

NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS

Technical specification of UHPLC at Clinical Pharmacology Department, NIRT.Chennai

Sl. No.	Specification	Complaints Yes or No	Remarks
1	QUATERNARY GRADIENT SOLVENT DELIVERY UNIT		
	Pumping Method :Parallel-type double plunger		
	Flow Rate Settings Range:0.001 - 3.0000 mL/min or above		
	System Pressure : Minimum 15000 psi or above		
	Flow Rate Accuracy: $\pm 1\%$		
	Flow Rate Precision :0.06% RSD or 0.02 minSD		
	Gradient mode: Quaternary low-pressure gradient		
	Gradient Range of Set Concentrations: 0~100% (in 0.1% steps)		
	Gradient Concentration Accuracy: $\pm 0.5\%$		
	Automatic Rinsing Kit to be built in as standard		
	It must have a leak sensor as safety feature		
	pH Range: 1 – 14		
	It should employ active check valves that allow stable delivery of even non-polar organic solvents.		
2	DEGASSER		
	Online Membrane degassing unit with 4 flow lines or above		
	An internal capacity of 400 μ l per flow line should be available for decreasing the time.		
	It must have a leak sensor as a safety feature		
	The liquid contact surfaces of the degasser should employ special synthetic polymers designed for all solvents		
3	COLUMN OVEN		
	It should be forced-air-circulation type for uniform temperature distribution with a quick feedback mechanism to maintain constant temperature level even when power source voltage fluctuates		
	The temperature range should be ambient $\pm 10^{\circ}\text{C}$ to 85°C or above		
	Temperature control precision should be $\pm 0.1^{\circ}\text{C}$		
	Temperature control accuracy should be $\pm 0.8^{\circ}\text{C}$		
	The column oven compartment should have capacity to contain up to 3x300 mm L. column, or 6x250 mm L. Column		
	The oven should have temperature limit device and temperature fuse and a solvent leak sensor		
4	AUTOSAMPLER WITH SAMPLE COOLER		
	The auto sampler design should be a flow through design with variable total volume injection.		
	Injection Volume : 0.1 to 50 μ L		
	Operating Pressure: 15000 psi or above		
	System injection volume accuracy should be $\leq \pm 1\%$		
	Injection linearity ≥ 0.9999		

	Injection cycle time : \leq 10 seconds or better		
	Samples capacity: 140 (1.5 mL) or above		
	Injection Volume Reproducibility :RSD \leq 1.0%		
	Carryover : <0.00015%		
	Sample cooler temperature setting range :4 ~ 45 °C		
	Sample cooler temperature accuracy : \pm 2°C		
	pH Range :1 – 14		
	It should have safety features like leak sensor and automatic rack and vial recognition.		
	Should Equipped with Automatic Pre Treatment facility for diluting samples online, adding internal standard samples online		
5	PHOTO DIODE ARRAY DETECTOR		
	Light source : Deuterium (D2) lamp		
	Wavelength range : 190 nm to 800 nm		
	No of Diodes 1024		
	Slit width : 1.2 nm (high-resolution mode) or better		
	Wavelength accuracy \pm 1 nm max		
	Wavelength precision: \pm 0.1 nm max.		
	Linearity should be equal or more than 2.5 AU		
	Flow cell of 8 uL volume and 10 mm cell path length with temperature control should be available		
	Functions : Contour output, spectrum library, MAX plotting		
6	FLOURESCENCE DETECTOR		
	Light source : XENON lamp or Equivalent		
	Wavelength range : 200 to 650 nm		
	Bandwidth : 20 nm		
	Wavelength Reproducibility : 0.2 nm		
	S/N Ratio for Raman water peak should be minimum 1000 nm		
	Cell volume : 12 micro litre, 2 mpa pressure or equivalent		
	Capable of monitoring any two wavelength between 200 to 650 nm		
7	SYSTEM CONTROLLER OR CONTROL MODULE		
	Necessary system controller or equivalent to be quoted		
8	SOFTWARE		
	Software should be latest, genuine and original. It should cover full one-point digital instrument control, qualitative and quantitative processing, report creation and self-diagnosis		
	The software should be 21 CFR Part 11 compliance.		
	Suitable System Controller/Communication Module should be quoted		
	The reporting format should be flexible and easy to use in any desired format		

	The data can be converted to other (AIA, ASCII) formats. Spread Sheet software and word-processing software can be readily employed to provide data in tables or graphs through industry standard protocols		
	The software should allow automatic execution of system checks, auto-purge and baseline checks		
	Software must register all events (log files) audit trails for Data, Method, Batch, Report, System Policy and User Administration		
	Software must display the online status of instruments (Name, Type, Analysis, Status, User Running, Queued Count, Estimated End time)		
	Functions to check PC Information, Software Program Files Check, User List, User Groups, Group Rights, Security Policy, Instrument Connection information from software and printable in pdf format		
	An audio-visual multi-media CD-ROM for Maintenance and Troubleshooting must be provided		
	System suitability, System security as well as System check functions must be provided which comply with Good Laboratory Practice (GLP) and Regulatory Conformity		
	IQ,PQ,OQ,DQ should be done and to be provided with Validation binder.		
9	COMPUTER, UPS		
	The system should be supplied with computer and printer to be offered		
	Branded Computer with latest version OS, 8 GB RAM DDR3 , latest i5 Processor , 1 TB GB hard disk capacity ,DVD-RW drive ,LED monitor 21 inch or more		
	Branded on line UPS with 3 KVA capacity & 1 hours battery back up Should be offered		
10	Column and Accessories		
	UHPLC C-18-column, SUB 2 micron (2.1x150mm) – 2 no		
	UHPLC C 8 column 2 micron, 2.1,150 mm)-2no		
	UHPLC NH2 column (2.1x150mm,3um) -1 no		
	Mobile Phase Solvent Bottles -5 nos of 1 litre Capacity		
	500 nos of 1.5 ml Vials		
11	OTHERS		
	Power requirement: 220-240 V; 50 Hz (suitable for Indian Laboratory)		
	Warranty: 36 months for the complete system followed by 2 years Free AMC		
	Annual Maintenance Contract for complete UHPLC Should be Quoted separately		
	1) The Annual maintenance Contract for a period of 5 years after 5 years of installation.		
	2) AMC rates not to exceed 1-2% of the cost of equipment.		
	3). All the spares should be available for a minimum period of 10 years with the supplier of the equipment.		

4) Annual Maintenance Contract should include preventive maintenance and breakdown calls.		
5) The vendor should have service and training facility in Chennai.		
6) Training for two people to be provided at NIRT FOC with certificate.		
Availability of local service support and response time for a service call during and after warranty specified		
7) The company should provide installation qualification, operational qualification and performance qualification of the equipment at no extra cost.		
8) The firm should provide necessary original documentary evidence of the features of the offered model in the technical bid to facilitate proper technical evaluation.		
9) Purchase orders, contact details and user satisfactory reports of the quoted model from Nationalized or reputed laboratories all over the India must be shared with quotation		
10) Indicate the year in which the model offered was introduced into the market and confirm whether the spares for the system would be available for a minimum period of 10 years and shall not be obsolete within ten years of procurement		