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भारतीय खाद्य सुरक्षा एवं मानक प्राधिकरण  
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(गुणवत्ता आश्वासन प्रभाग)  
FDA भवन, कोटला रोड, नई दिल्ली – 110002

दिनांक: 06<sup>th</sup> May, 2026

सूचना/ Notice

**Subject: Approved technical specifications of High End Equipment (HEE) – LC/EA-IRMS- reg.**

FSSAI has finalised the technical specifications of High End Equipment (HEE) – LC/EA-IRMS.

2. In this regard, approved technical specifications of LC/EA-IRMS, are placed at **Annexure-I**.

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<b><u>Technical Specifications of LC &amp; EA-IRMS</u></b>		
<b>Sl. No.</b>	<b>SPECIFICATION</b>	<b>REQUIREMENT</b>
<b>1</b>	<b>LC &amp; EA IRMS (Instrument Details &amp; Application)</b>	<p>(i) LC-IRMS system with all accessories, consumables etc. required and mentioned in the specifications for the analysis of C3 sugars, authentication of various food and Honey, identification of the source of origin along with latest software to meet Indian and global food regulation requirements.</p> <p>(ii) EA-IRMS system with all accessories, consumables etc. required and mentioned in the specifications for the analysis of adulteration C4 sugars, authentication of various food and Honey, organic products and nitrogen estimation along with latest software to Indian and global food regulation requirements.</p> <p>(iii) Data library &amp; developed method may be provided for honey &amp; other food matrices.</p>
<b>2</b>	<b>Mass Spectrometer</b>	
<b>2.1</b>	<b>Mass Range</b>	1-75 amu or better
<b>2.2</b>	<b>Mass Resolution</b>	100 or better
<b>2.2</b>	<b>Sensitivity &amp; Linearity</b>	<p>(i) Sensitivity: 1200 Molecules/Ion or more with continuous flow mode.</p> <p>(ii) Linearity: CO<sub>2</sub>: ≤ 0.02 N<sub>2</sub>: ≤ 0.02 SO<sub>2</sub>: ≤ 0.04</p>
<b>2.4</b>	<b>Source</b>	<p>(i) The instrument ion source must have suitable robust vacuum system with minimum maintenance requirement, low noise level and automatic vacuum lock.</p> <p>(ii) Minimum 3kv accelerating voltage for all masses from 1-75 amu or entire range</p> <p>(iii) Source must be self-aligning with a plug in design and should be easy to replace by user</p>
<b>2.5</b>	<b>Filament</b>	<p>(i) Filament should be inert to oxygen.</p> <p>(ii) Two additional filament shall be offered with each IRMS (LC &amp; EA)</p>
<b>2.6</b>	<b>Collector Array</b>	<p>(i) The System should supplied with universal triple faraday cup collector assembly along with the collectors for Hydrogen analysis. Collector array should allow the measurement of C, N, S, O and H.</p> <p>(ii) The detector should last for the minimum 10 years.</p>
<b>3</b>	<b>Software</b>	

3.1	<b>Software &amp; Data system for IRMS</b>	(i) The instrument control software must have a library of routine parameters which automates the measurement.
		(ii) The software must allow ready definition of novel inlet systems, allowing the addition of valves, traps, splits, and ovens; the software must provide complete control and automation of all interface functions during data acquisition to enable programming of novel inlet systems.
		(iii) Software shall support creation of user based data base/libraries.
		(iv) Software must contain data for corrections of measured delta values for <sup>17</sup> O isotopomers of CO <sub>2</sub> .
		(v) The dilution of the sample and reference gases from should be software controlled.
		(vi) Free upgrades of software during the life span of the equipment.
<b>4</b>	<b>Liquid Chromatography &amp; Interface (LC)</b>	
4.1	<b>LC</b>	(i) LC should be compatible with IRMS and should be able to use independently for analysis of Sugar. (ii) LC should be compatible with IRMS and should controlled by the same operating software.
4.2	<b>Pump</b>	High pressure isocratic or binary pump (150 bar or better).
4.3	<b>Auto sampler</b>	(i) Integrated / inbuilt auto-sampler capable of handling minimum 100 samples
		(ii) Temperature range ambient to 40°C (Accuracy ±1 °C).
		(iii) Injection volume range:0.5-100µl
		(iv) Sample delivery precision:< 1% RSD or better
4.4	<b>Column Oven</b>	Temperature: ambient to 65°C or higher
4.6	<b>Columns</b>	Three additional carbohydrate columns for sugar analysis
4.7	<b>Interface</b>	Suitable interface to convert the sugars eluted form LC into CO <sub>2</sub> . The interface should ensure moisture free delivery of CO <sub>2</sub> to the IRMS. The interface should be free from crystallization.
4.8	<b>Gas consumption</b>	Gas cylinders (He-2 No.), ( CO <sub>2</sub> , O <sub>2</sub> , N <sub>2</sub> ,SO <sub>2</sub> -One each) along with associated parts (regulators, purification panels, tubings & plumbing etc.)
<b>5</b>	<b>Elemental Analyser &amp; Interface</b>	

<b>5.1</b>	<b>Auto sampler</b>	(i) Auto sampler capacity should be minimum 80 sample position. (ii) The system should ensure complete removal of atmospheric gases. Zero blank auto sampler should be provided to avoid interferences of atmospheric gases.
<b>5.2</b>	<b>Furnace</b>	The system should have 2 furnaces with individual temperature control
<b>5.4</b>	<b>Reactors</b>	Reactors for carbon, nitrogen and sulphur analysis along with O, H requirement. Two additional spare reactors should be provided along with consumables/filling materials for 1000 CNS, 4000 CN and 1000 OH analysis.
<b>5.5</b>	<b>Standalone operation</b>	All necessary software and hardware should be supplied as a standard part of the EA. EA should be capable of operating as a standalone unit for CNS elemental analysis.
<b>5.6</b>	<b>Precision</b>	The trace gas should qualify the below specified precision. a) $\delta^{13}\text{C} \leq 0.1 \text{ ‰}$ b) $\delta^{15}\text{N} \leq 0.15 \text{ ‰}$ c) $\delta^{34}\text{S} \leq 0.20 \text{ ‰}$
<b>5.7</b>	<b>Continuous flow interface</b>	(i) The system should have an automatic diluter for the sample gas dilution and must be possible to dilute Sample gases by 2.5% to 100% or better. (ii) Be expandable to minimum 3 preparation devices, to allow easy addition of future analytical capabilities. (iii) The accessible dynamic system range should be 1: 5000 or more. (iv) Interface must allow coupling of devices from <1 mL/min of He to >100 mL/min of He. It must be possible to choose the appropriate dilution for each analyte, so that different dilutions can be used for CO <sub>2</sub> , N <sub>2</sub> and SO <sub>2</sub> during a multi-isotope analysis. (v) It must be possible to change reference gas intensity by a factor of 10 in <1 second. (vi) Reference gas intensity must be variable over an intensity range of 2-30 V (CO <sub>2</sub> , N <sub>2</sub> ) OR other equivalent unit range (vii) The precision of gases in continuous flow mode should be as below or better: 1. $\delta^{13}\text{C} \leq 0.06 \text{ ‰}$ 2. $\delta^{15}\text{N} \leq 0.06 \text{ ‰}$ 3. $\delta^{18}\text{O} \leq 0.08 \text{ ‰}$ 4. $\delta^{34}\text{S} \leq 0.2 \text{ ‰}$ 5. $\delta^2\text{H} \leq 0.2 \text{ ‰}$
<b>6</b>	<b>Computer system for EA &amp; LC (Separate computer systems and other required accessories as mentioned below for EA and LC)</b>	

6.1	<b>Minimum configuration of processing PCs/System</b>	Single Windows based computer systems of reputed international brands with latest processor for Acquisition and processing of results
		Monitor: Minimum 42" CPU with factory certified RAM of appropriate capacity, Harddrive/SSD, Processor The system should be complete in all aspects ensuring smooth functioning of instrument operating software & the instrument.
	<b>Data Processing Computer</b>	Monitor: Minimum 42" RAM: Minimum 32 GB or more as per the equipment requirement Hard drive/SSD: Minimum 4 TB or more as per the equipment requirement Mouse and keypad should be supplied Laser jet b/w duplex printer should be provided.
6.2	<b>Software</b>	Software should have following features: a) Interrogate the data for peak quality, other parameters. b) Create and edit quantitation methods quickly. Acquisition of samples on LC-IRMS should be through one software only. c) Compatible software(s) to use EA IRMS and LC IRMS in stand alone mode.
7	<b>Microbalance</b>	a) Balance of reputed brand with range from 0.001 mg to 50gm or better with the vibration free table. b) Balance should have Automatic doors with detection support, c) Display with touchscreen and d) Automatic static control
		(i) Reputed Branded online UPS of 15 KVA capacity or above better suitable with power factor correction and harmonic. Three phase 440V/240V for the smooth running with back-up of minimum 1 hr with 80 % load capacity for the complete system should be provided.
		(ii) The electrical work of the UPS should be done by the supplier for the connection of instrument including proper earthing as per the instrument requirement.
		(iii) Comprehensive warranty of minimum 5 years inclusive of SMF batteries should be provided

8	<b>UPS system</b>	<p>(iv) All the UPS batteries should be replaced by brand new batteries with warranty certificate two months before completion of warranty period of LC&amp; EA IRMS and the performance of UPS should be verified. Satisfactory performance certificate of UPS should submit to the laboratory by the equipment supplier and UPS supplier together.</p> <p>(v) The maintenance of UPS and batteries is responsibility of IRMS supplier. Any malfunction of EA&amp; LC-IRMS due to UPS and its batteries failure, the supplier of EA&amp; LC-IRMS has to take whole responsibility and rectify the same during warranty period.</p> <p>(vi) Minimum two 2-ton AC required to maintain the temperature <math>20\pm 2</math> C</p>
9	<b>Other Pre-requisite</b>	Any other gas cylinder (Gas purity: $\geq 99.999\%$ UHP grade) for the working of the system shall be provided minimum one number with all accessories such as dual pressure SS regulator, gas purification panel unit, cylinder cage or Bracket etc. should be supplied.
10	<b>Instrument and Software Qualification / Performance Verification IPV (IQ,OQ,PQ)</b>	<p>(i) The instrument must be "Qualified" along with the Software. Necessary reagents along with Documents must be provided. During installation and qualification, Instrument should perform as per submitted specification in presence of user.</p> <p>(ii) IQ/OQ/PQ to be performed as per OEM protocol, should be done free of cost with necessary traceable standards along with necessary performance kit standard solutions</p> <p>(iii) Documents, Kits &amp; standards etc. as required being supply along with the instrument</p> <p>(iv) To be done free of cost with traceable calibration standards for the first 5 years' warranty period (at installation &amp; at every maintenance visit of each year) along with PM kits.</p> <p>(v) OQ/IPV should be done free of cost with supply of PM Kits and calibration standards at least once in a year during warranty period.</p> <p>(vi) Documents, PM Kits &amp; calibration standards etc. to be supply along with instrument at every PM visit free of cost during warranty period.</p> <p>(vii) Satisfactory performance certificate should submit to the laboratory after calibration of LC&amp;EA IRMS before one month of warranty period expired with supply and fixation of PM kits of EA, LC and IRMS system.</p>
		<p>(i) Minimum 5 years from the date of completion of IQ, OQ and PQ of system to the satisfaction of lab including supporting accessories.</p> <p>(ii) The furnace &amp; Detector should be covered with 10 years warranty.</p>

10	<b>Warranty and CMC</b>	<p>(iii) The date of warranty period for EA&amp; LC IRMS , UPS with batteries, PC, Printer, Gas cylinders with its accessories and all associated supply will start from the date completion of IQ, OQ and PQ of LC &amp; EA IRMS.</p> <p>(iv) It should cover hardware, software as well as wear and tear consumables (except column and sample preparation), Up-gradation of software to the latest version (if applicable), prompt service (within 24-48 hours on-call), training and application support during the period.</p> <p>(v) In case of breakdown of the system, the servicing to be done immediately by the supplier during the warranty period and maximum down time period is 24-48 hrs, if it's not attended the warranty will extend accordingly.</p> <p>(vi) At least two minimum preventive maintenance visit shall be carried out annually.</p>
11	<b>After sales service/ Post warranty</b>	<p>(i) The supplier shall have application laboratory in India/abroad to support the application requirement and training needs.</p> <p>(ii) The supplier shall have service facility and trained engineers located in nearby metros to provide breakdown services within 24-48hrs of complaint registration.</p> <p>(iii) Should have a good after sales service/technical support capable of reaching at short notice within 24-48 hours to the places where LC/EA IRMS is proposed to be installed. Visits and unlimited breakdown calls by service/application support engineers.</p> <p>(iv) Troubleshooting training (Instrumentation/Application) as and when required free of cost.</p> <p>(v) The application and method development support must be rendered, as and when required</p> <p>(vi) The vendor should also assure supply of spares, accessories, consumables and service for at least 10 years.</p> <p>(vii) Both AMC &amp; CMC Price for LC &amp; EA - IRMS to be quoted separately, for 3 years after warranty. Terms and conditions for the AMC &amp; CMC after the warranty period has to be specified.</p> <p>(viii) AMC price for 3 years after warranty quoted by the vendor will be considered for finalizing the L1. However it needs to be submitted separately as a price breakup document.</p>

12	<b>Demonstration and Training of personnel</b>	(i) Demonstration and Training on system to our Lab personal at site to be incorporated, responsibility of the supplier for training of the lab personnel at supplier site/installation site
		(ii) Basic training for a period of not less than 10 working days after installation of the equipment to technical personnel and further for method development whenever required during warranty and AMC period should be provided free of cost
		(iii) One general entry-level training-cum-workshop and one advanced-level training-cum-workshop must be arranged at the user's site by the vendor on experimental and data analysis part, with no extra cost involved.
		(iv) Trouble shooting training along with Application support for developing validating at least one priority parameter or selected by the lab.
		(v) Supplier has to demonstrate on site validation as per the laboratory /regulatory requirements / protocols.
13	<b>Spares and accessories</b>	The following accessories, but not limited to should be supplied along with instrument:
		(i) PM kit for LC and EA IRMS sufficient for trouble free operation during warranty period should be provided along with instrument.
		(ii) Injector loops of appropriate capacity (6 Nos.) additionally shall be provided with other necessary accessories required for injection, Vacuum pump oil, etc. and any other material required to make the instrument functional should be provided.
		(iii) All required standards for calibration (NBS-22 or equivalent), Glucose, Fructose and Maltose/Sucrose along with miliQ water 20 lit. (mobile phase).
		(iv) Vials (1.5/2.0 mL) with cap and septa 1000 Nos should be provided.
		(v) Tin capsule for weighing 5000 Nos
		(vi) Syringe PTFE Filter, 13mm, 022µ – 1000 No. s
		(vii) Standard Tool kit should be provided for Instrument maintenance
		(viii) Branded filtration unit with pump and required accessories to be provided
		(ix) Branded Mobile phase bottles 500 ml-12 no's and 1000 ml -12 no's with caps fixing solvent lines amber color
		(x) 12 nos. of one-litre mobile phase branded bottles should be supplied.
(xi) Low volume 500 µl sintered/recovery vials with suitable caps/septa – 1000 nos. to be supplied		

		(xii) Glass capillaries - 10 Nos.
		(xiii) One no. of Portable Bench top heavy duty Multi tube vortex mixer to be supplied along with instrument which is designed to facilitate hands-free mixing in tubes, flasks, vials with digital display.
		(xiv) Branded Single Channel micro pipettes with one decimal with capacity of 50-1000 µl- 04 nos. 10-100 µl- 04 nos., 1000-5000 µl- 02 nos to be supplied along with the instrument.
		(xv) Accessories tube racks required for variety of tubes :
		(a) 50 x 1.5/2 ml (2 no's) or more
		(b) 50 x 15 ml (2 no's) or more
		(c) 15 x 50 ml (6 no's) or more
14	<b>System Performance Certificate</b>	(i) The requirements in this section pertain to the working requirements of the system. Any claims made in the compliance statement should be substantiated by giving suitable detailed outputs from the quoted model of the instrument generated at the applications lab of the supplier, in the form of reports for easy reference.
		(ii) Proof of Performance documents must be provided with the Compliance sheet.
		(iii) The reports should necessarily include the instrument output data, graphs and chromatograms. Using the quoted model of the instrument at the applications lab of the supplier/manufacturer.
		(iv) The model offered by the vendor should have capability to demonstrate the above mention parameter in presence of user.
		(v) All provided brochures or technical data sheet should be provided at the time of bidding process or procurement or on request.
		(vi) Satisfactory performance certificate taken from government organization along with technical bid shall be submitted.
		(vii) The details of nearest service support centre with available engineer's and application specialist's name and contact details must be provided in the technical bid.
15	<b>Experience</b>	(i) The supplier should have at least three successful installations or more of the model/series of model quoted in India.
		(ii) The Complete users list for the quoted model in India, with contact addresses, emails and phone numbers should be provided.
		No part of the offered instrument shall be refurbished or used in demonstration purpose, undertaking for the same is required.

<b>16</b>	<b>General conditions of supply</b>	(i) The instrument and all its sub units should operate on 240 volts 50 Hz power supply.
		(ii) All the operation and maintenance manuals, circuit diagrams, application notes and application software's to be supplied should be in English language.
<b>17</b>	<b>Manpower</b>	Trained and Experienced manpower for operating the Instrument must be provided for a period of 3 Years