PHILIPPINE BIDDING DOCUMENTS

Procurement of Supply Delivery, Installation, Commissioning and Testing of High-Performance Liquid Chromatographs for Alabang Testing and Quality Assurance (ATQAL)

ITB No. 2021-0207-ATQAL

Government of the Republic of the Philippines

Sixth Edition
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Preface

These Philippine Bidding Documents (PBDs) for the procurement of Goods through Competitive Bidding have been prepared by the Government of the Philippines for use by any branch, constitutional commission or office, agency, department, bureau, office, or instrumentality of the Government of the Philippines, National Government Agencies, including Government-Owned and/or Controlled Corporations, Government Financing Institutions, State Universities and Colleges, and Local Government Unit. The procedures and practices presented in this document have been developed through broad experience, and are for mandatory use in projects that are financed in whole or in part by the Government of the Philippines or any foreign government/foreign or international financing institution in accordance with the provisions of the 2016 revised Implementing Rules and Regulations of Republic Act No. 9184.

The Bidding Documents shall clearly and adequately define, among others: (i) the objectives, scope, and expected outputs and/or results of the proposed contract or Framework Agreement, as the case may be; (ii) the eligibility requirements of Bidders; (iii) the expected contract or Framework Agreement duration, the estimated quantity in the case of procurement of goods, delivery schedule and/or time frame; and (iv) the obligations, duties, and/or functions of the winning bidder.

Care should be taken to check the relevance of the provisions of the PBDs against the requirements of the specific Goods to be procured. If duplication of a subject is inevitable in other sections of the document prepared by the Procuring Entity, care must be exercised to avoid contradictions between clauses dealing with the same matter.

Moreover, each section is prepared with notes intended only as information for the Procuring Entity or the person drafting the Bidding Documents. They shall not be included in the final documents. The following general directions should be observed when using the documents:

a. All the documents listed in the Table of Contents are normally required for the procurement of Goods. However, they should be adapted as necessary to the circumstances of the particular Procurement Project.

b. Specific details, such as the "*name of the Procuring Entity*" and "*address for bid submission*," should be furnished in the Instructions to Bidders, Bid Data Sheet, and Special Conditions of Contract. The final documents should contain neither blank spaces nor options.

c. This Preface and the footnotes or notes in italics included in the Invitation to Bid, Bid Data Sheet, General Conditions of Contract, Special Conditions of Contract, Schedule of Requirements, and Specifications are not part of the text of the final document, although they contain instructions that the Procuring Entity should strictly follow.

d. The cover should be modified as required to identify the Bidding Documents as to the Procurement Project, Project Identification Number, and Procuring Entity, in addition to the date of issue.

e. Modifications for specific Procurement Project details should be provided in the Special Conditions of Contract as amendments to the Conditions of Contract. For easy completion, whenever reference has to be made to specific clauses in the Bid Data Sheet or Special Conditions of Contract, these terms shall be printed in bold typeface on Sections I (Instructions to Bidders) and III (General Conditions of Contract), respectively.

f. For guidelines on the use of Bidding Forms and the procurement of Foreign-Assisted Projects, these will be covered by a separate issuance of the Government Procurement Policy Board.

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Glossary of Acronyms, Terms, and Abbreviations

ABC – Approved Budget for the Contract.

BAC – Bids and Awards Committee.

Bid – A signed offer or proposal to undertake a contract submitted by a bidder in response to and in consonance with the requirements of the bidding documents. Also referred to as *Proposal* and *Tender*. (2016 revised IRR, Section 5[c])

Bidder – Refers to a contractor, manufacturer, supplier, distributor and/or consultant who submits a bid in response to the requirements of the Bidding Documents. (2016 revised IRR, Section 5[d])

Bidding Documents – The documents issued by the Procuring Entity as the bases for bids, furnishing all information necessary for a prospective bidder to prepare a bid for the Goods, Infrastructure Projects, and/or Consulting Services required by the Procuring Entity. (2016 revised IRR, Section 5[e])

BIR – Bureau of Internal Revenue.

BSP – Bangko Sentral ng Pilipinas.

Consulting Services – Refer to services for Infrastructure Projects and other types of projects or activities of the GOP requiring adequate external technical and professional expertise that are beyond the capability and/or capacity of the GOP to undertake such as, but not limited to: (i) advisory and review services; (ii) pre-investment or feasibility studies; (iii) design; (iv) construction supervision; (v) management and related services; and (vi) other technical services or special studies. (2016 revised IRR, Section 5[i])

CDA - Cooperative Development Authority.

Contract – Refers to the agreement entered into between the Procuring Entity and the Supplier or Manufacturer or Distributor or Service Provider for procurement of Goods and Services; Contractor for Procurement of Infrastructure Projects; or Consultant or Consulting Firm for Procurement of Consulting Services; as the case may be, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

CIF – Cost Insurance and Freight.

CIP – Carriage and Insurance Paid.

CPI – Consumer Price Index.

DDP – Refers to the quoted price of the Goods, which means "delivered duty paid."

DTI – Department of Trade and Industry.

EXW – Ex works.

FCA – "Free Carrier" shipping point.

FOB – "Free on Board" shipping point.

Foreign-funded Procurement or Foreign-Assisted Project– Refers to procurement whose funding source is from a foreign government, foreign or international financing institution as specified in the Treaty or International or Executive Agreement. (2016 revised IRR, Section 5[b]).

Framework Agreement – Refers to a written agreement between a procuring entity and a supplier or service provider that identifies the terms and conditions, under which specific purchases, otherwise known as "Call-Offs," are made for the duration of the agreement. It is in the nature of an option contract between the procuring entity and the bidder(s) granting the procuring entity the option to either place an order for any of the goods or services identified in the Framework Agreement List or not buy at all, within a minimum period of one (1) year to a maximum period of three (3) years. (GPPB Resolution No. 27-2019)

GFI – Government Financial Institution.

GOCC – Government-owned and/or –controlled corporation.

Goods – Refer to all items, supplies, materials and general support services, except Consulting Services and Infrastructure Projects, which may be needed in the transaction of public businesses or in the pursuit of any government undertaking, project or activity, whether in the nature of equipment, furniture, stationery, materials for construction, or personal property of any kind, including non-personal or contractual services such as the repair and maintenance of equipment and furniture, as well as trucking, hauling, janitorial, security, and related or analogous services, as well as procurement of materials and supplies provided by the Procuring Entity for such services. The term "related" or "analogous services" shall include, but is not limited to, lease or purchase of office space, media advertisements, health maintenance services, and other services essential to the operation of the Procuring Entity. (2016 revised IRR, Section 5[r])

GOP – Government of the Philippines.

GPPB – Government Procurement Policy Board.

INCOTERMS – International Commercial Terms.

Infrastructure Projects – Include the construction, improvement, rehabilitation, demolition, repair, restoration or maintenance of roads and bridges, railways, airports, seaports, communication facilities, civil works components of information technology projects, irrigation, flood control and drainage, water supply, sanitation, sewerage and solid waste management systems, shore protection, energy/power and electrification facilities, national

buildings, school buildings, hospital buildings, and other related construction projects of the government. Also referred to as *civil works or works*. (2016 revised IRR, Section 5[u])

LGUs – Local Government Units.

NFCC – Net Financial Contracting Capacity.

NGA – National Government Agency.

PhilGEPS - Philippine Government Electronic Procurement System.

Procurement Project – refers to a specific or identified procurement covering goods, infrastructure project or consulting services. A Procurement Project shall be described, detailed, and scheduled in the Project Procurement Management Plan prepared by the agency which shall be consolidated in the procuring entity's Annual Procurement Plan. (GPPB Circular No. 06-2019 dated 17 July 2019)

PSA – Philippine Statistics Authority.

SEC – Securities and Exchange Commission.

SLCC – Single Largest Completed Contract.

Supplier – refers to a citizen, or any corporate body or commercial company duly organized and registered under the laws where it is established, habitually established in business and engaged in the manufacture or sale of the merchandise or performance of the general services covered by his bid. (Item 3.8 of GPPB Resolution No. 13-2019, dated 23 May 2019). Supplier as used in these Bidding Documents may likewise refer to a distributor, manufacturer, contractor, or consultant.

UN – United Nations.

Section I. Invitation to Bid

Notes on the Invitation to Bid

The Invitation to Bid (IB) provides information that enables potential Bidders to decide whether to participate in the procurement at hand. The IB shall be posted in accordance with Section 21.2 of the 2016 revised IRR of RA No. 9184.

Apart from the essential items listed in the Bidding Documents, the IB should also indicate the following:

a. The date of availability of the Bidding Documents, which shall be from the time the IB is first advertised/posted until the deadline for the submission and receipt of bids;

b. The place where the Bidding Documents may be acquired or the website where it may be downloaded;

c. The deadline for the submission and receipt of bids; and

d. Any important bid evaluation criteria (*e.g.*, the application of a margin of preference in bid evaluation).

The IB should be incorporated in the Bidding Documents. The information contained in the IB must conform to the Bidding Documents and in particular to the relevant information in the Bid Data Sheet.

BIDS AND AWARDS COMMITTEE

FDA-BAC Ref. No. ITB No. 2021-0207-ATQAL

INVITATION TO BID

Procurement of Supply Delivery, Installation, Commissioning and Testing of High-Performance Liquid Chromatographs for Alabang Testing and Quality Assurance (ATQAL)

1. The ***Food and Drug Administration***, through the **Special Alloted General Funds (SAGF**) intends to apply the sum of **Thirty Two Million Seven Hundred Sixty Nine Thousand Nine Hundred Fifty One Pesos Only (Php32,769,951.00)** being the ABC to payments under the contract for **Procurement of Supply Delivery, Installation, Commissioning and Testing of High-Performance Liquid Chromatographs for Alabang Testing and Quality Assurance (ATQAL).** Bids received in excess of the ABC shall be automatically rejected at bid opening.

2. The ***Food and Drug Administration*** now invites bids for the above Procurement Project. Delivery of the Goods is required by ***Ninety (90) Calendar days after receipts of Notice to Proceed.*** Bidders should have completed, within ***Five (5) Years*** from the date of submission and receipt of bids, a contract similar to the Project. The description of an eligible bidder is contained in the Bidding Documents, particularly, in Section II (Instructions to Bidders).

3. Bidding will be conducted through open competitive bidding procedures using a non-discretionary "*pass/fail*" criterion as specified in the 2016 revised Implementing Rules and Regulations (IRR) of Republic Act (RA) No. 9184.

    a. Bidding is restricted to Filipino citizens/sole proprietorships, partnerships, or organizations with at least sixty percent (60%) interest or outstanding capital stock belonging to citizens of the Philippines, and to citizens or organizations of a country the laws or regulations of which grant similar rights or privileges to Filipino citizens, pursuant to RA No. 5183.

4. Prospective Bidders may obtain further information from ***Food and Drug Administration*** and inspect the Bidding Documents at the address given below during *8:00AM to 5:00AM*.

5. A complete set of Bidding Documents may be acquired by interested Bidders on ***22 – September 2021 to 12 October 2021*** from the given address and website(s) below *pursuant to the latest Guidelines issued by the GPPB, in the amount of Twenty Five*

Thousand Pesos (Php25,000.00). The Food and Drug Administration shall allow the bidder to present its proof of payment for the fees

6. The ***Food and Drug Administration*** will hold a Pre-Bid Conference[1] on *30 September 2021 at 1:00PM* through video conferencing or webcasting *via Zoom meeting:* https://us06web.zoom.us/j/81749613845?pwd=UW9GenhuVm5OQmR3QnE0OTU5MlZRZz09 which shall be open to prospective bidders.

7. Bids must be duly received by the BAC Secretariat through **manual submission on or before 12 October 2021, 8:30AM** at the Food and Drug Administration BAC Secretariat Room, FDA Annex Bldg. Late bids shall not be accepted.

8. All Bids must be accompanied by a bid security in any of the acceptable forms and in the amount stated in **ITB** Clause 14.

9. Bid opening shall be on *12 October 2021, 9:00AM* at the given address below Food and Drug Administration BAC Secretariat Room, FDA Annex Bldg. Bids will be opened in the presence of the bidders' representatives who choose to attend the activity.

10. The *Food and Drug Administration* reserves the right to reject any and all bids, declare a failure of bidding, or not award the contract at any time prior to contract award in accordance with Sections 35.6 and 41 of the 2016 revised IRR of RA No. 9184, without thereby incurring any liability to the affected bidder or bidders.

11. For further information, please refer to:

    Maria Essa C. Tuason
    FDA Head, BAC Secretariat
    Food and Drug Administration BAC Secretariat Room,
    FDA Annex Bldg
    Tel No. 8857-1900 Loc 8307
    bacsec@fda.gov.ph
    www.fda.gov.ph

12. You may visit the following websites:

    For downloading of Bidding Documents: *https:www.fda.gov.ph*

20 September 2021

ORIGINAL COPY SIGNED
ENGR. ANA TRINIDAD F. RIVERA, MSc
FDA, BAC Chairperson

DTN: 20210910135401

[1] May be deleted in case the ABC is less than One Million Pesos (PhP1,000,000) where the Procuring Entity may not hold a Pre-Bid Conference.

Section II. Instructions to Bidders

Notes on the Instructions to Bidders

This Section on the Instruction to Bidders (ITB) provides the information necessary for bidders to prepare responsive bids, in accordance with the requirements of the Procuring Entity. It also provides information on bid submission, eligibility check, opening and evaluation of bids, post-qualification, and on the award of contract.

1. Scope of Bid

The Procuring Entity, *Food and Drug Administration* wishes to receive Bids for the *Procurement of Supply Delivery, Installation, Commissioning and Testing of High-Performance Liquid Chromatographs for Alabang Testing and Quality Assurance (ATQAL) with ITB No. 2021-0207-ATQAL*

The Procurement Project (referred to herein as "Project") is composed of *Five (5)*, the details of which are described in Section VII (Technical Specifications).

2. Funding Information

2.1. The GOP through the source of funding as indicated below ***F.Y 2021*** in the amount of **Php32,769,951.00.**

2.2. The source of funding is:

a. NGA, the General Appropriations Act or Special Appropriations.

3. Bidding Requirements

The Bidding for the Project shall be governed by all the provisions of RA No. 9184 and its 2016 revised IRR, including its Generic Procurement Manuals and associated policies, rules and regulations as the primary source thereof, while the herein clauses shall serve as the secondary source thereof.

Any amendments made to the IRR and other GPPB issuances shall be applicable only to the ongoing posting, advertisement, or **IB** by the BAC through the issuance of a supplemental or bid bulletin.

The Bidder, by the act of submitting its Bid, shall be deemed to have verified and accepted the general requirements of this Project, including other factors that may affect the cost, duration and execution or implementation of the contract, project, or work and examine all instructions, forms, terms, and project requirements in the Bidding Documents.

4. Corrupt, Fraudulent, Collusive, and Coercive Practices

The Procuring Entity, as well as the Bidders and Suppliers, shall observe the highest standard of ethics during the procurement and execution of the contract. They or through an agent shall not engage in corrupt, fraudulent, collusive, coercive, and obstructive practices defined under Annex "I" of the 2016 revised IRR of RA No. 9184 or other integrity violations in competing for the Project.

5. Eligible Bidders

5.1. Only Bids of Bidders found to be legally, technically, and financially capable will be evaluated.

5.2. *[Select one, delete other/s]*

a. Foreign ownership exceeding those allowed under the rules may participate pursuant to:

i. When a Treaty or International or Executive Agreement as provided in Section 4 of the RA No. 9184 and its 2016 revised IRR allow foreign bidders to participate;

ii. Citizens, corporations, or associations of a country, included in the list issued by the GPPB, the laws or regulations of which grant reciprocal rights or privileges to citizens, corporations, or associations of the Philippines;

iii. When the Goods sought to be procured are not available from local suppliers; or

iv. When there is a need to prevent situations that defeat competition or restrain trade.

b. Foreign ownership limited to those allowed under the rules may participate in this Project.

5.3. Pursuant to Section 23.4.1.3 of the 2016 revised IRR of RA No.9184, the Bidder shall have an SLCC that is at least one (1) contract similar to the Project the value of which, adjusted to current prices using the PSA's CPI, must be at least equivalent to:

[Select one, delete the other/s]

a. For the procurement of Non-expendable Supplies and Services: The Bidder must have completed a single contract that is similar to this Project, equivalent to at least fifty percent (50%) of the ABC.

b. For the procurement of Expendable Supplies: The Bidder must have completed a single contract that is similar to this Project, equivalent to at least twenty-five percent (25%) of the ABC.

c. For procurement where the Procuring Entity has determined, after the conduct of market research, that imposition of either (a) or (b) will likely result to failure of bidding or monopoly that will defeat the purpose of public bidding: the Bidder should comply with the following requirements: [*Select either failure or monopoly of bidding based on market research conducted*]

i. Completed at least two (2) similar contracts, the aggregate amount of which should be equivalent to at least *fifty percent (50%) in the case of non-expendable supplies and services or twenty-five percent (25%) in the case of expendable supplies*] of the ABC for this Project; and

ii. The largest of these similar contracts must be equivalent to at least half of the percentage of the ABC as required above.

5.4. The Bidders shall comply with the eligibility criteria under Section 23.4.1 of the 2016 IRR of RA No. 9184.

6. Origin of Goods

There is no restriction on the origin of goods other than those prohibited by a decision of the UN Security Council taken under Chapter VII of the Charter of the UN, subject to Domestic Preference requirements under **ITB** Clause 18.

7. Subcontracts

7.1. The Bidder may subcontract portions of the Project to the extent allowed by the Procuring Entity as stated herein, but in no case more than twenty percent (20%) of the Project.

The Procuring Entity has prescribed that:

a. Subcontracting is not allowed.

8. Pre-Bid Conference

The Procuring Entity will hold a pre-bid conference for this Project on the specified date and time through videoconferencing/webcasting} as indicated in paragraph 6 of the **IB.**

9. Clarification and Amendment of Bidding Documents

Prospective bidders may request for clarification on and/or interpretation of any part of the Bidding Documents. Such requests must be in writing and received by the Procuring Entity, either at its given address or through electronic mail indicated in the **IB**, at least ten (10) calendar days before the deadline set for the submission and receipt of Bids.

10. Documents comprising the Bid: Eligibility and Technical Components

10.1. The first envelope shall contain the eligibility and technical documents of the Bid as specified in **Section VIII (Checklist of Technical and Financial Documents)**.

10.2. The Bidder's SLCC as indicated in **ITB** Clause 5.3 should have been completed within *[state relevant period as provided in paragraph 2 of the **IB**]* prior to the deadline for the submission and receipt of bids.

10.3. If the eligibility requirements or statements, the bids, and all other documents for submission to the BAC are in foreign language other than English, it must be accompanied by a translation in English, which shall be authenticated by the

appropriate Philippine foreign service establishment, post, or the equivalent office having jurisdiction over the foreign bidder's affairs in the Philippines. Similar to the required authentication above, for Contracting Parties to the Apostille Convention, only the translated documents shall be authenticated through an apostille pursuant to GPPB Resolution No. 13-2019 dated 23 May 2019. The English translation shall govern, for purposes of interpretation of the bid.

11. Documents comprising the Bid: Financial Component

11.1. The second bid envelope shall contain the financial documents for the Bid as specified in **Section VIII (Checklist of Technical and Financial Documents)**.

11.2. If the Bidder claims preference as a Domestic Bidder or Domestic Entity, a certification issued by DTI shall be provided by the Bidder in accordance with Section 43.1.3 of the 2016 revised IRR of RA No. 9184.

11.3. Any bid exceeding the ABC indicated in paragraph 1 of the **IB** shall not be accepted.

11.4. For Foreign-funded Procurement, a ceiling may be applied to bid prices provided the conditions are met under Section 31.2 of the 2016 revised IRR of RA No. 9184.

11.5. *[Include if Framework Agreement will be used:]* Financial proposals for single or multi-year Framework Agreement shall be submitted before the deadline of submission of bids as prescribed in the **IB**. For multi-year Framework Agreement, evaluation of the financial proposal during this stage is for purposes of determining eligibility and whether or not such financial proposal is within the ABC.

12. Bid Prices

12.1. Prices indicated on the Price Schedule shall be entered separately in the following manner:

a. For Goods offered from within the Procuring Entity's country:

i. The price of the Goods quoted EXW (ex-works, ex-factory, ex-warehouse, ex-showroom, or off-the-shelf, as applicable);

ii. The cost of all customs duties and sales and other taxes already paid or payable;

iii. The cost of transportation, insurance, and other costs incidental to delivery of the Goods to their final destination; and

iv. The price of other (incidental) services, if any, listed in the **BDS.**

b. For Goods offered from abroad:

i. Unless otherwise stated in the **BDS**, the price of the Goods shall be quoted delivered duty paid (DDP) with the place of destination in the Philippines as specified in the **BDS**. In quoting the price, the Bidder shall be free to use transportation through carriers registered in any eligible country. Similarly, the Bidder may obtain insurance services from any eligible source country.

ii. The price of other (incidental) services, if any, as listed in the **BDS.**

13. Bid and Payment Currencies

13.1. For Goods that the Bidder will supply from outside the Philippines, the bid prices may be quoted in the local currency or tradeable currency accepted by the BSP at the discretion of the Bidder. However, for purposes of bid evaluation, Bids denominated in foreign currencies, shall be converted to Philippine currency based on the exchange rate as published in the BSP reference rate bulletin on the day of the bid opening.

13.2. Payment of the contract price shall be made in:

a. Philippine Pesos.

14. Bid Security

14.1. The Bidder shall submit a Bid Securing Declaration[2] or any form of Bid Security in the amount indicated in the **BDS**, which shall be not less than the percentage of the ABC in accordance with the schedule in the **BDS**.

14.2. The Bid and bid security shall be valid until *[indicate date]*. Any Bid not accompanied by an acceptable bid security shall be rejected by the Procuring Entity as non-responsive.

15. Sealing and Marking of Bids

Each Bidder shall submit one copy of the first and second components of its Bid.

The Procuring Entity may request additional hard copies and/or electronic copies of the Bid. However, failure of the Bidders to comply with the said request shall not be a ground for disqualification.

If the Procuring Entity allows the submission of bids through online submission or any other electronic means, the Bidder shall submit an electronic copy of its Bid, which must be digitally signed. An electronic copy that cannot be opened or is corrupted shall be considered non-responsive and, thus, automatically disqualified.

[2] In the case of Framework Agreement, the undertaking shall refer to entering into contract with the Procuring Entity and furnishing of the performance security or the performance securing declaration within ten (10) calendar days from receipt of Notice to Execute Framework Agreement.

16. Deadline for Submission of Bids

16.1. The Bidders shall submit on the specified date and time and either at its physical address or through online submission as indicated in paragraph 7 of the **IB.**

17. Opening and Preliminary Examination of Bids

17.1. The BAC shall open the Bids in public at the time, on the date, and at the place specified in paragraph 9 of the **IB**. The Bidders' representatives who are present shall sign a register evidencing their attendance. In case videoconferencing, webcasting or other similar technologies will be used, attendance of participants shall likewise be recorded by the BAC Secretariat.

In case the Bids cannot be opened as scheduled due to justifiable reasons, the rescheduling requirements under Section 29 of the 2016 revised IRR of RA No. 9184 shall prevail.

17.2. The preliminary examination of bids shall be governed by Section 30 of the 2016 revised IRR of RA No. 9184.

18. Domestic Preference

18.1. The Procuring Entity will grant a margin of preference for the purpose of comparison of Bids in accordance with Section 43.1.2 of the 2016 revised IRR of RA No. 9184.

19. Detailed Evaluation and Comparison of Bids

19.1. The Procuring Entity's BAC shall immediately conduct a detailed evaluation of all Bids rated "*passed*," using non-discretionary pass/fail criteria. The BAC shall consider the conditions in the evaluation of Bids under Section 32.2 of the 2016 revised IRR of RA No. 9184.

19.2. If the Project allows partial bids, bidders may submit a proposal on any of the lots or items, and evaluation will be undertaken on a per lot or item basis, as the case maybe. In this case, the Bid Security as required by **ITB** Clause 14 shall be submitted for each lot or item separately.

19.3. The descriptions of the lots or items shall be indicated in **Section VII (Technical Specifications)**, although the ABCs of these lots or items are indicated in the **BDS** for purposes of the NFCC computation pursuant to Section 23.4.2.6 of the 2016 revised IRR of RA No. 9184. The NFCC must be sufficient for the total of the ABCs for all the lots or items participated in by the prospective Bidder.

19.4. The Project shall be awarded as follows:

One Project having several items, which shall be awarded as separate contracts per item.

19.5. Except for bidders submitting a committed Line of Credit from a Universal or Commercial Bank in lieu of its NFCC computation, all Bids must include the NFCC computation pursuant to Section 23.4.1.4 of the 2016 revised IRR of RA No. 9184, which must be sufficient for the total of the ABCs for all the lots or items participated in by the prospective Bidder. For bidders submitting the committed Line of Credit, it must be at least equal to ten percent (10%) of the ABCs for all the lots or items participated in by the prospective Bidder.

20. Post-Qualification

20.2. Within a non-extendible period of five (5) calendar days from receipt by the Bidder of the notice from the BAC that it submitted the Lowest Calculated Bid, {*[Include if Framework Agreement will be used:]* or in the case of multi-year Framework Agreement, that it is one of the eligible bidders who have submitted bids that are found to be technically and financially compliant,}the Bidder shall submit its latest income and business tax returns filed and paid through the BIR Electronic Filing and Payment System (eFPS) and other appropriate licenses and permits required by law and stated in the **BDS**. {*[Include if Framework Agreement will be used:]* For every mini-competition in Framework Agreement, the LCB shall likewise submit the required documents for final Post Qualification.}

21. Signing of the Contract

21.1. The documents required in Section 37.2 of the 2016 revised IRR of RA No. 9184 shall form part of the Contract. Additional Contract documents are indicated in the **BDS**.

Section III. Bid Data Sheet

Notes on the Bid Data Sheet

The Bid Data Sheet (BDS) consists of provisions that supplement, amend, or specify in detail, information, or requirements included in the ITB found in Section II, which are specific to each procurement.

This Section is intended to assist the Procuring Entity in providing the specific information in relation to corresponding clauses in the ITB and has to be prepared for each specific procurement.

The Procuring Entity should specify in the BDS information and requirements specific to the circumstances of the Procuring Entity, the processing of the procurement, and the bid evaluation criteria that will apply to the Bids. In preparing the BDS, the following aspects should be checked:

a. Information that specifies and complements provisions of the ITB must be incorporated.

b. Amendments and/or supplements, if any, to provisions of the ITB as necessitated by the circumstances of the specific procurement, must also be incorporated.

Bid Data Sheet

<table>
<tr><th>ITB Clause</th><th></th></tr>
<tr><td>5.3</td><td>For this purpose, contracts similar to the Project shall be:

a. Similar contract to be bid

b. Completed within last five (5) prior to the deadline for the submission and receipt of bids.</td></tr>
<tr><td>7.1</td><td>Subcontracting are not allowed</td></tr>
<tr><td>12</td><td>The price of the Goods shall be quoted DDP [state place of destination] or the applicable International Commercial Terms (INCOTERMS) for this Project.</td></tr>
<tr><td>14.1</td><td>The bid security shall be in the form of a Bid Securing Declaration, or any of the following forms and amounts:

a. The amount of not less than _____ [Indicate the amount equivalent to two percent (2%) of ABC], if bid security is in cash, cashier’s/manager’s check, bank draft/guarantee or irrevocable letter of credit; or

b. The amount of not less than _____ [Indicate the amount equivalent to five percent (5%) of ABC] if bid security is in Surety Bond.</td></tr>
<tr><td>19.3</td><td>Project will be awarded by item,

<table>
<tr><th>Item Number</th><th>Item Description</th><th>Quantity</th><th>Unit</th><th>Unit Cost</th><th>Total Cost</th></tr>
<tr><td>1</td><td>Supply, Delivery, Installation, Commissioning And Testing Of High Performance Liquid Chromatograph With Photodiode Array Detector (HPLC-PDA) Complete With All Necessary Parts And Accessories For FDA-Alabang Testing Quality Assurance Laboratory (ATQAL)</td><td>2</td><td>Lot</td><td>P4,066,667.00</td><td>P8,133,334.00</td></tr>
</table>
</td></tr>
</table>

	2	Supply, Delivery, Installation, Commissioning And Testing Of High Performance Liquid Chromatograph With Photodiode Array And Refractive Index Detector (HPLC-PDA-RID) Complete With All Necessary Parts And Accessories For Fda-Alabang Testing Quality Assurance Laboratory (ATQAL)	1	Lot	P6,050,000.00	P6,050,000.00
	3	Supply, Delivery, Installation, Commissioning And Testing Of High Performance Liquid Chromatograph With Photodiode Array And Fluorescence Detector (HPLC-PDA-FLD) Complete With All Necessary Parts And Accessories For Fda-Alabang Testing Quality Assurance Laboratory (ATQAL)	1	Lot	P6,248,784.00	P6,248,784.00
	4	Supply, Delivery, Installation, Commissioning And Testing Of High Performance Liquid Chromatograph	1	Lot	P4,204,500.00	P4,204,500.00

		With Photodiode Array And UV-VIS Detector (HPLC-PDA-UV-VIS) Complete With All Necessary Parts And Accessories For Fda-Alabang Testing Quality Assurance Laboratory (Atqal)				
	5	Supply, Delivery, Installation, Commissioning And Testing Of Ultra High Performance Liquid Chromatograph With Photodiode Array And Electrochemical Detector (UHPLC-PDA-ECD) Complete With All Necessary Parts And Accessories For FDA-Alabang Testing Quality Assurance Laboratory (ATQAL)	1	Lot	P8,133,333000	P8,133,333000
20.2	*[List here any licenses and permits relevant to the Project and the corresponding law requiring it.]*					
21.2	*[List here any additional contract documents relevant to the Project that may be required by existing laws and/or the Procuring Entity.]*					

Section IV. General Conditions of Contract

Notes on the General Conditions of Contract

The General Conditions of Contract (GCC) in this Section, read in conjunction with the Special Conditions of Contract in Section V and other documents listed therein, should be a complete document expressing all the rights and obligations of the parties.

Matters governing performance of the Supplier, payments under the contract, or matters affecting the risks, rights, and obligations of the parties under the contract are included in the GCC and Special Conditions of Contract.

Any complementary information, which may be needed, shall be introduced only through the Special Conditions of Contract.

1. Scope of Contract

This Contract shall include all such items, although not specifically mentioned, that can be reasonably inferred as being required for its completion as if such items were expressly mentioned herein. All the provisions of RA No. 9184 and its 2016 revised IRR, including the Generic Procurement Manual, and associated issuances, constitute the primary source for the terms and conditions of the Contract, and thus, applicable in contract implementation. Herein clauses shall serve as the secondary source for the terms and conditions of the Contract.

This is without prejudice to Sections 74.1 and 74.2 of the 2016 revised IRR of RA No. 9184 allowing the GPPB to amend the IRR, which shall be applied to all procurement activities, the advertisement, posting, or invitation of which were issued after the effectivity of the said amendment.

Additional requirements for the completion of this Contract shall be provided in the **Special Conditions of Contract** (**SCC).**

2. Advance Payment and Terms of Payment

2.1. Advance payment of the contract amount is provided under Annex "D" of the revised 2016 IRR of RA No. 9184.

2.2. The Procuring Entity is allowed to determine the terms of payment on the partial or staggered delivery of the Goods procured, provided such partial payment shall correspond to the value of the goods delivered and accepted in accordance with prevailing accounting and auditing rules and regulations. The terms of payment are indicated in the **SCC**.

3. Performance Security

Within ten (10) calendar days from receipt of the Notice of Award by the Bidder from the Procuring Entity but in no case later than the signing of the Contract by both parties, the successful Bidder shall furnish the performance security in any of the forms prescribed in Section 39 of the 2016 revised IRR of RA No. 9184.*{[Include if Framework Agreement will be used:] In the case o*f Framework Agreement, the Bidder may opt to furnish the performance security or a Performance Securing Declaration as defined under the Guidelines on the Use of Framework Agreement.*}*

4. Inspection and Tests

The Procuring Entity or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Project *{[Include if Framework Agreement will be used:]* or Framework Agreement*}* specifications at no extra cost to the Procuring Entity in accordance with the Generic Procurement Manual. In addition to tests in the **SCC**, **Section VII (Technical Specifications)** shall specify what inspections and/or tests the Procuring Entity requires, and where they are to be conducted. The Procuring Entity shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

All reasonable facilities and assistance for the inspection and testing of Goods, including access to drawings and production data, shall be provided by the Supplier to the authorized inspectors at no charge to the Procuring Entity.

5. Warranty

5.1 In order to assure that manufacturing defects shall be corrected by the Supplier, a warranty shall be required from the Supplier as provided under Section 62.1 of the 2016 revised IRR of RA No. 9184.

5.2 The Procuring Entity shall promptly notify the Supplier in writing of any claims arising under this warranty. Upon receipt of such notice, the Supplier shall, repair or replace the defective Goods or parts thereof without cost to the Procuring Entity, pursuant to the Generic Procurement Manual.

6. Liability of the Supplier

The Supplier's liability under this Contract shall be as provided by the laws of the Republic of the Philippines.

If the Supplier is a joint venture, all partners to the joint venture shall be jointly and severally liable to the Procuring Entity.

Section V. Special Conditions of Contract

Notes on the Special Conditions of Contract

Similar to the BDS, the clauses in this Section are intended to assist the Procuring Entity in providing contract-specific information in relation to corresponding clauses in the GCC found in Section IV.

The Special Conditions of Contract (SCC) complement the GCC, specifying contractual requirements linked to the special circumstances of the Procuring Entity, the Procuring Entity's country, the sector, and the Goods purchased. In preparing this Section, the following aspects should be checked:

a. Information that complements provisions of the GCC must be incorporated.

b. Amendments and/or supplements to provisions of the GCC as necessitated by the circumstances of the specific purchase, must also be incorporated.

However, no special condition which defeats or negates the general intent and purpose of the provisions of the GCC should be incorporated herein.

Special Conditions of Contract

GCC Clause	
1	*[List here any additional requirements for the completion of this Contract. The following requirements and the corresponding provisions may be deleted, amended, or retained depending on its applicability to this Contract:]* **Delivery and Documents –** For purposes of the Contract, "EXW," "FOB," "FCA," "CIF," "CIP," "DDP" and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of INCOTERMS published by the International Chamber of Commerce, Paris. The Delivery terms of this Contract shall be as follows: *[For Goods supplied from abroad, state:]* "The delivery terms applicable to the Contract are DDP delivered [*indicate place of destination*]. In accordance with INCOTERMS." *[For Goods supplied from within the Philippines, state:*] "The delivery terms applicable to this Contract are delivered *[indicate place of destination]*. Risk and title will pass from the Supplier to the Procuring Entity upon receipt and final acceptance of the Goods at their final destination." Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in Section VI (Schedule of Requirements). For purposes of this Clause the Procuring Entity's Representative at the Project Site is *[indicate name(s)]*. **Incidental Services –** The Supplier is required to provide all of the following services, including additional services, if any, specified in Section VI. Schedule of Requirements: *Select appropriate requirements and delete the rest.* 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. f. *[Specify additional incidental service requirements, as needed.]* The Contract price for the Goods shall include the prices charged by the Supplier for incidental services and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services. **Spare Parts –** The Supplier is required to provide all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the Supplier: *Select appropriate requirements and delete the rest.* 1. such spare parts as the Procuring Entity may elect to purchase from the Supplier, provided that this election shall not relieve the Supplier of any warranty obligations under this Contract; and 2. in the event of termination of production of the spare parts: i. advance notification to the Procuring Entity of the pending termination, in sufficient time to permit the Procuring Entity to procure needed requirements; and ii. following such termination, furnishing at no cost to the Procuring Entity, the blueprints, drawings, and specifications of the spare parts, if requested. The spare parts and other components required are listed in **Section VI (Schedule of Requirements)** and the costs thereof are included in the contract price. The Supplier shall carry sufficient inventories to assure ex-stock supply of consumable spare parts or components for the Goods for a period of [*indicate here the time period specified. If not used indicate a time period of three times the warranty period*]. Spare parts or components shall be supplied as promptly as possible, but in any case, within [*insert appropriate time period*] months of placing the order.

	Packaging – The Supplier shall provide such packaging of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in this Contract. The packaging shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packaging 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. The packaging, 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 below, and in any subsequent instructions ordered by the Procuring Entity. The outer packaging must be clearly marked on at least four (4) sides as follows: Name of the Procuring Entity Name of the Supplier Contract Description Final Destination Gross weight Any special lifting instructions Any special handling instructions Any relevant HAZCHEM classifications
	A packaging list identifying the contents and quantities of the package is to be placed on an accessible point of the outer packaging if practical. If not practical the packaging list is to be placed inside the outer packaging but outside the secondary packaging. **Transportation –** Where the Supplier is required under Contract to deliver the Goods CIF, CIP, or DDP, transport of the Goods to the port of destination or such other named place of destination in the Philippines, as shall be specified in this Contract, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price. Where the Supplier is required under this Contract to transport the Goods to a specified place of destination within the Philippines, defined as the Project Site, transport to such place of destination in the Philippines, including insurance and storage, as shall be specified in this Contract, shall be arranged by the Supplier, and related costs shall be included in the contract price.

	Where the Supplier is required under Contract to deliver the Goods CIF, CIP or DDP, Goods are to be transported on carriers of Philippine registry. In the event that no carrier of Philippine registry is available, Goods may be shipped by a carrier which is not of Philippine registry provided that the Supplier obtains and presents to the Procuring Entity certification to this effect from the nearest Philippine consulate to the port of dispatch. In the event that carriers of Philippine registry are available but their schedule delays the Supplier in its performance of this Contract the period from when the Goods were first ready for shipment and the actual date of shipment the period of delay will be considered force majeure. The Procuring Entity accepts no liability for the damage of Goods during transit other than those prescribed by INCOTERMS for DDP deliveries. In the case of Goods supplied from within the Philippines or supplied by domestic Suppliers risk and title will not be deemed to have passed to the Procuring Entity until their receipt and final acceptance at the final destination. **Intellectual Property Rights –** The Supplier shall indemnify the Procuring Entity against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof.
2.2	*[If partial payment is allowed, state]* "The terms of payment shall be as follows: _____."
4	The inspections and tests that will be conducted are: *[Indicate the applicable inspections and tests]*

Section VI. Schedule of Requirements

The delivery schedule expressed as weeks/months stipulates hereafter a delivery date which is the date of delivery to the project site.

Item Number	Description	Quantity	Total	Delivered, Weeks/Months
01	**SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY DETECTOR (HPLC-PDA) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)**	Lots	2	Ninety (90) calendar days after receipt of Notice to Proceed
02	**SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY AND REFRACTIVE INDEX DETECTOR (HPLC-PDA-RID) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)**	Lot	1	Ninety (90) calendar days after receipt of Notice to Proceed
03	**SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY AND FLUORESCENCE DETECTOR (HPLC-PDA-FLD) COMPLETE WITH ALL**	Lot	1	Ninety (90) calendar days after receipt of Notice to Proceed

	NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)			
04	**SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY AND UV-VIS DETECTOR (HPLC-PDA-UV-VIS) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)**	Lot	1	Ninety (90) calendar days after receipt of Notice to Proceed
05	**SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF ULTRA HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY AND ELECTROCHEMICAL DETECTOR (UHPLC-PDA-ECD) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)**	Lot	1	Ninety (90) calendar days after receipt of Notice to Proceed

Section VII. Technical Specifications

Notes for Preparing the Technical Specifications

A set of precise and clear specifications is a prerequisite for Bidders to respond realistically and competitively to the requirements of the Procuring Entity without qualifying their Bids. In the context of Competitive Bidding, the specifications (*e.g.* production/delivery schedule, manpower requirements, and after-sales service/parts, descriptions of the lots or items) must be prepared to permit the widest possible competition and, at the same time, present a clear statement of the required standards of workmanship, materials, and performance of the goods and services to be procured. Only if this is done will the objectives of transparency, equity, efficiency, fairness, and economy in procurement be realized, responsiveness of bids be ensured, and the subsequent task of bid evaluation and post-qualification facilitated. The specifications should require that all items, materials and accessories to be included or incorporated in the goods be new, unused, and of the most recent or current models, and that they include or incorporate all recent improvements in design and materials unless otherwise provided in the Contract.

Samples of specifications from previous similar procurements are useful in this respect. The use of metric units is encouraged. Depending on the complexity of the goods and the repetitiveness of the type of procurement, it may be advantageous to standardize the General Technical Specifications and incorporate them in a separate subsection. The General Technical Specifications should cover all classes of workmanship, materials, and equipment commonly involved in manufacturing similar goods. Deletions or addenda should then adapt the General Technical Specifications to the particular procurement.

Care must be taken in drafting specifications to ensure that they are not restrictive. In the specification of standards for equipment, materials, and workmanship, recognized Philippine and international standards should be used as much as possible. Where other particular standards are used, whether national standards or other standards, the specifications should state that equipment, materials, and workmanship that meet other authoritative standards, and which ensure at least a substantially equal quality than the standards mentioned, will also be acceptable. The following clause may be inserted in the Special Conditions of Contract or the Technical Specifications.

Sample Clause: Equivalency of Standards and Codes

Wherever reference is made in the Technical Specifications to specific standards and codes to be met by the goods and materials to be furnished or tested, the provisions of the latest edition or revision of the relevant standards and codes shall apply, unless otherwise expressly stated in the Contract. Where such standards and codes are national or relate to a particular country or region, other authoritative standards that ensure substantial equivalence to the standards and codes specified will be acceptable.

Reference to brand name and catalogue number should be avoided as far as possible; where unavoidable they should always be followed by the words "*or at least equivalent*." References to brand names cannot be used when the funding source is the GOP.

Where appropriate, drawings, including site plans as required, may be furnished by the Procuring Entity with the Bidding Documents. Similarly, the Supplier may be requested to provide drawings or samples either with its Bid or for prior review by the Procuring Entity during contract execution.

Bidders are also required, as part of the technical specifications, to complete their statement of compliance demonstrating how the items comply with the specification.

Technical Specifications

Item	Specification	Statement of Compliance
		[Bidders must state here either "Comply" or "Not Comply" against each of the individual parameters of each Specification stating the corresponding performance parameter of the equipment offered. Statements of "Comply" or "Not Comply" must be supported by evidence in a Bidders Bid and cross-referenced to that evidence. Evidence shall be in the form of manufacturer's un-amended sales literature, unconditional statements of specification and compliance issued by the manufacturer, samples, independent test data etc., as appropriate. A statement that is not supported by evidence or is subsequently found to be contradicted by the evidence presented will render the Bid under evaluation liable for rejection. A statement either in the Bidder's statement of compliance or the supporting evidence that is found to be false either during Bid evaluation, post-qualification or the execution of the Contract may be regarded as fraudulent and render the Bidder or supplier liable for prosecution subject to the applicable laws and issuances.]

Technical Specifications

SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY DETECTOR (HPLC-PDA) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)

Name of the Manufacturer:		**Quantity: 2 Lots**
Brand:		**Country of Origin:**
Estimated Cost: Php 8,133,334.00		**Model:**
PURCHASER'S SPECIFICATION		**SUPPLIER'S SPECIFICATION**
This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of High Performance Liquid Chromatograph with Photodiode Array Detector complete with all necessary parts and accessories. The key applications include: analysis of pharmaceutical products.		Note: Supplier must fill-up this column item by item and that the word "as per FDA Specifications" or "Same Specifications as required by FDA" would be rejected and declared as non-responsive.
A. HPLC SYSTEM Note: Please indicate page number from the brochure submitted		
Quantity	Two (2) complete systems	
A.1 SOLVENT DELIVERY SYSTEM		
Gradient System	Low Pressure Gradient System	
Number of solvent	Up to four (4) solvents	
Degasser	Integrated or online; at least 4 chambers/channels	
Operating Flow Rate range	≥ 0.1 mL to 5 mL/min	
Maximum Operating Pressure	≥ 5000 psi (≥34.47 MPa)	
A.2 AUTOSAMPLER SYSTEM		
Sample vial capacity	At least 100 placer x 1.5 – 2 mL vials	
Injection precision	≤1.0% RSD (at varying injection volume)	
Injection volume setting range	≥ 0.1 to 100 µL	
Sample Compartment Temperature Control	≥ 4 to 35°C	
A.3 COLUMN OVEN		

Containable column size/Column capacity	≥ 2 columns (length ≥ 25 cm)	
Temperature control range	≥ -10°C from room temperature or ambient temperature to 65°C	
A.4 PHOTODIODE ARRAY DETECTOR		
Light source	Deuterium and Tungsten or D2 Arc	
Wavelength range	≥ 190nm to 800nm	
Wavelength accuracy	≤ ± 1nm	
B. INSTRUMENT CONTROL, HARDWARE AND SOFTWARE		
B.1 HARDWARE (COMPUTER SET) Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid		
● Includes branded PC ● Processor- at least Intel Core i5 2.5ghz or equivalent ● Monitor- at least 24-inches or higher LED Monitor ● Memory- 8GB DDR3 1600 ● Hard Drive-at least 256gb Solid State Drive ● Graphics Card- Separate card at least 1GB or higher ● I/O Ports- Audio jack; USB 3.0; LAN port; USB 2.0; VGA ● Network Interface- 10/1000 Mbps ● Audio- HD Audio ● Input Device- USB or wireless Keyboard and Mouse ● Includes 1 TB portable hard disk; ● with DVD writer; ● with separate graphics card (at least 1 GB); ● with USB or wireless keyboard & mouse; ● with all necessary hardware required to operate the instrument ● 1 unit USB WiFi adapter		
B.2 PRINTER Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid		

● 3-in-1 Printer (print, scan, copy) compatible with the HPLC System ● with 4 color-ink; continuous ink-tank system ● with two (2) extra sets of ink (set composed of Black, Magenta, Cyan and Yellow)	
B.3 SOFTWARE (compatible with the HPLC System) Note: Commitment Letter must be provided if brochure or other documents to verify compliance with the specifications below cannot be provided during submission of bid	
PC SOFTWARE: ● Includes software which is upgradable for networked chromatography data system and can be connected to a software that can control a wide range of analytical instruments (i.e. HPLC, UHPLC, GC) even from multi-vendor ● Latest applicable OS (Windows or equivalent), at least 64 bit ● Licensed latest MS Office Business or equivalent ● At least 1-year licensed compatible Anti-Virus ● Includes all necessary software required to operate the instrument and peripherals	
INSTRUMENT SOFTWARE: ● Must be 21 CFR Part 11 Compliant ● Must be LIMS ready ● software must be fully compatible with the computer OS ● software must be able to export information to other programs through industry standard protocols and file formats (e.g..PDF, Clipboard, ASCII, DDE and others) ● instrument software must control and display all components of the LC system including pumping, autosampler, column oven, detector/s etc. ● must have multi-level security and automated custom calculation features and must export information to other programs and file formats ● Includes system suitability ● includes all necessary software required to operate the instrument	

C. ACCESSORIES, SPARE PARTS AND CONSUMABLES Note: Please provide a list of accessories, with part numbers or catalog number, and submit brochure or webpage link to verify compliance to the requirements below, upon submission of bid. Any deviation will not be allowed.	
C.1 HPLC system tool kit set	
● One (1) set of alloy steel wrench of varying sizes depending on the equipment requirement ● One (1) pc. Adjustable wrench	
C.2 HPLC starter kit and maintenance kit	
● Two (2) pcs. Rotor seal or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Two (2) pcs. Rotor peek or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Two (2) pcs. Needle seal	
● One (1) pc. PDA lamp or D2 Arc Lamp	
C.3 HPLC COLUMNS (1 pc. each) Note: brochure and catalog number must be provided upon submission of bid	
a. Cyano based deactivated (L10) 4.6mm x 150mm, 5µm	
b. Octadecylsilane (C18) 4. mm x 150mm, 5µm	
c. Octadecylsilane (C18) 4.6mm x 250mm, 5µm	
d. Octylsilane (C8) 4.6mm x 250mm, 5µm	
e. Octylsilane (C8) 4.6mm x 150mm, 5µm	
f. Phenyl (L11) 4.6mm x 150mm, 5µm	
C.4 STANDARDS (at least one (1) bottle each) **NOTE:** *Traceability:* Standards must be traceable to NIST or equivalent international standard *Expiration:* must be current lot for USP RS; for other standards, expiration, if possible, must not be less than one (1) year upon delivery. *Certificate of analysis*: must be submitted upon delivery *Presented below are standards for Set A and Set B HPLC System. It means that Bidder should provide Set A for 1 unit HPLC and Set B for another unit of HPLC.*	

Brochure and catalog/product name must be provided upon submission of bid	
SET A: Primary Reference standards	
a. Isoniazid (CAS #54-85-3); purity of at least 99.9%, 200mg	
b. Pyridoxine HCl (CAS #58-56-0); purity of at least 99.7%, 200mg	
c. Thiamine HCl (CAS #67-03-8); purity of at least 99.8%, 500mg	
d. Itraconazole (CAS #84625-61-6); purity of at least 99.7%, 100mg	
e. Ivermectin (CAS #70288-86-7); purity of at least 90.8%, 200mg	
f. Human Insulin (CAS #11061-69-0); purity of at least 26.5 USP units, 100mg	
SET A: Pharmaceutical Secondary Standard or Certified Reference Material with minimum amount of 500mg/ bottle	
g. Ascorbic acid (CAS #50-81-7); purity of at least 95%	
h. Pyridoxine (CAS #588-56-0); purity of at least 95%	
i. Thiamine HCl (CAS #67-03-8); purity of at least 95%	
j. Ivermectin (CAS #70288-86-7) purity of at least 90%	
k. Isoniazid (CAS #54-85-3) purity of at least 95%	
SET B: Primary Reference standards	
a. N-Nitrosodiethylamine (NDMA) (CAS #62-75-9);purity at least 99.9%, 1mL	
b. Bisacodyl (CAS #603-50-9); purity of at least 99.7%, 150mg	
c. Lidocaine HCl (CAS #6108-05-0); purity of at least 93.7%, 150mg	
d. Epinephrine bitartrate (CAS #51-42-3); purity of at least 99.9%, 200mg	
e. Ephedrine HCl (CAS #50-98-6); purity of at least 99.8%, 200mg	
f. Prednisone tablets (CAS #53-03-3); at least 30 tablets	
SET B: Pharmaceutical Secondary Standard or Certified Reference Material with minimum amount of 500mg/ bottle	

g. Losartan potassium (CAS #124750-99-8); purity of at least 95%	
h. Metformin HCl (CAS #1115-70-4); purity of at least 95%	
i. Ranitidine HCl (CAS #66357-59-3); purity of at least 95%	
j. Amlodipine besylate (CAS #111470-99-6) purity of at least 95%	
k. Aspirin (CAS #50-78-2); purity of at least 95%	
C.5 One (1) complete system of Filter Assembly - 1 unit Vacuum pump (oil-free) - 1 pc. Borosilicate glass receiver (at least 4L) – 1 pc. Suction filter (funnel ≥ 90mm)	
C.6 GLASSWARES	
a. Four (4) pcs. 1000mL bottle for Mobile phase, Clear	
b. Four (4) pcs. 2000mL bottle for Mobile phase, Clear	
c. Thirty (30) pcs. 20mL Volumetric flask, Class A	
d. Thirty (30) pcs. 50mL Volumetric flask, Class A	
e. Thirty (30) pcs. 100mL Volumetric flask, Class A	
C.7 OTHER LABORATORY SUPPLIES/ CONSUMABLES	
a. At least 500 pcs. membrane filters (90mm diameter, 0.45µm pore size, hydrophilic PVDF)	
b. At least 100 pcs. Magnetic Stir Bar without pivot ring (25x5mm or 25x8mm)	
c. At least 1000 pcs. Clear Autosampler vials with septa	
d. At least 1000 pcs. Amber Autosampler vials with septa	
e. At least 1000 pcs. Syringe Filters, Hydrophilic PVDF, 0.45µm, 25mm	
f. One (1) bottle tray assembly	
D. POWER SUPPLY	
D.1 Power input 230 V or Autovolt AC, 60 Hertz	

D.2 Provision of Online UPS of suitable rating with voltage range of 230V±20%, frequency of 60Hz and capable of at least 20 minutes backup of the instrument and all its attachments. It should also have an output voltage of 230VAC, an audible alarm, LED display for parameters and built-in line conditioners for spike, swell and over voltages Note: Brochure must be provided upon submission of bid	
E. WARRANTY, AND AFTER SALES SERVICES **Note:** Commitment Letter must be provided upon submission of bid	
E.1 A minimum of one (1) year warranty on parts and services of HPLC System, minimum of one (1) year warranty on Computer Set Parts and UPS. Both commencing after successful installation by Supplier and its acceptance by FDA. During the warranty period, Supplier must repair or replace any system component on site at no charge to FDA. Labor and travel must be included in the warranty program.	
E.2 Provision of annual preventive maintenance (PM) for a period of three (3) years for the HPLC system and one (1) year for UPS, after acceptance by FDA. The PM must include at minimum the cleaning, testing, checking of various functions, and carrying out Quality Control (QC) checks and all PM parts (PM Kits) and other necessary consumables.	
E.3 Provision of a qualification package. Package must include Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), whichever is applicable.	
E.4 If upgraded software to operate the instrument is released during the warranty period, the Supplier should provide this to FDA free of charge.	

E.5 Instrument should be attended for repair by trained service personnel within 24 hours from the time fault is reported by the user. The equipment shall have to be made fully operational within 48 hours from the time the fault is reported by the user. In the event of extended down times for the instrument (> 48 hours), the warranty will be extended by the amount of time elapsed until the instrument is back in operation.	
E.6 The Supplier must provide technical support, free of charge, for software and for questions concerning maintenance, service, troubleshooting and repairs during the entire period of the warranty.	
E.7 In case there is a transfer of sole-distributor rights, the former distributor shall ensure that the warranties and after sales services given to FDA shall be honored and continued by the new distributor. **Note:** Bidder must provide Certification from the manufacturer.	
F. TESTING AND ACCEPTANCE **Note:** Commitment Letter must be provided upon submission of bid	
F.1 Acceptance testing will occur after completion of the training course and after the supplier states the system is installed and ready to perform in compliance with specifications	
F.2 If the system does not meet standard performance expectations, the Supplier will have one month to rectify the defects and clear the acceptance test, failing which, the FDA reserves the right to get the equipment replaced by FDA at no extra cost to the purchaser. The succeeding conduct of the validation/qualification shall also be the responsibility and at the cost of the Supplier	
G. TRAINING **Note:** Commitment Letter must be provided upon submission of bid	

The training should cover lectures on the theory and principles of the instrument, its applications, software applications, data processing and interpretation, as well as intensive hands-on operation. Troubleshooting, maintenance and service, including the verification of equipment's performance should also be discussed. Considering the new normal situation, lectures may be conducted virtually. However, hands-on training should be conducted at the FDA Office for at least ten (10) participants, which should be done in batches in observance of the safety protocols to prevent the spread of COVID-19 virus. The training shall be provided at no cost to the FDA If necessary, provision of free yearly refresher courses on the operations, post processing and maintenance of the instrument within 3 years from the date of installation. The refresher course is not limited to hands-on operation but may also include actual sample tests.	.
H. DOCUMENTATION **Note:** Commitment Letter must be provided upon submission of bid.	
H.1 Training certificate of Service Personnel from the manufacturer related to the installation, equipment maintenance, and troubleshooting must be provided	
H.2 Manufacturer's certificate of compliance and inspection must be provided.	
H.3 One (1) original copy and/or one electronic copy in a storage device of operating and service manuals in English must be provided.	
H.4 IQ, OQ, and PQ protocols, whichever is applicable. The protocols must provide the necessary information and test procedures required to prove that the instrument meets the specified requirements.	
H.5 Submission of IQ, OQ, and PQ reports, whichever is applicable, within five (5) working days after completion of qualification. Test data (raw data) and calibration certificates of the calibrating instruments used must be attached, whenever applicable.	
H.6 Inventory of all the deliverable components/hardware, software, spare parts, and installation accessories with their part number.	

H.7. Checklist for recommended maintenance with corresponding instructions and recommended frequency. A post PM performance check procedure to confirm that the system meets the manufacturer's performance specification must also be submitted.	
I. OTHER REQUIREMENTS **Note:** Documentary evidence must be provided upon submission of bid	
I.1 The brand must be in the market for at least ten (10) years	
I.2 Supplier must be in the Manufacturing and/or Distributing business of Liquid chromatograph for at least five (5) years.	
I.3 Supplier must submit a proof of authorization from the Manufacturer of the offered equipment. Authorization must include sales, distribution of equipment and its parts, and after sales services, at a minimum.	
I.4 Provide certification of availability and continuity of spare parts for at least 5 years after delivery	
I.5 The supplier must have at least ten (10) local installations of HPLC that can be viewed and demo to the end user, if necessary. Two (2) out of ten (10) local installations must be the same model as the one being offered. **Note:** Upon submission of bid, the bidder must submit a list of companies with installed units. Contact person and contact details (telephone number/mobile number and e-mail address) for each listed company must also be submitted.	
J. DELIVERY PERIOD	
Not more than ninety (90) calendar days upon receipt of Notice to Proceed. To be delivered at FDA-ATQAL, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City.	

Technical Specifications

SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY AND REFRACTIVE INDEX DETECTOR (HPLC-PDA-RID) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)

Name of the Manufacturer:		**Quantity: 1 Lot**
Brand:		**Country of Origin:**
Estimated Cost: Php 6,050,000.00		**Model:**
PURCHASER'S SPECIFICATION		**SUPPLIER'S SPECIFICATION**
This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of High Performance Liquid Chromatograph with Photodiode Array and Refractive Index Detector (HPLC-PDA-RID) complete with all necessary parts and accessories. The key applications include: analysis of pharmaceutical products.		Note: Supplier must fill-up this column item by item and that the word "as per FDA Specifications" or "Same Specifications as required by FDA" would be rejected and declared as non-responsive.
A. HPLC SYSTEM Note: Please indicate page number from the brochure submitted		
A.1 SOLVENT DELIVERY SYSTEM		
Gradient System	Low Pressure Gradient System	
Number of solvent	Up to four (4) solvents	
Degasser	Integrated or online; at least 4 chambers/channels	
Operating Flowrate range	≥ 0.1 mL to 5 mL/min	
Maximum Operating Pressure	≥ 5000 psi (≥ 34.47 MPa)	
A.2 AUTOSAMPLER SYSTEM		
Sample vial capacity	At least 100 placer x 1.5 – 2 mL vials	
Injection precision	≤1.0% RSD (at varying injection volume)	
Injection volume setting range	≥ 0.1 to 100 µL	
Sample Compartment Temperature Control	≥ 4 to 35°C	
A.3 COLUMN OVEN		

Containable column size/Column capacity	≥ 2 columns (length ≥ 25 cm)	
Temperature control range	≥ −10°C from room temperature or ambient temperature to 65°C	
A.4 PHOTODIODE ARRAY DETECTOR		
Light source	Deuterium and Tungsten or D2 Arc	
Wavelength range	≥ 190nm to 800nm	
Wavelength accuracy	≤ ± lnm	
A.5 REFRACTIVE INDEX DETECTOR		
Refractive Index range	≥ 1.00 to 1.75 RIU	
Noise	≤ 2.5 x 10^{-9} RIU	
Drift	≤ 2.0 x 10^{-7} RIU/hr	
B. INSTRUMENT CONTROL, HARDWARE AND SOFTWARE		
B.1 HARDWARE (COMPUTER SET) Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid		
● Includes branded PC ● Processor- at least Intel Core i5 2.5ghz or equivalent ● Monitor- at least 24-inches or higher LED Monitor ● Memory- 8GB DDR3 1600 ● Hard Drive-at least 256gb Solid State Drive ● Graphics Card- Separate card at least 1GB or higher ● I/O Ports- Audio jack; USB 3.0; LAN port; USB 2.0; VGA ● Network Interface- 10/1000 Mbps ● Audio- HD Audio ● Input Device- USB or wireless Keyboard and Mouse ● Includes 1 TB portable hard disk; ● with DVD writer; ● with separate graphics card (at least 1 GB); ● with USB or wireless keyboard & mouse; ● with all necessary hardware required to operate the instrument ● 1 unit USB WiFi adapter		

B.2 PRINTER Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid	
● 3-in-1 Printer (print, scan, copy) compatible with the HPLC System ● with 4 color-ink; continuous ink-tank system ● with two (2) extra sets of ink (set composed of Black, Magenta, Cyan and Yellow)	
B.3 SOFTWARE (compatible with the HPLC System) Note: Commitment Letter must be provided if brochure or other documents to verify compliance with the specifications below cannot be provided during submission of bid	
PC SOFTWARE: ● Includes software which is upgradable for networked chromatography data system and can be connected to a software that can control a wide range of analytical instruments (i.e. HPLC, UHPLC, GC) even from multi-vendor ● Latest applicable OS (Windows or equivalent), at least 64 bit ● Licensed latest MS Office Business or equivalent ● At least 1-year licensed compatible Anti-Virus ● Includes all necessary software required to operate the instrument and peripherals	

INSTRUMENT SOFTWARE: ● Must be 21 CFR Part 11 Compliant ● Must be LIMS ready ● software must be fully compatible with the computer OS ● software must be able to export information to other programs through industry standard protocols and file formats (e.g..PDF, Clipboard, ASCII, DDE and others) ● instrument software must control and display all components of the LC system including pumping, autosampler, column oven, detector/s etc. ● must have multi-level security and automated custom calculation features and must export information to other programs and file formats ● Includes system suitability ● includes all necessary software required to operate the instrument	
C. ACCESSORIES, SPARE PARTS AND CONSUMABLES Note: Please provide a list of accessories, with part numbers or catalog number, and submit brochure or webpage link to verify compliance to the requirements below, upon submission of bid. Any deviation will not be allowed.	
C.1 HPLC system tool kit set	
● One (1) set of alloy steel wrench of varying sizes depending on the equipment requirement ● One (1) pc. Adjustable wrench	
C.2 HPLC starter kit and maintenance kit	
● Four (4) pcs. Rotor seal or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Four (4) pcs. Rotor peek or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Four (4) pcs. Needle seal	
● One (1) pc. PDA lamp or D2 Arc Lamp	
C.3 HPLC COLUMNS (1 pc. each) Note: brochure and catalog number must be provided upon submission of bid	

a. L1 4.0mm x 250mm, 10µm	
b. L1 4.0mm x 300mm, 10µm	
c. L1 3.9mm x 300mm, 10µm	
d. L44 4.6mm x 300mm (any particle size is allowed)	
e. L11 4.0mm x 300mm (any particle size is allowed)	
f. L15 4.6mm x 150mm, 5µm	
g. L21 4.6mm x 250mm (any particle size is allowed)	
h. L11 4.6mm x 150mm, 3µm	
i. L67 4.6mm x 150mm, 5µm	
j. L1 4.6mm x 250mm, 5µm base-deactivated (must include a pH range of 7-10)	
k. L10 4.6mm x 150mm, 5µm base-deactivated (must include a pH range of 6-8)	
C.5 One (1) complete system of Filter Assembly - 1 unit Vacuum pump (oil-free) - 1 pc. Borosilicate glass receiver (at least 4L) – 1 pc. Suction filter (funnel ≥ 90mm)	
C.6 GLASSWARES	
a. Two (2) pcs. 1000mL bottle for Mobile phase, Clear	
b. Four (4) pcs. 2000mL bottle for Mobile phase, Clear	
c. Thirty (30) pcs. 0.5mL Volumetric pipette, Class A, with Calibration Certificate	
d. Thirty (30) pcs. 1mL Volumetric pipette, Class A, with Calibration Certificate	
e. Fifty (50) pcs. 4mL Volumetric pipette, Class A, with Calibration Certificate	
f. Fifty (50) pcs. 5mL Volumetric pipette, Class A, with Calibration Certificate	
g. Thirty (30) pcs. 6mL Volumetric pipette, Class A, with Calibration Certificate	
C.7 OTHER LABORATORY SUPPLIES/ CONSUMABLES	
a. At least 300 pcs. membrane filters (90mm diameter, 0.45µm pore size, hydrophilic PVDF) compatible with the size of suction filter funnel	

b. At least 100 pcs. Magnetic Stir Bar without pivot ring (25x5mm or 25x8mm)	
c. At least 1000 pcs. Clear Autosampler vials with septa	
d. At least 1000 pcs. Amber Autosampler vials with septa	
e. At least 1000 pcs. Syringe Filters, Hydrophilic PVDF, 0.45µm, 25mm	
f. One (1) bottle tray assembly	
C.8 One (1) unit Benchtop pH Meter - Power input: 220-230V; 60Hz – pH range: ≥ 2 to 14; Resolution: pH=0.01 – Temperature range: ≥ 0 to 60°C; Resolution=0.1°C – Number of Calibration points: ≥ 3 points - Display: at least LCD with backlight - with at least one (1) pc. glass electrode	
C.9 One (1) unit Small Volume Stirrer - Power input: 220-230V; 60Hz - Number of stirring position: ≥ 10 - Stirring volume (H_2O): ≥ 300mL - Speed range: ≥ 0 to 1000rpm	
C.10 Two (2) units Branded Data Logger – Temperature measurement range: ≥ –10 to 40°C – Temperature resolution: ≤ 0.1°C – Hygrometer measurement range: ≥ 25 to 90% – Hygrometer resolution: ≤ 1% - can be wall mounted or with stand - battery operated (AA or AAA); better if rechargeable - with USB connector for transfer of data - with alarms if close to specified limits	
C.11 One (1) unit Laboratory Mill with separate Grind Container – Speed range: ≥ 20,000rpm – capacity: ≥ 500mL	
D. POWER SUPPLY	
D.1 Power input 230 V or Autovolt AC, 60 Hertz	

D.2 Provision of Online UPS of suitable rating with voltage range of 230V±20%, frequency of 60Hz and capable of at least 20 minutes backup of the instrument and all its attachments. It should also have an output voltage of 230VAC, an audible alarm, LED display for parameters and built-in line conditioners for spike, swell and over voltages **Note:** Brochure must be provided upon submission of bid	
E. WARRANTY, AND AFTER SALES SERVICES **Note:** Commitment Letter must be provided upon submission of bid	
E.1 A minimum of one (1) year warranty on parts and services of HPLC System, minimum of one (1) year warranty on Computer Set Parts and UPS. Both commencing after successful installation by Supplier and its acceptance by FDA. During the warranty period, Supplier must repair or replace any system component on site at no charge to FDA. Labor and travel must be included in the warranty program.	
E.2 Provision of annual preventive maintenance (PM) for a period of three (3) years for the HPLC system and one (1) year for UPS, after acceptance by FDA. The PM must include at minimum the cleaning, testing, checking of various functions, and carrying out Quality Control (QC) checks and all PM parts (PM Kits) and other necessary consumables.	
E.3 Provision of a qualification package. Package must include Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), whichever is applicable.	
E.4 If upgraded software to operate the instrument is released during the warranty period, the Supplier should provide this to FDA free of charge.	

E.5 Instrument should be attended for repair by trained service personnel within 24 hours from the time fault is reported by the user. The equipment shall have to be made fully operational within 48 hours from the time the fault is reported by the user. In the event of extended down times for the instrument (> 48 hours), the warranty will be extended by the amount of time elapsed until the instrument is back in operation.	
E.6 The Supplier must provide technical support, free of charge, for software and for questions concerning maintenance, service, troubleshooting and repairs during the entire period of the warranty.	
E.7 In case there is a transfer of sole-distributor rights, the former distributor shall ensure that the warranties and after sales services given to FDA shall be honored and continued by the new distributor. **Note:** Bidder must provide Certification from the manufacturer.	
F. TESTING AND ACCEPTANCE **Note:** Commitment Letter must be provided upon submission of bid	
F.1 Acceptance testing will occur after completion of the training course and after the supplier states the system is installed and ready to perform in compliance with specifications	
F.2 If the system does not meet standard performance expectations, the Supplier will have one month to rectify the defects and clear the acceptance test, failing which, the FDA reserves the right to get the equipment replaced by FDA at no extra cost to the purchaser. The succeeding conduct of the validation/qualification shall also be the responsibility and at the cost of the Supplier	
G. TRAINING **Note:** Commitment Letter must be provided upon submission of bid	

The training should cover lectures on the theory and principles of the instrument, its applications, software applications, data processing and interpretation, as well as intensive hands-on operation. Troubleshooting, maintenance and service, including the verification of equipment's performance should also be discussed. Considering the new normal situation, lectures may be conducted virtually. However, hands-on training should be conducted at the FDA Office for at least ten (10) participants, which should be done in batches in observance of the safety protocols to prevent the spread of COVID-19 virus. The training shall be provided at no cost to the FDA If necessary, provision of free yearly refresher courses on the operations, post processing and maintenance of the instrument within 3 years from the date of installation. The refresher course is not limited to hands-on operation but may also include actual sample tests.	.
H. DOCUMENTATION **Note:** Commitment Letter must be provided upon submission of bid.	
H.1 Training certificate of Service Personnel from the manufacturer related to the installation, equipment maintenance, and troubleshooting must be provided	
H.2 Manufacturer's certificate of compliance and inspection must be provided.	
H.3 One (1) original copy and/or one electronic copy in a storage device of operating and service manuals in English must be provided.	
H.4 IQ, OQ, and PQ protocols, whichever is applicable. The protocols must provide the necessary information and test procedures required to prove that the instrument meets the specified requirements.	
H.5 Submission of IQ, OQ, and PQ reports, whichever is applicable, within five (5) working days after completion of qualification. Test data (raw data) and calibration certificates of the calibrating instruments used must be attached, whenever applicable.	
H.6 Inventory of all the deliverable components/hardware, software, spare parts, and installation accessories with their part number.	

H.7. Checklist for recommended maintenance with corresponding instructions and recommended frequency. A post PM performance check procedure to confirm that the system meets the manufacturer's performance specification must also be submitted.	
I. OTHER REQUIREMENTS **Note:** Commitment Letter or any other documentary evidence must be provided upon submission of bid	
I.1 The brand must be in the market for at least ten (10) years	
I.2 Supplier must be in the Manufacturing and/or Distributing business of Liquid chromatograph for at least five (5) years.	
I.3 Supplier must submit a proof of authorization from the Manufacturer of the offered equipment. Authorization must include sales, distribution of equipment and its parts, and after sales services, at a minimum.	
I.4 Provide certification of availability and continuity of spare parts for at least 5 years after delivery	
I.5 The supplier must have at least ten (10) local installations of HPLC that can be viewed and demo to the end user, if necessary. Two (2) out of ten (10) local installations must be the same model as the one being offered. **Note:** Upon submission of bid, the bidder must submit a list of companies with installed units. Contact person and contact details (telephone number/mobile number and e-mail address) for each listed company must also be submitted.	
J. DELIVERY PERIOD	
Not more than ninety (90) calendar days upon receipt of Notice to Proceed. To be delivered at FDA-ATQAL, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City.	

Technical Specifications

SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY AND FLUORESCENCE DETECTOR (HPLC-PDA-FLD) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)

Name of the Manufacturer:		**Quantity: 1 Lot**
Brand:		**Country of Origin:**
Estimated Cost: Php 6,248,784.00		**Model:**
PURCHASER'S SPECIFICATION		**SUPPLIER'S SPECIFICATION**
This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of High Performance Liquid Chromatograph with Photodiode Array and Fluorescence Detector complete with all necessary parts and accessories. The key applications include: analysis of contaminants in child-care articles, household urban pesticides and other matrices.		Note: Supplier must fill-up this column item by item and that the word "as per FDA Specifications" or "Same Specifications as required by FDA" would be rejected and declared as non-responsive.
A. HPLC SYSTEM Note: Please indicate page number from the brochure submitted		
A.1 SOLVENT DELIVERY SYSTEM		
Gradient System	Low Pressure Gradient System	
Number of solvent	Up to four (4) solvents	
Degasser	Integrated or online; at least 4 chambers/channels	
Operating Flow rate range	≥ 0.1mL to 5mL/min	
Maximum Operating pressure	≥ 5000psi (≥ 34.47 MPa)	
A.2 AUTOSAMPLER SYSTEM		
Sample vial capacity	≥ 100 placer x 1.5 – 2mL vials	
Injection precision	≤1.0% RSD (at varying injection volume)	
Sample compartment Temperature setting range	≥ 4 to 35°C	
Injection Volume setting range	≥ 0.1 to 100µL	

A.3 COLUMN OVEN		
Containable column size/ Column capacity	≥ 2 columns (length ≥ 25cm)	
Temperature control range	≥ −10°C from room temperature or ambient temperature to 65°C	
A.4 PHOTODIODE ARRAY DETECTOR		
Light source	Deuterium and Tungsten or Deuterium Arc Lamp	
Wavelength range	≥ 190nm to 800nm	
Wavelength accuracy	≤ ± lnm	
A.5 MULTIWAVELENGTH FLUORESCENCE DETECTOR		
Light source	Xenon lamp or Xenon Arc lamp or Xenon Flash lamp	
Wavelength range	≥ 200 − 700nm	
Wavelength Accuracy	≤ ± 3 nm	
B. INSTRUMENT CONTROL, HARDWARE AND SOFTWARE		
B.1 HARDWARE (COMPUTER SET) Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid		

● Includes branded PC ● Processor- at least Intel Core i5 2.5ghz or equivalent ● Monitor- at least 24-inches or higher LED Monitor ● Memory- 8GB DDR3 1600 ● Hard Drive-at least 256gb Solid State Drive ● Graphics Card- Separate card at least 1GB or higher ● I/O Ports- Audio jack; USB 3.0; LAN port; USB 2.0; VGA ● Network Interface- 10/1000 Mbps ● Audio- HD Audio ● Input Device- USB or wireless Keyboard and Mouse ● Includes 1 TB portable hard disk; ● with DVD writer; ● with separate graphics card (at least 1 GB); ● with USB or wireless keyboard & mouse; ● with all necessary hardware required to operate the instrument ● 1 unit USB WiFi adapter	
B.2 PRINTER Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid	
● 3-in-1 Printer (print, scan, copy) compatible with the HPLC System ● with 4 color-ink; continuous ink-tank system ● with two (2) extra sets of ink (set composed of Black, Magenta, Cyan and Yellow)	
B.3 SOFTWARE (compatible with the HPLC System) Note: Commitment Letter must be provided if brochure or other documents to verify compliance with the specifications below cannot be provided during submission of bid	

PC SOFTWARE: ● Includes software which is upgradable for networked chromatography data system and can be connected to a software that can control a wide range of analytical instruments (i.e. HPLC, UHPLC, GC) even from multi-vendor ● Latest applicable OS (Windows or equivalent), at least 64 bit ● Licensed latest MS Office Business or equivalent ● At least 1-year licensed compatible Anti-Virus ● Includes all necessary software required to operate the instrument and peripherals	
INSTRUMENT SOFTWARE: ● Must be 21 CFR Part 11 Compliant ● Must be LIMS ready ● software must be fully compatible with the computer OS ● software must be able to export information to other programs through industry standard protocols and file formats (e.g..PDF, Clipboard, ASCII, DDE and others) ● instrument software must control and display all components of the LC system including pumping, autosampler, column oven, detector/s etc. ● must have multi-level security and automated custom calculation features and must export information to other programs and file formats ● Includes system suitability ● includes all necessary software required to operate the instrument	
C. ACCESSORIES, SPARE PARTS AND CONSUMABLES Note: Please provide a list of accessories, with part numbers or catalog number, and submit brochure or webpage link to verify compliance to the requirements below, upon submission of bid. Any deviation will not be allowed.	
C.1 HPLC system tool kit set	

● One (1) set of alloy steel wrench of varying sizes depending on the equipment requirement ● One (1) pc. Adjustable wrench	
C.2 HPLC starter kit and maintenance kit	
● Four (4) pcs. Rotor seal or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Four (4) pcs. Rotor peek or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Four (4) pcs. Needle seal	
● One (1) pc. PDA lamp	
C.3 HPLC COLUMNS (1 pc. each) Note: brochure and catalog number must be provided upon submission of bid	
a. L10 4.6mm x 150mm, 5µm	
b. Octadecylsilane (C18) 4.6mm x 150mm, 5µm	
c. Octadecylsilane (C18) 4.6mm x 250mm, 5µm	
C.4 STANDARDS (at least two (2) bottles) **NOTE:** *Traceability:* **S**tandards must be traceable to NIST or equivalent international standard *Expiration:* must be current lot for USP RS; for other standards, expiration, if possible, must not be less than one (1) year upon delivery. *Certificate of analysis*: must be submitted upon delivery **Brochure and catalog/product name must be provided upon submission of bid**	
a. Bisphenol A (CAS #80-05-7); 99% purity, 50g/bottle	
C.5 One (1) complete system of Filter Assembly - 1 unit Vacuum pump (oil-free) - 1 pc. Borosilicate glass receiver (at least 4L) – 1 pc. Suction filter (funnel ≥ 90mm)	
C.6 GLASSWARES	
a. Four (4) pcs. 1000mL bottle for Mobile phase, Clear	
b. Four (4) pcs. 2000mL bottle for Mobile phase, Clear	

c. Fifty (50) pcs. 20mL Volumetric pipette, Class A	
d. Fifty (50) pcs. 50mL Evaporating dish, Round bottom, porcelain	
e. Thirty (30) pcs. 100mL Volumetric flask, Clear, Class A	
C.7 OTHER LABORATORY SUPPLIES/ CONSUMABLES	
a. At least 500 pcs. membrane filters (90mm diameter, 0.45 µm pore size, hydrophilic PVDF)	
b. At least 100 pcs. Magnetic Stir Bar without pivot ring (25mm x 5mm)	
c. At least 500 pcs. Clear Autosampler vials with septa	
d. At least 500 pcs. Amber Autosampler vials with septa	
e. At least 1000 pcs. Syringe Filters, Hydrophilic PVDF 0.45µm, 25mm	
f. One (1) bottle tray assembly	
D. POWER SUPPLY	
D.1 Power input 230 V or Autovolt AC, 60 Hertz	
D.2 Provision of Online UPS of suitable rating with voltage range of 230V±20%, frequency of 60Hz and capable of at least 20 minutes backup of the instrument and all its attachments. It should also have an output voltage of 230VAC, an audible alarm, LED display for parameters and built-in line conditioners for spike, swell and over voltages **Note:** Brochure must be provided upon submission of bid	
E. WARRANTY, AND AFTER SALES SERVICES **Note:** Commitment Letter must be provided upon submission of bid	
E.1 A minimum of one (1) year warranty on parts and services of HPLC System, minimum of one (1) year warranty on Computer Set Parts and UPS. Both commencing after successful installation by Supplier and its acceptance by FDA. During the warranty period, Suppliers must repair or replace any system component on site at no charge to FDA. Labor and travel must be included in the warranty program.	

E.2 Provision of annual preventive maintenance (PM) for a period of three (3) years for the HPLC system and one (1) year for UPS, after acceptance by FDA. The PM must include at minimum the cleaning, testing, checking of various functions, and carrying out Quality Control (QC) checks and all PM parts (PM Kits) and other necessary consumables.	
E.3 Provision of a qualification package. Package must include Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), whichever is applicable.	
E.4 If upgraded software to operate the instrument is released during the warranty period, the Supplier should provide this to FDA free of charge.	
E.5 Instrument should be attended for repair by trained service personnel within 24 hours from the time fault is reported by the user. The equipment shall have to be made fully operational within 48 hours from the time the fault is reported by the user. In the event of extended down times for the instrument (> 48 hours), the warranty will be extended by the amount of time elapsed until the instrument is back in operation.	
E.6 The Supplier must provide technical support, free of charge, for software and for questions concerning maintenance, service, troubleshooting and repairs during the entire period of the warranty.	
E.7 In case there is a transfer of sole-distributor rights, the former distributor shall ensure that the warranties and after-sales services given to FDA shall be honored and continued by the new distributor. **Note:** Bidder must provide Certification from the manufacturer.	
F. TESTING AND ACCEPTANCE **Note:** Commitment Letter must be provided upon submission of bid	
F.1 Acceptance testing will occur after completion of the training course and after the supplier states the system is installed and ready to perform in compliance with specifications	

F.2 If the system does not meet standard performance expectations, the Supplier will have one month to rectify the defects and clear the acceptance test, failing which, the FDA reserves the right to get the equipment replaced by FDA at no extra cost to the purchaser. The succeeding conduct of the validation/qualification shall also be the responsibility and at the cost of the Supplier	
G. TRAINING **Note:** Commitment Letter must be provided upon submission of bid	
The training should cover lectures on the theory and principles of the instrument, its applications, software applications, data processing and interpretation, as well as intensive hands-on operation. Troubleshooting, maintenance and service, including the verification of equipment's performance should also be discussed. Considering the new normal situation, lectures may be conducted virtually. However, hands-on training should be conducted at the FDA Office for at least ten (10) participants, which should be done in batches in observance of the safety protocols to prevent the spread of COVID-19 virus. The training shall be provided at no cost to the FDA If necessary, provision of free yearly refresher courses on the operations, post processing and maintenance of the instrument within 3 years from the date of installation. The refresher course is not limited to hands-on operation but may also include actual sample tests.	.
H. DOCUMENTATION **Note:** Commitment Letter must be provided upon submission of bid.	
H.1 Training certificate of Service Personnel from the manufacturer related to the installation, equipment maintenance, and troubleshooting must be provided	
H.2 Manufacturer's certificate of compliance and inspection must be provided.	
H.3 One (1) original copy and/or one electronic copy in a storage device of operating and service manuals in English must be provided.	

H.4 IQ, OQ, and PQ protocols, whichever is applicable. The protocols must provide the necessary information and test procedures required to prove that the instrument meets the specified requirements.	
H.5 Submission of IQ, OQ, and PQ reports, whichever is applicable, within five (5) working days after completion of qualification. Test data (raw data) and calibration certificates of the calibrating instruments used must be attached, whenever applicable.	
H.6 Inventory of all the deliverable components/hardware, software, spare parts, and installation accessories with their part number.	
H.7. Checklist for recommended maintenance with corresponding instructions and recommended frequency. A post PM performance check procedure to confirm that the system meets the manufacturer's performance specification must also be submitted.	
I. OTHER REQUIREMENTS **Note:** Commitment Letter or any other documentary evidence must be provided upon submission of bid	
I.1 The brand must be in the market for at least ten (10) years	
I.2 Supplier must be in the Manufacturing and/or Distributing business of Liquid chromatograph for at least five (5) years.	
I.3 Supplier must submit a proof of authorization from the Manufacturer of the offered equipment. Authorization must include sales, distribution of equipment and its parts, and after sales services, at a minimum.	
I.4 Provide certification of availability and continuity of spare parts for at least 5 years after delivery	
I.5 The supplier must have at least ten (10) local installations of HPLC that can be viewed and demo to the end user, if necessary. Two (2) out of ten (10) local installations must be the same model as the one being offered. **Note:** Upon submission of bid, the bidder must submit a list of companies with installed units. Contact person and contact details (telephone number/mobile number and e-mail address) for each listed company must also be submitted.	

J. DELIVERY PERIOD	
Not more than ninety (90) calendar days upon receipt of Notice to Proceed. To be delivered at FDA-ATQAL, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City.	

Technical Specifications

SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY AND UV-VIS DETECTOR (HPLC-PDA-UV-VIS) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)

Name of the Manufacturer:		**Quantity: 1 Lot**
Brand:		**Country of Origin:**
Estimated Cost: Php 4,204,500.00		**Model:**
PURCHASER'S SPECIFICATION		**SUPPLIER'S SPECIFICATION**
This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of High Performance Liquid Chromatograph with Photodiode Array and UV-Vis Detector complete with all necessary parts and accessories. The key applications include: analysis of reference standards.		Note: Supplier must fill-up this column item by item and that the word "as per FDA Specifications" or "Same Specifications as required by FDA" would be rejected and declared as non-responsive.
A. HPLC SYSTEM Note: Please indicate page number from the brochure submitted		
A.1 SOLVENT DELIVERY SYSTEM		
Gradient System	Low Pressure Gradient System	
Number of solvent	Up to four (4) solvents	
Degasser	Integrated or online; at least 4 chambers/channels	
Operating Flow rate range	≥ 0.1mL to 5mL/min	
Maximum operating pressure	≥ 5000psi (≥ 34.47MPa)	
A.2 AUTOSAMPLER SYSTEM		
Sample vial capacity	≥ 100 placer x 1.5 – 2mL vials	
Injection precision	≤1.0% RSD (at varying injection volume)	
Sample compartment temperature setting range	≥ 4 to 35°C in ≤ 1°C increment	
Sample injection volume	≥ 0.1 to 100µL	
A.3 COLUMN OVEN		

Containable column size/ Column capacity	≥ 2 columns (length ≥ 25cm)	
Temperature control range	≥ −10°C from room temperature or ambient temperature to 65°C	
A.4 PHOTODIODE ARRAY DETECTOR		
Light source	Deuterium and Tungsten or Deuterium Arc Lamp or equivalent	
Wavelength range	≥ 190nm to 800nm	
Wavelength accuracy	≤ ± 1nm	
A.5 UV-Vis DETECTOR		
Light source	Deuterium Lamp or equivalent	
Wavelength range	≥ 190nm to 600nm	
Wavelength accuracy	≤ ± 1nm	
B. INSTRUMENT CONTROL, HARDWARE AND SOFTWARE		
B.1 HARDWARE (COMPUTER SET) Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid		
● Includes branded PC ● Processor- at least Intel Core i5 2.5ghz or equivalent ● Monitor- at least 24-inches or higher LED Monitor ● Memory- 8GB DDR3 1600 ● Hard Drive-at least 256gb Solid State Drive ● Graphics Card- Separate card at least 1GB or higher ● I/O Ports- Audio jack; USB 3.0; LAN port; USB 2.0; VGA ● Network Interface- 10/1000 Mbps ● Audio- HD Audio ● Input Device- USB or wireless Keyboard and Mouse ● Includes 1 TB portable hard disk; ● with DVD writer; ● with separate graphics card (at least 1 GB); ● with USB or wireless keyboard & mouse;		

● with all necessary hardware required to operate the instrument ● 1 unit USB WiFi adapter	
B.2 PRINTER Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid	
● 3-in-1 Printer (print, scan, copy) compatible with the HPLC System ● with 4 color-ink; continuous ink-tank system ● with two (2) extra sets of ink (set composed of Black, Magenta, Cyan and Yellow)	
B.3 SOFTWARE (compatible with the HPLC System) Note: Commitment Letter must be provided if brochure or other documents to verify compliance with the specifications below cannot be provided during submission of bid	
PC SOFTWARE: ● Includes software which is upgradable for networked chromatography data system and can be connected to a software that can control a wide range of analytical instruments (i.e. HPLC, UHPLC, GC) even from multi-vendor ● Latest applicable OS (Windows or equivalent), at least 64 bit ● Licensed latest MS Office Business or equivalent ● At least 1-year licensed compatible Anti-Virus ● Includes all necessary software required to operate the instrument and peripherals	

INSTRUMENT SOFTWARE: ● Must be 21 CFR Part 11 Compliant ● Must be LIMS ready ● software must be fully compatible with the computer OS ● software must be able to export information to other programs through industry standard protocols and file formats (e.g..PDF, Clipboard, ASCII, DDE and others) ● instrument software must control and display all components of the LC system including pumping, autosampler, column oven, detector/s etc. ● must have multi-level security and automated custom calculation features and must export information to other programs and file formats ● Includes system suitability ● includes all necessary software required to operate the instrument	
C. ACCESSORIES, SPARE PARTS AND CONSUMABLES Note: Please provide a list of accessories, with part numbers or catalog number, and submit brochure or webpage link to verify compliance to the requirements below, upon submission of bid. Any deviation will not be allowed.	
C.1 HPLC system tool kit set	
● One (1) set of alloy steel wrench of varying sizes depending on the equipment requirement ● One (1) pc. Adjustable wrench	
C.2 HPLC starter kit and maintenance kit	
● Two (2) pcs. Rotor seal or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Two (2) pcs. Rotor peek or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Two (2) pcs. Needle seal	
● One (1) pc. PDA Detector Lamp	
● One (1) pc. UV-Vis Detector Lamp	

C.3 HPLC COLUMNS (1 pc. each) Note: brochure and catalog number must be provided upon submission of bid	
a. L1 3.9mm x 30cm, 5µm	
b. L1 4.0mm x 25cm, 5µm	
c. L1 4.6mm x 5cm, 3µm	
d. L1 4.6mm x 10cm, 5µm	
e. L1 4.6mm x 15cm, 5µm	
f. L1 4.6mm x 20cm, 5µm	
g. L1 4.6mmx 25cm, 5µm	
h. L1 4.6mm x 30cm, 5µm	
i. L3 4.0mm x 25cm, 5µm	
j. L3 6.0mm x 5.0cm, 5µm	
k. L7 (end-capped) 4.6mm x 25cm, 5µm	
l. L7 4.6mm x 25cm, 5µm	
m. L13 4.6mm x 25cm, 5µm	
n. L60 4.6mm x 15cm, 3µm	
C.7 OTHER LABORATORY SUPPLIES/ CONSUMABLES	
a. At least 300 pcs. membrane filters (47mm diameter, 0.45 µm pore size, Nylon)	
b. At least 500 pcs. Clear Autosampler vials with septa	
c. At least 500 pcs. Amber Autosampler vials with septa	
d. At least 500 pcs. Syringe Filters, Nylon, 0.45µm, 25-33mm diameter	
e. One (1) bottle tray assembly	
D. POWER SUPPLY	
D.1 Power input 230 V or Autovolt AC, 60 Hertz	
D.2 Provision of Online UPS of suitable rating with voltage range of 230V±20%, frequency of 60Hz and capable of at least 20 minutes backup of the instrument and all its attachments. It should also have an output voltage of 230VAC, an audible alarm, LED display for parameters and built-in line conditioners for spike, swell and over voltages **Note:** Brochure must be provided upon submission of bid	
E. WARRANTY, AND AFTER SALES SERVICES **Note:** Commitment Letter must be provided upon submission of bid	

E.1 A minimum of one (1) year warranty on parts and services of HPLC System, minimum of one (1) year warranty on Computer Set Parts and UPS. Both commencing after successful installation by Supplier and its acceptance by FDA. During the warranty period, Supplier must repair or replace any system component on site at no charge to FDA. Labor and travel must be included in the warranty program.	
E.2 Provision of annual preventive maintenance (PM) for a period of three (3) years for the HPLC system and one (1) year for UPS, after acceptance by FDA. The PM must include at minimum the cleaning, testing, checking of various functions, and carrying out Quality Control (QC) checks and all PM parts (PM Kits) and other necessary consumables.	
E.3 Provision of a qualification package. Package must include Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), whichever is applicable.	
E.4 If upgraded software to operate the instrument is released during the warranty period, the Supplier should provide this to FDA free of charge.	
E.5 Instrument should be attended for repair by trained service personnel within 24 hours from the time fault is reported by the user. The equipment shall have to be made fully operational within 48 hours from the time the fault is reported by the user. In the event of extended down times for the instrument (> 48 hours), the warranty will be extended by the amount of time elapsed until the instrument is back in operation.	
E.6 The Supplier must provide technical support, free of charge, for software and for questions concerning maintenance, service, troubleshooting and repairs during the entire period of the warranty.	
E.7 In case there is a transfer of sole-distributor rights, the former distributor shall ensure that the warranties and after sales services given to FDA shall be honored and continued by the new distributor. **Note:** Bidder must provide Certification from the manufacturer.	
F. TESTING AND ACCEPTANCE	

Note: Commitment Letter must be provided upon submission of bid	
F.1 Acceptance testing will occur after completion of the training course and after the supplier states the system is installed and ready to perform in compliance with specifications	
F.2 If the system does not meet standard performance expectations, the Supplier will have one month to rectify the defects and clear the acceptance test, failing which, the FDA reserves the right to get the equipment replaced by FDA at no extra cost to the purchaser. The succeeding conduct of the validation/qualification shall also be the responsibility and at the cost of the Supplier	
G. TRAINING **Note:** Commitment Letter must be provided upon submission of bid	
The training should cover lectures on the theory and principles of the instrument, its applications, software applications, data processing and interpretation, as well as intensive hands-on operation. Troubleshooting, maintenance and service, including the verification of equipment's performance should also be discussed. Considering the new normal situation, lectures may be conducted virtually. However, hands-on training should be conducted at the FDA Office for at least ten (10) participants, which should be done in batches in observance of the safety protocols to prevent the spread of COVID-19 virus. The training shall be provided at no cost to the FDA If necessary, provision of free yearly refresher courses on the operations, post processing and maintenance of the instrument within 3 years from the date of installation. The refresher course is not limited to hands-on operation but may also include actual sample tests.	.
H. DOCUMENTATION **Note:** Commitment Letter must be provided upon submission of bid.	
H.1 Training certificate of Service Personnel from the manufacturer related to the installation, equipment maintenance, and troubleshooting must be provided	
H.2 Manufacturer's certificate of compliance and inspection must be provided.	

H.3 One (1) original copy and/or one electronic copy in a storage device of operating and service manuals in English must be provided.	
H.4 IQ, OQ, and PQ protocols, whichever is applicable. The protocols must provide the necessary information and test procedures required to prove that the instrument meets the specified requirements.	
H.5 Submission of IQ, OQ, and PQ reports, whichever is applicable, within five (5) working days after completion of qualification. Test data (raw data) and calibration certificates of the calibrating instruments used must be attached, whenever applicable.	
H.6 Inventory of all the deliverable components/hardware, software, spare parts, and installation accessories with their part number.	
H.7. Checklist for recommended maintenance with corresponding instructions and recommended frequency. A post PM performance check procedures to confirm that the system meets the manufacturer's performance specification must also be submitted.	
I. OTHER REQUIREMENTS **Note:** Commitment Letter or any other documentary evidence must be provided upon submission of bid	
I.1 The brand must be in the market for at least ten (10) years	
I.2 Supplier must be in the Manufacturing and/or Distributing business of Liquid chromatograph for at least five (5) years.	
I.3 Supplier must submit a proof of authorization from the Manufacturer of the offered equipment. Authorization must include sales, distribution of equipment and its parts, and after sales services, at a minimum.	
I.4 Provide certification of availability and continuity of spare parts for at least 5 years after delivery	

I.5 The supplier must have at least ten (10) local installations of HPLC that can be viewed and demo to the end user, if necessary. Two (2) out of ten (10) local installations must be the same model as the one being offered. **Note:** Upon submission of bid, the bidder must submit a list of companies with installed units. Contact person and contact details (telephone number/mobile number and e-mail address) for each listed company must also be submitted.	
J. DELIVERY PERIOD	
Not more than ninety (90) calendar days upon receipt of Notice to Proceed. To be delivered at FDA-ATQAL, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City.	

Technical Specifications

SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF ULTRA HIGH PERFORMANCE LIQUID CHROMATOGRAPH WITH PHOTODIODE ARRAY AND ELECTROCHEMICAL DETECTOR (UHPLC-PDA-ECD) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)

Name of the Manufacturer:		**Quantity: 1 Lot**
Brand:		**Country of Origin:**
Estimated Cost: Php 8,133,333.00		**Model:**
PURCHASER'S SPECIFICATION		**SUPPLIER'S SPECIFICATION**
This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of Ultra High Performance Liquid Chromatograph with Photodiode Array and Electrochemical Detector complete with all necessary parts and accessories. The key applications include: analysis of pharmaceutical products.		Note: Supplier must fill-up this column item by item and that the word "as per FDA Specifications" or "Same Specifications as required by FDA" would be rejected and declared as non-responsive.
A. HPLC SYSTEM Note: Please indicate page number from the brochure submitted		
A.1 SOLVENT DELIVERY SYSTEM		
Gradient System	Low Pressure Gradient System	
Number of solvent	Up to four (4) solvents	
Degasser	Integrated or online; at least 4 chambers/channels	
Operating Flow Rate range	≥ 0.1 mL to 2.0 mL/min	
Maximum Operating Pressure	≥ 65 MPa (≥ 9,427.45 psi)	
A.2 AUTOSAMPLER SYSTEM		
Sample vial capacity	≥ 90 placer x 1.5 – 2 mL vials	
Injection volume precision	≤ 1.0%RSD (at varying injection volume)	
Sample Injection volume	≥ 0.1 to 100 µL	
Sample Compartment Temperature setting range	≥ 4 to 35°C	
A.3 COLUMN OVEN		

Containable column size/Column capacity	≥ 2 columns (length ≥ 25 cm)	
Temperature control range	≥ −10°C from room temperature or ambient temperature to 65°C	
A.4 PHOTODIODE ARRAY DETECTOR		
Light source	Deuterium and Tungsten or Deuterium Arc Lamp	
Wavelength range	≥ 190 nm to 800 nm	
Wavelength accuracy	≤ ± 1 nm	
A.5 ELECTROCHEMICAL DETECTOR (ECD)		
- At a minimum, the ECD must be capable to analyze Amikacin Sulfate Injection, Azithromycin for Injection (impurities), Azithromycin Capsule, Erythromycin Ointment, Kanamycin Injection, Kanamycin Sulfate Capsule, Streptomycin sulfate and Streptomycin Sulfate for Injection following USP 43/NF38 method. All other parts and accessories of this detector necessary to analyze the above-mentioned active pharmaceutical ingredient and dosage forms must be provided. Please see attachment for the complete details. Note: Documentary evidence must be provided for each analyte		
A.6 FEATURE - Can perform method transfer from traditional HPLC system to UHPLC system without method validation needed		
B. INSTRUMENT CONTROL, HARDWARE AND SOFTWARE		
B.1 HARDWARE (COMPUTER SET) Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid		
● Includes branded PC ● Processor- at least Intel Core i5 2.5ghz or equivalent ● Monitor- at least 24-inches or higher LED Monitor ● Memory- 8GB DDR3 1600		

● Hard Drive-at least 256gb Solid State Drive ● Graphics Card- Separate card at least 1GB or higher ● I/O Ports- Audio jack; USB 3.0; LAN port; USB 2.0; VGA ● Network Interface- 10/1000 Mbps ● Audio- HD Audio ● Input Device- USB or wireless Keyboard and Mouse ● Includes 1 TB portable hard disk; ● with DVD writer; ● with separate graphics card (at least 1 GB); ● with USB or wireless keyboard & mouse; ● with all necessary hardware required to operate the instrument ● 1 unit USB WiFi adapter	
B.2 PRINTER Note: Brochure and/or any other document or web link where the specifications below can be verified must be provided upon submission of bid	
● 3-in-1 Printer (print, scan, copy) compatible with the UHPLC System ● with 4 color-ink; continuous ink-tank system ● with two (2) extra sets of ink (set composed of Black, Magenta, Cyan and Yellow)	
B.3 SOFTWARE (compatible with the UHPLC System) Note: Commitment Letter must be provided if brochure or other documents to verify compliance with the specifications below cannot be provided during submission of bid	
PC SOFTWARE: ● Includes software which is upgradable for networked chromatography data system and can be connected to a software that can control a wide range of analytical instruments (i.e. HPLC, UHPLC, GC) even from multi-vendor ● Latest applicable OS (Windows or equivalent), at least 64 bit ● Licensed latest MS Office Business or equivalent ● At least 1-year licensed compatible Anti-Virus ● Includes all necessary software required to operate the instrument and peripherals	

INSTRUMENT SOFTWARE: ● Must be 21 CFR Part 11 Compliant ● Must be LIMS ready ● software must be fully compatible with the computer OS ● software must be able to export information to other programs through industry standard protocols and file formats (e.g..PDF, Clipboard, ASCII, DDE and others) ● instrument software must control and display all components of the LC system including pumping, autosampler, column oven, detector/s etc. ● must have multi-level security and automated custom calculation features and must export information to other programs and file formats ● Includes system suitability ● includes all necessary software required to operate the instrument	
C. ACCESSORIES, SPARE PARTS AND CONSUMABLES Note: Please provide a list of accessories, with part numbers or catalog number, and submit brochure or webpage link to verify compliance to the requirements below, upon submission of bid. Any deviation will not be allowed.	
C.1 HPLC system tool kit set	
● One (1) set of alloy steel wrench of varying sizes depending on the equipment requirement ● One (1) pc. Adjustable wrench	
C.2 HPLC starter kit and maintenance kit	
● Two (2) pcs. Rotor seal or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Two (2) pcs. Rotor peek or equivalent (if applicable as maintenance and/or starter kit of the equipment)	
● Two (2) pcs. Needle seal	
● One (1) pc. PDA lamp	
C.3 HPLC COLUMNS (1 pc. each) Note: brochure and catalog number must be provided upon submission of bid	
a. L49 4.6mm x 15cm, 3µm	

b. L29 4.6mm x 15cm, 5µm with L29 4.6mm x 5cm, 5µm guard column	
c. L50 4.0mm x 25cm, 8µm with L50 4.0mm x 5cm, 8 µm guard column	
d. L47 4.0mm x 25cm, 7.5µm with L47 guard column	
e. L46 4.0mm x 25cm with L46 4.0mm x 5cm guard column	
f. L67 4.6mm x 15cm, 5µm with L67 4.6mm x 1cm, 5µm guard column	
g. L67 4.6mm x 15cm, 5µm with L67 4.6mm x 1cm, 5µm guard column	
h. L1 4.6mm x 25cm, 5µm	
i. L7 2.1mm x 5cm, 1.7-1.9µm with L7 1.7-19µm guard column	
j. L1 4.6mm x 15cm, 3 - 4 µm	
C.4 STANDARDS **NOTE:** *Traceability:* Standards must be traceable to NIST or equivalent international standard *Expiration:* must be current lot for USP RS; for other standards, expiration, if possible, must not be less than one (1) year upon delivery. *Certificate of analysis*: must be submitted upon delivery **Brochure and catalog/product name must be provided upon submission of bid**	
Primary Reference standards (One (1) vial each)	
a. USP Kanamycin Sulfate RS	
b. USP Desoaminylazithromycin RS	
c. USP N-Demethylazithromycin RS	
d. USP Azaerythromycin A RS	
e. USP Azithromycin Related Compound F RS	
f. USP Erythromycin Related Compound N RS	
g. USP Erythromycin B RS	
h. USP Erythromycin C RS	
i. USP Gentamicin Sulfate RS	
j. USP Sisomicin Sulfate RS	
k. USP Streptomycin Sulfate RS	
l. USP Methacycline Hydrochloride RS	
m. USP Doxycycline Related Compound A RS	

n. USP Levofloxacin Related Compound A RS	
o. USP Moxifloxacin Related Compound A RS	
p. USP Moxifloxacin Related Compound F RS	
q. USP Moxifloxacin Hydrochloride RS	
r. Amikacin sulfate BPCRS	
s. Rifampicin quinone EPCRS	
t. Rifampicin N-oxide BPCRS	
u. 3-formylrifamycin SV BPCRS	
Reagents (One (1) bottle each)	
a. Hydranal Composite 5 (CAS #111-90-0, 7553-56-2, 288-32-4); 1L	
b. Hydranal Methanol Dry (CAS #67-56-1); 2.5L	
c. Sodium Hydroxide Pellets; low in carbonate or carbonate-free (CAS #1310-73-2); 1kg	
d. Buffer Solution pH 2.00 (CAS #7447-40-7, 7647-01-0, 50-00-0, 67-56-1, 7732-18-5); 500mL	
e. Buffer Solution pH 12.00 (CAS #7558-79-4, 1310-73-2); 500mL	
f. Hexane LC Grade (CAS #110-54-3); 2.5L	
g. Edetate disodium (Ethylenediaminetetraacetic acid disodium salt dihydrate) (CAS #6381-92-6); ACS Reagent, purity of at least 99%, 100g	
h. Trifluoroacetic acid (TFA) (CAS #76-05-1); 100mL	
C.5 OTHER LABORATORY SUPPLIES/ CONSUMABLES	
a. At least 1000 pcs. Clear Autosampler vials with septa	
b. At least 1000 pcs. Amber Autosampler vials with septa	
c. At least 500 pcs. Syringe Filters, Hydrophilic PVDF, 0.45µm, 25mm	
d. At least 200 pcs. membrane filters, 47mm diameter, 0.45µm pore size, hydrophilic PVDF	
e. At least 300 pcs. membrane filters, 47mm diameter, 0.45µm pore size, hydrophilic PVDF	

f. One (1) bottle tray assembly	
D. POWER SUPPLY	
D.1 Power input 230 V or Autovolt AC, 60 Hertz	
D.2 Provision of Online UPS of suitable rating with voltage range of 230V±20%, frequency of 60Hz and capable for at least 20 minutes back up of the instrument and all its attachments. It should also have an output voltage of 230VAC, an audible alarm, LED display for parameters and built-in line conditioners for spike, swell and over voltages **Note:** Brochure must be provided upon submission of bid	
E. WARRANTY, AND AFTER SALES SERVICES **Note:** Commitment Letter must be provided upon submission of bid	
E.1 A minimum of one (1) year warranty on parts and services of HPLC System, minimum of one (1) year warranty on Computer Set Parts and UPS. Both commencing after successful installation by Supplier and its acceptance by FDA. During the warranty period, Supplier must repair or replace any system component on site at no charge to FDA. Labor and travel must be included in the warranty program.	
E.2 Provision of annual preventive maintenance (PM) for a period of three (3) years for the HPLC system and one (1) year for UPS, after acceptance by FDA. The PM must include at minimum the cleaning, testing, checking of various functions, and carrying out Quality Control (QC) checks and all PM parts (PM Kits) and other necessary consumables.	
E.3 Provision of a qualification package. Package must include Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), whichever is applicable.	
E.4 If upgraded software to operate the instrument is released during the warranty period, the Supplier should provide this to FDA free of charge.	

E.5 Instrument should be attended for repair by trained service personnel within 24 hours from the time fault is reported by the user. The equipment shall have to be made fully operational within 48 hours from the time the fault is reported by the user. In the event of extended down times for the instrument (> 48 hours), the warranty will be extended by the amount of time elapsed until the instrument is back in operation.	
E.6 The Supplier must provide technical support, free of charge, for software and for questions concerning maintenance, service, troubleshooting and repairs during the entire period of the warranty.	
E.7 In case there is a transfer of sole-distributor rights, the former distributor shall ensure that the warranties and after sales services given to FDA shall be honored and continued by the new distributor. **Note:** Bidder must provide Certification from the manufacturer.	
F. TESTING AND ACCEPTANCE **Note:** Commitment Letter must be provided upon submission of bid	
F.1 Acceptance testing will occur after completion of the training course and after the supplier states the system is installed and ready to perform in compliance with specifications	
F.2 If the system does not meet standard performance expectations, the Supplier will have one month to rectify the defects and clear the acceptance test, failing which, the FDA reserves the right to get the equipment replaced by FDA at no extra cost to the purchaser. The succeeding conduct of the validation/qualification shall also be the responsibility and at the cost of the Supplier	
G. TRAINING **Note:** Commitment Letter must be provided upon submission of bid	
The training should cover lectures on the theory and principles of the instrument, its applications, software applications, data processing and interpretation, as well as intensive hands-on operation. Troubleshooting, maintenance and service, including the verification of equipment's performance should also be discussed. Considering the new normal situation, lectures	.

may be conducted virtually. However, hands-on training should be conducted at the FDA Office for at least ten (10) participants, which should be done in batches in observance of the safety protocols to prevent the spread of COVID-19 virus. The training shall be provided at no cost to the FDA If necessary, provision of free yearly refresher courses on the operations, post processing and maintenance of the instrument within 3 years from the date of installation. The refresher course is not limited to hands-on operation but may also include actual sample tests.	
H. DOCUMENTATION **Note:** Commitment Letter must be provided upon submission of bid.	
H.1 Training certificate of Service Personnel from the manufacturer related to the installation, equipment maintenance, and troubleshooting must be provided	
H.2 Manufacturer's certificate of compliance and inspection must be provided.	
H.3 One (1) original copy and/or one electronic copy in a storage device of operating and service manuals in English must be provided.	
H.4 IQ, OQ, and PQ protocols, whichever is applicable. The protocols must provide the necessary information and test procedures required to prove that the instrument meets the specified requirements.	
H.5 Submission of IQ, OQ, and PQ reports, whichever is applicable, within five (5) working days after completion of qualification. Test data (raw data) and calibration certificates of the calibrating instruments used must be attached, whenever applicable.	
H.6 Inventory of all the deliverable components/hardware, software, spare parts, and installation accessories with their part number.	
H.7. Checklist for recommended maintenance with corresponding instructions and recommended frequency. A post PM performance check procedure to confirm that the system meets the manufacturer's performance specification must also be submitted.	
I. OTHER REQUIREMENTS	

Note: Commitment Letter or any other documentary evidence must be provided upon submission of bid	
I.1 The brand must be in the market for at least ten (10) years	
I.2 Supplier must be in the Manufacturing and/or Distributing business of Liquid chromatograph for at least five (5) years.	
I.3 Supplier must submit a proof of authorization from the Manufacturer of the offered equipment. Authorization must include sales, distribution of equipment and its parts, and after sales services, at a minimum.	
I.4 Provide certification of availability and continuity of spare parts for at least 5 years after delivery	
I.5 The supplier must have at least ten (10) local installations of HPLC that can be viewed and demo to the end user, if necessary. Two (2) out of ten (10) local installations must be the same model as the one being offered. **Note:** Upon submission of bid, the bidder must submit a list of companies with installed unit. Contact person and contact details (telephone number/mobile number and e-mail address) for each listed company must also be submitted.	
DELIVERY PERIOD	
Not more than ninety (90) calendar days upon receipt of Notice to Proceed. To be delivered at FDA-ATQAL, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City.	

ATTACHMENT FOR: Ultra High Performance Liquid Chromatograph with Photodiode Array Detector and Electrochemical Detector (HPLC-PDA-ECD) complete with all necessary parts and accessories

Name of Product (Note: Reference method is based in USP 43/NF 38)	Mode	Detector	Detector Mode	Electrodes	Column
Amikacin Sulfate Injection	LC	Electrochemical	Integrated amperometric mode	Working: Gold Reference: Silver-silver chloride	Guard: Packing L47 Analytical: 4-mm x 25-cm; packing L47
Azithromycin for injection (Impurities)	LC	Amperometric Electrochemical Detector		Dual series glassy carbon electrodes Mode: Oxidative screen mode Electrode 1: +0.70 ± 0.05V Electrode 2: +0.82 ± 0.05V Background Current: 95 ± 25 nanoamperes	Guard: 4.6-mm x 1-cm; 5um packing L67 Analytical: 4.6-mm x 25-cm; 5um packing L67 Analytical: 4.6-mm × 15-cm; 3-µm packing L49
Azithromycin Capsules	LC	Amperometric Electrochemical Detector		Dual glassy carbon electrodes Mode: Oxidative screen mode Electrode 1: +0.70 ± 0.05V Electrode 2: +0.82 ± 0.05V Background Current: 85 ± 15 nanoampheres	Guard: 4.6-mm x 5-cm; 5um packing L29 Analytical: 4.6-mm x 15-cm; 5-um packing L29 or 3um packing L49 without the guard column
Erythromycin Ointment	LC	Electrochemical	Pulsed integrated amperometric mode with a range of 10nC, an output of 1 V full scale, a rise time of 0.6 second, positive polarity, E = 0.9V; t1 = 400ms; E2 = 0.9 V; t2 = 100ms; E3 = -0.9V; t3 = 100ms	Glassy carbon electrode fitted with three gaskets	4-mm x 5-cm guard column that contains 8-um packing L50, 4-mm x 25-cm analytical column that contains 8um packing L50
Gentamicin Sulfate (Specific Tests -Content of Gentamicin)	LC	Pulsed amperometric electrochemical detector		Indicator Electrode: Gold Reference Electrode: Silver-silver chloride Auxiliary electroded: Stainless steel. [Note -	4.6-mm x 25-cm; 5um packing L1

				If the cell body is made of stainless steel, it can	
Kanamycin Injection	LC	Electrochemical	Integrated amperometric Range: 300nC Output: 1 V full-scale	be used as the auxiliary electrode] Indicator: Gold Reference: pH silver-silver chloride	Guard: Packing L47 Analytical: 4-mm x 25-cm; packing L47
Kanamycin Sulfate Capsules	LC	Electrochemical	Integrated amperometric Range: 300nC Output: 1 V full-scale	Indicator: Gold Reference: pH silver-silver chloride	Guard: Packing L47 Analytical: 4-mm x 25-cm; packing L47
Streptomycin Sulfate		Electrochemical	Integrated amperometric mode with a rane of 300 nC, an ouput of 1V full scale, and a rsie time of 0.5 second, positive polarity	Gold working electrode, pH silver-silver chloride reference electrode	4-mm x 5-cm guard column that contains packing L46, and a 4-mm x 25-cm analytical column that containspacking L46

Section VIII. Checklist of Technical and Financial Documents

Notes on the Checklist of Technical and Financial Documents

The prescribed documents in the checklist are mandatory to be submitted in the Bid, but shall be subject to the following:

a. GPPB Resolution No. 09-2020 on the efficient procurement measures during a State of Calamity or other similar issuances that shall allow the use of alternate documents in lieu of the mandated requirements; or

b. Any subsequent GPPB issuances adjusting the documentary requirements after the effectivity of the adoption of the PBDs.

The BAC shall be checking the submitted documents of each Bidder against this checklist to ascertain if they are all present, using a non-discretionary "pass/fail" criterion pursuant to Section 30 of the 2016 revised IRR of RA No. 9184.

Checklist of Technical and Financial Documents

I. TECHNICAL COMPONENT ENVELOPE

Class "A" Documents

Legal Documents

☐ (a) Valid PhilGEPS Registration Certificate (Platinum Membership) (all pages);
or

☐ (b) Registration certificate from Securities and Exchange Commission (SEC), Department of Trade and Industry (DTI) for sole proprietorship, or Cooperative Development Authority (CDA) for cooperatives or its equivalent document,
and

☐ (c) Mayor's or Business permit issued by the city or municipality where the principal place of business of the prospective bidder is located, or the equivalent document for Exclusive Economic Zones or Areas;
and

☐ (d) Tax clearance per E.O. No. 398, s. 2005, as finally reviewed and approved by the Bureau of Internal Revenue (BIR).

Technical Documents

☐ (e) Statement of the prospective bidder of all its ongoing government and private contracts, including contracts awarded but not yet started, if any, whether similar or not similar in nature and complexity to the contract to be bid; **and**

☐ (f) Statement of the bidder's Single Largest Completed Contract (SLCC) similar to the contract to be bid, except under conditions provided for in Sections 23.4.1.3 and 23.4.2.4 of the 2016 revised IRR of RA No. 9184, within the relevant period as provided in the Bidding Documents; **and**

☐ (g) Original copy of Bid Security. If in the form of a Surety Bond, submit also a certification issued by the Insurance Commission;
or
Original copy of Notarized Bid Securing Declaration; **and**

☐ (h) Conformity with the Technical Specifications, which may include production/delivery schedule, manpower requirements, and/or after-sales/parts, if applicable; **and**

☐ (i) Original duly signed Omnibus Sworn Statement (OSS);
and if applicable, Original Notarized Secretary's Certificate in case of a corporation, partnership, or cooperative; or Original Special Power of Attorney of all members of the joint venture giving full power and authority to its officer to sign the OSS and do acts to represent the Bidder.

Financial Documents

☐ (j) The Supplier's audited financial statements, showing, among others, the Supplier's total and current assets and liabilities, stamped "received" by the BIR or its duly accredited and authorized institutions, for the preceding calendar year which should not be earlier than two (2) years from the date of bid submission; **and**

☐ (k) The prospective bidder's computation of Net Financial Contracting Capacity (NFCC);

or

A committed Line of Credit from a Universal or Commercial Bank in lieu of its NFCC computation.

Class "B" Documents

☐ (l) If applicable, a duly signed joint venture agreement (JVA) in case the joint venture is already in existence;

or

duly notarized statements from all the potential joint venture partners stating that they will enter into and abide by the provisions of the JVA in the instance that the bid is successful.

II. FINANCIAL COMPONENT ENVELOPE

☐ (m) Original of duly signed and accomplished Financial Bid Form; **and**

☐ (n) Original of duly signed and accomplished Price Schedule(s).

Other documentary requirements under RA No. 9184 (as applicable)

☐ (o) *[For foreign bidders claiming by reason of their country's extension of reciprocal rights to Filipinos]* Certification from the relevant government office of their country stating that Filipinos are allowed to participate in government procurement activities for the same item or product.

☐ (p) Certification from the DTI if the Bidder claims preference as a Domestic Bidder or Domestic Entity.

BIDS AND AWARDS COMMITTEE

ITB No.		**Date /Time of Opening and Evaluation of Bids:**	

Project Title:
Approved Budget for the Contract:
Name of Bidder:
Address:

CHECKLIST OF DOCUMENTS FOR THE OPENING AND BID EVALUATION OF BIDDING DOCUMENTS

(Note: Write if PASSED or FAILED on the left space provided.)

I. PRELIMINARY EXAMINATION OF BIDS;

A. Two Envelope System

	1. Original Bid Copy
	2. Copy 1 & 2

B. Marking of Bids

	1. Arranged
	2. Numbered/Tabbed
	3. Original Copies of the Bid Document must be duly signed by prospective bidder or authorized representative using blue ink pen

I. TECHNICAL COMPONENTS - (ENVELOPE ONE)

Passed/Failed Remarks	**Eligibility Documents (Class "A" Documents)**	
	Page No.	**LEGAL DOCUMENTS**
	1	(a) Valid PhilGEPS Registration Certificate (Platinum Membership) (all pages);or
	1.1	(b) Registration certificate from Securities and Exchange Commission (SEC), Department of Trade and Industry (DTI) for sole proprietorship, or

		Cooperative Development Authority (CDA) for cooperatives or its equivalent document, and (c) Mayor's or Business permit issued by the city or municipality where the principal place of business of the prospective bidder is located, or the equivalent document for Exclusive Economic Zones or Areas; and (d) Tax clearance per E.O. No. 398, s. 2005, as finally reviewed and approved by the Bureau of Internal Revenue (BIR).
LEGAL DOCUMENTS		
	2.	Statement of the prospective bidder of all its ongoing government and private contracts, including contracts awarded but not yet started, if any, whether similar or not similar in nature and complexity to the contract to be bid; and
	3.	Statement of the bidder's Single Largest Completed Contract (SLCC) similar to the contract to be bid, except under conditions provided for in Sections 23.4.1.3 and 23.4.2.4 of the 2016 revised IRR of RA No. 9184, within the relevant period as provided in the Bidding Documents; and
	4.	Original copy of Bid Security. If in the form of a Surety Bond, submit also a certification issued by the Insurance Commission; or Original copy of Notarized Bid Securing Declaration; and
	5.	Conformity with the Technical Specifications, which may include production/delivery schedule, manpower requirements, and/or after-sales/parts, if applicable; and
	6.	Original duly signed Omnibus Sworn Statement (OSS); and if applicable, Original Notarized Secretary's Certificate in case of a corporation, partnership, or cooperative; or Original Special Power of Attorney of all members of the joint venture giving full power and authority to its officer to sign the OSS and do acts to represent the Bidder.
FINANCIAL DOCUMENTS		
	7.	The Supplier's audited financial statements, showing, among others, the Supplier's total and current assets and liabilities, stamped "received" by the BIR or its duly accredited and authorized institutions, for the preceding calendar year which should not be earlier than two (2) years from the date of bid submission; and
	8.	The prospective bidder's computation of Net Financial Contracting Capacity (NFCC); or A committed Line of Credit from a Universal or Commercial Bank in lieu of its NFCC computation.

II. FINANCIAL COMPONENTS - (ENVELOPE TWO)

	Financial Proposal Submission Form, to include the following	
	A	Duly accomplished and signed Bid Form; Bid Amount in Figures: Php_____ Bid Amount in Words: _____ _____ _____
Other documentary requirements under RA No. 9184 (as applicable)		
	B	[For foreign bidders claiming by reason of their country's extension of reciprocal rights to Filipinos] Certification from the relevant government office of their country stating that Filipinos are allowed to participate in government procurement activities for the same item or product.
		Certification from the DTI if the Bidder claims preference as a Domestic Bidder or Domestic Entity.

III. OVER-ALL REMARKS

	PASSED	**FAILED**
TECHNICAL COMPONENTS		
FINANCIAL COMPONENTS		

OTHERS (e.g. ground/s for failed bid):

_____

_____

_____

_____

Republic of the Philippines
gppb
Government Procurement Policy Board