



BIDS AND AWARDS COMMITTEE

SUPPLEMENTAL BID BULLETIN

For ITB No. 2021-0208-ATQAL

**PROCUREMENT OF SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING
AND TESTING OF EQUIPMENT FOR TESTING PHARMACEUTICAL
PRODUCTS FOR THE ALABANG TESTING AND QUALITY ASSURANCE
LABORATORY (ATQAL)**

11 October 2021

In response to the issues/ concerns raised during the Pre-Bid Conference held on 04 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:

A. Under Invitation to Bid for Submission of Price Quotation:

FROM	TO
Special Alloted General Funds (SAGF)	Special Account in the General Fund (SAGF)
Checklist of Documents (Legal Documents) Item (3) Statement of the bidder's Single Largest Completed Contract (SLCC) <u>similar to the contract to be bid</u> , 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	Since the procurement allows partial bids, the procurement of which 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 (<u>GPPB NPM No. 149-2015</u>)
Payment of Bid Documents, if bid would be specific for a lot or line item	In case of lot procurement, the maximum fee for the bidding documents for each lot shall be based on its ABC, in accordance with the Guidelines issued by the GPPB

Handwritten signature



B. Under Section VII – Technical Specification:

DESCRIPTION	FROM	TO
ITEM NOS. 1,2,3,4,5 AND 6 (ALL ITEMS)		
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	Not more than one hundred twenty (120) calendar days upon receipt of Notice to Proceed. To be delivered at FDA-ATQAL, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City
ITEM NO. 1: SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF FOURIER TRANSFORM INFRARED SPECTROPHOTOMETER (FT-NIR) COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)		
A. MAIN UNIT		
SPECTRAL RANGE	includes 12,500 to 4,000 cm ⁻¹ , at a minimum	includes 11,500 to 4,000 cm ⁻¹ , at a minimum
Beam splitter	Calcium Fluoride	Calcium Fluoride or Quartz or equivalent
B.3 SOFTWARE (compatible with the FT-NIR) 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	<input type="checkbox"/> INSTRUMENT SOFTWARE: <ul style="list-style-type: none"> ● Must be 21 CFR Part 11 Compliant ● Must be LIMS ready, as supported by certificate or pertinent document ● Must be able to perform performance verification/validation with parameters complying with USP/BP/EP/IP or any other internationally recognized references ● software must be fully compatible with the computer OS and able to support both Advanced and Basic experiment setup functionality ● Must also include a set of spectral libraries with appropriate documentation and must support validation for all modules for future upgrades 	<input type="checkbox"/> INSTRUMENT SOFTWARE: <ul style="list-style-type: none"> ● Must be 21 CFR Part 11 Compliant ● Must be LIMS ready, as supported by certificate or pertinent document ● Must be able to perform performance verification and/or validation with parameters complying with USP/BP/EP/IP or any other internationally recognized references ● Must also be capable of multicomponent or multivariate or equivalent quantitative analysis ● Must provide a library that includes pharmaceuticals with appropriate documentation ● Must support validation for all modules for future upgrades ● software must be fully compatible with the computer OS and able to support both Advanced and Basic experiment setup functionality (identification, quantitation, multi component analysis for wide range of pharmaceutical products)

ITEM NO. 2 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF UV-Vis SPECTROPHOTOMETER COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)

A.2 Optical System	Czerny-Turner monochromator with diffraction gratings	Czerny-Turner monochromator with diffraction gratings or equivalent monochromator. Note: If equivalent monochromator is offered, supporting documents that it has the same design and performance as that of Czerny Turner monochromator must be submitted
A.6 Wavelength Reproducibility/ Repeatability	$\leq \pm 0.02$ nm	$\leq \pm 0.03$ nm
A.8 Photometric Range	± 4.0 Abs	retained as : ± 4.0 Abs
A.3 Light Source	Tungsten-Deuterium Lamp or Xenon Lamp	retained as : Tungsten-Deuterium Lamp or Xenon Lamp
A.7 Stray Light	$\leq 0.05\%$ T at 220 nm	retained as : $\leq 0.05\%$ T at 220 nm
C.1 Additional Set of spares and consumables	a. One (1) pc. each lamp/s	a. One (1) pc. each lamp/s if the service life of the lamp/s is <u>less than ten (10) years</u> . If the service life of the lamp is 10 years and above, Bidder must provide a certificate or any documentation which guarantees the service life of the lamp, as claimed. In addition, a commitment letter to replace the said item in case the service life does not reach ten (10) years must be submitted.
C.2 Accessories	a. Multi-cell compartment	a. Multi-cell compartment - must be able to hold a 3.5mL sized cuvette
	b. Fiber optic probe	b. Fiber optic probe - suitable for analysis of formaldehyde, nitrates, phenol and cyanide

ITEM NO. 3 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF UV-VIS SPECTROPHOTOMETER COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)

A.2 Optical System	Czerny-Turner monochromator with diffraction gratings	Czerny-Turner monochromator with diffraction gratings or equivalent monochromator. If equivalent monochromator is offered, supporting documents that it has the same design and performance as that of Czerny Turner monochromator must be submitted
A.6 Wavelength Reproducibility/ Repeatability	$\leq \pm 0.02$ nm	$\leq \pm 0.03$ nm
A.8 Photometric Range	± 4.0 Abs	retained as : ± 4.0 Abs
A.3 Light Source	Tungsten-Deuterium Lamp or Xenon Lamp	retained as : Tungsten-Deuterium Lamp or Xenon Lamp
A.7 Stray Light	$\leq 0.05\%$ T at 220 nm	retained as : $\leq 0.05\%$ T at 220 nm
C.1 Additional Set of spares and consumables	a. One (1) pc. each lamp/s	a. One (1) pc. each lamp/s if the service life of the lamp/s is <u>less than ten (10) years</u> . If the service life of the lamp is 10 years and above, Bidder must provide a certificate or any documentation which guarantees the service life of the lamp, as claimed. In addition, a commitment letter to replace the said item in case the service life does not reach ten (10) years must be submitted.

ITEM NO. 4 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF TABLET HARDNESS TESTER COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)

A. MAIN UNIT		
Force Measuring Range	includes 5-600 N, at a minimum	retained as: includes 5-600 N, at a minimum
Accuracy or Repeatability	≤ 1 N	$\leq \pm 1$ N

B.1 Additional Set of spares and consumables	<ul style="list-style-type: none"> • 1 set Calibration Weight and Gauge blocks 	<ul style="list-style-type: none"> • 1 set Calibration Weight and Gauge blocks <p>Note: Calibration certificate must be submitted</p>												
D. WARRANTY, AND AFTER SALES SERVICES	A minimum of two (2) year warranty on parts and services of Tablet Hardness Tester, Printer and UPS. Both commencing after successful installation by Supplier and its acceptance by FDA.	<p>retained as:</p> <p>A minimum of two (2) year warranty on parts and services of Tablet Hardness Tester, Printer and UPS. Both commencing after successful installation by Supplier and its acceptance by FDA.</p>												
ITEM NO. 5 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF POTENTIOMETER COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (TOTAL)														
A.1 ANALYTICAL BALANCE	<p>A.1 ANALYTICAL BALANCE</p> <p>Note: Please indicate page number from the brochure submitted.</p> <table border="1" data-bbox="624 965 1031 1070"> <tr> <td>Capacity:</td> <td>≥220g</td> </tr> <tr> <td>Readability:</td> <td>≤0.1mg</td> </tr> <tr> <td>Repeatability:</td> <td>≤0.1mg</td> </tr> </table>	Capacity:	≥220g	Readability:	≤0.1mg	Repeatability:	≤0.1mg	<p>A.1 ANALYTICAL BALANCE</p> <p>Note: Please indicate page number from the brochure submitted.</p> <table border="1" data-bbox="1062 965 1469 1070"> <tr> <td>Capacity:</td> <td>≥220g</td> </tr> <tr> <td>Readability:</td> <td>≤0.1mg</td> </tr> <tr> <td>Repeatability:</td> <td>≤0.1mg</td> </tr> </table> <p>Additional Requirements:</p> <ul style="list-style-type: none"> - should be suitable with the Potentiometer/ tandem with the Potentiometer - With instrument software compliant with 21 CFR Part 11 - with calibration certificate traceable to International Standards 	Capacity:	≥220g	Readability:	≤0.1mg	Repeatability:	≤0.1mg
Capacity:	≥220g													
Readability:	≤0.1mg													
Repeatability:	≤0.1mg													
Capacity:	≥220g													
Readability:	≤0.1mg													
Repeatability:	≤0.1mg													
B.3 SOFTWARE (compatible with the HPLC System)	B.3 SOFTWARE (compatible with the HPLC System)	B.3 SOFTWARE (compatible with the Potentiometer)												
C. ACCESSORIES, SPARE PARTS AND CONSUMABLES	<p>C.1 ELECTRODES</p> <ul style="list-style-type: none"> • One (1) pc. electrode for volumetric KF reactions 	<p>C.1 ELECTRODES</p> <ul style="list-style-type: none"> • One (1) pc. electrode for volumetric KF reactions (e.g. Water content) 												
I. OTHER REQUIREMENTS	<p>I.5 The supplier must have at least ten (10) local installations of Potentiometer that can be viewed and demonstrated to the end user, if necessary</p> <p>Five (5) out of ten (10) local installations must be the same model as the one being offered.</p> <p>Note: Upon submission of bid, the bidder must submit list of companies with installed unit. Contact person and contact details</p>	<p>I.5 The supplier must have at least one (1) local or international installation of Potentiometer with the same brand and model as the equipment being offered, that can be viewed and demonstrated to the end user, if necessary.</p> <p>Note: Upon submission of bid, the bidder must submit list of companies with installed unit. Contact person and contact details</p>												

	(telephone number/mobile number and e-mail address) for each listed company must also be submitted.	(telephone number/mobile number and e-mail address) for each listed company.
ITEM NO. 6 SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING AND TESTING OF DISINTEGRATION APPARATUS COMPLETE WITH ALL NECESSARY PARTS AND ACCESSORIES FOR FDA-ALABANG TESTING QUALITY ASSURANCE LABORATORY (ATQAL)		
A. MAIN UNIT		
Heating mechanism	circulating pump or flow through system	circulating pump or flow through system or bathless. Note: For the bathless heating mechanism, additional document/s must be provided to verify that the model offered will have the equivalent performance, in terms of heating mechanism as that of the circulating pump or flow through system.
H. OTHER REQUIREMENTS	I.5 The supplier must have at least five (5) local installations of the same brand of Disintegration Apparatus that can be viewed and demonstrated to the end user, if necessary.	H.5 The supplier must have at least five (5) local installations of the same brand and model of Disintegration Apparatus that can be viewed and demonstrated to the end user, if necessary. AND/OR The supplier must have at least one (1) installation of the same brand and model of Disintegration Apparatus, within the Asia Pacific, that can be viewed and demonstrated to the end user, if necessary. Note: Upon submission of bid, the bidder must submit list of companies with installed unit. Contact person and contact details (telephone number/mobile number and e-mail address) for each listed company.


ENGR. ANA TRINIDAD F. RIVERA, MSc
 Chairperson, FDA-Bids and Awards Committee