

GLP & 21 CFR Part 11 Complied LC-MS/MS - Triple Quadrupole Mass Spectrometer System of CSIR-IICB

Item	Specification	Requirement
1	Ion Source:	Dedicated ESI and APCI sources for polar and non-polar molecules quantification.
2	Mass Range	≤ 10 to $\geq 2,000$ m/z or better.
3	Analyser Type	Triple Quadrupole Geometry.
4	Scan Speed	The scan speed should be at least 12,000 Da/sec or amu/sec or u/ sec or higher.
5	Mass stability	≤ 0.1 Da/u over a 24-hour period
6	Mass acquisition mode	Must be capable to do all analysis including Full Scan MS, Full scan MS/MS, Precursor ion scan, Product Ion Scans, Neutral Scans and SRM/MRM scans
7	Desolvation temperature	Should be 500 degree or higher in both ESI and APCI mode.
8	Sensitivity	a. For positive ionization mode 1pg of reserpine should have S/N 15,00,000:1 or higher. IDL 0.3 femtogram or better. b. For negative ionization mode 1pg Chloramphenicol should have S/N 15,00,000:1 or higher. IDL 0.3 femtogram or better.
9	Linear Dynamic Range	≥ 6 orders of magnitude.
10	Polarity Switching Time	Should be 25ms or less.
11	Dwell time and Inter channel delay time	It should have 1ms or less dwell time and Inter channel delay/ pause of 1ms or less.

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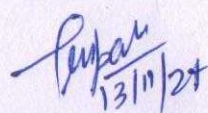
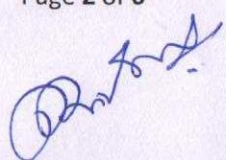
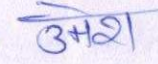

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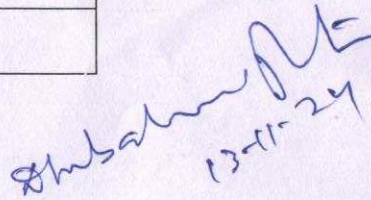
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12	Nitrogen gas generator	A suitable Low noise nitrogen gas generator with in-built compressor, filters, or any other accessory required for functioning of system, should be supplied.
13	Start- up Kit	LC-MS/MS start-up kit should be supplied as standard.
14	Preventive maintenance kit	Should be supplied every year during warranty period.

Liquid Chromatography Specifications

Item	Specification	Description
15	Pump	Binary high pressure gradient pump with a minimum pressure of 15,000-psi or better equipped with in line degasser.
16	Flow Rate	Operating range 0.01-2 ml/min or better.
17	Auto Sampler	Auto sampler should be compatible with the following sample capacity of approximately: 288 (microtiter plate, 96 well \times 3 plates), 1152 (microtiter plate, 384 well \times 3 plates) 252 (1 mL sample vial, 84 \times 3 plates), 162 (1.5 mL sample vial, 54 \times 3 plates),
18	Autosampler temperature	Range from 4°C to 40°C or better.
19	PDA Detector	Wave Length Range: 190-700 nm or higher, Two flow cells 1 with standard (13 or less micro litre volume) and another one with volume 2.5 micro litre or less for micro volume applications
20	Column Oven	Column oven temperature should go up to 80°C or better.

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21	Column and Accessories	<u>Chemistry</u>	<u>Dimension</u>	<u>Quantity</u>
A		Phenyl	2.1x100 mm, sub 2µm	3 Nos
B		C18	2.1x100 mm, sub 2µm	3 Nos
C		C8	2.1x100 mm, sub 2µm	3 Nos
D		HILIC,	2.1x100 mm, sub 2µm	3 Nos
E		PFP	2.1x100 mm, sub 2µm	3 Nos
F		Amide column	4.6 × 150 mm, 3.5µm	3 Nos
G		Amino (NH ₂) column	2.1 × 150 mm, 3 µm	3 Nos
H		Phenyl Hexyl column	2.1 × 150 mm 3 µm	3 Nos
I		Low pH C18	2.1x100 mm, sub 2µm	3 Nos
J		Low pH C8	2.1x100 mm, sub 2µm	3 Nos
22	Vials with Cap and Pre-slit PTFE/Silicone Septa	3000 Nos.		
23	Suitable Peek Tube Cutter	2 Nos		
24	Suitable Stainless Steel Tubing Cutter with Blades	2 Nos		

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25	Spare Capillary tubes for LC and MS	20 Meters	
26	Branded Micropipettes with stand each	0.5-10 μ L	2 Nos
		10-100 μ L	2 Nos
		20-200 μ L	2 Nos
		100-1000 μ L	2 Nos
27	Peak tubing	10 meter	
28	SS capillary ferrules	10 Nos	
29	Tune Mix Solution	02 Nos	
30	SS Nuts for ferrules	10 Nos	
31	Nebulizer capillary assembly	02 Nos	
32	PDA Lamp (Deuterium, Tungsten)	02 Nos Each	
33	UPS	15 KVA online Capacity, 60 min back up, with warranty for 5 years	
34	Gas Cylinder	Nitrogen/Argon as suitable for the instrument	02 Nos Each.
35	S.S Gas Regulators Double Stage	02 Nos Each (Per cylinder)	

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36	Table	Suitable Sturdy Anti-vibration table with SS/Granite top for instrument, with drawers for keeping documents and spare parts must be quoted. Except the electrical connectivity and room-space entire installation will be vendor's responsibility.
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Workstation and software

Items	Specifications with Description	
37	Computer	Latest and suitable workstation should be provided for controlling the Mass Spectrometer, LC and Auto-Sampler with data acquisition & for data processing and analysis to be supplied along with instrument.
38	Printer	Laser Jet Multifunctional Printer.
39	Monitor	23 Inch or More
40	Software	Licensed integrated software to control MS and LC together. Software must be fully complied with GLP/GMP & 21 CFR PART 11 & documents such as Audit Trail, Meta Data etc. must be submitted related to it. The Software should be capable of characterization and quantification of all types of samples.
41	Data base	NIST Library of 20,000 and above molecules.
42	Computer for data processing	A separate latest CPU and monitor must be quoted for offline data processing (64 GB RAM or more, 4 TB HDD or more, 23-inch monitor or more) which should be

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42	Computer for data processing	A separate latest CPU and monitor must be quoted for offline data processing (64 GB RAM or more, 4 TB HDD or more, 23-inch monitor or more) which should be accommodated with the quoted software. A network access storage (NAS) with 60 TB or more capacity.
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Other Requirements

Items	Specifications with Description	
43	Model.	The vendor should quote the latest and advanced model
44	IQ, OQ and PQ.	The complete IQ, OQ and PQ must be done and the supplier should provide these quantifications and qualification documentations for the entire system.
45	Warranty	5 years comprehensive onsite warranty must be quoted on complete instrument and accessories including Nitrogen Generator with PM Kits.
46	Training	Training has to be imparted for 5 days at the time of installation and commissioning and then again 5 days spread across three months from the commissioning of the equipment.
47	Service and Support.	Both the Liquid Chromatograph and Mass Spectrometer and other accessories supplied with the instrument must be fully supported by the supplier. The spare parts and any updates on its software / Hardware should be supplied for 10 years.

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