SPECIFICATIONS FOR HIGH PERFOMANCE LIQUID CHROMATOGRAPHY (HPLC) FOR THE DEPARTMENT OF CLINICAL PHARMACOLOGY, BYLNAIR HOSPITAL, MUMBAI

Sr. No.		Particular	Specification
1.		**Pump**	
	a	Operating Principle	Parallel- type/ or series type double plunger
	b	Gradient formation	Quaternary gradient pump
	c	Flow rate range	0.001-5.0 ml/min or more
	d	Flow rate accuracy	±0.1- ±1.0%
	e	Flow rate precision	≤0.05 - ≤0.075%RSD
	f	Pressure range	8000 psi or more
	g	No. of eluent lines	4 solutions
	h	Solvent degassing	Built – in, minimum 4 channels
	i	Safety Measures	Liquid leakage sensor
	j	Composition accuracy	0.50-0.80%RSD
	k	Composition precision	≤0.25%
2.		**Autosampler injector with cooler**	
	a	Sample capacity	Minimum 90 × 1.5 ml / 2 ml
	b	Sample injection system	Loop injection / total volume sample injection /direct injection system
	c	Sample injection volume	0.1 – 100µl
	d	Injection volume accuracy	≤1.0 %
	e	Injection volume precision	≤ 0.4 % RSD (when 10µl is injected)
	f	Carryover of sample	≤ 1.0% with Caffeine/ Chlorhexidine
	g	Sample thermostatting	1 to 35˚C
	h	Safety Measures	Liquid leakage sensor
	i	Injection cycle time	≤20 seconds
3.		**Column Oven**	
	a	Type of column oven	Forced-air-circulation type / Peltier type
	b	Temperature range	5°C-65°C or more
	c	Temperature Accuracy	≤ 1°C
	d	Temperature precision	≤0.2°C
	e	Column capacity	Minimum 2 columns
	f	Safety Measures	Liquid leakage sensor
4.		**UV-Vis Detector**	
	a	UV VIS detector provided	Yes
	b	Data acquisition	80 - 100 Hz
	c	Noise, Single wavelength	≤ 0.5×10^{-5} AU/hour
	d	Drift	≤1.0×10^{-4} AU/hour
	e	Linearity in AU	2.5 or more
	f	Light Source	Deuterium and Tungsten lamp,

			minimum life 2000 working hours
	g	Wavelength range	190 to 700 nm or more
	h	Wavelength Accuracy	±1nm
	i	Optical Bandwidth	≤ 6 nm
	j	Flow cell must be temperature controlled	Yes
	k	Flow cell path length	≤10mm or better
5.		**Photo Diode Array (PDA) Detector**	
	a	Provision of Photo diode array	Yes
	b	PDA detector Wavelength range in nm	190 – 900 nm or better
	c	No. of diodes	1024
	d	PDA detector light source	Deuterium & Tungsten (Hg lamp optional)
	e	PDA detector wavelength accuracy	≤1nm
	f	Data rate in Hz	100
	g	Noise in AU	$0.8x10^{-5}$ AU or less
	h	PDA detector Drift in AU/hour	0.5×10^{-3}AU/hr or less
6.		**Fluorescence detector**	
	a	Data acquisition	12 Hz or better
	b	Light Source	Xenon lamp, minimum life of 2000 working hours
	c	Wavelength Range	Excitation -200 -850nm Emission -250-900 nm
	d	Spectral Bandwidth	15nm
	e	Wavelength Accuracy	±3nm
	f	Safety Measures	Liquid leakage sensor
7.		**Column**	
	a	Type of column	C-18
	b	No. of columns	2
	c	Dimensions of column	250mm x 4.6mm x 5µ
8.		**Accessories/ Consumables**	
	a	Computer	i5 Processor with 8 GB RAM, 500 GB HDD, Windows 10 and 19" LED Monitor. Compatible and with latest configuration
	b	Printer	Black and White laser printer
	c	UPS	Online UPS of 5KVA for 1hour back up should be provided for whole system
	d	Bottles	4
	e	HPLC Vials 1.5ml/2ml capacity with septa	1000 nos- 1 packets
	f	Micro inserts	1000 nos.- 1 packets
	g	HPLC tubing	2 sets
	h	Fully autoclavable variable single channel pipettes 2 to 20ul.	01
	i	Fully autoclavable variable single channel pipettes 100 to 1000 ul	01
	j	Fully autoclavable variable single	01

		channel pipettes 0.5 to 5.0 ml	
9.		**Chromatography software**	
	a	Type of operating system	32/64/ bit
	b	Operating Windows	Windows 10 or latest
	c	Licensed copy	
	d	Software should full support of all compliance requirement mandated by US FDA- 21 CFR Part 11. Software should provide the necessary controls for managing system access, user management, data transfer handling and audit trail functionality	
	e	Software must be able to link with Windows Users or Active Directory Users	
	f	Software controls	Full one-point digital instrument control, qualitative and quantitative processing, report creation and self-diagnosis
	g	Data saving through software	all events (log files) audit trails for Data, Method, Batch, Report, System Policy and User Administration
	h	System suitability, System security as well as System check functions must be provided which comply with Good Laboratory Practice (GLP) and Regulatory Conformity	
10		**General Requirements**	
	a	All the above equipment shall be new and manufactured from virgin materials. All the requirements of this supply shall be necessary sourced from the original equipment manufacturer of the model quoted except UPS, Computer, Printer etc which shall not be necessary sourced from the original equipment manufacturer of the model quoted but should be compatible with the quoted model.	
	b	Equipment shall operate on 230 V, single phase, 50 Hz electric supply. The necessary protective relaying / circuitry shall be there with the machines. The mains supply voltage variation may be max.±10% and frequency variation maximum ±3 %.	
	c	CE certified by European Notified Body (under IVD) along with declaration of conformity or US FDA approved for offered model and accessories. In case of CE (Class-I), the following documents are required to be enclosed: a. Declaration of conformity by manufacturer or EU representative of Manufacturer for the quoted model. b. Documentary evidence regarding firm registered with EEA (European Economic Area) Competent authority is required. Or European Representative registered with EEA (European Economic Area) Competent authority appointed by firm is required.	

		Or Other documents like certificates from Notified body along with declaration of conformity.
	d	Three-year comprehensive warranty to be followed by 7 years CMC. Technical support, required spares and consumables should be assured for two years after initial 3 + 7years period is over.
	e	The equipment should be provided with one hard copy in original of the detailed service manual and operation manual. Further, a soft copy is also required.
	f	The equipment must be tropicalized as below: • Operating room temperature: upto 40° C • Storage room temperature: upto 60º C • Relative Humidity: upto 90% non-condensing
	g	Among the other things, the responsiveness of the bid will be based on successful demonstration of the offered model of the equipment
	h	The bidder has to submit users list with address & contact telephone number/s.
	i	Prospective tenderers should have a full-fledged and well-established service centre in Mumbai with engineers qualified in servicing of HPLC.

Sd/-
Dr. Renuka Munshi
Professor & Head
Department of Clinical Pharmacology
TNMC & BYL Nair Ch Hospital

Sd/-
Dean (N&T)
TNMC & BYL Nair Ch Hospital