

TECHNICAL SPECIFICATIONS

1.0 GENERAL DESCRIPTION

The following technical specifications, code of practice etc. referred herein are part of the Item Specification and work shall be executed accordingly. The technical requirements given hereunder are only indicative and not descriptive and the Supplier shall ensure that the equipment and accessories supplied are complete in all respects for the smooth operation of the plant and should be suitable for the rated output.

Items which are not covered under Technical Specification shall be carried out as per relevant IS Specification or as per manufactures specification approved by Accepting Authority or as directed by Engineer-in-charge. In case of discrepancy between technical specification and item specification provided along with Bill of Quantities, the Item Specification shall prevail.

2.0 SCOPE OF WORK

The scope of work shall include supply, erection, testing, commissioning of mechanical, instrumentation and electrical works for Procurement of **High-Performance Liquid Chromatographic system with Detectors** for Oushadhi Plant at Kuttanellur, Thrissur. All electrical and necessary instrumentation and controls for smooth and safe operation of various systems of plant shall be in the scope of the Supplier. These shall conform to the specifications and standards laid down by the Kerala State Electrical Inspectorate. The Supplier would do all necessary activities to get prior advice/approval from the Inspectorate for the design/ schematic diagrams of all power/control wiring of all equipment, including those supplied by other manufacturers prior to commencement of manufacture in order to avoid rework and consequent delay.

3.0 CODES AND STANDARDS

The design, manufacture and testing of the equipment shall comply with the latest editions of appropriate standards.

Unless mentioned otherwise, all applicable codes and standards in their latest editions as published by the Bureau of Indian Standards shall govern in respect of design, workmanship and properties of materials and methods of testing. In case where suitable Indian Standards are not available, generally accepted codes and practices shall be adopted.

All equipment shall comply with the statutory requirements of the Govt. of India and Government of Kerala. The equipment fabrication and installation shall conform to the provision of statutory and other regulations in force such as the Indian Factories Act, Indian Explosives Regulations, Kerala State Pollution Control Board, etc. Approval of

drawings by statutory agencies, if required, shall be arranged by the successful Contractor at no extra cost to the Purchaser.

In cases where the offer deviates from the specified standards, the Tenderer shall indicate clearly in his offer the reasons for deviation, standards proposed to be adopted by him and the details thereof.

4.0 SPECIAL REQUIREMENTS

4.1 SITE FACILITIES

The Tenderer shall indicate clearly the proposed work and procedure to be carried out at the Purchaser's site and take approval prior commencement of works at site.

Electricity for work to be executed at site will be made available near the work site free of cost. The Contractor shall ensure that the facilities are not misused or wasted. The Purchaser will not be responsible for the delays arising from non-availability of power due to reasons beyond the control of the Purchaser.

Only open area at work site will be allotted to the Contractor for carrying out site work. The Contractor shall indicate approximate space requirements.

Accommodation, transportation and food of workmen and supervisors of the Contractor shall be the responsibility of the Contractor.

4.2 STORAGE

All equipment and material to be stored at site in Contractor's risk. The Contractor shall store the equipment, commissioning spares etc. in a place which is dry and free of dust and frost. He shall also ensure that there is no penetration of impurities in the equipment, damage or rusting during storage.

4.3 SAFETY AND ENVIRONMENTAL ASPECTS

The total system should have adequate built-in precautions to prevent any fire or explosive hazards.

Safety systems should be as per relevant IS codes.

4.4 STATUTORY APPROVALS

Obtaining all statutory approvals shall be in the scope of the Supplier. These include but not restricted to approvals from Electrical Inspectorate, Pollution Control Board, Inspectorate of Factories and Boilers, Inspector of Explosives, etc. including prior approvals, wherever required.

5.0 SPECIFICATIONS

Technical Specifications for the purchase of High-Performance Liquid Chromatographic system with Detectors, consumables and local supplies

High Performance Liquid Chromatographic system for separation, identification, and quantification of phytocomponents, aflatoxins, adulterants, active pharmaceutical ingredients etc. in Ayurvedic formulations, Siddha formulations and herbal raw materials with following items: Quaternary Low Pressure Gradient Solvent Delivery Unit with Degassing Unit, Photodiode Array Detector (PDA), Auto-Sample Injector with cooler, Fluorescence Detector, Post Column Derivatization unit, Aerosol-based (evaporative) Detector, Column Oven, Data Management System and compatible accessories for gas supply, system cooling and routine maintenance. The specific requirements with respect to each component are as follows.

I. System requirements

- Fully integrated all-in-one system with system controller, solvent delivery pump, auto sampler, detector and column oven readily available and integrated into a single system.
- Provision for One-button power-on to activate all compartments simultaneously.
- Capable of automated functions including time-controlled startup, auto purge, automatic validation, and auto-shutdown.
- System should be compatible with both organic and aqueous solvents.
- Must have auto-shutdown functionality to reduce energy consumption and enhance safety.
- The system should have provisions for upgradability with Mass Spectrometer.

II. Column oven

- The Column Oven must be compatible with the instrument specifications and must be must be of same original equipment manufacturer (OEM).
- The oven should be forced-air-circulation type for uniform temperature distribution
- The Oven shall accommodate a minimum of 3 HPLC columns or more simultaneously.
- Provision for safety features for preventing overheating.
- **Column** - C18 Analytical column 250 x 4.6mm, 5µm- 2 No, with compatible guard column.

- Temperature ramp rates
 - Heating rate: **10°C/min** (from 40°C to 60°C).
 - Cooling rate: **2°C/min** (from 60°C to 40°C).
- Temperature control settings
 - Temperature setting range: **5°C to 90°C**.
 - Temperature adjustable in **1°C increments**.
 - Temperature accuracy: **±1°C**.

III. Quaternary Low Pressure Gradient Solvent Delivery Unit with Degassing Unit

- The system shall include a quaternary low-pressure gradient pump with a parallel double-plunger design.
- It shall support delivery of up to four solvents simultaneously.
- The flow rate should be 0.0001 mL/min -10 mL/min.
- Flow rate accuracy should be ±1% or ±2 uL/min of set value whichever is larger.
- Flow rate precision should be less than ±0.06% RSD.
- The maximum pressure setting range should not be less than 7200psi.
- The composition accuracy should be below 0.5% & composition precision below 0.1% RSD.
- Concentrations setting range from 0 to 100% with 0.1% increment.
- Degassing unit should have 4 or 5 flow lines & membrane-type online degasser.

IV. Auto-Sample Injector with cooler

- Injector must be designed for total sample injection of variable volume.
- Injection volume range: 0.1 µL to 100 µL, adjustable in 0.1 µL increments.
- Zero sample loss during injection.
- Capable of high throughput analysis with an injection time of <20sec/sample.
- Injection volume accuracy: ≤ 1%.
- Injection precision: < 1% RSD.
- Carryover: ≤ 0.003%; lower carryover preferred.
- Capable of Flow line rinse before and after sampling to prevent contamination.
- Provision for accessing up to 200 or more samples (1.5 mL vials).
- Temperature control: Adjustable from 4°C to 45°C.
- Provision for auto-dilution, sample pre-treatment, and co-injection functionality.

V. Detectors

A. Photodiode Array Detector (PDA)

- Spectral Range: 190 nm – 800 nm.
- Detector Elements: 1024-element photodiode array.
- Wavelength Accuracy: ± 0.5 nm or better.
- Deuterium lamp (D_2) as light source
- Temperature-Controlled Flow Cell with a range of $19^\circ\text{C} - 50^\circ\text{C}$ (or better).
- Noise Level: $\leq 0.3 \times 10^{-5}$ AU.
- Baseline Drift: $\leq 0.5 \times 10^{-3}$ AU/hr.
- The light source warranty must be specified as minimum of 2000 hours of operation or one year from date of installation (whichever comes first).

B. Fluorescence Detector

- Suitable for high-sensitivity applications including aflatoxins, vitamins, pharmaceuticals, food contaminants, and trace-level analytes.
- Excitation and emission wavelength: 200 to 650 nm.
- Wavelength accuracy: ± 2 nm.
- Wavelength precision: ± 0.2 nm.
- Detector must support multi-wavelength monitoring function.
- S/N: Water Raman Peak S/N should be 1200 or better.
- Sensitivity: < 1 pg on-column (suitable for aflatoxins, vitamins, and trace analytes).
- Dynamic range ≥ 4 orders of magnitude.

C. Aerosol-based (evaporative) Detector

- Detection system based on a photomultiplier tube (PMT) using a high-efficiency blue LED light source.
- Compatible with low-flow, micro, semi-micro, and standard analytical flow applications.
- Standard mobile phase flow rate should be from 0.005 to 5 mL/min.
- Must have Nanogram level sensitivity.
- Provision for **zero adjustment function** for baseline correction and signal stabilization.
- Use Nitrogen gas as the nebulizing gas.
- Gas flow rate control with manual or automatic control.
- Auto power-down function for reduced gas consumption.
- Maximum nitrogen gas consumption must be up to 3 L/min.
- Temperature adjustment range from ambient to 100°C
- Support a minimum data rate of 100 Hz,
- Nitrogen Cylinder with suitable accessories should be provided.
- The detector shall be fully compatible and integrated with the offered HPLC system and its data acquisition software.

VI. Post Column Derivatisation Unit

- Suitable Photo Chemical Reactor for post-column derivatisation for aflatoxin analysis, fully integrated with the offered HPLC system

- Photochemical Reactor based on UV-induced post-column derivatization.

VII. Software requirements for data evaluation

- Hardware with Intel i5 Processor or above & 16GB RAM on board or higher
- 1TB hard disk or higher & DVD-RW drive & 23" LED monitor & 101 keys key board and mouse & Pre-installed Windows 10 Original OS (64bit) & Laser printer
- OEM chromatography data system (CDS) software for full control of all HPLC modules and detectors.
- Software shall be 64-bit Windows 10 compatible and provide a user-friendly, intuitive graphical interface for easy operation.
- Chromatography software with 3D analysis functions that comply with Good Laboratory Practice (GLP) and Regulatory Conformity.
- IQ/OQ Documentation
- Desirable: Artificial intelligence integration for method development and data analysis.

VII. Accessories

- 5 KVA UPS with one hour backup.
- Sample Solvent Filtration Kit
- Operation kit, comprising all required items, pump tubings, transfer tubings, work coils, etc., for start-up/regular operation of the instrument.
- Operation and maintenance manual for each unit in both hard copy and soft copy.
- Service manual with a set of required tools for each system/unit
- Gas cylinders -2
- HPLC microliter syringes
- Stainless steel high-pressure solvent delivery tubings with suitable fittings.
- The tubings and connectors for low-pressure and post-column connections.
- Solvent inlet filters for all solvent lines.
- Solvent reservoir bottles with caps and tubing (minimum 4 sets).
- Inline solvent filters.
- Column connecting capillaries (zero-dead-volume).
- Union fittings, ferrules, nuts, and necessary connectors.
- Waste tubing and waste bottle with cap.
- Spare fuses and power cables.

VIII. Comprehensive maintenance contract -5 year with preventive maintenance kits.

IX. IQ/OQ/PQ of the system is required

X. General conditions

- The System should be a complete functional unit in terms of hardware and software to demonstrate the intended specifications and applications to be supplied with all necessary ancillaries.
- The quote should be for supply, installation, commissioning, and successful working demonstration of the instrument at the premises of M/s. Oushadhi Ltd, Kuttanellur, Thrissur, Kerala.
- Specifications should be confirmed from the Technical Brochure and the website of the manufacturer.
- Standard warranty of 36 months should be provided.
- Good Service and Technical support are essential. Please provide testimonials from three reputed customers.
- The service engineer shall be available in Kerala, and contact details should be provided.
- Training: 2 levels – 5 days during installation in our lab and subsequently at the supplier's application lab for 2 persons at the supplier's cost, twice over a duration of 5 years.
- A compliance statement of the specifications should be provided along with the quote before placing order.
- The offered system shall be **CE certified or equivalent**, complying with internationally accepted safety and electromagnetic compatibility standards. Documentary evidence in the form of **CE Declaration of Conformity or equivalent certification** shall be provided with the technical bid.
- The list of installations and users of complete system in India & abroad should be provided for reference. The company must have at least five working installations of the complete instrument globally. User list for this period, current contact details of users, Supply Orders and certificates of successful completion issued by the clients must be enclosed.
- Installation, calibration, standardization and commissioning shall be the responsibility of the vendor.
- Pre-installation requirements, including requirement for water/power supply, should be enclosed along with the tender.

6.0 GENERAL REQUIREMENTS

- 6.1 The equipment supplied shall be complete in all respects with all necessary accessories and commissioning spares for operating it for the specified application. Equipment which are either operated under pressure or are likely to develop pressure shall be

provided with safety valves, pressure gauges and vents with isolation valves. Electrically operated equipment shall be complete with necessary starters, control panel, push button stations, cabling, earthing etc. The earthing shall be linked to the nearest existing earth grid which will be available within 5-10 m from the equipment.

- 6.2 The thickness given in the data sheets is indicative only and the Tenderer shall check and satisfy before quoting. Nozzles shall be provided with stiffeners for reinforcement.
- 6.4 All rotating/moving parts shall be provided with adequate guard for safety.
- 6.5 The Supplier shall furnish complete design calculation with backup details for review and approval by the Purchaser/Consultant.
- 6.6 Pressure testing shall be arranged in the presence of a competent person and their certificate shall to be issued before provisional acceptance of the equipment.
- 6.7 Tenderer should include the cost of all required accessories in the quoted rate.
- 6.8 The Purchaser reserves the right to procure all the items specified in the tender or part thereof without assigning any reason.

7.0 DESIGN IMPROVEMENT/ ALTERNATE DESIGN

- 7.1 The system or equipment requirements given are indicative only. The Tenderer is free to quote the equipment of their own design provided it is superior to the specifications given and it satisfies with the Pre-qualification criteria. The Tenderers are advised to examine the feed materials and quote for suitable equipment to meet the performance requirement.
- 7.2 The Tenderer may incorporate latest designs in any of the specifications mentioned above with the prior approval of the Accepting Authority, which in his opinion are sure to give better performance. The technical deviations shall be clearly spelt out as per the Technical Deviation Statement Form provided in this tender document.

8.0 BATTERY LIMITS

8.1 FOUNDATION AND STRUCTURAL WORKS

The civil foundation required will be in the scope of supplier. Supply of foundation bolts, anchor bolts, grouting mixture etc. and grouting shall be in the scope of the Contractor. Grouting shall be carried out as per approved specifications. The supply and erection of working platform, if required, shall be in the scope of the Contractor. The supply of bolts, welding materials etc, for erecting those equipment to be supported on existing structural platform shall be included in the Contractor's scope.

8.2 ELECTRICAL AND INSTRUMENTATION

Based on the electrical details submitted by the Contractor, the Purchaser will arrange cabling upto the incomer of the electrical panel of the equipment. However, termination of the same will be in the scope of the Contractor. The Contractor shall also arrange the supply of electrical panels, interconnecting cables, starters, push button stations, earthing materials etc. The Purchaser will provide earthing network in the plant premises within 5-10 m. Earthing the equipment by connecting to the existing grid will be in the scope of the Contractor. The Contractor shall also provide necessary instrumentation and control systems, if specified.

9.0 SHOP INSPECTION AND TESTING

9.1 PROCEDURE

- 9.1.1 The Contractor shall conduct all tests required to ensure that the equipment supplied shall confirm to requirements of the applicable codes at various stages of fabrication / procurement, including raw material identification. All fabrication works, tests, test procedures and detailed quality plan proposed by the Contractor shall be submitted to the Purchaser / Consultants for approval. The Purchaser / Consultants shall be intimated well in advance regarding the testing of material / equipment so that they could witness the tests at the works. In certain cases, the Purchaser/Consultant may waive the witnessing of the tests, but it does not absolve the Contractor for carrying out the same and submitting the test reports for approval.
- 9.1.2 All material used shall be tested for quality. The test certificate shall be made available to the Purchaser's / Consultant's representative. In case of non-availability of test certificates, material shall be tested by the Contractor at his own cost, to establish the conformance of the relative standards.
- 9.1.3 The representative of the Purchaser/ Consultant shall be given full access to the shop in which the equipment is being manufactured or tested and the Supplier shall carry out any change or modifications as pointed out by the Purchaser/ Consultants during inspection at no extra cost.
- 9.1.4 The Supplier shall despatch the equipment only after obtaining clearance from the Purchaser/ Consultants. However, the inspection and certification of the Purchaser/Consultant does not absolve the Supplier of his responsibilities towards the satisfactory operation and the guarantee/warranty of the system.

10.0 TESTS PROPOSED

The following are the tests that shall be arranged by the Contractor at his works.

- 10.1 Visual inspection for general workmanship and welding.
- 10.2 Dimensional check and nozzles shall be as per the approved drawings.
- 10.3 Hydraulic test to detect leakage:

11.0 PAINTING

11.1 SURFACE PREPARATION

All external surfaces shall be cleaned of loose substance and foreign material, e.g. dirt, rust, scale, oil, grease, welding flux, etc. so that the zinc phosphate primer coat adheres to the original metal surface. The work shall be carried out generally in accordance with IS:1477 (Part I) amended upto December 2010. The surface shall be cleaned either by sand blast to grade S.A.2.5 using graded sand or by acid pickling using dilute sulphuric or hydrochloric acid followed by thorough rinsing with fresh water.

11.2 PRIMER AND FINISH COATS

The prime coat shall be applied immediately after the surface preparation.

Paint shall be applied in accordance with manufacturer's recommendations as supplemented by this specification. The work shall generally follow IS: 1477 (Part II) amended up to December 2010.

The prime coats shall consist of two coat of Zinc phosphate primer.

Finish painting shall consist of three coats of epoxy paint as per manufacturer's specification.

Dry film thickness for each coat shall be about 25 microns and total dry film thickness shall not be lower than 125 microns.

No shipment shall be made unless clear despatch instructions are obtained from the Purchaser's representative.

All projected parts shall be properly protected to avoid damage during transit.

Touch up painting for damaged coats doing transit / erection should be done by the Contractor.

Prior to touch up painting, proper cleaning of the damaged portions shall be done.

12.0 COMMISSIONING

12.1 INSPECTION AND TESTING

After erection at the site and before commencement of commissioning, the Contractor shall arrange to demonstrate the tests as per clause 10.2 of this specification. He shall also ensure that all rotating/ moving parts of the equipment are moving freely without any undue fouling/vibration. Necessary precautions shall be taken before testing of all electrically operated equipment. The same shall be tested as per approved procedures.

12.2 PERFORMANCE TRIAL RUN

After completion of inspection and testing, the Contractor shall arrange the guarantee and performance run. The feed/ raw material required for conducting the performance run will be arranged by the Purchaser. The performance run shall include continuous operation of the equipment for a duration of 72 hours at the rated performance or operation of 6 ½ hours per day for a duration of 5 days

The performance trial run is to ensure that the system installed conforms to the required/demanded specification including the power consumption. All the parameters shall be demonstrated during the guarantee and performance run. Maximum deviation from the approved parameters shall be less than 5%. The Contractor shall arrange any spares that may become necessary during performance run or due to damage/break down free of cost and repeat the performance and guarantee run. Any consumable like grease, oil etc. required for trial run/commissioning shall be arranged by the Contractor at no extra cost.

12.3 POWER REQUIREMENT

Power required shall be quantified for two aspects: for normal operating conditions and power needed during start up conditions and peak load. The gland losses and losses in the driving system shall also be determined and submitted.

12.4 VIBRATION TESTING

The Contractor has to test and validate that the system is free of undue vibrations under normal operating mode.

12.5 The Contractor shall arrange training of the Purchaser's operators and maintenance personnel for operating it as per standard practice/safely.

13.0 DATA TO BE FURNISHED BY THE TENDERER

13.1 AT THE TIME OF SUBMISSION OF BID

The Tenderer shall submit all detailed technical specification, catalogues etc. for the equipment being quoted. Detailed drawings showing all the design, operational and maintenance features, major dimensions, details of foundations including layout, etc., shall be submitted along with the offer. Technical data for individual items of equipment in the form of a data sheet and details of all equipment within the battery limit shall be submitted along with the tender. The Tenderer shall also submit a general arrangement drawing and approximate layout showing the space requirement etc. Other specifications and relevant data shall be furnished by the Tenderer, wherever applicable. The following details are to be submitted along with the bid.

- Data Sheets
- Tentative General arrangement (GA) drawings
- Tentative drawings with dimensions of equipment
- Equipment specifications
- Empty weight
- Any special requirement during erection
- List of customers to whom similar units have been supplied
- Compliance Statement

13.2 AFTER AWARD OF WORK

The following details have to be submitted by the Contractor within **fifteen days of receipt of Letter of Intent or Letter of Award of work** for approval by the Purchaser/Consultants.

- Foundation drawings with load details, if applicable.
- Manufacturing, inspection and delivery schedule
- GA drawings
- Drawings with dimensions of equipment
- Equipment layout and elevation
- Empty weight
- Electrical control panel and other electrical system details, if applicable.
- Safety devices provided
- Details of bought out items like motors, gear box, electrical items etc.
- List of spare parts for 1 year operation.
- Service and spare parts availability with contact details
- Erection Manual.

13.3 BEFORE COMMENCEMENT OF TESTING / COMMISSIONING

The contractor shall submit six copies of the Operation and Maintenance Manual and As-built drawings along with a soft copy before the commencement of testing/commissioning.

