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Chapter 4: HPLC systems (2nos) with Server based Chromatography Network Software for Compliance Environment funded under TIES programme, Ministry of Commerce & Industry, Government of India

Technical specifications

HPLC WITH PDA AND FLD – 1no		
Specifications		Amended Specifications
Solvent Management System:	• The system should have pump which has two independent pistons with independent motors and pressure transducers, which must help in reducing the baseline ripples and provides the smooth base line in detecting and quantifying the smallest peaks. • Continuous and Automatic compressibility compensation provided in the pumping mechanism helps in greater accuracy of flow rate when working with gradient analysis and help in reproducibility of retention time in results.	No change
	• Integrated Vacuum Degasser: Integrated high efficiency vacuum degassing (with < 500 µl internal volume per chamber) of minimum 4 channels must be provided	No change
	• Flow rate up to 10 ml / min or higher. • Flow precision of < 0.075% RSD or better.	No change
	• Dry prime and wet prime should be Automatic and controlled from front panel • Effective delay volume of < 650 µl strictly, independent of system backpressure or better. • Facility for Automated Solvent Blending, online pH, ionic strength & organic modifier blending from solvents must be present to attain a perfect pH without human intervention. The pump shall have a means within the method for the on-line blending of eluents to a specific pH based on experimental pH calibration files that are created by the user. • 5000 psi or higher operating pressure for both Solvent and Sample Management functions • Ten (10 or more) different programmable	No change

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	gradient profiles including linear, step, concave and convex. • Integrated active, programmable and continuous plunger seal-wash • Tool-free, simple access to plungers, plunger seals, plunger wash seals. • Column Heater: Should be present integrated there with the system at a Temperature range upto 60^0 C or better.	
In-Built / Integrated Auto Sampler:	-	In-Built / Integrated/***Modular Auto Sampler:***
	• The flow through needle design with active and continuous needle wash help in reducing the carry over effect of the previous sample. • Number of sample vials/wells: More than 110 no. with five trays • Volume of sample: Up to 2ml • Sample carryover must be ≤ 0.0025% or better. • Sample delivery precision: 0.3% RSD • Injection Needle wash: Integral, active and programmable.	No Change
	• The Autosampler must be fully integrated / integral part of the entire system.	The Autosampler must be fully integrated / integral or ***modular part*** of the entire system.
	• Sample temperature: 4˚C to 40˚C	
Photo Diode Array Detector:	--	**Photo Diode Array Detector or DAD**
	• Wavelength range: 190-800 nm or better. • Wavelength repeatability: ± 0.1 nm or better. • Wavelength Accuracy: ± 1 nm or better. • Data Acquisition: Up to 80 points / sec or higher. • Light Source: Preferably must be a Single Deuterium lamp covering entire range; Lamp should be of 2000 hrs warranty without drop in the energy level with appropriate backup from software and hardware. It should be associated with Lamp optimization software to ensure consistent high sensitivity applications & reproducibility. • Flow cell Design: Suitable flow cell design for avoiding total internal reflection with a Cell Volume must be less than 10 µl. • Spectral Resolution/Optical Band pass: 1.2nm per photodiode with a total of 512	No Change

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	photodiodes, digital and optical (3D mode) • Operating mode: Both 2D and 3D • Linearity Range: ≤ 5% at 2.0 AU • Noise: ≤ 10 x 10^{-6} AU • Drift : ≤ 1 x 10^{-3} AU/hour	
Fluorescence Detector	• Wavelength Range: 200 to 890 nm • Emission Wavelength Range: 210 to 900 nm • Bandwidth: 20 nm • Wavelength Accuracy: ± 3nm	No Change
	• Wavelength Repeatability: ±0.25 nm	Omitted
	• Sensitivity: S/N, Raman peak of Water ≥ 1000 • Measurement Range: 0.001 to 100,000.000 emission units. • Data Channels: Up to Four 2D channels or One 3D channels. • Sampling Rate: Upto 20 points / s. • Light Source: Xenon Lamp, should have 2000 hrs warranty.	No Change
	Flow cell design: Axially Illuminated	Flow cell design: Axially Illuminated **or equivalent technology**
	• **Flow Cell Volume: 13 µl**	**Omitted**
Instrument along with Detectors and Software Qualification Service & Certification	• System Qualification (as per GLP Compliance) along with all detectors and Software (IQ/OQ) must be quoted. • Vendors must quote the Qualification kits with defined list of items along with valid Cat. No./Product ID etc. • During installation and qualification, Instrument should perform as per submitted specification in presence of user.	No Change
HPLC WITH PDA AND RI DETECTOR – 1 no.		
Solvent Management System:	• The system should have pump which has two independent pistons with independent motors and pressure transducers, which must help in reducing the baseline ripples and provides the smooth base line in detecting and quantifying the smallest peaks. • Continuous and Automatic compressibility compensation provided in the pumping mechanism helps in greater accuracy of flow rate when working with gradient	No Change

	analysis and help in reproducibility of retention time in results. • Integrated Vacuum Degasser: Integrated high efficiency vacuum degassing (with < 500 µl internal volume per chamber) of minimum 4 channels must be provided. • Flow rate up to 10 ml / min or higher. • Flow precision of < 0.075% RSD or better. • Dry prime and wet prime should be Automatic and controlled from front panel • Effective delay volume of < 650 µl strictly, independent of system backpressure or better. • Facility for Automated Solvent Blending, online pH, ionic strength & organic modifier blending from solvents must be present to attain a perfect pH without human intervention. The pump shall have a means within the method for the on-line blending of eluents to a specific pH based on experimental pH calibration files that are created by the user. • 5000 psi or higher operating pressure for both Solvent and Sample Management functions • Ten (10 or more) different programmable gradient profiles including linear, step, concave and convex. • Integrated active, programmable and continuous plunger seal-wash • Tool-free, simple access to plungers, plunger seals, plunger wash seals. • Column Heater: Should be present integrated there with the system at a Temperature range upto 60^0 C or better.	
In-Built / Integrated Auto Sampler:	• The flow through needle design with active and continuous needle wash help in reducing the carry over effect of the previous sample. • Number of sample vials/wells: More than 110 no. with five trays • Volume of sample: Up to 2ml • Sample carryover must be ≤ 0.0025% or better. • Sample delivery precision: 0.3% RSD • Injection Needle wash: Integral, active and programmable.	•

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	• The Auto sampler must be fully integrated / integral part of the entire system	• The Auto sampler must be fully integrated / integral/***modular*** part of the entire system
	• Sample temperature: 4˚C to 40˚C	• No Change
Photo Diode Array Detector:	-	**Photo Diode Array/DAD Detector:**
	• Wavelength range: 190-800 nm or better. • Wavelength repeatability: ± 0.1 nm or better. • Wavelength Accuracy: ± 1 nm or better. • Data Acquisition: Up to 80 points / sec or higher. • Light Source: Preferably must be a Single Deuterium lamp covering entire range; Lamp should be of 2000 hrs warranty without drop in the energy level with appropriate backup from software and hardware. It should be associated with Lamp optimization software to ensure consistent high sensitivity applications & reproducibility. • Flow cell Design: Suitable flow cell design for avoiding total internal reflection with a Cell Volume must be less than 10 µl. • Spectral Resolution/Optical Band pass: 1.2nm per photodiode with a total of 512 photodiodes, digital and optical (3D mode) • Operating mode: Both 2D and 3D • Linearity Range: ≤ 5% at 2.0 AU • Noise: ≤ 10 x 10^{-6} AU Drift : ≤ 1 x 10^{-3} AU/hour	• No change • No change • No change • No change • Light Source: Preferably must be a Single Deuterium and ***tungsten*** lamp covering entire range; Lamp should be of 2000 hrs warranty without drop in the energy level with appropriate backup from software and hardware. It should be associated with Lamp optimization software to ensure consistent high sensitivity applications & reproducibility. • **Omitted** • No change • No change • No change • No change
Refractive Index Detector	• RI Units: 1.00 to 1.75 with measuring range of 5x10^{-4} to 7.0x10^{-9} RIU. • Flow cell should be temperature controlled or with heat exchangers to have minimum noise of 1.5 x 10^{-9} RIU with 2s time constant. • Cell should have minimum volume of 10microliter or less to be compatible with flow rates upto 10ml/min. • Flow Cell: Fused Quartz. • Light source: LED	• No change
	• Flow cell volume: 10 µl	• **Omitted**
Instrument along with Detectors and Software Qualification Service & Certification	• System Qualification (as per GLP Compliance) along with all detectors and Software (IQ/OQ) must be quoted. • Vendors must quote the Qualification kits with defined list of items along with valid	• No Change

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	Cat. No./Product ID etc. • During installation and qualification, Instrument should perform as per submitted specification in presence of user.	
Columns & Accessories:	• Suitable analytical C18 (1 No.), Normal phase column (1 No.) and Chiral column (01 No.) should be quoted with the system with the dimension of 4.6×250 mm, with 5um particle size	• No change • Omitted • 3.5-µm particle 4.6 × 150 mm amide column
	• Suitable 03 columns each (Total of 3*6=18)	• Omitted
	• 3.5-µm particle 4.6 × 150 mm amide column • Amino (NH2) column (3 µm, 100A 2 × 150 mm) • Phenyl Hexyl column (3 µm, 100A 2.1 × 150 mm) • RRHD SB-CN column (1.8 µm, 3.0 × 100 mm) • XDB C18,3.0 x100mm, 3.5 µm • High strength Silica or equivalent chemistry SS UPLC T3 column (1.8 µm particle 50 × 2.1 mm)	• 3.5-µm particle 4.6 × 150 mm amide column **(03 numbers)** • Amino (NH2) column (3 µm, 100A 2 × 150 mm) **(03 numbers** • Phenyl Hexyl column (3 µm, 100A 2.1 × 150 mm) **(03 numbers** • RRHD SB-CN column (1.8 µm, 3.0 × 100 mm) **(03 numbers)** • XDB C18,3.0 x100mm, 3.5 µm **(03 numbers)** • High strength Silica or equivalent chemistry SS UPLC T3 column (1.8 µm particle 50 × 2.1 mm) **(03 numbers)**
	should be quoted along with the system. • 2ml Vial with Cap and Pre-slit PTFE/Silicone Septa – 1000 nos • Total recovery Vial with Cap and Pre-slit PTFE/Silicone Septa – 500 nos	• No Change
	• 150µl Glass insert – 2000 nos	• 150µl Glass insert **with bottom spring** – 2000 nos both with bottom spring also
	• Syringe Filter for sample (0.2µm particle size) – 2000 no. • Membrane Filtration for solvent (0.45 µm pore size and 47 mm diameter) - 2000 nos • Suitable Peek Tube Cutter – 2 no. • Suitable Stainless-Steel Tubing Cutter with Blades – 2 no. • Suitable Solvent Inlet Filter – 10nos • Suitable Stainless-steel Union – 2 no. • Solvent Filtration Apparatus (47 mm glass filter funnel) with oil-less vacuum pump with two gauges and regulators – 2	• No Change

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	no. each • HPLC bottles 500 mL (20 no.), 1000 mL (20 numbers) and 500 mL (20 numbers), 250 mL (20 numbers) and 100 mL (20 numbers) • Branded Micropipette with stand each (0.5-10 µL, 100-1000µL, 20-200µL and 10-100µL) • Solvent will be arranged by supplier for the smooth demonstration and qualification of the system. • HPLC grade solvent Acetonitrile (50 litre), Methanol (50 litre), and isopropyl alcohol (30 litre) should be quoted with the system. • Na_2HPO_4(500 gram), Sodium acetate (250 gram), sodium chloride (250gram), EDTA (100 gram), Citric acid(500gram), Ortho-phosphoric acid(250mL), triethylamine (500mL) and KH_2PO_4 (500 gram) should be quoted with the system.	
Server based Chromatography Network Software		
Original Server based Network Chromatography Data Software	• Network based Chromatography Data Software must contain a structurally validated andORACLE relational database management system which should allow searching and filtering of information using multiple search parameters. • Network based Chromatography data software can connect 10 nos Chromatography systems. • Oracle database must be present for easy tracking and trending, Instrument Method, Processing Method, Report Method, etc. • The software must come with System Suitability facility for checking Detector noise and drift, USP Resolution, Signal to Noise ratio, USP Peak Tailing, Plate count etc. • Vendor should quote 2 nos LC control Licenses (with catalogue no.)to connect above HPLC systems & 5 numbers of user's licenses for the creation of separate user names & passwords. • Software should have extensive custom calculation capabilities, eliminating the need for external applications to meet the laboratory needs. For example, these might include calculations for multi-component assay, impurities and system suitability. • software must be able to store each	• No Change

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	analytical method including instrument set points, data acquisition, data evaluation and reporting parameters as one analytical specification. • Apex peak integration algorithm should be available. • Software must allow the system to run unattended, and it must be capable of monitoring the instrument during acquisition and recording both instrument performance parameters: temperature, pressure and including ambient temperature and any unusual or unexpected events that would affect the integrity or quality of the results. A log to record each functional step the software executes. A log to record when and who modified the methods. The software must allow programmed shutdown of the instrument, including the lamps in the detector. • Pre-made templates, customizable data reports, online help and answer Wizards must be included to help maximize your lab's productivity. • Each injection is time and date stamped for easy archiving, retrieval of data. • Report publisher facility for customized reports. • Software should offer multiple levels of password, security to ensure the integrity of all your raw data and results. • The Software must be associated with Audit Trail. • It must be complied with GLP/GMP & 21 CFR PART 11 & documents must be submitted related to same.	
Server for Network Chromatography Data Software	• Intel® Xeon® E5 series Single Quad Core 2.1 GHz or more • 16 GB RAM • Dual RAID Controller Card • HDD – 300 GB SAS 15K - 6 nos. • DVD ROM Drive • LAN card 1GBPS - 2 no's (Including on board) • Windows 2016 Server Standard edition (64bit OS) • SVGA Monitor (27 inch), keyboard and Mouse • DLT Tape backup systems and DLT Tapes for Backups.	• Intel® Xeon® E5 series Single Quad Core 2.1 GHz or more • 16 GB RAM • Dual RAID Controller Card • HDD – 300 GB SAS 15K - 6 nos. • DVD ROM Drive • LAN card 1GBPS - 2 no's (Including on board) • Windows 2016 Server Standard edition (64bit OS), SVGA Monitor (27 inch), keyboard and Mouse • DLT Tape backup systems and DLT Tapes for Backups.
Computer (2nos) for connecting	• Intel i7 processor 2.4 Ghz or More • 12 GB RAM	• Intel i7 processor 2.4 Ghz or More

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HPLC Systems with inbuilt wifi	• 300 GB Hard Disk
	• DVD ROM Drive
	• LAN card 1GBPS - 2 no's (Including on board)
	• Windows 10 Professional (64 bit – OS)
	• 27 inch Monitor, keyboard and Mouse.
		• 12 GB RAM
		• 300 GB Hard Disk
		• DVD ROM Drive
		• LAN card 1GBPS - 2 no's (Including on board)
		  • License version of latest windows professional OS & latest MS-Office professional and driver with original CD.
		  • License version of adobe creative cloud
		  • 27 inch Monitor, keyboard and Mouse.

Printer (2Nos)	• Laser Jet Printer (3 in one)	• No Change
Warranty and AMC	•	• 3 Years comprehensive warranty for all parts including detectors. Price details for additional five years of AMC after completion of three years of warranty and five years of AMC to be quoted