
TENDER NOTICE

AIC-LMCP Foundation, invites quotations for the instruments listed in **Annexure I** in two bid system. The interested vendors/companies can submit their quotations in two separate bids (one for technical and one for financial) by 27-July-2018 up to 17:00 at (<https://www.nprocure.com> & <https://www.lmcp.ac.in>). The technical bids will be opened on 30-July-2018 at 10:30 onwards. The terms and conditions are as follows:

Terms & Conditions:

The technical and financial bids should be quoted separately for each equipment (See **Annexure I** for the list of equipments and **Annexure V** for technical specifications).

Applicant should not have been blacklisted by the Departments/Ministries of the Govt. of India/State Govt./PSUs/any other organization (A declaration has to be submitted).

The tenderer/bidder should submit duly filled checklist of technical bid (**Annexure II** along with supporting documents and catalogues of equipment quoted).

The financial bids of those bidders will be considered who qualify under technical bid. The date of opening the financial bids of qualified technical bidders will be informed separately.

The prices quoted must include CIF (Cost, Insurance and Freight) charges.

The bidder shall furnish INR 1000 (One thousand only) as bid processing (Tender) fee and as part of the bid, an interest free EARNEST MONEY DEPOSIT (EMD) of amount mentioned in **Annexure III** for each equipment separately in the form of Demand draft /Account payee cheque at par (valid for 90 days) drawn in favour of AIC-LMCP Foundation, L. M. College of Pharmacy, Navrangapura, Ahmedabad - 380 009, Gujarat, India, payable at Ahmedabad or through RTGS or NEFT transfer (Refer **Annexure III** for details).

The EMD of the unsuccessful bidders will be discharged/returned at the earliest after completion of the tender process. The successful bidder's EMD will be discharged upon the bidder's acceptance of the Letter of Intent satisfactorily. The EMD may be forfeited under following circumstances:

- If the bidder withdraws his/her bid during the period of bid validity specified by the bidder in the Bid form;
- In the case of successful bidder, if the bidder fails to sign the contract; or Fails or refuses to honour his/her own quoted price for any of the items or part thereof.
- In both the above cases bidder will not be eligible to participate in the tender for one year from the date of issue of Letter of Intent.

The delivery of equipment needs to be done within 45-60 days or earlier of confirmed Purchase Order. The delivery period should be clearly indicated in the quotation.

Submitted quotations (Refer **Annexure IV** – Price bid format) should clearly mention the validity period, preferably for a minimum of 3 months.

Incomplete and conditionally submitted tenders would be summarily rejected.

The mode of payment should be clearly indicated.

Necessary certificate(s) should be enclosed by the vendor in case of proprietary nature of the quoted items.

The prices quoted (*Total Value*) must be inclusive of all taxes, cost of software, training/equipment installation, qualification and demonstration, loading and unloading, transport insurance (wherever applicable) and transportation charges to deliver the equipment/machine at AIC-LMCP Foundation, L. M. College of Pharmacy, Navrangapura, Ahmedabad - 380 009, Gujarat, India.

The bidder with the lowest Total Value (including Qualification and Training) will be selected.

Excise Duty / Custom Duty: The AIC-LMCP Foundation, Ahmedabad will provide the duty exemption certificate (DSIR Certificate). Taxes, as applicable, should be charged according to the existing norms.

For Indigenous items: 80% payment shall be made against satisfactory delivery and balance 20% after satisfying all the conditions as per the tender terms and conditions, successful installation and commissioning of the equipment certified by the Indenter and after furnishing of Guarantee/Warranty documents.

For imported items: All bank charges inside India will be borne by AIC-LMCP Foundation, L. M. College of Pharmacy, Ahmedabad, and outside will be borne by the Principals/Vendors.

a) Foreign currency payment- 80 to 100% payment by an irrevocable Letter of Credit or Telegraphic transfer favouring Principal and for opening of Letter of Credit, two weeks prior to dispatch of the equipment on submission of letter from Principals confirming that machine is ready for dispatch and on receipt of documents without any discrepancies and balance upto 20%, where applicable, will be paid after satisfactory installation and commissioning of equipment as certified by the indenter.

b) Reimbursement of Expenses in Indian Rupees -

Payment will be made after receipt/ satisfactory installation, testing and commissioning of equipment as certified by the Indenter. The payment of indigenous items, nominal custom duty, Custom Clearance, Insurance and transportation charges or any other charges will be paid in Indian currency to Indian Agent on production of bill supported by documentary proof Verified by the Indenter. (Upto the amount defined in the Bid and the amount will be paid on the basis of actual bills raised against the amount mentioned in the bid, whichever is less)

Note.I. All bank charges outside India shall be borne by the supplier.

II. LC will be opened on receipt of unconditional acceptance of purchase order.

III. Accepted term of payment shall be clearly indicated in Tender/ Offer document.

The quotation should include comprehensive warranty for at least 2 years from date of delivery and three years free service effective after expiry of warranty period.

In case the quotation is being submitted by authorized agent of the principal manufacturing company, the AUTHORISED SALES AGENCYSHIP certificate from the PRINCIPAL should be furnished along with the quotation. Quotations without this authorization certificate will be rejected.

Vendors should attach the relevant brochure/leaflet for the models/options quoted.

Vendors should attach users list with their contact details.

The Bidder shall bear all costs associated with the preparation and submission of the Bid. AIC-LMCP Foundation shall, in no case, be responsible or liable for these costs, regardless of the conduct or the outcome of the Bidding process.

The tenderer should ensure that the technical and financial bid documents and all its annexures are complete.

In case two or more agencies are found to have quoted the same rates, the competent authority, AIC-LMCP Foundation shall decide about the agency to which the offer shall be granted based on the past credentials/ report on the past performance of the firm, and length of experience etc. The decision of the competent authority, AIC-LMCP Foundation shall be final and binding, and no communication in this regard will be entertained.

The conflicts or disputes that may arise in relation to the subject, content, interpretation, implementation and enforcement of this agreement will be solved, firstly, by the Monitoring Committee for good governance and then, by equity arbitration. In the event, efforts by Monitoring Committee and an equity arbitration attempt fails, then the legal jurisdiction to be approached shall be within the jurisdictions of Ahmedabad only.

The procurement is subject to release of grants from funding agency.

The tender/procurement process may be cancelled at any stage by competent authority without informing on any reason.

Annexure I

Brief description of items/equipments to be procured (the detailed specifications of each Instrument/equipment is specified in Annexure V) :

Sr. No.	Instrument/Equipment Description	Quantity
1	Automated Flash Chromatography System	1
2	HPLC with PDA detector	1
3	UV-VIS Spectrophotometer	1
4	Fourier Transform Infrared Spectrophotometer	1
5	Rotary Tablet Machine (Bi-Layer; Multi tooling; GMP Model)	1
6	Bench-top Lyophilizer	1
7	Ultracentrifuge	1
8	Stability Chambers	2
9	Photostability chamber	1
10	CO ₂ Incubator	1
11	Flow-through Cell Dissolution Tester (USP Type IV Apparatus)	1
12	Analytical Balance	1
13	Rotary Evaporator	1
14	Particle size analyser	1
15	Microbalance	1
16	Water Purification System	1
17	Incubator with Shaker (Refrigerated)	1
18	-80°C Deep Freezer	1
19	Gel Electrophoresis and visualisation system	1

Annexure II

Format for technical bid of the Tender for AIC-LMCP Foundation (AIC-LMCP/Tender/2018-19/001):

Sr. No.	Description of requirement	Enclosed	Enclosure No.
1.	Whether the firm is registered with proprietary firm, Partnership firm, Limited Company, Corporate body legally constituted engaged in manufacturing/marketing of machines/equipment	Yes/No	
2.	Declaration by the bidder that he/she/company has not been blacklisted by the Deptts/Ministries of the Govt. of India/State Govt./PSUs	Yes/No	
3.	Copies of Balance Sheet and Income Tax Return for last 3 years duly Certified by CA-whether enclosed?	Yes/No	
4.	Copy of Registration Certificate/Allotment Letter of PAN/ TAN From Income Tax Dept.	Yes/No	
5.	Copy of Registration Certificate/Allotment Letter of Service Tax Document relating Service Tax Number	Yes/No	
6.	Partnership deed, if applicable	Yes/No	
7.	Details/List of other organizations where similar instruments/machines have been supplied	Yes/No	
8.	Demand draft / Cheque of Rs 1000/- as Bid processing (Tender) fee (Mention Dispatch details – Date and Mode) OR Through RTGS/NEFT (Mention Transaction details)	Yes/No	
9.	Demand draft / Cheque of Rs /- as EMD (Mention Dispatch details – Date and Mode) OR Through RTGS/NEFT (Mention Transaction details)	Yes/No	
10.	Technical specification of the Instrument/machine	Yes /No	
11.	Financial Bid proforma/quotation completed online	Yes/No	

Declaration of the Tenderer:-

This is to certify that I/we before signing this tender have read and fully understood all the terms and conditions contained herein and undertake myself/ourselves to abide by them.

(Signature of Tenderer with seal)

Name:

Place:

Date:

Seal:

Office Address:

Annexure III**List of Instrument/Equipment and their EMD**

Sr. No.	Instrument/Equipment Description	EMD (INR)
1	Automated Flash Chromatography System	45000
2	HPLC with PDA detector	55000
3	UV-VIS Spectrophotometer	10000
4	Fourier Transform Infrared Spectrophotometer	25000
5	Rotary Tablet Machine (Bi-Layer; Multi tooling; GMP Model)	25000
6	Bench-top Lyophilizer	20000
7	Ultracentrifuge	5000
8	Stability Chambers	10000 (per unit)
9	Photostability Chamber	10000
10	CO ₂ Incubator	9000
11	Flow-through Cell Dissolution Tester (USP Type IV Apparatus)	75000
12	Analytical Balance	5000 (per unit)
13	Rotary evaporator	5000
14	Particle size analyzer	100000
15	Microbalance	30000(per unit)
16	Water Purification System	12000
17	Incubator with Shaker (Refrigerated)	5000
18	-80°C Deep Freezer	8000
19	Gel Electrophoresis and visualization system	20000

Cheque/DD should be prepared in favour of **AIC-LMCP Foundation (PAN No. AAQCA0646K)**

OR

RTGS/NEFT (Bank details):

Company Name: **AIC-LMCP FOUNDATION**

Bank: **Kotak Mahindra Bank**; Branch: **Navrangpura, Ahmedabad**

Branch Address: **Kalpana Complex, Memnagar Fire Station, Navrangpura, Ahmedabad– 380013**

SBA/CNo.: **7512032628**

IFSCode: **KKBK0002588**

Annexure IV:

Price bid format (to be filled for each instrument/equipment separately)	
Vendor name/Address	
PAN No.	
Principal	
Instrument/Equipment name	
Model/Capacity	
Price per unit	Tender currency INR/USD/Yen/Euro/GBP
Accessories	Description
Price of Accessories	Tender currency INR/USD/Yen/Euro/GBP
Warranty	Yrs
Taxes	
Qualification (IQ/OQ/PQ) and training	(inclusive)
Packing/Forwarding/Air freight/Insurance charges	Tender currency INR/USD/Yen/Euro/GBP
Total Value (Including Qualification and Training)	Tender currency INR/USD/Yen/Euro/GBP
Delivery period	days
Mode of payment (Preferred and Alternate mode)	
Banker (Details)	

Annexure V

Technical specifications of Instrument/Equipment

Automated Flash Chromatography System

Controller	Laptop/Desktop/Touch screen (Branded PC or All in ONE Touch Pad with latest windows based operating system, minimum 2 GB RAM, hard disk 300 GB (minimum) or Built-in Touch Pad, with storage capacity of a minimum of 200GB)
Pumping System	Flow rate range: 0 to 300 mL/min; Maximum pressure: 300 psi Isocratic and low pressure gradient (up to 4 solvents, binary/quaternary) modes Programmable Gradients: Linear and step
Sample Loading	Liquid and Solid (standard) Sample loading range: 1 mg to 20 gm Empty Sample Loader for Liquid and Solids - 10 numbers
Fraction collector	Manual and Automatic with standard rack size
TLC image reader	254nm lamp, Streamlined from TLC scan to optimized column separation and purification (creation of Automatic Gradient method)
Detection	Variable UV-Visible (200-400 nm or more), Facility to connect additional external detector (Mass, ELSD or RI detector) Flow cell with adjustable pathway
Software	Simple and easy change of method parameters on the fly. Automatic method set-up based on inputting TLC Rf value for the single target compound and/or multiple targets. Scale up/method transfer from one column to another. Real time monitoring and method editing, Active Solvent and Waste Level Monitoring. Compliance to regulatory requirements (including 21 CFR Part 11)
Flexibility	Flexibility to use any make Flash columns available in the market and necessary adapters or holders should be provided by default, integrated column holder with fume enclosure Flexibility to use self-packing Glass columns and Pre-packed refillable Flash columns having different dimensions, Scale-up/method transfer from one column to another
Safety features	Audible Alarm, Solvent and waste level monitor, leak sensor, Column air purge, Internal vapor sensor, Rack Sensors to automatic stop the flow /System
Floor space	As minimum as possible
Columns to be supplied with system	Puriflash_C18-HP_50uM_F0012_Flash column or equivalent (minimum 2 no.), Puriflash_C18-HP_50uM_F0025_Flash column or equivalent (minimum 1 no.), Puriflash_C18-HP_50uM_F0040_Flash column or equivalent (minimum 1 no.), Puriflash_Silica-HP_50uM_F0012_Flash column or equivalent (minimum 5 no.), Puriflash_Silica-HP_50uM_F0025_Flash column or equivalent (minimum 5 no.), Puriflash_Silica-HP_50uM_F0040_Flash column or equivalent (minimum 5 no.)
Qualification	IQ, OQ and PQ with documentation; protocols shall be provided with equipment.
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

HPLC with PDA detector

General specifications	All-in-one system with all units integrated into a single system (solvent delivery pump, autosampler, detector, column oven and any other required units for operation of system) Usable solvent types: both organic and aqueous solutions Operable pH range: 1 to 13 Automated functions like time-controlled instrument auto-startup, auto-purge and automatic validation should be available as Standard features
Pump system	Quaternary low pressure gradient pump with integrated 5-channel degassing unit (Mobile Phase 4 + Rinse Solution 1), column, connecting capillaries, solvent cabinet, solvent bottles and CAN cable Flow Rate Setting Range: 0.0001 to 10 mL/min Flow Rate Precision: <0.06% RSD Maximum Pressure: 44 MPa (0.0001 to 5 mL/min), 22 MPa (5.0001 to 10 mL/min) Flow rate accuracy: $\pm 0.1\%$
Autosampler with cooler	Injection Method: Total Volume Sample Injection Injection Volume Setting Range: 0.1 to 100 μl Injection Volume Accuracy: less than $\pm 1\%$ Sample Vials Capacity: minimum 120 (1.5ml vial) or well-plates Injection Linearity: >0.9999 Sample Cooler: 4-45°C, individual tray cooling Auto pre-treatment function on injector should be available, which should have features like: <ul style="list-style-type: none"> • Ability to do Dilution • Should be able to spike set volume of internal standard or reaction reagent. • Co-injection – Analysis with co-injection function should be available.
Column Oven	Heating & Cooling: Forced Air Circulation Method Column compartment for multiple columns of different size Temperature Control Range: 5 to 80°C Temperature Accuracy: Not more than $\pm 0.8^\circ\text{C}$ Temperature Stability: Not more than $\pm 0.2^\circ\text{C}$ Temperature Precision: Not more than $\pm 0.2^\circ\text{C}$
PDA detector	Programmable with following specifications Wavelength Range: 190-800 nm Spectral Resolution: 1.4 nm No. of Photodiodes: 1024 Wavelength Accuracy: $<\pm 1$ nm Slit Width: minimum 1.2 nm (high resolution mode), 8nm (high sensitivity mode) Device Resolution: <1 nm/pixel Light Source: Deuterium lamp, tungsten lamp, temperature control for both lamps Linearity: <5% RSD and corr. coeff. ≥ 0.999 up to 2.0 AU Noise Level: $<\pm 3 \times 10^{-6}$ AU Flow Cell: 10 μl (10mm, TC), 12 Mpa
Software	21 CFR part 11 compliant System suitability, System security as well as System check functions must be provided

	which comply with Good Laboratory Practice (GLP) and Current Regulatory requirements
Qualification	IQ, OQ and PQ with documentation; protocols shall be provided with equipment.
Other features	e.g. Peak Deconvolution Algorithm for separating co-eluting impurities; Dynamic Range Extension Calculation
HPLC Columns	Analytical C18 Column (250 x 4.6, 5 micron) – 1 nos. Analytical C8 Column (250 x 4.6, 5 micron) – 1 nos.
Other Items to be supplied	Tools and accessory kit, 1 L Mobile Phase Bottle (5 pcs), 1.5 ml Vials and Septa (100/pkt) Suitable branded computer, printer and UPS of 3 KVA with minimum 1 hr battery back-up should be supplied along with the Instrument. Installation and Qualification hardware and software, OQ/PQ substances (caffeine, pyrene)
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

UV-VIS Spectrophotometer

Instrument Bundle	Instrument, suitable desktop PC, operating software and cell holder Instrument user guide, software user guide Other accessories required for operation of instrument 10mm Quartz UV cells, Matched Pair (With transmission certificate), Microfibre Cleaning Cloth
Instrument Specifications	System: Double beam optics Wavelength range: 190 to 1100 nm Spectral bandwidth: 1 nm on entire spectral range Wavelength setting and display: 0.1 nm increments Wavelength accuracy: ± 0.1 nm at D2 spectral line Wavelength reproducibility: ± 0.1 nm Lamp Interchange: Automatically linked to wavelength Photometric accuracy: ± 0.002 Abs at 0.5 Abs or better Photometric range: more than 3.5 (absorbance) Light source: Tungsten-halogen and Deuterium lamp or equivalent Monochromator: Holographic diffraction grating Detector: Silicon photodiode
Software	Spectrum, Data processing, Multitasking Photometric, Kinetics and time-course, Report Generation and Inspection mode
Other requirements	Data storage and transfer through USB pen drive Compliance with all Pharmacopoeial and regulatory requirements IQ, OQ and PQ protocols and execution
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Fourier Transform Infrared Spectrophotometer

Interferometer	Michelson's interferometer with completely sealed and desiccated optics
Modules	Transmission and ATR modules with all accessories for measurement of solid, liquid and semisolid samples
Light source	High energy ceramic or equivalent
Beam splitter	Germanium-coated KBr or Equivalent
Detector	DTGS detector with temperature control
Spectral range	7800-350 cm^{-1}
Wavenumber precision	0.001 cm^{-1} at 2000 cm^{-1} or better
Wavenumber accuracy	0.1 cm^{-1} at 2000 cm^{-1} or better
Resolution	0.9 cm^{-1} or better
S/N ratio	30,000:1 or better
Data sampling	Semiconductor laser with temperature control
Software	Integrated software for the acquisition, processing, evaluation and reporting of IR-spectroscopic data in laboratory and process environments. Complete collection of spectral processing and analysis tools (including but not limited to Peak analysis tools, Data processing tools, Data conversion and corrections, Correlation for verification of samples against one or many reference spectra, Spectral Search, Infrared spectral interpretation with online interpretation guide, Spectral peak picking and annotation, Non-editable audit trail, history log, Spectral group statistical analysis, Automatic atmospheric suppression to remove H ₂ O and CO ₂ interferences (no standards needed), Full-featured report generator, Extensive on-line help and tutorials, Quant prediction such as PLS, PCR, Beer's Law, CLS, peak ratio, and Discriminant Analysis) Upgradation available at no extra cost for a period of at least 5 years
Qualification	Auto and manual calibration (IQ, OQ and PQ with documentation and protocols) All requirements to be supplied for manual qualification along with protocols and documentation
Others	Standard accessories kit, User and installation guides, any other accessories required for smooth operation of instrument
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Microbalance

Maximum capacity	22 g	52 g
Readability	0.001 mg	0.001 mg
Repeatability (Test Weight)	0.0015 mg (1 g)	0.0015 mg (2 g)
Linearity	0.006 mg	0.02 mg
USP minimum sample weight (5% load, k=2, U=0.10%)	1.4 mg	1.4 mg
Connectivity	Built in RS232 and optional second interface (Bluetooth or Ethernet)	
Other specifications	Automatic internal adjustment and testing With Touch screen display and suitable printer, FACT, GWP and Admin history	
Compliance	ISO, FDA/USP, GMP, GLP, UL Listed, CE compliant, Compliance with current regulatory requirements	
Qualification	IQ, OQ and PQ documentation and protocols shall be provided with equipment	
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost	

Analytical balance

Maximum capacity	220 g	520 g
Readability	0.01 mg	0.1 mg
Repeatability (Test Weight)	0.015 mg (10 g)	0.08 mg (20 g)
Linearity	0.1 mg	0.4 mg
USP minimum sample weight (5% load, k=2, U=0.10%)	14 mg	82 mg
Connectivity	Built in RS232 and optional second interface (Bluetooth or Ethernet)	
Other specifications	Automatic internal adjustment and testing; With suitable printer FACT, GWP and Admin history	
Compliance	ISO, FDA/USP, GMP, GLP, UL Listed, CE compliant, Compliance with current regulatory requirements	
Qualification	IQ, OQ and PQ documentation and protocols shall be provided with equipment.	
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost	

Stability Chamber

Construction	Double-walled with insulation provided with outer stainless steel metal door and inner glass viewing door
Material	Inner Chamber: SS 304 Grade/ Mirror finish Outer Chamber: Mild Steel Powder Coated/ SS 304 Grade
Temperature range	20 to 60°C or broader
Temperature Accuracy	±0.2°C or better
Temperature Uniformity	±1°C or better
Temperature Resolution	±0.1°C
Humidity range	40% to 95% RH or 20% to 95% RH (optional lower RH should be available)
Humidity Accuracy	±2% RH or better
Humidity Uniformity	±3% RH or better
Humidity Resolution	1% or better
No of shelves	3
General	Interior illumination for working area, U shaped S.S. Nichrome wire air heaters, Humidity system with evaporation tray and reservoir tank with water level arrangement, Compressor with CFC-Free (Eco-friendly) refrigerant Digital/touch screen display Castor wheels, MCB, Adjustable Tray Height Arrangement. Heavy duty latches with lock and key and imported hinges
Connectivity	Printer Interface, PC Interface, Connectivity through Ethernet
Controller and software	Microprocessor based programmable PID Controller with Auto-tune 21 CFR Part 11 compliant controller with built-in features including data logging, Ethernet control and monitoring, alarm notification via email and/or phone text message, data file backup system, full system security, audit trail, electronic signatures, power recovery options and more
Calibration and Validation	Temperature sensor probe calibration with traceability, Temperature controller calibration with traceability, Temperature mapping IQ, OQ and PQ documentation and protocols shall be provided with equipment.
Safety Features	High temperature safety cut-off Low water level boiler cut-off Electrical overload cut-off relay for compressor Time delay for compressor switch ON
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Photostability chamber

General	Double walled modular structure with insulation Inside Stainless Steel and Outside Mild Steel Powder Coated OR Stainless Steel Inside full length observation glass door with secure gasket Racks and trays – Stainless Steel with adjustable height U shaped S.S. Nichrome wire air heaters Compressor with CFC-Free (Eco-friendly) refrigerant PLC control system with touch screen display with Ethernet
Light Exposure	Exposure of cool white florescent light for 1.2 mil lux hours and UV-A light for 200 watt hours per square meter on the test samples Cool white, near-ultraviolet, full spectrum, and dual source cool white/UV banks designed to meet Options 1 and 2 of current ICH/FDA guidelines Combined light exposure or individual light exposure with automatic light cut-off system after exposure is achieved
Software and Controller	Microprocessor based programmable PID Controller with Auto-tune 21 CFR Part 11 compliant controller with built-in features including data logging, Ethernet control and monitoring, alarm notification via email and/or phone text message, data file backup system, full system security, audit trail, electronic signatures, power recovery options and more Log data, Event data, Audit Trail data, E-Records and E-signatures, Graphical analysis and Data acquisition.
Temperature Range	20°C to 60°C or broader
Temperature Accuracy	± 0.2°C or better
Temp Uniformity	± 2°C or better
Humidity Range	40-70% RH
Humidity Control	± 3%
Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment
Safety Features	High temperature safety cut-off Low water level boiler cut-off Electrical overload cut-off relay for compressor Time delay for compressor switch ON Automatic door open cut-off of UV light as a safety measure
Compliance	Current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Rotary Tablet Machine (Bi-layer; Multi Tooling; GMP model)

General	<ul style="list-style-type: none"> • cGMP Table Top Model • 10 station multi tooling (D and BB, 5+5) • Easy product changeover operation • Acrylic material guard with operational interlock • Anti-vibration mounting pad • Stainless Steel Turret Guards • Easy accessibility for setting, maintenance and cleaning • Servo Variable Frequency Drive (VFD) for main motor to change the speed of machine • Digital Tablet Counter/ Turret RPM Meter • Main Compression measurement using Load cell and instrumentation amplifier • Pre Compression measurement using Load cell and instrumentation amplifier • Level sensor to get alarm for low powder level in Hopper • Force Feeding System • 3 piece Turret with SS Die Plate and ELNP • Main compression: 8 to 10 tons • Ejection Force measurement using Load cell and instrumentation amplifier • Industrial Panel Computer with inbuilt touch screen or standard computer • SS 316 contact parts • Adaptability to both gravity feeder and force feeder • ELNP – Turret and Cam Tracks to give protection against wear and tear • SS trolley 															
Software and control	<ul style="list-style-type: none"> • Fully computerized control • Compression Force Monitoring System • Variable Dwell time setup and control • Compliant to current regulatory requirements, 21CFR Part 11 															
Qualification	<ul style="list-style-type: none"> • DQ, IQ, OQ, PQ with documents; protocols and test certificates provided 															
Dies and Punches	<ul style="list-style-type: none"> • Die/Punch details: <table border="0" style="margin-left: 20px;"> <thead> <tr> <th style="text-align: left;">- Size (mm)</th> <th style="text-align: left;">Nos</th> <th style="text-align: left;">Type</th> </tr> </thead> <tbody> <tr> <td>- 4</td> <td>5</td> <td>Flat beveled</td> </tr> <tr> <td>- 6</td> <td>5</td> <td>Deep concave</td> </tr> <tr> <td>- 12</td> <td>5</td> <td>Flat beveled</td> </tr> <tr> <td>- 23</td> <td>5</td> <td>Capsule shape</td> </tr> </tbody> </table> 	- Size (mm)	Nos	Type	- 4	5	Flat beveled	- 6	5	Deep concave	- 12	5	Flat beveled	- 23	5	Capsule shape
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- 4	5	Flat beveled														
- 6	5	Deep concave														
- 12	5	Flat beveled														
- 23	5	Capsule shape														
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost															

Ultracentrifuge

Max RPM	> 80,000, Speed Range 1,000 rpm to max. speed in 100 rpm increments, Speed Control Accuracy ± 10 rpm or better
Min RCF	1,00,000 x g
Rotors	1.5-2 mL, 5 mL and 12.5-15 mL (separate rotors)
Temperature Range	+2 to +40 °C, Temperature Accuracy ± 0.5 °C or better
Control panel	Touch sensitive LCD panel
Data Communication	USB: Host x 1, Device x 1 / LAN x 1
Certifications/Compliance	GMP/GLP Data Compliance and Management: traceability and quality control for biopharmaceutical processing needs
Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment.
Compliance	With current regulatory requirements
Others	Programmability with step-runs Timer with HOLD function
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Flow-Through Cell Dissolution Tester (USP Type IV Apparatus)

Display	Touch screen display
Bath temperature	30 to 40°C
Bath temperature accuracy	0.1°C
Piston pump stroke rate	120 strokes/min
Piston pump stroke rate accuracy	1 stroke
Programmable flow rate for individual channel	1.5 ml/min to 32 ml/min
Accuracy of flow rate	5%
Number of cells	7 cells in a row
Water bath	6-liter volume, level indicator, emptying via 3-way-valve
Others	Set (7 pcs) of 22.6 mm tablet cells, Set (7 pcs) of gel and cream cell adapter, Glass beads 1 mm and 5 mm; 150 g; Set of USP 4 tablet holders (7 pcs) Type A; cell 22.6 mm
Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years' annual maintenance (service support) at no cost

Rotary Evaporator

Heating unit	Insulated heating bath (4.5 L) with digital display Temperature accuracy: $\pm 1^{\circ}\text{C}$ or better Overheat cut-off protection Bath temperature setting: LCD Display Heating bath temperature control: Digital No Variable temperature limiter
Motor	Drive: DC Motor with electronic speed control Rotation speed (rpm) : 10 – 280 Rotation speed setting: LCD Display Hand / Motor lift Height adjustment speed: Manual
Vacuum Pump	Valve Regulated Diaphragm Vacuum Pump, Two-stage diaphragm pump made from chemically resistant materials, High suction capacity for fastest evacuation, Achieve an ultimate vacuum of $> \text{ or } = 7 \text{ mbar}$
Capacity	50 ml to 5000 ml evaporation flasks. 1 Liter Receiving Flask.
Others	Adjustable angle Vertical glass condenser
Chiller	Temp. Control: $\pm 0.2^{\circ}\text{C}$. Cooling capacity at 0°C : 140 W, 20°C : 200 W Coolant volume: 6 Liters Supply voltage: 230 V/50 Hz
Compliance	With current regulatory requirements
Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment.
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Particle size analyzer

Measuring principle	Mie Scattering Theory according ISO 13320
Measuring range	0.01 μm - 3000 μm Number of size classes 100 (user adjustable) Accuracy Better than 1% Repeatability Better than 0.5% variation Reproducibility Better than 1% variation
Type of analysis	Dry and wet analysis (Capable of measuring particle size distribution in Suspensions, emulsions, dry powders)
Measurement time	<10 seconds
Optical system	Inverse fourier-optics Light Source: He-Ne laser/diode laser with suitable power and wavelength or better
Software and connectivity	Operating mode that assists with ER/ES compliance, Integrated 21 CFR Part 11 compliant software available with user administration, audit trail, and electronic signature functionality Computer interface: at least 1 high speed USB port required; computer with suitable configuration
Qualification	IQ, OQ and PQ documentation and protocols shall be provided with equipment; calibration standards
Other	Samplers or any other accessories required for dry and wet sample analysis
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Water Purification System

System	RO permeate and final product water quality should be monitored by separate resistivity cell with low cell constant Should have inbuilt storage reservoir of 5 to 10 L with vent filter for storing pure water System should have a remote dispenser (with display) attached with 0.22 micron filter to deliver water 2 m away from main system Online conductivity and TOC measurement
Product flow rate	≥ 1 L/min (Ultrapure water), ≥ 5 L/min (pure water)
Resistivity of product water	15-20 MΩ·cm @ 25° C
TOC	< 1 Particulate/ml
Bacteria levels	< 0.1 cfu/ml
Endotoxin	< 0.005 EU/ml
DNase	< 5 pg/μL
RNase	< 0.05 ng/ml
Display	Bright, colour graphic display showing system parameters, operational functions and product water quality
Particulates (size >0.22 μm)	< 1 Particulate/ml
Other	Suitable pretreatment pack for feed water with required accessories Any other accessories required for smooth functioning of system Standard accessories / consumables
Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

CO₂ Incubator

Volume	150-200 L
Temperature Control	Control Range: 5°C above ambient (to a 30°C max ambient) to 55°C Uniformity: ± 0.35°C @ 37°C Accuracy: ± 0.1°C or better Recovery: 0.12°C/min on Average Display Resolution: 0.1°C
Relative Humidity	>90% @ 37°C
CO₂ Control	Range: 1 to 20%, 5% Default Set Point Accuracy: ± 0.1% or better CO ₂ Display Resolution: 0.1% CO ₂ Sensor Type: Infrared (NDIR)/TC sensor
RH control	Control range: Ambient to 90 % Accuracy: ± 3% Recovery: 90% + 5%/-3% within 25 minutes on average Display resolution: 0.1 %
Material	Inner Side SS, 3 SS shelves each capacity 10 to 30 Kg, Outer: at least 18 Gauge Powder coated steel
Voltage	230 V
Data Outputs	USB / RS232
Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment
Other	Any other accessories required for smooth functioning of system
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Incubator with Shaker (Refrigerated)

Internal body	Stainless Steel 304 grade
External body	Powder coated CRCA Steel
Capacity	Upto 18 Ltrs
Speed range	15-500 rpm (unstacked) or 15-300 rpm (stacked)
Temp. Range	5°C to 60°C or broader, Accuracy: $\pm 0.1^\circ\text{C}$
Controller	Microprocessor controller with LCD Display
Max. Shaking Capacity (Volume x No. of Flasks)	100 ml x 49 Nos., 150 ml x 49 Nos., 250 ml x 33 Nos., 500 ml x 24 Nos., 1000 ml x 15 Nos. and 2000 ml x 9 Nos. (with corresponding flask holding clamps) Microplate clamp
Others	With Voltage Stabilizer
Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment
Other	Any other accessories required for smooth functioning of system
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

-80°C Deep Freezer

General	<p>Structure: upright type, rust- and corrosion-proof outside and stainless steel inside</p> <p>Door: Hinged, fully insulated, externally made of the same material of the structure. Internally consisting of non-conductive material. Appropriate lock system</p> <p>Internal equipment: Compartments with hinged inner-doors. 3 standard supplied storage plates (SS 304) and they can be adjusted in height. Internal half doors, made of insulating material stainless steel, equipped with an independent blocking system.</p>
Temperature Range	-50 to -86 °C
Ambient Temperature Range	15 to 32°C (59 to 90 °F)
Capacity	400-500 L
Control panel	<p>Microprocessor type allowing to control freezer functions consisting of a display showing the actual temperature with an accuracy of $\pm 0.5^{\circ}\text{C}$</p> <p>Alarm led for high/low temperature deviations, low battery, cooling status, working of the back-up system</p> <p>Touchpad managing the complete system (on-off power, set-point setting, checking of the battery status, acoustic alarm muting, password protection)</p>
Alarm system	Audible and visual alarm system for temperature deviation (both minimum and maximum values), power failure, high condenser temperature, low battery tension, open door (standard delay = 30 seconds), power peaks, faulty probes
Refrigerant	CFC-free
Others	CO ₂ back-up system, Connectivity through USB and Ethernet, Voltage stabilizer
Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Gel Electrophoresis and visualization system

System	<p>Vertical Electrophoresis system</p> <ul style="list-style-type: none"> ✓ Number of gels: 1–4 ✓ Gel size (W x L): Handcast (8.3 x 7.3 cm), Precast (8.6 x 6.8 cm) ✓ Total buffer volume: ~700 ml (for 2 gels), ~1,000 ml (for 4 gels) ✓ System must include 15- and 20-well combs, gel caster, 15 x 10 cm (W x L) UV-transparent tray <p>Horizontal electrophoresis system</p> <ul style="list-style-type: none"> ✓ Gel sizes (W x L): 15 x 7 cm, 15 x 10 cm ✓ Sample throughput: 10-60 ✓ Base buffer volume (L): ~0.65 ✓ Gel thickness: 0.75 mm ✓ System must include (minimum) casting stand, 2 casting frames, 10-well combs, 5 short plates, and 5 spacer plates, with Starter Kit <p>Both systems must be able to run with precast gels and handcast gels.</p>
Basic Power Supply	<p>Output: Constant voltage or constant current with automatic crossover and programmable output range (10–300 V, fully adjustable in 1 V steps; 4–400 mA, fully adjustable in 1 mA steps, maximum 75 W)</p> <p>Timer: 1–999 min, fully adjustable with pause/resume function</p> <p>Display: LED</p> <p>Operating conditions: 0–40°C; 0–95% humidity (noncondensing)</p> <p>Safety features: must detect no-load, sudden load change, overload or short-circuit, must have overvoltage protection, Input protection (Fuse on both hot and neutral)</p> <p>Must be operable with both horizontal and vertical systems</p>
Software	<p>Compliance with 21 CFR part 11</p> <p>Gel imaging system, includes darkroom, UV transilluminator, epi-white illumination, trans-white illumination, camera, cables, software compatible with Windows</p> <p>Imaging system with software should include</p> <ul style="list-style-type: none"> • Automated workflow from image to results • Automated camera controls • Automated image focus, capture, optimization and analysis • simple and reproducible image capture • Quick and accurate gel and blot imaging and analysis • System optimization at setup • Comprehensive, automated, quantitative analysis of protein and DNA samples in seconds • Reports with customized and organized data • Quick publication-quality results • Focused images at all times, regardless of zoom level or sample position • Appropriate, automatic, and consistent correction of image • Automatic correction of imaging artifacts
Others	All accessories needed to make the equipment functional, must be supplied.

Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment
Compliance	With current regulatory requirements
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost

Bench-top Lyophilizer

Condenser capacity	3 litres
Condenser Temperature	-75 to -85°C
Water Holding Capacity	Minimum 2 Litres/24 hr
Temperature measurement range	-105 to +60°C
Compressor	Dual compressor cascaded design, Compressor horsepower 1/3 & 3/8
General	<p>PLC-based controller, including pressure control, alarms, data trending, start-up check-list</p> <p>Suitable touch screen display showing essential running conditions of the instrument</p> <p>Choice of manifolds, chambers, drying racks</p> <p>Manifold for at least flasks, round bottom flasks, wide-neck filter, bottles, test tubes or distributors for ampoules</p> <p>All accessories needed to make the equipment functional, must be supplied</p> <p>Suitable Vacuum pump (approximately minimum 100 lpm, 2 stage direct drive, resistant to organic solvents, suitable for all types of solvents, low noise), UPS, Wide Mouth Filter Seal Flask Assembly (40, 150, 300, 600 mL) including O-Ring, Filter Paper, Wide mouth Flask Cover, Flask Bottom, Filter Disk along with adapters, Ampoule Adapter to be provided with the Instrument</p>
Cooling Media	CFC- and HCFC-free Refrigerant
Compliance	With current regulatory requirements
Qualification	IQ, OQ and PQ with documentation and protocols shall be provided with equipment
Warranty and AMC	Minimum 2 years from date of installation and additional 3 years annual maintenance (service support) at no cost