

Annexure - AItem No. 1. HPLC System:-**1. HPLC Pump:-**

2 nos. Of HPLC integrated pumps, dual reciprocating pistons , programmable with non circular gear driven, should be provided to work in isocratic, binary gradient and semi preparative mode.

- Programmable flow range: 0.001 – 22 ml/min/pump or higher in each individual pump with 0.001 ml/min increment or better.
- Flow Precision: 0.1% RSD or better.
- Maximum Pressure: 6000 psi or better.
- The system delay volume should be lesser than 200 µl for sensitivity.
- Flow accuracy: $\pm 1\%$ or better.
- Should have the capability to operate in at least 11 or more various gradient curve mode including Linear, Step, concave, convex, exponential etc.

2. Injector:

- Rheodyne analytical injector with 5 µl, 20µl, 50 µl, 200 µl and 500µl loops.
- Dual Injector Facility should be provided. Both Analytical & Semi-Prep or Preparative should be done in the same panel but in a separate mode.

3. Detector:

Photodiode Array Detector:

- Wavelength range: 190 – 800nm.
- No. of Diode elements: 512 or better
- Light Source: Deuterium arc lamp ; Lamp should be of 2000 hrs warranty.
- Spectral Resolution: 1.2nm – 600 nm.
- Data Acquisition : Up to 80 Hz
- Wavelength accuracy: ± 1 nm or better
- Linearity range: $>5\%$ at 2 AU, 257 nm.
- Flow cell Design: Taper Slit only.
- Operating mode : Both 2D and 3D.
- Appropriate flow cell for semi preparative work should be quoted.
- Sensitivity Setting Range: 0.0001 – 2.0000 AUFS.

4. Evaporative light scattering detector (ELSD):

- Flow rate of nebulizer: 300 to 3000 µl/ min or better with Temperature control nebulizer chamber: Heater 0-100%, thermally controlled, cooler on/off.
- Gas supply: Nitrogen to be supplied at least 65 psi
- Gain setting: 0 to 1000.
- Sampling rate: upto 80 points / s or better.
- Light source: Tungsten halogen polychromatic front mounted, pre-aligned, user installable, Lamp calibration: Pre-aligned assembly or better.
- Detector: Photomultiplier tube.
- Scattering angle: 60 degrees.
- Measurement Range: 0.1 to 2000 light scattering units full scale.
- Optics: Heated optics bench (constant 50°C) or better.

5. Software:

User friendly chromatographic software compatible with the Photodiode Array detector and ELSD capable of following:

- Must be able to control the instrument fully.
- Should be Embedded Oracle data base of 10G.
- Should have archive and restore facility with the capability to rebuild all the projects and their relations of the project as they were upto the last archival.
- Measurement of retention times & component identification.

- Automatic peak detection, peak area measurement and baseline correction facilities.
- Software should be able to analyse GPC data.
- The software should be able to show the capability of the system to operate in at least 11 or more various gradient curve mode including Liner, Step, concave, convex, exponential etc.

6. Columns:

- Guard column: C18 and normal phase/silica-one each
- C18, 4.6x250 mm, 5 μ - one
- C18, 10x250 mm, 5 μ -one
- Normal phase/silica, 4.6x250 mm, 5 μ -one
- Normal phase/silica 10x250 mm, 5 μ -one

7. Syringe:

- 25 μ l – two
- 250 μ l – one
- 500 μ l – one

8. Essential Accessories:

Any other accessories required to make the system complete to be quoted.

Item No. 2 Real Time PCR:-

1. System & reagents both are CE-IVD / US-FDA certified
2. Light source is Broad spectrum high intensity Xenon arc Lamp
3. Simultaneous, scan –free detection of signals from all wells with telecentric optics & CCD Camera.
4. Block cycler unit is 96-well format including Thermo- base
5. Peltier based heating /cooling from 37° C to 95°C, (20° C staging temperature to perform specific melting curve analysis)
6. Heating rate: 96-well block: 4.4°C & Cooling rate: 96-well block 2.2°C
7. Reaction volume is 10 μ l to 100 μ l
8. System offer full traceability: Date, time, lot numbers, QC checks, patient ID and test results captured in a single report.
9. System should have 2 platforms, one is laboratory/user-developed protocols or UDF & another is existing IVD-approved test menu.
10. System is 21 CFR Part 11 Compatible.
11. Maintenance & ROX calibration is not requiring for the system.
12. IVD approved cancer marker assays like KRAS, BRAF and EGFR mutation tests with the system.
13. The tests are able to reliably detect mutations in cell lines and clinical FFPET specimens at > 5% mutation levels
14. The KRAS mutation test offer broad mutation coverage of KRAS codons 12, 13 and 61 to identify colorectal cancer patients not likely to respond to anti-EGFR monoclonal antibody therapies
15. The BRAF mutation test detects BRAF V600 mutations in FFPET samples and should aid in selecting patients for treatment with Zelboraf
16. The EGFR mutation test detects and identifies mutations in exons 18, 19, 20 and 21 of the EGFR gene from FFPET non-small cell lung cancer samples.
17. The system provides automate result interpretation
18. Up gradation option for HPV 16, HPV 18 & other high risk group screening & genotyping with automation.
19. Manufacturer should have standardized protocol & assay for H1N1 & Ebola
20. System should capable of multiplexing of 5 or more targets.



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