**Annexure A**

QUESTIONAIRE FOR COMPLIANCE OF TERMS AND CONDITIONS

**Tender No.:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Due Date**

**NOTE:**

1. Quotation will not be considered without submission of this format.
2. If a particular question is not at all applicable please write NA in compliance part in Col. No. 4 below.
3. Kindly see the relevant terms & conditions of the tender document in each question before replying to the questions mentioned in Col. 2 below).

|  |  |  |  |
| --- | --- | --- | --- |
| **S No** | **Terms & condition of Tender document** | **Whether acceptable (say ‘Yes’ or ‘No’ (preferably use different colour ink for ‘No’)** | **Deviation from tender terms, if any, with reasons for noncompliance or alternative condition quoted for** |
| 1 | a.) Whether quotation is direct from Principal supplier/manufacturer or their own office in India (Please specify) |  |  |
| b) Whether quotation is being submitted by Indian Agent/authorized distributor/ dealer |  |  |
| c) Whether the agent is registered with DGS&D/NSIC |  |  |
| 2 | a) Whether the Techno-commercial and price bids (for two bid tender system) have been kept in separate envelopes duly marked with “Techno­commercial Bid” and “Price Bids” respectively. |  |  |
|  | b) Whether the tender No., Due date & Opening dates have been written outside all the envelopes |  |  |
| 3 | a) If the prices are on Ex-Works basis or 1. FOB (names port of shipment) or FCA (named place of delivery abroad)
 |  |  |
|  | 1. b) Whether specific amounts or percentage of expenses

like packing, forwarding, handling, freight, insurance, documentation etc. have been mentioned in quotation separately in clear terms. |  |  |
| 4 | a) Whether prevailing rates of sales tax, excise duty & other govt. levies (for indigenous supplies) have been given in quotation |  |  |
| **S No** | **Terms & condition of Tender document** | **Whether acceptable (say ‘Yes’ or ‘No’ (preferably use different colour ink for ‘No’)** | **Deviation from tender terms, if any, with reasons for noncompliance or alternative condition quoted for** |
| 5 | Have you mentioned the validity period of the quotation as per our requirements |  |  |
| 6 | a) Whether the Price reasonability Certificate and Least Price Certificate is submitted with quotation |  |  |
|  | b) Whether copies of last two supply orders of the same item from other customers have been attached with the quotation |  |  |
| 7 | Whether rates/amount of AMC after the warranty period is over has been mentioned |  |  |
| 8 | Have you gone through the specification Clause & complied with the same |  |  |
| 9 | Whether the Make/Brand, Model number and name of manufacturer has been mentioned in the quotation and Printed technical literature/ leaflets of quoted items have been submitted |  |  |
| 10 | Whether compliance statement of specifications has been attached with the quotation. |  |  |
| 11 | a) Whether the delivery period for supply of the items has been mentioned |  |  |
|  | b) Whether mode of delivery & tentative size & weight of the consignment has also been indicated |  |  |
| 12 | Do you agree to the submission of Performance Bank Guarantee and have you mentioned in your quotation about this? |  |  |
| 13 | a) Do you agree with the payment terms for indigenous supplies? |  | No deviation permitted |
|  | b) Do you agree with the payment terms for imports supplies? |  |
| 14 | Do you agree about the date of commencement of warranty period & its extension is necessary? |  |  |
| **SNo** | **Terms & condition of Tender document** | **Whether acceptable (say ‘Yes’ or ‘No’ (preferably use different colour ink for ‘No’)** | **Deviation from tender terms, if any, with reasons for noncompliance or alternative condition quoted for** |
| 15 | a) Who will install/commission and demonstrate the equipment at National Facility site of BCP, FREE OF COST. |  |  |
|  | b) Will you be able to do it within a month |  |  |
| 16 | Have you mentioned the guarantee/warranty period in your quotation and do you agree with guarantee clause? |  |  |
| 17 | Spare parts |  |  |
| 18 | After Sales service |  |  |
| 19 | a) Do you agree that on receipt of material in damaged condition or short supply you will replace the same on CIF basis, free of cost pending the settlement of the insurance claim? |  |  |
|  | b) Do you agree with the clause of physical inspection? |  |  |
| 20 | Whether list of specific user’s for the same item & model as quoted along-with performance certificates from the users is submitted with offer |  |  |
| 21 | Whether you agree to the penalty clause for late delivery & installation? |  |  |
| 22 | Whether training to our scientist/technical person will be given free of cost. If yes, have you specified in quotation whether it will be in our lab? Or at supplier’s site in India or abroad. |  |  |
| 23 | a) Whether all the pages have been page numbered? |  |  |
|  | b) Whether quotation has been signed and designation & name of signatory mentioned. |  |  |
|  |  |  |  |

**ANNEXURE – B**

MANUFACTURER'S AUTHORIZATION FORM

[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that re binding on the Manufacturer]

Date: [Insert date (as Day, month and year) of Bid submission]

Tender No.: [Insert number from Invitation for Bids]

To: [Insert complete name and address of Purchaser]

WHEREAS

We [insert completer name of Manufacturer], who are official manufacturers of [Insert type of goods manufactured] having factories at [insert full address of Manufacturer’s factories], do hereby authorize [insert complete name of Bidder] to submit a bid the purpose of which is to provide the following goods, manufactured by us [insert name and or brief description of the goods], and to subsequently negotiate and sign the contract.

We hereby extend our full guarantee and warranty in accordance with the Terms and Conditions of Contract with respect to the Goods offered by the above firm.

Signed: [insert signature(s) of authorized representative(s) of the Manufacturer]

Name: [insert complete name(s) of authorized representative(s) of the Manufacturer]

Title: [insert title]

Duly authorized to sign this Authorization on behalf of: [insert complete name of Bidder]

Dated on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [*insert date of signing*]

**ANNEXURE – C**

PREVIOUS SUPPLY ORDERS FORMAT

Name of the Firm

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Order placed by{Full address of Purchaser] | Order No. and Date | Description and quantity of ordered equipment | Value of order | Date of completion of delivery as per contract | Date of actual completion of delivery | Remarks indicating reasons for late delivery, if any and justification for price difference of their supply order & those quoted to us. | Has the equipment been installed satisfactorily?(Attach a certificate from the Purchaser/ Consigner] | Contact Person along with Telephone no., Fax no. and e­mail address. |
|  |  |  |  |  |  |  |  |  |

Signature and Seal of the Manufacturer/ bidder

Place:

Date:

**ANNEXURE - D**

BIDDER INFORMATION FORM

**[The Bidder shall fill in this form in accordance with the instructions indicated below. No alterations to its format shall be permitted and no substitutions shall be accepted. This should be done on the letter head of the firm]**

Date: [Insert date (as day, month and year) of Bid Submission]

Tender No.: [Insert number from invitation of bids]

Page 1 of pages

1. Bidder’s Legal Name [Insert Bidder’s legal name]
2. In case of JV, legal name of each party: [insert legal name of each [arty in JV]
3. Bidders actual or intended Country of Registration: [insert actual or intended country of registration]
4. Bidder’s year of registration: [insert Bidder’s year of registration]
5. Bidder’s Legal Address in Country of Registration: [insert bidder’s legal address in country of

registration]

1. Bidder’s Authorization Representative Information Name: [insert Authorization Representative’s name]

Address: [insert Authorization Representative’s address], Telephone/Fax numbers: [insert Authorization Representative’s telephone/fax numbers]

Email address: [insert Authorization Representative’s email address]

1. Attach are copies of original documents of: [check the box(es) of the attached original documents] Articles of Incorporation or Registration of firm names in 1 above.

IMPORTANT NOTICE

TENDERERS RESPONDING TO THIS ENQUIRY SHALL BE DEEMED TO BE AGREEABLE TO THE TERMS AND CONDITIONS HEREIN CONTAINED. THESE TERMS AND CONDITIONS SHALL BE BINDING ON THE SUCCESSFUL TENDERER.CONDITIONAL TENDERS ARE LIABLE TO BE REJECTED. BCP/RSBCP WILL PROCESS THE TENDER AS PER BCP/RSBCP STANDARD PROCEDURES. THE DIRECTOR OF THE INSTITUTE RESERVES THE RIGHT TO REJECT ANY OR ALL OR PART OF TENDER WITHOUT ASSIGNING ANY REASON AND SHALL ALSO NOT BE BOUND TO ACCEPT THE LOWEST TENDER. BCP WOULD NOT BE UNDER ANY OBLIGATION TO GIVE ANY CLARIFICATIONS TO THE AGENCIES WHOSE BIDS ARE REJECTED.

I agree to all terms and conditions mentioned in the tender document of the Institute

Signature of the Tenderer

**Annexure – E: Tender specifications for all instruments**

**TENDER SPECIFICATIONS fOR LC-MS-MS (TRIPLE QUADRUPOLE WITH ION TRAP MASS SPECTROMETER WITH HPLC AND UHPLC GRADIENT SYSTEM AND ACCESSORIES)**

**TENDER NUMBER: BCP/TENDER/PHARMACEUTICAL ANALYSIS/VAS/KM/12/2017-2018**

|  |
| --- |
| **APPLICATIONS:** Quantitative and Qualitative analysis for Active Pharmaceutical Ingredients (APIs), Drug intermediates, Drug impurities, Herbal entities, Metabolites will be conducted using LC-MS-MS. Instrument quoted should be 21 CFR part 11 compliant and should meet all pharma regulations like USP & ICH etc. |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| **Specifications for uHPLC system to be used as a front end for MSMS** |
| **1** | **SOLVENT DELIVERY PUMP** |  |  |  |  |
|  | Solvent delivery pump should be high pressure quaternary, with automatic rinsing kit |  |  |  |  |
| Maximum operating pressure should be 15000 psi or more |  |  |  |  |
| Flow rate should be 0.0001 mL/min - 10.0000mL/min (in 0.001ml/ min increments) with accuracy of 1% or better |  |  |  |  |
| Flow Rate Precision- RSD <0.06% |  |  |  |  |
| Pump should have feature of leak sensor |  |  |  |  |
| It should have built-in mixer as well as online membrane type degasser having four or more channels |  |  |  |  |
| Solvent delivery pump should be supplied with solvent tray, solvent bottles, filters, appropriate tubings, tool kit etc |  |  |  |  |
| pH range: 2 to 12 |  |  |  |  |
| **2** | **AUTOSAMPLER** |  |  |  |  |
|  | Appropriate autosampler shall be included with this UHPLC system |  |  |  |  |
| Sample Capacity- 2 Trays, Standard or deep 96-well & 105 x 1.5 mL vials |  |  |  |  |
| A flexible format sample tray for minimum of 100 vials or more. |  |  |  |  |
| It should have operating pressure of 12000 psi or better |  |  |  |  |
| Injection volume range should be from 0.1ul – 100ul or better |  |  |  |  |
| Injection volume accuracy shall be 1% or better |  |  |  |  |
| Injection volume precision shall be 0.25 RSD or better |  |  |  |  |
| Sample carryover / cross contamination shall be 0.0015% or better |  |  |  |  |
| Sample Cooling Thermostat for Auto sampler required from 4- 40°C or similar |  |  |  |  |
| It must have a leak sensor and automatic rack & vial recognition features  |  |  |  |  |
| Provision for repeat injections and needle rinsing should be available |  |  |  |  |
| Injection needle wash should be integral, active and programmable |  |  |  |  |
| Temperature Accuracy: ± 0.5° C at Sensor |  |  |  |  |
| Temperature Stability: ± 1.0°C at Sensor |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| 3 | **COLUMN OVEN** |  |  |  |  |
|  | Suitable multi-column oven with provision for simultaneous guard column attachment shall be supplied with this UHPLC system |  |  |  |  |
| It should have temperature range from 5 – 85 °C |  |  |  |  |
| Temperature stability of ±0.1°C.  |  |  |  |  |
| Temperature accuracy of ±0.8°C & with calibration of ±0.5°C or better |  |  |  |  |
| 4 | **PDA DETECTOR** |  |  |  |  |
|  | Photo Diode Array Detector should be supplied with this UHPLC system |  |  |  |  |
| It should have wavelength range of 190-800 nm with a Deuterium/Tungsten source |  |  |  |  |
| Detector linearity should be 2.0 AU |  |  |  |  |
| Slit width should be 1nm and 8 nm with wavelength accuracy of 1nm or better |  |  |  |  |
| Detector noise should be 0.4 X 10-5 AU or less & Drift should be less than 0.5 X 10-3 AU/h  |  |  |  |  |
| Detector should have flow cell of 1µl capacity with 10mm path length |  |  |  |  |
| Wavelength accuracy must be at least ±1.0nm. [Data Rate: 120Hz] |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| 5 | **INSTALLATION AND DEMONSTRATION** |  |  |  |  |
|  | Basic training for a period of one weeks after installation & commissioning of the equipment to technical personnel to be provided at our site. |  |  |  |  |
| 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. |  |  |  |  |
| Documents, Kits & standards etc as required being supply along with the instrument. |  |  |  |  |
| 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. |  |  |  |  |
| 6 | **ACCESSORIES** |  |  |  |  |
|  | UHPLC columns |  |  |  |  |
| Software for qualitative and quantitative analysis. |  |  |  |  |
| **Specifications for HPLC system to be used as a front end for MSMS** |
|  |  |  |  |  |  |
| 1 | **SOLVENT DELIVERY PUMP** |  |  |  |  |
|  | Solvent delivery pump should be high pressure quaternary, with automatic rinsing kit |  |  |  |  |
| Maximum operating pressure should be 7000 psi or more |  |  |  |  |
| Flow rate should be 0.0001 mL/min - 5.0000mL/min (in 0.001ml/ min increments) with accuracy of 1% or better |  |  |  |  |
| Flow Rate Precision- RSD <0.06% |  |  |  |  |
| Pump should have feature of leak sensor |  |  |  |  |
| It should have built-in mixer as well as online membrane type degasser having four or more channels |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
|  | Solvent delivery pump should be supplied with solvent tray, solvent bottles, filters, appropriate tubings, tool kit etc |  |  |  |  |
| pH range: 2 to 12 |  |  |  |  |
| **2** | **AUTOSAMPLER** |  |  |  |  |
|  | Appropriate autosampler shall be included with this HPLC system |  |  |  |  |
| Sample Capacity- 2 Trays, Standard or deep 96-well & 105 x 1.5 mL vials |  |  |  |  |
| A flexible format sample tray for minimum of 100 vials or more. |  |  |  |  |
| It should have operating pressure of 5000 psi or better |  |  |  |  |
| Injection volume range should be from 0.1ul – 100ul or better |  |  |  |  |
| Injection volume accuracy shall be 1% or better |  |  |  |  |
| Injection volume precision shall be 0.25 RSD or better |  |  |  |  |
| Sample carryover / cross contamination shall be 0.0015% or better |  |  |  |  |
| Sample Cooling Thermostat for Auto sampler required from 4- 40°C or similar |  |  |  |  |
| It must have a leak sensor and automatic rack and vial recognition features  |  |  |  |  |
| Provision for repeat injections and needle rinsing should be available |  |  |  |  |
| Injection needle wash should be integral, active and programmable |  |  |  |  |
| Temperature Accuracy: ± 0.5° C at Sensor |  |  |  |  |
| Temperature Stability: ± 1.0°C at Sensor |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| **3** | **COLUMN OVEN** |  |  |  |  |
|  | Suitable multi-column oven with provision for simultaneous guard column attachment shall be supplied with this HPLC system |  |  |  |  |
| It should have temperature range from 5 – 85 °C |  |  |  |  |
| Temperature stability of ±0.1°C.  |  |  |  |  |
| Temperature accuracy of ±0.8°C & with calibration of ±0.5°C or better |  |  |  |  |
| **4** | **PDA DETECTOR** |  |  |  |  |
|  | Photo Diode Array Detector should be supplied with this HPLC system |  |  |  |  |
| It should have wavelength range of 190-800 nm with a Deuterium/Tungsten source |  |  |  |  |
| Detector linearity should be 2.0 AU |  |  |  |  |
| Slit width should be 1nm and 8 nm with wavelength accuracy of 1nm or better |  |  |  |  |
| Detector noise should be 0.4 X 10-5 AU or less & Drift should be less than 0.5 X 10-3 AU/h  |  |  |  |  |
| Detector should have flow cell of 1µl capacity with 10mm path length |  |  |  |  |
| Wavelength accuracy must be at least ±1.0nm. [Data Rate: 120Hz] |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| **5** | **INSTALLATION AND DEMONSTRATION** |  |  |  |  |
|  | 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. |  |  |  |  |
| Documents, Kits & standards etc as required being supply along with the instrument. |  |  |  |  |
| 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. |  |  |  |  |
| Basic training for a period of one weeks after installation & commissioning of the equipment to technical personnel to be provided at our site. |  |  |  |  |
| **6** | **ACCESSORIES** |  |  |  |  |
|  | RP- HPLC columns |  |  |  |  |
| Software for qualitative and quantitative analysis. |  |  |  |  |
| **SPECIFICATION FOR TRIPLE QUADRUPOLE WITH ION TRAP SPECTROMETER** |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| **1** | **MASS RANGE**: 5 to 1250 Da |  |  |  |  |
| **2** | **RESOLUTION:** Resolution 9200 at m/z 922 for Scan Speed 50 Da/Sec |  |  |  |  |
| **3** | **MASS STABILITY**: 0.1amu over 24 hrs at m/z 906.7 |  |  |  |  |
| **4** | **SENSITIVITY** |  |  |  |  |
| **ESI Positive Mode**: 1 pg reserpine injection on column, at unit mass resolution (0.7±amu at half height), the instrument must have a S/N > 90,000:1. S/N measurements are calculated based on 3 standard deviation of at least 3 points of noise which produce the smallest standard deviation |  |  |  |  |
| **ESI Negative Mode:** 1 pg chloramphenicol injection on column, at unit mass resolution (0.7± 0.1 amu at half height), the instrument must have a S/N > 90,000:1. S/N measurements are calculated based on 3 standard deviation of at least 3 points of noise which produce the smallest standard deviation,  |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| **5** | **SCAN SPEED:** Triple Quad Scan Speed: 12,000 Da/sec. Ion trap Scan Speed: 20,000 Da/Sec |  |  |  |  |
| **6** | **SOURCE INTERFACE** |  |  |  |  |
|  | The system must have an active source exhaust for the removal of gases within the ionization source. |  |  |  |  |
| The system must be compatible with a variety of commercially available LC pumps, autosamplers, manual injectors and detectors. |  |  |  |  |
| Dual / Orthogonal or off-axis spray or any other equally efficient technology capable of avoiding interference from solvents and other extraneous matter. |  |  |  |  |
| Both ESI and APCI probes to be provided, with facility of interchanging easily by the user, and auto-detection of installed probe by the instrument and software. |  |  |  |  |
| An infusion device must be integral (to minimize space and tubing) to the instrument and must be controllable from the instrument software |  |  |  |  |
| Source Interface should maintain cleanliness of ion optics and capable of handling large batches of complex samples for long period of time without performance degradation |  |  |  |  |
| The source should be easily removable from the system to facilitate user cleaning without venting the vacuum, with automatic shutdown of system while the source / probe is being removed |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
|  | The source should be able to handle 0.5ul/min to 2ml / min flow, without flow splitting. |  |  |  |  |
| Desolvation Temperature: 600 °C or higher |  |  |  |  |
| **Interface:** Simple interface for maintaining analyzer cleanliness of ion optics and optimized ion de-clustering. Capable of handling large batches of complex samples in chemical matrices, biological matrices and natural/herbal extracts over a long period of time without maintenance or performance degradation. Preferably the interface should be capable of ambient temperature operation and without complex apertures to maintain structural integrity of thermally labile and fragile molecules. |  |  |  |  |
| **7** | **POLARITY SWITCHING TIME:** 25msec or better |  |  |  |  |
| **8** | **VACUUM SYSTEM** |  |  |  |  |
|  | Robust high efficiency vacuum system with minimum maintenance and utility with low noise level.  |  |  |  |  |
| The instrument must have a differentially pumped vacuum system featuring air-cooled turbo molecular pumps with fail-safe vacuum system protection. |  |  |  |  |
| It must automatically shut-down and restart after power failures. |  |  |  |  |
| **9** | **MASS ANALYZER**  |  |  |  |  |
|  | High quality mechanical tolerance and minimum coefficient of thermal expansion for high standard of mass stability in varying lab temperature conditions. |  |  |  |  |
| A pre-filter must be located between the RF quadrupole and the first mass filter to help further focus the ions. Hybrid Linear Ion Trap and Triple Quadrupole Analyzer |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
|  | A high-pressure quadrupole collision cell with 180º curve must follow the first mass filter and be used for high efficiency MS/MS fragmentation. The second mass analyzer is also a gold-coated ceramic quadrupole mass filter/linear ion trap. |  |  |  |  |
|  | The instrument must contain a single thin aperture from atmosphere into the vacuum chamber, followed immediately by a high-efficiency RF-only ion guide for ion focusing and containment. This must be followed by a high-pressure RF quadrupole followed by a gold-coated ceramic quadrupole mass filter. |  |  |  |  |
| **10** | **COLLISION CELL:** High-pressure quadrupole collision cell with Curved collision cell technology must follow the first mass filter and be used for high efficiency MS/MS fragmentation |  |  |  |  |
|  | Confined collision cell capable of high energy fragmentation, producing reproducible MS/MS spectra should have a minimum dwell time of 1 milliseconds or better without sacrificing sensitivity. |  |  |  |  |
| Eliminate cross talk to enable multiple MRM studies with a single run. |  |  |  |  |
| Fast data collection of at least 500 MRM data points per sec or better without compromising performanceMS and MS/MS along with matrix monitoring to be performed in single run |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| **11** | **GAS CONTROL:** All gases must be controlled by the software. |  |  |  |  |
| **12** | **DYNAMIC RANGE:** Wide dynamic linear range of 5 orders. |  |  |  |  |
| **13** | **OPERATING MODES:** Full scan MS and selected ion monitoring for both Q1 and Q3  |   |  |  |  |
|  | Product Ion Scan |  |  |  |  |
| Precursor Ion Scan |  |  |  |  |
| Neutral Loss or Gain Scan |  |  |  |  |
| Multiple Reaction Monitoring (MRM) and MRM 3  |  |  |  |  |
| Enhanced MS Scan, Enhanced Product Ion Scan, Enhanced Resolution Scan |  |  |  |  |
| MS3 scan, MRM3 Scan, and TripleTrap™ Scan Modes. |  |  |  |  |
| MS and MS/MS in a single injection with matrix background monitoring) |  |  |  |  |
| Simultaneous full scan and MRM |  |  |  |  |
| **14** | **DETECTOR:** A latest technology continuous dynode Electron Multiplier (CEM)/PMT detector that is operated in the pulse counting mode. |  |  |  |  |
|  | A high sensitivity, high throughput detector with zero dead time, low noise and high accuracy at low level detections. |  |  |  |  |
| Detector must operate in both positive and negative ion modes. |  |  |  |  |
| The detector polarity must be able to switch between alternate scans |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| **15** | **NITROGEN GENERATOR:** High purity nitrogen, Zero grade air or high purity nitrogen should be used for the ion source. Filtered,dry air (free from oil) must be used for the ion source exhaust pump |  |  |  |  |
| **16** | **NITROGEN EVAPORATOR:** Nitrogen Evaporator with Nitrogen GeneratorUnattended operation for up to 50 samplesDifferent interchangeable racks available for tube size from 1.5ml to 30mlControlled water bath adjustable from ambient to 800CBuilt-in nitrogen regulator LED display for better visibility under fume hood [Convenient size- no hood space required]Exhaust open to atmosphere or within fume hoodEasy to use water drain pumpSmall foot print |  |  |  |  |
| 17 | **WORKSTATION & SOFTWARE** |  |  |  |  |
|  | **Computer with min. specification must be quoted:**  |  |  |  |  |
| Make: Reputed brand such as HP/Compaq/IBM/Dell |  |  |  |  |
| Operating System: Windows 7 Professional, 64bit, SP1 |  |  |  |  |
| Processor: Intel® I7 |  |  |  |  |
| Memory: 8 GB  |  |  |  |  |
| Hard Disk: 2 TB  |  |  |  |  |
| Optical Drive: HP DVD-RW Super Multi Drive |  |  |  |  |
| **Graphics: Intel HD Graphics P530** |  |  |  |  |
| Audio: Integrated Realtek HD ALC221 |  |  |  |  |
| Ports: 8x USB 3.0 (2 in front, 6 rear), 2x USB 2.0 (2 in front), RS232 Serial Port (2 in total) |  |  |  |  |
| Input Devices: Keyboard, Optical Scroll Mouse |  |  |  |  |
| Monitor: 27-inch or more IPS Monitor with high resolution |  |  |  |  |
| Printer: LaserJet Printer |  |  |  |  |
| UPS: 15 KVA with 60-minute backup |  |  |  |  |
| This PC should be RoHS compliant and can be used as an acquisition workstation or stand-alone processing computer.  |  |  |  |  |
| The system must include a Windows®-based data acquisition and editing software package that incorporates a graphical user interface utilizing multi-pane windows for easy data acquisition and analysis. The system must be compatible with a variety of commercially available LC pumps, autosamplers, manual injectors and detectors. The software must provide automatic, dynamic adjustment of the acquiring MRM transitions such that only compounds that elute within a specified time window are monitored. In addition, the process of creating the acquisition method to utilize this feature must accept a simple list of compound names, MRM transitions, and expected retention times and use this list to dynamically schedule MRM scans during the experiment. (*Schedulin* MRM™ Algorithm). The system software must include powerful library generation and search capability (searches based on mass and UV spectra at different fragmentation voltages and different polarities). The software must have direct and easy data transfer to popular word processing programs such as MS Word, Excel, Power Point, etc. The software must have completely automated quantitative data processing and reporting capabilities.Must be CFR 21 PART 11 Compliance  |  |  |  |  |
| **18** | **ACCESSORIES:** Roughing Pump Oil, Swabs, capillaries  |  |  |  |  |
| **19** | **WARRANTY:** As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| **20** | **TRAINING AND SUPPORT:** As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| **21** | **SITE PREPARATION:**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| **22** | **Installation and Demonstration:** As mentioned in **Tender Terms and Conditions**. |  |  |  |  |

**TENDER SPECIFICATIONS fOR INDUCTIVELY COUPLED PLASMA MASS SPECTROMETERAND ACCESSORIES**

**TENDER NUMBER: BCP/TENDER/PHARMACEUTICAL ANALYSIS/VAS/KM/13/2017-2018**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 1 | **APPLICATION** |  |  |  |  |
| All Elements of the Periodic Table from Pharma/Chemical/API/Formulations/Herbal analysis up from higher ppm to ppt at a time.  |  |  |  |
| Instrument should be quoted to comply all regulatory requirements like 21 CFR Part 11, EPA and FDA regulatory compliance, ICH guidelines and pharmacopoeial specifications. |  |  |  |
| 2 | **BASIC DESIGN**Instrument mainframe should be bench top utilizing minimum lab bench space |  |  |  |  |
| 3 | **SAMPLE INTRODUCTION SYSTEM** |  |  |  |  |
| **Spray Chamber**Cyclonic Peltier-cooled quartz spray chamber and capability to handle both aqueous and organic solvent medium. |  |  |  |  |
| **Nebulizer**Concentric nebulizer with minimum sample consumption  |  |  |  |  |
| **Torch** The plasma torch must be made of quartz.The system should consume lowest argon gas consumption.**Computer control of torch**The torch position should be fully computer controlled & auto tunable in XYZ axes with movement in each axis independent of other two**.** Torch position resolution & reproducibility should be 0.1 mm in all three axes. |  |  |  |  |
|  |  |  |  |
| **Peristaltic Pump**It should have high precision minimum 3-channel roller pump allowing precise computer control of sample pumping for transfer of sample to nebulizer. |  |  |  |  |
| **Injector**High purity quartz self-aligning injector |  |  |  |  |
| **Others**The system should be able to handle other types of samples having HF, sodium borohydride& organic media as and when required. |  |  |  |  |
| System shall include computer controlled peristaltic pump for sample transfer to nebulizer which will be capable to run sample solution, acid solution, sodium borohydride etc. |  |  |  |  |
| The system should be quoted with all the accessories required to handle dirty high matrix, high TDS samples like interface cones, dilution accessories etc. avoiding manual liquid dilutions. |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 4 | **PLASMA** |  |  |  |  |
| Digitally driven with solid state generator of 27 or 40 MHz RF with range 500- 1600 watts (max) or better power output. |  |  |  |  |
| High plasma stability when changed from aqueous samples to organic samples and all three plasma gases must be should be computer controlled. |  |  |  |  |
| The plasma ignition method must be completely automated. |  |  |  |  |
| Plasma TV – for monitoring plasma status  |  |  |  |  |
| 5 | **AUTO SAMPLER** |  |  |  |  |
| The system shall include an auto sampler capable of performing automatic analysis and should have minimum 50 vial per tray with ≥15 mL vial capacity. (At least 3 trays must be accommodated) |  |  |  |  |
| Auto sampler operation should be completely software controlled. |  |  |  |  |
| Rinsing port should be provided for in-between sample rinse. |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 6 | **INTERFACE** |  |  |  |  |
| Sample and skimmer cones should be easily mountable and dismountable |  |  |  |  |
| **Sample and skimmer cones**Should be made up of platinum and nickel metal base for routine applications (three quantities for Ni and two for Pt each).Should provide low backgrounds with high matrix tolerance |  |  |  |  |
| **Extraction Lens**Capability to eliminate light emission from plasma source and allow efficient ion transmission. |  |  |  |  |
| Provision for maintaining vacuum in the event of power failure |  |  |  |  |
| 7 | **ION GUIDE OR LENS SYSTEM** |  |  |  |  |
| System should have some mechanism to remove photons & neutrals from ion path. |  |  |  |  |
| All ion lenses should be outside the high vacuum region for maintenance free replacement by operator. Lens cleaning and replacement procedure should be without the need to put off or open the main vacuum system to minimize the down time of instrument.  |  |  |  |  |
| 8 | **COLLISION/REACTION CELL TECHNOLOGY** |  |  |  |  |
| Collision reaction cell of ICP-MS must be operated effectively in collision mode, using pure Helium (99.999%) for all the elements in periodic table if required in reaction mode using reactive gases like Hydrogen, oxygen. The cell should be fitted with suitable mass flow control s to connectcollision as well as reaction gases together. |  |  |  |  |
| Vendor should quote gas lines as required to meet above applications along with its gas cylinders & dual stage regulators. |  |  |  |  |
| The cell should be capable of upgrading with the reaction cell gas line if required in future. |  |  |  |  |
| Published international journal papers or application notes should be enclosed along with technical specification of equipment used to demonstrate the applicability of the instrument proposed using;* pure helium
* mixture of helium with other reaction gases such as mixtures oxygen, hydrogen and ammonia
 |  |  |  |  |
| Helium gas flow controller must be provided as standard and cell gas should be CPU controlled in the range of 0 to 8 mL/min or better for method optimization**.** |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 9 | **QUADRUPOLE**  |  |  |  |  |
| Quadrupole should be resolving between 0.3 to 0.8 amu or better |  |  |  |  |
| Quadrupole is driven by fully Digital RF generator with frequency 2-3 MHz |  |  |  |  |
| Back Ground Equivalent Count (BEC) would be less than 3 cps (in No gas mode) |  |  |  |  |
| Back Ground Equivalent count (BEC) would be less than <0.5cps (in gas mode) |  |  |  |  |
| Abundance Sensitivity (at Cs): Low Mass side: ≤5 x 10-7High Mass side: ≤1 x 10-7 |  |  |  |  |
| The system must have quadrupole mass analyzer based separation and capable to cover a mass number range from 6.9Li to 238U. |  |  |  |  |
| Mass spectrometer should show excellent mass stability of ± 0.03 amu or better for 8/24 hours. |  |  |  |  |
| The quadrupole rods must be hyperbolic type and made up of inert materials |  |  |  |  |
| 10 | **ION DETECTOR ASSEMBLY** |  |  |  |  |
| Discrete dynode electron multiplier type detectors that can operate in simultaneous dual-mode. |  |  |  |  |
| Minimum 9 orders or more of linear dynamic rangeDwell time of minimum 100 Micro seconds (in both pulse count and analog modes) |  |  |  |  |
| Working concentration range of the detectors should be from the detection limit to 500 ppm or more with a maximum of 1000 ppm in Gas mode without any adjustment of settings such as resolution, detector voltage, etc. |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 11 | **VACUUM SYSTEM** |  |  |  |  |
| Vacuum system shall consist of multi stage vacuum system utilizing a double inlet turbo molecular pump to maintain vacuum at 10-9Bar (or lower).Single turbo molecular pump located inside the mass compartment and one external rotary pump should be capable to achieve desired vacuum. Rotary pump should be provided by vendor. |  |  |  |  |
| Auto recovery of vacuum when electrical power is resumed after power failure, saving valuable time. No need to manually start the vacuum system or wait for system pump down following an overnight power failure. |  |  |  |  |
| 12 | **MINIMUM COMPUTER CONFIGURATION** |  |  |  |  |
| **Make**Reputed brand such as HP/Compaq/IBM/Dell |  |  |  |  |
| **Operating System**Windows 7 Professional (64Bit Windows 8.1 License, Media) English |  |  |  |  |
| **Processor**Intel® i7 |  |  |  |  |
| **Memory**8GB RAM |  |  |  |  |
| **Hard Disk**2TB |  |  |  |  |
| **Optical Drive**HP DVD RW Super multidrive |  |  |  |  |
| **Graphics**Intel HD graphicsP530 |  |  |  |  |
| **Audio**Integrated realtek HD ALC221 |  |  |  |  |
| **Ports**8x USB 3.0 (2 in front, 6 rear) 2x USB 2.0 (2 in front) RS232 Serial Port (2 in total) |  |  |  |  |
| **Input Devices**Keyboard, Optical Scroll Mouse |  |  |  |  |
| **Monitor**27-inch IPS Monitor with high resolution |  |  |  |  |
| **Printer**LaserJet Printer |  |  |  |  |
| **UPS**15 KVA with 60-minute backup |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 13 | **PERFORMANCE SPECIFICATION** |  |  |  |  |
| The CeO/Ce ratio should less than 2.5%. |  |  |  |  |
| Doubly charged ratio (Ce++/Ce+) is ≤3% |  |  |  |  |
| Sensitivity of elemental mass should be ≥ 50Mcps/ ppm across the mass range. |  |  |  |  |
| The resolution of the quadrupole should not be changed during the analysis. |  |  |  |  |
| Auto tune facility should optimize Plasma condition, lens & cell voltages, mass resolution & mass accuracy for best ionization and sensitivity. |  |  |  |  |
| Semi Quantitative mode should be able to operate in collision mode to generate qualitative scan of elements in less than a minute. |  |  |  |  |
| The ICP-MS system should have capability to integrate with any commercially available laser ablation device for routine/research applications in future. |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 14 | UTILITY & ACCESSORIES TO BE QUOTED WITH THE MAIN SYSTEM |  |  |  |  |
| Dilution accessory to handle high matrix & high TDS samples  |  |  |  |  |
| Cooling water circulator (chiller) should be provided as standard with instrument and not from local supplier. It should be capable of giving minimum flow rate of 1L/min or better with temperature range of 10- 40ºC as required for plasma unit. |  |  |  |  |
| Imported Gas filters for the gases used |  |  |  |  |
| Interface for dirty, high matrix & high sensitivity  |  |  |  |  |
| Suitable capacity UPS with 1-hour battery backup shall be provided. |  |  |  |  |
| Organic solvent injection kit and associated accessories |  |  |  |  |
| HF acid sample injection kit and associated accessories |  |  |  |  |
| Hydride generator kit and associated accessories |  |  |  |  |
| Main ICPMS unit and all accessories should be capable to operate with single phase power supply of 200-240V. |  |  |  |  |
| Single hose exhaust should be sufficient for total ICPMS system. Ventilation capacity of 2 m3/ min or better should be satisfactory for the instrument exhaust requirement. |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 15 | **SOFTWARE** |  |  |  |  |
| The software should work with windows 7 based operating system. |  |  |  |  |
| The software must be capable to perform measurement of sample with one data file for 250 samples or less and pasting sample information from the clipboard into sample tables. |  |  |  |  |
| The software must do qualitative Analysis with:a) Built in data based library, b) Auto selecting mass number for each sample, c) Correction for data base. |  |
| The software must do **quantitative analysis** with calibration curve method / standard additionmethod and capable of:a) **Measuring mass number**: setting several mass numbers for each element and all mass number profiles measurementb) **Data export**: The file type can be selected as "CSV" file or "Tab delimited text" auto exporting analytical results at measurement, batch export.c) **Re-calculation**: Re-calculation with changing the condition of calibration curve (order /calibration curve coefficients etc.), re-calculation with changing the correction method, recalculation and addition of measurement element and mass number using all mass profilesdatad) **QA/QC**: Judgment and re-correction for calibration curve, judgment quantity of change for internal standard element, judgment, re-correction and re-measurement for drift correction during measurement, test for recovery rate / test for dilution rate / test for re-measurement etc,.e) Should have quick method setup option by automatic suggesting suitable mass for all-elements be measured, possible polyatomic interference, recommended internal standard correction, and information about the calibration curve concentrations. Also guides for Collision cell conditions to remove spectral interferences for elements for which interference cannot be avoided.f) Should have a suitable feature to evaluate the causes of errors for each measurement sample. Correction solutions are displayed and allowed simple adjustment of the method to ensure accurate measurement result with minimal errors. |  |
| Software must be compliant with stand-alone FDA 21CFR Part 11. |  |  |  |  |
| Software must have capability to connect to central server. |  |  |  |  |
| Automatic generates IEC information if interference cannot be avoided. |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 16 | **STANDARDS**Multi-elemental and single element standards - One set for USP/ICH &Q3D guidelines |  |  |  |  |
| 17 | **INSTRUMENT VALIDATION PERFORMANCE CHECK**Validation Performance Check Solution (1 Set each) to be provided. |  |  |  |  |
| 18 | **OPERATION KIT**Operation kit comprising all required items pump tubings, transfer tubings, work coils etc. for startup/regular operation of instruments to be quoted |  |  |  |  |
| 19 | **GAS CYLINDER** |  |  |  |  |
| Ar gas cylinder 4 Nos with 2 stage regulator & gas purification panel shall be provided. System should have facility to use 99.999% purity argon gas. |  |  |  |  |
| He gas cylinder 2 Nos with 2 stage regulator & gas purification panel shall be provided. (With Accessories). Other reaction gases if required of one quantity each. |  |  |  |  |
| Higher Pressure Seamless Stainless-Steel Cylinders filled with High Purity 99.999 % gases. Gas Capacity 7 M3, Water capacity 47 liters,  |  |  |  |  |
| Cylinder should be ISI marked conformed to IS- 7285 specifications. |  |  |  |  |
| 20 | **GAS REGULATORS**2 stage Regulators for all the gas cylinders to be quoted |  |  |  |  |
| **MICROWAVE DIGESTER** |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 21 | Since, the requirement includes sample preparation for samples from regulated industries viz. pharmaceuticals and healthcare, the quoted system must have features to comply with the requirements of regulatory bodies including 21 CFR Part 11, GAMP5, etc. |  |  |  |  |
| A | **MICROWAVE DIGESTION SYSTEM** |  |  |  |  |
| Atleast 15 nos. high pressure vessel rotor for quick dissolution of various samples. |  |  |  |  |
| Option of pressurized reaction with user selection for continuous or pulsed microwave reaction. |  |  |  |  |
| B | **MAGNETRON** |  |  |  |  |
| The microwave system should have dual Magnetron system |  |  |  |  |
| Microwave frequency: 2450MHz |  |  |  |  |
| Installed power: minimum 1900W. |  |  |  |  |
| Dual magnetron system with rotating diffuser for homogeneous microwave distribution in the cavity. |  |  |  |  |
| C | **CAVITY** |  |  |  |  |
| The cavity should be made of stainless steel housing with PTFE plasma coating for corrosion resistance.  |  |  |  |  |
| All hardware should have protective coating for the resistance from acid. |  |  |  |  |
| Cavity volume of more than 60 ltrs for safety purpose of the user. |  |  |  |  |
| D | **HARDWARE AND SAFETY** |  |  |  |  |
| Stainless steel housing with multi-layer PTFE coating. |  |  |  |  |
| Protected against acids and solvents with polymer coating on both inner and outer surfaces |  |  |  |  |
| Self-resealing pressure responsive door mounted on sprigs, to ensure maximum safety even in case of overpressure release. |  |  |  |  |
| Door material should be made of materials considering adequate safety. |  |  |  |  |
| An automatic door locking system ensures to keep the door closed until the set temperature is reached. User can modify the set temperature according to the lab needs. |  |  |  |  |
| Must have possibility to store, modify and recall custom programmes for process runs. |  |  |  |  |
| Door safety interlocks to prevent microwave emission |  |  |  |  |
| Built-in exhaust system located above the microwave cavity and separated from the electronics to prevent corrosion. |  |  |  |  |
| Should meet emission and safety Norms with respect to current regulatory requirements  |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
|  | **REACTION SENSORS** |  |  |  |  |
| E | Must have temperature sensor for remote/non-invasive measurement of internal reaction temperature at all the vessel positions including in-situ temperature sensor in one of the vessels. |  |  |  |  |
| F | **ROTORS AND VESSELS** |  |  |  |  |
| Minimum 15 position high-pressure rotor should be offered with 15 vessels. Vessels on the rotor should be segmented for easy use. |  |  |  |  |
| **No of vessels can be used in run-** 1 to maximum specified vessels (even single vessel digestion should be possible.)Must have active pressure measurement and control on all vessels. Rotor should be offered with 15 numbers of vessels (minimum) and highest safety during operation. |  |  |  |  |
| Each vessel cost should be specified |  |  |  |  |
| Maximum Temperature capacity of vessel - Up to 250 degree C Maximum Pressure capacity of vessel- Up to 100 bar (1500psi )Volume of Vessel- 100ml Vessel Material- PTFE-TFM Safety Shield- PEEK reinforced with glass fiberEvery vessel must have a vent-and-reseal spring to safely release the pressure in case of overpressure.  |  |  |  |  |
| For handling of small sample size /acids quartz inserts (30-50mL capacity) should be quoted with each vessel |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| G | **CONTROLLER** |  |  |  |  |
| user friendly software and touch screen display with good resolution |  |  |  |  |
| Adequate memory storage capacity. |  |  |  |  |
| Multiple levels access by password, such as User, Administrator and Service |  |  |  |  |
| The software must control all parameter online and display: temperature, pressure, time and power directly on the terminal |  |  |  |  |
| H | **OPTIONAL ACCESSORIES** |  |  |  |  |
| Any other accessories like organic solvent extraction or high temperature furnace can be quoted as optional |  |  |  |  |
| **GENERAL CONDITIONS OF SUPPLY** |
| 22 | **OPERATION AND TRAINING COMPONENT MAINTENANCE**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 23 | **WARRANTY**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 24 | **SUPPORT** |  |  |  |  |
| As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 25 | **SITE PREPARATION:**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 26 | **DELIVERY**6-8 weeks from the receipt of PO & IVL license |  |  |  |  |

**TENDER SPECIFICATIONS fOR HPTLC applicator and scanner with tlc mass SPECTROMETER INTERFACE** **WITH ACCESSORIES**

 **tender notice number: bcp/tender/Pharmaceutical analysis/vas/km/14/2017-2018**

|  |
| --- |
| Quantitative and Qualitative analysis for Active Pharmaceutical Ingredients (APIs), Drug intermediates, Drug impurities, Herbal entities will be conducted using HPTLC applicator and scanner with tlc mass SPECTROMETER INTERFACE. Instrument quoted should be 21 CFR part 11 compliant and should meet all pharma regulations like USP & ICH etc. |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 1 | **SOFTWARE**System Manager Software - 1 server, 3 or more clients |  |  |  |  |
| 2 | **AUTOMATIC SAMPLER**Automatic Sampler with all accessories |  |  |  |  |
| 3 | **CONSUMABLES FOR AUTOMATIC SAMPLER** |  |  |  |  |
| Sample syringe starter kit |  |  |  |  |
| Chromacol sample vials N-11 with snap caps pack of 1000 |  |  |  |  |
| TLC foil down holder |  |  |  |  |
| Compensation ledge for 10 x 10 cm plates |  |  |  |  |
| 4 | **CHROMATOGRAM DEVELOPMENT DEVICE** |  |  |  |  |
| Twin trough chamber for 20 x 20 cm plates [5 numbers] |  |  |  |  |
| Twin trough chamber for 20 x 10 cm plates [5 numbers] |  |  |  |  |
| Twin trough chamber for 10 x 10 cm plates [5 numbers] |  |  |  |  |
| 5 | **POST CHROMATOGRAPHY VISUALIZATION**High Tech UV Cabinet for TLC/HPTLC comprising dual wave UV Lamp and Viewing box |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 6 | **DERIVATIZATION SYSTEM**Dip Tank 20 x 10 cm, with lid |  |  |  |  |
| 7 | **AUTOMATIC DEVELOPING CHAMBER**Automatic Developing Chamber including Humidity ControlUnit & Plate clamping device |  |  |  |  |
| 8 | **PROFESSIONAL PHOTO DOCUMENTATION SYSTEM**TLC Visualizer Documentation & Evaluation System |  |  |  |  |
| 9 | **VISUALIZER SOFTWARE**Visualizer High-Resolution Documentation Package:Image Enhancement, HDRIVisualizer Comparison Viewer PackageVisualiser Enhanced Evaluation Package: Image-based Evaluation |  |  |  |  |
| 10 | **QUANTITATIVE MEASUREMENT & DATA HANDLING**TLC Scanner with software package |  |  |  |  |
| 11 | **SCANNER SOFTWARE**Scanner Multi Wavelength PackageSpectrum Scanning PackageScanner Quantification Package |  |  |  |  |
| 12 | **HPTLC- INTERFACE (MASS SPECTRA)**HPTLC/ TLC - MS interface with oval head |  |  |  |  |
| 13 | **POST-CHROMATOGRAPHIC DERIVATIZATION**Post-chromatographic Derivatizer package- Derivatizer main unit |  |  |  |  |
| 14 | TLC Plate Heater |  |  |  |  |
| 15 | **CONSUMABLES FOR SCANNER** |  |  |  |  |
| Spare Mercury vapor lamp |  |  |  |  |
| Spare Deuterium lamp |  |  |  |  |
| Spare Tungsten Halogen lamp |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 16 | **SAMPLE APPLICATION DEVICE** Manual sample applicator of highest specifications  |  |  |  |  |
| 17 | **CONSUMABLES FOR MANUAL SAMPLE APPLICATOR** |  |  |  |  |
| Spare sample syringe, 100µl |  |  |  |  |
| Spare sample syringe, 500µl |  |  |  |  |
| 18 | **CONSUMABLES FOR AUTOMATIC SAMPLER** |  |  |  |  |
| 10µl Dosing syringe without needle |  |  |  |  |
| 25µl Dosing syringe without needle |  |  |  |  |
| 100µl Dosing syringe without needle |  |  |  |  |
| Needle for spray application |  |  |  |  |
| Needle for contact application |  |  |  |  |
| 19 | **GRADIENT AUTOMATIC MULTIPLE DEVELOPMENT CHAMBER**GRADIENT Automatic Multiple Development Chamber with Advanced Technology. Latest model with highest specification |  |  |  |  |
| 20 | Vacuum Connection Kit |  |  |  |  |
| 21 | **HPTLC PLATES MERCK**HPTLC plates MERCK silica gel 60 F 254, 20 x 10 cm, pack of 50 [2 numbers] |  |  |  |  |
| 22 | **WORKSTATION & SOFTWARE** |  |  |  |  |
| **Computer with min. specification must be quoted:**  |  |  |  |  |
| Make: Reputed brand such as HP/Compaq/IBM/Dell |  |  |  |  |
| Operating System: Windows 7 Professional, 64bit, SP1 |  |  |  |  |
| Processor: Intel® I7 |  |  |  |  |
| Memory: 8 GB  |  |  |  |  |
| Hard Disk: 2 TB  |  |  |  |  |
| Optical Drive: HP DVD-RW Super Multi Drive |  |  |  |  |
| **Graphics: Intel HD Graphics P530** |  |  |  |  |
| Audio: Integrated Realtek HD ALC221 |  |  |  |  |
| Ports: 8x USB 3.0 (2 in front, 6 rear), 2x USB 2.0 (2 in front), RS232 Serial Port (2 in total) |  |  |  |  |
| Input Devices: Keyboard, Optical Scroll Mouse |  |  |  |  |
| Monitor: 27-inch or more IPS Monitor with high resolution |  |  |  |  |
| Printer: LaserJet Printer |  |  |  |  |
| UPS: 15 KVA with 60-minute backup |  |  |  |  |
| This PC should be RoHS compliant and can be used as an acquisition workstation or stand-alone processing computer.  |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| **SPECIFICATION FOR SINGLE QUADRUPOLE MASS SPECTROMETER** |
| 23 | **MASS RANGE:** 30 to 1250 m/z |  |  |  |  |
| 24 | **RESOLUTION:** Automated mass resolution control (0.7Da) for constant data quality |  |  |  |  |
| 25 | **MASS STABILITY:** Mass drift is less than 0.1 Da over a 24 hour period |  |  |  |  |
| 26 | **SENSITIVITY:** **SIR sensitivity (ESI+)**A 100 pg on column injection (5µL of 20 pg/µL) of sulfadimethoxime, with a mobile phase flow rate of 800 µL/min will give a chromatographic signal-to-noise for *m/z* 311 greater than 2000:1 (400:1 with integrated diaphragm backing pump)**SIR sensitivity (ESI-)**A 50 pg on column injection (5 µL of 10 pg/µL) of chloramphenicol, with a mobile phase flow rate of 800 µL/min give a chromatographic signal-to-noise for *m/z* 321 greater than 300:1 (60:1 with integrated diaphragm backing pump) |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 27 | **SCAN SPEED:** Automatically-optimized for enhanced data quality for acquisition rates of up to e.g. 10Hz form/z 100 to 1000 or 20 Hz for m/z 50 to 500 |  |  |  |  |
| 28 | **SOURCE INTERFACE:** Adjustment-free high performance dual-orthogonal atmospheric pressure ionization (API), electrospray (ES) interface for robustness and reliability.  |  |  |  |  |
|  | Ion polarity switching for comprehensive compound coverage |  |  |  |  |
| Integrated adjustment-free plug and play probe for reduced dispersion and reliability De-clustering cone gas |  |  |  |  |
| Disposable sample aperture for minimized maintenance and repeatability Tool free access to customer serviceable elements |  |  |  |  |
| Automated control of gas flows and heating elements. |  |  |  |  |
| Dual off-axis ion guides for elimination of neutral noise with increased sensitivity and robustness. Includes high efficiency conjoined stacked ling ion guide and second stage quadrupole ion guide. |  |  |  |  |
| 29 | **POLARITY SWITCHING TIME:** 25 msec |  |  |  |  |
| 30 | **MASS ANALYZER:**Automated mass calibration and resolution verification for constant data quality. Single high-resolution quadrupole analyzer, plus pre-filter to maximize resolution and transmission while preventing contamination of the mass analyzer |  |  |  |  |
| Mass calibration and accuracy to be verified on every startup of the MS detector using the internal calibrant fluid. |  |  |  |  |
| 31 | **Gas Control**: All gases must be controlled by the software. |  |  |  |  |
| 32 | **DYNAMIC RANGE:** Digital dynamic range up to 4 order |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 33 | **OPERATING MODES:** Full scan MSSelected Ion Recording |  |  |  |  |
| 34 | **DETECTOR:** Low noise of axis, long life photomultiplier/electron multiplier detector |  |  |  |  |
| 35 | **OPERATION AND TRAINING COMPONENT MAINTENANCE**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 36 | **WARRANTY**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 37 | **TRAINING AND SUPPORT**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 38 | **SITE PREPARATION** As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 39 | **INSTALLATION AND DEMONSTRATION**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |

**TENDER SPECIFICATIONS fOR HPLC WITH PDA DETECTOR AND ACCESSORIES (CONSTITUENT PART OF LC-MS-MS)**

**TENDER NUMBER: BCP/TENDER/PHARMACEUTICAL ANALYSIS/VAS/KM/15/2017-2018**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| **Specifications for uHPLC system to be used as a front end for MSMS** |
| **1** | **SOLVENT DELIVERY PUMP** |  |  |  |  |
|  | Solvent delivery pump should be high pressure quaternary with automatic rinsing kit |  |  |  |  |
| Maximum operating pressure should be 7000 psi or more |  |  |  |  |
| Flow rate should be 0.0001 mL/min - 5.0000mL/min (in 0.001ml/ min increments) with accuracy of 1% or better |  |  |  |  |
| Flow Rate Precision- RSD <0.06% |  |  |  |  |
| Pump should have feature of leak sensor |  |  |  |  |
| It should have built-in mixer as well as online membrane type degasser having four or more channels |  |  |  |  |
| Solvent delivery pump should be supplied with solvent tray, solvent bottles, filters, appropriate tubings, tool kit etc |  |  |  |  |
| pH range: 2 to 12 |  |  |  |  |
| **2** | **AUTOSAMPLER** |  |  |  |  |
|  | Appropriate autosampler shall be included with this HPLC system |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
|  | Sample Capacity- 2 Trays, Standard or deep 96-well & 105 x 1.5 mL vials |  |  |  |  |
| A flexible format sample tray for minimum of 100 vials or more. |  |  |  |  |
| It should have operating pressure of 5000 psi or better |  |  |  |  |
| Injection volume range should be from 0.1ul – 100ul or better |  |  |  |  |
| Injection volume accuracy shall be 1% or better |  |  |  |  |
| Injection volume precision shall be 0.25 RSD or better |  |  |  |  |
| Sample carryover / cross contamination shall be 0.0015% or better |  |  |  |  |
| Sample Cooling Thermostat for Auto sampler required from 4- 40°C or similar |  |  |  |  |
| It must have a leak sensor and automatic rack and vial recognition features  |  |  |  |  |
| Provision for repeat injections and needle rinsing should be available |  |  |  |  |
| Injection needle wash should be integral, active and programmable |  |  |  |  |
| Temperature Accuracy: ± 0.5° C at Sensor |  |  |  |  |
| Temperature Stability: ± 1.0°C at Sensor |  |  |  |  |
| 3 | **COLUMN OVEN** |  |  |  |  |
|  | Suitable multi-column oven with provision for simultaneous guard column attachment shall be supplied with this HPLC system |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
|  | It should have temperature range from 5 – 85 °C |  |  |  |  |
| Temperature stability of ±0.1°C.  |  |  |  |  |
| Temperature accuracy of ±0.8°C & with calibration of ±0.5°C or better |  |  |  |  |
| 4 | **PDA DETECTOR** |  |  |  |  |
|  | Photo Diode Array Detector should be supplied with this HPLC system |  |  |  |  |
| It should have wavelength range of 190-800 nm with a Deuterium/Tungsten source |  |  |  |  |
| Detector linearity should be 2.0 AU |  |  |  |  |
| Slit width should be 1nm and 8 nm with wavelength accuracy of 1nm or better |  |  |  |  |
| Detector noise should be 0.4 X 10-5 AU or less & Drift should be less than 0.5 X 10-3 AU/h  |  |  |  |  |
| Detector should have flow cell of 1ul capacity with 10mm path length |  |  |  |  |
| Wavelength accuracy must be at least ±1.0nm. [Data Rate: 120Hz] |  |  |  |  |
| 5 | **INSTALLATION AND DEMONSTRATION** |  |  |  |  |
|  | Basic training for a period of one weeks after installation & commissioning of the equipment to technical personnel to be provided at our site. |  |  |  |  |
| 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. |  |  |  |  |
|  |  |  |  |
| Documents, Kits & standards etc as required being supply along with the instrument. |  |  |  |  |
| 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. |  |  |  |  |
| 6 | **ACCESSORIES** |  |  |  |  |
|  | RP-HPLC columns |  |  |  |  |
| Software for qualitative and quantitative analysis. |  |  |  |  |

**TENDER SPECIFICATIONS fOR UHPLC WITH PDA DETECTOR AND ACCESSORIES (CONSTITUENT PART OF LC-MS-MS)**

**TENDER NUMBER: BCP/TENDER/PHARMACEUTICAL ANALYSIS/VAS/KM/16/2017-2018**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| **Specifications for uHPLC system to be used as a front end for MSMS** |
| **1** | **SOLVENT DELIVERY PUMP** |  |  |  |  |
|  | Solvent delivery pump should be high pressure quaternary with automatic rinsing kit |  |  |  |  |
| Maximum operating pressure should be 15000 psi or more |  |  |  |  |
| Flow rate should be 0.0001 mL/min - 10.0000mL/min (in 0.001ml/ min increments) with accuracy of 1% or better |  |  |  |  |
| Flow Rate Precision- RSD <0.06% |  |  |  |  |
| Pump should have feature of leak sensor |  |  |  |  |
| It should have built-in mixer as well as online membrane type degasser having four or more channels |  |  |  |  |
| Solvent delivery pump should be supplied with solvent tray, solvent bottles, filters, appropriate tubings, tool kit etc |  |  |  |  |
| pH range: 2 to 12 |  |  |  |  |
| **2** | **AUTOSAMPLER** |  |  |  |  |
|  | Appropriate autosampler shall be included with this UHPLC system |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
|  | Sample Capacity- 2 Trays, Standard or deep 96-well & 105 x 1.5 mL vials |  |  |  |  |
| A flexible format sample tray for minimum of 100 vials or more. |  |  |  |  |
| It should have operating pressure of 12000 psi or better |  |  |  |  |
| Injection volume range should be from 0.1ul – 100ul or better |  |  |  |  |
| Injection volume accuracy shall be 1% or better |  |  |  |  |
| Injection volume precision shall be 0.25 RSD or better |  |  |  |  |
| Sample carryover / cross contamination shall be 0.0015% or better |  |  |  |  |
| Sample Cooling Thermostat for Auto sampler required from 4- 40°C or similar |  |  |  |  |
| It must have a leak sensor and automatic rack and vial recognition features  |  |  |  |  |
| Provision for repeat injections and needle rinsing should be available |  |  |  |  |
| Injection needle wash should be integral, active and programmable |  |  |  |  |
| Temperature Accuracy: ± 0.5° C at Sensor |  |  |  |  |
| Temperature Stability: ± 1.0°C at Sensor |  |  |  |  |
| **S. N** | **Specifications of quoted Model/ Item by BCP** | **Specifications of quoted Model/ Item by vendors** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any,to be indicatedin unambiguousterms** | **Whether thecompliance /deviation isclearly mentionedin technical leaflet/literature**  |
| 3 | **COLUMN OVEN** |  |  |  |  |
|  | Suitable multi-column oven with provision for simultaneous guard column attachment shall be supplied with this UHPLC system |  |  |  |  |
|  | It should have temperature range from 5 – 85 °C |  |  |  |  |
| Temperature stability of ±0.1°C.  |  |  |  |  |
| Temperature accuracy of ±0.8°C & with calibration of ±0.5°C or better |  |  |  |  |
| 4 | **PDA DETECTOR** |  |  |  |  |
|  | Photo Diode Array Detector should be supplied with this UHPLC system |  |  |  |  |
| It should have wavelength range of 190-800 nm with a Deuterium/Tungsten source |  |  |  |  |
| Detector linearity should be 2.0 AU |  |  |  |  |
| Slit width should be 1nm and 8 nm with wavelength accuracy of 1nm or better |  |  |  |  |
| Detector noise should be 0.4 X 10-5 AU or less & Drift should be less than 0.5 X 10-3 AU/h  |  |  |  |  |
| Detector should have flow cell of 1ul capacity with 10mm path length |  |  |  |  |
| Wavelength accuracy must be at least ±1.0nm. [Data Rate: 120Hz] |  |  |  |  |
| 5 | **INSTALLATION AND DEMONSTRATION** |  |  |  |  |
|  | Basic training for a period of one weeks after installation & commissioning of the equipment to technical personnel to be provided at our site. |  |  |  |  |
| 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. |  |  |  |  |
|  |  |  |  |
|  | Documents, Kits & standards etc as required being supply along with the instrument. |  |  |  |  |
| 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. |  |  |  |  |
| 6 | **ACCESSORIES** |  |  |  |  |
|  | UHPLC columns |  |  |  |  |
| Software for qualitative and quantitative analysis. |  |  |  |  |

**TENDER SPECIFICATIONS fOR MICROWAVE DIGESTER (CONSTITUENT PART OF ICP-MS)**

**TENDER NUMBER: BCP/TENDER/PHARMACEUTICAL ANALYSIS/VAS/KM/17/2017-2018**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 1 | Since, the requirement includes sample preparation for samples from regulated industries viz. pharmaceuticals and healthcare, the quoted system must have features to comply with the requirements of regulatory bodies including 21 CFR Part 11, GAMP5, etc. |  |  |  |  |
| A | **MICROWAVE DIGESTION SYSTEM** |  |  |  |  |
| Atleast 15 nos. high pressure vessel rotor for quick dissolution of various samples. |  |  |  |  |
| Option of pressurized reaction with user selection for continuous or pulsed microwave reaction. |  |  |  |  |
| B | **MAGNETRON** |  |  |  |  |
| The microwave system should have dual Magnetron system |  |  |  |  |
| Microwave frequency: 2450MHz |  |  |  |  |
| Installed power: minimum 1900W. |  |  |  |  |
| Dual magnetron system with rotating diffuser for homogeneous microwave distribution in the cavity. |  |  |  |  |
| C | **CAVITY** |  |  |  |  |
| The cavity should be made of stainless steel housing with PTFE plasma coating for corrosion resistance.  |  |  |  |  |
| All hardware should have protective coating for the resistance from acid. |  |  |  |  |
| Cavity volume of more than 60 ltrs for safety purpose of the user. |  |  |  |  |
| D | **HARDWARE AND SAFETY** |  |  |  |  |
| Stainless steel housing with multi-layer PTFE coating. |  |  |  |  |
| Protected against acids and solvents with polymer coating on both inner and outer surfaces |  |  |  |  |
| Self-resealing pressure responsive door mounted on sprigs, to ensure maximum safety even in case of overpressure release. |  |  |  |  |
| Door material should be made of materials considering adequate safety. |  |  |  |  |
| An automatic door locking system ensures to keep the door closed until the set temperature is reached. User can modify the set temperature according to the lab needs. |  |  |  |  |
| Must have possibility to store, modify and recall custom programmes for process runs. |  |  |  |  |
| Door safety interlocks to prevent microwave emission |  |  |  |  |
| Built-in exhaust system located above the microwave cavity and separated from the electronics to prevent corrosion. |  |  |  |  |
| Should meet emission and safety Norms with respect to current regulatory requirements  |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
|  | **REACTION SENSORS** |  |  |  |  |
| E | Must have temperature sensor for remote/non-invasive measurement of internal reaction temperature at all the vessel positions including in-situ temperature sensor in one of the vessels. |  |  |  |  |
| F | **ROTORS AND VESSELS** |  |  |  |  |
| Minimum 15 position high-pressure rotor should be offered with 15 vessels. Vessels on the rotor should be segmented for easy use. |  |  |  |  |
| **No of vessels can be used in run-** 1 to maximum specified vessels (even single vessel digestion should be possible.)Must have active pressure measurement and control on all vessels. Rotor should be offered with 15 numbers of vessels (minimum) and highest safety during operation. |  |  |  |  |
| Each vessel cost should be specified |  |  |  |  |
| Maximum Temperature capacity of vessel - Up to 250 degree C Maximum Pressure capacity of vessel- Up to 100 bar (1500psi )Volume of Vessel- 100ml Vessel Material- PTFE-TFM Safety Shield- PEEK reinforced with glass fiberEvery vessel must have a vent-and-reseal spring to safely release the pressure in case of overpressure.  |  |  |  |  |
| For handling of small sample size /acids quartz inserts (30-50mL capacity) should be quoted with each vessel |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| G | **CONTROLLER** |  |  |  |  |
| user friendly software and touch screen display with good resolution |  |  |  |  |
| Adequate memory storage capacity. |  |  |  |  |
| Multiple levels access by password, such as User, Administrator and Service |  |  |  |  |
| The software must control all parameter online and display: temperature, pressure, time and power directly on the terminal |  |  |  |  |
| H | **OPTIONAL ACCESSORIES** |  |  |  |  |
| Any other accessories like organic solvent extraction or high temperature furnace can be quoted as optional |  |  |  |  |
| **GENERAL CONDITIONS OF SUPPLY** |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 2 | **OPERATION AND TRAINING COMPONENT MAINTENANCE** |  |  |  |  |
| As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 3 | **WARRANTY**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 4 | **SUPPORT** |  |  |  |  |
| As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 5 | **SITE PREPARATION:**As mentioned in **Tender Terms and Conditions**. |  |  |  |  |
| 6 | **DELIVERY**6-8 weeks from the receipt of PO & IVL license |  |  |  |  |

**TENDER SPECIFICATIONS fOR SINGLE QUADRUPOLE MASS SPECTROMETER AND ACCESSORIES (CONSTITUENT PART OF HPTLC-MS)**

**TENDER NUMBER: BCP/TENDER/PHARMACEUTICAL ANALYSIS/VAS/KM/18/2017-2018**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| **SPECIFICATION FOR SINGLE QUADRUPOLE MASS SPECTROMETER** |
| 1 | **MASS RANGE:** 30 to 1250 m/z |  |  |  |  |
| 2 | **RESOLUTION:** Automated mass resolution control (0.7Da) for constant data quality |  |  |  |  |
| 3 | **MASS STABILITY:** Mass drift is less than 0.1 Da over a 24- hour period |  |  |  |  |
| 4 | **SENSITIVITY:** **SIR sensitivity (ESI+)**A 100 pg on column injection (5µL of 20 pg/µL) of sulfadimethoxime, with a mobile phase flow rate of 800 µL/min will give a chromatographic signal-to-noise for *m/z* 311 greater than 2000:1 (400:1 with integrated diaphragm backing pump)**SIR sensitivity (ESI-)**A 50 pg on column injection (5 µL of 10 pg/µL) of chloramphenicol, with a mobile phase flow rate of 800 µL/min give a chromatographic signal-to-noise for *m/z* 321 greater than 300:1 (60:1 with integrated diaphragm backing pump) |  |  |  |  |
| 5 | **SCAN SPEED:** Automatically-optimized for enhanced data quality for acquisition rates of up to e.g. 10Hz form/z 100 to 1000 or 20 Hz for m/z 50 to 500 |  |  |  |  |
| **S. N.** | **Name of specifications/ part / Accessories of tender enquiry** | **Specifications of quoted Model/ Item** | **ComplianceWhether “YES”Or “NO** | **Deviation, if any, to be indicated in unambiguous terms** | **Whether the compliance /deviation is clearly mentionedin technical leaflet/ literature** |
| 6 | **SOURCE INTERFACE:** Adjustment-free high performance dual-orthogonal atmospheric pressure ionization (API), electrospray (ES) interface for robustness and reliability.  |  |  |  |  |
| 7 | Ion polarity switching for comprehensive compound coverage |  |  |  |  |
| Integrated adjustment-free plug and play probe for reduced dispersion and reliability De-clustering cone gas |  |  |  |  |
| Disposable sample aperture for minimized maintenance and repeatability Tool free access to customer serviceable elements |  |  |  |  |
| Automated control of gas flows and heating elements. |  |  |  |  |
| Dual off-axis ion guides for elimination of neutral noise with increased sensitivity and robustness. Includes high efficiency conjoined stacked ling ion guide and second stage quadrupole ion guide. |  |  |  |  |
| 8 | **POLARITY SWITCHING TIME:** 25 msec |  |  |  |  |
| 9 | **MASS ANALYZER:**Automated mass calibration and resolution verification for constant data quality. Single high-resolution quadrupole analyzer, plus pre-filter to maximize resolution and transmission while preventing contamination of the mass analyzer |  |  |  |  |
| Mass calibration and accuracy to be verified on every startup of the MS detector using the internal calibrant fluid. |  |  |  |  |
| 10 | **Gas Control**: All gases must be controlled by the software. |  |  |  |  |
| 11 | **DYNAMIC RANGE:** Digital dynamic range up to 4 order |  |  |  |  |
| 33 | **OPERATING MODES:** Full scan MSSelected Ion Recording |  |  |  |  |
| 34 | **DETECTOR:** Low noise of axis, long life photomultiplier/electron multiplier detector |  |  |  |  |