

REVISED TENDER DOCUMENT FOR LIQUID CHROMATOGRAPH TANDEM MASS SPECTROMETER (LC-MS/MS) ALONG WITH ALL ACCESSORIES AND SAMPLE PREPARATION FACILITY



Food Safety & Standards Authority of India Ministry of Health & Family Welfare FDA Bhawan, Kotla Road New Delhi – 110002

Letter for invitation:

Dear Sir/Madam,

FSSAI has undertaken a major programme for strengthening of Food Testing System in the country. As part of this programme, 45 State Food Testing Labs will be modernised with the induction of state-of-the-art analytical instruments. FSSAI proposes to enter into rate contract with reputed Original Equipment Manufacturers/Authorized Suppliers in India for the supply of Liquid Chromatograph Tandem Mass Spectrometer (LC-MS/MS)

Sealed tenders are, therefore, invited from reputed manufacturers/Authorized suppliers in India for finalising the rate contract for and on behalf of Food Safety and Standards Authority of India for the purchase of Liquid Chromatograph Tandem Mass Spectrometer (LC-MS/MS). The bids are to be submitted under a two bid system i.e. Technical and Financial Bids in the prescribed format. Financial bids of only technically qualified bidders would be opened.

FSSAI reserves the right to accept or reject any or all of the offers at any stage of the process without assigning any reason thereof and any claim /dispute on this shall not be entertained.

Yours Sincerely,

Head (Quality Assurance) Food Safety and Standards Authority of India, FDA Bhawan, Kotla Road, New Delhi – 110002

DATA SHEET

1	Name of Tendering Authority: FOOD SAFETY AND STANDARDS AUTHORITY OF				
	INDIA, FDA Bhavan, Kotla Road, New Delhi.				
2	1) Method of Selection: Selection of the Bidders will be a two stage process. In				
	the first stage the Bidders will be pre-qualified based on the compliance to				
	specification and other requirement mentioned in the Technical Bids. The				
	bids of only the Technically qualified bidders will be considered for opening				
	the Financial Bid.				
	2) L1 bidder will be selected from among the technically qualified bidder and all				
	other bidders will be given an opportunity to match the L1 price. Rate				
	contract would be signed with only those bidders who will match the L1				
	price.				
3	A Pre- Bid conference will be held: Yes				
	Date: 22 nd November 2016 at 12:00 pm				
	Venue: FSSAI HQ				
	Details.				
	A maximum of two representatives of each Ridder shall be allowed to participate				
	on production of a letter from the Bidder				
	Bidders requiring any clarification on the tender may send their queries to the				
	Head (Quality Assurance), FSSAI by email at softel.fssai@gov.in. All queries				
	should reach FSSAI by Email with an attachment in 'MS-Word format' at least				
	two days prior to the pre-bid conference date as per details provided below.				
	FSSAI shall endeavor to respond to the queries within the specified period				
	specified therein but not less than 5 days prior to the Bid Due Date. FSSAI				
	reserves the right not to respond to any question(s) or provide any clarifications.				
4	Point of contact for any queries related to the tender:				
	Head Quality Assurance				
	Food Safety & Standards Authority of India,				
	FDA Bhawan, Kotla Road,				
	New Delhi – 110002				

	Tele-No: 011-23220990			
	Website: <u>http://www.fssai.gov.in</u>			
	Email: <u>softel.fssai@gov.in</u>			
5	The Bidder must submit one copy each of the technical bid and the			
	Financial Bid in separate sealed cover. Bids received in unsealed conditions			
	will be summarily rejected.			
6	The Bidders are required to submit two envelops, one labeled 'Technical Bid' the			
	other labeled 'Financial bid' Both the bids must be sealed in one larger envelop			
	and should be marked, "Tender for Rate contract for(Name of the			
	Equipment)- Do not open except in presence of the Evaluation Committee" The			
	name of the Bidder submitting the bid must also be clearly indicated on the			
	envelope.			
	Each bid (Technical and Financial separately) shall be page numbered and			
	Financial figures shall be laminated/covered with transparent adhesive tape.			
7	The Technical bid must not contain any pricing information. If the technical bid			
	contains any commercial information, the bid is liable to be rejected. In			
	submitting additional information, please mark it as "supplementary" to the			
	enhanced levels of services) beyond the scope of this tender the hid must			
	include a description of such services as a separate and distinct attachment of			
	proposal.			
8	Bids must be submitted not later than on 16th December 2016 at 1730 hours .			
	Bid received after this will not be entertained or considered.			
9	Address for submission of the Bid:			
	Head (Quality Assurance)			
	Food Safety and Standards Authority of India,			
	FDA Bhawan, Kotla Road, New Delhi – 110002			
10	Date for public opening of Technical Bids- (To be notified)			
11	Date for opening of Financial Bids of Eligible Bidders (to be notified)			
12	Expected date for contract negotiations to be notified)			
13	Documents to be submitted by the bidder:			
	a) Technical bid in the format prescribed in this document along with			
	supporting documents as mentioned herein with signature, name,			
	uesignation and seal of the authorized representative of the bidder on			
	each page of the technical bid.			
	b) At least two Performance certificates from the organizations where the			
	quoteu equipment model has already been installed are to be provided by			
	a) Financial hid in the format prescribed in this document with signature			
1	j rinancial blu in the format prescribed in this document with signature,			

	name, designation and seal of the authorized representative of the bidder on each page of the financial bid.d) Acceptance of the terms and conditions contained herein in the format as given in the tender document.
14.	FSSAI reserves the right to accept or reject any or all of the offers at any stage of the process without assigning any reasons thereof and any claim /dispute on this shall not be entertained.

1. INTRODUCTION

The Food Safety and Standards Act, 2006 was enacted in 2006 in order to consolidate all the laws relating to food and to establish the Food Safety and Standards Authority of India (FSSAI) for laying down science-based standards for articles of food and for regulating their manufacture, storage, distribution, sale and import, for ensuring availability of safe and wholesome food for human consumption in the Country. By virtue of the mandate given to FSSAI, Rules and Regulations hitherto implemented under various regulatory orders were repealed with effect from 5th August 2011.

The Food Authority is mandated to lay down the procedure, guidelines and notification of the accredited laboratories. FSSAI may notify laboratories and research institutions accredited by NABL or any other accreditation agency. In addition to above, it also mandates the Food Authority to develop regulations for food testing laboratories, protocols for testing, audit of food safety systems and undertaking training and capacity building for laboratory staff and professional food analysts.

2. SCOPE OF THE WORK:

The scope of the work is divided into following components:

- a) Providing, Installing and commissioning Testing of the equipment Liquid Chromatograph Tandem Mass Spectrometer (LC-MS/MS)) along with all accessories and sample preparation facility.
- b) Provision of Manpower
- c) Operation and maintenance of equipment during the contract period

4.a Equipment to be provided:

Liquid Chromatograph Tandem Mass Spectrometer (LC-MS/MS) along with all accessories and sample preparation facility as per the specification given in the technical Bid format.

Note:

- a) The cost should be quoted separately for all the accessories, consumables, equipment for sample preparation, CRM etc required for the functioning of the respective equipment.
- b) The purchased equipment should be able to meet the requirements of the LOD and LOQ (Limit of detection and Limit of quantification) for the relevant parameters as specified in FSSR, FSSAI Manuals, Relevant test methods and be compliant to the requirements of ISO 17025.

4.b Manpower to be provided:

Successful bidder will have to provide full time one trained personnel for seven years who will be responsible for the working of the instrument i.e. sample preparation, method validation, operation of instrument and data interpretation. The personnel will not claim to be an employee of FSSAI/ state Laboratory. The person will work under the supervision of state laboratory head and carry out the required analysis of various samples received in the lab. He will also be responsible for providing training on the instrument to the laboratory staff.

Bidders will have to maintain backup of the manpower supplied in case of prolonged leave or any unforeseen circumstances.

In case the person provided by the bidder is found to be involved in any unlawful activity, the bidder will be liable to remove him immediately and provide a replacement. The decision of the state food lab would be final and binding to the bidder in this regard.

3. FORMAT OF THE TECHNICAL BID:

The bids of only the technically qualified bidders will be eligible for consideration for opening of financial bid. The technical bid of the bidders will be evaluated on the basis of specification of the offered model vis-à-vis the prescribed specification given below :

- 1. Name of the Equipment:
- 2. Offered Model:
- 3. **Brief details of the offered Model:** (in terms of sensitivity, specification, LOD, LOQ, etc.) (not more than 150 words)
- 4. Specification:

S. No.	Main Heads/ Components	Prescribed Specification	Please specify whether the quoted model meets the specification	Specification of the Quoted Model
			(Yes/No)	
1.	LC-MS/MS	A compact High resolution LC-MS/MS equipment for qualitataive and quantitative estimation of food contaminants (Pesticides, Mycotoxins, antibiotics etc) residues analysis with user friendly software to meet the global food regulations like EU/USFDA/Japan/FSSAI, etc		
1.1.	Mass Stability	0.1 Da over 24 hours (please provide graphical data)		
1.2.	Dynamic range	Should be 5 orders of magnitude or better		
1.3.	Mass analyzer	 Quadrupole Analyzer: The instrument should be configured with a quadrupole mass filter for the efficient transmission of ions in MS mode and selection of precursor ions for MS-MS analysis The Quadrupole mass range 20 – 1200 m/z or better The Analyzer should have more than one aspect for the efficient ion separation with maximum resolution. 		

1.4.	Sensitivity	Lower detection and highest sensitivity
		 ESI positive Ion Sensitivity: The signal/noise ratio for 1pg of reserpine should be >75000:1 or better, in MRM mode of reserpine at the transition m/z 609 – m/z 195(Proof document/application note to be enclosed along with technical tender document). ESI negative Ion Sensitivity: The signal/noise ratio for 1pg of chloramphenicol should be >30000:1 or better, in MRM mode of chloramphenicol at the transition m/z 321 – m/z 152(Proof document/application note to be enclosed along with technical tender
1.5.	Scan speed	Should have the scan speed of 12,000
		amu per sec or better
1.6.	Ionization	 Electrospray with Concentric Gas Flow for Nebulisation to cover flow rates upto 2ml/min. Multimode Ionization: ESI / APCI combined source: A combined ESI/APCI source must be provided as standard with the instrument. ESI and APCI ionization must be achieved using a single probe. It should able to perform both ESI and APCI
1.7.	Source Interface	 Orthogonal off-axis spray (Electrospray) or any other equally efficient technology capable of avoiding interference from solvents and other extraneous matter. Interface should maintain cleanliness of ion optics and capable of handling large batches of complex samples. Capable of handling large batches of complex sample matrix like Animal feeds, Fish and fishery products, poultry and poultry products, Honey, Milk and Milk products, Agriculture products (Fruits & Vegetables) etc. over a long period of time witheat reaformance degradation

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1.8.	Integrated Fluidic Device(to	 Cleaning of source should be done without venting the system and facility to vacuum interlock. Interface capable of ambient temperature operation and without complex apertures to maintain structural integrity of thermally labile and fragile molecules. An infusion device must be integral to the instrument or equivalent and must
	minimize space and tubing)	be controllable from the instrument software. At least 2 user-changeable sample vials should be built into the system to allow tuning and calibration solutions to be infused into the probe via the switching valve
1.9.	Polarity switching time	 +ve / -ve polarity switching time between alternate MRM scans should be 50 msec or better with supporting documents
1.10.	Vacuum System	 Robust high efficiency vacuum system with minimum maintenance and utility with low noise level. Vacuum read backs must be digitally monitored and controlled through software to ensure fail-safe operation in the event of power failure. All accessories required for the proper functioning of the vacuum system should be supplied. Fore line pump: Oil free Scroll type pump with arrangements of AUTO- ON after Power auto age. High vacuum pump must be Turbomolecular pump: 250 L/Sec or better
1.11.	Gas Control	• All gases must be controlled by the software.
1.15.	Operating modes	 Mass spectrometer should have the following scan options: Full scan Selected Ion monitoring/ recording (SIM/SIR) Product ion scan Precursor ion scan Neutral loss scan Multiple Reaction Monitoring (MRM) MS and MS/MS in a single

1.16.	Detector	 monitoring or equivalent. (Proof document /application note to be enclosed along with technical tender document with onsite verification) Simultaneous full scan and MRM or better (Optional) A high sensitivity, high throughput 	
		 detector with zero dead time, low noise and high accuracy at low level detections. An off-axis dynolite photomultiplier/Electron Multiplier detector Detector must operate in both positive and negative ion modes. Capable of switching polarity rapidly. Should have a better long life. (Life time shall be furnished and the better 	
		one will be given preference during technical evaluation).	
1.17	Nitrogen Generator	 Should be supplied with the system along with the trouble free inbuilt compressor and appropriate capacity reservoir which should be sufficient enough to deliver the gases (purity > 99.999%) required to run the system Should be complete with all necessary accessories with Two Years comprehensive warranty with at least one Preventive maintenance along with PM kit each year and Three years CMC after the warranty period including all spares, accessories and consumables , at least one Preventive maintenance along with PM kit each year and unlimited breakdown visits 	
1.18	Vacuum Manifold with compatible SPE Cartridges	 Minimum 10 cartridges extraction at one time Minimum 1000 cartridges for different analytes i.e pesticide residues, antibiotic residues etc 	
2.	High Performance Liquid Chromatograph y System	 List of column with Specification: a) C-18, 2.1×100 mm× 1.7 μm with suitable Guard column b) C-18, 2.1×150 mm× 1.7 μm with suitable Guard column c) C-18, 4.6 ×250 mm× 5 μm with suitable Guard column 	

		 d) C-8, 4.6 ×250 mm× 5 µm with suitable Guard column e) Phenyl-Hexyl 2.1mm ×100 x, 3µm or equivalent HILIC column with Guard column The complete system and the MS should be controlled by the single software PUMP: Binary pump pressure handling capability. Operating flow range should be 0.010-2.0ml/min or better with 1µl increments Autosampler: with 1 to 10 ul/min injection, minimum of 100 samples capacity. Capability to handle pressure range of 15000 psi or better. Column Oven: 30°C to 80°C, capability to accommodate a minimum of 1 or more columns of ≥ 15 cm. Temperature Stability: ±0.1°CTemp. Accuracy:±0.5°C DAD/PDA Detector: 190-700 nm, 80 Hz, Standard flow cell with flow cell
3.	Spares and accessories	 Hz, Standard flow cell with flow cell of 1.0 ul or better LC-MS/MS startup kit should be supplied as standard. All required traceable standards for Mass calibration and tuning, HPLC calibration should be provided 5µl, 10µl, 20µl, 50µl, 100µl loops, Vacuum pump oil, etc. and any other material required to make the instrument functional should be provided. Standard Tool kit should be provided Deruted highly hyperded external
		Reputed highly branded solvent filtration unit with pump and required accessories 02 nos
4.	System Controller and Operating system	 Software must be Multitasking type. It must acquire and process the data simultaneously Application manager must be compatible with data of full scan, SIM/SIR or MRM Data Acquisition, Peak Integration, Calibration, Quantification and QC calculations must be fully automated.

		 The Quantification method editor must be viewable in page view or spreadsheet. Application manager must allow to monitor the molecular ion and up to 04 (four) Confirmatory ions or better. Must be capable of performing the
		 following functions and should be upgradable: Workstation must be able to control the MS, acquire, store, process and reproduce the data by the same computer.
		 Workstation must be able to control LC, Detector and auto sampler. It must be able to regulate the gas pressure and flow during the data acquisition and
		 append to the relevant data file. Software must have automated calibration and Quantitative optimization. Automated MS to MS/MS switching during a single run with
		 user selectable criteria Perform alternating positive/negative scans in one run Automated Quantitation and reporting of acquired samples. Data may be processed as it is
5.	Calibration Standards	 being acquired Two sets each NIST or other traceable standards for all the Pesticides, Mycotoxins, antibiotics as per FSSAI requirement with a minimum expiry period of two years for seven years
		Or supply of NIST or other traceable standards every year with a validity of one year upto 7 years As per Annexure A
0.	PC with Printer	 Minimum Intel core 15/17 processor, 2.0 Ghz or more, 19"or more LCD/TFT Monitor, 500 GB HDD, DVD Read/Write, 4 GB RAM,4 USB Port or higher configuration for use with the above system to be provided.

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		Reputed Branded automatic back to back
		colour Laser jet printer should be provided
7.	Power Supply	The system should have UPS (minimum 10 KVA) of suitable rating with voltage regulation, spike protection and minimum 60 minutes back up for the supplied equipment.
8.	Additional items	 Bidders should quote a startup package for 100 samples. In addition, the bidders should give a list of recommended consumables along with their source and budgetary prices. Operation kit comprising all required items for startup/regular operation of instrument. Firm should also quote all essential pre- installation requirements and utility requirement for LC-MS/MS. Operation and maintenance manual for each unit in both hard copy and soft copy. Service manual with set of required tools for each system/unit. The system should have Server connectivity and should be capable of 21 CFR Part 11 and food safety compliance. The necessary validations will have to be carried out by the equipment suppliers. Complete methods library with MRMs of Mycotoxins, Veterinary drugs, Pesticides, antibiotics with instrument method details and SOPs, related software's and user manuals to be provided. PLEASE PROVIDE MAINTENANCE CHART FOR ALL OF THE COMPONENTS IN LC-MS/MS SYSTEM.
9.	Operation and maintenance & Training Component	 The supplier will have to carry out successful installation at our laboratory premises (where ever the system has to be installed) and provide on – site comprehensive training for scientific personnel operating the system and support services till customer satisfaction with the system and a training at the suppliers lab premises is also required.
		One trained personnel should be provided by instrument suppliers for seven years

10.	IQ/OQ/PQ	 who will be responsible for the working of the instrument i.e. sample preparation, method validation, operation of instrument and data interpretation. The personnel will not claim as an employee of FSSAI/ state Laboratory. The personnel will work under state laboratory head. He will also be responsible for providing training of the instrument to the laboratory staff. IQ/OQ/PQ of the system is required
11	Warranty	 Standard Warranty of 24 months starting
		 from date of satisfactory and faultless functioning of the equipment for 60 days at the respective laboratory premises. Comprehensive Maintenance Contract Service for 60 months after expiry of standard Guarantee/Warranty should be quoted Annual calibration of the equipment shall be a part of the CMC. It shall also be mandatory to perform calibration after every major repair/breakdown. The vendor should have available for ten years guaranteed parts and CMC service The supplier or his authorized agent should have after sales and service centre near each of our laboratory location where the equipment is to be supplied. Current user's / performance list with contact details (Customer name, phone email id etc) and date of installations of the model quoted) Number and details of the service engineers has to be provided Onsite performance evaluation of the equipment will be carried out for those who qualify in the technical bid.
12.	Preinstallation	Provide all pre installation requirements
	requirements	

5. List of Installations of the quoted Model or a comparable model of equivalent sensitivity preferably in food analysis sector in India (Attach Performance certificate from the organizations where the quoted model or a comparable model of equivalent sensitivity has already been installed)

Note:

- The technical bids have to be filled in the above format only. Separate application notes and details can be attached but the above format is to be filled mandatorily.
- The bidders should enclose with the technical bid a list of at least 5 Installations of the quoted model or a comparable model of equivalent sensitivity in the country, preferably in Food sector along with the Contact Name, contact no, mail ID and complete address.
- The bidders shall also provide along with the technical bid at least two Performance certificate from the organizations (at least one from the Government sector), where the quoted model/ or any other model of equivalent sensitivity has already been installed, indicating LOD/LOQ of at least 10 parameters relevant to food sector. In case he bidders are unable to obtain such a certificate, they may provide the full contact details of the users to enable FSSAI to get the certificates.
- The supplier should aim at a turnkey supply and installation of the equipment. Any accessory which is felt mandatory for the proper working of the equipment but not mentioned in the specification has to be quoted and supplied along with.
- Any unfair practice detected at any stage of the tendering process will lead to automatic disqualification/blacklisting of the concerned firm.
- No financial costs should be mentioned in the technical bid and the same shall be provided separately in a sealed envelope marked financial bid.

Name: Signature: Date: Seal:

(To be filled in the format given above and signed by the authorized representative of the bidder.)

4. FORMAT FOR FINANCIAL BID:

S. No	Main Heads/	Prescribed Specification	Price in INR
1	LC-MS/MS	A compact High resolution LC-MS/MS equipment for qualitataive and quantitative estimation of food contaminants (Pesticides, Mycotoxins, antibiotics etc) residues analysis with user friendly software to meet the global food regulations like EU/USFDA/Japan/FSSAI, etc	
1.1	Mass Stability	0.1 Da over 24 hours (please provide graphical data)	
1.2	Dynamic range	Should be 5 orders of magnitude or better	
1.3	Mass analyzer	Quadrupole Analyzer:	
		 The instrument should be configured with a quadrupole mass filter for the efficient transmission of ions in MS mode and selection of precursor ions for MS-MS analysis The Quadrupole mass range 20 - 1200 m/z or better The Analyzer should have more than one aspect for the efficient ion separation with maximum resolution. 	
1.4	Sensitivity	 Lower detection and highest sensitivity ESI positive Ion Sensitivity: The signal/noise ratio for 1pg of reserpine should be >75000:1 or better, in MRM mode of reserpine at the transition m/z 609 – m/z 195(Proof document/application note to be enclosed along with technical tender document). ESI negative Ion Sensitivity: The signal/noise ratio for 1pg of chloramphenicol should be >30000:1 or better, in MRM mode of chloramphenicol at the transition m/z 321 – m/z 152(Proof document/application note to be enclosed along with technical tender document). 	
1.5	Scan speed	 Should have the scan speed of 12,000 amu per sec or better 	
1.6	Ionization	 Electrospray with Concentric Gas Flow for Nebulisation to cover flow rates upto 2ml/min. Multimode Ionization: ESI / APCI combined source: A combined ESI/APCI source must be provided as standard with the instrument. ESI and APCI ionization must be achieved using a single probe. It should able to perform both ESI and APCI 	
1.7	Source Interface	• Orthogonal off-axis spray (Electrospray) or any other equally efficient technology capable of avoiding interference from solvents and other extraneous	

	<u> </u>			
		matter.		
		• Interface should maintain cleanliness of ion optics and		
		capable of handling large batches of complex samples.		
		• Capable of handling large batches of complex sample		
		matrix like Animal feeds, Fish and fishery		
		products, poultry and poultry products, Honey,		
		Milk and Milk products, Agriculture products (Fruits		
		& Vegetables) etc. over a long period of time without		
		performance degradation		
		• Cleaning of source should be done without venting	should be done without venting	
		the system and facility to vacuum interlock.		
		• Interface capable of ambient temperature operation		
		and without complex apertures to maintain structural		
		integrity of thermally labile and fragile molecules.		
1.8	Integrated	• An infusion device must be integral to the instrument		
	Fluidic Device(to	or equivalent and must be controllable from the		
	minimize space	instrument software. At least 2 user-changeable		
	and tubing)	sample vials should be built into the system to allow		
		probe via the switching value		
18	Polority	• type / we polarity switching time between alternate		
1.0	switching time	• +ve / -ve polarity switching time between alternate MPM scaps should be 50 msec or better with		
	switching thirt	supporting documents		
1 10	Vacuum System	Robust high efficiency vacuum system with minimum		
1.10	vucuum bystem	maintenance and utility with low noise level		
		• Vacuum read backs must be digitally monitored and		
		controlled through software to ensure fail-safe		
		operation in the event of power failure.		
		• All accessories required for the proper functioning of		
		the vacuum system should be supplied.		
		• Fore line pump: Oil free Scroll type pump with		
		arrangements of AUTO- ON after Power auto age.		
		High vacuum pump must be Turbomolecular pump:		
		250 L/Sec or better		
1.11	Gas Control	All gases must be controlled by the software.		
1.12	Onerating	• Mass spectrometer should have the following scan		
	modes	options.		
		• Full scan		
		Selected Ion monitoring/ recording (SIM/SIR)		
		Product ion scan		
		Precursor ion scan		
		Neutral loss scan		
		Multiple Reaction Monitoring (MRM)		
		• MS and MS/MS in a single injection with		
		matrix background monitoring or equivalent.		
		(Proof document /application note to be enclosed		
		along with technical tender document with onsite		
		verification)		
		Simultaneous full scan and MIKM or better		

		(Ontional)
1.13	Detector	 A high sensitivity, high throughput detector with zero dead time, low noise and high accuracy at low level detections. An off-axis dynolite photomultiplier/Electron Multiplier detector Detector must operate in both positive and negative ion modes. Capable of switching polarity rapidly. Should have a better long life. (Life time shall be furnished and the better one will be given preference during technical evaluation).
1.14	Nitrogen Generator	 Should be supplied with the system along with the trouble free inbuilt compressor and appropriate capacity reservoir which should be sufficient enough to deliver the gases (purity > 99.999%) required to run the system Should be complete with all necessary accessories with Two Years comprehensive warranty with at least one Preventive maintenance along with PM kit each year and Three years CMC after the warranty period including all spares, accessories and consumables, at least one Preventive maintenance along with PM kit each year and unlimited breakdown visits
1.15	Vacuum Manifold with compatible SPE Cartridges	 Minimum 10 cartridges extraction at one time Minimum 1000 cartridges for different analytes i.e pesticide residues, antibiotic residues etc
2	High Performance Liquid Chromatograph y System	 List of column with Specification: f) C-18, 2.1×100 mm× 1.7 µm with suitable Guard column g) C-18, 2.1×150 mm× 1.7 µm with suitable Guard column h) C-18, 4.6 ×250 mm× 5 µm with suitable Guard column i) C-8, 4.6 ×250 mm× 5 µm with suitable Guard column j) Phenyl-Hexyl 2.1mm ×100 x, 3µm or equivalent HILIC column with Guard column The complete system and the MS should be controlled by the single software PUMP: Binary pump pressure handling capability. Operating flow range should be 0.010-2.0ml/min or better with 1µl increments Autosampler: with 1 to 10 ul/min injection, minimum of 100 samples capacity. Capability to handle pressure range of 15000 psi or better.

3.	Spares and accessories	 Column Oven: 30°C to 80°C, capability to accommodate a minimum of 1 or more columns of ≥ 15 cm. Temperature Stability: ±0.1°CTemp. Accuracy:±0.5°C DAD/PDA Detector: 190-700 nm, 80 Hz, Standard flow cell with flow cell of 1.0 ul or better LC-MS/MS startup kit should be supplied as standard. All required traceable standards for Mass calibration and tuning, HPLC calibration should be provided 5µl, 10µl, 20µl, 50µl, 100µl loops, Vacuum pump oil, etc. and any other material required to make the instrument functional should be provided. Standard Tool kit should be provided for Instrument maintenance Reputed highly branded solvent filtration unit with pump and required accentrice 02 post
4.	System Controller and Operating system	 pump and required accessories 02 nos Software must be Multitasking type. It must acquire and process the data simultaneously Application manager must be compatible with data of full scan, SIM/SIR or MRM Data Acquisition, Peak Integration, Calibration, Quantification and QC calculations must be fully automated. The Quantification method editor must be viewable in page view or spreadsheet. Application manager must allow to monitor the molecular ion and up to 04 (four) Confirmatory ions or better.
		 Must be capable of performing the following functions and should be upgradable: Workstation must be able to control the MS, acquire, store, process and reproduce the data by the same computer. Workstation must be able to control LC, Detector and auto sampler. It must be able to regulate the gas pressure and flow during the data acquisition and append to the relevant data file. Software must have automated calibration and Quantitative optimization. Automated MS to MS/MS switching during a single run with user selectable criteria Perform alternating positive/negative scans in one run Automated Quantitation and reporting of acquired samples. Data may be processed as it is being acquired

5.	Calibration Standards	• Two sets each NIST or other traceable standards for all the Pesticides, Mycotoxins, antibiotics as per FSSAI requirement with a minimum expiry period of two years for seven years Or supply of NIST or other traceable standards every year with a validity of one year upto 7 years As per Annexure A	
6.	PC with Printer	 Minimum Intel core i5/i7 processor, 2.0 Ghz or more, 19"or more LCD/TFT Monitor, 500 GB HDD, DVD Read/Write, 4 GB RAM,4 USB Port or higher configuration for use with the above system to be provided. Reputed Branded automatic back to back colour Laser jet printer should be provided 	
7.	Power Supply	• The system should have UPS (minimum 10 KVA) of suitable rating with voltage regulation, spike protection and minimum 60 minutes back up for the supplied equipment.	
8.	Additional items	 Bidders should quote a startup package for 100 samples. In addition, the bidders should give a list of recommended consumables along with their source and budgetary prices. Operation kit comprising all required items for startup/regular operation of instrument. Firm should also quote all essential pre-installation requirements and utility requirement for LC-MS/MS. Operation and maintenance manual for each unit in both hard copy and soft copy. Service manual with set of required tools for each system/unit. The system should have Server connectivity and should be capable of 21 CFR Part 11 and food safety compliance. The necessary validations will have to be carried out by the equipment suppliers. Complete methods library with MRMs of Mycotoxins, Veterinary drugs, Pesticides, antibiotics with instrument method details and SOPs, related software's and user manuals to be provided. PLEASE PROVIDE MAINTENANCE CHART FOR ALL OF THE COMPONENTS IN LC-MS/MS SYSTEM. 	
9.	Operation and maintenance & Training Component	 The supplier will have to carry out successful installation at our laboratory premises (where ever the system has to be installed) and provide on – site comprehensive training for scientific personnel operating the system and support services till customer satisfaction with the system and a training at the suppliers lab premises is also required. 	
		• One trained personnel should be provided by instrument suppliers for seven years who will be responsible for the working of the instrument i.e. sample preparation, method	

	•		
		validation, operation of instrument and data interpretation.	
		state Laboratory. The personnal will work under state	
		state Laboratory hand. He will also be responsible for providing	
		training of the instrument to the laboratory staff	
10			
10.	IQ/OQ/PQ	• IQ/OQ/PQ of the system is required	
11.	Warranty	 Standard Warranty of 24 months starting from date of satisfactory and faultless functioning of the equipment for 60 days at the respective laboratory premises. Comprehensive Maintenance Contract Service for 60 months after expiry of standard Guarantee/Warranty should be quoted Annual calibration of the equipment shall be a part of the CMC. It shall also be mandatory to perform calibration after every major repair/breakdown. The vendor should have available for ten years guaranteed parts and CMC service The supplier or his authorized agent should have after sales and service centre near each of our laboratory location where the equipment is to be supplied. Current user's / performance list with contact details (Customer name, phone email id etc) and date of installation to be provided (Minimum 5 installations of the model quoted) Number and details of the service engineers has to be provided 	
		carried out for those who qualify in the technical bid.	

12. Pre installation requirements: List out all pre-installation requirements (which are to be provided by the Lab)

Note:

- 1. The financial bid has to be filled necessarily in the format given above and has to be signed by the authorized representative of the bidder with full name designation and seal on each page.
- 2. Price quoted should be valid for minimum 2 years.
- 3. Explanatory notes if so desired can be separately submitted along with the financial bid but financial bid in the above format is required to be submitted.
- 4. Equipment delivery time will be 90 days from the date of issue of Purchase order
- 5. Payment terms:
 - a. Seventy percent (70%) of the cost of equipment / item shall be released within fifteen (15) days of receipt of such a request in writing from the Supplier, accompanied by a certificate from the Food Safety Commissioner/ laboratory In charge to the effect that the quantities ordered have been received and that the equipment / item has been installed & commissioned satisfactorily.

- b. Balance thirty percent (30%) of the cost of equipment / item shall be released within fifteen (15) days of receipt of such a request in writing from the Supplier, accompanied by a certificate from the Food Safety Commissioner / laboratory In charge to the effect that the required training and validation (wherever applicable) has been imparted satisfactorily.
- 6. The bidder shall provide one full time trained personnel for seven years, who will be responsible for the working of the instrument i.e. sample preparation, method validation, operation of instrument and data interpretation. The personnel will not claim to be an employee of FSSAI/state Laboratory. The person will work under the supervision of state laboratory head and carry out the required analysis of various samples received in the lab. He will also be responsible for providing training on the instrument to the laboratory staff.
- 7. All costs to be quoted shall be exclusive of taxes and duties FOR destination anywhere in India.

Name:

Signature:

Date:

Seal:

(To be filled in the format given above and signed by the authorized representative of the bidder.)

<u>Annex- A</u>

Veterinary Drug	Reference standard	Internal Standard
residues/hormones		
Chloramphenicol	Chloramphenicol base	Deuterated
_		Chloramphenicol-d5
Nitrofurans	1) Semicarbazide, 3-amino-2	AMOZ-d5 & AOZd-4
	oxazolidinone (AOZ),	
	2) 1-aminohydantoin,	
	3) 3-amino- 5-morpho linomethyl-	
	2-oxazolidinon (AMOZ)e	
Tetracycline	1) Tetracycline Hydrochloride	Nil
-	(TC),	
	2) Oxytetracycline Hydrochloride	
	(OTC)	
	3) Chlortetracycline Hydrochloride	
	(CTC) and their epimers,	
Sulphonamides	1. Sulfaquinoxaline (SQX)	Sulfapyridine (SPY)
	2. Sulfathiazole (STZ)	
	3. Sulfaethoxypyridazine (SEP)	
	4. Sulfadiazine (SDZ)	
	5. Sulfadimethoxine (SDM)	
	6. Sulfachloropyridazine (SCP)	
	7. Sulfadoxine (SDX)	
	8. Sulfamethazine (SMZ)	
	9. Sulfamerazine (SMRZ)	
	10. Sulfamethoxazole (SMX)	
	11. Sulfisoxazole (SSXZ)	
	12. Sulfamethoxypyridazine(SMP)	
	13. Sulfamethizole (SMZL)	
Quinolones	1. Flumequine (FLU),	
	2. oxolinic acid (OXO),	
	3. nalidixic acid (NAL),	
	4. cinoxacin (CIN),	
	5. piromidic acid (PIR)	
	6. nd pipemidic acid (PIP),	
	7. marbofloxacin (MAR),	
	8. norfloxacin (NOR),	
	9. ciprofloxacin (CIP),	
	10. lomefloxacin (LOM),	
	11. danofloxacin(DAN),	
	12. enrofloxacin (ENR),	
	13. sartloxacin (SAR),	
	14. difloxacin (DIF),	
	15. ofloxacin (OFL),	
	16. enoxacin (ENO),	

	17. orbifloxacin (ORB).	
Nitroimidazoles	1. Metronidazole (MNZ),	1. DMZ-d3,
	2. Dimetridazole (DMZ),	2. RNZ-d3,
	3. Ronidazole (RNZ),	3. IPZ-d3,
	4. Ipronidazole (IPZ) and t	4. IPZ-OHd3
	5. hydroxyl metabolites MNZ-OH,	
	6. HMMNI and IPZ-OH,	
	7. Carnidazole (CRZ),	
	8. Ornidazole (ONZ),	
	9. Ternidazole (TRZ)	
	10. Tinidazole (TNZ),	
Oxytocin		

Terms and Conditions of the Contract:

Liability of the successful bidder:

- 1) The bidder should enclose with the technical bid a list of at least 5 Installations of the quoted model or a comparable model of equivalent sensitivity in the country, preferably in Food sector along with the Contact Name, contact no, mail ID and complete address.
- 2) The bidder shall also provide along with the technical bid at least two Performance certificate from the organizations (at least one from the Government sector), where the quoted model/ or any other model of equivalent sensitivity has already been installed, indicating LOD/LOQ of at least 10 parameters relevant to food sector. In case he bidders are unable to obtain such a certificate, they may provide the full contact details of the users to enable FSSAI to get the certificates.
- 3) Price quoted should be valid for minimum 2 years.
- 4) The bidders need to give an undertaking that application support and services would be available for minimum 10 years.
- 5) Service support should be available throughout the country with a maximum turnaround time of 3 working days.
- 6) 5% of the cost of equipment need to be submitted as Performance Bank Guarantee at the time of placing the order by the respective lab.
- 7) The successful bidder shall have complete responsibility for the equipment in consultation with the staff of state lab where the equipment will be installed. In the event of any equipment going out of calibration the successful bidder shall be responsible for carrying out required repairs and adjustments.
- 8) The bidders will have to enter into tripartite agreement with FSSAI and with the respective state Governments before placement of actual supply order for the equipment

Name: Signature: Date: Seal: