



**BIDS AND AWARDS COMMITTEE  
FOR VISAYAS CLUSTER**

**SUPPLEMENTAL BID BULLETIN  
For ITB No. 2021-004-FDA-VC/CTQAL**

**PROCUREMENT OF TECHNICAL AND SCIENTIFIC LABORATORY  
EQUIPMENT FOR THE CEBU TESTING AND QUALITY ASSURANCE  
LABORATORY (CTQAL)**

29 October 2021

In response to the issues/ concerns raised during the Pre-Bid Conference held on 28 October 2021 for the above mentioned ITB, hereunder are the amendments, clarifications and recommendations.

Refer to the comparative table given below for the previous (from) and revised (to) specifications:

**Section I. Invitation to Bid**

<b>FROM:</b>	<b>TO:</b>
Deadline of Submission of Bids: on or before 09 November 2021 at 9:00 AM	Deadline of Submission of Bids: <b>on or before 11 November 2021 at 9:00 AM</b>
Opening of Bids: 09 November 2021 at 9:30 AM	Opening of Bids: <b>11 November 2021 at 9:30 AM</b>
Post Qualification Conference: 01 December 2021 at 1:00 PM	Post Qualification Conference: <b>03 December 2021 at 1:00 PM</b>

**Section III. Bid Data Sheet**

<b>FROM:</b>	<b>TO:</b>
20.2 7. Summary of Conformity with Section VII. Technical Specification	<b>Deletion of 7. Summary of Conformity with Section VII. Technical Specification</b>

**Section VII. Technical Specifications:**

<b>FROM:</b>	<b>TO:</b>
<b>ITEM NO. 2 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF TABLET HARDNESS TESTER FOR ALL SIZE, SHAPE AND MATERIAL COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR</b>	



<b>FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)</b>	
<p><b>PURCHASER'S SPECIFICATION</b> This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of Automated Disintegration Tester, Bathless, 4 Positions complete with all necessary parts and accessories. The application for this equipment includes various pharmaceutical products.</p> <p><b>Measuring principle</b></p> <p>Linear force increase: programmable between 0.05 to 5 mm/s or better</p>	<p><b>PURCHASER'S SPECIFICATION</b> This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of Tablet Hardness Tester for all size, shapes and materials complete with all necessary parts and accessories. The application for this equipment includes analysis of various pharmaceutical products.</p> <p><b>Measuring principle</b></p> <p>Linear force increase: programmable between 10 to 200 N/s</p>
<b>ITEM NO. 3 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF UV-VIS SPECTROPHOTOMETER COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING QUALITY ASSURANCE LABORATORY (CTQAL)</b>	
<p><b>A. MAIN UNIT</b></p> <p>Spectral bandwidth: 1.00 nm max.</p> <p>Photometric system/optical design: Double beam optics with sample and reference cuvette positions</p> <p>Photometric repeatability: <math>\pm 0.0002</math> Abs (1 Abs)</p> <p>Baseline stability: Within <math>\pm 0.0003</math> Abs/h (700 nm), one hour after light source turned on</p> <p><b>D.1</b></p> <p>c. 5 pcs. Xenon lamp*</p>	<p>Spectral bandwidth: 1.5 nm max.</p> <p>Photometric system/optical design: Double beam optics with sample and reference cuvette positions or dual beam with detectors for simultaneous sample and reference beam measurements</p> <p>Photometric repeatability: at 400 - 600 nm using neutral density filters traceable to NIST: <math>\leq 0.004</math> Abs (0.5 Abs), <math>\leq 0.006</math> Abs (1 Abs), <math>\leq 0.010</math> Abs (2 Abs)</p> <p>Baseline stability: Within 0.0003 to 0.0005 Abs/hr at min. 500 nm after maximum of one-hour warmup</p> <p><b>D.1</b></p> <p>c. <math>\leq 5</math> pcs. Xenon* lamp (optional, only if applicable to make the unit functional; for lamps with shelf life of more than 10 years, provision of document/proof is required).</p>
<b>ITEM NO. 4 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY – ULTRAVIOLET-VISIBLE AND PHOTODIODE ARRAY DETECTOR COMPLETE</b>	

<b>WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)</b>	
<p><b>PURCHASER'S SPECIFICATION</b></p> <p>This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of Automated Disintegration Tester, Bathless, 4 Positions complete with all necessary parts and accessories. The application for this equipment includes various pharmaceutical products.</p> <p><b>D.4</b>  <b>b.</b> 25 pcs. magnetic stir bar without pivot ring (25 x 5 mm)  <b>J.5</b> The supplier must have at least 1-2 installations of HPLC with UV-Vis &amp; PDA detector in the Philippines.</p>	<p><b>PURCHASER'S SPECIFICATION</b></p> <p>This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of HPLC with UV-Vis &amp; PDA Detector complete with all necessary part and accessories. The application for this equipment includes analysis of various pharmaceutical products.</p> <p><b>b.</b> 25 pcs. magnetic stir bar without pivot ring (25 x 5 to <b>8</b> mm)  <b>J.5</b> The supplier must have at least 1-2 installations of the latest model of HPLC being offered with UV-Vis &amp; PDA / UV-Vis / PDA detector in the Philippines.</p>
<b>ITEM NO. 5 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY – PHOTODIODE ARRAY DETECTOR COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)</b>	
<p><b>PURCHASER'S SPECIFICATION</b></p> <p>This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of Automated Disintegration Tester, Bathless, 4 Positions complete with all necessary parts and accessories. The application for this equipment includes various pharmaceutical products.</p> <p><b>D.3</b>  a. 2 vials Retinol (Vitamin A), <math>\geq</math> 95% purity, at least 100 mg, (CAS No. 68-28-6)  <b>D.4</b>  c. 25 pcs. magnetic stir bar without pivot ring (25 x 5 mm)  j. At least 1000 pcs. membrane filters, 0.35 <math>\mu</math>m, PTFE</p>	<p><b>PURCHASER'S SPECIFICATION</b></p> <p>This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of HPLC-PDA complete with all necessary parts and accessories. The application for this equipment includes analysis of various food and cosmetic products</p> <p><b>D.3</b>  a. 2 vials Retinol (Vitamin A), &gt; 95% purity, at least 100 mg, (CAS No. <b>68-28-8</b>)  <b>D.4</b>  c. 25 pcs. magnetic stir bar without pivot ring (25 <b>mm</b> x 5 mm)  j. At least 1000 pcs. membrane filters, <b>0.45</b></p>

<p>k. At least 1000 pcs. membrane filters, 0.20-0.22 µm HVLP</p>	<p>µm, PTFE</p> <p>k. at least 2000 pcs. membrane filters, 0.20-0.22 µm PVDF</p>
<p><b>ITEM NO. 8 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF INDUCTIVELY COUPLED PLASMA-OPTICAL EMISSION SPECTROPHOTOMETER COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)</b></p>	
<p><b>A. ICP SYSTEM</b>  Wavelength range: 165-900 nm  Frequency: &gt;30 MHz  Power Efficiency: ≥ 80%  Argon Consumption: 9 L/min or lower.  <b>D2.</b></p> <p>1 set of Metal Standard (Ag, Al, As, Ba, Be, Bi, Ca, Cd, Co, Cr, Cs, Cu, Fe, Ga, In, K, Li, Mg, Mn, Na, Ni, Pb, Rb, Se, Sr, Tl, U, V, Zn).</p>	<p>Wavelength range: Within 165 to 900 nm  Frequency: within 27 to 30 MHz  Power Efficiency: ≥ 75%  Argon Consumption: ≤ 10 L/minute  <b>D.2</b></p> <p>1 set of Metal Standard (Ag, Al, As, Ba, Be, Bi, Ca, Cd, Co, Cr, Cs, Cu, Fe, Ga, In, K, Li, Mg, Mn, Na, Ni, Pb, Rb, Se, Sr, Tl, U, V, Zn) with concentration of 10 ppm in 100 mL to 125 mL</p>
<p><b>ITEM NO. 10 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF RAPID FULLY AUTOMATED MACHINE FOR IDENTIFICATION OF BACTERIA AND YEAST WITH SUSCEPTIBILITY TESTING CAPABILITIES AND AIR SAMPLER COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)</b></p>	
<p><b>B.1 HARDWARE</b></p> <p>a.-perpetual license of Microsoft Business Office or equivalent</p> <p><b>b.</b> Processor: at least <b>Intel Core i5 10th</b> generation or higher</p> <p>c. Monitor: at least <b>24-inches</b> LED or higher</p> <p>d. Memory: at least <b>8GB</b> DDR4</p> <p><b>e.</b> Hard Drive: at least 1TB Hard Drive/<b>Solid State Drive</b></p> <p><b>f.</b> Graphics Card: at least 1GB <b>dedicated</b> graphics card</p> <p>l. 1 unit USB wifi adapter compatible with the unit;</p> <p><b>B.2 HARDWARE (3-in-1: Printer, Scanner, Photocopier)</b></p> <p>a. Colored printer (with 4 color-ink) with</p>	<p><b>Deletion of a</b> - perpetual license of Microsoft Business Office or equivalent</p> <p><b>b.</b> Processor: at least <b>Intel Core i3 8th</b> generation or higher</p> <p>c. Monitor: at least <b>20-inches</b> LED or higher</p> <p>d. Memory: at least <b>16 GB</b> DDR4</p> <p><b>e.</b> Hard Drive: at least 1TB Hard Drive/<b>256 GB Solid State Drive</b></p> <p><b>f.</b> Graphics Card: at least 1GB <b>integrated</b> graphics card</p> <p><b>Deletion of l.</b> 1-unit USB wifi adapter compatible with the unit;</p> <p><b>B.2 HARDWARE (Printer)</b></p> <p>a. Colored printer with continuous ink-tank system</p>

continuous ink-tank system b. Five (5) sets of ink (set composed of Black, Magenta, Cyan and Yellow)	<b>Deletion of</b> b. Five (5) sets of ink (set composed of Black, Magenta, Cyan and Yellow)
<b>ITEM NO. 11</b> SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF LABORATORY FUMEHOOD FOR PERCHLORIC ACID COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)	
<b>PURCHASER'S SPECIFICATION</b>  This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of Automated Disintegration Tester, Bathless, 4 Positions complete with all necessary parts and accessories. The application for this equipment includes various pharmaceutical products	<b>PURCHASER'S SPECIFICATION</b>  This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of Laboratory Fume Hood for Perchloric Acid complete with all necessary parts and accessories. The application for this equipment includes engineering control (exhaust ventilation system) to exhaust hazardous gases, dusts, mists, and vapors during physico-chemical analysis.
<b>ITEM NO. 12</b> SUPPLY, DELIVERY, COMMISSIONING AND TESTING OF VORTEX SHAKER COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)	
<b>PURCHASER'S SPECIFICATION</b>  This specification covers the design and operation requirements for the supply, delivery, installation, commissioning and testing of Automated Disintegration Tester, Bathless, 4 Positions complete with all necessary parts and accessories. The application for this equipment includes various pharmaceutical products.	<b>PURCHASER'S SPECIFICATION</b>  This specification covers the design and operation requirements for the supply, delivery, commissioning and testing of Vortex Shaker complete with all necessary parts and accessories. The application for this equipment includes analysis of various cosmetic, food, and pharmaceutical products.
<b>ITEM NO. 13</b> SUPPLY, DELIVERY, COMMISSIONING AND TESTING OF LABORATORY REFRIGERATOR COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)	
<b>A. MAIN UNIT</b>  Temperature Range : +1 °C to + 16 °C	Temperature Range: <b>within</b> +1 °C to + 16 °C
<b>ITEM NO. 21</b> SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF FULLY AUTOMATED MACHINE FOR ENUMERATION OF QUALITY	

<p>INDICATORS USING TRADITIONAL MPN-BASED METHOD IN FOOD PRODUCTS COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)</p>	
<p>a.-perpetual license of Microsoft Business Office or equivalent  <b>b. Processor: at least Intel Core i5 10th generation or higher</b>  c. Monitor: at least <b>24-inches</b> LED or higher  d. Memory: at least <b>8GB</b> DDR4  <b>e. Hard Drive: at least 1TB Hard Drive/Solid State Drive</b>  <b>f. Graphics Card: at least 1GB dedicated graphics card</b>  l. 1-unit USB wifi adapter compatible with the unit;  1. n. Internet router</p> <p><b>B.2 HARDWARE (3-in-1: Printer, Scanner, Photocopier)</b>  a. Colored printer (with 4 color-ink) with continuous ink-tank system  b. Five (5) sets of ink (set composed of Black, Magenta, Cyan and Yellow)</p>	<p><b>Deletion of</b> a.- perpetual license of Microsoft Business Office or equivalent  <b>b. Processor: at least Intel Core i3 8th generation or higher</b>  c. Monitor: at least <b>20-inches</b> LED or higher  d. Memory: at least <b>16 GB</b> DDR4  <b>e. Hard Drive: at least 1TB Hard Drive/256 GB Solid State Drive</b>  <b>f. Graphics Card: at least 1GB integrated graphics card</b>  <b>Deletion of</b> 1-unit USB wifi adapter compatible with the unit;  n. Internet router</p> <p><b>B.2 HARDWARE (Printer)</b>  a. Colored printer with continuous ink-tank system  <b>Deletion of</b> b. Five (5) sets of ink (set composed of Black, Magenta, Cyan and Yellow)</p>
<p><b>ITEM NO. 22 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF AUTOMATIC DIGITAL POLARIMETER COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)</b></p>	
<p><b>B.2</b></p>	<p><b>B.2</b>  - 21 CFR Part 11 compliant.</p>
<p><b>ITEM NO. 26 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF MOLECULAR DETECTION SYSTEM FOR BACTERIAL PATHOGENS COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-CEBU TESTING AND QUALITY ASSURANCE LABORATORY (CTQAL)</b></p>	
<p><b>B.1</b>  d.1-unit USB wifi adapter compatible with the unit  <b>D.2</b>  e. 1 bot MLRB Supplement  f. 1 bot Demi Fraser Broth  g. 1 bot Fraser Broth Supplement</p>	<p><b>B.1</b>  d.1-unit USB adapter compatible with the unit  <b>D.2</b>  <b>Deletion of</b> e ,f and g  e. 1 bot MLRB Supplement  f. 1 bot Demi Fraser Broth  g. 1 bot Fraser Broth Supplement</p>

<p><b>E.</b>  <b>E.4</b> Provision of a qualification package. The package must include Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).  Note: IQ, OQ and PQ protocols must be submitted</p>	<p><b>E.</b>  <b>E.4</b> Provision of a qualification package. The package must include Installation Qualification (IQ), Operational Qualification (OQ)    <b>Note:</b> IQ and OQ protocols must be submitted</p>
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**Warranty and After Sales Services**

**Samples and Reference Standards shall be provided by the End-User during the conduct of Performance Qualification (PQ) of the following Equipment:**

Item No. 3 Supply, Delivery, Installation, Commissioning and Testing of UV-VIS Spectrophotometer

Item No. 4 Supply, Delivery, Installation, Commissioning and Testing of High-Performance Liquid Chromatography with Photodiode Array and UV-VIS Detectors

Item No. 5 Supply, Delivery, Installation, Commissioning and Testing of High-Performance Liquid Chromatography with Photodiode Array Detector

Item No. 8 Supply, Delivery, Installation, Commissioning and Testing of Inductively Coupled Plasma - Optical Emission Spectrophotometer

Item No. 14 Supply, Delivery, Installation, Commissioning and Testing of Automatic Titration, Two (2) Channel

Item No. 19 Supply, Delivery, Installation, Commissioning and Testing of Density Meter

Item No. 22 Supply, Delivery, Installation, Commissioning and Testing of Polarimeter

Item No. 24 Supply, Delivery, Installation, Commissioning and Testing of Water Activity Meter

**Section VIII Checklist of Technical and Financial Documents**

<b>FROM:</b>	<b>TO:</b>
<b>Technical Documents</b>	
(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 R.A. No. 9184, within the relevant period as provided in the Bidding Documents;	Thus, in the case of a procurement that is divided into several lots, where each awarded lot gives rise to a separate contract, the SLCC requirement shall be based on the ABC for each lot. (GPPB NPM No. 149-2015)
(j) 6. Summary of Conformity with Section VII. Technical Specifications.	<b>Deletion of</b> (j) 6. Summary of Conformity with Section VII. Technical Specifications.

**Additional Required forms to be submitted by the Bidders (GPPB Circular No. 16-2020 dated 16 September 2020)**

1. Price Schedule for Goods Offered from Abroad [ *shall be submitted with the Bid if Bidder is offering goods from Abroad*]
2. Price Schedule for Goods Offered from Within the Philippines [ *shall be submitted with the Bid if Bidder is offering goods from within the Philippines*]
3. Contract Agreement Form for the Procurement of Goods (Revised). [ *Not required to be submitted with the Bid, but it shall be submitted within ten (10) days after receiving the Notice of Award*]

These clarifications on the issues/concerns mentioned above are being issued to modify the Bid Documents and shall form an integral part of it.

For information and guidance of all concerned.

  
**MA. ANGELES D. GUZMAN**  
 BAC Chairperson -Visayas Cluster