderer, directly or through common third parties, that puts it in a position to influence the Tender of another Tenderer, or influence the decisions of the Procuring Entity regarding this Tendering process; or
  - e or any of its affiliates participated as a consultant in the preparation of the design or technical specifications of the goods that are the subject of the Tender; or
  - f or any of its affiliates has been hired (or is proposed to be hired) by the Procuring Entity or Procuring Entity for the Contract implementation; or
  - g would be providing goods, works, or non-consulting services resulting from or directly related to consulting services for the preparation or implementation of the project specified in the TDS ITT 2.1 that it provided or were provided by any affiliate that directly or indirectly controls, is controlled by, or is under common control with that firm; or
  - h has a close business or family relationship with a professional staff of the Procuring Entity who: (i) are directly or indirectly involved in the preparation of the tendering document or specifications of the Contract, and/or the Tender evaluation process of such Contract; or (ii) would be involved in the implementation or supervision of such contract unless the conflict stemming from such relationship has been resolved in a

manner acceptable to the Procuring Entity throughout the Tendering process and execution of the Contract.

A firm that is a Tenderer (either individually or as a JV member) shall not participate in more than one Tender, except for permitted alternative Tenders. This includes participation as a subcontractor. Such participation shall result in the disqualification of all Tenders in which the firm is involved. A firm that is not a Tenderer or a JV member may participate as a subcontractor in more than one Tender.

- 4.4 A Tenderer may have the nationality of any country, subject to the restrictions pursuant to ITT4.9. A Tenderer shall be deemed to have the nationality of a country if the Tenderer is constituted, incorporated or registered in and operates in conformity with the provisions of the laws of that country, as evidenced by its articles of incorporation (or equivalent documents of constitution or association) and its registration documents, as the case may be. This criterion also shall apply to the determination of the nationality of proposed subcontractors or sub-consultants for any part of the Contract including related Services.
- 4.5 A tenderer that has been debarred from participating in public procurement shall be ineligible to be prequalified for, initially selected for, tender for, propose for, or be awarded a contract during such period of time as the PPRA shall have determined. The list of debarred firms and individuals is available at **PPRA's website** [info@ppra.go.ke](mailto:info@ppra.go.ke) or [complaints@ppra.go.ke](mailto:complaints@ppra.go.ke).
- 4.6 Tenderers that are state-owned enterprises or institutions in Kenya may be eligible to compete and be awarded a Contract(s) only if they can establish, in a manner acceptable to the Procuring Entity, that they (i) are legally and financially autonomous (ii) operate under commercial law, and (iii) are not under supervision of the Procuring Entity.
- 4.7 A tenderer shall not be under suspension from tendering by the Procuring Entity as the result of the operation of a Tender-Securing Declaration or Proposal-Securing Declaration.
- 4.8 Firms and individuals may be ineligible if (a) as a matter of law or official regulations, Kenya prohibits commercial relations with that country, or (b) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, Kenya prohibits any import of goods or contracting of works or services from that country, or any payments to any country, person, or entity in that country.
- 4.9 Foreign tenderers are required to source at least forty (40%) percent of their contract inputs (in supplies, subcontracts and labor) from national suppliers and contractors. To this end, a foreign tenderer shall provide in its tender documentary evidence that this requirement is met. Foreign tenderers not meeting this criterion will be automatically disqualified. Information required to enable the Procuring Entity determine if this condition is met shall be provided in for this purpose is be provided in "*SECTION III - EVALUATION AND QUALIFICATION CRITERIA, item 9*".
- 4.10 Pursuant to the eligibility requirements of ITT 4.10, a tender is considered a foreign tenderer, if the tenderer is not registered in Kenya or if the tenderer is registered in Kenya and has less than 51 percent ownership by Kenyan citizens. JVs are considered as foreign tenderers if the individual member firms are not registered in Kenya or if are registered in Kenya and have less than 51 percent ownership by Kenyan citizens. The JV shall not subcontract to foreign firms more than 10 percent of the contract price, excluding provisional sums.

- 4.11 The Competition Act of Kenya requires that firms wishing to tender as Joint Venture undertakings which may prevent, distort or lessen competition in provision of services are prohibited unless they are exempt in accordance with the provisions of Section 25 of the Competition Act, 2010. JVs will be required to seek for exemption from the Competition Authority. Exemption shall not be a condition for tender, but it shall be a condition of contract award and signature. A JV tenderer shall be given opportunity to seek such exemption as a condition of award and signature of contract. Application for exemption from the Competition Authority of Kenya may be accessed from the website [www.cak.go.ke](http://www.cak.go.ke).
- 4.12 A Kenyan tenderer shall provide evidence of having fulfilled his/her tax obligations by producing a valid tax compliance clearance certificate or tax exemption certificate issued by the Kenya Revenue Authority.

## **5 Eligible Goods and Related Services**

- 5.1 All the Goods and Related Services to be supplied under the Contract may have their origin in any eligible country.
- 5.2 For purposes of this ITT, the term “goods” includes any goods that are the subject of this Invitation to Tender, and “Related Services” includes services such as transportation, insurance, commissioning and training.
- 5.3 The term “origin” means the country where the goods have been mined, grown, cultivated, produced, manufactured or processed; or, through manufacture, processing, or assembly, another commercially recognized article results that differs substantially in its basic characteristics from its components.
- 5.4 Any goods, works and production processes with characteristic that have been declared by the relevant national environmental protection agency or by other competent authority as harmful to human beings and to the environment shall not be eligible for procurement.

## **B. Contents of Tendering Document**

### **6 Sections of Tendering Document**

The tendering document consists of Parts 1, 2, and 3, which includes all the sections indicated below, and should be read in conjunction with any Addenda issued in accordance with ITT 8.

#### **PART 1 - Tendering Procedures**

Section I - Instructions to Tenderers (ITT)

Section II - Tendering Data Sheet (TDS)

Section III - Evaluation and Qualification Criteria

Section IV - Tendering Forms

#### **PART 2 - Supply Requirements**

Section V - Schedule of Requirements

#### **PART 3 - Contract**

Section VI - General Conditions of Contract

Section VII - Special Conditions of Contract

## Section VIII - Contract Forms

The Specific Procurement Notice-Invitation to Tender (ITT) notice issued by the Procuring Entity is not part of this tendering document.

Unless obtained directly from the Procuring Entity, the Procuring Entity is not responsible for the completeness of the document, responses to requests for clarification, or Addenda to the tendering document in accordance with ITT 10. In case of any contradiction, documents obtained directly from the Procuring Entity shall prevail.

The Tenderer is expected to examine all instructions, forms, terms, and specifications in the tendering document and to furnish with its Tender all information or documentation as is required by the tendering document.

### 7. Clarification of Tendering Document

- 7.1 A Tenderer requiring any clarification of the tendering document shall contact the Procuring Entity in writing at the Procuring Entity's address specified **in the TDS**. The Procuring Entity will respond in writing to any Invitation to clarification, provided that such request is received prior to the deadline for submission of Tenders within a period specified **in the TDS**. The Procuring Entity shall forward copies of its response to all Tenderers who have acquired the tendering document in accordance with ITT 6, including a description of the inquiry but without identifying its source. If so specified **in the TDS**, the Procuring Entity shall also promptly publish its response at the web page identified **in the TDS**. Should the clarification result in changes to the essential elements of the tendering document, the Procuring Entity shall amend the tendering document following the procedure under ITT 8 and ITT 22.2.

### 8. Amendment of Tendering Document

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. The Procuring Entity shall also promptly publish the addendum on the Procuring Entity's web page in accordance with ITT 7.1.

To give prospective Tenderers reasonable time in which to take an addendum into account in preparing their Tenders, the Procuring Entity may, at its discretion, extend the deadline for the submission of Tenders, pursuant to ITT 22.2.

### C. Preparation of Tenders

#### 9. Cost of Tendering

- 9.1 The Tenderer shall bear all costs associated with the preparation and submission of its Tender, and the Procuring Entity shall not be responsible or liable for those costs, regardless of the conduct or outcome of the Tendering process.

## 10. Language of Tender

- 10.1 The Tender, as well as all correspondence and documents relating to the Tender exchanged by the Tenderer and the Procuring Entity, shall be written in the English Language.

Supporting documents and printed literature that are part of the Tender may be in another language provided they are accompanied by an accurate translation of the relevant passages into the English Language, in which case, for purposes of interpretation of the Tender, such translation shall govern.

## 11. Documents Comprising the Tender

The Tender shall comprise the following:

- a) **Form of Tender** prepared in accordance with ITT 12;
- b) **Price Schedules:** completed in accordance with ITT 12 and ITT 14;
- c) **Tender Security or Tender-Securing Declaration**, in accordance with ITT 19.1;
- d) **Alternative Tender**, if permissible, in accordance with ITT 13;
- e) **Authorization:** written confirmation authorizing the signatory of the Tender to commit the Tenderer, in accordance with ITT20.3;
- f) **Tenderer's Qualifications:** documentary evidence in accordance with ITT 17 establishing the Tenderer's qualifications to perform the Contract if its Tender is accepted;
- g) **Tenderer's Eligibility:** documentary evidence in accordance with ITT 17 establishing the Tenderer's eligibility to Tender;
- h) **Eligibility of Goods and Related Services:** documentary evidence in accordance with ITT 16, establishing the eligibility of the Goods and Related Services to be supplied by the Tenderer;
- i) **Conformity:** documentary evidence in accordance with ITT 16, that the Goods and Related Services conform to the tendering document; and
- j) Any other document required **in the TDS**.

In addition to the requirements under ITT 11.1, Tenders submitted by a JV shall include a copy of the Joint Venture Agreement entered into by all members. Alternatively, a Form of intent to execute a Joint Venture Agreement in the event of a successful Tender shall be signed by all members and submitted with the tender, together with a copy of the proposed Agreement. The Tenderer shall chronologically serialize pages of all tender documents submitted.

The Tenderer shall furnish in the Form of Tender information on commissions and gratuities, if any, paid or to be paid to agents or any other party relating to this Tender.

## 12. Form of Tender and Price Schedules

- 12.1 The Form of Tender and Price Schedules shall be prepared using the relevant forms furnished in Section IV, Tendering Forms. The forms must be completed without any alterations to the text, and no substitutes shall be accepted except as provided under ITT 20.3. All blank spaces shall be filled in with the information requested.

## 13. Alternative Tenders

- 13.1 Unless otherwise specified **in the TDS**, alternative Tenders shall not be considered.

## 14 Tender Prices and Discounts

The prices and discounts quoted by the Tenderer in the Form of Tender and in the Price Schedules shall conform to the requirements specified below.

All lots (contracts) and items must be listed and priced separately in the Price Schedules.

The price to be quoted in the Form of Tender in accordance with ITT 11.1 shall be the total price of the Tender, including any discounts offered.

The Tenderer shall quote any discounts and indicate the methodology for their application in the Form of Tender.

Prices quoted by the Tenderer shall be fixed during the Tenderer's performance of the Contract and not subject to variation on any account, unless otherwise specified **in the TDS**. A Tender submitted with an adjustable price quotation shall be treated as non-responsive and shall be rejected, pursuant to ITT 29. However, if in accordance with the TDS, prices quoted by the Tenderer shall be subject to adjustment during the performance of the Contract, a Tender submitted with a fixed price quotation shall not be rejected, but the price adjustment shall be treated as zero.

If so specified in ITT 1.1, Tenders are being invited for individual lots (contracts) or any combination of lots (packages). Unless otherwise specified **in the TDS**, prices quoted shall correspond to 100 % of the items specified for each lot and to 100% of the quantities specified for each item of a lot. Tenderers wishing to offer discounts for the award of more than one Contract shall specify in their Tender the price reductions applicable to each package, or alternatively, to individual Contracts within the package. Discounts shall be submitted in accordance with ITT 14 provided the Tenders for all lots (contracts) are opened at the same time.

The terms EXW, CIP, and other similar terms shall be governed by the rules prescribed in the current edition of Incoterms, published by The International Chamber of Commerce, as specified **in the TDS**.

Prices shall be quoted as specified in each Price Schedule included in Section IV, Tendering Forms. The dis- aggregation of price components is required solely for the purpose of facilitating the comparison of Tenders by the Procuring Entity. This shall not in any way limit the Procuring Entity's right to contract on any of the terms offered. In quoting prices, the Tenderer shall be free to use transportation through carriers registered in any eligible country, in accordance with Section V, Eligible Countries. Similarly, the Tenderer may obtain insurance services from any eligible country in accordance with Section V, Eligible Countries. Prices shall be entered in the following manner:

- a) For Goods manufactured in Kenya:
  - i) the price of the Goods quoted EXW (ex-works, ex-factory, ex warehouse, ex showroom, or off-the- shelf, as applicable), including all customs duties and sales and other taxes already paid or payable on the components and raw material used in the manufacture or assembly of the Goods;
  - ii) any Kenya sales tax and other taxes which will be payable on the Goods if the Contract is awarded to the Tenderer; and

- iii) the price for inland transportation, insurance, and other local services required to convey the Goods to their final destination (Project Site) **specified in the TDS**;
- b) for Goods manufactured outside Kenya, to be imported:
  - i) the price of the Goods, quoted DAP named place of destination, in Kenya, as **specified in the TDS**; and
  - ii) the price for inland transportation, insurance, local taxes payable on the goods and other local services required to convey the Goods from the named place of destination to their final destination (Project Site) **specified in the TDS**;
- c) for Goods manufactured outside Kenya, already imported:
  - i) the price of the Goods, including the original import value of the Goods; plus, any mark-up (or rebate); plus, any other related local cost, and custom duties and other import taxes already paid or to be paid on the Goods already imported;
  - ii) the custom duties and other import taxes already paid (need to be supported with documentary evidence) or to be paid on the Goods already imported;
  - iii) the price of the Goods, obtained as the difference between (i) and (ii) above;
  - iv) any Kenya sales and other taxes which will be payable on the Goods if the Contract is awarded to the Tenderer; and
  - v) the price for inland transportation, insurance, and other local services required to convey the Goods from the named place of destination to their final destination (Project Site) **specified in the TDS**.
- d) for Related Services, other than inland transportation and other services required to convey the Goods to their final destination, whenever such Related Services are specified in the Schedule of Requirements:
  - i) the price of each item comprising the Related Services (inclusive of any applicable taxes).

## 15. Currencies of Tender and Payment

The currency(ies) of the Tender and the currency(ies) of payments shall be the same. The Tenderer shall quote in the currency of Kenya the portion of the Tender price that corresponds to expenditures incurred in Kenya Shillings, unless otherwise specified **in the TDS**.

The Tenderer may express the Tender price in any currency. If the Tenderer wishes to be paid in a combination of amounts in different currencies; it may quote its price accordingly but shall use no more **than two foreign currencies in** addition to the currency of Kenya.

The rates of exchange to be used by the Tenderer shall be the selling exchange rate provided by the Central Bank of Kenya on the tender closing date.

## 16. Documents Establishing the Eligibility and Conformity of the Goods and Related Services

16.1 To establish the eligibility of the Goods and Related Services in accordance with ITT 5, Tenderers shall complete the country of origin declarations in the Price Schedule Forms, included in Section IV, Tendering Forms.

16.2 To establish the conformity of the Health Sector Goods and Related Services to the tendering document, the Tenderer shall furnish as part of its Tender the documentary evidence that the Goods conform to the technical specifications and standards specified in Section VII, Schedule of Requirements.

16.3 The documentary evidence may be in the form of literature, drawings or data, and shall consist of:

- a) an item-by-item commentary on the provisions of Section VII, Schedule of Requirements demonstrating substantial responsiveness of the Goods and Services to the specifications, or a statement of deviations and exceptions to the provisions of the specifications; and
- b) any other procurement-specific documentation requirement as stated **in the TDS**.

16.4 Unless the **TDS** stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the relevant authority in Kenya. A Tenderer who has already registered its Goods by the time of Tendering should submit a copy of the Registration Certificate with its Tender. Otherwise, the successful Tenderer, by the time of Contract signing, shall submit to the Procuring Entity either:

- a) A copy of the Registration Certificate of the Goods for use in Kenya; or
- b) If such Registration Certificate has not yet been obtained, evidence establishing to the Procuring Entity's satisfaction that the Tenderer has complied with all the documentary requirements for registration as specified **in the TDS**

16.5 The Procuring Entity shall at all times cooperate with the successful Tenderer to facilitate the registration process within Kenya. The agency and contact person able to provide additional information about registration are identified **in the TDS**.

If the Goods of the successful Tenderer have not been registered in Kenya at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained.

16.6 Standards for workmanship, process, material, and equipment, as well as references to brand names or catalogue numbers specified by the Procuring Entity in the Schedule of Requirements, are intended to be descriptive only and not restrictive. The Tenderer may offer other standards of quality, brand names, and/or catalogue numbers, provided that it demonstrates, to the Procuring Entity's satisfaction, that the substitutions ensure substantial equivalence or are superior to those specified in the Section VII, Schedule of Requirements.

## **17. Documents Establishing the Eligibility and Qualifications of the Tenderer**

17.1 To establish Tenderer's eligibility in accordance with ITT 4, Tenderers shall complete the Form of Tender, included in Section IV, Tendering Forms.

17.2 The documentary evidence of the Tenderer's qualifications to perform the Contract if its Tender is accepted shall establish to the Procuring Entity's satisfaction:

- a) that a Tenderer that does not manufacture or produce the Health Sector Goods it offers to supply shall submit the Manufacturer's Authorization using the form included in Section IV, Tendering Forms to demonstrate that it has been duly authorized by the manufacturer or producer of the Goods to supply these Goods in Kenya;



- b) that in case of a Tenderer not doing business within Kenya (or for other reasons will not itself carry out service obligations), the Tenderer is or will be (if awarded the Contract) represented by a local service provider in Kenya equipped and able to carry out the Tenderer's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and
- c) that the Tenderer meets each of the qualification criterion specified in Section III, Evaluation and Qualification Criteria (see additional ITT for Health Products and vaccines).

17.3 Tenderers shall be asked to provide, as part of the data for qualification, such information, including details of ownership, as shall be required to determine whether, according to the classification established by the Procuring Entity a supplier or group of suppliers' qualifies for a margin of preference. Further the information will enable the Procuring Entity identify any actual or potential conflict of interest in relation to the procurement and/or contract management processes, or a possibility of collusion between tenderers, and thereby help to prevent any corrupt influence in relation to the procurement process or contract management.

17.4 The purpose of the information described in ITT 17.2 above overrides any claims to confidentiality which a tenderer may have. There can be no circumstances in which it would be justified for a tenderer to keep information relating to its ownership and control confidential where it is tendering to undertake public sector work and receive public sector funds. Thus, confidentiality will not be accepted by the Procuring Entity as a justification for a Tenderer's failure to disclose, or failure to provide required information on its ownership and control.

17.5 The Tenderer shall provide further documentary proof, information or authorizations that the Procuring Entity may request in relation to ownership and control which information on any changes to the information which was provided by the tenderer under ITT17.3. The obligations to require this information shall continue for the duration of the procurement process and contract performance and after completion of the contract, if any change to the information previously provided may reveal a conflict of interest in relation to the award or management of the contract.

17.6 All information provided by the tenderer pursuant to these requirements must be complete, current and accurate as at the date of provision to the Procuring Entity. In submitting the information required pursuant to these requirements, the Tenderer shall warrant that the information submitted is complete, current and accurate as at the date of submission to the Procuring Entity.

17.7 If a tenderer fails to submit the information required by these requirements, its tenderer will be rejected. Similarly, if the Procuring Entity is unable, after taking reasonable steps, to verify to a reasonable degree the information submitted by a tenderer pursuant to these requirements, then the tender will be rejected.

17.8 If information submitted by a tenderer pursuant to these requirements, or obtained by the Procuring Entity (whether through its own enquiries, through notification by the public or otherwise), shows any conflict of interest which could materially and improperly benefit the tenderer in relation to the procurement or contract management process, then:

- i) If the procurement process is still ongoing, the tenderer will be disqualified from the procurement process,

- ii) If the contract has been awarded to that tenderer, the contract award will be set aside,
- iii) the tenderer will be referred to the relevant law enforcement authorities for investigation of whether the tenderer or any other persons have committed any criminal offence.

17.9 If a tenderer submits information pursuant to these requirements that is incomplete, inaccurate or out-of-date, or attempts to obstruct the verification process, then the consequences of ITT 17.7 will ensue unless the tenderer can show to the reasonable satisfaction of the Procuring Entity that any such act was not material, or was due to genuine error which was not attributable to the intentional act, negligence or recklessness of the tenderer.

## **18 Period of Validity of Tenders**

18.1 Tenders shall remain valid for the Tender Validity period specified **in the TDS**. The Tender Validity period starts from the date fixed for the Tender submission deadline (as prescribed by the Procuring Entity in accordance with ITT 22.1). A Tender valid for a shorter period shall be rejected by the Procuring Entity as non-responsive.

18.2 In exceptional circumstances, prior to the expiration of the Tender validity period, the Procuring Entity may request Tenderers to extend the period of validity of their Tenders. The request and the responses shall be made in writing. If a Tender Security is requested in accordance with ITT 19, it shall also be extended for a corresponding period. A Tenderer may refuse the request without forfeiting its Tender Security. A Tenderer granting the request shall not be required or permitted to modify its Tender.

## **19 Tender Security**

19.1 The Tenderer shall furnish as part of its Tender, either a Tender-Securing Declaration or a Tender Security, as specified **in the TDS**, in original form and, in the case of a Tender Security, in the amount and currency specified **in the TDS**.

19.2 A Tender-Securing Declaration shall use the form included in Section IV, Tendering Forms.

If a Tender is specified pursuant to ITT 19.1, the Tender Security shall be a:

- i) cash;
- ii) a bank guarantee;
- iii) a guarantee by an insurance company registered and licensed by the Insurance Regulatory Authority listed by the Authority; or
- iv) a guarantee issued by a financial institution approved and licensed by the Central Bank of Kenya.
- v) Any other Form specified in the **TDS**.

19.3 If a Tender Security is specified pursuant to ITT 19.1, any Tender not accompanied by a substantially responsive Tender Security shall be rejected by the Procuring Entity as non-responsive.

- 19.4 If a Tender Security is specified pursuant to ITT 19.1, the Tender Security of unsuccessful Tenderers shall be returned as promptly as possible upon the successful Tenderer's signing the Contract and furnishing the Performance Security pursuant to ITT 45. The Procuring Entity shall also promptly return the tender security to the tenderers where the procurement proceedings are terminated, all tenders were determined non-responsive or abider declines to extend tender validity period.
- 19.5 The Tender Security of the successful Tenderer shall be returned as promptly as possible once the successful Tenderer has signed the Contract and furnished the required Performance Security.
- 19.6 The Tender Security may be forfeited or the Tender-Securing Declaration executed:
- a) if a Tenderer withdraws its Tender during the period of Tender validity specified by the Tenderer on the Form of Tender, or any extension thereto provided by the Tenderer; or
  - b) if the successful Tenderer fails to:
    - i) sign the Contract in accordance with ITT 44; or
    - ii) furnish a Performance Security in accordance with ITT 45.
- 19.7 Where tender securing declaration is executed, the Procuring Entity shall recommend to the PPRA that PPRA debar the Tenderer from participating in public procurement as provided in the law.
- 19.8 The Tender Security or Tender- Securing Declaration of a JV must be in the name of the JV that submits the Tender. If the JV has not been legally constituted into a legally enforceable JV at the time of Tendering, the Tender Security or Tender-Securing Declaration shall be in the names of all future members as named in the Form of intent referred to in ITT 4.1 and ITT 11.2.

## **20. Format and Signing of Tender**

- 20.1 The Tenderer shall prepare one original of the documents comprising the Tender as described in ITT 11 and clearly mark it "ORIGINAL." Alternative Tenders, if permitted in accordance with ITT 13, shall be clearly marked "ALTERNATIVE" In addition, the Tenderer shall submit copies of the Tender, in the number specified **in the TDS** and clearly mark them "COPY." In the event of any discrepancy between the original and the copies, the original shall prevail.
- 20.2 Tenderers shall mark as "CONFIDENTIAL" information in their Tenders which is confidential to their business. This may include proprietary information, trade secrets or commercial or financially sensitive information.
- 20.3 The original and all copies of the Tender shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Tenderer. This authorization shall consist of a written confirmation as specified **in the TD** and shall be attached to the Tender. The name and position held by each person signing the authorization must be typed or printed below the signature. All pages of the Tender where entries or amendments have been made shall be signed or initialed by the person signing the Tender.

20.4 In case the Tenderer is a JV, the Tender shall be signed by an authorized representative of the JV on behalf of the JV, and so as to be legally binding on all the members as evidenced by a power of attorney signed by their legally authorized representatives.

20.5 Any inter-lineation, erasures, or overwriting shall be valid only if they are signed or initialed by the person signing the Tender.

## **D. Submission and Opening of Tenders**

### **21. Sealing and Marking of Tenders**

21.1 The Tenderer shall deliver the Tender in a single, sealed envelope (one-envelope Tendering process). Within the single envelope the Tenderer shall place the following separate, sealed envelopes:

- a) In an envelope marked "ORIGINAL", all documents comprising the Tender, as described in ITB11; and
- b) in an envelope marked "COPIES", all required copies of the Tender; and
- c) if alternative Tenders are permitted in accordance with ITB13, and if relevant:
  - i) in an envelope marked "ORIGINAL-ALTERNATIVE", the alternative Tender; and
  - ii) in the envelope marked "COPIES-ALTERNATIVE TENDER" all required copies of the alternative Tender.

21.2 The outer envelopes, shall:

- d) Be addressed to the Procuring Entity in accordance with ITT 22.1;
- e) Bear the specific identification of this Tendering process indicated in ITT 1.1; and
- f) bear a warning not to open before the time and date for Tender opening.

The inner envelopes shall bear the name and address (include email and telephone number) of the Tenderer and all the information above ITT21.2 (a) to (c).

21.3 If all envelopes are not sealed and marked as required, the Procuring Entity will assume no responsibility for the misplacement or premature opening of the Tender. Tenders that are misplaced or opened prematurely will not be accepted.

### **22. Deadline for Submission of Tenders**

Tenders must be received by the Purchaser at the address specified in the TDS no later than the time and date specified in the TDS.

22.2 The Procuring Entity may, at its discretion, extend the deadline for the submission of Tenders by amending the tendering document in accordance with ITT8, in which case all rights and obligations of the Procuring Entity and Tenderers previously subject to the deadline shall thereafter be subject to the deadline as extended.

### **23. Late Tenders**

23.1 Any tender received by the Purchaser after the deadline for submission of tenders prescribed by the Purchaser in the TDS pursuant will be rejected and returned unopened to the Tenderer.

### **24. Withdrawal, Substitution, and Modification of Tenders**

24.1 A Tenderer may withdraw, substitute, or modify its Tender after it has been submitted by sending a written notice, duly signed by an authorized representative, and shall include a copy of the authorization (the power of attorney) in accordance with ITT 20.3, (except that withdrawal notices do not require copies). The corresponding substitution or modification of the Tender must accompany the respective written notice. All notices must be:

- a) prepared and submitted in accordance with ITT 20 and 21 (except that withdrawal notices do not require copies), and in addition, the respective envelopes shall be clearly marked "WITHDRAWAL," "SUBSTITUTION," or "MODIFICATION;" and
- b) received by the Procuring Entity prior to the dead line prescribed for submission of Tenders, in accordance with ITT 22.1.

24.2 Tenders requested to be withdrawn in accordance with ITT24 shall be returned unopened to the Tenderers.

24.3 No Tender may be withdrawn, substituted, or modified in the interval between the deadline for submission of Tenders and the expiration of the period of Tender validity specified by the Tenderer on the Form of Tender or any extension thereof.

### **25. Tender Opening**

25.1 Except as in the cases specified in ITT23 and ITT24.2, the Procuring Entity shall publicly open and read out in accordance with this ITT all Tenders received by the deadline at the date, time and place specified **in the TDS** in the presence of Tenderers' designated representatives and anyone who choose to attend. All Tenderers, or their representatives and any interested party may attend a public opening. Any specific electronic Tender opening procedures required if electronic Tendering is permitted in accordance with ITT22.1, shall be as specified **in the TDS**.

25.2 First, envelopes marked "WITHDRAWAL" shall be opened and read out and the envelope with the corresponding Tender shall not be opened, but returned to the Tenderer. If the withdrawal envelope does not contain a copy of the "power of attorney" confirming the signature as a person duly authorized to sign on behalf of the Tenderer, the corresponding Tender will be opened. No Tender withdrawal shall be permitted unless the corresponding withdrawal notice contains a valid authorization to request the withdrawal and is read out at Tender opening.

25.3 Next, envelopes marked "SUBSTITUTION" shall be opened and read out and exchanged with the corresponding Tender being substituted, and the substituted Tender shall not be opened, but returned to the Tenderer. No Tender substitution shall be permitted unless the corresponding substitution notice contains a valid authorization to request the substitution and is read out at Tender opening.

- 25.4 Next, envelopes marked “MODIFICATION” shall be opened and read out with the corresponding Tender. No Tender modification shall be permitted unless the corresponding modification notice contains a valid authorization to request the modification and is read out at Tender opening.
- 25.5 Next, all remaining envelopes shall be opened one at a time, reading out: the name of the Tenderer and whether there is a modification; the total Tender Prices, per item or lot (contract) if applicable, including any discounts and alternative Tenders; the presence or absence of a Tender Security, if required; and any other details as the Procuring Entity may consider appropriate.
- 25.6 Only Tenders, alternative Tenders and discounts that are opened and read out at Tender opening shall be considered further for evaluation. The Form of Tender and the Price Schedules are to be initialed by representatives of the Procuring Entity attending Tender opening in the manner specified **in the TDS**.
- 25.7 The Procuring Entity shall neither discuss the merits of any Tender nor reject any Tender (except for late Tenders, in accordance with ITT 23.1).
- 25.8 The Procuring Entity shall prepare a record of the Tender opening that shall include, as a minimum:
- a) The name of the Tenderer and whether there is a withdrawal, substitution, or modification;
  - b) The Tender Price, per lot(contract)if applicable, including any discounts;
  - c) any alternative Tenders; and
  - d) the presence or absence of a Tender Security or Tender Securing Declaration, if one was required.
  - e) Number of pages of each tender document submitted
- 25.9 The Tenderers' representatives who are present shall be requested to sign the record. The omission of a Tenderer's signature on the record shall not invalidate the contents and effect of the record. A copy of the tender opening register shall be issued to a tenderer upon request.

## **E. Evaluation and Comparison of Tenders**

### **26. Confidentiality**

- 26.1 Information relating to the evaluation of Tenders and recommendation of contract award, shall not be disclosed to Tenderers or any other persons not officially concerned with the Tendering process until the Notification of Intention to Award the Contract is transmitted to all Tenderers in accordance with ITT 40.
- 26.2 Any effort by a Tenderer to influence the Procuring Entity in the evaluation or contract award decisions may result in the rejection of its Tender.
- 26.3 Notwithstanding ITT 26.2, from the time of Tender opening to the time of Contract Award, if any Tenderer wishes to contact the Procuring Entity on any matter related to the Tendering process, it should do so in writing.

## **27. Clarification of Tenders**

27.1 To assist in the examination, evaluation, comparison of the Tenders, and qualification of the Tenderers, the Procuring Entity may, at its discretion, ask any Tenderer for a clarification of its Tender. Any clarification submitted by a Tenderer in respect to its Tender and that is not in response to a request by the Procuring Entity shall not be considered. The Procuring Entity's Invitation to clarification and the response shall be in writing. No change, including any voluntary increase or decrease, in the prices or substance of the Tender shall be sought, offered, or permitted, except to confirm the correction of arithmetic errors discovered by the Procuring Entity in the Evaluation of the Tenders, in accordance with ITT 31.

27.2 If a Tenderer does not provide clarifications of its Tender by the date and time set in the Procuring Entity's Invitation to clarification, its Tender may be rejected.

## **28. Deviations, Reservations, and Omissions**

28.1 During the evaluation of Tenders, the following definitions apply:

- a) "Deviation" is a departure from the requirements specified in the tendering document;
- b) "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in the tendering document; and
- c) "Omission" is the failure to submit part or all of the information or documentation required in the tendering document.

## **29. Determination of Responsiveness**

29.1 The Procuring Entity's determination of a Tender's responsiveness is to be based on the contents of the Tender itself, as defined in ITT 11.

29.2 A substantially responsive Tender is one that meets the requirements of the tendering document without material deviation, reservation, or omission. A material deviation, reservation, or omission is one that:

- a) If accepted, would:
  - i) affect in any substantial way the scope, quality, or performance of the Goods and Related Services specified in the Contract; or
  - ii) limit in any substantial way, inconsistent with the tendering document, the Procuring Entity's rights or the Tenderer's obligations under the Contract; or
- b) if rectified, would unfairly affect the competitive position of other Tenderers presenting substantially responsive Tenders.

29.3 The Procuring Entity shall examine the technical aspects of the Tender submitted in accordance with ITT 16 and ITT 17, in particular, to confirm that all requirements of Section VII, Schedule of requirements have been met without any material deviation or reservation, or omission.

29.4 If a Tender is not substantially responsive other requirements of tendering document, it shall be rejected by the Procuring Entity and may not subsequently be made responsive by correction of the material deviation, reservation, or omission.

### **30. Non-conformities, Error sand Omissions**

- 30.1 Provided that a Tender is substantially responsive, the Procuring Entity may waive any non-conformity in the Tender.
- 30.2 Provided that a Tender is substantially responsive, the Procuring Entity may request that the Tenderer submit the necessary information or documentation, within a reasonable period of time, to rectify nonmaterial non- conformities or omissions in the Tender related to documentation requirements. Such omission shall not be related to any aspect of the price of the Tender. Failure of the Tenderer to comply with the request may result in the rejection of its Tender.
- 30.3 Provided that a Tender is substantially responsive, the Procuring Entity shall rectify quantifiable nonmaterial non-conformities related to the Tender Price. To this effect, the Tender Price shall be adjusted, for comparison purposes only, to reflect the price of a missing or n on-conforming item or component in the manner specified **in the TDS**.

### **31. Arithmetical Errors**

- 31.1 The tenders submitted and read out during the tender opening shall be absolute and final and shall not be the subject of correction, adjustment or amendment in any way by any person or entity.
- 31.2 Provided that the Tender is substantially responsive, the Procuring Entity shall handle errors on the following basis:
- a) Any error detected if considered a major deviation that affects the substance of the tender, shall lead to disqualification of the tender as non-responsive.
  - b) Any errors in the submitted tender arising from a miscalculation of unit price, quantity, and subtotal and total bid price shall be considered as a major deviation that affects the substance of the tender and shall lead to disqualification of the tender as non-responsive. and
  - c) If there is a discrepancy between words and figures, the amount in words shall prevail
- 31.3 Tenderers shall be notified of any error detected in their bid during the notification of award.

### **32. Conversion to Single Currency**

- 32.1 For evaluation and comparison purposes, the currency (ies) of the Tender shall be converted in a single currency as specified **in the TDS**.

### **33. Margin of Preference and Reservations**

- 33.1 A margin of preference may be allowed on locally manufactured Health goods only when the contract is open to international tendering, where the tender is likely to attract foreign goods and where the contract exceeds the threshold specified in the Regulations. A margin of preference shall not be allowed unless it is specified so in the **TDS**.
- 33.2 Contracts procured on basis of international competitive tendering shall not be subject to reservations to specific groups as provided in ITT 33.3.



33.3 Where it is intended to reserve a contract to a specific group of businesses (these groups are Small and Medium Enterprises, Women Enterprises, Youth Enterprises and Enterprises of persons living with disability, as the case maybe), and who are appropriately registered as such by a competent authority, a procuring entity shall ensure that the invitation to tender specifically indicates that only businesses or firms belonging to the group are eligible to tender. No tender shall be reserved to more than one group. If not so stated in the Tender documents, the invitation to tender will be open to all interested tenderers.

#### **34 Evaluation of Tenders**

34.1 The Procuring Entity shall use the criteria and methodologies listed in this ITT and Section III, Evaluation and Qualification criteria. No other evaluation criteria or methodologies shall be permitted. By applying the criteria and methodologies, the Procuring Entity shall determine the Lowest Evaluated Tender. This is the Tender of the Tenderer that meets the qualification criteria and whose Tender has been determined to be:

- a) Substantially responsive to the tendering document; and
- b) The lowest evaluated cost.

34.2 To evaluate a Tender, the Procuring Entity shall consider the following:

- c) Price adjustment due to discounts offered in accordance with ITT 14.
- d) Price adjustment due to quantifiable non material non-conformities in accordance with ITT 30.3; and
- e) converting the amount resulting from applying (a) and (b) above, if relevant, to a single currency in accordance with ITT 32;
- f) any additional evaluation factors specified in Section III, Evaluation and Qualification Criteria.

34.3 The estimated effect of the price adjustment provisions of the Conditions of Contract, applied over the period of execution of the Contract, shall not be taken in to account in Tender evaluation.

34.4 In the case of multiple contracts or lots, Tenderers are allowed to tender for one or more lots and the methodology to determine the lowest evaluated cost of the lot (contract) and for combinations, including any discounts offered in the Form of Tender, is specified in Section III, Evaluation and Qualification Criteria.

34.5 The Procuring Entity's evaluation of a Tender will exclude and not taken to account:

- g) in the case of Goods manufactured in Kenya, sales and other similar taxes, which will be payable on the goods if a contract is awarded to the Tenderer;
- h) in the case of Goods manufactured outside Kenya, already imported or to be imported, customs duties and other import taxes levied on the imported Good, sales and other similar taxes, which will be payable on the Goods if the contract is awarded to the Tenderer;
- i) any allowance for price adjustment during the period of execution of the contract, if provided in the Tender.

34.6 The Procuring Entity's evaluation of a Tender may require the consideration of other factors, in addition to the Tender Price quoted in accordance with ITT 14. These factors may be related to the characteristics, performance, and terms and conditions of purchase of the Goods and Related Services. The effect of the factors selected, if any, shall be expressed in monetary terms to facilitate comparison of Tenders, unless otherwise specified **in the TDS** from amongst those set out in Section III, Evaluation and Qualification Criteria. The criteria and methodologies to be used shall be as specified in ITT 34.2

### **35. Comparison of Tenders**

35.1 The Procuring Entity shall compare the evaluated costs of all substantially responsive Tenders established in accordance with ITT 34.2 to determine the Tender that has the lowest evaluated cost. The comparison shall be on the basis of CIP (place of final destination) prices for imported goods and EXW prices, plus cost of inland transportation and insurance to place of destination, for goods manufactured within Kenya, together with prices for any required installation, training, commissioning and other services. The evaluation of prices shall not take into account custom duties and other taxes levied on imported goods quoted CIP and sales and similar taxes levied in connection with the sale or delivery of goods.

### **36. Abnormally Low Tenders and Abnormally**

#### **High Tenders Abnormally Low Tenders**

36.1 An Abnormally Low Tender is one where the Tender price in combination with other constituent elements of the Tender, appears unreasonably low to the extent that the Tender price raises material concerns with the Procuring Entity as to the capability of the Tenderer to perform the Contract for the offered Tender price.

37.2 In the event of identification of a potentially Abnormally Low Tender by the evaluation committee, the Procuring Entity shall seek written clarification from the Tenderer, including a detailed price analyses of its Tender price in relation to the subject matter of the contract, scope, delivery schedule, allocation of risks and responsibilities and any other requirements of the tendering document.

37.3 After evaluation of the price analyses, in the event that the Procuring Entity determines that the Tenderer has failed to demonstrate its capability to perform the contract for the offered Tender price, the Procuring Entity shall reject the Tender.

#### **Abnormally High Tenders**

37.4 An abnormally high tender price is one where the tender price, in combination with other constituent elements of the Tender, appears unreasonably too high to the extent that the Procuring Entity is concerned that it (the Procuring Entity) may not be getting value for money or it may be paying too high a price for the contract compared with market prices or that genuine competition between Tenderers is compromised.

37.5 In case of an abnormally high price, the Procuring Entity shall make a survey of the market prices, check if the estimated cost of the contract is correct and review the Tender Documents to check if the specifications, scope of work and conditions of contract are contributory to the abnormally high tenders. The Procuring Entity may also seek written clarification from the tenderer on the reason for the high tender price. The Procuring Entity shall proceed as follows:

- (i) If the tender price is abnormally high based on wrong estimated cost of the contract, the Procuring Entity may accept or not accept the tender depending on the Procuring Entity's budget considerations.
- (ii) If specifications, scope of work and/or conditions of contract are contributory to the abnormally high tender prices, scope of work and conditions of contract, as the case may be.

37.6 If the Procuring Entity determines that the Tender Price is abnormally too high because genuine competition between tenderers is compromised (*often due to collusion, corruption or other manipulations*), the Procuring Entity shall reject all Tenders and shall institute or cause competent Government Agencies to institute an investigation on the cause of the compromise, before retendering.

### **37. Qualification of the Tenderer**

37.1 The Procuring Entity shall determine to its satisfaction whether the Tenderer that is selected a shaving submitted the lowest evaluated cost and substantially responsive Tender is eligible and meets the qualifying criteria specified in ITT 11.1 as applicable, and Section III, Evaluation and Qualification Criteria.

37.2 The determination shall be based upon an examination of the documentary evidence of the Tenderer's qualifications submitted by the Tenderer, pursuant to ITT 17. The determination shall not take into consideration the qualifications of other firms such as the Tenderer's subsidiaries, parent entities, affiliates, sub-contractors or any other firm (s) different from the Tenderer.

37.3 An affirmative determination shall be a prerequisite for award of the Contract to the Tenderer. A negative determination shall result in disqualification of the Tender, in which event the Procuring Entity shall proceed to the Tenderer who offers a substantially responsive Tender with the next lowest evaluated cost to make a similar determination of that Tenderer's qualification stopper form satisfactorily.

### **38. Procuring Entity's Right to Accept Any Tender, and to Reject Any or All Tenders**

38.1 The Procuring Entity reserves the right to accept or reject any tender, and to annul the Tendering process and reject all Tenders at any time prior to Contract Award, without thereby incurring any liability to Tenderers. In case of annulment, all Tenderers shall be notified with reasons and all Tenders submitted and specifically, tender securities, shall be promptly returned to the Tenderers.

## **F. Award of Contract**

### **39. Award Criteria**

39.1 The Procuring Entity shall award the Contract to the successful tenderer whose tender has been determined to be the Lowest Evaluated Tender.

### **40. Notice of Intention to enter into a Contract**

40.1 Upon award of the contract and Prior to the expiry of the Tender Validity Period the Procuring Entity shall issue a Notification of Intention to Enter in to a Contract/Notification of award to all tenderers which shall contain, at a minimum, the following information:

- a) The name and address of the Tenderer submitting the successful tender;
- b) The Contract price of the successful tender;
- c) a statement of the reason(s) the tender of the unsuccessful tenderer to whom the letter is addressed was unsuccessful, unless the price information in (c) above already reveals the reason;
- d) the expiry date of the Stands till Period; and
- e) instructions on how to request a de briefing and/or submit a complaint during the stand still period;

#### **41. Standstill Period**

- 41.1 The Contract shall not be signed earlier than the expiry of a Standstill Period of 14 days to allow any dissatisfied tender to launch a complaint. Where only one Tender is submitted, the Standstill Period shall not apply.
- 41.2 Where a Standstill Period applies, it shall commence when the Procuring Entity has transmitted to each Tenderer the Notification of Intention to enter in to a Contract with the successful Tenderer.

#### **42. Debriefing by the Procuring Entity**

- 42.1 On receipt of the Procuring Entity's Notification of Intention to Enter into a Contract referred to in ITT 40, an unsuccessful tenderer may make a written request to the Procuring Entity for a debriefing on specific issues or concerns regarding their tender. The Procuring Entity shall provide the debriefing within five days of receipt of the request. Debriefings of unsuccessful full Tenderers may be done in writing or verbally. The Tenderer shall bear its own costs of attending such a debriefing meeting.

#### **43. Letter of Award**

- 46.1 Prior to the expiry of the Tender Validity Period and upon expiry of the Standstill Period specified in ITT 41.1, upon addressing a complaint that has been filed within the Standstill Period; the Procuring Entity shall transmit the Letter of Award to the successful Tenderer. The letter of award shall request the successful tenderer to furnish the Performance Security within 21days of the date of the letter.

#### **44. Signing of Contract**

- 44.1 Upon the expiry of the fourteen days of the Notification of Intention to enter in to contract and upon the parties meeting their respective statutory requirements, the Procuring Entity shall send the successful Tenderer the Contract Agreement.
- 44.2 Within fourteen (14) days of receipt of the Contract Agreement, the successful Tenderer shall sign, date, and return it to the Procuring Entity.
- 44.3 The written contract shall be entered into within the period specified in the notification of award and before expiry of the tender validity period.

#### **45. Performance Security**

- 45.1 Within twenty-Eight (28) days of the receipt of the Letter of Award from the Procuring Entity, the successful Tenderer shall furnish the Performance Security and, any other documents required in the **TDS**, in accordance with the General Conditions of Contract, using the Performance Security and other Forms included in Section X, Contract Forms, or another form acceptable to the Procuring Entity. A foreign institution providing a bank guarantee shall have a correspondent financial institution located in Kenya, unless the Procuring Entity has agreed in writing that a correspondent bank is not required.
- 45.2 Failure of the successful Tenderer to submit the above-mentioned Performance Security and other documents required in the **TDS** or sign the Contract shall constitute sufficient grounds for the annulment of the award and forfeiture of the Tender Security. In that event the Procuring Entity may award the Contract to the Tenderer offering the next Best Evaluated Tender.
- 45.3 Performance security shall not be required for contracts estimated to cost less than the amount specified in the Regulations.

#### **46. Publication of Procurement Contract**

- 46.1 Within fourteen days after signing the contract, the Procuring Entity shall publish the awarded contract at its noticeboards and websites; and on the Website of the Authority. At the minimum, the notice shall contain the following information:
- a) Name and address of the Procuring Entity;
  - b) Name and reference number of the contract being awarded, a summary of its scope and the selection method used;
  - c) the name of the successful Tenderer, the final total contract price, the contract duration.
  - d) Dates of signature, commencement and completion of contract;
  - e) names of all Tenderers that submitted Tenders, and their Tender prices as read out at Tender opening.

#### **47. Procurement Related Complaint**

- 47.1 The procedures for making a Procurement-related Complaint are as specified in the **TDS**.

## SECTION II - TENDER DATA SHEET (TDS)

The following specific data for the Maintenance Services to be procured shall complement, supplement, or amend the provisions in the Instructions to Tenderers (ITT). Whenever there is a conflict, the provisions here in shall prevail over those in ITT.

*[Where an e-procurement system issued, modify the relevant parts of the TDS accordingly to reflect the e-procurement process].*

*[Instructions for completing the Tender Data Sheet are provided, as needed, in the notes in italics mentioned for the relevant ITT].*

ITT Reference	A. General
<b>ITT 1.1</b>	<b><i>The reference number of the Invitation to Tenders (ITT) is: GF ATM TB NFM - 21/22 - OIT - 003 SUPPLY OF LIQUID CHROMATOGRAPHY/MASS SPECTROSCOPY SYSTEM</i></b> <b><i>The Procuring Entity is: Kenya Medical Supplies Authority (KEMSA)</i></b> <b><i>The name of the ITT is: GF ATM TB NFM - 21/22 - OIT - 003 SUPPLY OF LIQUID CHROMATOGRAPHY/MASS SPECTROSCOPY SYSTEM</i></b> <b><i>The number and identification of lots (contracts) comprising this ITT is: 24 Items</i></b>
ITT 1.2(a)	<i>Not Applicable</i>
ITT 4.1	Maximum number of members in the Joint Venture (JV) shall be: 3
B. Contents of Tendering Document	

ITT 7.1	<p>Purchaser's address:</p> <p>Kenya Medical Supplies Authority (KEMSA)</p> <p>Office address:</p> <p>The Chief Executive Officer Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya</p> <p>Postal address:</p> <p>P.O. Box: 47715 -00100 Nairobi, Kenya Tel No: +254 719033000/ +254 726618520/1 E- mail <a href="mailto:procurement.program@kemsa.co.ke">procurement.program@kemsa.co.ke</a></p> <p>For clarifications on the Tender document please contact:</p> <p>The Chief Executive Officer P. O. Box 47715 - 00100 Nairobi/Kenya Tel: +254 719033000/ +254 726618520/1 E- mail: <a href="mailto:procurement.program@kemsa.co.ke">procurement.program@kemsa.co.ke</a></p> <p>Requests for clarification should be received by the Procuring Entity not later than <b>12<sup>th</sup> May, 2022</b> (a third of number of days before deadline for tender submission).</p> <p>The Procuring Entity shall publish its response at the website: <a href="http://www.kemsa.co.ke/tenders/">http://www.kemsa.co.ke/tenders/</a> and <a href="http://www.tenders.go.ke">www.tenders.go.ke</a></p>
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<b>C. Preparation of Tenders</b>	
ITT 11.1(j)	The Tenderer shall submit the following additional documents in its Tender: <i>As detailed under section III</i>
ITT 13.1	Alternative Tenders <i>shall not be considered.</i>
ITT 14.5	The prices quoted by the Tenderer <i>shall not</i> be subject to adjustment during the performance of the Contract.
ITT 14.6	Prices quoted for each lot (contract) shall correspond at least to <i>[insert figure]</i> percent of the items specified for each lot (contract): <b>Not Applicable.</b> Prices quoted for each item of a lot shall correspond at least to <i>[insert figure]</i> percent of the quantities specified for this item of a lot: <b>Not Applicable.</b>
ITT 14.7	The Incoterms edition is: <b>incoterms 2020</b> edition.
ITT 14.8 (a) iii, (b) (i) and (c)	Place of destination: <b>DAP, named place of destination National Quality Control Laboratory, KNH Complex in Upper Hill - Nairobi - Kenya</b>
ITT 14.8 (a) (iii),	Final Destination (Project Site): <b>DAP, named place of destination National Quality Control Laboratory, KNH Complex in Upper Hill - Nairobi - Kenya</b>

ITT 15.1	<p>The Tenderer may express the Tender price in any currency. If the Tenderer wishes to be paid in a combination of amounts in different currencies; it may quote its price accordingly but shall use no more <b>than two foreign currencies in</b> addition to the currency of Kenya.</p> <p>The date of exchange rate determination is the selling rate on the tender closing date</p>
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ITT 16.3(b)

Applicable Guidelines: Government of Kenya (GOK), The Public Procurement and Asset Disposal Act 2015. The Global Fund's Policies on Procurement and Supply Management, June 2021 The Global Fund Quality Assurance Policy as amended and restated on 14 December, 2010.

Note: In the event of a conflict between the Public Procurement and Asset Disposal Act and the Global Fund's PSM Policies, the Global Fund's PSM Policies shall prevail.

Other procurement-specific documentation requirements are:

(a) The bidder must provide evidence of Good Manufacturing Practices (GMP) including for quality management system of pharmaceutical product; or an equivalent quality management system recognized by a regulatory authority, which is a member of GHTF or ISO 9000.

(b) The Tenderer is requested to provide, in support of their technical offer, a sample for evaluation under separate cover at or before the tender closing date and time. The sample is to be clearly labeled with the tenderer's name, tender reference and identification of the product. The sample requested is to be submitted as per technical specification offered by the Tenderer and shall represent exactly the product that is intended to be supplied in case of contract award.

(c) If, for reasons other than the tender specific labeling requirements, the sample is not consistent with the required technical specifications then the offer for the particular item shall be rejected.

(d) For quality assurance reasons, for each sample provided, a protocol (certificate of analysis) of a product test conducted by the laboratory of the manufacturer has to be provided from the same batch of production in case of award of contract.

ITT 193 (v)	<i>Not Applicable</i>
ITT 19.6	If the Tenderer performs any of the actions prescribed in subparagraphs ITT 19.6 (a) or (b) of this provision, the Procuring Entity will declare the Tenderer ineligible to be awarded a contract by the Procuring Entity for a period not less than 3 years.
ITT 20.1	<i>Tenderers shall electronically upload complete bid document(s) and copies of all required documents specified under Section III (Evaluation and Qualification Criteria) on the IFMIS Supplier Portal: <a href="http://www.supplier.treasury.go.ke">www.supplier.treasury.go.ke</a>. The documents shall be serialized/paginated, in PDF format and clearly marked with the Tender Number and description – NOT APPLICABLE TO THIS TENDER</i>
ITT 20.3	The written confirmation of authorization to sign on behalf of the Tenderer shall consist of: <i>A written Power of Attorney</i>
ITT 21.1	Applicable to submission of tender security.
ITT 16.4	Goods to be supplied under the Contract shall be registered with the Pharmacy & Poisons Board in Kenya.
ITT 16.5	The contact person in the Procuring Entity able to provide additional information about registration is: <i>The Chief Executive Officer</i>
ITT 18.1	The Tender validity period shall be 120 days.
ITT 18.3 (a)	Not Applicable
ITT 19.1	<i>A Tender Security shall be required.</i> The amount and currency of the Tender security shall be <b>USD 5,000.00 or KES 575,000.00</b> or equivalent in freely convertible currency.

D. Submission and Opening of Tenders

ITT 22.1	<p>For <u>Tender submission purposes only</u>, the Procuring Entity's address is: <i>Kenya Medical Supplies Authority clarifications</i>  The Chief Executive Officer  Kenya Medical Supplies Authority (KEMSA)  Commercial Street, Industrial Area  Nairobi/Kenya</p> <p>Postal address:  P.O. Box: 47715  00100 Nairobi  Kenya</p> <p>Tel No: +254 719033000/ +254 726618520/1  E- mail: <a href="mailto:procurement.programs@kemsa.co.ke">procurement.programs@kemsa.co.ke</a></p> <p><b>The deadline for Tender submission is: 12<sup>th</sup> May, 2022 Time: 10:00 a.m</b></p>
ITT 25.1	<p>Tender opening shall take place at:</p> <p>The Tender Opening Hall  Kenya Medical Supplies Authority (KEMSA)  Commercial Street, Industrial Area  Nairobi/Kenya</p> <p>Postal address:  P.O. Box: 47715-00100 Nairobi, Kenya</p> <p><b>Date: 12<sup>th</sup> May, 2022 Time: 10.00 a.m.</b></p>
ITT 25.1	<p><i>Applicable to tender security</i></p>
ITT 25.6	<p>The Form of Tender and Price Schedules shall be initialed by a minimum of 3 representatives of the Procuring Entity conducting Tender opening.</p>
<p><b>E. Evaluation and Comparison of Tenders</b></p>	
ITT 30.3	<p>Not Applicable</p>
ITT 32.1	<p>The currency that shall be used for Tender evaluation and comparison purposes to convert at the selling exchange rate all Tender prices expressed in various currencies into a single currency is: <i>[Kenya Shillings]</i></p> <p>The source of exchange rate shall be: <i>Central Bank in Kenya</i></p> <p>The date for the exchange rate shall be: <i>Date of tender closing.</i></p>
ITT 33.1	<p>A margin of domestic preference <b>Not APPLICABLE</b></p>
ITT 33.3	<p>Not applicable</p>

ITT 34.6	<i>Not Applicable</i>
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## F. Award of Contract

### ITT 47.1

The procedures for making a Procurement-related Complaint are detailed in the “Notice of Intention to Award the Contract” herein and are also available from the PPRA website [www.ppra.go.ke](http://www.ppra.go.ke).

If a Tenderer wishes to make a Procurement-related Complaint, the Tenderer should submit its complaint following these procedures, in writing (by the quickest means available, that is by email), to:

The Chief Executive Officer  
Kenya Medical Supplies Authority (KEMSA)  
Commercial Street, Industrial Area  
Nairobi/Kenya  
E- mail: [procurement.programs@kemsaco.ke](mailto:procurement.programs@kemsaco.ke)

In summary, a Procurement-related Complaint may challenge any of the following:

1. the terms of the Tendering Documents; and.
2. the procuring Entity's decision to award the contract.

## SECTION III - EVALUATION AND QUALIFICATION CRITERIA

### 1. General Provision

1.1 This section contains the criteria that the Procuring Entity shall use to evaluate tender and qualify tenderers. No other factors, methods or criteria shall be used other than specified in this tender document. The Tenderer shall provide all the information requested in the forms included in Section IV, Tendering Forms. The Procuring Entity should use **the Standard Tender Evaluation Report for Health products for** evaluating Tenders.

### 2. Evaluation and contract award Criteria

2.1 The Procuring Entity shall use the criteria and methodologies listed in this Section to evaluate tenders and arrive at the Lowest Evaluated Tender. The tender that (i) meets the qualification criteria, (ii) has been determined to be substantially responsive to the Tender Documents, and (iii) is determined to have the Lowest Evaluated Tender price shall be selected for award of contract.

### 3. Preliminary examination for Determination of Responsiveness

3.1 The Procuring Entity will start by examining all tenders to ensure they meet in all respects the eligibility criteria and other mandatory requirements in the ITT, and that the tender is complete in all aspects in meeting the requirements provided for in the preliminary evaluation criteria outlined below. The Standard Tender Evaluation Report Document for Goods and Works for evaluating Tenders provides very clear guide on how to deal with review of these requirements. Tenders that do not pass the Preliminary Examination will be considered non-responsive and will not be considered further.

*[The Procuring Entity will provide the preliminary evaluation criteria. To facilitate, a template may be attached or clearly described all information and list of documentation to be submitted by Tenderers to enable preliminary evaluation of the Tender]*

### 4. Tender Evaluation (ITT 34)

a) In addition to the criteria listed in ITT 34.2(a)-(c) the additional evaluation factors as per ITT 34.2 (d) is specified as follows:

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4.1 To evaluate Items or Lots that include at least the percentages of items per lot and quantity per item as specified in ITT 14.6, if applicable. Tender evaluation of such tenders will be carried out as per the following procedures. The average price (or highest price as specified in TDS 30.3) of an item quoted by substantially responsive Tenders will be added to the Tender price of those who did not quote for that item and the equivalent total cost of the tender so determined will be used for Tender comparison, evaluation, and award.

b) **Delivery schedule.** (As specified in the TDS)

*The Goods specified in the List of Goods are required to be delivered within the acceptable time range (1-16 weeks) specified in Section VII, Schedule of Requirements.*

c) **Deviation in payment schedule.***[insert tone of the following]*

- i) *Tenderers shall state their Tender price for the payment schedule outlined in the SCC. Tenders shall be evaluated on the basis of this base price. tenderers are, however, permitted to state an alternative payment schedule and indicate the reduction in Tender price they wish to offer for such alternative payment schedule. The Procuring Entity may consider the alternative payment schedule and the reduced Tender price offered by the tenderer selected on the basis of the base price for the payment schedule out lined in the SCC.*

**Or**

- i) *The SCC stipulates the payment schedule specified by the Procuring Entity. If a Tender deviate from the schedule and if such deviation is considered acceptable to the Procuring Entity ,the Tender will be evaluated by calculating interest earned for any earlier payments involved in the terms outlined in the Tender as compared with those stipulated in the SCC, at the rate per annum [insert adjustment rate].*

d) **Specific additional criteria**

*[Other specific additional criteria to be considered in the evaluation, and the evaluation method shall be detailed in TDS34.6][If specific **sustainable procurement technical requirements** have been specified in Section VII- Specification, **either** state that (i) those requirements will be evaluated on a pass/fail (compliance basis) **or** otherwise (ii)in addition to evaluating those requirements on a pass s/fail (compliance basis), if applicable, specify the monetary adjustments to be applied to Tender Prices for comparison purposes on account of Tenders that exceed the specified minimum sustainable procurement technical requirements.]not applicable*

**5. Multiple Contracts (ITT 34.4)**

5.1 Multiple contracts will be permitted in accordance with ITT 34.4. Tenderers are evaluated on basis of individual items and the lowest evaluated tenderer identified for each item .

- i) If a tenderer wins only one item, the tenderer will be awarded a contract for that item, provided the tenderer meets the Eligibility and Qualification Criteria for that item.
- ii) If a tenderer wins more than one item, the tender will be awarded contracts for all won items, provided the tenderer meets the aggregate Eligibility and Qualification Criteria for all the items.

**6. Alternative Tenders (ITT13.1)**

6.1 *An alternative if permitted under ITT 13, will be evaluated as follows: The Procuring Entity shall consider Tenders offered for alternatives as specified in Part II Section II, Schedule of Requirements. Only the technical alternatives, if any, of the Tenderer with the Lowest Evaluated Tender conforming to the basic technical shall be considered by the Procuring Entity. **Not applicable***

## 7. MARGIN OF PREFERENCE – NOT APPLICABLE FOR THIS TENDER

7.1 *If the TDS so specifies, the Procuring Entity will grant a margin of preference of 15% (fifteen percent) to Tenderers offering goods manufactured, mined, extracted, grown, assembled or semi-processed in Kenya.*

7.2 *The margin of preference will be applied in accordance with, and subject to, the following provisions:*

- a) *Tenderers applying for such preference on goods offered shall be asked to provide, as part of the data for qualification, such information, including details of the goods produced in Kenya, so as to determine whether, according to the classification established by the Procuring Entity, a particular category of goods or group of goods qualifies for a margin of preference.*
- b) *After Tenders have been received and reviewed by the Procuring Entity, goods offered in the responsive Tenders shall be assessed to ascertain they are manufactured, mined, extracted, grown, assembled or semi- processed in Kenya. Responsive tenders shall be classified into the following groups:*
  - i) **Group A:** *Tenders offering goods manufactured in Kenya, for which (a) labor, raw materials, and components from within Kenya account for more than forty (40) percent of the Ex-Works price; and (b) the production facility in which they will be manufactured or assembled has been engaged in manufacturing or assembling such goods at least since the date of Tender submission date;*
  - ii) **Group B:** *All other Tenders offering Goods manufactured in Kenya;*
  - iii) **Group C:** *Tenders offering Goods manufactured outside Kenya that have been already imported or that will be imported.*
    - a) *To facilitate this classification by the Procuring Entity, the tenderer shall complete whichever version of the Price Schedule furnished in the Tendering document is appropriate, provided however, that the completion of an incorrect version of the Price Schedule by the Tenderer shall not result in rejection of its Tender, but merely in the Procuring Entity's reclassification of the Tender in to its appropriate Tender group.*
    - b) *The Tenders in each group will then be compared to determine the Tender with the lowest evaluated cost in that group. The lowest evaluated cost Tender from each group shall then be compared with each other and if as a result of this comparison a Tender from Group A or Group B is the lowest, it shall be selected for the award.*
    - c) *If as a result of the preceding comparison, a Tender from Group C is the lowest evaluated cost, an amount equal to or 15% of the respective tender price, including unconditional discounts and excluding provisional sums, if any, shall be added to the evaluated price offered in each tender from Group C. If the tender from Group C is still the lowest tender, it shall be selected for award. If not, the lowest evaluated tender from Group A or B based on the first evaluation price shall be selected.*

## 8. Post qualification and Contract award (ITT37), more specifically,-

### TO BE SPECIFIED UNDER SPECIFIC EVALUATION CRITERIA

8.1 After determining the substantially responsive tender which offers the lowest-evaluated price, whether the tenderer is a manufacturer or just a supplier: The Procuring Entity shall carry out the post-qualification, if no prequalification was done using the following criteria:

- a) In case the tender was subject to post-qualification, the contract shall be awarded to the lowest evaluated tenderer, subject to confirmation of prequalification data, if so required.
- b) In case the tender was not subject to post-qualification, the tender that has been determined to be the lowest evaluated tenderer shall be considered for contract award, subject to meeting each of the following conditions.
  - i) The Tenderer shall demonstrate that it has access to, or has available, liquid assets, unencumbered real assets, lines of credit, and other financial means sufficient to meet the cash flow of Kenya Shillings\_\_\_\_\_.
  - ii) Minimum average annual turnover of Kenya Shillings\_\_\_\_\_ [insert amount], equivalent calculated as total certified payments received for contracts in progress and/or completed within the last \_\_\_\_\_ [insert of year] years.
  - iii) At least \_\_\_\_\_ (insert number) of contract(s) of asimilar nature executed within Kenya, or the East African Community or abroad, that have been satisfactorily and substantially completed as a prime contractor, or joint venture member or sub-contractor each of minimum value Kenya shillings\_\_\_\_\_ equivalent.
  - iv) Other conditions depending on their seriousness.

a) **History of non-performing contracts:**

Tenderer and each member of JV in case the Tenderer is a JV, shall demonstrate that Non- performance of a contract did not occur because of the default of the Tenderer, or the member of a

JV in the last \_\_\_\_\_ (specify years). The required information shall be furnished in the appropriate form.

b) **Pending Litigation**

Financial position and prospective long-term profitability of the Single Tenderer, and in the case the Tenderer is a JV, of each member of the JV, shall remain sound according to criteria established with respect to Financial Capability under Paragraph (i) above if all pending litigation will be resolved against the Tenderer. Tenderer shall provide information on pending litigations in the appropriate form.

c) **Litigation History**

There shall be no consistent history of court/arbitral award decisions against the Tenderer, in the last \_\_\_\_\_ (specify years). All parties to the contract shall furnish the information in the appropriate form about any litigation or arbitration resulting from contracts completed or ongoing under its execution over the years specified. A consistent history of awards against the Tenderer or any member of a JV may result in.



## **SPECIFIC EXPERIENCE REQUIREMENTS TO BE SPECIFIED UNDER SPECIFIC EVALUATION**

*The Specific Experience Requirements under 4.2 (b) (from the table above) are as follows:*

### **4.2(b)(i) Documentary evidence in accordance with TDS ITT 11.1 4.2(b)**

#### **(ii) Technical and Production Capability.**

*The Tenderer shall provide evidence that it has the technical, and production capability necessary to perform the Contract:*

- (i) *That it has successfully completed or substantially completed at least [3] similar contracts for supply of the goods and within the last three years.[The number of similar contracts required should be not less than three and not more than five (normally four), depending on the size and complexity of the subject contract].Similar contracts are those of approximately the same size and that includes comparable products, e.g., capsules, tablets, vaccines.*

*The goods may have been supplied by the Tenderer as a manufacturer or by its agent, with references being submitted to confirm satisfactory performance.*

- (ii) *That it has achieved an annual average production rate of \_\_\_\_\_[The annual production rate required should be at least three times the quantities specified under the contract] during the last three years.*

#### **4.2 (b) (iii) Experience on Packaging, Distribution and Transportation**

*The Tenderer should provide proof of experience with and knowledge of modes of packing, distribution, and transportation of **Health Products** similar to those subject to Tendering under logistical and climatic conditions similar to the ones in Kenya. It should provide names of countries to which the Tenderer has supplied (including packaged, distributed, and transported) products worth at least the amount [insert the amount] within the past three years.*

*[Note to the Procuring Entity: If Tenders for individual lots are permitted; the qualification criteria for each lot should be given separately].*

## SPECIFIC EVALUATION CRITERIA

### A) PRELIMINARY EXAMINATION

#### Requirements

1. Tender documents must be paginated/serialized. All bidders are required to submit their documents paginated in a continuous ascending order from the first page to the last in this format; (i.e. 1, 2, 3..... n where n is the last page) **(MANDATORY)**.
2. Provide a copy of Certificate of Incorporation/Registration **(MANDATORY)**.
3. Provide a copy of valid and current Tax Compliance Certificate **(MANDATORY FOR LOCAL BIDDERS)**.
4. Tender form (on a letterhead showing the tenderers complete name and business address) duly **completed and signed**. *The Form of Tender shall include the following Forms duly completed and signed by the Tenderer or authorized representative (attach power of attorney where applicable)* **(MANDATORY)**.
  - i. *Tenderer's Eligibility-Confidential Business Questionnaire* **(MANDATORY)**.
  - ii. *Certificate of Independent Tender Determination* **(MANDATORY)**.
  - iii. *Self-Declaration of the Tenderer* **(MANDATORY)**.
    - a) Duly completed and signed self-Declaration that the person/ Tenderer is not debarred in the matter of the PPADA 2015 **(MANDATORY)**.
    - b) Duly completed and signed self-Declaration that the person/ Tenderer will not engage in any corrupt/fraudulent practice **(MANDATORY)**.
    - c) Duly completed and signed declaration and commitment to the code of ethics **(MANDATORY)**.
5. Provide Original Bid Security valid for 150 days from date of tender opening. Value of Bid Security should be **USD 5,000.00 or KES 575,000.00** or equivalent in a freely convertible currency. **(MANDATORY)**.

**NOTE:** Failure to comply with Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

### B) TECHNICAL EVALUATION

Bidders are required to submit the following documents:

- a) Manufacturers Authorization which must be on a manufacturer's letterhead and addressed to KEMSA that is both tender and item specific and signed by an authorized signatory (Applicable to bidders who are not manufacturers) **(MANDATORY)**.
- b) Current and valid manufacturing Certificate of Quality issued by an independent recognized body to the manufacturer of the product. The certificate must be item specific. **(MANDATORY)**.

## **C) PRODUCT EVALUATION**

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 system.

- 1) Evaluation of the Physical Properties and presentation of the products - The evaluation will be based on product type, product form i.e. the physical configuration and shape, product ingredients i.e. content, components and composition, measurements i.e. dimension and weight, elasticity where applicable, absorbency where applicable, texture where applicable
- 2) Evaluation of the product packaging based on Good Manufacturing and pharmaceutical practices of the particular dosage form and specifications in this Tender document.
- 3) Evaluation of the product labeling criteria based on technical specifications spelt out in this tender document.

These parameters must be highlighted with a bright marker on the catalogue

- 4) Tenderers will be required to submit in addition to manufacturers catalogue a compliance sheet for each of the product offered. The tenderer must indicate on the compliance sheet whether the product offered comply with each item of the technical specifications in the tender document.
- 5) The tenderer shall be required to commit in writing and present supporting data for compliance with items in the tender technical specifications which are not supported by original manufacturers brochure.
- 6) In case of conflict between information/ data presented in the original manufacturers brochure and the tenders compliance sheet the information/ data in the original manufacturers brochure shall prevail.

The evaluation will be on a "Yes/No" basis;

**NOTE:** Only bidders who are successful at this stage will proceed to the next stage of evaluation.

## **D) FINANCIAL EVALUATION**

Bidders who are successful at preceding stages of evaluation will have their prices compared and award recommended to the lowest evaluated responsive bid.

## **E) POST QUALIFICATION**

In line with ITT 37 After determining the substantially responsive tender, which offers the lowest-evaluated price, whether the tenderer is a manufacturer or just a supplier: The Procuring Entity shall carry out the post-qualification, if no prequalification was done using the following criteria:

1. The bidder must provide evidence of maximum number of 3 (three) supply contracts for medical commodities within the past 3 years equivalent to the contract sum. The value of one of the contracts must be at least 60 % of the tender sum. The Tenderer should provide documentary evidence in support of the experience of previous supply (Contracts, Purchase Orders, Reference letters and Contact details of previous supply contracts).
2. The bidder must provide evidence of average annual turnover in the last three (3) years that is equivalent to the tender sum. (Provide certified financial statements for the past immediate three (3) years.
3. The bidder must provide statement of annual production capacity by a manufacturing firm, (should be at least three times the quantities specified under the contract).

## F) PAST PERFORMANCE

A supplier performance measurement tool with detailed performance indicators has been developed and will be used to measure the performance of contracted suppliers. Suppliers who will have had unsatisfactory past performance on specific items of less than 71% shall not be recommended for award of similar items in subsequent tenders.

### PERFORMANCE INDICATORS

The performance of suppliers, contractors, service providers and consultants are monitored at contract level to ensure the terms and conditions of the contract are met. The extent of performance monitoring applied shall be determined by the level of risk and the nature of the items. Good monitoring of suppliers anticipates, identifies and facilitates correction of shortcomings before the relationship with the supplier is adversely affected and before compromising value for money.

#### 1. Time

The time indicator measures the duration in days for the supplier to deliver or complete the task as specified in the contract. The required data to be captured from the source documents into the performance tool shall include: Item code, item description, contract number, purchase order number, supplier name, contract signing date, contract effective date, contractual delivery date, earliest delivery date, extended delivery date, actual delivery date, supplier offered delivery date, and latest delivery date. For each item, the earliest delivery date and the latest delivery date are derived from the issued tender document. The supplier offered delivery date is derived from the bid.

**Contract Delivery Period:** The number of calendar days from the date of signing the contract to the date the delivery is required per the contract. If a contract is extended, the additional days are confirmed through addendum (letter) to the contract and the duration added to the Contract Delivery Period. In call-off orders under framework contracts, Contract Delivery Period is the number of calendar days from the date of call-off order to the required delivery date.

**Actual Delivery Period:** The number of calendar days from the contract effective date to the actual delivery date. Where call off orders apply, the Actual Delivery Period is the number of calendar days from the date of call-off order to actual delivery date. For staggered deliveries under definite quantity contracts, actual delivery period is the number of calendar days from date of notification of the required quantity.

**Delivery on Time:** Delivery of goods on or within the Contract Delivery Period yields a Delivery on Time indicator score of 100%. Delivery within 2 weeks after Contract Delivery Period still yields a Time indicator score of 100%. Delivery made thereafter yields a time Indicator score of zero (0). Failure to fully deliver within 8 weeks from lapse of Contract Delivery Period will result in contract termination.

#### 2. Quantity

The supplier is required to deliver the ordered quantity of the product in full. Contractors should deliver the product per the required specifications.

Sometimes, due to practical reasons, a supplier may be requested in writing to deliver a portion of the order. In that event, the measurement will be done after substantial completion of contracted quantity.

The quantity indicator measures Delivery in Full, which is the difference between the quantity of the product in the purchase order or contract and the quantity that is certified received.

Delivery in Full: The indicator is measured by the percentage of the ordered quantity which is actually certified received. Example: If the purchase order quantity was 200,000 units. Of this, the quantity received was 190,000 units. The indicator of Delivery in Full is computed as  $(190,000/200,000) * 100 = 95\%$ . The target performance score for Delivery in Full indicator is 100%.

The required data are order quantity, delivered quantity, and deferred quantity.

### 3. Cost

The historical unit prices for each item are captured in the ERP system. The Award Price arise from recommendations for award and signed supplier contract. The Final Price is the award price plus the price variation that is approved at contract implementation; excluding those from the application of a price adjustment formula if provided for in the signed contract.

The Price Ratio is defined as  $[Award\ Price \times 100 / Final\ Price]$ ; which should be 100% where the Final Price is equal to the Award Price. Where the Final Price is higher than the Award Price, the performance score is prorated. Example: if the Final Price is KES2,700, Award Price is KES2,400, then the Price Ratio is  $[2,400 * 100 / 2700 = 89\%]$ . The data to be captured in the ERP system include the following: Item Code, Item Description, Contract Number, Order Number, Supplier Name, Plan Price, Award Price, Price Variation, Final Price.

### 4. Quality

The contract provides the technical specifications. At the delivery point, the products are inspected and tested to ensure they comply with the quality specifications. Products that do not comply with Quality Specifications will be rejected. However, an assessment shall be made to check if there is suitable product packaging. Percentage of damaged cartons acceptable is 0.5%. Above this %, the damaged cartons will be rejected.

### 5. Ratings and Scores

The supplier contract performance scores provide a structured way of rating suppliers with an aim of identifying areas of improvement and a basis for future engagement depending on historical performance. The scorecard will be used to measure, rate and rank suppliers with the aim of ensuring suppliers consistently meet and surpass their contractual obligations. Table 3 summarizes the ratings and scores.

Table 1. Ratings and scores measurement system

Rating	Range	Performance Description
1	0-30	Falls far below expectations: Performance jeopardized the achievement of contract requirements, despite contract administrative interventions.
2	31-50	Missed expectations: There are a number of performance issues

		that required KEMSA to provide additional contract administrative interventions to ensure that contract requirements are met.
3	51-70	Does not fully meet expectations: There are performance issues but supplier has somehow met contract requirements.
4	71-80	Mostly meets expectations: There are minor performance issues but the supplier has largely met the contract requirements
5	81-100	Exceeds Expectations: Supplier has demonstrated a performance level in measurable within contract requirements

## 6. Performance Index

The Performance Index combines the indices for (1) time, (2) quantity, (3) cost and (4) quality. Each of the four performance indicators is scored out of 100%. The parameters are then weighted using a predefined matrix and the overall Supplier Performance Index is the sum of the weighted scores.

Table 2. Supplier Performance Index (Example)

#	Indicator	Score (%)	Weight	Weighted Score
1	Time	100	0.5	50.00
2	Quantity	95	0.3	28.50
3	Cost	89	0.1	8.90
4	Quality	83	0.1	8.30
	Supplier Performance Index			95.70

## 6. Performance Decision

A supplier with a Performance Index Score of less than 71% shall not be eligible for award of contracts by KEMSA for a period of ONE YEAR from the date of notification of the performance score. This information shall form part of the Post Contract Qualification Criteria in the subsequent tender document and evaluation stated as follows:

“Non-performance of a contract did not occur as a result of supplier default since 1 January [insert year] or the bidder has a Performance Score of less than 71% as measured using the KEMSA Supplier Performance Measurement Tool as notified to the supplier or service provider in writing prior to this tender notice.”

The Procurement Directorate shall debrief the supplier and prepare minutes to record the debriefing, which shall form part of the permanent records.

## SECTION IV - TENDERING FORMS

### FORM OF TENDER

#### INSTRUCTIONS TO TENDERERS

- i) *The Tenderer must prepare this Form of Tender on stationery with its letterhead clearly showing the Tenderer's complete name and business address.*
- ii) *All italicized text is to help Tenderer in preparing this form.*
- iii) *Tenderer must complete and sign TENDERER'S ELIGIBILITY - CONFIDENTIAL BUSINESS QUESTIONNAIRE, CERTIFICATE OF INDEPENDENT TENDER DETERMINATION and the SELF DECLARATION OF THE TENDERER, all attached to this Form of Tender.*
- iv) *The Form of Tender shall include the following Forms duly completed and signed by the Tenderer.*
  - *Tenderer's Eligibility-Confidential Business Questionnaire*
  - *Certificate of Independent Tender Determination*
  - *Self-Declaration of the Tenderer*

**Date of this Tender submission: 12<sup>th</sup> May, 2022**

#### **Invitation to Tender No.: GF ATM TB NFM - 21/22 - OIT - 003 SUPPLY OF LIQUID CHROMATOGRAPHY/MASS SPECTROSCOPY SYSTEM**

**Alternative No.:** [N/A] *To: Kenya Medical Supplies Authority*

- a) **No reservation:** We have examined and have no reservations to the tendering document, including Add and issued in accordance with Instructions to Tenderers (ITT 8);
- b) **Eligibility:** We meet the eligibility requirements and have no conflict of interest in accordance with ITT 4;
- c) We have not been suspended nor declared in eligible by the Procuring Entity based on execution of a Tender- Securing Declaration or Proposal-Securing Declaration in Kenya in accordance with ITT 4.8;
- d) **Conformity:** We offer to supply in conformity with the tendering document and in accordance with the Delivery Schedules specified in the Schedule of Requirements the following Goods: [GF ATM TB NFM - 21/22 - OIT - 003 SUPPLY OF LIQUID CHROMATOGRAPHY/MASS SPECTROSCOPY SYSTEM
- e) **Tender Price:** The total price of our Tender, is: *[[insert the total price of the Tender in words and figures .....*)
- f) **Tender Validity Period:** Our Tender shall be valid for the period specified in TDS 18.1 (as amended if applicable) from the date fixed or the Tender submission deadline specified in TDS 22.1 (as amended if applicable), and it shall remain binding upon us and may be accepted at any time before the expiration of that period;

- g) **Performance Security:** If our Tender is accepted, we commit to obtain a Performance Security in accordance with the tendering document;
- h) **One Tender per Tenderer:** We are not submitting any other Tender(s) as an individual Tenderer, and we are not participating in any other Tender(s) as a Joint Venture partner or as a sub-contractor, and meet the requirements of ITT 4.4, other than alternative Tenders submitted in accordance with ITT 13;
- i) **Suspension and Debarment:** We, along with any of our sub-contractors, suppliers, consultants, manufacturers, or service providers for any part of the contract, are not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the PPRRA. Further, we are not ineligible under Kenya laws or official regulations or pursuant to a decision of the United Nations Security Council;
- j) **State-owned enterprise or institution:** *[select the appropriate option and delete the other] [We are not a state-owned enterprise or institution]/ [We are a state-owned enterprise or institution but meet the requirements of ITT 4.7];*
- k) **Commissions, gratuities, fees:** We have paid, or will pay the following commissions, gratuities, or fees with respect to the Tendering process or execution of the Contract:*[insert complete name of each Recipient, its full address, the reason for which each commission or gratuity was paid and the amount and currency of each such commission or gratuity]*

Name of Recipient	Address	Reason	Amount

(If none has been paid or is to be paid, indicate “none.”)

- l) **Binding Contract:** We understand that this Tender, together with your written acceptance thereof included in your notification of award, shall constitute a binding contract between us, until a formal contract is prepared and executed;
- m) **Procuring Entity Not Bound to Accept:** We understand and that you are not bound to accept the lowest evaluated cost Tender, the Lowest Evaluated Tender or any other Tender that you may receive; and
- p) **Fraud and Corruption:** We here by certify that we have taken steps to ensure that no person acting for us or on our behalf engages in any type of Fraud and Corruption.
- p) **Collusive practices:** We hereby certify and confirm that the tender is genuine, non-collusive and made with the intention of accepting the contract if awarded. To this effect we have signed the “Certificate of Independent tender Determination” attached below.
- q) We undertake to adhere by the Code of Ethics for Persons Participating in Public Procurement and Asset Disposal, copy available from \_\_\_\_\_(specify website) during the procurement process and the execution of any resulting contract.
- r) We, the Tenderer, have completed fully and signed the following Forms as part of our Tender:



- a) Tenderer's Eligibility; Confidential Business Questionnaire – to establish we are not in any conflict to interest.
- b) Certificate of Independent Tender Determination - to declare that we completed the tender without colluding with other tenderers.
- c) Self-Declaration of the Tenderer–to declare that we will, if awarded a contract, not engage in any form of fraud and corruption.
- d) Declaration and commitment to the Code of Ethics for Persons Participating in Public Procurement and Asset Disposal.

Further, we confirm that we have read and understood the full content and scope of fraud and corruption as in formed in “**Appendix 1-Fraud and Corruption**” attached to the Form of Tender.

**Name of the Tenderer:***\*[insert complete name of the Tenderer]*

**Name of the person duly authorized to sign the Tender on behalf of the Tenderer:** *\*\*[insert complete name of person duly authorized to sign the Tender]*

**Title of the person signing the Tender:** *[insert complete title of the person signing the Tender]*

**Signature of the person named above:** *[insert signature of person whose name and capacity are*

*shown above]* **Date signed** *[insert date of signing]* **day of** *[insert month],[insert year]*

\*: In the case of the Tender submitted by a Joint Venture specify the name of the Joint Venture as Tenderer.

\*\*.: Person signing the Tender shall have the power of attorney given by the Tenderer. The power of attorney shall be attached with the Tender Schedules.

## TENDERER'S ELIGIBILITY- CONFIDENTIAL BUSINESS QUESTIONNAIRE

### Instruction to Tenderer

Tender is instructed to complete the particulars required in this Form, *one form for each entity if Tender is a JV*. Tenderer is further reminded that it is an offence to give false information on this Form.

#### a) Tenderer's details

	ITEM	DESCRIPTION
1	Name of the Procuring Entity	
2	Reference Number of the Tender	
3	Date and Time of Tender Opening	
4	Name of the Tenderer	
5	Full Address and Contact Details of the Tenderer.	1.Country 2. City 3.Location 4. Building 5.Floor 6. Postal Address 7. Name and email of contact person.
6	Current Trade License Registration Number and Expiring date	
7	Name, country and full address ( <i>postal and physical addresses, email, and telephone number</i> ) of Registering Body/Agency	
8	Description of Nature of Business	
9	Maximum value of business which the Tenderer handles.	
10	State if Tenders Company is listed in stock exchange, give name and full address ( <i>postal and physical addresses, email, and telephone number</i> ) of state which stock exchange	

### General and Specific Details

b) **Sole Proprietor**, provide the following details.

Name in full \_\_\_\_\_ Age \_\_\_\_\_ Nationality \_\_\_\_\_  
 \_\_\_\_\_ Country of Origin \_\_\_\_\_ Citizenship \_\_\_\_\_

c) **Partnership**, provide the following details.

	Names of Partners	Nationality	Citizenship	% Shares owned
1				
2				
3				

d) **Registered Company**, provide the following details.

i) Private or public Company \_\_\_

ii) State the nominal and issued capital of the Company:-

Nominal                                      Kenya                                      Shillings                                      (Equivalent)  
 .....

Issued    Kenya                                      Shillings                                      (Equivalent)  
 .....

iii) Give details of Directors as follows.

	Names of Director	Nationality	Citizenship	% Shares owned
1				
2				
3				

e) **DISCLOSURE OF INTEREST -Interest of the Firm in the Procuring Entity.**

i) Are there any person/persons in.....(Name of Procuring Entity) who has/ have an interest or relationship in this firm?Yes/No..... If yes, provide details as follows.

	Names of Person	Designation in the Procuring Entity	Interest or Relationship with Tenderer
1			
2			
3			

ii) **Conflict of interest disclosure**

	Type of Conflict	Disclosure YES OR NO	If YES provide details of the relationship with Tenderer
1	Tenderer is directly or indirectly controls, is controlled by or is under common control with another tenderer.		
2	Tenderer receives or has received any direct or indirect subsidy from another tenderer.		
3	Tenderer has the same legal representative as another tenderer		
4	Tender has a relationship with another tenderer, directly or through common third parties, that puts it in a position to influence the tender of another tenderer, or influence the decisions of the Procuring Entity regarding this tendering process.		
5	Any of the Tenderer's affiliates participated as a consultant in the preparation of the design or technical specifications of the works that are the subject of the tender.		
6	Tenderer would be providing goods, works, non-consulting services or consulting services during implementation of the contract specified in this Tender Document.		
7	Tenderer has a close business or family relationship with a professional staff of the Procuring Entity who are directly or indirectly involved in the preparation of the Tender document or specifications of the Contract, and/or the Tender evaluation process of such contract.		
8	Tenderer has a close business or family relationship with a professional staff of the Procuring Entity who would be involved in the implementation or supervision of the such Contract.		
9	Has the conflict stemming from such relationship stated in item 7 and 8 above been resolved in a manner acceptable to the Procuring Entity throughout the tendering process and execution of the Contract.		

f) **Certification**

On behalf of the Tenderer, I certify that the information given above is complete, current and accurate as at the date of submission.

Full Name \_\_\_\_\_ Title or Designation \_\_\_\_\_

\_\_\_\_\_

(Signature)

(Date)

## CERTIFICATE OF INDEPENDENT TENDER DETERMINATION

I, the undersigned, in submitting the accompanying Letter of Tender to the \_\_\_\_\_ [Name of Procuring Entity] for: \_\_\_\_\_ [Name and number of tender] in response to the request for tenders made by: \_\_\_\_\_ [Name of Tenderer] do hereby make the following statements that I certify to be true and complete in every respect:

I certify, on behalf of \_\_\_\_\_ [Name of Tenderer] that:

1. I have read and I understand the contents of this Certificate;
2. I understand that the Tender will be disqualified if this Certificate is found not to be true and complete in every respect;
3. I am the authorized representative of the Tenderer with authority to sign this Certificate, and to submit the Tender on behalf of the Tenderer;
4. For the purposes of this Certificate and the Tender, I understand that the word "competitor" shall include any individual or organization, other than the Tenderer, whether or not affiliated with the Tenderer, who:
  - a) Has been requested to submit a Tender in response to this request for tenders;
  - b) could potentially submit a tender in response to this request for tenders, based on their qualifications, abilities or experience;
5. The Tenderer discloses that [check one of the following, as applicable]:
  - a) The Tenderer has arrived at the Tender independently from, and without consultation, communication, agreement or arrangement with, any competitor;
  - b) the Tenderer has entered into consultations, communications, agreements or arrangements with one or more competitors regarding this request for tenders, and the Tenderer discloses, in the attached document(s), complete details thereof, including the names of the competitors and the nature of, and reasons for, such consultations, communications, agreements or arrangements;
6. In particular, without limiting the generality of paragraphs (5) (a) or (5) (b) above, there has been no consultation, communication, agreement or arrangement with any competitor regarding:
  - a) prices;
  - b) methods, factors or formulas used to calculate prices;
  - c) the intention or decision to submit, or not to submit, a tender; or
  - d) the submission of a tender which does not meet the specifications of the request for Tenders; except as specifically disclosed pursuant to paragraph (5)(b) above;
7. In addition, there has been no consultation, communication, agreement or arrangement with any competitor regarding the quality, quantity, specifications or delivery particulars of the works or services to which this request for tenders relates, except as specifically authorized by the procuring authority or as specifically disclosed pursuant to paragraph(5)(b) above;
8. The terms of the Tender have not been, and will not be, knowingly disclosed by the Tenderer, directly or indirectly, to any competitor, prior to the date and time of the official tender opening, or of the awarding of the Contract, whichever comes first, unless otherwise

required by law or as specifically disclosed pursuant to paragraph (5)(b) above.

Name \_\_\_\_\_ Title \_\_\_\_\_

Date \_\_\_\_\_

*[Name, title and signature of authorized agent of Tenderer and Date]*

**SELF- DECLARATION FORMS**

**FORM SD1**

**SELF DECLARATION THAT THE PERSON / TENDERER IS NOT DEBARRED IN THE MATTER OF THE PUBLIC PROCUREMENT AND ASSET DISPOSAL ACT 2015**

I, ....., of Post Office Box ..... being a resident of ..... in the Republic of ..... do hereby make a statement as follows:-

1. THAT I am the Company Secretary/ Chief Executive/Managing Director/Principal Officer/ Director of ..... (*insert name of the Company*) who is a Bidder in respect of **Tender No.....**for..... (*insert tender title / description*) for..... (*insert name of the Procuring entity*) and duly authorized and competent to make this statement.
2. THAT the aforesaid Bidder, its Directors and subcontractors have not been debarred from participating in procurement proceeding under Part IV of the Act.
3. THAT what is deponed to here in above is true to the best of my knowledge, information and belief.

.....  
.....  
.....  
(Title) (Signature) (Date)

Bidder Official Stamp

FORM SD2

**SELF DECLARATION THAT THE PERSON/TENDERER WILL NOT ENGAGE IN ANY CORRUPT OR FRAUDULENT PRACTICE**

I,.....of P. O. Box.....being a resident of  
..... in the Republic of.....do hereby make a statement as follows:-

1. THAT I am the Chief Executive / Managing Director /Principal Officer/Director of.....  
.....(*insert name of the Company*) who is a Bidder in respect of **Tender No.**  
.....for.....(*insert tender title /description*)  
for.....(*insert name of the Procuring entity*) and duly authorized and competent to make this statement.
2. THAT the aforesaid Bidder, it's servants and/or agents/sub-contractors will not engage in any corrupt or fraudulent practice and has not been requested to pay any inducement to any member of the Board, Management, Staff and/or employees and/or agents of .....(*insert name of the Procuring entity*) which is the procuring entity.
3. THAT the aforesaid Bidder, its servants and/or agents /subcontractors have not offered any inducement to any member of the Board, Management, Staff and/or employees and/or agents of.....(*name of the procuring entity*).
4. THAT the aforesaid Bidder will not engage /has not engaged in any corrosive practice with other bidders participating in the subject tender
5. THAT what is deponed to herein above is true to the best of my knowledge information and belief.

.....  
.....  
(Title)

.....  
.....  
(Signature)

.....  
.....  
(Date)

Bidder's Official Stamp



**DECLARATION AND COMMITMENT TO THE CODE OF ETHICS**

I, (person) on behalf of (*Name of the Business/Company / Firm*) ..... declare that I have read and fully understood the contents of the Public Procurement & Asset Disposal Act, 2015, Regulations and the Code of Ethics for persons participating in Public Procurement and Asset Disposal and my responsibilities under the Code.

I do here by commit to abide by the provisions of the Code of Ethics for persons participating in Public Procurement and Asset Disposal.

Name of Authorized signatory.....

Sign.....

Position.....

Office address.....

Telephone.....Email.....

Name of the Firm/Company.....

Date.....

*(Company Seal/ Rubber Stamp where applicable)*

Witness Name  
.....

Sign.....

Date.....

## APPENDIX 1- FRAUD AND CORRUPTION

*(Appendix 1 shall not be modified)*

### 1. Purpose

1.1 The Government of Kenya's Anti-Corruption and Economic Crime laws and their sanction's policies and procedures, Public Procurement and Asset Disposal Act (*no. 33 of 2015*) and its Regulation, and any other Kenya's Acts or Regulations related to Fraud and Corruption, and similar offences, shall apply with respect to Public Procurement Processes and Contracts that are governed by the laws of Kenya.

### 2. Requirements

2.1 The Government of Kenya requires that all parties including Procuring Entities, Tenderers, (applicants/proposers), Consultants, Contractors and Suppliers; any Sub-contractors, Sub-consultants, Service providers or Suppliers; any Agents (whether declared or not); and any of their Personnel, involved and engaged in procurement under Kenya's Laws and Regulation, observe the highest standard of ethics during the procurement process, selection and contract execution of all contracts, and refrain from Fraud and Corruption and fully comply with Kenya's laws and Regulations as per paragraphs 1.1 above.

2.2 Kenya's public procurement and asset disposal act (*no. 33 of 2015*) under Section 66 describes rules to be followed and actions to be taken in dealing with Corrupt, Coercive, Obstructive, Collusive or Fraudulent practices, and Conflicts of Interest in procurement including consequences for offences committed. A few of the provisions noted below highlight Kenya's policy of no tolerance for such practices and behavior:

- 1) A person to whom this Act applies shall not be involved in any corrupt, coercive, obstructive, collusive or fraudulent practice; or conflicts of interest in any procurement or asset disposal proceeding;
- 2) A person referred to under subsection (1) who contravenes the provisions of that subsection commits an offence;
- 3) Without limiting the generality of the subsection (1) and (2), the person shall be –
  - a) disqualified from entering into a contract for a procure mentor asset disposal proceeding; or
  - b) if a contract has already been entered into with the person, the contract shall be voidable;
- 4) The voiding of a contract by the procuring entity under subsection (7) does not limit any legal remedy the procuring entity may have;
- 5) An employee or agent of the procuring entity or a member of the Board or committee of the procuring entity who has a conflict of interest with respect to a procurement: -
  - a) Shall not take part in the procurement proceedings;
  - b) shall not, after a procurement contract has been entered into, take part in any decision relating to the procurement or contract; and
  - c) shall not be a subcontractor for the tenderer to whom was awarded contract, or a

member of the group of tenderers to whom the contract was awarded, but the subcontractor appointed shall meet all the requirements of this Act.

- 6) An employee, agent or member described in subsection (1) who refrains from doing anything prohibited under that subsection, but for that subsection, would have been within his or her duties shall disclose the conflict of interest to the procuring entity;
- 7) If a person contravenes subsection (1) with respect to a conflict of interest described in sub section (5)(a) and the contract is awarded to the person or his relative or to another person in whom one of them had a direct or indirect pecuniary interest, the contract shall be terminated and all costs incurred by the public entity shall be made good by the awarding officer. Etc.

In compliance with Kenya's laws, regulations and policies mentioned above, the Procuring Entity:

- a) Defines broadly, for the purposes of the above provisions ,the terms set forth below as follows:
  - i) "corrupt practice" is the offering, giving, receiving, or soliciting, directly or indirectly, anything of value to influence improperly the actions of another party;
  - ii) "fraudulent practice" is any act or omission, including misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain financial or other benefit or to avoid an obligation;
  - iii) "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;
  - iv) "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;
  - v) "obstructive practice" is:
    - Deliberately destroying, falsifying, altering, or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede investigation by Public Procurement Regulatory Authority (PPRA) or any other appropriate authority appointed by Government of Kenya in to allegations of a corrupt, fraudulent, coercive, or collusive practice; and/or threatening, harassing, or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or
    - Acts intended to materially impede the exercise of the PPRA's or the appointed authority's inspection and audit rights provided for under paragraph 2.3 e. below.
- b) Defines more specifically, in accordance with the above procurement Act provisions set forth for fraudulent and collusive practices as follows:

"fraudulent practice" includes a misrepresentation of fact in order to influence a procurement or disposal process or the exercise of a contract to the detriment of the procuring entity or the tenderer or the contractor, and includes collusive practices amongst tenderers prior to or after tender submission designed to establish tender prices at artificial non-competitive levels and to deprive the procuring entity of the benefits of free and open competition.
- c) Rejects a proposal for award<sup>1</sup>of a contract if PPRA determines that the firm or individual recommended for award, any of its personnel, or its agents, or its sub-consultants, sub-contractors, service providers, suppliers and/ or their employees, has, directly or indirectly, engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices in competing for the contract in question;
- d) Pursuant to the Kenya's above stated Acts and Regulations, may sanction or recommend to appropriate authority(ies) for sanctioning and debarment of a firm or individual, as applicable under the Acts and Regulations;
- e) Requires that a clause be included in Tender documents and Request for Proposal documents requiring (i) Tenderers(applicants/proposers),Consultants, Contractors, and Suppliers, and their Sub-contractors, Sub- consultants, Service providers, Suppliers, Agents personnel, permit the PPRA or any other appropriate authority appointed by

Government of Kenya to inspect<sup>2</sup> all accounts, records and other documents relating to the procurement process, selection and/or contract execution, and to have them audited by auditors appointed by the PPRA or any other appropriate authority appointed by Government of Kenya; and

- f) Pursuant to Section 62 of the above Act, requires Applicants/Tenderers to submit along with their Applications/Tenders/Proposals a “Self-Declaration Form” as included in the procurement document declaring that they and all parties involved in the procurement process and contract execution have not engaged/will not engage in any corrupt or fraudulent practices.

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<sup>1</sup>For the avoidance of doubt, a party's ineligibility to be awarded a contract shall include, without limitation, (i) applying for pre-qualification expressing interest in A consultancy, and tendering, either directly or as a nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider, in respect of such contract, and (ii) entering into an addendum or amendment introducing a material modification to any existing contract.

<sup>2</sup> Inspections in this context usually are investigative (i.e., forensic) in nature. They involve fact-finding activities undertaken by the Investigating Authority or persons appointed by the Procuring Entity to address specific matters related to investigations/audits, such as evaluating the veracity of an allegation of possible Fraud and Corruption, through the appropriate mechanisms. Such activity includes but is not limited to: accessing and examining a firm's or individual's financial records and information, and making copies thereof as relevant; accessing and examining any other documents, data and information (whether in hard copy or electronic format) deemed relevant for the investigation/audit, and making copies thereof as relevant; interviewing staff and other relevant individuals; performing physical inspections and site visits; and obtaining third party verification of information.

## TENDERER INFORMATION FORM

*[The Tenderer shall fill in this Form in accordance with the instructions indicated below. No alterations to its format shall be permitted and no substitutions shall be accepted.]*

Date:.....*[insert date(as day ,month and year)of Tender*

*submission]* ITT No.:.....*[insert number of tendering process]*

Alternative No.:..... *[insert identification No. if this is a Tender for an alternative]*

Page \_\_\_\_\_ of \_\_\_\_\_ pages

1.Tenderer's Nam <i>[insert Tenderer's legal name]</i>
2.IncaseofJV,legalnameofeachmember: <i>[insert legal name of each member in JV]</i>
3.Tenderer's actualorintendedcountryofregistration: <i>[insertactualorintendedcountryofregistration]</i>
4.Tenderer's yearofregistration: <i>[insertTenderer's yearofregistration]</i>
5.Tenderer's Addressincountryofregistration: <i>[insertTenderer's legaladdressincountryofregistration]</i>
6.Tenderer's Authorized Representative Information Name: <i>[insert Authorized Representative's name]</i> Address: <i>[insert Authorized Representative's Address]</i> Telephone/Fax numbers: <i>[insert Authorized Representative's telephone/ fax numbers]</i> Email Address: <i>[insert Authorized Representative's email address]</i>
<ul style="list-style-type: none"> <li>• 7. Attached are copies of original documents of <i>[check the box(es) of the attached original documents]</i></li> <li>• <input type="checkbox"/> Articles of Incorporation (or equivalent documents of constitution or association), and/ or documents of registration of the legal entity named above, in accordance with ITT 4.4.</li> <li><input type="checkbox"/> Incase of JV, Form of intent to form JV or JV agreement, in accordance with ITT 4.1.</li> <li><input type="checkbox"/> Incaseofstate-ownedenterpriseorinstitution,inaccordancewithITT4.7documentsestablishing:</li> </ul>
2. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership.

**FORM ELI - 1.1 (continued)****Tenderer Information Form**Date: *[insert day, month, year]*ITT No. and title: *[insert ITT number and title]*Page *[insert page number]* of *[insert total number]* pages

1. Tenderer's name			
2.2. Street Address:	Postal Code:	City:	Country:
P.O. Box and Mailing Address:			
3. Telephone Number:			
4. Fax Number:			
5. E-mail Address:			
6. Web Site:			
7. Contact Name:			
8. Contact Title:			
10. Type of Business:			
9.			
11. If Other, specify:			
12. Nature of Business:			
13. Year Established:			
14. Dates, Numbers, and Expiration Dates of Current Licenses and Permits:			
15. Current health authority registration information:			
16. Proof of product and facility registrations with Kenya regulatory authority and international agencies Certification Scheme, GMP) (e.g.,WHO			
17. Name of government agency(ies) responsible for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods:			
Date of last inspection:			
18. Quality Assurance Certification (Please include a copy of your latest certificate):			

19. Production capacity: *[insert peak and average production capacity over the last three years in units/day or units/month, etc.]*



20. List of names and addresses of sources of raw material and what products they will be used in:
21. Proof of raw material product and facility registrations with Kenya regulatory authority and international agencies (e.g., WHO Certification Scheme, GMP):
22. Raw materials tested prior to use:
23. Presence and characteristics of in-house quality control laboratory
24. Names and addresses of external quality control laboratories used:
25. Are all finished products tested and released by quality control prior to release for sale? Yes ___ No ___, If not, why?
26. List control tests done during production? If so list.
27. Procedures for dealing with rejected batches:
28. List tests conducted after production and prior to release of product on market:
29. List product recalls linked to defects during the last 36 months. Include reason and date of recall.
30. Are technical documents available in: <i>[Procuring Entity should insert language]</i> Yes or No

## TENDERER'S JV MEMBERS INFORMATION FORM

[The Tenderer shall fill in this Form in accordance with the instructions indicated below. The following table shall be filled in for the Tenderer and for each member of a Joint Venture]].

Date:..... [insert date (as day, month and year) of Tender submission]

ITT No.: .....[insert number of tendering process]

AlternativeNo.:.....[insert identification No if this is a Tender for an alterna

tive] Page\_\_of\_\_\_\_\_pages

Tenderer's Name:[insert Tenderer's legal name]

1. Tenderer's JV Member's name: [insert JV's Member legal name]
2. Tenderer's JV Member's country of registration: [insert JV's Member country of registration]
3. Tenderer's JV Member's year of registration: [insert JV's Member year of registration]
4. Tenderer's JV Member's legal address in country of registration: [insert JV's Member legal address in country of registration]
5. Tenderer's JV Member's authorized representative information
6. Name:[insert name of JV's Member authorized representative] Address:[insert address of JV's Member authorized representative] Telephone/Fax numbers: [insert telephone/ fax numbers of JV's Member authorized representative] Email Address: [insert email address of JV's Member authorized representative]
Attached are copies of original documents of [check the box(es) of the attached original documents]
<input checked="" type="checkbox"/> Articles of Incorporation (or equivalent documents of constitution or association), and/or registration documents of the legal entity named above, in accordance with ITT 4.4 <input type="checkbox"/> Tax Obligations for Kenyan Tenderers, attach copy of current tax clearance certificate or tax exemption certificate issued by the Kenya Revenue Authority in accordance with ITT 4.13. <input type="checkbox"/> In case of a state-owned enterprise or institution, documents establishing legal and financial autonomy, operation in accordance with commercial law, and not under the supervision of the Procuring Entity, in accordance with ITT 4.7.
2. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership.

**FORM FIN – 3.1**

**FINANCIAL SITUATION AND PERFORMANCE**

*[The following table shall be filled in for the Tenderer and for each member of a Joint Venture]*

Tenderer's Name: *[insert full name]*

Date: *[insert day, month, year]*

Joint Venture Member Name: *[insert full name]* ITT No. and title: *[insert ITT number and title]*

Page *[insert page number]* of *[insert total number]* pages

Type of Financial information in (currency)	Historic information for previous <i>[insert number]</i> years, <i>[insert in words]</i> (amount in currency, currency, exchange rate, USD equivalent)				
	Year 1	Year 2	Year 3		
Statement of Financial Position (Information from Balance Sheet)					
Total Assets (TA)					
Total Liabilities (TL)					
Total Equity/Net Worth (NW)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital (WC)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					
Cash Flow Information					
Cash Flow from Operating Activities					

### 3. FINANCIAL DOCUMENTS

The Tenderer and its parties shall provide copies of financial statements for the last [3] years pursuant Section III, Qualifications Criteria and Requirements, Sub-factor 3.1. The financial statements shall:

- a) reflect the financial situation of the Tenderer or in case of JV member, and not an affiliated entity(such as parent company or group member).
  - b) Be independently audited or certified in accordance with local legislation.
  - c) Be complete, including all notes to the financial statements.
  - d) Correspond to accounting periods already completed and audited.
- Attached are copies of financial statements for the last [3] years required above; and complying with the requirements

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*<sup>4</sup>If the most recent set of financial statements is for a period earlier than 12 months from the date of tendering, the reason for this should be justified.*

**FORM FIN - 3.2**

**AVERAGE ANNUAL TURNOVER (ANNUAL SALES VALUE)**

*[The following table shall be filled in for the Tenderer and for each member of a Joint Venture]*

Tenderer's Name: *[insert full name]*

Date: *[insert day, month, year]*

Joint Venture Member Name: *[insert full*

*name]* ITT No. and title: *[insert ITT number*

*and title]*

Page *[insert page number]* of *[insert total number]* pages

Annual turn over data			
Year	Amount Currency	Exchange rate	USD equivalent
<i>[indicate calendar year]</i>	<i>[insert amount and indicate currency]</i>		

\_\_\_\_\_

	Average Annual Turnover *	
--	------------------------------	--

\* Total USD equivalent for all years divided by the total number of years.

**FORM CON-1**  
**CURRENT CONTRACT COMMITMENTS / CONTRACTS IN PROGRESS FORM**

1. Name of Contract(s)
2. Procuring Entity Contact Information [ <i>insert address, telephone, fax, e-mail address</i> ]
3. Value of outstanding contracts [ <i>current US\$ equivalent</i> ]
4. Estimated delivery date
5. Average monthly invoices over the last six months (US\$/mon.)

**FORM - EXP - 1 - EXPERIENCE**

Contracts over..... <i>[insert amount]</i> during the last three years:				
<b>Procuring Entity</b>	<b>Value</b>	<b>Year</b>	<b>Goods/Services Supplied</b>	<b>Country of Destination</b>

**FORM - PER 1**

**HISTORICAL CONTRACT NON-PERFORMANCE, AND PENDING LITIGATION AND LITIGATION HISTORY**

*[The following table shall be filled in for the Tenderer and for each member of a Joint Venture]*

Tenderer's Name:.....*[insert full name]*

Date:.....*[insert day, month, year]*

Joint Venture Member Name:..... *[insert full name]* ITT No. and title:.....*[insert ITT number and title]*

Page..... *[insert page number]* of .....*[insert total number]* pages.

Non-Performed Contracts in accordance with Section III, Qualification Criteria and Requirements			
Contract non-performance did not occur since 1 <sup>st</sup> January <i>[insert year]</i> specified in Section III, Qualification Criteria and Requirements, Sub-Factor 2.1.			
Contract(s) not performed since 1 <sup>st</sup> January <i>[insert year]</i> specified in Section III, Qualification Criteria and Requirements, requirement 2.1			
Year	Non-performed portion of contract	Contract Identification	Total Contract Amount (current value, currency, exchange rate and US\$ equivalent)
<i>[insert year]</i>	<i>[insert amount and percentage]</i>	Contract Identification: <i>[indicate complete contract name/number, and any other identification]</i> Name of Procuring Entity: <i>[insert full name]</i> Address of Procuring Entity: <i>[insert street/city/country]</i> Reason(s) for nonperformance: <i>[indicate main reason(s)]</i>	<i>[insert amount]</i>
Pending Litigation, in accordance with Section III, Qualification Criteria and Requirements			
No pending litigation in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.3			
Pending litigation in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.3 as indicated below.			
Year of dispute	Amount in dispute (currency)	Contract Identification	Total Contract Amount (currency), USD Equivalent (exchange rate)



<i>[insert year]</i>	<i>[insert amount]</i>	<p>Contract Identification: [indicate complete contract name, number, and any other identification]</p> <p>Name of Procuring Entity: <i>[insert full name]</i></p> <p>Address of Procuring Entity: <i>[insert street/city/country]</i></p> <p>Matter in dispute: <i>[indicate main issues in dispute]</i></p> <p>Party who initiated the dispute: <i>[indicate "Procuring Entity" or "Supplier"]</i></p> <p>Status of dispute: <i>[Indicate if it is being treated by the Adjudicator, under Arbitration or being dealt with by the Judiciary]</i></p>	<i>[insert amount]</i>
<p><input type="checkbox"/> No consistent history of court/arbitral award decisions in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.4.</p> <p><input type="checkbox"/> Consistent history of court/arbitral award decisions in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.4 as indicated below.</p>			

<b>Year of award</b>	<b>Outcome as percentage of Net Worth</b>	<b>Contract Identification</b>	<b>Total Contract Amount (currency), USD Equivalent (exchange rate)</b>
<i>[insert year]</i>	<i>[insert percentage]</i>	<p>Contract Identification: [indicate complete contract name, number, and any other identification]</p> <p>Name of Procuring Entity: <i>[insert full name]</i></p> <p>Address of Procuring Entity: <i>[insert street/city/country]</i></p> <p>Matter in dispute: <i>[indicate main issues in dispute]</i></p> <p>Party who initiated the dispute: <i>[indicate "Procuring Entity" or "Supplier"]</i></p> <p>Court/ arbitral award decision: <i>[Indicate if the award decision was against the Tenderer or any member of a</i></p>	<i>[insert amount]</i>

**PRICE SCHEDULE FOR GOODS**

	1	2	3	4			5	6	7	8	9
No	Product Description	UOM	Quantity Unit Packs Offered	(a)	(b)	(c)	Total Unit Pack price (4a+b+c)	Total Price (3 x5)	Manufacturer	Delivery Period	Delivery Period Offered by Bidder
				Unit Price FOB port of Loading	Inland transport, insurance and other local costs incidental to delivery	Other incidental cost as defined in the SCC					
1.	Liquid chromatography/mass spectroscopy system	Unit	1							1 to 12 weeks	

*\*Note: In case of discrepancy between the unit price and total, the unit price shall prevail*

DAP, named place of destination National Quality Control Laboratory, KNH Complex, Upper Hill - Nairobi - Kenya	Currency	Grand Total Price (Sum of Column 6)	In Figures	
			In words	

Procurement financed under GF ATM is **free from any** customs duties, tariffs, import taxes, or similar levies (including Value Added Tax) imposed under Laws in effect in Kenya..

<b>Bidder's Name and Address</b>	<b>Date</b>	<b>Signature and Stamp</b>

**NOTE:**

1. Incoterm - **DAP, named place of destination; National Quality Control Laboratory, KNH Complex in Upper Hill - Nairobi - Kenya**
2. Supplier supplying Goods from abroad shall be entirely responsible for all taxes, stamp, duties, license fees, and other such levies imposed outside the Purchaser's country. Commodities being procured under this GFATM grant are free of local taxes and duties. The Purchaser will facilitate the tax exemptions upon receipt of the required documentation from the supplier.
3. A Supplier supplying Goods offered locally shall be entirely responsible for all taxes, duties, license fees, etc., incurred until

delivery of the contracted Goods to the Purchaser. The charge of VAT is not applicable for commodities being procured with this GFATM grant. The Purchaser will facilitate VAT exemption upon receipt of the required documentation from the supplier.

4. Margin of Preference not Applicable.

## **DELIVERY SCHEDULE**

One (1) item will be procured under this tender as described above.

Full quantity of all items shall be delivered **between 1-12 weeks** from effective date of contract.

**Delivery Terms: DAP, named place of destination National Quality Control Laboratory, KNH Complex in Upper Hill - Nairobi - Kenya**

## FORM OF TENDER SECURITY - (BANK GUARANTEE)

*[The bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.] [Guarantor letterhead or SWIFT identifier code] Beneficiary: [Procuring Entity to insert its name and address] ITT No.: [Procuring Entity to insert reference number for the Invitation to Tender] Alternative No.: [Insert identification No if this is a Tender for an alternative] Date: [Insert date of issue]*

TENDER GUARANTEE No.: *[Insert guarantee reference number]*

Guarantor: *[Insert name and address of place of issue, unless indicated in the letterhead]*

We have been informed that            *[insert name of the Tenderer, which in the case of a joint venture shall be the name of the joint venture (whether legally constituted or prospective) or the names of all members there of] (herein after called" the Applicant")* has submitted or will submit to the Beneficiary its Tender (hereinafter called" the Tender") for the execution of            under Invitation to Tender No.            ("the ITT").

Furthermore, we understand that, according to the Beneficiary's conditions, Tenders must be supported by a Tender guarantee.

At the request of the Applicant, we, as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of            upon receipt by us of the Beneficiary's complying demand, supported by the Beneficiary's statement, whether in the demand itself or a separate signed document accompanying or identifying the demand, stating that either the Applicant:

- (a) Has withdrawn its Tender during the period of Tender validity set forth in the Applicant's Form of Tender ("the Tender Validity Period"), or any extension there to provide by the Applicant; or
- (b) Having been notified of the acceptance of its Tender by the Beneficiary during the Tender Validity Period or any extension there to provide by the Applicant, (i) has failed to execute the contract agreement, or (ii) has failed to furnish the Performance Security, in accordance with the Instructions to Tenderers ("ITT") of the Beneficiary's tendering document.

This guarantee will expire: (a) if the Applicant is the successful Tenderer, upon our receipt of copies of the contract agreement signed by the Applicant and the Performance Security issued to the Beneficiary in relation to such contract agreement; or (b) if the Applicant is not the successful Tenderer, upon the earlier of (i) our receipt of a copy of the Beneficiary's notification to the Applicant of the results of the Tendering process; or (ii) twenty-eight days after the end of the Tender Validity Period.

Consequently, any demand for payment under this guarantee must be received by us at the office indicated above on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No. 758.

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[Signature(s)]

*Note: All italicized text is for use in preparing this form and shall be deleted from the final product.*

**FORM OF TENDER SECURITY (TENDER BOND)**

*[The Surety shall fill in this Tender Bond Form in accordance with the instructions indicated.]*

BOND NO. \_\_\_\_\_

BY THIS BOND [*name of Tenderer*] as Principal (here in after called "the Principal"), and [*name, legal title, and address of surety*], authorized to transact business in Kenya, as Surety (hereinafter called "the Surety"), are held and firmly bound unto [*name of Procuring Entity*] as Oblige (here in after called "the Procuring Entity") in the sum of [*amount of Bond*]<sup>5</sup>[*amount in words*], for the payment of which sum, well and truly to be made, we, the said Principal and Surety, bind ourselves, our successors and as signs, jointly and severally, firmly by these presents.

WHEREAS the Principal has submitted or will submit a written Tender to the Procuring Entity dated the \_\_\_\_\_ day of \_\_, 20\_\_\_\_, for the supply of [*name of Contract*](herein after called the "Tender").

NOW, THEREFORE, THE CONDITION OF THIS OBLIGATION is such that if the Principal:

- a) has withdrawn its Tender during the period of Tender validity set forth in the Principal's Form of Tender ("the Tender Validity Period"), or any extension there to be provided by the Principal; or
- b) having been notified of the acceptance of its Tender by the Procuring Entity during the Tender Validity Period or any extension thereto provided by the Principal; (i) failed to execute the contract agreement; or (ii) has failed to furnish the Performance Security, in accordance with the Instructions to Tenderers ("ITT") of the Procuring Entity's tendering document.

Then the Surety under takes to immediately pay to the Procuring Entity up to the above amount upon receipt of the Procuring Entity's first written demand, without the Procuring Entity having to substantiate its demand, provided that in its demand the Procuring Entity shall state that the demand arises from the occurrence of any of the above vents, specifying which event(s) has occurred.

The Surety hereby agrees that its obligation will remain in full force and effect up to and including the date 30 days after the date of expiration of the Tender Validity Period set forth in the Principal's Form of Tender or any extension thereto provided by the Principal.

IN TESTIMONY WHERE OF, the Principal and the Surety have caused these presents to be executed in the irrelative names this \_\_ day of \_\_\_\_\_ 20\_\_\_\_\_.

Principal: \_\_\_\_\_  
Corporate Seal (where appropriate)

Surety: \_\_\_\_\_

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Printed name and title)

\_\_\_\_\_  
(Printed name and title)

<sup>5</sup>The amount of the Bond shall be denominated in the currency of Kenya or the equivalent amount in a freely convertible currency.

**TENDER - SECURING DECLARATION FORM**

*[The Bidders shall complete this Form in accordance with the instructions indicated]*

Date: .....*[insert date (as day, month and year) of Tender Submission]*

Tender No.: .....*[insert number of tendering process]*

To: .....*[insert complete name of Purchaser]*

I/We, the undersigned, declare that:

1. I / We understand that, according to your conditions, bids must be supported by a Tender-Securing Declaration.
2. I/We accept that I/ we will automatically be suspended from being eligible for tendering in any contract with the Purchaser for the period of time of *[insert number of months or years]* starting on *[insert date]*, if we are in breach of our obligation(s) under the bid conditions, because we-(a) have withdrawn our tender during the period of tender validity specified by us in the Tendering Data Sheet; or (b) having been notified of the acceptance of our Bid by the Purchaser during the period of bid validity, (i) fail or refuse to execute the Contract, if required, or (ii) fail or refuse to furnish the Performance Security, in accordance with the instructions to tenders.
3. I / We understand that this Tender Securing Declaration shall expire if we are not the successful Tenderer(s), upon the earlier of:
  - a) our receipt of a copy of your notification of the name of the successful Tenderer; or
  - b) thirty days after the expiration of our Tender.
4. I / We understand that if I am/we are/in a Joint Venture, the Tender Securing Declaration must be in the name of the Joint Venture that submits the bid, and the Joint Venture has not been legally constituted at the time of bidding, the Tender Securing Declaration shall be in the names of all future partners as named in the letter of intent.

Signed:.....

Capacity / title (director or partner or sole proprietor, etc.)

Name:.....

Duly authorized to sign the bid for and on behalf of: *[insert complete name of Tenderer]*

Dated on..... day of..... *[Insert date of signing]*



Seal or stamp

**MANUFACTURER'S AUTHORIZATION**

[The Tenderer shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This Form of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Tenderer shall include it in its Tender, if so indicated in the TDS.]

Date: .....[insert date (as day, month and year) of Tender submission]

ITT No.: .....[insert number of tendering process]

Alternative No.: .....[insert identification No if this is a Tender for an alternative]

To: .....[insert complete name of Procuring Entity]

**WHEREAS**

We [insert complete name of Manufacturer], who are official manufacturers of [insert type of goods manufactured], having factories at [insert full address of Manufacturer's factories], do hereby authorize [insert complete name of Tenderer] to submit a Tender the purpose of which is to provide the following Goods, manufactured by us [insert name and or brief description of the Goods], and to subsequently negotiate and sign the Contract.

We here by extend our full guarantee and warranty in accordance with Clause 28 of the General Conditions of Contract, with respect to the Goods offered by the above firm.

Signed: .....[insert signature(s) of authorized representative(s) of the

Manufacturer] Name: .....[insert complete name(s) of authorized

representative(s) of the Manufacturer] Title: .....[insert title]

Dated on \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_ [insert date of signing]

# SPECIMEN CERTIFICATE OF A HEALTH PRODUCT

Certificate of a Health Product 1

This certificate conforms to the format recommended by the World Health Organization (general instructions and explanatory notes attached).

No. of certificate:.....

Exporting (certifying) country:.....

Importing (requesting) country: .....

1. Name and dosage form of product:

.....

Active ingredients 1 and amount(s) per unit dose 3

.....

.....

.....

For complete qualitative composition including excipients, see attached 4

Is this product licensed to be placed on the market for use in the exporting country 5 yes/no (key in as appropriate)?

Is this product actually on the market in the exporting country? yes/no/unknown (key in as appropriate) If the answer to 1.2 is yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B 6

2A.1 Number of product license<sup>7</sup> and date of issue:

.....

2A.2 Product-license holder (*name and address*):

.....

.....

.....

2A.3 Status of product-license holder 8 a/b/c (key in appropriate category as defined in note 8)

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage for are: 9

2A.4 Is Summary Basis of Approval appended 10 yes/no (key in as appropriate)

2A.5 Is the attached, officially approved product information complete and consonant with the license 11 yes/no/not provided (key in as appropriate)

2A.6 Applicant for certificate, if different from license holder (name and address): 12

2B.1 Applicant for certificate (name and address):

2B.2 Status of applicant: a/b/c (key in appropriate category as defined in note 8

2B.2.1 For categories band c the name and address of the manufacturer producing the dosage for mare: 9

.....  
.....  
.....

2B.3 Why is marketing authorization lacking?

Not required/not requested/under consideration/ refused (key in as appropriate)

2B.4 Remarks: 13

3. Does the certifying authority arrange for period inspection of the manufacturing plant in which the dosage form is produced?

Yes /no/ not applicable 14 (key in as appropriate) If no or not applicable proceed to question

4. Periodicity of routine inspections(years): Has the manufacture of this type of dosage form been inspected? yes/no(key in as appropriate) Do the facilities and operations conform to

GMP as recommended by the World Health Organization<sup>15</sup>yes/ no/notapplicable<sup>16</sup>(key in as appropriate)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 11

yes/no (key in as appropriate) If no, explain:

.....  
.....  
.....

Address of certifying authority:

Telephone

number:.....Fax

number:.....

Name of authorized person:

.....

Signature:

.....

Stamp and date:

.....

## General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

### Explanatory notes

<sup>1</sup> This certificate, which is in the format recommended by WHO, establishes the status of the Health product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

<sup>2</sup> Use whenever possible international nonproprietary names (INNs) or national nonproprietary names

<sup>3</sup> The formula (complete composition) of the dosage form should be given on the certificate or be appended

<sup>4</sup> Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder

<sup>5</sup> When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license. <sup>6</sup> Sections 2A and 2B are mutually exclusive.

<sup>7</sup> Indicate, when applicable, if the license is provisional or if the product has not yet been approved.

<sup>8</sup> Specify whether the person responsible for placing the product on the market:

- a) Manufactures the dosage form;
- b) Packages and/or labels a dosage form manufactured by an independent company; or
- c) Is involved in none of the above.

<sup>9</sup> This information can be provided only with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non completion of this Section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

<sup>10</sup> This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed. <sup>11</sup> This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

<sup>12</sup> In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.

<sup>13</sup> Please indicate the reason that the applicant has provided for not requesting registration:

- a) The product has been developed exclusively for the treatment of conditions—particularly tropical diseases—not endemic in the country of export.
- b) The product has been reformulated with a view to improving its stability under tropical conditions.
- c) The product has been reformulated to exclude excipients not approved for use in **Health** products in the country of import.
- d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.

e) *Any other reason, please specify.*

<sup>14</sup>*Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.*

<sup>15</sup>*The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for **Health Products** Preparations (WHO Technical Report Series, No.823,1992, Annex1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No.822,1992, Annex1).*

<sup>16</sup>*This section is to be completed when the product-license holder or applicant conforms to status(b) or(c) as described in note7above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.*

## TAX EXEMPTION PROCESS

- ❑ All procurements under GF are exempt from Duty and Taxes.
- ❑ All goods must be consigned to KEMSA because tax waiver is granted to KEMSA. Delivery address should be Kenya Medical Supplies Authority, P.O. Box 47715-00100 Nairobi. Notified party is the supplier.
- ❑ The following are documents required for purpose of application of Import Declaration Form (IDF) and Import permit by KEMSA through the KenTrade System:
  - a. Proforma/Commercial Invoice
  - b. Retention/Product listing by Pharmacy & Poisons Board (PPB)
- ❑ The IDF and Import Permit are used by the supplier to apply for Pre-Export Verification of Conformity to Standards (PVoC). If products conform to standards, a Certificate of Conformity (COC) is issued.
- ❑ As per the PVoC Program operations Manual issued on 1st October 2018, there are Six (6) inspection companies (PVoC Agents) namely;
  - a. Messrs Bureau Veritas
  - b. Cotecna
  - c. China Certification & Inspection (Group) Inspection Co. Ltd
  - d. Intertek International
  - e. SGS
  - f. QISJ.

(The PVoC manual can be accessed on the KEBS website: [https://www.kebs.org/index.php?option=com\\_content&view=category&layout=blog&id=59&Itemid=274](https://www.kebs.org/index.php?option=com_content&view=category&layout=blog&id=59&Itemid=274) )

- ❑ The supplier should only release shipment (both Sea and air) when the COC has been issued and a copy must be forwarded to KEMSA.

Please note that any goods shipped/arriving in Kenya without the CoC is considered to have not been inspected and therefore subjected to **Destination Inspection by KEBS at a cost of 20% of CIF**. A new directive was enforced by the PS-Trade and Industrialization with effect 23rd January 2019 that any goods arriving in Kenya without inspection at country of origin will be returned back to country of origin at suppliers cost.

### **Documents required for application of Tax waiver:**

- ❑ Certificate of Conformity (COC)
- ❑ Draft shipping documents: i.e.
  - a. Air Waybill/Bill of Lading,
  - b. Commercial Invoice,
  - c. Packing List,

d. Copy of marine Insurance to KEMSA.

- ❑ The process takes approximately 2-3 weeks for a tax waiver to be issued through the Ministry of Health (MOH) and the National Treasury. MOH confirms to the National Treasury that goods are eligible for exemption and National Treasury thereafter forwards documents to Kenya Revenue Authority for issuing of exemption code.
- ❑ The supplier/Clearing agent is required to clear consignments within the stipulated days as provided for by the Container Freight Station (CFS).
- ❑ For Air shipments, they must be cleared within 48 hours on notification by the CFS.
- ❑ Sea shipment must be cleared within 5 days or within the negotiated days between the shipper and the CFS. Suppliers should note that there is mandatory haulage of all imports through Mombasa by SGR to the Inland Container Depot (ICD) Nairobi. If all the goods are meant to be distributed within Coast region, suppliers should consign their goods to Kenya Medical Supplies Authority (KEMSA), Mombasa.
- ❑ If the named place of destination is KEMSA warehouse, supplier must arrange for clearing and forwarding through their clearing agent.
- ❑ The supplier representative/appointed agent should arrange with KEMSA Warehouse for delivery date and be present to confirm that goods are received in good order and condition.
- ❑ It is the supplier's responsibility to arrange for offloading process.

The requirements for submitting a pre-delivery sample;

1. Have a signed contract
2. Copy of Purchase Order
3. Copy of Delivery Note and product/brochure to be evaluated.
4. Certificate of Analysis
5. Delivery Address is DAP, named place of destination National Quality Control Laboratory, KNH Complex in Upper Hill - Nairobi - Kenya.

Pre-delivery samples form part of the consignment.



## **PART 2 - SUPPLY REQUIREMENTS**

### **SECTION VII - SCHEDULE OF REQUIREMENTS**

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## NOTES FOR PREPARING THE SCHEDULE OF REQUIREMENTS

The Schedule of Requirements shall be included in the tendering document by the Procuring Entity, and shall cover, at a minimum, a description of the goods and services to be supplied and the delivery schedule.

The objective of the Schedule of Requirements is to provide sufficient information to enable Tenderers to prepare their Tenders efficiently and accurately, in particular, the Price Schedule, for which a form is provided in Section IV. In addition, the Schedule of Requirements, together with the Price Schedule, should serve as a basis in the event of quantity variation at the time of award of contract pursuant to ITT 42.1.

The date or period for delivery should be carefully specified, taking into account (a) the implications of delivery terms stipulated in the Instructions to Tenderers pursuant to the *Incoterms* rules (i.e., EXW, or CIP, FOB, FCA terms-that “delivery” takes place when goods are delivered **to the carriers**), and (b) the date prescribed here in from which the Procuring Entity's delivery obligations start (i.e., notice of award, contract signature, opening or confirmation of the Form of credit).

Section VII – Schedule of Requirements

**1. LIST OF GOODS AND DELIVERY SCHEDULE**

*[The Procuring Entity shall fill in this table, with the exception of the column "Tenderer's offered Delivery date "to be filled by the Tenderer]*

Line Item N°	Description of Goods	Quantity	Unit Of Measure	Place of Delivery	Delivery (as per Incoterms) Date		
					Earliest Delivery Date	Latest Delivery Date	Tenderer's offered Delivery date <i>[to be provided by the Tenderer]</i>
<i>[insert item No]</i>	<i>[insert description of Goods]</i>	<i>[insert quantity of item to be supplied]</i>	<i>[insert physical unit for the quantity]</i>	<b>DAP, named place of destination National Quality Control Laboratory, KNH Complex, Upper Hill - Nairobi - Kenya)</b>	One Week	Twelve Weeks	<i>[insert the number of days following the date of effectiveness the Contract]</i>



## TECHNICAL SPECIFICATIONS FOR LIQUID CHROMATOGRAPHY, MASS SPECTROSCOPY SYSTEM (LC-MS-MS)

An automated, bench top, Triple Quadrupole, Mass Spectrometer, Interfaced to an Ultra High Performance Liquid Chromatography system, with an additional Photodiode Array detector and control software for use in pharmaceutical Quality Control, in a Good Laboratory Practices (GLP) regulated environment.

The system will be brand new, easy to use and from a reputable brand with an established technical presence in the market. It shall be the latest model offered by the manufacturer, able to analyse pharmaceutical samples in accordance with Pharmacopoeial requirements and in compliance with GLP standards in a strictly regulated Official Medicines Control Laboratory (OMCL).

The equipment must come with direct manufacturer support – engineer application and logistics locally. It must have a strong track record for reliability, robustness and reproducibility. It shall include individual stackable self-contained UHPLC modules, capable of standalone operation and have internal diagnostics to monitor the instrument's performance and record in a logbook. Modules must be connected via fiber optic noise resistant high-speed transmission technology to enhance the reliability and sensitivity of the UHPLC.

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

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 system.

The successful bidder will be expected to perform the necessary IQ/OQ/PQ of the complete system package in accordance to the manufacturer's SOP and in compliance with specifications stipulated in USP general chapters <1058: Analytical equipment qualification> and the EDQM guidelines (see attached)

## DETAILED TECHNICAL SPECIFICATIONS

### A) Ultra High-Performance Liquid Chromatography System (UHPLC)

Ultra High Performance Liquid Chromatography System (UHPLC)		
Component:	Parameter:	Specifications:
1) Quaternary, Gradient LC pump:	a) Number of Solvents	4
	b) Flow rate range:	0.001 to 3 mL/min. in 0.001 mL/min. increments
	c) Pressure:	Maximum pressure : 1200 Bar
	d) Pressure pulsation:	< 2 % amplitude (typically < 1.0 %) or < 0.3 MPa (3 bar), whatever is greater, at 1 mL/min isopropanol, at all pressures > 1 MPa (10 bar, 147 psi).
	e) Composition Range:	0 - 100 % in 0.1% increments, user settable.
	f) Composition precision:	Typically < 0.2 % RSD
	g) Flow precision:	0.07% RSD or 0.02 min. SD
	h) Flow accuracy	± 1% or ≤ 10 µL/min
	i) Delay Volume:	600 – 900 µL,
	j) Error detection:	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.
	k) EMF:	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with pre-defined and user settable limits and feedback messages. Electronic records of maintenance and errors.
2) PDA (Photo Diode Array) Detector	a) Light source	Pre-aligned voltage regulated Deuterium lamp
	b) Wavelength Range	190 – 800 nm
	c) Number of diode elements	≥ 1024
	d) Wavelength accuracy	± 1 nm

Ultra High Performance Liquid Chromatography System (UHPLC)		
	e) Linearity	≤ 5% @ 2.0 AU @257 nm propyl paraben
	f) Resolution	1.2 nm (Optical, 1.2 nm/pixel (Digital))
	g) Wavelength Repeatability	± 0.1 nm
	h) Bandwidth	1.2 nm
	i) Noise	± 7 x 10 <sup>-6</sup> AU @ 254 nm
	j) Drift	0.0001 AU/hr @254 nm
	k) Sample flow cell	Quartz, 10mm path length
	l) Error Detection:	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.
3) Solvent rack and degasser:	a) Degasser:	Integrated Degasser (not a separate unit) with 4 degassing channels
	b) Volume:	Internal Volume per channel: 1.5 mL
4) Chilled/refrigerated Automated Sampler:	a) Sample carry over	< 0.004% (40 ppm)
	b) Injection range:	0.1 to 100 µL in 0.1 µL increments with 100 µL up to 600 bar
	c) Precision:	Typically < 0.25% RSD
	d) Sample Capacity:	132 × 2-ml HPLC vials in 1 tray or 2 trays and 2 x 96 well microtiter plates and 2 x 96 well deep well plates.
	e) Injection Cycle time:	50s or less
	f) Temperature Control Range:	Hold samples at 4 °C - 45°C
	g) Temperature Accuracy (Sample cooler):	± 2°C
	h) Rinsing:	In - built needle and injection port rinsing.
	i) Injection modes:	The auto-sampler design must offer a flow through design with variable injection volume (loop, Cut)

Ultra High Performance Liquid Chromatography System (UHPLC)		
	j) Error detection:	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.
5) Temperature Controlled Column Compartment:	a) Column oven:	Integrated column oven
	b) Temperature Range:	Temperature range: 5 °C below ambient to 80 °C or better.
	c) Temp. Precision	Temperature stability: ± 0.1 °C or better
	d) Temperature accuracy:	Temperature accuracy: ± 1 °C or better
	e) Capacity:	2 columns up to 30 cm and 4.6 mm ID
	f) Solvent Conditioning	The module must enable pre column heating.
	g) Temperature Control Type:	Forced air circulation or Peltier cooling and heating'
	h) Error detection:	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.
6) Ancillary components for the UHPLC	a) UHPLC Start up Kit	An LCMS start-up kit should be supplied as standard to enable operation and maintenance (Including all the required Qualification Chemical Reference Standards)
	b) Tool Kit	Standard Manufacturers HPLC tool kit to enable servicing, maintenance and PQ
	c) UHPLC Columns	4 in number (2 C18 and 2 C8 )



## B) Triple Quadrupole Mass Analyzer

The mass analyzer must consist of 2, high standard, fast scanning Quadrupoles and one high efficiency multipole type collision cell. It should be capable of handling large batches of samples with complex matrices over a long period of time. The maintenance and cleaning of the interface must be simple.

Triple Quadrupole Mass analyzer		
Component:	Parameter	Specifications:
1) Mass Detector	a) Detector type	The detector should be an Electron multiplier, Photo multiplier or appropriate alternative.
2) Ion Source	a) Ionisation Modes	One set of ESI (Electro spray Ionisation) must be available as standard. APCI (Atmospheric Pressure Chemical Ionisation) interface must be available and necessary probes included.
	b) ESI Flow rate	0.001 to 2mL/min.
	c) Ion source temperature	The heating block temperature of APCI/ESI must withstand high temperature up to 500°C
	d) Direct infusion	An extra syringe pump must be available as an option for direct infusion of sample.
	e) Operation Software	The software must be able to recognize the ion Source automatically.
	f) Ionisation probes	The ionization probes switching should be simple and tool free.
	g) Flow diverter	Automated programmable flow diverter capable of diverting column effluent from source should be present.
3) Mass analyzer	a) Analyzer	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.
	b) Flow sprayer	The MS should employ an orthogonal angle flow sprayer.
	c) Mass range	Mass range should be from m/z 2 to 2000
	d) Mass Stability	The mass stability should be 0.05 Da over 12 hours or more.
	e) Scanning speed	The mass analyzer must have a scanning speed capability up to 30,000 Da/s with increments of 0.1Da

**Triple Quadrupole Mass analyzer**

f) Polarity switching rate	Detection of Positive/Negative ions should be no more than 5 msec.
g) Scanning Modes	MS full scan, MS/MS Product ion scan, MS/MS neutral Loss/gain scan, precursor ion scans, mixed mode scan, SIM (Single Ion Monitoring)
h) Resolution	$\leq 0,7$ amu
i) MS-MS capability	MS-MS capability must be available in Quadrupole 2 [Q2] via Collision Induced Dissociation (CID). The gas used for fragmentation should be Argon
j) Dwell times	The collision cell must be capable of doing MRM analysis with shortest Dwell time of 0.8msec.
k) MRM scan speed	Must be able to measure 555 MRM in one Second
l) Tuning	Auto-tuning should be standard with a syringe pump that delivers accurate calibrate injection under full workstation control in both positive and negative modes. Manual tuning should be possible as well
m) Sensitivity, Positive ESI	Minimum Signal-to-Noise ratio [RMS] 250,000:1, following injection of 1 pg or below of Reserpine in MRM mode.
n) Sensitivity, negative ESI	Minimum Signal-to-Noise ratio [RMS] 90,000:1, following injection of 1 pg or below of Chloramphenicol in MRM mode.
o) Sensitivity, Positive APCI	Minimum Signal-to-Noise ratio [RMS] 1000:1, following injection of 10 pg or below of Reserpine in MRM mode.
p) Dynamic range	The instrument should have a Dynamic range of 1 to $2 \times 10^7$ pulse counting.
q) Vacuum system	Turbo- molecular pump and rotary pump.
r) Mass Spectrometer start up Kit	An LCMS start-up kit should be supplied as standard.to enable operation and maintenance (Including all the required pre-qualification Chemical Reference Standards)

Triple Quadrupole Mass analyzer		
4) Gas generator and Compressor	a) Nitrogen gas generation	<p>Include autonomous Nitrogen gas generator and compressor utilizing membrane technology to selectively remove Oxygen, moisture and other gases.</p> <p>Rate of Nitrogen generation should meet the requirements of the system offered.</p>

### C) Data Management and Acquisition System

Data Management and Acquisition System		
Component:	Parameter	Specifications:
1) Desktop computer System	a) CPU	Intel Core i7 - 10 <sup>th</sup> generation Processor or better
	b) Memory	8.0 GB RAM Memory
	c) Hard drive	1TB Hard disk Storage
	d) Monitor	19" LCD wide monitor
	e) Printer	WIFI enabled Laser Jet duplex printer
	f) Operating system software	Fully licensed, activated, latest and compatible Microsoft Windows.
	g) Other Software	Fully licensed, activated, latest version of Microsoft Office Professional Plus.
2) Software System		Validated, Multiuser, with full GLP/GMP compliance (FDA 21, CFR part 11) and pre-installed standard methods.
		Single software platform must be provided for a seamless control of all the modules of LC and MS
		It should cover full digital instrument control, qualitative and quantitative processing, report creation, self-diagnosis and auto-tuning
		Upgradeable easy to use software allowing; <ul style="list-style-type: none"> <li>• Remote control operation</li> <li>• Enables data integration, audit trails,</li> <li>• Customizable data reporting</li> <li>• Capable of integrating with a LIMS.</li> <li>• Capable of controlling multiple LC-MS-MS systems.</li> </ul>
		The software should simultaneously control and process mass-spectrometry and PDA data
	System suitability, System security as well as System check functions must be provided which comply with Good Laboratory Practice (GLP) and Regulatory Conformity	

Data Management and Acquisition System		
		Auto Start-up and shutdown of the MS should be possible using a single key operation
		Auto-tuning with sensitivity and resolution optimization for both positive ion and negative ion modes should be standard.
		The data can be converted to other formats. Spread Sheet software and word-processing software can be readily employed to provide data in tables or graphs through industry standard protocols
		Single software platform must be provided for a seamless control of all the modules of LC and MS
		It should cover full digital instrument control, qualitative and quantitative processing, report creation, self-diagnosis and auto-tuning

#### D) Mandatory support requirements

Mandatory Support Requirements		
Component:	Parameter:	Specifications:
1) UPS	Capacity	≥ 10 kVA, should be capable of holding power for at least 1 hour
2) Testing Capabilities	Specific compounds of pharmaceutical importance	<p>System should have demonstrated sensitivity in the detection and quantification of each of the following <i>N</i>-Nitrosamine impurities in active pharmaceutical ingredients and formulations at a Limit of Quantification &lt; 0.02 ppm:</p> <ul style="list-style-type: none"> <li>• <i>N</i>-Nitrosodimethylamine (NDMA)</li> <li>• <i>N</i>-Nitrosodiethylamine (NDEA)</li> <li>• <i>N</i>-Nitrosomethylphenylamine (NMPA)</li> <li>• <i>N</i>-Nitrosodiisopropylamine (NDIPA)</li> <li>• <i>N</i>-Nitrosoisopropylethylamine (NIPEA)</li> <li>• <i>N</i>-Nitroso-<i>N</i>-methyl-4-aminobutyric Acid (NMBA)</li> </ul> <p><i>(Supplier to provide evidence in form of Official technical application notes or peer reviewed scientific journal articles describing the instrumentation used)</i></p>
3) Air Conditioning Unit		Split type, ≥ 24,000 BTU/h
4) Training & Warranty	Training & Warranty	<p>The vendor shall install the system at NQCL 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 system should be covered by a minimum <b>1 year warranty</b> including <b>spare parts</b> and <b>labour</b>.</p>

**Mandatory Support Requirements**

5) Installation, Operational & Performance Qualification (IQ/OQ/PQ)	(IQ/OQ/PQ)	Supplier <b>MUST</b> undertake comprehensive and thoroughly documented <b><u>IQ</u> &amp; <u>OQ</u></b> including <b><u>PQ</u> (System Suitability Test &amp; Calibration)</b> of the equipment at time of commissioning (receipt) in accordance with the manufacturer's guidelines and in conformance with International Standards ( <b>WHO/ISO/EDQM</b> ).
6) After Sales Service	After Sales Service	Supplier must commit to undertake after sales service as and when required.

## COMPLIANCE SHEET

Ultra High Performance Liquid Chromatography System (UHPLC)			
Component:	Parameter:	Specifications:	Compliance Sheet To be completed by the Bidder with the required "Relevant Information", duly signed and submitted with the Bid
<b>Liquid Chromatography/Mass Spectroscopy System</b>	<p>An automated, bench top, Triple Quadrupole, Mass Spectrometer, Interfaced to an Ultra High Performance Liquid Chromatography system, with an additional Photodiode Array detector and control software for use in pharmaceutical Quality Control, in a Good</p> <p>Laboratory Practices (GLP) regulated environment.</p> <p>The system will be brand new, easy to use and from a reputable brand with an established technical presence in the market. It shall be the latest model offered by the manufacturer, able to analyse pharmaceutical samples in accordance with Pharmacopoeial requirements and in compliance with GLP standards in a strictly regulated Official Medicines Control Laboratory (OMCL).</p> <p>The equipment must come with direct manufacturer support - engineer application and logistics locally. It must have a strong track record for reliability, robustness and reproducibility. It shall include individual stackable self-contained UHPLC modules, capable of standalone operation and have internal diagnostics to monitor the instrument's performance and record in a logbook. Modules must be connected via fiber optic noise resistant high-speed transmission technology to enhance the reliability and sensitivity of the UHPLC.</p> <p>The offer must be by a single vendor supplier for all components of the system. This vendor should have demonstrated local technical competence to train, perform Installation Qualification, Operation Qualification and Performance Qualification (IQ/OQ/PQ) and service the equipment.</p> <p>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 system.</p> <p>The successful bidder will be expected to perform the necessary IQ/OQ/PQ of the complete system package in accordance to the manufacturer's SOP and in compliance with specifications stipulated in USP general chapters &lt;1058: Analytical equipment qualification&gt; and the EDQM guidelines (see attached)</p>		
7) Quaternary, Gradient LC pump:	l) Number of Solvents	4	
	m) Flow rate range:	0.001 to 3 mL/min. in 0.001 mL/min. increments	

Ultra High Performance Liquid Chromatography System (UHPLC)		
	n) Pressure:	Maximum pressure : 1200 Bar
	o) Pressure pulsation:	< 2 % amplitude (typically < 1.0 %) or < 0.3 MPa (3 bar), whatever is greater, at 1 mL/min isopropanol, at all pressures > 1 MPa (10 bar, 147 psi).
	p) Composition Range:	0 - 100 % in 0.1% increments, user settable.
	q) Composition precision:	Typically < 0.2 % RSD
	r) Flow precision:	0.07% RSD or 0.02 min. SD
	s) Flow accuracy	± 1% or ≤ 10 µL/min
	t) Delay Volume:	600 – 900 µL,
	u) Error detection:	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.
v) EMF:	Early maintenance feedback (EMF) for continuous tracking of instrument usage in terms of seal wear and volume of pumped mobile phase with pre-defined and user settable limits and feedback messages. Electronic records of maintenance and errors.	
8) PDA (Photo Diode Array) Detector	m) Light source	Pre-aligned voltage regulated Deuterium lamp
	n) Wavelength Range	190 – 800 nm
	o) Number of diode elements	≥ 1024
	p) Wavelength accuracy	± 1 nm
	q) Linearity	≤ 5% @ 2.0 AU @257 nm propyl paraben
	r) Resolution	1.2 nm (Optical, 1.2 nm/pixel (Digital))
	s) Wavelength Repeatability	± 0.1 nm
	t) Bandwidth	1.2 nm
	u) Noise	± 7 × 10 <sup>-6</sup> AU @ 254 nm
	v) Drift	0.0001 AU/hr @254 nm
w) Sample flow cell	Quartz, 10mm path length	

Ultra High Performance Liquid Chromatography System (UHPLC)			
	x) Error Detection:	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.	
9) Solvent rack and degasser:	h) Degasser:	Integrated Degasser (not a separate unit) with 4 degassing channels	
	i) Volume:	Internal Volume per channel: 1.5 mL	
10) Chilled/refrigerated Automated Sampler:	k) Sample carry over	< 0.004% (40 ppm)	
	l) Injection range:	0.1 to 100 µL in 0.1 µL increments with 100 µL up to 600 bar	
	m) Precision:	Typically < 0.25% RSD	
	n) Sample Capacity:	132 × 2-ml HPLC vials in 1 tray or 2 trays and 2 × 96 well microtiter plates and 2 × 96 well deep well plates.	
	o) Injection Cycle time:	50s or less	
	p) Temperature Control Range:	Hold samples at 4 °C - 45°C	
	q) Temperature Accuracy (Sample cooler):	± 2°C	
	r) Rinsing:	In - built needle and injection port rinsing.	
	s) Injection modes:	The auto-sampler design must offer a flow through design with variable injection volume (loop, Cut)	
	t) Error detection:	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.	
11) Temperature Controlled Column Compartment:	i) Column oven:	Integrated column oven	
	j) Temperature Range:	Temperature range: 5 °C below ambient to 80 °C or better.	
	k) Temp. Precision	Temperature stability: ± 0.1 °C or better	
	l) Temperature accuracy:	Temperature accuracy: ± 1 °C or better	
	m) Capacity:	2 columns up to 30 cm and 4.6 mm ID	
	n) Solvent Conditioning	The module must enable pre column heating.	



Ultra High Performance Liquid Chromatography System (UHPLC)			
	o Temperature Control Type:	Forced air circulation or Peltier cooling and heating'	
	p Error detection:	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.	
12) Ancillary components for the UHPLC	d) UHPLC Start up Kit	An LCMS start-up kit should be supplied as standard to enable operation and maintenance (Including all the required Qualification Chemical Reference Standards)	
	e) Tool Kit	Standard Manufacturers HPLC tool kit to enable servicing, maintenance and PQ	
	f) UHPLC Columns	4 in number (2 C18 and 2 C8 )	
<b>E) Triple Quadrupole Mass Analyzer</b>	g) The mass analyzer must consist of 2, high standard, fast scanning Quadrupoles and one high efficiency multipole type collision cell. It should be capable of handling large batches of samples with complex matrices over a long period of time. The maintenance and cleaning of the interface must be simple.		
<b>A) Triple Quadrupole Mass analyzer</b>			
<b>Component:</b>	<b>Parameter</b>	<b>Specifications:</b>	
5) Mass Detector	b) Detector type	The detector should be an Electron multiplier, Photo multiplier or appropriate alternative.	
6) Ion Source	b) Ionisation Modes	One set of ESI (Electro spray Ionisation) must be available as standard.	

Ultra High Performance Liquid Chromatography System (UHPLC)			
		APCI (Atmospheric Pressure Chemical Ionisation) interface must be available and necessary probes included.	
	c) ESI Flow rate	0.001 to 2mL/min.	
	j) Ion source temperature	The heating block temperature of APCI/ESI must withstand high temperature up to 500°C	
	k) Direct infusion	An extra syringe pump must be available as an option for direct infusion of sample.	
	l) Operation Software	The software must be able to recognize the ion Source automatically.	
	m) Ionisation probes	The ionization probes switching should be simple and tool free.	
	n) Flow diverter	Automated programmable flow diverter capable of diverting column effluent from source should be present.	
7) Mass analyzer	s) Analyzer	Extensive diagnostics, error detection and display through. Leak detection, safe leak handling, leak output signal for shutdown of the pumping system. Low voltage in major maintenance areas.	
	t) Flow sprayer	The MS should employ an orthogonal angle flow sprayer.	
	u) Mass range	Mass range should be from m/z 2 to 2000	
	v) Mass Stability	The mass stability should be 0.05 Da over 12 hours or more.	
	w) Scanning speed	The mass analyzer must have a scanning speed capability up to 30,000 Da/s with increments of 0.1Da	
	x) Polarity switching rate	Detection of Positive/Negative ions should be no more than 5 msec.	
	y) Scanning Modes	MS full scan, MS/MS Product ion scan, MS/MS neutral Loss/gain scan, precursor ion scans, mixed mode scan, SIM (Single Ion Monitoring)	

Ultra High Performance Liquid Chromatography System (UHPLC)		
	z) Resolution	≤ 0,7 amu
	aa) MS-MS capability	MS-MS capability must be available in Quadrupole 2 [Q2] via Collision Induced Dissociation (CID). The gas used for fragmentation should be Argon
	bb) Dwell times	The collision cell must be capable of doing MRM analysis with shortest Dwell time of 0.8msec.
	cc) MRM scan speed	Must be able to measure 555 MRM in one Second
	dd) Tuning	Auto-tuning should be standard with a syringe pump that delivers accurate calibrate injection under full workstation control in both positive and negative modes. Manual tuning should be possible as well
	ee) Sensitivity, Positive ESI	Minimum Signal-to-Noise ratio [RMS] 250,000:1, following injection of 1 pg or below of Reserpine in MRM mode.
	ff) Sensitivity, negative ESI	Minimum Signal-to-Noise ratio [RMS] 90,000:1, following injection of 1 pg or below of Chloramphenicol in MRM mode.
	gg) Sensitivity, Positive APCI	Minimum Signal-to-Noise ratio [RMS] 1000:1, following injection of 10 pg or below of Reserpine in MRM mode.
	hh) Dynamic range	The instrument should have a Dynamic range of 1 to 2 x 10 <sup>7</sup> pulse counting.
	ii) Vacuum system	Turbo- molecular pump and rotary pump.
	jj) Mass Spectrometer start up Kit	An LCMS start-up kit should be supplied as standard to enable operation and maintenance (Including all the required pre-qualification Chemical Reference Standards)

Ultra High Performance Liquid Chromatography System (UHPLC)			
8) Gas generator and Compressor	b) Nitrogen gas generation	<p>Include autonomous Nitrogen gas generator and compressor utilizing membrane technology to selectively remove Oxygen, moisture and other gases.</p> <p>Rate of Nitrogen generation should meet the requirements of the system offered.</p>	
<b>B) Data Management and Acquisition System</b>			
<b>Component:</b>	<b>Parameter</b>	<b>Specifications:</b>	
3) Desktop computer System	h) CPU	Intel Core i7 - 10 <sup>th</sup> generation Processor or better	
	i) Memory	8.0 GB RAM Memory	
	j) Hard drive	1TB Hard disk Storage	
	k) Monitor	19" LCD wide monitor	
	l) Printer	WIFI enabled Laser Jet duplex printer	
	m) Operating system software	Fully licensed, activated, latest and compatible Microsoft Windows.	
	n) Other Software	Fully licensed, activated, latest version of Microsoft Office Professional Plus.	
4) Software System		Validated, Multiuser, with full GLP/GMP compliance (FDA 21, CFR part 11) and pre-installed standard methods.	
		Single software platform must be provided for a seamless control of all the modules of LC and MS	
		It should cover full digital instrument control, qualitative and quantitative processing, report creation, self-diagnosis and auto-tuning	
		Upgradeable easy to use software allowing: <ul style="list-style-type: none"> <li>• Remote control operation</li> <li>• Enables data integration, audit trails,</li> <li>• Customizable data reporting</li> <li>• Capable of integrating with a LIMS.</li> <li>• Capable of controlling multiple LC-MS-MS systems.</li> </ul>	

Ultra High Performance Liquid Chromatography System (UHPLC)		
		The software should simultaneously control and process mass-spectrometry and PDA data
		System suitability, System security as well as System check functions must be provided which comply with Good Laboratory Practice (GLP) and Regulatory Conformity
		Auto Start-up and shutdown of the MS should be possible using a single key operation
		Auto-tuning with sensitivity and resolution optimization for both positive ion and negative ion modes should be standard.
		The data can be converted to other formats. Spread Sheet software and word-processing software can be readily employed to provide data in tables or graphs through industry standard protocols
		Single software platform must be provided for a seamless control of all the modules of LC and MS
		It should cover full digital instrument control, qualitative and quantitative processing, report creation, self-diagnosis and auto-tuning
F) Mandatory Support Requirements		
Component:	Parameter:	Specifications:
7) UPS	Capacity	≥ 10 kVA, should be capable of holding power for at least 1 hour

Ultra High Performance Liquid Chromatography System (UHPLC)			
8) Testing Capabilities	Specific compounds of pharmaceutical importance	<p>System should have demonstrated sensitivity in the detection and quantification of each of the following <i>N</i>-Nitrosamine impurities in active pharmaceutical ingredients and formulations at a Limit of Quantification &lt; 0.02 ppm:</p> <ul style="list-style-type: none"> <li>• <i>N</i>-Nitrosodimethylamine (NDMA)</li> <li>• <i>N</i>-Nitrosodiethylamine (NDEA)</li> <li>• <i>N</i>-Nitrosomethylphenylamine (NMPA)</li> <li>• <i>N</i>-Nitrosodiisopropylamine (NDIPA)</li> <li>• <i>N</i>-Nitrosoisopropylethylamine (NIPEA)</li> <li>• <i>N</i>-Nitroso-<i>N</i>-methyl-4-aminobutyric Acid (NMBA)</li> </ul> <p><i>(Supplier to provide evidence in form of Official technical application notes or peer reviewed scientific journal articles describing the instrumentation used)</i></p>	
9) Air Conditioning Unit		Split type, ≥ 24,000 BTU/h	
10) Training & Warranty	Training & Warranty	<p>The vendor shall install the system at NQCL 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 system should be covered by a minimum <b>1</b> year warranty including <b>spare parts</b> and <b>labour</b>.</p>	
11) Installation, Operational & Performance Qualification (IQ/OQ/PQ)	(IQ/OQ/PQ)	<p>Supplier <b>MUST</b> undertake comprehensive and thoroughly documented <b><u>IQ &amp; OQ</u></b> including <b><u>PQ (System Suitability Test &amp; Calibration)</u></b> of the equipment at time of commissioning (receipt) in accordance with the manufacturer's guidelines and in conformance with International Standards (<b><u>WHO/ISO/EDQM</u></b>).</p>	
12) After Sales Service		Supplier must commit to undertake after sales service as and when required.	

## **SAMPLE TECHNICAL SPECIFICATIONS HEALTH TECHNOLOGIES**

### **1. Product and Package Specifications**

1.1.1 These specifications describe the basic requirements for the Health Technologies. Bidders are requested to submit with their offers the detailed specifications and **Samples** for the products they intend to supply. The sample requested is to be submitted as per technical specification offered by the Tenderer and shall represent exactly the pharmaceutical product that is intended to be supplied in case of contract award and must be submitted by the deadline for submission of tenders.

The Bidders are requested to present information along with their offers indicating the shortest possible delivery period of each product.

### **Particulars**

#### **1. Qualifications of Manufacturers.**

The Tenderer shall provide copies of all certificates and documents issued by the authorized National Regulatory authorities, that the Manufacturer of the Health products and technologies proposed is authorised to manufacture and sell these products.

#### **2. Appraisal**

A manufacturer, must provide evidence of certification by a recognized authority (e.g. ISO, KEBS) or be subject, at the Manufacturer's expense, to inspection by a competent authority designated by the Procuring entity in conjunction with the national regulatory authority.

#### **3. Documentary Evidence**

3.1 Bidders must provide the following documentary evidence of the Tenderer's qualifications to perform the Contract in support of their bid;

(i) That in the case of a bidder offering to supply Health Products under the Contract that the Tenderer manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder:

(a) Is incorporated in the country of manufacture of the Health Products and Technologies.

(ii) That, in the case of a Tenderer offering to supply Health Products and Technologies under the Contract that the Tenderer does not manufacture or otherwise produce,

(a) That the Tenderer has been duly authorized by a manufacturer of the Health Products and Technologies that meets the Criteria under (i) above to supply the Health Products and Technologies in Kenya.

#### **4. Certificates**

4.1 All certificates granted to distributors and or manufacturers from the country of origin or/and recognized regulatory authorities should be valid and clear.

4.2.1 The certificate of quality should indicate

- a) That the manufacturing plant in which the Health Products and Technologies are produced is subject to inspection at regular intervals
- b) The date the certificate is issued and the period of its validity.

4.3 All certificates indicated above and all other technical documents required to qualify for the tender participation should be submitted together with the bid on or before the closing date. Any bid not accompanied by the certificates shall be rejected as non-responsive

## 5. Standards of Quality Assurance for Supply.

5.1 All products must:

- a) Meet the requirements of manufacturing legislation and regulation of Health Products and Technologies in the country of Origin;
- b) Conform to all the specifications contained herein; and

5.2 In case of new bidders to the procuring entity who succeed to win an item or more in price and other preliminary evaluation parameters, the procuring entity reserves the right to send samples to the National Quality Control laboratory or other competent laboratory for quality control test. In such cases, the bidder shall cover the expense up on request by the procuring entity.

5.3 The successful Bidder will be required to provide to the Procuring entity:

- a) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.
- b) Ensure that Health Products and Technologies arrive at KEMSA warehouse with a remaining shelf life of at least 75%.

5.4 The successful Bidder will also be required to provide the Procuring entity with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods and in-process tests.

5.5 All labeling and packaging inserts shall be in English.

5.6 Goods requiring refrigeration or freezing *or those that should not fall below a certain minimum temperature* or stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.

## 6 General

1.2 Not only the **Health Products** item, but also the packaging and labeling components (e.g., bottles, closures, and labeling) should also meet specifications suitable for distribution, storage, and use in a climatic zones assigned to Kenya. All packaging must be properly sealed and tamper-proof, and packaging components must meet the latest compendium standards



and be approved for **Health Products** packaging by the manufacturer's national regulatory authority (RA). The Procuring Entity should specify any additional special requirements.

- 1.2.1 The successful bidder shall provide such packing of the Health Products as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Health Products' final destination and the absence of heavy handling facilities at all points in transit.
- 1.2.2 Whenever plastics are used as packing for I.V. Fluids, the type of plastics used should be clearly indicated in the offer and specification relating to their properties.
- 1.2.3 Certificate of quality control
- 1.2.4 Method of analysis of the same accompanied with the samples, if different method of analysis is used than indicates in USP or BP, should be submitted along with the offer
- 1.2.5 Light-sensitive **Health Products** must be packed in containers that allow maximum protection from light. Labels on the containers should bear " Protect from Light"
- 1.2.6 Packing should be suitable to resist heat & humidity at the port of embarkation for:-
  - Humidity up to 12-100%
  - Temperature up to 50° C
  - All plastic and glass containers should be of **Health Products** Grade and should meet the parameters in BP or USP for containers.

packed in well closed and light resistant containers of appropriate size. The containers should be tamper-proof and sealed.

### 1.3 Packaging of Products

Items should be packaged as follows:

- (i) 100 ml bottles, not more than 100 per carton
- (ii) 200 ml bottles, not more than 50 per carton
- (iii) 500 ml bottles, not more than 24 per carton
- (iv) 1.0 litre bottles, not more than 12 per carton
- (v) 2.5 litre bottles, not more than 6 per carton
- (vi) 5.0 litre bottles, not more than 4 per carton
- (vii) For ear- and eye drops a maximum of 24 should be packed in each carton and the box must be partitioned if the contents are more than 6.

Specifications for plastic containers used shall be as follows:

- 5 Litre Jerry can- High Density
- 2 Litre Jerry can- High Density
- 1 Litre jerry can- High Density

**1.4 Tertiary Packing** (Not applicable to tender sample but at pre-delivery and full consignment for the successful tenderer, however bidders are advised to verify the nature of packaging material before bidding.)

1.5.1 Tertiary packing shall be undertaken in Heavy Duty five-ply non-recycled cartons **(175K/B/175K/C/175K)** duly labeled, marked and double strapped. The shapes of the cartons must be consistent and complementary to allow stacking. Sample available at KEMSA Procurement Offices for viewing.

1.5.2 The cartons must have consistent dimensions of length, width and height. .

1.5.3 The size of the carton should be proportional to its content, with the addition of appropriate padding to prevent damage to the product during transportation.

1.5.4 All carton flaps must be properly secured and sealed with special repackers gum paper tapes and double strapped..

1.5.5 To facilitate manual loading and off-loading, the dimensions of each carton should not exceed 610mm x 460mm x 355 mm. The Gross weight of each packed carton should not exceed 30kg

## **2 Labeling Instructions**

2.1 The label of the primary container for each **Health Products** and vaccine product shall meet the W210 GMP standard and include:

- a) The international nonproprietary name (INN) or generic name prominently displayed., where a brand name has been given it must be in addition ti the INN.
- b) Dosage form, e.g., tablet, ampoule, syrup, etc.;
- c) The active ingredient“ per unit, dose, tablet or capsule, etc.”;
- d) The applicable pharmacopoeia standard;
- e) the procurering entity unique marking (to be checked at predelivery);
- f) Content per pack;
- g) Instructions for use;
- h) Storage requirements;
- i) Batch/ lot number;
- j) Date of manufacture and date of expiry (in clear English language, not code);
- k) Name and address of manufacture;
- l) Any additional cautionary statement.

All labeling and packaging inserts shall be in English.

**THE SAMPLE INCLUDING LITERATURE (INSERTS) SHOULD BE SUBMITTED.**

All outer cartons should be labeled as follows:

**“GoK-Not for Sale”**

**“Funded by the Global Fund**

2.2 The outer case or carton should also display the above information.

### **3. Cartons/ Case Identification**

3.1 All cases/cartons should prominently indicate the following:

- a) Procuring entity's Name and Address
- b) The generic name of the product;
- c) The dosage form(tablet, ampoule, syrup);
- d) Date of manufacture and expiry (in clear English language not code);
- e) Batch number;
- f) Quantity per case;
- g) instructions for storage
- h) The phrase " Keep out of the reach of children"
- i) Name and address of both the manufacturer and manufacturing site.
- j) All labeling shall be original and imprinted (by use of indelible ink) on the product package
- k) Any additional cautionary statements.

3.2 No case/carton should contain **Health Products** from more than one batch.

### **4. Unique Identifiers**

4.1 The word "**KEMSA**" shall be extensively and conspicuously imprinted (by use of indelible ink) on the primary, secondary and tertiary packaging of products to be supplied to the procuring entity. (Not applicable to tender sample but at pre-delivery and full consignment for the successful tenderer.)

#### **Bar coding Requirements for All KEMSA Medical Supplies**

**(Application of International Barcoding Standards).**

#### **Bar code Requirements**

##### **Product, primary and secondary packaging**

These barcode requirements must be provided together with any other requirements in this document.

The barcode should be an internationally recognised barcode.

**Product barcode:** The product barcode should be provided on the product and the primary product packaging. The barcode should be an internationally recognised barcode. The product barcode should be clearly printed on the product in both barcode format and human readable format.

In addition, the following should be provided in barcode format and human readable format.

1. Manufacture date ( barcode format and human readable format)
2. Expiry date ( barcode format and human readable format)

3. Batch No. ( barcode format and human readable format)

*All other human readable Information on product packaging shall be as required under Existing Regulatory labeling & marking requirements*

**5. Standards of Quality Control for Supply**

5.1 The successful bidder will be required to furnish to the Procuring Entity:

- a) With a certificate of analysis for each batch containing the requisite test parameters as per the compendia or in house test methods
- b) Assay methodology of any or all tests if requested.
- c) Evidence of bio-availability and/or bio-equivalence for certain critical Goods upon request. *This information would be supplied on a strictly confidential basis only.*
- d) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

5.2 The Supplier will also be required to provide the Procuring Entity with access to its manufacturing facilities to inspect the compliance with the GMP requirements and quality

**6. Tender Sample**

6.1 A properly labeled sample of each item quoted must be delivered to Kenya Medical Supplies Authority on or before closing of the tender at 10.00 a.m. on 28<sup>th</sup> October, 2021 The sample must be of the required pack size as indicated in the schedule of requirements.

6.2 The sample including literature (**inserts**) should be submitted in their normal or usual commercial packing as registered by the Kenya Pharmacy and Poison's Board, and should be labeled in English. The sample must be a true representative of the product tendered for and remaining shelf life of at least 120 days from date of submission.

6.3 Bidders should provide one sample to represent both lots per item. Bidders who submit two different samples for any given item will have their samples disqualified.

**3. INSPECTIONS AND TESTS**

The following inspections and tests shall be performed: *[insert list of inspections and tests]*.

1.0 *In-house Examination by KEMSA*

2.0 *Test conducted by the NQCL*

3.0 *Tests conducted by Kenya Bureau of Standards ( KEBS)*

## PART 3 - CONTRACT

### SECTION VIII - GENERAL CONDITIONS OF CONTRACT

#### 1. Definitions

1.1 The following words and expressions shall have the meanings here by assigned to them:

“Completion” means the fulfillment of the Related Services by the Supplier in accordance with the terms and conditions set forth in the Contract.

“Contract Documents” means the documents listed in the Contract Agreement, including any amendments thereto.

“Contract Price” means the price payable to the Supplier as specified in the Contract Agreement, subject to such additions and adjustments thereto or deductions therefrom, as may be made pursuant to the Contract.

“Contract” means the Contract Agreement entered into between the Procuring Entity and the Supplier, together with the Contract Documents referred to therein, including all attachments, appendices, and all documents incorporated by reference therein.

“Day” means calendar day. “GCC ” means the General Conditions of Contract.

“Goods” means all of the **Health Products** including nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms Supplier is required to supply to the Procuring Entity under the Contract.

“Laws” means all national legislation, statutes, ordinances, and regulations and by-laws of any legally constituted public authority.

“**Letter of Acceptance**” means the letter of formal acceptance, signed by the contractor. Procuring Entity, including any annexed memoranda comprising agreements between and signed by both Parties.

“**Procuring Entity**” means the Entity named in the Special Conditions of Contract.

“Procuring Entity” means the entity purchasing the Goods and Related Services, as specified **in the SCC**.

“Public Procurement Regulatory Authority (PPRA)” shall mean the agency responsible in Kenya for regulating and monitoring the public procurement function

“Registration Certificate” means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in Kenya in accordance with the Applicable Law.

“Related Services” means the services incidental to the supply of the goods, such as insurance, installation, training and initial maintenance and other such obligations of the Supplier under the Contract.

“Supplier” means the person, private or government entity, or a combination of the above, who’s Tender to perform the Contract has been accepted by the Procuring Entity and is named as such in the Contract Agreement.

“The Project Site,” where applicable, means the place named **in the SCC**.

SCC” means the Special Conditions of Contract.

## 2. Contract Documents

Subject to the order of precedence set forth in the Contract Agreement, all documents forming the Contract (and all parts thereof) are intended to be correlative, complementary, and mutually explanatory. The Contract Agreement shall be read as a whole. The documents forming the Contract shall be interpreted in the following order of priority:

- a) The Contract Agreement,
- b) The Letter of Acceptance,
- c) The Special Conditions- Part A,
- d) The Special Conditions-Part B
- e) The General Conditions of Contract
- f) The Form of Tender,
- g) The Specifications and Schedules of the Drawings(if any),and
- h) The Schedules of Requirements and any other documents forming part of the Contract.

## 3. Fraud and Corruption

- 3.1 The Procuring Entity requires compliance with anti-corruption laws and guidelines and its prevailing sanctions policies and procedures as set forth in Laws of Kenya.
- 3.2 The Procuring Entity requires the Supplier to disclose any commissions or fees that may have been paid or are to be paid to agents or any other party with respect to the Tendering process or execution of the Contract. The information disclosed must include at least the name and address of the agent or other party, the amount and currency, and the purpose of the commission, gratuity or fee.

## 4. Interpretation

- 4.1 If the context so requires it, singular means plural and vice versa.
- 4.2 Incoterms
  - a) Unless inconsistent with any provision of the Contract, the meaning of any trade term and the rights and obligations of parties there under shall be as prescribed by Incoterms specified **in the SCC**.
  - b) The terms EXW, CIP, FCA, CFR and other similar terms, when used, shall be governed by the rules prescribed in the current edition of Incoterms specified **in the SCC** and published by the International Chamber of Commerce in Paris, France.
- 4.3 Entire Agreement

The Contract constitutes the entire agreement between the Procuring Entity and the Supplier and supersedes all communications, negotiations and agreements (whether written or oral) of the parties with respect there to made prior to the date of Contract.

#### 4.4 Amendment

No amendment or other variation of the Contract shall be valid unless it is in writing, is dated, expressly refers to the Contract, and is signed by a duly authorized representative of each party thereto.

#### 4.5 Non waiver

- a. Subject to GCC Sub-Clause 4.5 (b) below, no relaxation, forbearance, delay, or indulgence by either party in enforcing any of the terms and conditions of the Contract or the granting of time by either party to the other shall prejudice, affect, or restrict the rights of that party under the Contract, neither shall any waiver by either party of any breach of Contract operate as waiver of any subsequent or continuing breach of Contract.
- b. Any waiver of a party's rights, powers, or remedies under the Contract must be in writing, dated, and signed by an authorized representative of the party granting such waiver, and must specify the right and the extent to which it is being waived.

#### 4.6 Severability

If any provision or condition of the Contract is prohibited or rendered invalid or unenforceable, such prohibition, invalidity or unenforceability shall not affect the validity or enforceability of any other provisions and conditions of the Contract.

### 5. Language

5.1 The Contract as well as all correspondence and documents relating to the Contract exchanged by the Supplier and the Procuring Entity, shall be written in the English language. Supporting documents and printed literature that are part of the Contract may be in another language provided they are accompanied by an accurate translation of the relevant passages in the English language, in which case, for purposes of interpretation of the Contract, this translation shall govern.

5.2 The Supplier shall bear all costs of translation to the governing language and all risks of the accuracy of such translation, for documents provided by the Supplier.

### 6. Joint Venture, Consortium or Association

6.1 If the Supplier is a joint venture, consortium, or association, all of the parties shall be jointly and severally liable to the Procuring Entity for the fulfillment of the provisions of the Contract and shall designate one party to act as a leader with authority to bind the joint venture, consortium, or association. The composition or the constitution of the joint venture, consortium, or association shall not be altered without the prior consent of the Procuring Entity.

### 7. Eligibility

7.1 The Supplier and its Subcontractors shall have the nationality of an eligible country. A Supplier or Subcontractor shall be deemed to have the nationality of a country if it is a citizen or constituted, incorporated, or registered, and operates in conformity with the provisions of the laws of that country.

7.2 All Goods and Related Services to be supplied under the Contract shall have their origin in Eligible Countries. For the purpose of this Clause, origin means the country where the goods have been grown, mined, cultivated, produced, manufactured, or processed; or through manufacture, processing, or assembly, another commercially recognized article results that differs substantially in its basic characteristics from its components.

## **8. Notices**

8.1 Any notice given by one party to the other pursuant to the Contract shall be in writing to the address specified **in the SCC**. The term "in writing" means communicated in written form with proof of receipt.

8.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

## **9. Governing Law**

9.1 The Contract shall be governed by and interpreted in accordance with the laws of Kenya.

9.2 Throughout the execution of the Contract, the Supplier shall comply with the import of goods and services prohibitions in Kenya when

- a) As a matter of law or official regulations, Kenya prohibits commercial relations with that country; or
- b) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, Kenya prohibits any import of goods from that country or any payments to any country, person, or entity in that country.

## **10. Settlement of Disputes**

10.1 The Procuring Entity and the Supplier shall make every effort to resolve amicably by direct negotiation any disagreement or dispute arising between them under or in connection with the Contract.

10.1.1 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Procuring Entity or the Supplier may give notice to the other party of its intention to commence arbitration, as herein after provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given. Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract.

10.2 Arbitration proceedings shall be conducted as explained in SCC

10.2.1 Any claim or dispute between the Parties arising out of or in connection with the Contract not settled amicably in accordance with Sub-Clause 10.1 shall be finally settled by arbitration.

10.2.2 No arbitration proceedings shall be commenced on any claim or dispute where notice of a claim or dispute has not been given by the applying party within thirty days of the occurrence or discovery of the matter or issue giving rise to the dispute.



10.2.3 Notwithstanding the issue of a notice as stated above, the arbitration of such a claim or dispute shall not commence unless an attempt has in the first instance been made by the parties to settle such claim or dispute amicably with or without the assistance of third parties. Proof of such attempt shall be required.

10.2.4 The Arbitrator shall, without prejudice to the generality of his powers, have powers to direct such measurements, computations, or valuations as may in his opinion be desirable in order to determine the rights of the parties and assess and award any sums which ought to have been the subject of or included in any due payments.

10.2.5 Neither Party shall be limited in the proceedings before the arbitrators to the evidence, or to the reasons for the dispute given in its notice of a claim or dispute.

10.2.6 Arbitration may be commenced prior to or after delivery of the goods. The obligations of the Parties shall not be altered by reason of any arbitration being conducted during the progress of the delivery of goods.

10.2.7 The terms of the remuneration of each or all the members of Arbitration shall be mutually agreed upon by the Parties when agreeing the terms of appointment. Each Party shall be responsible for paying one-half of this remuneration.

### 10.3 Arbitration Proceedings

10.3.1 Arbitration proceedings with both national suppliers will be conducted in accordance with the Arbitration Laws of Kenya. In case of any claim or dispute, such claim or dispute shall be notified in writing by either party to the other with a quest to submit it to arbitration and to concur in the appointment of an Arbitrator within thirty days of the notice. The dispute shall be referred to the arbitration and final decision of a person or persons to be agreed between the parties. Failing agreement to concur in the appointment of an Arbitrator, the Arbitrator shall be appointed, on the request of the applying party, by the Chairman or Vice Chairman of any of the following professional institutions;

- i) Kenya National Chamber of Commerce
- ii) Chartered Institute of Arbitrators (Kenya Branch)
- iii) The Law Society of Kenya

10.3.2 The institution written to first by the aggrieved party shall take precedence over all other institutions.

### 10.4 Arbitration with Foreign Suppliers

10.4.1 Arbitration with foreign suppliers shall be conducted in accordance with the arbitration rules of the United Nations Commission on International Trade Law (UNCITRAL); or with proceedings administered by the International Chamber of Commerce (ICC) and conducted under the ICC Rules of Arbitration; by one or more arbitrators appointed in accordance with said arbitration rules.

10.4.2 The place of arbitration shall be a location specified in the **SCC**; and the arbitration shall be conducted in the language for communications defined in Sub-Clause 1.4 [Law and Language].

### 10.5 Alternative Arbitration Proceedings

10.5.1 Alternatively, the Parties may refer the matter to the Nairobi Centre for International Arbitration (NCIA) which offers a neutral venue for the conduct of national and international arbitration with commitment to providing institutional support to the arbitral process.

## **11. Inspections and Audit by the PPRA**

11.1 The Supplier shall keep, and shall make all reasonable efforts to cause its Subcontractors and sub-consultants to keep accurate and systematic accounts and records in respect of the Goods in such form and details as will clearly identify relevant time changes and costs.

11.2 Pursuant to paragraph 2.2e. of Appendix to the General Conditions the Supplier shall permit and shall cause its subcontractors and sub-consultants to permit, PPRA and/or persons appointed by the PPRA to inspect the Site and/or the accounts and records relating to the procurement process, selection and/or contract execution, and to have such accounts and records audited by auditors appointed by the PPRA. The Supplier's and its Subcontractors' and sub-consultants' attention is drawn to Sub-Clause 3.1 which provides, inter alia, that acts intended to materially impede the exercise of the PPRA's inspection and audit rights constitute a prohibited practice subject to contract termination.

## **12. Scope of Supply**

12.1 The Goods and Related Services to be supplied shall be as specified in the Schedule of Requirements.

## **13. Delivery and Documents**

13.1 Subject to GCC Sub-Clause 33.1, the Delivery of the Goods and Completion of the Related Services shall be in accordance with the Delivery and Completion Schedule specified in the Schedule of Requirements. The details of shipping and other documents to be furnished by the Supplier are specified **in the SCC**.

## **14. Supplier's Responsibilities**

14.1 The Supplier shall supply all the Goods and Related Services included in the Scope of Supply in accordance with GCC Clause 12, and the Delivery and Completion Schedule, as per GCC Clause 13.

## **15. Contract Price**

15.1 Prices charged by the Supplier for the Goods supplied and the Related Services performed under the Contract shall not vary from the prices quoted by the Supplier in its Tender, with the exception of any price adjustments authorized **in the SCC**.

## **16. Terms of Payment**

16.1 The Contract Price, including any Advance Payments, if applicable, shall be paid as specified **in the SCC**.

16.2 The Supplier's Invitation to payment shall be made to the Procuring Entity in writing, accompanied by invoices describing, as appropriate, the Goods delivered and Related Services performed, and by the documents submitted pursuant to GCC Clause 13 and upon fulfillment of all other obligations stipulated in the Contract.

- 16.3 Payments shall be made promptly by the Procuring Entity, but in no case later than sixty (60) days after submission of an invoice or Invitation to payment by the Supplier, and after the Procuring Entity has accepted it.
- 16.4 The currencies in which payments shall be made to the Supplier under this Contract shall be those in which the Tender price is expressed.
- 16.5 In the event that the Procuring Entity fails to pay the Supplier any payment by its due date or within the period set forth **in the SCC**, the Procuring Entity shall pay to the Supplier interest on the amount of such delayed payment at the rate shown **in the SCC**, for the period of delay until payment has been made in full, whether before or after judgment or arbitration award.

## **17. Taxes and Duties**

- 17.1 For goods manufactured outside Kenya, the Supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside Kenya. Commodities being procured under this GF ATM grant are free of local taxes and duties. The Purchaser will facilitate the tax exemptions upon receipt of the required documentation from the supplier.
- 17.2 For goods Manufactured within Kenya, the Supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Procuring Entity. The charge of VAT is not applicable for commodities being procured with this GF ATM grant. The Purchaser will facilitate VAT exemption upon receipt of the required documentation from the supplier.
- 17.3 If any tax exemptions, reductions, allowances or privileges may be available to the Supplier in Kenya, the Procuring Entity shall use its Lowest efforts to enable the Supplier to benefit from any such tax savings to the maximum allowable extent.

## **18. Performance Security**

- 18.1 If required as specified in the SCC, the Supplier shall, within twenty-eight (28) days of the notification of contract award, provide a Performance Security for the performance of the Contract in the amount specified **in the SCC**.
- 18.2 The proceeds of the Performance Security shall be payable to the Procuring Entity as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.
- 18.3 As specified in the SCC, the Performance Security, if required, shall be denominated in the currency (ies) of the Contract, or in a freely convertible currency acceptable to the Procuring Entity; and shall be in one of the format stipulated by the Procuring Entity **in the SCC**, or in another form at acceptable to the Procuring Entity.
- 18.4 The Performance Security shall be discharged by the Procuring Entity and returned to the Supplier not later than twenty-eight (28) days following the date of Completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless specified otherwise **in the SCC**.

## **19. Certification of Goods in Accordance with Laws of Kenya**

- 19.1 If required under the Applicable Law, Goods supplied under the Contract shall be registered for use in Kenya. The Procuring Entity undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in Kenya as specified **in the SCC**.
- 19.2 Unless otherwise specified **in the SCC**, the Contract shall become effective on the date (“the Effective Date”) that the Supplier receives written notification from the relevant authority in Kenya that the Goods have been registered for use in Kenya.
- 19.3 If thirty (30) days, or such longer period specified **in the SCC**, elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 19.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's Performance Security shall be promptly returned.

## **20. Confidential Information**

- 20.1 The Procuring Entity and the Supplier shall keep confidential and shall not, without the written consent of the other party hereto, divulge to any third party any documents, data, or other information furnished directly or indirectly by the other party hereto in connection with the Contract, whether such information has been furnished prior to, during or following completion or termination of the Contract. Notwithstanding the above, the Supplier may furnish to its Subcontractor such documents, data, and other information it receives from the Procuring Entity to the extent required for the Subcontractor to perform its work under the Contract, in which event the Supplier shall obtain from such Subcontractor an undertaking of confidentiality similar to that imposed on the Supplier under GCC Clause 20.
- 20.2 The Procuring Entity shall not use such documents, data, and other information received from the Supplier for any purposes unrelated to the contract. Similarly, the Supplier shall not use such documents, data, and other information received from the Procuring Entity for any purpose other than the performance of the Contract.
- 20.3 The obligation of a party under GCC Sub-Clauses 20.1 and 20.2 above, however, shall not apply to information that:
- a) the Procuring Entity or Supplier need to share with the PPRA or other institutions participating in the financing of the Contract;
  - b) now or here after enters the public domain through no fault of that party;
  - c) can be proven to have been possessed by that party at the time of disclosure and which was not previously obtained, directly or indirectly, from the other party; or
  - d) otherwise lawfully becomes available to that party from a third party that has no obligation of confidentiality.
- 20.4 The above provisions of GCC Clause 20 shall not in any way modify any undertaking of confidentiality given by either of the parties hereto prior to the date of the Contract in respect of the Supply or any part thereof.
- 20.5 The provisions of GCC Clause 20 shall survive completion or termination, for whatever reason, of the Contract.

## **21. Subcontracting**

21.1 The Supplier shall notify the Procuring Entity in writing of all subcontracts awarded under the Contract if not already specified in the Tender. Such notification, in the original Tender or later shall not relieve the Supplier from any of its obligations, duties, responsibilities, or liability under the Contract.

21.2 Subcontractors shall comply with the provisions of GCC Clauses 3 and 7.

## **22 Specifications and Standards**

22.1 The Goods supplied under this Contract shall conform to technical specifications and standards mentioned in Section VII, Schedule of Requirements and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

## **23 Packing and Documents**

23.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. During transit, the packing shall be sufficient to withstand, without limitation, rough handling and exposure to extreme temperatures, salt and precipitation, and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.

23.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified **in the SCC**, and in any other instructions ordered by the Procuring Entity.

## **24 Insurance**

24.1 Unless otherwise specified **in the SCC**, the Goods supplied under the Contract shall be fully insured-in a freely convertible currency from an eligible country – against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery, in accordance with the applicable Incoterms or in the manner specified in the **SCC**.

## **25 Transportation and Incidental Services**

25.1 Unless otherwise specified **in the SCC**, responsibility for arranging transportation of the Goods shall be in accordance with the specified Incoterms.

25.2 The Supplier may be required to provide any or all of the following services, including additional services, if any, specified **in SCC**:

- a) Performance or supervision of on-site assembly and/or start-up of the supplied Goods;
- b) Furnishing of tools required for assembly and/or maintenance of the supplied Goods;
- c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied Goods;
- d) performance or supervision or maintenance and/or repair of the supplied Goods, for a period of time agreed by the parties, provided that this service shall not relieve the Supplier of any warranty obligations under this Contract; and
- e) training of the Procuring Entity's personnel, at the Supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied Goods.

25.3 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services

## **26. Inspections and Tests**

26.1 The Supplier shall at its own expense and at no cost to the Procuring Entity carry out all such tests and/or inspections of the Goods and Related Services as are specified **in the SCC**.

26.2 The inspections and tests may be conducted on the premises of the Supplier or the manufacturer, at point of delivery, and /or at the Goods' final destination, or in another place in Kenya as specified **in the SCC**. Subject to GCCSub-Clause 26.3, if conducted on the premises of the Supplier or the manufacturer, all reasonable facilities and assistance, including access to production data, shall be furnished to the inspectors at no charge to the Procuring Entity.

26.3 The Procuring Entity or its designated representative shall be entitled to attend the tests and/or inspections referred to in GCC Sub-Clause 26.2, provided that the Procuring Entity bear all of its own costs and expenses incurred in connection with such attendance including, but not limited to, all traveling and board and lodging expenses.

26.4 Whenever the Supplier is ready to carry out any such test and inspection, it shall give a reasonable advance notice, including the place and time, to the Procuring Entity. The Supplier shall obtain from any relevant third party or manufacturer any necessary permission or consent to enable the Procuring Entity or its designated representative to attend the test and/or inspection.

a) Said inspection and testing is for the Procuring Entity's account. In the event that inspection and testing is required prior to dispatch, the Goods shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those Goods.

b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.

c) Upon receipt of the Goods at place of final destination, the Procuring Entity's representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Procuring Entity that the Goods were received in apparent good order. The Procuring Entity will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued within ten (10) days of receipt of the Goods or part of Goods at place of final destination.

26.5 Where the Supplier contests the validity of the rejection by the Procuring Entity or his representative, of any inspection as required by 26.4 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Procuring Entity or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Procuring Entity and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party;

26.6 The Procuring Entity may require the Supplier to carry out any test and/or inspection not required by the Contract but deemed necessary to verify that the characteristics and performance of the Goods comply with the technical specifications codes and standards

under the Contract, provided that the Supplier's reasonable costs and expenses incurred in the carrying out of such test and/or inspection shall be added to the Contract Price. Further, if such test and/or inspection impedes the progress of manufacturing and/or the Supplier's performance of its other obligations under the Contract, due allowance will be made in respect of the Delivery Dates and Completion Dates and the other obligations so affected.

- 26.7 The Supplier shall provide the Procuring Entity with a report of the results of any such test and/or inspection.
- 26.8 The Procuring Entity may reject any Goods or any part thereof that fail to pass any test and/or inspection or do not conform to the specifications. The Supplier shall either rectify or replace such rejected Goods or parts thereof or make alterations necessary to meet the specifications at no cost to the Procuring Entity, and shall repeat the test and/or inspection, at no cost to the Procuring Entity, upon giving a notice pursuant to GCC Sub- Clause 26.4.
- 26.9 The Supplier agrees that neither the execution of attest and/or inspection of the Goods or any part thereof, nor the attendance by the Procuring Entity or its representative, nor the issue of any report pursuant to GCC Sub-Clause 26.7, shall release the Supplier from any warranties or other obligations under the Contract.

## **27. Liquidated Damages**

- 27.1 Except as provided under GCC Clause 32, if the Supplier fails to deliver any or all of the Goods by the Date (s) of delivery or perform the Related Services within the period specified in the Contract, the Procuring Entity may without prejudice to all its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified **in the SCC** of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified **in the SCC**. Once the maximum is reached, the Procuring Entity may terminate the Contract pursuant to GCC Clause 35.

## **28. Warranty**

- 28.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at port/airport of entry for goods with a shelf life of more than two years and three-fourths (3/4) for goods with shelf life of two years or less, unless otherwise specified **in the SCC**; have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

- 28.2 The Procuring Entity shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Procuring Entity, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Procuring Entity. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.

28.3 In the event of a dispute by the Procuring Entity, a counter-analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Procuring Entity and the Supplier. If the counter-analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Procuring Entity will meet all costs for such analysis.

28.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 28.2 above, the Supplier fails to replace the defective Goods within the period specified **in the SCC** the Procuring Entity may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Procuring Entity may have against the Supplier under the Contract. The Procuring Entity will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract. *Recalls.* In the event any of the Goods are recalled, the Supplier shall notify the Procuring Entity within fourteen (14) Days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Procuring Entity will, at the Supplier's expense, carry out the recall.

## **29. Patent Indemnity**

- 29.1 The Supplier shall, subject to the Procuring Entity's compliance with GCC Sub-Clause 29.2, indemnify and hold harmless the Procuring Entity and its employees and officers from and against any and all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which the Procuring Entity may suffer as a result of any infringement or alleged infringement of any patent, utility model, registered design, trade mark, copyright, or other intellectual property right registered or otherwise existing at the date of the Contract by reason of:
- a) The installation of the Goods by the Supplier or the use of the Goods in the country where the Site is located; and
  - b) the sale in any country of the products produced by the Goods. Such indemnity shall not cover any use of the Goods or any part thereof other than for the purpose indicated by or to be reasonably inferred from the Contract, neither any infringement resulting from the use of the Goods or any part thereof, or any products produced there by in association or combination with any other equipment, plant, or materials not supplied by the Supplier, pursuant to the Contract.
- 29.2 If any proceedings are brought or any claim is made against the Procuring Entity arising out of the matters referred to in GCC Sub-Clause 29.1, the Procuring Entity shall promptly give the Supplier a notice thereof, and the Supplier may at its own expense and in the Procuring Entity's name conduct such proceedings or claim and any negotiations for the settlement of any such proceedings or claim.
- 29.3 If the Supplier fails to notify the Procuring Entity within twenty-eight (28) days after receipt of such notice that it intends to conduct any such proceedings or claim, then the Procuring Entity shall be free to conduct the same on its own behalf.



29.4 The Procuring Entity shall, at the Supplier's request, afford all available assistance to the Supplier in conducting such proceedings or claim, and shall be reimbursed by the Supplier for all reasonable expenses incurred in so doing.

29.5 The Procuring Entity shall indemnify and hold harmless the Supplier and its employees, officers, and Subcontractors from and against any and all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which the Supplier may suffer as a result of any infringement or alleged infringement of any patent, utility model, registered design, trademark, copyright, or other intellectual property right registered or otherwise existing at the date of the Contract arising out of or in connection with any design, data, drawing, specification, or other documents or materials provided or designed by or on behalf of the Procuring Entity.

### **30 Limitation of Liability**

31.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 29,

- a) the Supplier shall not be liable to the Procuring Entity, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Procuring Entity and
- b) the aggregate liability of the Supplier to the Procuring Entity, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment, or to any obligation of the supplier to indemnify the Procuring Entity with respect to patent infringement.

### **31. Change in Laws and Regulations**

31.1 Unless otherwise specified in the Contract, if after the date of 30 days prior to date of Tender submission, any law, regulation, ordinance, order or bylaw having the force of law is enacted, promulgated, abrogated, or changed in the place of Kenya where the Site is located (which shall be deemed to include any change in interpretation or application by the competent authorities) that subsequently affects the Delivery Date and/or the Contract Price, then such Delivery Date and/or Contract Price shall be correspondingly increased or decreased, to the extent that the Supplier has thereby been affected in the performance of any of its obligations under the Contract. Notwithstanding the foregoing, such additional or reduced cost shall not be separately paid or credited if the same has already been accounted for in the price adjustment provisions where applicable, in accordance with GCC Clause 15.

### **32 Force Majeure**

32.1 The Supplier shall not be liable for forfeiture of its Performance Security, liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

32.2 For purposes of this Clause, "Force Majeure" means an event or situation beyond the control of the Supplier that is not foreseeable, is unavoidable, and its origin is not due to negligence or lack of care on the part of the Supplier. Such events may include, but not be limited to, acts of the Procuring Entity in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

32.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Procuring Entity in writing of such condition and the cause thereof. Unless otherwise directed by the Procuring Entity in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

### **33. Change Orders and Contract Amendments**

33.1 The Procuring Entity may at any time order the Supplier through notice in accordance GCC Clause 8, to make changes within the general scope of the Contract in any one or more of the following:

- a) drawings, designs, or specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Procuring Entity;
- b) the method of shipment or packing;
- c) the place of delivery; and
- d) the Related Services to be provided by the Supplier.

33.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or in the Delivery/Completion Schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this Clause must be asserted within twenty-eight (28) days from the date of the Supplier's receipt of the Procuring Entity's change order.

33.3 Prices to be charged by the Supplier for any Related Services that might be needed but which were not included in the Contract shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services.

33.4 Subject to the above, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties. This includes, if specified **in the SCC**, any variation to the contract resulting from a value engineering proposal agreed between the parties.

### **34. Extensions of Time**

34.1 If at any time during performance of the Contract, the Supplier or its sub-contractors should encounter conditions impeding timely delivery of the Goods or completion of Related Services pursuant to GCC Clause 13, the Supplier shall promptly notify the Procuring Entity in writing of the delay, its likely duration, and its cause. As soon as practicable after receipt of the Supplier's notice, the Procuring Entity shall evaluate the situation and may at its discretion extend the Supplier's time for performance, in which case the extension shall be ratified by the parties by amendment of the Contract.

34.2 Except in case of Force Majeure, as provided under GCC Clause 32, a delay by the Supplier in the performance of its Delivery and Completion obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 27, unless an extension of time is agreed upon, pursuant to GCC Sub-Clause 34.1.

## **35. Termination**

### **35.1 Termination for Default**

- a) The Procuring Entity, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate the Contract in whole or in part:
  - i) if the Supplier fails to deliver any or all of the Goods within the period specified in the Contract, or within any extension thereof granted by the Procuring Entity pursuant to GCC Clause 34;
  - ii) if the Supplier fails to perform any other obligation under the Contract; or
  - iii) if the Supplier, in the judgment of the Procuring Entity has engaged in Fraud and Corruption, as defined in paragraph 2.2a of the Appendix to the GCC, in competing for or in executing the Contract.
- b) In the event the Procuring Entity terminates the Contract in whole or in part, pursuant to GCC Clause 35.1(a), the Procuring Entity may procure, upon such terms and in such manner as it deems appropriate, Goods or Related Services similar to those undelivered or not performed, and the Supplier shall be liable to the Procuring Entity for any additional costs for such similar Goods or Related Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

### **35.2 Termination for Insolvency.**

- c) The Procuring Entity may at any time terminate the Contract by giving notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In such event, termination will be without compensation to the supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Procuring Entity.

### **35.3 Termination for Convenience.**

- d) The Procuring Entity, by notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Procuring Entity's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.
- e) The Goods that are complete and ready for shipment within twenty-eight (28) days after the Supplier's receipt of notice of termination shall be accepted by the Procuring Entity at the Contract terms and prices. For the remaining Goods, the Procuring Entity may elect:
  - i) To have any portion completed and delivered at the Contract terms and prices; and/or
  - ii) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Related Services and for materials and parts previously procured by the Supplier.

## **36. Assignment**

36.1 Neither the Procuring Entity nor the Supplier shall assign, in whole or in part, their obligations under this Contract, except with prior written consent of the other party.

### **37. Export Restriction**

Notwithstanding any obligation under the Contract to complete all export formalities, any export restrictions attributable to the Procuring Entity, to Kenya or to the use of the products/goods, systems or services to be supplied, which arise from trade regulations from a country supplying those products/goods, systems or services, and which substantially impede the Supplier from meeting its obligations under the Contract, shall release the Supplier from the obligation to provide deliveries or services, always provided, however, that the Supplier can demonstrate to the satisfaction of the Procuring Entity that it has completed all formalities in a timely manner, including applying for permits, authorizations and licenses necessary for the export of the products/goods, systems or services under the terms of the Contract. Termination of the Contract on this basis shall be for the Procuring Entity's convenience pursuant to Sub-Clause 35.3.

## **APPENDIX TO GENERAL CONDITIONS**

**Section IX-Special Conditions of Contract** The following Special Conditions of Contract (SCC) shall supplement and/ or amend the General Conditions of Contract (GCC). Whenever there is a conflict, the provisions here in shall prevail over those in the GCC.

*[The Procuring Entity shall select insert the appropriate wording using the samples below or other acceptable wording, and delete the text in italics]*

## Special Conditions of Contract

GCC 1.1 (j)	The Procuring Entity is: Kenya Medical Supplies Authority (KEMSA)
GCC 1.1 (o)	The project site/ final destination is: KEMSA Embakasi Supply Chain Centre
GCC 4.2 (a)	Incoterms 2020
GCC 4.2 (b)	DAP Incoterms 2020
GCC 5.1	The Language shall be English
GCC 8.1	<p>For <b>notices</b> the procuring entity's address shall be:  Kenya Medical Supplies Authority (KEMSA)  Commercial Street, Industrial Area  Nairobi/Kenya  Postal address:  P.O. Box: 47715  00100 Nairobi  Kenya  Tel No: +254 719033000/ +254 726618520/1    E- mail <a href="mailto:procurement.programs@kemsa.co.ke">procurement.programs@kemsa.co.ke</a></p>
GCC 10.2.4	The place of arbitration shall be: Nairobi, Kenya-the venue shall be as agreed by the parties
GCC 10.2	<p>Clause 10.2 (a) shall be retained in the case of a Contract with a foreign Supplier and Clause 10.2 (b) shall be retained in the case of a Contract with a national of the Purchaser's country. The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 10.2 shall be as follows:</p> <p>(i) <b>Contracts with foreign Supplier:</b></p> <p>GCC 10.2 (a) –All disputes arising in connection with the present Contract shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said rules.</p> <p>(ii) <b>Contracts with Supplier national of the Purchaser's country:</b></p> <p>In the case of a dispute between the Purchaser and a Supplier who is a national of the Purchaser's country, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Purchaser's country.</p>
GCC 13.1	<p><b>For goods supplied from abroad under Incoterms DAP, KEMSA</b></p> <p>Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. Under all transport modes, the Supplier shall send the following documents to the Purchaser, with a copy to the insurance company:</p> <p>(i) Three originals and two copies of the Supplier's invoice, showing Purchaser as Consignee; the Contract number, grant no., goods description, quantity,</p>

unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;

- (ii) one original and two copies of the negotiable, clean, on-board through MT Document marked "freight prepaid" and showing Purchaser as Consignee and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multi-modal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements;
- (iii) copy of the packing list identifying contents of each package;
- (iv) copy of the Insurance Certificate, showing the Purchaser as the Beneficiary;
- (v) one original of the manufacturer's or supplier's Warranty Certificate covering all items supplied;
- (vi) one original of the Supplier's Certificate of Origin covering all items supplied;
- (vii) each batch to be accompanied by Certificate of Analysis (CoA) stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods origin;
- (viii) any other procurement-specific documents required for delivery/payment purposes;
- (ix) one original of the Certificate of Pharmaceutical Product as per the WHO's recommended template for each of the items supplied;
- (x) one original and one copy of a protocol (certificate of analysis) of a product test per batch conducted by the laboratory of the manufacturer .

At arrival of the goods at port of clearance, the Supplier or its Shipping agent shall provide the Purchaser with:

1) Arrival notice

and

2) Delivery note.

The above documents 1) and 2) shall be received by the Purchaser immediately after arrival of the Goods at port of clearance and, if not received, the Supplier will be responsible for any consequent expenses.

**Note:** In the event that the documents presented by the Supplier are not in accordance with the Contract, payment will be made against issue of the Acceptance Certificate, to be issued in accordance with SCC 9 (GCC 9) above.

As a policy requirement of the Government of Kenya and for all goods contracted by KEMSA; All cargo imported and or exported by the government agencies, including project cargo for GoK projects undertaken by 3rd Parties be moved on Standard Gauge

	Railway.
	<p><b>For goods supplied from within the Purchaser's country under Incoterms EXW, delivered to named place of destination:</b></p> <p>The Supplier shall notify the Purchaser at least forty-eight (48) hours ahead of delivery of the goods in writing and deliver the following documents to the Purchaser:</p> <ul style="list-style-type: none"> <li>(i) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number, grant number, goods description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;</li> <li>(ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as consignee and delivery through to final destination as stated in the Contract;</li> <li>(iii) copy of the Insurance Certificate, showing the Purchaser as the Beneficiary;</li> <li>(iv) four copies of the packing list identifying contents of each package;</li> <li>(v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied;</li> <li>(vi) one original of the Supplier's Certificate of Origin covering all items supplied;</li> <li>(vii) each batch to be accompanied by Certificate of Analysis (CoA) stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods</li> <li>(viii) other procurement-specific documents required for delivery/payment purposes</li> </ul> <p>As a policy requirement of the Government of Kenya and for all goods contracted by KEMSA; All cargo imported and or exported by the government agencies, including project cargo for GoK projects undertaken by 3rd Parties be moved on Standard Gauge Railway.</p>
GCC 15.1	The prices charged for the goods supplied and the related services performed <i>shall not</i> be adjustable
GCC 16.1	Payment shall be made in supplier's currency.
GCC 16.5	Not Applicable
GCC 18.1	A performance Security shall be required for awards above Kenya Shillings Five Million. Performance Security shall not exceed 10% of the contract value.
GCC 18.3	The Performance Security shall be in the form of a Bank Guarantee The Performance Security shall be denominated in a freely convertible currency.
GCC 18.4	Discharge of Performance Security shall be done twenty- Eight (28) days following the date of Completion of the Supplier's performance obligations under the Contract.
GCC 19.1	The registration and other certification necessary to prove registration in Kenya shall be: Product registration and retention with Pharmacy and Poisons Board of Kenya (PPB).

GCC 19.2	Not Applicable
GCC 19.3	Not used
GCC 23.2	Additional requirements for packing and transport are indicated in Technical Specifications
GCC 24.1	The insurance coverage shall be as specified in the incoterms
GCC 25.1	Responsibility for transportation shall be as specified in the incoterms
GCC 25.2	Incidental services to be provided:  The Supplier shall provide all necessary licenses and permissions for use of the Goods in the Purchaser's country that may be required for the Goods. The cost shall be deemed included in the Contract Price.
GCC 26.1	The Supplier shall demonstrate conformity to Kenya Standards or approved equivalents by evidence of Test report or Certificate from ISO/IEC 17025 accredited laboratory, recognized by the International Laboratory Accreditation Co-operation (ILAC) or preferable from any conformity body recognized by the International Federation of Inspection Agencies (IFIA) prior to shipment. Cost shall be borne by the supplier.
GCC 26.2	The tests and inspection can be conducted at an ISO/IEC 17025 accredited laboratory, recognized by the International Laboratory Accreditation Co-operation (ILAC) or preferable from any conformity body recognized by the International Federation of Inspection Agencies (IFIA)
GCC 27.1	The applicable rate is one-half (0.5) percent per week, the maximum rate is ten (10) percent of the Contract Price and this shall be deducted from the payment due to the supplier.
GCC 28.1	All Goods supplied under the Contract will have a remaining minimum of seventy-five percent (75%) of the shelf life but for commodities that have a shelf life of less than one year, a remaining shelf life of 50% shall be acceptable.
GCC 28.4	The Supplier shall remove, at his own risk and cost, the defective Goods Within fourteen (14) Days of the advice by the Procuring Entity.
GCC 33.4	Not Applicable

## HEALTH PRODUCTS

(Additional Clauses)

The below data should be included in the Special Conditions of Contract used in tendering document for the procurement of **Health Products**.



## Special Conditions of Contract

### VACCINES

#### Additional Clauses under SCC for Vaccines

GCC 13.1	1.
	2. A copy of the retention certificate from Pharmacy and Poisons Board of Kenya.
	3. A record of cold chain transportation conditions for goods on transit.
GCC 13.1	1.
	2. A copy of the retention certificate from Pharmacy and Poisons Board of Kenya.
	3. A record of cold chain transportation conditions for goods on transit.
	4. one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.
GCC 28.1	<p>The Procuring Entity reserves the right to request evidence of bio-availability and/or bio-equivalence data and/or evidence of the basis for expiration dating and other stability data concerning the Goods to verify shelf life claimed for the Goods.</p> <p>If an adverse event following immunization (AEFI) occurs in Kenya and the cause of such event cannot be immediately established, the Procuring Entity will, with all urgency and in accordance with the procedures laid down by the NCA of Kenya, take steps to advise the Supplier in order that an investigation may be launched immediately. If the vaccine has been supplied through an agency of the United Nations, the most current procedures laid down by the WHO for such situations will be used.</p>

## SECTION X - CONTRACT FORMS

This Section contains forms which, once completed, will form part of the Contract. The forms for Performance Security and Advance Payment Security, when required, shall only be completed by the successful Tenderer after Contract award.

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## NOTIFICATION OF INTENTION TO AWARD

*[This Notification of Intention to Award shall be sent to each Tenderer that submitted a Tender.]*

*[Send this Notification to the Tenderer's Authorized Representative named in the Tenderer Information Form]* For the attention of Tenderer's Authorized Representative Name:

.....*[insert Authorized Representative's name]*

Address:.....*[insert Authorized Representative's Address]* Telephone/Fax

numbers:.....*[insert Authorized Representative's telephone/fax numbers]*

Email Address:.....*[insert Authorized Representative's email address]*

*[IMPORTANT: insert the date that this Notification is transmitted to Tenderers. The Notification must be sent to all Tenderers simultaneously. This means on the same date and as close to the same time as possible.]*

**DATE OF TRANSMISSION:** This Notification is sent by:.....*[email/fax]* on *[date]* (local time)

**Notification of Intention to Award Procuring Entity:** *.Kenya Medical Supplies Authority*

**Contract title:**.....*[insert the name of the contract]*

**ITT No:**.....*[insert ITT reference number from Procurement Plan]*

This Notification of Intention to Award (Notification) notifies you of our decision to award the above contract. The transmission of this Notification begins the Standstill Period. During the Standstill Period you may:

- a) Request a debriefing in relation to the evaluation of your Tender, and/or
- b) Submit a Procurement-related Complaint in relation to the decision to award the contract.

### 1. The successful Tenderer

<b>Name:</b>	<i>[insert name of successful Tenderer]</i>
<b>Address:</b>	<i>[insert address of the successful Tenderer]</i>
<b>Contract price:</b>	<i>[insert contract price of the successful Tender]</i>

**2 Other Tenderers** [*INSTRUCTIONS: insert names of all Tenderers that submitted a Tender. If the Tender's price was evaluated include the evaluated price as well as the Tender price as readout.*]

Name of Tenderer	Tender price	Evaluated Tender price (if applicable)
[insert name]	[insert Tender price]	[insert evaluated price]
[insert name]	[insert Tender price]	[insert evaluated price]
[insert name]	[insert Tender price]	[insert evaluated price]
[insert name]	[insert Tender price]	[insert evaluated price]
[insert name]	[insert Tender price]	[insert evaluated price]

**3 Reason/s why your Tender was unsuccessful**

*[INSTRUCTIONS: State the reason/s why this Tenderer's Tender was unsuccessful. Do NOT include:(a) a point by point comparison with another Tenderer's Tender or (b) information that is marked confidential by the Tenderer in its Tender.]*

**5. How to request a debriefing**

**DEADLINE:** The deadline to request a debriefing expires at midnight on [the 3<sup>rd</sup> day after date of notification] (local time).

You may request a debriefing in relation to the results of the evaluation of your Tender. If you decide to request a debriefing your written request must be made within three (3) Business Days of receipt of this Notification of Intention to Award.

Provide the contract name, reference number, name of the Tenderer, contact details; and address the Invitation to debriefing as follows:

**Attention:**

The Chief Executive Officer  
Kenya Medical Supplies Authority (KEMSA)  
Commercial Street, Industrial Area  
Nairobi/Kenya

Postal address:

P.O. Box: 47715 -00100

Nairobi, Kenya

Tel No: +254 719033000/ +254 726618520/1

E-mail: [procurement.programs@kemsa.co.ke](mailto:procurement.programs@kemsa.co.ke)

If your Invitation to a debriefing is received within the 3 Business Days deadline, we will provide the debriefing within five (5) Business Days of receipt of your request.

The debriefing will be in writing.

If the deadline to request a debriefing has expired, you may still request a debriefing. In this case, we will provide the debriefing as soon as practicable, and normally no later than fifteen (15) Business Days from the date of publication of the Contract Award Notice.

## 5. How to make a complaint

**Period: Procurement-related Complaint challenging the decision to award shall be submitted by midnight, [of the 14th day after date of notification] (local time).**

Provide the contract name, reference number, name of the Tenderer, contact details; and address the Procurement- related Complaint as follows:

The Chief Executive Officer  
Kenya Medical Supplies Authority (KEMSA)  
Commercial Street, Industrial Area  
Nairobi/Kenya

Postal address:

P.O. Box: 47715  
00100 Nairobi  
Kenya

Tel No: +254 719033000/ +254 726618520/1

E- mail: [procurement.programs@kemsaco.ke](mailto:procurement.programs@kemsaco.ke) At this point in the procurement process, you may submit a Procurement-related Complaint challenging the decision to award the contract. You do not need to have requested, or received, a debriefing before making this complaint. Your complaint must be submitted within the Standstill Period and received by us before the Standstill Period ends.

### **Further information:**

Further information: For more information refer to the Public Procurement and Disposals Act 2015 and its Regulations available from the Website [info@ppra.go.ke](mailto:info@ppra.go.ke) or [complaints@ppra.go.ke](mailto:complaints@ppra.go.ke) provides a useful explanation of the process, as well as a sample Form of complaint.

In summary, there are four essential requirements:

1. You must be an 'interested party'. In this case, that means a Tenderer who submitted a Tender in this tendering process, and is the recipient of a Notification of Intention to Award.
2. The complaint can only challenge the decision to award the contract.
3. You must submit the complaint with in the period stated above.
4. You must include, in your complaint, all of the information required by the Procurement Regulations

## 6. Standstill Period

**DEADLINE: The Standstill Period is due to end on the 14th day after date of notification] at midnight on [insert date] (local time).**

The Stand still Period lasts fourteen (14) Days after the date of transmission of this Notification of Intention to Award. The Standstill Period may be extended as stated in Section 4 above.

If you have any questions regarding this Notification please do not hesitate to contact us. On behalf of the Procuring Entity:

**Signature:** \_\_\_\_\_ **Name:** \_\_\_\_\_

**Title/position:** \_\_\_\_\_ **Telephone:** \_\_\_\_\_

**Email:** \_\_\_\_\_

**NOTIFICATION OF AWARD-FORM OF ACCEPTANCE**

*[letterhead paper of the Procuring Entity] [date] To:[name and address of the Supplier]*

Subject: *Notification of Award Contract No.....*

This is to notify you that your Tender dated.....*[insert date]*.....for execution of the..... *[insert name of the contract and identification number, as given in the SCC]*.....for the Accepted Contract Amount of..... *[insert amount in numbers and words and name of currency]*, as corrected and modified in accordance with the Instructions to Tenderers is here by accepted by our Agency.

You are requested to furnish the Performance Security within 30days in accordance with the Conditions of Contract, using for that purpose the of the Performance Security Form included in Section X, Contract Forms, of the tendering document.

Authorized Signature: .....

Name and Title of Signatory: .....

Name of Agency: .....

**Attachment: Contract Agreement**



## CONTRACT AGREEMENT

*[The successful Tenderer shall fill in this form in accordance with the instructions indicated]*

THIS AGREEMENT made the *[insert: number]* day of *[insert: month]*, *[insert: year]*. BETWEEN

- 1) *[insert complete name of Procuring Entity]*, a *[insert description of type of legal entity, for example, an agency of the Ministry of... of the Government of Kenya, or corporation in Kenya]* and having its principal place of business at *[insert address of Procuring Entity]* (hereinafter called "the Procuring Entity"), of the one part, and
- 2) *[insert name of Supplier]*, a corporation incorporated under the laws of *[insert: country of Supplier]* and having its principal place of business at *[insert: address of Supplier]* (herein after called "the Supplier"), of the other part:

WHEREAS the Procuring Entity invited Tenders for certain Goods and ancillary services, viz., *[insert brief description of Goods and Services]* and has accepted a Tender by the Supplier for the supply of those Goods and Services.

The Procuring Entity and the Supplier agree as follows:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Contract documents referred to.
2. The following documents shall be deemed to form and be read and construed as part of this Agreement. This Agreement shall prevail overall other contract documents.
  - a) The Form of Tender
  - b) the Addenda Nos. (if any)
  - c) Special Conditions of Contract
  - d) General Conditions of Contract
  - e) The Specification (including Schedule of Requirements and Technical Specifications)
  - f) the completed Schedules (including Price Schedules)
  - g) The Purchaser's Notification of Award
  - h) Acceptance by the tenderer
  - i) Performance Bond (where applicable)
  - j) Bidders' current CR12 (should have been issued within the last 12 months)
3. In consideration of the payments to be made by the Procuring Entity to the Supplier as specified in this Agreement, the Supplier hereby covenants with the Procuring Entity to provide the Goods and Services and to remedy defects therein conformity in all respects with the provisions of the Contract.
4. The Procuring Entity here by covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

IN WITNESS where of the parties here to have caused this Agreement to be executed in accordance with the laws of

*Kenya* on the day, month and year

indicated above. For and on behalf of the

Procuring Entity

Signed:\_\_\_\_\_ *[insert signature]* in the capacity of *[insert title or other appropriate designation]* in the presence of *[insert identification of official witness]* For and on behalf of the Supplier

Signed:*[insert signature of authorized representative(s) of the Supplier]* in the capacity of *[insert title or other appropriate designation]* in the presence of *[insert identification of official witness]*

**PERFORMANCE SECURITY**

**Bank Guarantee** *[The bank, as requested by the successful Tenderer, shall fill in this form in accordance with the instructions indicated] [Guarantor letterhead or SWIFT identifier code] Beneficiary:*  
..... *[insert name and Address of Procuring Entity]*

Date:.....*[Insert date of issue]*

PERFORMANCE GUARANTEE No.:.....*[Insert guarantee reference number]*

Guarantor:.....*[Insert name and address of place of issue, unless indicated in the letterhead]*

We have been informed that.....*[insert name of Supplier, which in the case of a joint venture shall be the name of the joint venture]* (hereinafter called "the Applicant") has entered into Contract No. *[insert reference number of the contract]* dated *[insert date]* with the Beneficiary, for the supply of.....*[insert name of contract and brief description of Health Goods and related Services]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a performance guarantee is required.

At the request of the Applicant, we as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total amount of.....*[insert amount in figures]* (.....) *[insert amount in words]*,<sup>1</sup> such sum being payable in the types and proportions of currencies in which the Contract Price is payable, upon receipt by us of the Beneficiary's complying demand supported by the Beneficiary's statement, whether in the demand itself or in a separate signed document accompanying or identifying the demand, stating that the Applicant is in breach of its obligation (s) under the Contract, without the Beneficiary needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire, no later than the.....Day of.....,2.....<sup>2</sup>, and any demand for payment under it must be received by us at this office indicated above on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No.758, except that the supporting statement under Article 15(a) is here by excluded.

\_\_\_\_\_  
[Signature]

Note: All italicized text (including foot notes) is for use in preparing this form and shall be deleted from the final product.

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<sup>1</sup>The Guarantor shall insert an amount representing the percentage of the Accepted Contract Amount specified in the Form of Acceptance, and denominated either in the currency(ies) of the Contract or a freely convertible currency acceptable to the Beneficiary.

<sup>2</sup>Insert the date *twenty-eight days after the expected completion date as described in GC Clause 18.4. The Procuring Entity should note that in the event of an extension of this date for completion of the Contract, the Procuring Entity would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Procuring Entity might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed .....[six months][one year], in response to the Beneficiary's written Invitation to such extension ,such request to be presented to the Guarantor before the expiry of the guarantee."*

**ADVANCE PAYMENT SECURITY**

*[Guarantor letter head or SWIFT identifier code]*

Beneficiary:.....*[Insert name and Address of Procuring Entity]*

Date:.....*[Insert date of issue]*

ADVANCE PAYMENT GUARANTEE No.:.....*[Insert guarantee reference number]*

Guarantor:.....*[Insert name and address of place of issue, unless indicated in the letter head]*

We have been informed that.....*[insert name of Supplier, which in the case of a joint venture shall be the name of the joint venture]* (here in after called "the Applicant") has entered into Contract No. ....*[insert reference number of the contract]* dated.....*[insert date]* with the Beneficiary, for the execution of.....*[insert name of contract and brief description of Health Goods and related Services]* (herein after called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, an advance payment in the sum *[insert amount in figures]* () *[insert amount in words]* is to be made against an advance payment guarantee.

At the request of the Applicant, we as Guarantor, here by irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of.....*[insert amount in figures]* (.....) *[insert amount in words]*<sup>1</sup> upon receipt by us of the Beneficiary's complying demand supported by the Beneficiary's statement, whether in the demand itself or in a separate signed document accompanying or identifying the demand, stating either that the Applicant:

- a) Has used the advance payment for purposes other than toward delivery of Goods; or
- b) has failed to repay the advance payment in accordance with the Contract conditions, specifying the amount which the Applicant has failed to repay.

A demand under this guarantee may be presented as from the presentation to the Guarantor of a certificate from the Beneficiary's bank stating that the advance payment referred to above has been credited to the Applicant on its account number.....*[insert number]*at.....*[insert name and address of Applicant's bank]*.

The maximum amount of this guarantee shall be progressively reduced by the amount of the advance payment repaid by the Applicant as specified in copies of interim statements or payment certificates which shall be presented to us. This guarantee shall expire, at the latest, upon our receipt of a copy of the interim payment certificate indicating that ninety (90) percent of the Accepted Contract Amount, has been certified for payment, or on the.....*[insert day]* day of..... *[insert month]*, 2 *[insert year]*, whichever is earlier. Consequently, any demand for payment under this guarantee must be received by us at this office on or before that date.

---

[Signature]

***Note:** All italicized text (including foot notes) is for use in preparing this form and shall be deleted from the final product.*

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<sup>1</sup>*The Guarantor shall insert an amount representing the amount of the advance payment and denominated either in the currency (ies) of the advance payment as specified in the Contract, or in a freely convertible currency acceptable to the Procuring Entity.*