Amendment No. 1

Date: 19/08/2016

Sub: Amendment to the Tender Enquiry Document.

Ref: NIT No.: HLL/PCD/CDSCO-06/16-17 Dated 17.08.2016

The following changes are being incorporated in the referred tender enquiry.

1.) EXISTING:

SECTION I
NOTICE INVITING TENDERS (NIT)

Sch no	Event Number	Name of the Instrument	Total Qty.	EMD
1	3000001435	UV/VIS Spectrophotometer	7	₹ 1,40,000
2	3000001436	FT-IR Spectrophotometer with accessories	2	₹ 48,000
3	3000001437	HPLC (Gradient) System with PDA, fluorescent & RI detector, Auto sampler & essential Columns	2	₹ 1,00,000
4	3000001438	HPLC (Gradient) System with PDA & ELSD, auto sampler & essential columns	6	₹ 6,00,000
5	3000001439	HPLC (Gradient) System with UV detector, auto sampler & essential columns	41	₹ 20,50,000
6	3000001440	Fast HPLC (Gradient) with UV detector, autosampler & essential columns	6	₹ 3,60,000
7	3000001461	GLC with FID detector with head space	3	₹ 1,80,000
8	3000001441	Atomic Absorption Spectrophotometer (AAS) with hydride & graphite furnace	1	₹ 60,000
9	3000001442	HPTLC	2	₹ 2,80,000
10	3000001443	Potentiometric Titrator with necessary electrodes	9	₹ 1,80,000
11	3000001444	KF titrator	7	₹ 1,40,000
12	3000001445	Dissolution apparatus with auto sampler	8	₹ 1,92,000
13	3000001446	Dissolution Media Preparation System	7	₹ 2,10,000
14	3000001448	Polarimeter digital with multi wavelength	2	₹ 48,000
15	3000001449	Refractrometer digital	6	₹ 84,000
16	3000001450	Analytical Balance (5 digits) with printer along with Anti Vibration table	8	₹ 96,000
17	3000001451	Pharma Refrigerator (2-8 degrees centigrade) 1000 L	8	₹ 1,44,000
18	3000001452	Pharma Refrigerator (2-8 degrees centigrade) 500 L	9	₹ 1,08,000
19	3000001453	Water Purification System	10	₹ 1,60,000

Sch no	Event Number	Name of the Instrument	Total Qty.	EMD
20	3000001454	Bacterial Endotoxins Apparatus (KTA/KCA)	7	₹ 1,68,000
21	3000001455	Tensile Strength Tester	2	₹ 56,000
22	3000001456	Amino Acid Analyzer	2	₹ 2,00,000
23	3000001457	Liquid Nitrogen Storage System	1	₹ 20,000
24	3000001458	Ion Chromgraphic System	2	₹ 1,60,000
25	3000001459	KF titrator - Coulometer	1	₹ 20,000
26	3000001460	Cold Centrifuge	2	₹ 32,000

READ AS:

SECTION I
NOTICE INVITING TENDERS (NIT)

Sch no	Event Number	Name of the Instrument	Total Qty.	EMD
1	3000001435	UV/VIS Spectrophotometer	7	₹ 1,40,000
2	3000001436	FT-IR Spectrophotometer with accessories	2	₹ 60,000
3	3000001437	HPLC (Gradient) System with PDA, fluorescent & RI detector, Auto sampler & essential Columns	2	₹ 1,20,000
4	3000001438	HPLC (Gradient) System with PDA & ELSD, auto sampler & essential columns	6	₹ 6,00,000
5	3000001439	HPLC (Gradient) System with UV detector, auto sampler & essential columns	41	₹ 20,50,000
6	3000001440	Fast HPLC (Gradient) with UV detector, autosampler & essential columns	6	₹ 3,60,000
7	3000001461	GLC with FID detector with head space	3	₹ 1,80,000
8	3000001441	Atomic Absorption Spectrophotometer (AAS) with hydride & graphite furnace	1	₹ 60,000
9	3000001442	HPTLC	2	₹ 3,40,000
10	3000001443	Potentiometric Titrator with necessary electrodes	9	₹ 1,80,000
11	3000001444	KF titrator	7	₹ 1,40,000
12	3000001445	Dissolution apparatus with auto sampler	8	₹ 3,20,000
13	3000001446	Dissolution Media Preparation System	7	₹ 2,80,000
14	3000001448	Polarimeter digital with multi wavelength	2	₹ 60,000
15	3000001449	Refractrometer digital	6	₹ 84,000

Sch no	Event Number	Name of the Instrument	Total Qty.	EMD
16	3000001450	Analytical Balance (5 digits) with printer along with Anti Vibration table	8	₹ 96,000
17	3000001451	Pharma Refrigerator (2-8 degrees centigrade) 1000 L	8	₹ 1,44,000
18	3000001452	Pharma Refrigerator (2-8 degrees centigrade) 500 L	9	₹ 1,08,000
19	3000001453	Water Purification System	10	₹ 1,60,000
20	3000001454	Bacterial Endotoxins Apparatus (KTA/KCA)	7	₹ 1,68,000
21	3000001455	Tensile Strength Tester	2	₹ 56,000
22	3000001456	Amino Acid Analyzer	2	₹ 2,00,000
23	3000001457	Liquid Nitrogen Storage System	1	₹ 20,000
24	3000001458	Ion Chromgraphic System	2	₹ 1,60,000
25	3000001459	KF titrator - Coulometer	1	₹ 20,000
26	3000001460	Cold Centrifuge	2	₹ 32,000

2.) EXISTING:

SECTION - VI
LIST OF REQUIREMENTS

Part I

Sch no	Event Number	Name of the Instrument	Total Qty.	EMD
1	3000001435	UV/VIS Spectrophotometer	7	₹ 1,40,000
2	3000001436	FT-IR Spectrophotometer with accessories	2	₹ 48,000
3	3000001437	HPLC (Gradient) System with PDA, fluorescent & RI detector, Auto sampler & essential Columns	2	₹ 1,00,000
4	3000001438	HPLC (Gradient) System with PDA & ELSD, auto sampler & essential columns	6	₹ 6,00,000
5	3000001439	HPLC (Gradient) System with UV detector, auto sampler & essential columns	41	₹ 20,50,000
6	3000001440	Fast HPLC (Gradient) with UV detector, autosampler & essential columns	6	₹ 3,60,000
7	3000001461	GLC with FID detector with head space	3	₹ 1,80,000
8	3000001441	Atomic Absorption Spectrophotometer (AAS) with hydride & graphite furnace	1	₹ 60,000
9	3000001442	HPTLC	2	₹ 2,80,000
10	3000001443	Potentiometric Titrator with necessary electrodes	9	₹ 1,80,000

Sch no	Event Number	Name of the Instrument	Total Qty.	EMD
11	3000001444	KF titrator	7	₹ 1,40,000
12	3000001445	Dissolution apparatus with auto sampler	8	₹ 1,92,000
13	3000001446	Dissolution Media Preparation System	7	₹ 2,10,000
14	3000001448	Polarimeter digital with multi wavelength	2	₹ 48,000
15	3000001449	Refractrometer digital	6	₹ 84,000
16	3000001450	Analytical Balance (5 digits) with printer along with Anti Vibration table	8	₹ 96,000
17	3000001451	Pharma Refrigerator (2-8 degrees centigrade) 1000 L	8	₹ 1,44,000
18	3000001452	Pharma Refrigerator (2-8 degrees centigrade) 500 L	9	₹ 1,08,000
19	3000001453	Water Purification System	10	₹ 1,60,000
20	3000001454	Bacterial Endotoxins Apparatus (KTA/KCA)	7	₹ 1,68,000
21	3000001455	Tensile Strength Tester	2	₹ 56,000
22	3000001456	Amino Acid Analyzer	2	₹ 2,00,000
23	3000001457	Liquid Nitrogen Storage System	1	₹ 20,000
24	3000001458	Ion Chromgraphic System	2	₹ 1,60,000
25	3000001459	KF titrator - Coulometer	1	₹ 20,000
26	3000001460	Cold Centrifuge	2	₹ 32,000

READ AS:

Sr. No.	Name of Instrument	Requirements of the Laboratories							Total No. of Equipments
		CDL Kolkata	CDL Kasauli	CDTL Hyderabad	CDTL Mumbai	CDTL Chennai	RDTL Guwahati	RDTL Chandigarh	
1	UV/VIS Spectrophotometer	2	1	-	-	2	2	-	7
2	FT-IR Spectrophotometer with accesories	1	-	-	-	1		-	2
3	HPLC (Gradient) with PDA, fluorescent & RI detector, Auto sampler & essential Columns	1	1	-	-	0	0	-	2

4	HPLC (Gradient) with PDA, & , ELSD, Auto sampler & essential Columns	1	0	1	1	1	1	1	6
5	HPLC (Gradient) with UV detector, auto sampler & essential Columns	5	-	9	8	6	5	8	41
6	Fast HPLC (Gradient) with UV detector, autosampler & essential Columns	1	0	1	1	1	1	1	6
7	GLC with FID detector with head space	1	-	-	-	1	1	-	3
8	Atomic absorption spectrometer(AAS) with hydride & graphite furnace	Nil	-	-	1	0	0	-	1
9	HPTLC	Nil	-	-	1	1		-	2
10	Poteniometric Titrator with necessary electrodes	2	-	1	2	2	1	1	9
11	KF titrator	1	1	1	1	1	1	1	7
12	Dissolution apparatus with auto sampler	2	1	1	1	1	1	1	8
13	Dissolution Media Preparation System	1	1	1	1	1	1	1	7
14	Polari meter digital with multi wavelength	1	-	-	-	0	1	-	2
15	Refractrometer digital	1		1	1	1	1	1	6
16	Analytical balance (5 digit) with printer along with Anti Vibration table	2	1	1	1	1	1	1	8
17	Pharma Refrigerator (2-8 degrees Centigrade) 1000 L	1	2	1	1	1	1	1	8
18	Pharma Refrigerator (2-8 degrees Centigrade) 500 L	2	2	1	1	1	1	1	9
19	Water purification system	4	1	1	1	1	1	1	10
20	Bacterial Endotoxins Apparatous (KTA/KCA)	1	1	1	1	1	1	1	7
21	Tensil Strength Tester	1	-	-	1	-	-	-	2

22	Amino Acid Analyzer	1	-	-	1	-	-	-	2
23	Liquid Nitrogen Storage System	-	1	-	-	-	-	-	1
24	Ion Chromgraphic System		1		1				2
25	KF titrator - Coulometer		1	-					1
26	Cold Centrifuge	1	1	-	-	-	-	-	2

3.)

SECTION-VII

TECHNICAL SPECIFICATIONS

The existing technical specifications of tender enquiry document is replaced with the following technical specifications **:-**

S.No-1

Technical specification for UV-VIS SPECTRO PHOTOMETER

Microprocessor based Double beam computer control UV-Vis spectrophotometer

Optics	- Double beam sealed, quartz coated, with double -monochromator.
GRATING	- Double blazed / higher performance blazed
WAVE LENGTH RANGE	- 190 nm to900 nm
WAVE LENGTHACCURACY	- +/- 0.1 nm
STRAY LIGHT	-0.0025% OR LESS
RESOLUTION	- 0.1 nm
PHOTOMETRIC MODE	- Absorbance, Transmittance, Reflectance, Energy
PHOTOMETRIC RANGE	-Abs:- 3.8 to + 3.8, %T: 0 to 300%
SPECTRAL BAND WIDTH	- 0.1,0.2,0.5,1,2,5 nm (6 steps)
WAVELENGTH SLEW RATE	- VARIABLE UPTO 3000 nm/min
BASE LINE FLATNESS	- + 0.0003 Abs
DRIFT	- 0.0003 Abs/h
DETECTOR	-Photomultiplier(PMT)
DATA PROCESSING	- software based with integrating & derivative plot facility (min 2nd derivative)
Additional Spare	-1 PAIR QUARTZ CUVETTE (1-cm,5ml) - 1 No.

SOFTWARE WITH P.C. AND PRINTER

- Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification

DOCUMENTS AND TRAININGS:

- IQ - OQ and PQ documents
- On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.
- On Site successful Training at the time of installation.

OTHER CONDITIONS

- The system quoted should be of latest model and the spares and services should be available for next 10 years.
- Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
- All the consumables parts should be covered except curettes and Chemicals during warranty and CMC period.
- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

Sl.No-2.

Fourier Transform Infra Red Spectrophotometer (FT-IR)

TECHNICAL SPECIFICATION :

- Fully Computer Controlled COMPACT BENCH-TOP FTIR system with universal sample Compartment for working with all commercially available accessories.
- The system should comply with latest edition of IP/BP/USP.
- The system should have zero alignment optics for long-term stability reliability and reproducibility of the optical components.
- The system should have the self-compensating for dynamic alignment changes due to a tilt and shear.

- The system should have latest digital signal processor.
- The instrument should indicate whether the source and laser are operational.
- Wave number range: 7800 to 375 cm-1
- Source: Long Life IR Source
- Detector: MID-IR /DLTGS/DTGS detector with temperature control mechanism
- Resolution: 0.5 cm-1 or better
- S/N Ratio: 40000:1 Peak-Peak, 5 Seconds Scan
- Wave number precision: 0.01 cm-1 at 2000cm-1
- Beam splitter: KBR coated with Germanium (Ge)
- The system should be supplied with sealed and desiccated optical set up with built-in purge facility.
- The software should have real time data collection and should have the facility to continuously monitor the performance of source, detector, power supply and laser.
- The system should be supplied with multi-media tutorials.
- The software should also have: Compare Software, Spectral Search; Quantitative Analysis software Automatic atmospheric suppression; SOP builder; Spectral interpretation for unknowns; Quality checks programs and CFR-21 Part-11 Compliance.
- The system should have provisions to minimize the effect of atmospheric water and CO2 interference
- Libraries: BUILT IN LIBRARY WITH Minimum 2500 REFERENCE SPECTRA FOR DRUGS.
- 20×10gm of Rechargeable Desiccant packs.

Major Accessory

-1 Nos. ATR with monolithic diamond probe.
- 1 Nos. Fixed Volume Liquid Cell and fixed thickness (0.5 mm).
- 1 No. Sodium Chloride pellets with Holder for liquid paraffin mulls.
- 1 Nos. Hydraulic Press with 13mm KBr die and Pellet Holder should be supplied.
- 1 Nos. Polystyrene film of 0.3 mm having NIST Traceable certificates.
- 1 Nos. Agate Mortar Pestle (dia 2 inch)
- 1 Nos. Suitable Portable De Humidifier to maintain 30- 60% RH,

- Temperature and RH Digital Indicator having traceable certificate.

SOFTWARE WITH P.C. AND PRINTER

Suitable software 21 CFR PART II compliance, coloured Laser Printer and computer as per General Specification

DOCUMENTSAND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

OTHER CONDITIONS

- The system quoted should be of latest model and the spares and services should be available for next 10 years.
- Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
- All the consumables parts should be covered except chemicals, during warranty and CMC period.
- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

Sl.No-3.

HPLC Quaternary Gradient with PDA,RI & Fluorescence Detector with Auto sampler

Technical specification:

1. PUMP

Quaternary gradient with online degasser Should have pressure operating range minimum 7500psi or better	
Flow:	0.01 to 10 ml/min.
Flow Precision	0.1% RSD or below
Flow Rate Accuracy	±1%

Eluent Degassing	Online membrane Degasser for all channels
Gradient Mixer	Quaternary mixing & gradient capability using high speed proportionate valve
Solvent Setting Range	4 solvents setting range: 0-100% with 0.1% step
DIAGNOSTIC FEATURES	Error detection and display, Leak detection & safe leak handling

2. DETECTORS

(a) PDA

Wave length Range	190-700 nm
Diode Element	minimum 512
Wave length Accuracy	±1 nm
Wave length Precision	± 0.1 nm
Noise	0.6 x 10^{-5} AU
Drift	5 x 10^{-4} AU/h
Temperature Operating Range	5° C below ambient temp to 50ºC
Temperature Accuracy	±0.5 ºC
Path length	10 mm (standard Analytical cell)
Cell Volume	Approximately 10 µL
Light source	D_2 and Tungsten lamp
Lamp Hour	D_2 lamp >2000 hr lifetime

(b) RI DETECTOR

Refractive Index Range	1.00 to 1.75 RIU
Noise Level	± 1.5 x 10^{-9} RIU
Drift	1 x 10^{-7} RIU/hr
Cell Volume	Approximately 10 µL
Temperature Control	Temp controlled Flow cell unit
Temperature Operating Range	5º below ambient to 50ºC.
Temperature Accuracy	±0.5 ºC

(c) FLUORESCENCE DETECTOR

Light Source	Xe lamp with standard wattage
Wavelength Range	200-900 nm
Wavelength Accuracy	± 2 nm
Wavelength Reproducibility	±0.2 nm
Excitation Wavelength	200 nm to 700 nm
Emission Wavelength	280 nm 900 nm
Wavelength Scanning	Scanning of Excitation and Emission wavelengths
Flow Cell volume	approximately 10 µl
Pressure	2Mpa
Sensitivity	500:1 (Tangent method) 700:1 (Base line method)_
Temperature Operating Range	5º C below ambient to 50 º C
Temperature Accuracy	±0.5 ºC

3. THERMOSTATED COLUMN COMPARTMENT WITH COOLING FACILITY

WORKABLE TEMPERATURE RANGE	10 to 80 Degree C
For column length	300 mm
No of Columns accommodated	Minimum 2
Temperature Stability	±0.1 ºC of set temperature
Cooling system	Peltier based or equivalent technology

4. AUTOSAMPLER

Injection Mode	Total vol. Inj / Variable Inj method
Injection Volume Range	0.1-100µl (Standard)
Replicate Injection	per vial 1-50
Sample Capacity	100x 2 ml vials or more
Injection Volume Accuracy	±1%
Cross contamination	<0.1% with & without automated needle wash
Carry over	< 0.1% from previous injection
Tray Temperature Operating Range	10º C below ambient to 50 º C
Temperature Accuracy	±0.5 ºC

4. HPLC COLUMNS Columns C-18 column and C-8 Columns

C_8 = 250 X 4.6 X 5**µm = 2**
C_8 = 150 X 4.6 X 5**µm = 2**
C_{18} = 250 X 4.6 X 5**µm = 5**
C_{18} = 150 X 4.6 X 5**µm = 2**
Cyano = 150 X 4.6 X 5**µm = 1**
Amino = 250 X 4.6 X 5**µm = 1**
Phenyl = 250 X 4.6 X 5**µm = 1**
Silica = 250 X 4.6 X 5**µm = 1**

SOFTWARE WITH P.C. AND PRINTER

Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification

DOCUMENTSAND TRAININGS:

IQ - OQ and PQ documents

All consumable parts should covered except columns and vials during warranty and CMC period.

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

. OTHER CONDITIONS

- The system quoted should be of latest model and the spares and services should be available for next 10 years.
- Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
- All the consumables parts should be covered except cuvettes during warranty and CMC period.
- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

S.No-4

HPLC with ELSD, PDA Detector and Auto Sampler

Technical specification:

5. PUMP

Quaternary gradient with online degasser Should have pressure operating range minimum 7500psi or better	
Flow:	0.01 to 10 ml/min.
Flow Precision	0.1% RSD or below
Flow Rate Accuracy	±1%
Eluent Degassing	Online membrane Degasser for all channels
Gradient Mixer	Quaternary mixing & gradient capability using high speed proportionate valve
Solvent Setting Range	4 solvents setting range: 0-100% with 0.1% step
DIAGNOSTIC FEATURES	Error detection and display, Leak detection & safe leak handling

6. DETECTORS

(a) PDA

Wave length Range	190-700 nm
Diode Element	minimum 512
Wave length Accuracy	±1 nm
Wave length Precision	± 0.1 nm
Noise	0.6 x 10^{-5} AU
Drift	5 x 10^{-4} AU/h
Temperature Operating Range	5° C below ambient temp to 50ºC
Temperature Accuracy	±0.5 ºC
Path length	10 mm (standard Analytical cell)
Cell Volume	Approximately 10 µL
Light source	D_2 and Tungsten lamp
Lamp Hour	D_2 lamp >2000 hr lifetime

(b) Evaporative Light Scattering Detector (ELSD)

- The ELSD should be specifically designed to complement HPLC system for monitoring compounds with poor to no Ultraviolet / Visible response and analytes that do not ionize well in mass spectrometry.
- Nebulizer for high flow rate: 300 to 3000 µl/min.
- Temperature control nebulizer chamber: Heater 0-100%, thermally controlled, cooler on/off.
- Gas Supply: Nitrogen, to be supplied at least 65 psi
- Gain setting: 0 to 1000
- Sample rate: upto 80 points.
- Temperature range drift tube: 5-100°C; 0.1°C increment, feedback accuracy to 0.1°C.
- Optics: Heated optics bench (constant 50°C)
- Light source: Tungsten halogen polychromatic front mounted, pre-aligned, user installable.
- Lamp calibration: Pre-aligned assembly
- Detector: Photomultiplier tube (PMT)
- Scattering angle: 60°
- Measurement Range: 0.1 to 2000 light scattering units full scale
- Angle Output: Two, LS units, nebulizer, drift tube, CHM, gas pressure

7. THERMOSTATED COLUMN COMPARTMENT WITH COOLING FACILITY

WORKABLE TEMPERATURE RANGE	10 to 80 Degree C
For column length	300 mm
No of Columns accommodated	Minimum 2
Temperature Stability	±0.1 ºC of set temperature
Cooling system	Peltier based or equivalent technology

4. AUTOSAMPLER

Injection Mode	Total vol. Inj / Variable Inj method
Injection Volume Range	0.1-100µl (Standard)
Replicate Injection per vial	1-50
Sample Capacity	100x 2 ml vials or more
Injection Volume Accuracy	±1%
Cross contamination	<0.1% with & without automated needle wash
Carry over	< 0.1% from previous injection
Tray Temperature Operating Range	10º C below ambient to 50 º C
Temperature Accuracy	±0.5 ºC

SOFTWARE WITH P.C. AND PRINTER

Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification

DOCUMENTSAND TRAININGS:

IQ - OQ and PQ documents

All consumable parts should covered except columns and vials during warranty and CMC period.

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

OTHER CONDITIONS

- The system quoted should be of latest model and the spares and services should be available for next 10 years.
- Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
- All the consumables parts should be covered except cuvettes during warranty and CMC period.
- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

Sl.No-5.

HPLC Quaternary Gradient with UV-VIS Detector with Auto sampler

Technical specification:

8. PUMP

Quaternary gradient with online degasserShould havepressureoperating range minimum 7500psi or better	
Flow:	0.01 to 10 ml/min.
Flow Precision	0.1% RSD or below
Flow Rate Accuracy	±1%
Eluent Degassing	Online membrane Degasser for all channels
Gradient Mixer	Quaternary mixing & gradient capability using high speed proportionate valve
Solvent Setting Range	4 solvents setting range: 0-100% with 0.1% step
DIAGNOSTIC FEATURES	Error detection and display, Leak detection & safe leak handling

9. DETECTORS

MULTI WAVELENGTH UV-VIS	Simultaneous Multi wavelength Measurement at minimum four points.
Wave length Range	190-700 nm
Wave length Accuracy	±1 nm
Wave length Repeatability	0.1 nm
Drift	1 x 10^{-4} AU/h
Noise Level	0.25 x 10-4 AU or lesser

Light Source	D_2 and Tungsten Halide
Lamp Hour	D_2 lamp >2000 hr lifetime

10. THERMOSTATED COLUMN COMPARTMENT WITH COOLINGFACILITY

WORKABLE TEMPERATURE RANGE	10 to 80 Degree C
For column length	300 mm
No of Columns accommodated	Minimum 2
Temperature Stability	±0.1 ºC of set temperature
Cooling system	Peltier based or equivalent technology

4. AUTOSAMPLER

Injection Mode	Total vol. Inj / Variable Inj method
Injection Volume Range	0.1-100µl (Standard)
Replicate Injection	per vial 1-50
Sample Capacity	100x 2 ml vials or more
Injection Volume Accuracy	±1%
Cross contamination	<0.1% with & without automated needle wash
Carry over	< 0.1% from previous injection
Tray Temperature Operating Range	10º C below ambient to 50 º C
Temperature Accuracy	±0.5 ºC

11. HPLC COLUMNS **Columns C-18 column and C-8 Columns**

C_8 = 250 X 4.6 X 5**µm = 2**
C_8 = 150 X 4.6 X 5**µm = 2**
C_{18} = 250 X 4.6 X 5**µm = 5**
C_{18} = 150 X 4.6 X 5**µm = 2**
Cyano = 150 X 4.6 X 5**µm = 1**
Amino = 250 X 4.6 X 5**µm = 1**
Phenyl = 250 X 4.6 X 5**µm = 1**
Silica = 250 X 4.6 X 5**µm = 1**

SOFTWARE WITH P.C. AND PRINTER

Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification

DOCUMENTSAND TRAININGS:

IQ - OQ and PQ documents

All consumable parts should covered except columns and vials during warranty and CMC period.

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Successful Training at the time of installation.

OTHER CONDITIONS

- The system quoted should be of latest model and the spares and services should be available for next 10 years.
- Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
- All the consumables parts should be covered during warranty and CMC period.
- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

Sl.No-6.

Fast HPLC Quaternary Gradient System with UV- Detector and Auto Sampler

Technical specification:

The system must be capable of to carry out applications like the analysis of large Proteins and Amino Acid Analysis. The system must be MS compatible and also should be able to do chromatography for variety of macro molecules.

12. PUMP

Quaternary gradient with online degasser should have pressure operating range minimum 12000 psi or better	
Flow:	0.01 to 10 ml/min or better

Flow Precision	0.08% RSD or better
Flow Rate Accuracy	±1%
Composition Accuracy	±0.5% or better
Composition Precision	≤0.15% RSD or better
Flow precision	0.075% RSD or better
System dwell volume	≤ 400ul
Pump Seal wash	Automatic
Eluent Degassing	Online membrane Degasser for all Channels
Gradient Mixer	Quaternary mixing & gradient capability using high speed proportionate valve
Solvent Setting Range	4 solvents setting range: 0-100% with 0.1% step
DIAGNOSTIC FEATURES	Error detection and display, Leak detection & safe leak handling

13. DETECTORS

MULTI WAVELENGTH UV-VIS	Simultaneous Multi wavelength Measurement at minimum four points.
Wave length Range	190-700 nm
Wave length Accuracy	±1 nm
Wave length Repeatability	0.1 nm
Drift	1 x 10^{-4} AU/h
Noise Level	0.25 x 10-4 AU or lesser
Light Source	D_2 and Tungsten Halide
Lamp Hour	D_2 lamp >2000 hr lifetime

14. THERMOSTATED COLUMN COMPARTMENT WITH COOLING FACILITY

WORKABLE TEMPERATURE RANGE	10 to 80 Degree C
No of Columns accommodated	Minimum 2
Temperature Stability	±0.1 ºC of set temperature
Cooling system	Peltier based or equivalent technology

4. AUTOSAMPLER

Injection Mode	Total vol. Inj / Variable Inj method
Injection Volume Range	0.1-20µl (Standard)
Replicate Injection per vial	1-50
Sample Capacity	100x 2 ml vials or more
Injection Volume Accuracy	±1%
Cross contamination	<0.1% with & without automated needle wash
Carry over	< 0.1% from previous injection
Tray Temperature Operating Range	10º C below ambient to 60 º C
Temperature Accuracy	±0.5 ºC

15. HPLC COLUMNS

C_8 = 50mm **x 2.1** x 1.8**µm = 2**

C_8 = 100mm **x 1.8** X 1.8**µm = 2**

C_{18} = 50mm **x 2.1** x 1.8**µm = 2**

C_{18} = 100mm **x 1.8** X 1.8**µm = 2**

SOFTWARE WITH P.C. AND PRINTER

Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification

DOCUMENTSAND TRAININGS:

IQ - OQ and PQ documents

All consumable parts should covered except columns and vials during warranty and CMC period.

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Successful Training at the time of installation.

OTHER CONDITIONS

- The system quoted should be of latest model and the spares and services should be available for next 10 years.
- Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.

- All the consumables parts except columns and chemicals should be covered during warranty and CMC period.
- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

Sr. No.	Name of the instrument	Specification
1	Ultra Performance Liquid Chromatography	The Ultra Performance Liquid Chromatography should have minimum specificaton as below. 1. Solvent Delivery System (Quaternary Gradient) a. No. of solvents: Up to four solvents b. Gradient Formation : Low pressure mixing quaternary gradient. c. Degasser : Give or more Channel Vacuum Degasser d. Gradient profiles: 11 gradient curves or more e. g. Wet prime : Automatic h. Maximum operating pressure : 15000 psi or better i. Composition Accuracy : ±0.5% or better j. Composition Precision : ≤0.15% RSD or better k. Flow precision : 0.075% RSD or better l. Flow Accuracy : ±1.0% m. System dwell volume: ≤ 400ul n. Automatic and continuous compressibility compensation without user intervention. On demand automatically achieve desired pH and ionic strengthens gradients form pure solvents and concentrated stock buffers. 3. Auto Sampler : a. Injection Type : The mobile Phase should flow through needle at all the time except the time of injeciton in order to reduce the carry over. Also there should be a facility to wash the outer sheath of the needle. b. No. of samples vials : 90 vials of 2ml or more c. The Injection volume range must be 0.1-10µl with optional extension loops. d. Sample delivery precision : < 1.0% RSD or better e. Sample temp control : 4ºC to 40ºC in 0.1ºC increments f. Sample carryover : <0.004% g. Advanced features : Auto Dilution. 4. Column Oven a. Column temp control : 20ºC to 90ºC in 0.1ºC increments.

		b. Connector to connect with column chip for tracking and archive column usage history automatically. 5. UV Vis Detector a. Wavelength Range : 190 to 700 mm b. The detector must have a dry noise specification of ≤6µAU c. The detector must have a fixed bandwidth of 5nm d. Allowing for uncompromised optical resolution e. The detector must have linearity of 5% of 2.5AU f. The detector must have a measurement range of 0.0001 to 4.0000AU g. Lamp-The detector must have a high brightness lamp with a guaranteed life of 2000 hours h. The detector must have only one lamp source and not require more than one lamp for operation across the entire detector wavelength range. i. The detector must have lamp optimization software j. The detector must be able to operate in single or dual wavelength mode 6. Software a. Windows based chromatgraphy software should provide complete control of HPLC system b. The software should be quoted with a relational secured data base, independent of operating systems like SQL, Oracle and an interface for the software to the database for strong integrity and security of data c. The raw data should be available for processing at any time after modification of 'n' number of times. d. All meta data are automatically managed, linked and versioned e. Software should have customized reporting format f. The quoted software should have the capabilty of programming at least 1-8 different gradient curves. g. Apex intrgation & Gaussian skimming should be possible h. Fast LC system software shall provide a calculator for scaling HPLC methods for transferring from HPLC to Fast LC. The software will scale from fast LC to HPLC. The method setting shall be fully transferable into the Fast LC system instruments method to avoid transcription errors. The Fast LC system software shall include optional and programmable allowances for system dwell volumes and gradient differences. The calculator shall be available with all Fast LC system regardless of CDS used. 7. Columns : a. C18 column with less than 2 micron particle size should be quoted.

Sl.No-7

GLC WITH FID detector with head space

S.No-8

Atomic Absorption Spectrometer (AAS)

Technical Specification:

Fully automated and integrated Type PC controlled Atomic Absorption Spectrometer (AAS) with Flame and hydride Generator with an option to upgrade to Graphite furnace.

Gas Chromatography with Head Space
GAS CHROMATOGRAPH : Fully Microprocessor controlled with FID, Head Space and Liquid Auto sampler
Specification of Gas Chromatograph:
Four-line display plus graphic array provides all needed data, including all temperature and pressure/flow parameters, type of carrier gas, carrier gas column pressure, flow rates, split flow, detector gas flow rates and all detector parameters. Auto shut down of instrument in case of leaks in carrier gas. Auto adjustment of carrier gas flow to compensate for variations in ambient temperature and pressure. Voltage: 220V/ 50 Hz, Single phase. Automatic leak check and column characterization facility. GC Oven should Future up-gradable to Ultra fast option. GC must support two inlets and 2 FID detectors (one for packed and one for capillary columns and fittings)
Pneumatics must be electronic and programmable.
A) Temperature Programmable Oven for column:
1. Should have an operating range of few degrees above ambient to 450 °C or higher.
2. Heating rate: 50°C/min. or higher.
3. Column overheat protection.
4. Temperature programmer with at least 7 ramps and 8 plateaus or better.
5. Rapid cool down of the oven temperature.
6. Typical heat-up: from 50°C to 450°C in 500 seconds. Typical cool down: 450 °C to 50°C in 500 seconds.
B) Two Nos. Injector with independent heating: One Programmable split/ splitless injector and one packed column injector
a) Temperature range**:** 400°C or more.
b) The injector must be able to operate with all capillary and wide bore
c) The inlet chamber design has to avoid the contact of the sample with hot metal surface.
d) The injector must allow timed closure/opening of the purge line.
C) Two No. Flame Ionization Detector (FID) (one for packed and one for capillary columns)
1) Maximum operating temperature: 450°C.
2) Linear dynamic range: ≥ 10^6 .
3) Detectivity: 2 x 10^{-12}gC/sec
4) Auto flame out detection.
5) Acquisition rate 50 Hz or more.
HEAD SPACE&**LIQUID AUTOSAMPLER**:
Autosampler is a versatile automatic sampling system platform conceived on a 3-axis turret movement approach, designed. Should control through same GC software.
1. HEAD SPACE (AUTOSAMPLER)

. The autosampler must be able to transfer sample vapour to the injector with Transfer line.
. The auto sampler must permit adjustable and known sample volume to be introduced without requiring a change of sample loops
. Sample vapour of upto 15 ml can be injected for high sensitivity analysis.
. The autosampler must permit free access to the injection port for routine maintenance and manual injection.
. Must allow housing of 8 or more sample vials of 10 or 20 ml capacity
. Must permit sequential injections on the same inlet for sample enrichment.
. Must feature dedicated turret for handling of proprietary gas tight syringe.
. The syringe must be heated and feature a gas line for purging with inert gas, when required.
. The type and volume of the syringe must be automatically detected by the system. . Relative standard deviation 5% or less . Must handle any Large Volume injection techniques. (PTV-LV, LV Split less, LV- On column)
2. LIQUID AUTOSAMPLER
. Must be able to house up to 50 or more sample vial (2ml capacity)
. Must allow installation of two needle length syringes, so to be able to address any injection mode or injector type.
. The type and volume of the syringe must be automatically detected by the system.
. Must allow installation and automation of syringe featuring volumes from 0.5 to 100 µl.
. Must be able to perform sequential injections in **two** inlets using different methods and injection modes, regardless the type of injector.
1. The sampling system must be programmable with 8 different operating modes and, if required must allow access to a lower level of parameter setting.
2. Must be able to achieve combined multiple solvent rinsing with upto 4 different solvents.
Necessary Gas Cylinder with Regulators **(1) Hydrogen, Nitrogen, and Zero Air Gas Cylinder** Gas Manifold for Hydrogen, Nitrogen & Zero Air with indicative Oxygen, Moisture and Hydrocarbon trap with copper tubing from Cylinder to Manifold and Manifold to Instrument with universal colour code and direction of flow. Gas Station to run the system along with 10 KVA True Online UPS with 60 minutes backup should be quoted, **Accessories for Auto sampler:** a. 2ml Vials with septa for crimp seal : 500 Nos. b. Crimping tool for sealing vials : 02 Nos. c. Syringe 10ul FN for Auto sampler: 05 Nos. **Installation kit comprising;** • Stainless /suitable steel tubing

- Assorted Swagelok fittings,
- Nuts,
- Ferrules,
- Unions,
- Tees,

. Glass column 1 m x 3.2 mm, Packed with porus polymer beads(150-180 micrometer) Qty – 1

. Glass column 1.8 m x 2 mm, Packed with Acid washed diatomaceous support (80- 100 mesh) coated with 15 %w/w poly ethylene glycol 400 - Qty – 1

. Glass column 2 m x 3 mm, Packed with 10 % diethylene glycol succinate on Acid washed &silanised flux -calcinated siliceous earth (chromosorbs WHP 80-100 mesh)- Qty – 1

- A fused - silica capillary column 30m x 0.32 or 0.53 mm coated with cross linked 6 % polycyanopropyl phenyl siloxane and 94 % polydimethylsiloxane - **Qty - 1**

1. Stainless steel column 4mx2mm packed with diatomaceous support (125-180 mesh) impregnated with 5% carbowax 20M(polyethylene glycol compound 20M) - Qty - 1

Accessories:

1) All Flow Controller i.e. Carrier flow, Make-up flow, Hydrogen flow, Air flow etc. value should set through Software by PC.

2) Should have real time display for chromatogram.

3) Head Space Auto Sampler, Automation and event control from PC through same software.

Data handling system:

1) Suitable computer as per specification mentioned in General Specification
2) Suitable Software CFR – 21, Part -11 compliance.
3) Suitable Laser Printer

Documents and Trainings:

. IQ - OQ and PQ documents
. On site Calibration with traceable reference material , to be done by the supplier on installation and thereafter every six months during warranty and CMC period.
. On Site Training at the time of installation
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- **<u>Other conditions:</u>**
  - The system quoted should be of latest model and the spares and services should be available for next 10 years.
  - Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
  - All the consumables parts should be covered except Columns and Chemicals during warranty and CMC period.
  - Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

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Specification :	
TYPE	Real Time Double Beam Spectrometer
WAVELENGTH RANGE	190-900 nm
GRATING	Diffraction grating with dual blazed and ruling density of 1800 lines/mm RLD (Reciprocal Linear Dispersion)1.6 nm/mm
SPECTRAL BANDWITH	**Variable types programmable through software using auto slit selection mode from 0.2 - 1.0 nm or better**
Sensitivity	**System should provide at least 0.9 Abs with 0.5%RSD from 5-10 seconds integrations for 5 ppm copper (CU) standard solutions.**
LAMP SETUP	LAMP SETUP-8 or more Lamps position Automatic Lamp Holder with computer controlled lamp selection its alignment and Automatic optimization of energy using coded lamps. Built in power supply 4 special Lamp to enhance sensitivity
OPTICAL SYSTEM	Real time Double Beam optical system for automatic compensation for changes in instrumental parameters for high signal stability and performanceto give excellent S/N ratio
ATOMIZER	Built in Atomizer
DETECTOR	Solid-State Detector having quantum efficiency/PhotoMultiplier Tube (PMT).

GAS FLOW CONTROL	**Total Computer Controlled gas flow system** to maintain gas flows (Ratio of fuel/oxidant) at set levels even when subjected to outside variations like nebulizer adjustments. Automatic Gas Flow adjustment during change over between air C2H2 & N2O
BURNER HEAD TYPE	Acetylene- 10**0 mm** and Nitrous Oxide Burner –**50mm**
SAFETY INTERLOCKS	Burner head interlock, Nebulizer / End Cap Interlock,Drain Interlock etc to built in
BURNER ADJUSTMENT	Computer controlled motorized burner adjustment withhighest precision and reproducibility for adjustment ofFlame position in light path as well as fully automaticAdjustmentof Burner Head. The height of BurnerHead should also be stored with method file.
NEBULIZER TIP	**Nebulizer tip made up of anti-corrosive material** to take analysis with acids, corrosive samples including HF.
CARBON FILLED **PPS / inert Spray** chamber to analyze all types of samples, should have high mechanical strength & fast drainage characteristics	
ACCESSORY ADJUSTMENT	Fully computer controlled spectrometer for all major accessories, Burner Heads**, FIAS / equivalent technique**, Auto sampler etc under software control.

AUTOSAMPLER	Auto sampler with sample delivery up to 5**ml** with increment of 1 ml, automatic replicate analysis and automatic dilution
BACKGROUND CORRECTION	D_2 background correction facility
Manifold System	Gas Manifold: Argon Gas Acetylene, Gas, NitrousOxide Gas, Zero Air. Silica gel Potassium Hydroxidesuitable tubing from gas Generator/Gas Cylinder to manifold and Manifold to instrument
Gas Cylinders with regulators (of ISI Mark) and suitable tubing's for Argon Gas Acetylene gas Nitrous Oxide Gas andZero Air	

Exhaust hood and vent assembly to remove waste gas from AAS room , installation of this is to be done by the supplier
Hydride Generator for element As, Se, Hg, Si, Sb, Sn etc.
Lamps: Single Element coded hollow cathode lamps for the following elements : 1)Pb, 2)Hg, 3) Na, 4) K, 5) As, 6) Fe, 7) Cu, 8) Mn, 9), Se, 10) Zn, 11) Cr, 12) AI, 13)Sn, 14) Sb ,15 Ca, 16)Mg. Calibration Standard solution (min pack) for above elements should be provided with latest National / International traceability Certificate and NMT 6 months old.
SOFTWARE WITH P.C. AND PRINTER • Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification **DOCUMENTS AND TRAININGS:** • IQ - OQ and PQ documents • On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period. • On Site Training at the time of installation. **OTHER CONDITIONS:** • The system quoted should be of latest model and the spares and services should be available for next 10 years. • Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward. • All the consumables parts should be covered except Chemicals and gases during warranty and CMC period.

- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

Sl.No.9- HPTLC SYSTEM

Technical Specifications

(A) SEMI AUTOMATIC SPOT / BAND APPLICATOR

Sample spot / band applicator:

Spray on, 4 pattern Applicator ---Quantitative analysis, micro-preparative, in-situ and superimpose.
10-method memory storage, stand-alone or PC control. Sample positioning on X & Y axis freely
selectable, variable rate of delivery, accepts 100 ul & 500 ul syringes. Self diagnostic + validation +
Link to System Manager built-in.

(B) TLC SCANNER WITH DATA EVALUTION / DENSITOMETER:
Computer controlled Scanner / Densitometer for automatic spectrum scanning for identification and
purity check. Automatic quantitative measurement by absorbance & fluorescence. All TLC / HPTLC
plate sizes acceptable. Scan speed 100 mm / sec @ 25 _m resolution, Wavelength range 190-800
nm. Monochromator flushing by nitrogen. Data sampling rate – 4000 / sec. Optics for HPTLC
measurements. Spectrum scan speed 100 nm / sec. Max 999 spectra / plate. Visible pilot slit image /
scan compartment illumination with UV to check sample alignment with scan beam. D2, Hg, W
lamps + self diagnostic + Service dialog + Universal filter for fluorescence all built-in, scan slit size
variable, bandwidth selectable 5 & 20nm. EPROM upgradable.

Data evaluation 32 bit software (latest version), Linked to System Manager, Automatic / Manual
integration, Auto baseline correction. Spot check facility. 3D display with data storage. Calibration -
single level, multilevel, linear / non-linear. Statistics CV / CI. Reproducibility check facility. GLP

compliant. Auto calculation of data from wts and dil. factors , Computer generated random no. for
each report (GLP). Lamp use tracking. 2 level digital user manual. Service Dialog + self Diagnostics + Tutorial built in.

(C) CHROMATOGRAM DEVELOPMENT CHAMBERS
All glass, small internal volume chambers, bottom divided into two halves; maximum 5-15 ml mobile
phase / run, S.S. leak - proof corrosion free lid. Appropriate size chambers for 20 x 20, 20 x 10,10 x
10, 10 x 5 cm plates.

(D UV CABINET:
Dual wavelength 254 + 366 nm UV

(E) 20 X 10 CM DIP TANK WITH LID FOR DERIVATIZATION (Battery Operated)

(F) PROFESSIONAL TLC / HPTLC PHOTODOCUMENTATION SYSTEM under GLP :

Illumination unit – with 254 , 352 and 366 nm UV. Visible light (above & below object). Uniform
illumination. 60 KHz supply for instant, flickerless illumination. Easy access for changing tubes &
filters and PCB. Auto switch off. Total darkness. Viewing window to see plate. Safety - UV
switched off if door opened.

Camera 12 bit, high resolution industrial camera (4096 grey level resolution). Images of the highest
quality. Fixed focus for total reproducibility. True colours capture. Very linear response. Individually
calibrated.

(G) AUTOMATIC TLC SPRAYER
Pneumatic cordless TLC Sprayer with rechargeable batteries. Non – clogging very fine uniform
spray. Resistant to corrosive reagents. With accessories.

(H) TLC / HPTLC PLATE HEATER
Stain resistant ceran glass top; temp range 25 to 200_C. Uniform heating of plate. Digital display of
set & actual temp. Display on as long as plate is hot. Upto 20 x 20 cm size plates.

(I) CUTTING DEVICE FOR TLC/HPTLC GLASS PLATES:

Cuts glass TLC/HPTLC plates up to 20 x 20 cm to the desired format – precise, fast & efficiently.
Economises use of glass plates.

(J) Zero Air & Nitrogen Generator

Technical Specification
Max Output Flow Rate for N2 ATP : 600 cc/min
Max Zero Air Output Flow Rate for THC <0.1ppm (ATP) : 1500 cc/min
Pressure Dewpoint : -70°C / -94°F
Max Output Pressure : 0-80psi / 0-5.5bar
Build in Cylinder : Required
Internal Air Compressor : Required
Electrical Requirements : 220- -240v 50Hz
Outlet Port : suitable

Spares :

a) Chromatogram Development Glass Chambers
All glass, small internal volume chambers, bottom divided into two halves; maximum 5-15 ml mobile
phase / run, S.S. lid. Appropriate size tanks for 20 x 20, 20 x 10,10 x 10, 10 x 5 cm plates. One
number of Each size.
b) Precoated TLC or HPTLC Plates - One Packet of each.
c) Analytical sample syringe – 100ul - One number
Preparative sample syringe – 500 ul - One number
Teflon tips for 100ul & 500ul syringe - Ten num number each type
d) i) -UV tubes – 254, 366 nm - One number
ii) - White light UV filters - One number
e) Lamps – Mercury, Deuterium, Tungsten-Halogen – One each type

SOFTWARE WITH P.C. AND PRINTER

- Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification

DOCUMENTS AND TRAININGS:

- IQ - OQ and PQ documents
- On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

- On Site Training at the time of installation.
-

OTHER CONDITIONS

- The system quoted should be of latest model and the spares and services should be available for next 10 years.
- Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.

- All the consumables parts should be covered except Chemicals and HPTLC Plates during warranty and CMC period.
- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

S.No-10

Auto Potentiometric Titrator

1. Potentiometric sensor Measurement range: ± 1200 mV
2. Potentiometric sensor Resolution: 0.1 mV
3. Polarized Sensor Measurement range:0 … ±1200 mV / 0 … ±120 µA
4. Polarized Sensor Resolution: 0.1 mV / 0.1 µA
5. Burette resolution (for 10-mL burette): 0.5 µL (1/20'000 of the burette volume) with plug and play burettes
6. Terminal: Touch control, VGA atleast 5.0" colour TFT, 320 x 240 pixel, Adjustable Display.
7. Up to 12 one click (methods) on home page for up to 30 users each and individual home screens for the user (30 users) with password protection.
8. Two home keys to get back to home page immediately
9. Plug & play intelligent Burettes: Automatic update of setup data upon connection, Automatic selection of burette drive.
10. Plug & play Electrodes: Complete sensor set up, Sensor type, sensor name, serial no, Calibration data, zero point , slope, temperature, date and time of calibration, date of next calibration reminder are saved on sensor chip
11. Hot plug & play technology for other peripheral devices means if you connect during titration, system should recognize automatically without reset.
12. In built magnetic stirrer and propeller stirrer and Speed control by Titrator.
13. Ethernet connection: Built-in Ethernet connection to directly attach the Titrator to the network.
14. Method Development: Intelligent method editor, with clear scientific meaningful parameters.
15. Calculation: Very easy and clearly understandable, scientific calculation formulas and parameters, Same calculations for all the user and different methods (no need to remember)
16. Weight transfer from balance: Fast takeover of sample weights via balance or terminal means bidirectional control be possible.
17. Burette Validation: burette volume-To be certified with the reference burette (has been tested and certified at the Metrology Centre) to avoid complication of certification of temperature, humidity, gravity during traditional burette volume certification by weight and density of water.
18. Burette Drive validation: Dosing accuracy-Measure the piston stroke heights with a certified micrometer which measure burette resolution.
19. Fully integrated network software management and controlled in standalone or network dual mode operation touch-screen and PC software.
20. Software should have capability for continuous online audit trials monitoring without deactivation facility and should have facility for user lifetime password history and 21CFR

Compliance.

21. Should have provision of addition 3 more external burette drives and 1 internal to dispense and titrate and provide the electrode for acid base, non-aqueous, Complexometry and fluoride ions selective electrode each one.

SOFTWARE WITH P.C. AND PRINTER

- Suitable software compatible to 21 CFR Part 11 Compliance with valid license key provided through manufacturer. License key should supply along with instrument from original manufacturer along with instrument. DOCUMENTS AND TRAININGS:
- IQ - OQ and PQ documents
- On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.
  On Site Training at the time of installation.

OTHER CONDITIONS:

- The system quoted should be of latest model and the spares and services should be available for next 10 years.
- Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
- All the consumables parts should be covered except electrodes and Chemicals during warranty and CMC period.
- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

Sl.No-11.

Karl Fisher Titrator

Technical Specification:

1. Burette Drive resolution: 20,000 Steps.
2. Burette Resolver resolution : 0.07% of burette volume Or better
3. Burette Filling time and discharge time: 20 s at 100% filling rate
4. Burette resolution (for 5 mL burette): 0.25 µL
5. Polarized Measurement range : -1200…+1200 mV
6. Polarized sensor Resolution: 0.1 mV
7. Polarization current range: 0…..120 µA Or better
8. Polarization current resolution : 0.1 µA
9. Drift measurement: Online, < 5 µl/min
10. Measurement range: 10 ppm...100%
11. Repeatability: 0.3% at >10 mg H_2O

12. User Interface: User specific Home screen with Shortcuts, User management, online screen with direct start of sample and concentration Determination Complete online views with curves and data section online help.
13. Work at PC software and/or Touch screen always shows the curves and measured values.
14. RFID chip or equivalent on burette to make sure the correct use and is automatically found from the method.
15. Solvent Manager: Solvent fully controlled by the instrument and started with a Shortcut and Overflow protection valve on waste bottle.
16. Direct One Click start from Home screen with Auto start and direct weight entry.
17. All accessories are automatically recognized and ready to use immediately.
18. Modern communication (USB, Ethernet) and up-to-date technology.
19. User interface and printouts in English
20. Fully integrated network software management and controlled in standalone or network dual mode operation touch-screen and PC software.
21. Suitable 2 electrode with stand.
22. Suitable KF vessel.

SOFTWARE WITH P.C. AND PRINTER

Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification

DOCUMENTSAND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

OTHER CONDITIONS:

- The system quoted should be of latest model and the spares and services should be available for next 10 years.
- Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
- All the consumables parts should be covered except Electrode and Chemicals during warranty and CMC period.
- Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

S.No-12.

Dissolution Rate test Apparatus with Auto Sampler (Tablet/Capsule)

Technical Specification:

- Complies with USP, IP,EP and JP specifications
- Shaft locking mechanism for positive engagement andWobble free operation
- Bath drain for easy removal of water from bath
- Menu driven software with on-line help.
- 8 Paddle System with SNAP FIT Shaft or batter system for paddles & basket.
- Precise Individual Vessel Cantering system.
- Sturdy bath top plate with clear moulded bath.
- Real time digital clock.
- Temperature control wake up (Heater turns on at preset clock time)
- 10 Programmable sampling intervals & 15 programmable protocols
- Validation print out with summary of test.
- Power failure recovery.
- Off-line sampling facility
- Volume adjustable from 1 to 15 ml.
- Vibration free, smooth electrical lift movement
- Auto calibration of temperature
- Reduces Routine Validation
- Audio-Visual status and error indication
- On-line validation and printout of test parameters.
- Instrument levelling system.
- Vibration dampeners are to be provided to minimize the effect of vibration on thedissolution test.
- Sturdy Motorized lift.
- Water Circulating pump for precise temperature time control of water bath.
- Low evaporation vessel lid.

Accessories:

8 Nos. Paddles (USP II)
8 Nos. Baskets with Rods (USP I)
8 Nos. S.S. Cannulas (without Filters)
1 No. Water Circulating Pump
8 Nos. Clear and Amber Color Merlon Jars with lids.
1 No. Molded Perspex Water Bath with heater and sensor
1 No. External Probe.

With Programmable System Control with Splash proof operational
Panel, LCD Display for RPM, Temperature & Elapsed Time Displays
For 12 sampling intervals, Built-in control of speed, Bath vessel
Temperature, Interfaces for automated Collector & programmable for
12 Different products.

h) SINKERS as per USP (Set of 6 Nos.)
i) SINKER (SMALL SIZE : 5/15.5 mm)
ii) SINKER (SMALL SIZE : 6/18 mm)
iii) SINKER (SMALL SIZE : 8/23 mm)
iv) SINKER (BIG SIZE : 11/31mm)

Off Line Syringe Sampling Accessories For SampleCollectionIncludes
Motorised Sampling Manifold
Wherein user define different media volumes like 500 ml, 750 ml, 900ml, 1000 ml as well as the apparatus type such as Basket &Paddle.
No turbulence created to the agitation properties

Syringe Pump – 06 with 6 Syringes(12 ml or more P 4 Way Valve: can adapt 12 ml or more syringe.

FEATURES:
Station syringe sampler pump for 6 Channel.
Sampling accuracy ± 1%
Can adapt 12 ml or more syringe.
4 way Rugged Valve system for Sampling & Replenishment.
All syringe & Valves to operate synchronously for parallel selection.
Zero Setting for each Syringe.
Motor mounting with noise suspension.

PTFE Carrier Tube Set
(with connector for manifold syringe pump & sample collector)
0.8 MM PTFE TUBING WITH FERRULE CONNECTION
1. All PTFE Carrier tubing 1.6 mm × 0.8 mm.
2. Tube Connectors by flameless fittings for firm connection & easy change over.

SS. Tip Full Flow Filters:
Optimises filter Life by Providing Increased Surface Area.

FILTER - 15 – MICRON (SET OF 6)

Suitable Fraction Collector

Sample Collector:
To collect 6x 24 total samples with rinsing facility

Tablet Input Device: to insert 6 tablets simultaneously provided with polymer coated plate with low evaporation lids.

Individual Vessel Temperature Sensor, Indicator And Recorder With Printer Port (Set of 6).

Syringe Filter Manifold:
(8 Nos. disposable syringe filter can be inserted)

SOFTWARE must have following compliance.
All data safety requirements in the GMP and GLP guidelines as well as CFR 21 part 11.
Audit trail log for all the events, errors, warnings with electronic signatures
Access level security (Password Protection)

Data Handling System
Suitable Software CFR – 21, Part -11 compliance.
Suitable computer as per specification mentioned in General Specification
Suitable Laser Printer

Documents and Trainings:
IQ, OQ and PQ documents
Calibration certificate with traceability, to be done by the supplierevery six month during the warranty and CMC period.
On Site Training at the time of installation

S.No-13

Name of the Equipment : Media Preparation system for Dissolution apparatus

Technical Specification:

- The system should have the compliance with USP tool kit requirement of Media De-Aeration.
- The Media De-aeration system should be a portable/movable, automatic, dissolution Media De-aeration system.
- The system should have the capability to preheat, filter, measure, de-aerate and deliver dissolution media simultaneously into six vessel's at a time.
- The control panel should be user friendly design with digital readout of actual media temperature and temperature set point.
- Pressure/Vacuum air pump - The air pump should be within the cart frame for quiet operation. It is easily removed for service
- The system should have the facility to measure and validate the volume, temperature, vaccum pressure and dissolved gases with the help of external validated tools to be quoted with main system.
- Dispense Head - The Head connects to the Dispense Tubing with quick disconnects and is user configurable for filling six or seven dissolution vessels simultaneously. The Dispense Head is designed to interface with most of dissolution Test Stations available by different manufacturers.
- Heater Assembly - The heater should have an integral design comprised of the heater, element, temperature sensor, overload sensor and level sensor. The heater should be easily removed for cleaning or for placement in spare media tanks. Heating element of the heater with Teflon coating to avoid possible corrosion and reaction with media.
- Tank Capacity: the tank capacity should be min. 40 liters to cater max dissolution baths media dispensing task.
- The dispensing cycle for all the six or seven vessels should be simultaneously and should complete within less than 4.0 mins for quick and uniform temperature in all the vessels to meet latest USP guideline.
- The system should work in close loop so as to have the min media exposure so as to comply the USP TOOL Kit requirement of Media De-Aeration Norms.
- The media De-aeration should be performed under the vacuum with through the thin film technology.
- Volume setting - The dispense volume should be user selectable from 250 to 1000 ml in 50 ml increments at ± 1% accuracy. The measure system should be factory calibrated and is easily recalibrated by the user at the site.
- Media Tank - The tank should be chemically inert and is equipped with a 5 micron filter and standard hose bib for quick and easy connection.
- The tank should be easily removed for cleaning or for replacement with spare tanks. The system should have the facility to adopt extra tanks (one after other) to eliminate the cleaning validation.
- The extra tank should have a dedicated Teflon coated Heater, Filter cartridge and controller to pre-Heat the media simultaneously.

- A chemically inert cover prevents evaporation losses and provides a docking location for the Dispense Head.
- The Instrument should be on its own circuit to prevent instrument problems and circuit overload.
- The system should have removable tank to avoid cross contamination, carryover & cleaning validation.
- The system has the capability to configured dedicated tank for the Individual media (To be quoted as an optional)

DOCUMENTS AND TRAININGS:

- **IQOQPQ** of instrument and Software should be provided along with document.
- **Training** Technical and Application training to the personnel at site immediately after its installation
- The system should be quoted with all accessories required to make it fully operational.

- **Other conditions:**
  - The system quoted should be of latest model and the spares and services should be available for next 10 years.
  - Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
  - All the consumables parts should be covered except Chemicals during warranty and CMC period.
  - Suitable UPS with 01 hour backup and surge protector should be supplied with the system.

S.No-14

Automated Digital Polarimeter fully control by PC ,with the following features.

Technical Specification:

Display	LCD not less than 2 lines
Measuring Range	ANGLE OF ROTATION - 89 deg to +89 deg arc
	Optical Rotation
	Specific Rotation
	Concentration (g/mL, G/100mL, G/L)
	Sucrose
	Glucose
	User Defined Scales
Optical Rotation Specification	
a. Measuring Range	±89.9degree Arc
b. Resolution:	0.001 degree for entire measuring range
c. Accuracy	±0.002degree for entire measuring range

d. Repeatability	±0.002degree for entire measuring range
e. Response Time	<15 second for the entire measuring range
Optical Cell	Stainless steel cell of 100mm and 200mm length
Detector	PMT/Photodiode/Equivalent
Detection Limit	UPTO 2nd decimal or better
Measurement Accuracy	± 0.02 deg
Wavelength	365 nm, 405 nm, 435 nm, 546nm, 589 nm, 633 nm (All are mandatory)
Light Source	Appropriate light source to cover all the above stipulated wave length
Temperature Controlled Cell Compartment	
Temperature Control	15 deg ^{0}C to 35 deg ^{0}C
Min Tube Length	220 mm
Accessories	CELL: 1 dm (5 ml), 2 dm (10 ml)

SOFTWARE WITH P.C. AND PRINTER

Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification

DOCUMENTS AND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

S.No-15

Digital Refracrometer

Measurement Range	1.3200nD – 1.5600nD 0-95% Brix
Accuracy	PR-H: ±0.00002^{nD}; ±0.02% Brix
	PR-S: ±0.0002^{nD}; ±0.2% Brix
Resolution	PRB-H: 0.00001nD; 0.1%Brix
	PRB-S: 0.0001nD; 0.1%Brix
Measurement Units	Refractive Index [nD] Saccharose [%Brix] Glucose [%Brix] Fructose [%Brix]
Measurement Interval	3-60s

Temperature Sensor	PT100
Temperature Measurement	-10-99.9DegreeC
Temperature Resolution	0.1degree C
Temperature Accuracy	±0.2degree C
Temperature Compensation	ICUMSA, Arbitrary
Ambient Temperature	0-40degree C
Illumination	LED 590nm (est. Life: >100,000h)
Housing cast aluminium	Powder coated
Interfaces	RS-232
Analogue	0/4-20mA
Protection Class	IP65
Working Voltage	24V
Display	LCD 120 X 32 Pixel

PRINTER

Suitable Laser Printer as per General Specification

DOCUMENTS AND TRAININGS:

IQ, OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

S.No-16

Analytical balance with 5 digits display

Technical Specification

Max Capacity	Approximately 30 gms
Readability	0.01 mg
Repeatability (sd)	0.03 mg
Linearity	0.2 mg
Sensitivity Temperature Drift (10^{o}C …..30^{o}C)	2.5 ppm/^{o}C
Setting Time, Typical	4s/>15s
Adjustment Pan	Built In
Weighing Pan	Approximately 80 mm
Usable Height of Draft Shield	Approximately 225mm

PRINTER

Suitable Laser Printer as per General Specification

DOCUMENTS AND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

S.No-17

Pharma Refrigerator

Specification:
1- Temperature Range 2 to 8 ºC
2- Capacity: 900 to 1100 litre
3- Digital display of Temperature and Humidity.
4- CFC Free, Microprocessor Controlled, Noise Free Operation
5- Digital Temperature Programmable
6- Number of Doors: 2 glasses Doors
7- Shelves: More than 5 perforated shelves
8- Preventive Unauthorized Access Control
9- Inbuilt data logger with traceable certificate (Preferably with SD card, Data Cable for easy backup)
10- Alarm for power failure, temperature, sensor failure and incorrect voltage
11- Voltage Stabilizer and suitable power backup unit for 30 minutes.

PRINTER

Suitable Laser Printer

DOCUMENTS AND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

S.No-18

Pharma Refrigerator

Specification:
1- Temperature Range 2 to 8 ºC
2- Capacity: 450 to 550 litre
3- Digital display of Temperature and Humidity.
4- CFC Free, Microprocessor Controlled, Noise Free Operation
5- Digital Temperature Programmable
6- Number of Doors: 2 glasses Doors
7- Shelves: More than 3 perforated shelves
8- Preventive Unauthorized Access Control

9- Inbuilt data logger with traceable certificate (Preferably with SD card, Data Cable for easy backup)
10- Alarm for power failure, temperature, sensor failure and incorrect voltage
11- Voltage Stabilizer and suitable power backup unit for 30 minutes.

PRINTER

Suitable Laser Printer

DOCUMENTS AND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

S.No-19

Water Purification Unit

Technical Specification

Water purification unit with the following specification:

Two stage System should have RO and UV/HPLC grade purification facility and Water quality of the minimum specification of:

Type –II

Conductivity	: <0.2uS/cm @ 25 Deg. C
Resistivity @ 25 Deg C	: 5 to 15 Mega Ohms cm
TOC	: <20ppb
Output	: 15 to 25 Ltrs / Hr
Dispensing flow Rate	: 1 Litre / min
Bacterial	: < 1CFU/10ml
Particle using 0.2 µm filter	: <1/ml

Type - I

Conductivity	: 0.055uS/cm @ 25 Deg C
Resistivity at 25 degC	: 18.2 Mega-Ohm –cm
Dispensing flow Rate	: 1-2 Liters/Min
TOC	: < 5 ppb
Bacterial	: 1CFU/ 10ml
Bacterial Endotoxin	: <0.001 EU / ml .
Particle using 0.2 µm filter	: less than 20 particle/100 ml

Feed water specification:

Source of water : Municipal tap water / ground water
Capacity : 30 liters or more

The system should be table top model with on line TOC & LCD display facility, flow rate up to 1.5 L/min, Dual purification cartridges with organic absorbents, ion exchange resins and membrane processes to purify the water to 18.2 mega ohms, in order to satisfy ASTM TYPE 1, ISO 3696 and USP Specification, The system should have a pure water recirculation system to maintain consistent peak quality.

DOCUMENTS AND TRAININGS:

- IQ - OQ and PQ documents
- On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.
- On Site Training at the time of installation.

S.No-20

BACTERIAL ENDOTOXINS BY KINETIC TURBIDIMETRIC ASSAY (KTA) AND KINETIC CHROMOGENIC ASSAY (KCA)

Specifications for instrument for quantitative estimation of bacterial endotoxins by kinetic turbidimetric assay (KTA) and kinetic chromogenic assay (KCA)

1. Detection modes : Absobance
2. Read methods : End point, Kinetic and turbidmetric , linear scanning, Self test and self caliberation, capable of making calculations automatically.
3. Microplate types : 96- well plates
4. Temeratue control : Incubation up to 50ºC ± 0.2ºC
5. Shaking : Linear
6. Software : Compatible software for assay of Endotoxins by Kinetic Turbidimetric Assay & Kinetic Chromogenic Assay. Preferably CE certified.
7. Light Source : Tungsten halogen
8. Detector : Photodiode
9. Wavelength selection : Filters
10. Wavelength range : 340- 900 nm
11. Dynamic range : 0 to 4.0 OD
12. Resolution : 0.001 OD
13. Path length Correction : No
14. Filter wheel capacity : 6 positions
15. Filters supplied : 4 filters (5 with UV option)

16. OD accuracy : < 1% at 2.5 OD
< 2% at 3.5 OD
17. OD lineariy : < 1% at 2.5 OD
18. OD repeatability : < 0.5% at 2.5 OD
< 1.5% at 2.5 OD
19. Reading speed (kinetic) : 96 wells: Less than 10 seconds
20. Power : 100- 240 Volts AC.50/60 Hz

Justification:
1. One of the official methods in all pharmacopoeias including IP 2014.
2. Faster analysis- estimation of endotoxins can be done in 10 minutes instead of 1 hour in case of conventional gel clot method.
3. More number of samples can be tested at one point of time -up to 96 samples can be tested instead of maximum 10 samples by conventional gel clot method.
4. Less consumption of reagents as compared to conventional Gel clot method. Hence economic and time saving.
5. Less manpower s required.
6. No need of depyrigenation of reaction tubes as depyrogenated plate is used in this method.
7. Quantiative estimation of endotoxins is now incorporated in IP monographs such as Insulin Lispro Injection(IP 2014)
8. Quantitative estimation of endotoxins is prescribed in manufactuerer's specifications.
9. Helpful in controversial samples, court cases etc. Where quantitative estimation of endotoxins is necessary.

DOCUMENTS AND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

S.No-21

Tensile Strength Tester

Technical Specifications

1- Digital Tensile strength tester which is capable of determining tensile strength and elongation of textile, rubber, plastic, fabric, metals and other materials etc. The sample is held between two jaws, the upper one is stationary jaw while the other end is made to move at a known fixed speed with the help of motor, gear box and lead screw arrangement. The load exerted on the stationary jaw is sensed by a sensor connected with a load cell which directly

indicates the load in digital form in kg. the elongation of the test specimen is measured on the three type of testes can be operated on this unit. Graphs. Load, v/s Elongation and Stress v/s strain graphs. Auto scaling before print out. Special graph against specific need can be provided. For desired force value, corresponding the elongation value & vice-versa can be directly seen on the screen. Cross head Drive & Speeds. Variable test speed through variable frequency A.C. Drive. For speed range refer table and speed selection through computer key board.

2-The dual column-loading frame shall be capable of tension, compression, flexure, shear, and reverse stress testing. It should include a digital closed loop command and feedback motion control system which a high performance DC servo motor.

3-The load frame shall include a bright red ISO approved emergency stop switch. For safety purposes, the system shall not restart the crosshead moving when the emergency stop button is released.

DOCUMENTS AND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

S.No-22

Amino Acid Analyzer

Technical Specifications

1- Pump

Simultaneous 2- piston technology for 2 fluid lines

Pump head made of inert PEEK material

Max. Pressure:- 400 bar

Flow rate:- 0.01 – 9.9 mL/min

Reproducibility of flow rate:- 0.1 % (RSD) at 100 µL/min

2- Auto sampler

Sample cooling 8^0C by Peltier elements

Syringe pump, motor- injection valve

Sample rack: Minimum 50 (1.5 mL Standard)

Dosage: 1 - 40 µL in 1 µL- steps free programmable

3- Micro-photometer

Wave length: 570 nm, 440 nm

Noise: 0.02mAU, 1s

Drift: < 1.0 x 10 -5 AU / h

Linearity deviation: 0.3 % bei 1 AU

Measuring range: high, low

Analog signal: 0 - 5 V

Base line adjustment: free programmable

Auto-Zero function free programmable

Flow cell: 10 µL volume

4- Separation column

Cation exchange resin- 3µm

Different dimensions:- Stainless steel or PEEK

Temperature adjustment by Peltier elements

Temperature range 20 - 100° C

Temperature accuracy: 0.1° C

5- Reactor

Highly inert material

Peltier elements

Temperature range:- 50 - 150° C

Auto-Shut-down safety routine in case of failure alarm

6- Reagents

Reagent- and washing solution, integrated into central unit

5 eluent bottles, 1 regeneration bottle integrated in separate

eluent unit

7- Tubings

PEEK and FEP

8- Control- Software

Compatible to run the instrument and comfortable creation & modification of separation programs

9- Ready to use reagent kits

Kits including eluents, reagent and additional dilutions buffers

Pre- and separation column for the analysis of more than 500runs

Reproducibility of retention time: 1%, RSD

Reproducibility of peak area: 3%, RSD

DOCUMENTS AND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

S.No-23

Liquid NITROGEN Storage System

Technical Specification

Description	Cryocan (Liquid Nitrogen) Storage system alongwith racks for 2.0 ml. cryo vials (Capacity 2,000 – 3,000 vials)
Brand Name	IBP/ Thermo Scientific / Any other make

Specification	Capacity : 100 - 120 Litres. Static Evaporation rate : 0.3 – 0.7 litres/day. Diameter : 1.5 ft. to 2.0 ft. Height : 3.0 ft. to 3.5 ft. Neck Diameter : 6 Inch.

DOCUMENTS AND TRAININGS:

IQ - OQ and PQ documents

On site Calibration with traceable reference material, to be done by the supplier on installation and there after every six months during warranty and CMC period.

On Site Training at the time of installation.

S.No-24

Ion Chromatography System

Computer controlled Ion Chromatography System able to provide multiple flexibility of detection in series and in complex sample matrix to analyze carbohydrates, mono & di polysaccharides vaccines.

1. **Solvent Delivery Pump – Quantity 01 No.**

Pump with built-in quaternary/ternary low pressure gradient system and non-metallic PEEK base compatible for 0-14 pH & Reverse Phase (RP) compatibility for 4/3 solvents gradient as per the following specification.	
Flow range	0.001 – 10 mL/min or better.
Flow Accuracy	< 0.1 %
Pressure Ripple	<1% without dampner
Flow Precision	<0.1%
Operating Pressure	0-5000 psi or more.
Vacuum Degasser	Built in with gradient pump

2. **Chromatography Accessories & Detector Enclosure – Quantity: 01 No.**

To mount various accessories like sample injection valves, multiple columns with thermo-stated column compartment, and injection valves in temperature range of 10-70^0 C.

3. Electrochemical Detector Cell Kit – Quantity: 01 No.

The electrochemical detector must be capable of operating in an integrated Amperometry, pulsed amperometry, DC Amperometry mode, or Cyclovoltammetry.	
Potential Range	± 2.00 v in 0.001V increment
Cell volume	<0.2 µL
Range	50 pC-200 µC (Int. Amp) 5 PA – 74 µA (dc Amp)
Electronic Noise	DC : <10 pA, IPAD : <50 pC
Counter Electrode	Titanium/SST
Reference Electrode	Ag / AgCl Combination
Working Electrodes	Gold electrode with gasket and polishing kit (Non Disposable). Detector must accept other working electrode like Silver, Platinum & Glassy carbon.

4. Auto-Sampler

Auto-sampler must be capable of performing full-loop and partial-loop injections.	
Sample Capacity	100 x 2ml or more.
Variable Volume Range	0.1 µL to 100 µL (Standard)
Injection Precision	Fixed loop <0.5% RSD or better. Partial loop <0.5% RSD or better.
Dispensing Precision	<0.2% RSD
Replicate Injection	Per vial 1-50
Carryover	<0.01% with 500 µL flush volume
Sample Tray (Thermostatting)	4º C to Ambient temperature

5. Thermostated Column Compartment.

Body	Non metallic body
Working Temperature Range	4º C to Ambient temperature
Column Length to be accommodated	Must accommodate column of id 4mm and length upto 250 mm along with guard column
No of Columns accommodated	Minimum 2

6. System compatibility with Columns

The quoted instrument should be compatible with columns of different makes	
Anion Exchange Capacity	Approximately 100 µeq.
Maximum Operating Pressure	2000 psi (15 MPa)
Chemical Compatibility	pH 0–14 Up to 90% of common HPLC solvents and must be compatible with the eluents like Sodium acetate and Sodium hydroxide.
System should be compatible to use with 2mm id columns.	
100% solvent compatibility for all eluents.	

7. Installation Qualification (IQ) Kit with all necessary Documents / Binder (Complete Binder)

IQ / OQ / PQ Kit including for EC detectors & Documents / Complete Binder.

8. Chromatography Software

Chromatography software to control complete IC system, data acquisition, processing & reporting, etc.

- The software must be able to provide full automatic control of the process of analyzing samples.
- This must include acquiring data, quantitation, producing a report, and the option to upgrade to an incorporated excel like spreadsheet for report flexibility.
- The software must be able to automate integration updates without time consuming batch reprocessing of changes to an integration in a data set.
- 21 CFR Part II Compliance

All the above mentioned components of the instrument must be manufactured by one manufacturer and controlled through single software.PC & Printer with support software Windows 7 or any other compatible version & colored printer with automatic both side printing facility. Compatible branded Online 3KVA UPS with 1 hour back up .

9. Other Accessories :

- Solvent filtration assembly with vacuum pump and 0.2 micron &0.45 micron nylon 66 membrane filters Quantity 5000 for each size
- Sample filtration syringes with 0.2 micron &0.45 micron nylon 66 membrane filters Quantity 5000 filter for each size.
- Low insert volume studs:- Quantity 2000 No
- Vials 2000 No.
- Spares: like inline filters, fluidics, tubings, nuts, sample and prep. Syringes , needle assembly, etc. to suffice for 2 years.
- Counter Electrode:- Quantity 3 No
- Reference Electrode:- Quantity 3 No
- Working Electrodes:- Quantity 3 No
- Any other accessories for smooth functions should be provided.

10. Other Conditions

a. The system quoted should be of latest model and the spares and services should be available for minimum10 years.
b. Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
c. All the consumables parts should be covered except columns and vials during warranty and CMC Period.
d. On site calibration with traceable reference material to be done by the supplier on installation and thereafter every six months during warranty and CMC period.
On site successful training to staff should be provided at the time of installation.

S.No-25

Karl Fisher Titrator (Coulometer)

Technical Specification:-

1. The Equipment shall be fully automatic and microprocessor computer controlled compact instrument.
2. The instrument shall have coulometric cell without diaphragm.
3. Range: 10µg to 200 mg of water
4. Power Supply: 230 V AC ±15%, 50 Hz (±5%)
5. Facility to have user defined calculation. Number of results/calculations per method should be atleast 9.
6. Statistical function like mean value, relative and absolute standard deviation should be available for at least 15 determinations if required.
7. Instrument should be with default minimum 4 methods and Facility to store atleast 100 user methods.
8. Suitable magnetic stirrer should be provided with the instrument.
9. Conditioning of the cell should be completely automatic without the need to do any titration or manually otherwise.
10. The instrument should have the facility to stop the Titration based on the drift apart from the time. This is to ensure zero errors due to external drift.
11. The instrument should have a Real time curve display.
12. The instrument should start automatically on sample introduction.
13. The instrument should have a clear backlit LCD display for clear viewing.
14. Suitable 21 CFR Part II compliance software for computer compatibility should be provided with the instrument.

Accessories:

a) Accessory (Oven) for driving off the moisture of solid and liquid samples for subsequent coulometric determination of the water content according to Karl Fischer.
b) Temperature range 55^0C to 240^0C. Heating rate 15^0C/min and cooling rate of 9^0C/min. Digital gas flow monitoring and control. Live temperature display. Switch over between two preselected temperatures along with Manual sample introduction and built in air pump.
c) Compatible Online branded UPS with 1 hour back up. PC, Printer any other accessory required for smooth installation and working of the instrument should be quoted with main configuration.

Other Conditions:

e. The system quoted should be of latest model and the spares and services should be available for minimum10 years.
f. Warranty: 3 years standard warranty from the date of successful installation of Equipment and 3 years CMC afterward.
g. All the consumables parts (spares) should be covered during warranty and CMC Period.
h. IQ/OQ and PQ documents should be provided at the time of installation.
i. On site calibration with traceable reference material to be done by the supplier on installation and thereafter every six months during warranty and CMC period.
j. On site successful training to staff should be provided at the time of installation.

(A)	**KF Titrator Coulometer**	Karl Fisher Coulometer, operable by 220 volt, 5 amp. Plug with following specifications. 1. Power Supply: 230 V AC ±15%, 50 Hz (±5%) 2. The instrument shall have coulometric cell without diaphragm 3. Facility to have user defined calculation. Number of results/calculations per method should be atleast 9. 4. Statistical function like mean value, Relative and absolute standard deviation should be available for at least 15 determinations if required. 5. Instrument should be with default minimum 4 methods and Facility to store atleast 100 user methods. 6. Suitable magnetic stirrer should be provided with the instrument. 7. Range: 10µg to 200 mg of water 8. Conditioning of the cell should be completely automatic without the need to do any titration or manually otherwise. 9. The instrument should have the facility to stop the Titration based on the drift apart from the time. This is to ensure zero errors due to external drift. 10. The instrument should have a Real time curve display. 11. The instrument should start automatically on sample introduction. 12. The instrument should strictly follow the Good Laboratory Practice principles and should be able to a. User Right restriction manage routine and administrative log in. b. Validation and Service Interval Reminder facility. c. GLP method for Validation of the equipment. d. GLP complaint documentation. 13. The instrument should have a clear backlit LCD display for clear viewing. 14. Suitable software for computer compatibility should be provided with the instrument. 15. Accessory for driving off the moisture of solid and liquid samples for subsequent coulometric determination of the water content according to karl Fischer. Temperature range 55 to 240 deg C. Heating rate 15 C/min. and cooling rate of 9 C/min. Digital gas flow monitoring and control. Live temperature display. Switch over between two preselected temperatures. Manual sample introduction, built in air pump. 16. Instrument must have option to attach oven sampler to handle multiple samples in Future.
(C)	Warranty	3 years with spares.
(D)	Other Items	Compatible Online branded UPS with 1 hour back up , PC, Printer any other accessory required for smooth installation and working of the instrument should be quoted with main configuration.
(E)	Customer support	No. of offices/service engineers near Chandigarh, maximum expectable dead time to resolve problems and other such information such be communicated along with final quotation.

S.No-26

COLD CENTRIFUGE

Technical Specification:

1. **Max capacity with swing bucket rotor: 4x400ml**
2. Max capacity with fixed Angel rotor: 6x100ml
3. Max speed with swing bucket rotor: 6300 rpm
4. **Max speed with fixed angle rotor: 15200rpm**
5. Max RCF with swing bucket rotor: 7188xg
6. **Max RCF with fixed angle rotor: 25830xg**
7. Control system: microprocessor
8. **Rotor should have auto locking system**
9. Rotor shall be installed and removed with no tools in less than 5 seconds
10. Drive system should be Direct, brushless induction low profile motor
11. Should have imbalance detection system.
12. **Can be used for 30 x 2ml tube and 8 x 50 ml tube.**
13. Programs: 99(5 with direct access key)
14. Temperature set range**: -10 °C to +40 °C**
15. Should have pre-cooling system
16. Refrigeration system: CFC free
17. Should have pulse/short run system
18. **Acceleration / Deceleration Rates:** 9 / 10
19. **Centrifugation Chamber:** Stainless Steel
20. **Max Timer Range: 9h, 99min + continuous**
21. **Sound Level (dBA):** < 55
22. **Should have Certified ClickSeal biocontainment system, language selection, motorized lid latch**
23. **Max Power Consumption (W):** 1200

ROTOR:

24. **Should have provide a fixed angel rotor with capacity: 8x50ml, with speed 14000-14500 rpm and RCF 23500-24400xg along with adapter for 15 ml conical tube.**
25. **Fixed angel rotor with capacity: 30x2ml, with speed 15200 rpm**
26. **Rotor should be made of carbon fiber with 03 years warranty**

Documents and Trainings:

IQ, OQ and PQ documents
Calibration certificate with traceability, to be done by the supplierevery six month during the warranty and CMC period.
On Site Training at the time of installation

Other Conditions

k. The system quoted should be of latest model and the spares and services should be available for minimum10 years.
l. Warranty: 3 years standard warranty from the date of successful installation of the equipment and 3 years CMC afterward.
m. All the consumables parts should be covered except columns and vials during warranty and CMC Period.
n. On site calibration with traceable reference material to be done by the supplier on installation and thereafter every six months during warranty and CMC period.
o. On site successful training to staff should be provided at the time of installation.

GENERAL TECHNICAL SPECIFICATIONS

GENERAL POINTS:

1. Warranty:

   a) **Three years Comprehensive Warranty** as per Conditions of Contract of the TE document for complete equipment and Turnkey Work from the date of satisfactory installation, commissioning, trial run & handing over of equipment to Institution/Consignee/ User.
   b) 98% up time Warranty of complete equipment with extension of Warranty period by double the downtime period on 24 (hrs) X 7 (days) X 365 (days) basis.
   c) All software **updates and changes** should be provided free of cost during Warranty & CMC period.

2. After Sales Service:

   After sales service centre should be available at the city of Hospital/Institution/Medical College/Organisation/Consignee on 24 (hrs) X 7 (days) X 365 (days) basis. Complaints should be attended properly, maximum within 24 hrs. The service should be provided by Tenderer/Indian Agent. Undertaking by the Principals that the spares for the equipment shall be available for at least 10 years from the date of supply. If the manufacturer /agent do not have the service centres in India they will have to set up the same within 45 days after award of contract.

3. Training:

   IQ, OQ AND PQ documents.

   On site calibration with traceable reference material, to be done by the supplier on installation

   and there after every six months during warranty and CMC priod.

   On Site training to Technicians/ staff at the time of installation is to be provided by Principal/ Indian Agents (if they have the requisite know-how) for operation and maintenance of the equipment to the satisfaction of the consignee.

4. Annual Comprehensive Maintenance Contract (CMC) of subject equipment with Turnkey:

a) The cost of Comprehensive Maintenance Contract (CMC) which includes preventive maintenance including testing & calibration as per technical/ service /operational manual of the manufacturer, labour and spares, after satisfactory completion of Warranty period may be quoted for next **3 years on yearly basis** for complete equipment (including other vacuumatic parts wherever applicable) and Turnkey (if any). The supplier shall visit each consignee site as recommended in the manufacturer's technical/ service /operational manual, at least once in three months during the CMC period

b) The cost of CMC may be quoted along with taxes applicable on the date of Tender Opening. The taxes to be paid extra, to be specifically stated. In the absence of any such stipulation the price will be taken inclusive of such taxes and no claim for the same will be entertained later.

c) **Cost of CMC will be added for Ranking/Evaluation purpose. The same will be taken at Net Present Value with a 10% discounting factor each year.**

d) The payment of CMC will be made on six monthly basis after satisfactory completion of said period, duly certified by end user on receipt of bank guarantee for 2.5 % of the cost of the equipment as per Section XV valid till 2 months after expiry of entire CMC period.

e) There will be 98% uptime warranty during CMC period on 24 (hrs) X 7 (days) X 365 (days) basis, with penalty, to extend CMC period by double the downtime period.

f) During CMC period, the supplier is required to visit at each consignee's site at least once in 3 months commencing from the date of the successful completion of warranty period for preventive maintenance of the goods.

g) All software **updates and changes** should be provided free of cost during CMC.

h) All the consumables parts should be covered except curettes during warranty and CMC period.

i) Failure of the above [4. e) to 4. g)] by the supplier, may lead to the forfeiture of the Bank Guarantee for Annual CMC.

j) The payment of CMC will be made as stipulated in GCC Clause 21.

Turnkey:

Turnkey is indicated in the technical specification of the respective items, wherever required. The Tenderer shall examine the existing site where the equipment is to be installed, in consultation with the consignee. The Tenderers to quote prices indicating break-up of prices of the Machine and Turnkey Job of each equipment. The Turnkey costs may be quoted in Indian Rupee will be added for Ranking Purpose.

The taxes to be paid extra, to be specifically stated. In the absence of any such stipulation the price will be taken inclusive of such duties and taxes and no claim for the same will be entertained later.

The Turnkey Work should completely comply with AERB requirement, if any.

5. Installation and commissioning:

Pre requisite for installation & commissioning must be spelt out very clearly along with the technical bid (e.g. power requirements, AC, controlled air temperature, furniture etc.)

6. Wherever applicable, the instruments should be supplied along with suitable computer along with latest, certified operating system and software, laser printer the vendor should take full responsibility for Computer, Printer, UPS and other accessories. All spares parts and accessories supplied by third party through the vendor should cover under CMC.

7. Suitable UPS with 01 hour backup and surge protector should be supplied with the system

8. Software with P.C and Printer :

   Suitable software 21 CFR PART II compliance, Laser Printer and computer as per General Specification.

All other contents of the tender enquiry including terms & conditions remain unaltered.

Note: Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids