

## Rajasthan Medical Services Corporation Limited, Jaipur

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No. F-8( ) RMSC/EPM/M-2/18-19/NIB-412/ 362'13'

Dated: 5-02-19

### CLARIFICATION/CORRIGENDUM/ADDENDUM

**Sub:- Revised bid Schedule and amended technical specification of the rate contract for HPLC (Gradient) with UV Detector, Auto Sampler & Essential Columns for under NIB No. F-8( ) RMSC/EPM/M-2/18-19/NIB-412/100 dated 09.01.2019**

In reference to subject cited above and NIB-412, the representations received from the various firms and issues raised by the Bidders, are examined by the competent Authorities and technical committee and approved by purchase committee. The following Clarification/Corrigendum/Addendum is issued for inclusion in Bid document Amended Technical Specification of items as below:-

#### **Revised Technical Specifications for HPLC (Gradient) with UV Detector, Auto Sampler & Essential Columns:-**

HPLC system consisting of Quaternary Gradient pump, Integrated Auto Injector, Online Degasser, Column Heater, UV Detector along with software and Accessories.

#### QUATERNARY GRADIENT PUMP:

Principle : Low Pressure Mixing - Serial Dual Piston  
Automatic Gradient Profile Facility  
Quaternary Pressure Gradient pump  
Operating Flow Range: 0.001-10 mL/min  
Flow Accuracy:  $\pm 0.1\%$   
Flow Precision:  $<0.1\%$  RSD  
Prop. Accuracy :  $\pm 0.5\%$   
Precision :  $<0.3\%$  SD  
Pressure Range : 8500 psi or equivalent  
Pulsation :  $<2$  bar or  $<1\%$  whichever is greater  
Solvent Degassing: Built-in (Integrated), 4-channels  
Error detection, Leak detection and safe leak handling display feature should be available.

#### Autosampler

Operating Principle : Inline Split Loop  
Sample Capacity : 90 vails or more  
**Injection Volume : 0.1  $\mu$ L -100  $\mu$ L**  
Injection Volume Accuracy :  $\pm 1\mu$   
Injection Volume Precision:  $<0\%$  of RSD  
Injection Volume Linearity :  $> 0.9999$  RSD  $< 0.5\%$  at 5 - 90  $\mu$ L  
Sample Carry Over: Not more than 0.005% from previous injection  
Temperature Accuracy Sampler :  $\pm 2^\circ$ C  
Pressure Range : 8500 psi or equivalent  
Auto sampler should have auto dilution facility in needle derivations facility.

#### Column Heater:

Temperature Control Range :  $15^\circ$  C to  $80^\circ$  C  
Temperature accuracy :  $\pm 0.5^\circ$  C  
Colum heater should hold 3 columns of 30 cm length.

DETECTORS: UV-Vis. Detector

Wavelength Range: 190-800nm



**Light Source: Deuterium Lamp and Tungsten lamp**

Lamp hour : D2 lamp >2000 hr life time

Noise:  $\pm 0.3 \times 10^{-4}$  AU

Bandwidth: upto 6 nm

Drift:  $\leq 1 \times 10^{-3}$  AU/hour/0C at 254nm, dry cell

Data Rate: 120 Hz or More

Detector linearity  $\leq 5\%$  at 2 AU Propyl Paraben, 257 nm

Flow cell: Analytical 10 mm path length

Flow cell Volume : 10  $\mu$ l or equivalent

Detector should be based lamp optimization software for low noise performance or equivalent detection facility.

**Software :**

Same software should be able to control all modules of HPLC system.

To control, acquisition, online display, processing peak point integration and reporting HPLC data, Full 64 Bit Architecture software

Software must be 21 CFR part 11 compliant fulfilling all effective regulatory requirements.

Windows 10/8 environment or suitable

Data reports, online help and wizards

Data Integrity, Advanced Security, Audit Trails

System suitability min 5 Parameter can be checked

Template saving & Auto run of templates

Calibration curves facility

Facility for data security, audit trails and electronic signatures etc., should be available for GLP and 21 CFR compliance.

**Columns (Pore Size 5  $\mu$ ) :**

(i) C-18 Column : 6 No. (Two of 250x4.6 mm & Four of 150 x 4.6 mm).

(ii) C-8 Columns : Two of 250x4.6 mm

(iii) Phenyl Column : One of 250 x4.6 mm

(iv) CN Column : One of 250 x 4.6 mm

**Accessories:**

1.(A) Vials : 1 ml pack of 100 vials & 2 ml pack of 100 vials (One Each)

(B) Low insert vials (for low volumes) : A pack of 100 vials

2. Filtration Assembly consisting of

(A) Sample Filtration Kit – One Nos.

(B) Membranes [Type: Dual (Aqueous & Organic solvents)]

Size 13 mm diameter with Poresize 0.45  $\mu$  – 10 Pkt of 100 membranes

Size 47 mm of 0.45  $\mu$  Poresize ; Qty- 10pkt of 100 membranes

(C) Pre-filters – 10pkt of 100 circles

(D) Solvent filtration kit – One No

(E) Imported Oil Free Vacuum pump – One No.

(F) Nylon Syringe filters (13 mm ; 0.45  $\mu$ ) – 2 Box of 100 filters.

3. Deuterium or suitable Lamp- One No.

4. HPLC Grade solvents of reputed brand

(A) Methanol -10x2.5 Lit.

(B) Acetonitrile- 10x2.5 Lit

(C) Water- 10x2,5 Lit.

Suitable PC & Printer with 3 KVA UPS of 60 min. Back up of reputed brands specification as under:  
 Processor - Intel i7 Latest generation; RAM - 8 GB ; Hard disk - 1 TB ; Graphic Card; DVD writer; 21" TFT screen ; LAN Port ; USB 2.0 Ports (4 Nos.) ; Wi-Fi ; Multimedia Keyboard ; Optical Mouse  
 Operating System - Windows 10/8 64 Bit architecture  
 Printer- Laser Printer Monochrome with duplex printing and LAN port.

Documents /Training and other notes:

- (i)The equipment should be certified by European CE marking or UL marking.
- (ii)Should have safety certificate from a competent authority like CE/Equivalent or valid detail of electrical and functional safety test. Copy of the certificate/test report shall be produced along with the technical bid
- (iii)Comprehensive guarantee period with spare parts for at least three years from the date of installation.
- (iv)Instruction Manuals (Hard Copy or Soft copy as applicable) along with standard Operation Procedures (SOP) and appropriate Dust cover for the instrument.
- (v)Installation qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)documents should be provided at the time of supply of the instrument.
- (vi)Satisfactory technical and application training to the personals at the site after installation.
- (vii)CMC will be given @5% of net rate-inclusive of GST (as applicable) & yearly escalation of 5% on last year's CMC price. The CMC may be awarded for five years (on yearly basis) after completion guarantee period.
- (viii)Minimum of two routine maintenance services/inspections to be provided annually and any number of breakdown emergency calls should be attended during the guarantee period.
- (ix)Price quoted should be inclusive of their complete installation in all respects at site as per purchase order.
- (x)Final technical approval only after demonstration of the quoted product.
- (xi)Any other perquisite required (if any) with specifications should be included with the instrument to run and complete the installation.

**Revised bid schedule:-**

E-bids are invited as per following revised time schedule:-

Existing Dates			Extended Dates		
Last Date for Sale of Bid Form	Last Date of Receipt of Bid Form	Date of Opening of Technical Bid	Last Date for Sale of Bid Form	Last Date of Receipt of Bid Form	Date of Opening of Technical Bid
1	2	3	4	5	6
<u>13.02.2019</u> <u>11:00 AM</u>	<u>13.02.2019</u> <u>6:00 PM</u>	<u>14.02.2019</u> <u>11:00 AM</u>	<u>14.02.2019</u> <u>11:00 AM</u>	<u>14.02.2019</u> <u>6:00 PM</u>	<u>15.02.2019</u> <u>11:00 PM</u>

**Note:-** Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-V, Schedule of Supply, and Point no. 3) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

This bears an approval of Managing Director, Rajasthan Medical Services Corporation Limited, Jaipur.

  
 Executive Director (EPM)  
 RMSCL, Jaipur

