

Tender Specification

1. Autoclave SLEFA Single Lever Fully automatic top loading

Autoclave SLEFA-Single Lever Fully Automatic-Top Loading Capacity- 135/113L

❖ Installation and Documents and certification:

- Installation should be done by the supplier's certified person.
- To be supplied certificate of compliance for each modules
- To be supplied IQ/OQ Documents.

❖ Training:

- To be provided by the supplier's certified person at our site.

❖ Available size/Area for the subject equipment :

- Sufficient area for the instrument is available in the quality control area.

❖ Discussing/Review/Comments:

* The user requirement specification is prepared for communicating the user expectation from the subject equipment manufacturer/supplier with respect to the subject equipment. The requirements specified are the basic requirements based on the available information for the process, operation and GMP requirements. The vendor is encouraged to quote for the latest product with quality, process control, safety etc.

TENDER SPECIFICATION

2. Automatic Potentiometric Titrator

01. **Purpose :** To analyze product purity, %/ppm content of various ingredients in samples like Pharma finished products, API, Bulk Drug etc. by using Automatic Potentiometric Titrator as per monograph.

02. Specific Requirement:

- 1 It should be advanced microprocessor based standalone system with easy interchangeable imported burette assembly with Auto Burette Recognition via advance sensor technology. & imported Teflon coated valve.
- 2 Alphanumeric entries of Sample Name, Titrant Name, Identification No. & Date for report printout to comply GLP norms.
- 3 It should have minimum 50 Method storage capacity with two tier Password Protection & 10 ready methods for routine titrations.
- 4 System should have an optional provision to perform KF titration by simply changing Burette assembly with auto recognition.
- 5 It should have provision to connect electrode with BNC connector & also should have connectivity for Differential Electrode i.e. Indicator & reference electrodes separately
- 6 It should have Serial port for balance and PC and parallel port for printer.
- 7 System should give following report formats;
 - a. Complete Parameters with Result reading.
 - b. Data table.
 - c. Graphs – 1. mV / μ l 2. 1st derivative graph
3. 2nd Derivative graph 4. μ L/ Time.
 - d. Program Parameters for 50 programs (includes 10 default programs for routine titrations)
 - e. Condensed result print out includes time, Sample ID.
 - f. Statistical Data for 10 repeat runs with S.D, R.S.D & C.V.
 - g. Auto Evaluation for multi EP samples.
8. System should have compatibility for Imported as well as Indian electrodes.

The Auto-Titrator should have following Technical Specifications;

1. mV Range should be minimum **$\pm 3200\text{mV}$ with accuracy of $\pm 0.1\text{mV}$ [$\pm 0.0016\text{pH}$]**
2. Burette resolution should be minimum 1/10000 for 10ml burette.
3. End point detection up to 9.
4. System should be able to perform Acid-Base, Non-Aqueous, Redox, Complexometric, Precipitation Titrations by using respective electrodes.

03. Installation and Documents and certification:

* Installation should be done by the supplier's certified person.

* To be supplied certificate of compliance for each modules

* To be supplied IQ/OQ Documents.

04. **Training:**

* To be provided by the supplier's certified person at our site.

05. **Available size/Area for the subject equipment :**

* Sufficient area for the instrument is available in the quality control area.

06. **Discussing/Review/Comments:**

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3. Bacteriological Incubator 600 x 605 x 910 mm

1. Temperature is controlled by Microprocessor based Temperature controller cum indicator
2. Confirmatity To Standards: US FDA Approved
3. Storage Capacity: 300-350 Ltrs
4. Double Walled: Yes
5. Material Of Outer Chamber: M.S sheet with Epoxy Coated
6. Material Of Inner Chamber: Stainless Steel (SS304)
7. Insulation Material To Avoid Heat Loss: embedded in rids on three sides
8. Insulation Material Thickness: 75 mm
9. Temperature (Minimum): 5 °C
10. Temperature (Maximum): 70 °C
11. An air circulating fan
12. Door has double glass fitted for observation of specimen
13. Suitable to work on 220 / 230 Volts A.C. 50Hz..

4. BALANCE (0.0001 , 250 GM)

Backlight LCD Display

Customized, large, attractive LCD with multiparameter display illuminated by white backlite.

- **Bi directional RS 232 interface**

RS 232 port with selectable baud rate 4800, 9600. Various interface formats adopting this Balance in a setup to replace any other leading international brand Balance. Can be configured for an USB interface using optional RS 232 to USB converter.

- **GSM function**

GSM function for paper & cloth quality checking.

- **Multiple Weighing Units**

Grams, Ounces, Troy Ounces, Carats, Mommies, Pennyweights, Grains, tola, Mesghal, Chinese taels.

- **Percentage Weighing**

Display of Reference weight, sample weight, % of sample with respect to reference weight

- **Piece Counting**

Parts calibration using preset quantity of samples or programmable quantity.

Automatic count correction for precise calibration.

- **Fill Mode**

1 set point - Indication when sample weight exceeds the set limit.

2 set points – Indication when the sample weight is between the lower & upper limits..

Accumulation

Storage of maximum 200 samples.

- **Multiple Printing Mode**

0,1,2,3 modes for various formats. Pause in case data storage capacity in a Printer is less.

- **External Calibration**

Using preset weights.

Known weights can be corrected to ± 15 counts.

- **Response Time:**

User selectable – Slow / Normal /Fast.

- **Stability Band Width**

Stability indicator appears on display with counts variation $\pm 1, \pm 2, \pm 3, \pm 4$.

- **Auto Zero Tracking**

User selectable 0,1,2,3

- **Return to Zero Tracking**

Variables: 0, 1,2,3,4

- **Display Updation**

Speed setting: Fast / Normal.

5. Binocular Microscope (student)

Binocular Microscope (student) – IMPORTED

Microscope for Bright field, & upgradable for fluorescence

Microscope with AG treat – Touch points treated to inhibit the growth of bacteria for healthier laboratory environment.

Objective nosepiece to hold min 4 objective.

Observation tube - 45° viewing angle, IPD adjustment 50mm - 75 mm

Eye-piece 10x with eye guard

Objectives - tamper proof multipurpose for BF and fluorescence

Obj. PLAN 4x/0.10

Obj. PLAN 10x/0.25

Obj. PLAN 40x/0.65

Obj. PLAN 100x/1.25

Mechanical stage - Mechanical stage with double plate flat top with stainless steel slide holder

Condenser – condenser 0.90/1.25 oil with slot to accommodate phase and dark field slider.

Illumination – LED Illumination provides cool white light with a life time of over 20years of average use. 6000K temp.

Focusing – both side with coarse and fine focusing tension free with self adjusting focus mechanism. Focus 300 microns per fine focus rotation, calibrated in 3 micron increment.

.European CE certified [with four digit notified body no.]/US FDA

certified/BIS/Declaration of conformity under clause 98/79/EC (To comply the requirements of In vitro diagnostics medical devices Directive) with ISO 13485 with notified body no

Main components should pass the ISO standard DIN ISO 9022-11:1994

Future Upgradation : Possibility to upgrade with Digital Imaging and reflected light illumination LED fluorescence.

6. Biological Safety Cabinet

1. Class II, Type A2 – 70% Re-circulating 30% Exhaust.
2. Size: 4 feet,
3. NSF Certified
4. All Stainless Steel 16Gauge, Type 304 pressure tight design
5. HEPA Filter Seal Type: 99.99 % efficiency on 0.3 microns.
6. Sound level: ≤ 67 dBA
7. Zero Leak Airflow System,
8. Control System
9. 10° Sloped Front Window w/hinged frame for easy cleaning.
10. Metal Framed Large HEPA Filters 99.99% efficiency rated
11. External Fluorescent Lighting,
12. Front Filter Removal,
13. Sliding Tempered Glass View screen,
14. Removable Work Tray,
15. Metal diffuser over supply filter,
16. Removable Control Centre,
17. Armrest
18. One Service Valve (Right Sidewall)
19. Two Duplex outlet Back wall
20. ≤ 10 " (254mm) Access opening,
21. Window alarm,
22. Power Source: 220-230V- 50-60Hz.
23. Ultra violet light, 230V
24. Base stand ≤ 28 "

7. Blue Light Transilluminator

- 1) Instrument minimum dimensions: 195 × 325 × 65 mm (11.6 × 12.8 × 2.6 in)
- 2) Minimum viewing surface dimensions: 190 × 190 mm (7.5 × 7.5 in)
- 3) Complies with the European Community Safety requirements
- 4) The device contains Class 1 LED products
- 5) Light source: light emitting diodes (LED) producing a narrow emission peak centered at ~470 nm
- 6) Minimum LED life: 30,000 hours
- 7) Accessories: amber filter unit, viewing glasses (2 pairs), and Indian power cord

8 Conductivity Meter

01. **Purpose :** To measure conductivity of any aqueous solution of various liquid samples as per USP/EP/IP/BP monographs.

02. **Specific Requirement:**

The conductivity meter should have following features & specifications;

Conductivity Meter should have following specifications;

1. **Measuring Range : 0.01 μ S to 199.9 ms**

2. **Resolution : 0.01**

3. **Accuracy: 0.5 %**

4. **Temperature Range: 0 to 150.0°C.**

Temperature compensation : Automatic/ Manual

It should have following features;

1. Automatic range selection for faster measurement from 0.01 μ S to 199.9 ms with conductivity cells having constants 0.1 and 1.0 and 10 K.
2. User selectable temperature co-efficient for automatic temperature compensation through special TEMPCO key.
3. It should be advance micro controller based user friendly system with reading storage of 40 or more conductivity readings
4. Password protection for calibration data and stored readings.
5. Alpha- numeric entries of Sample name, Identification Number for sample reading printout authentication.
6. Instrument should have printer & PC connectivity.
7. System should have date & time locking facility by password.
8. System should have at-least two level password provision.

03. **Installation and Documents and certification:**

* Installation should be done by the certified personnel from supplier's end.

* To be supplied validation certificate for the instrument.

* To be supplied IQ/OQ Documents.

04. **Training:**

* To be provided by the supplier for at least one/two working days by their certified personnel at our site.

05. **Available size/Area for the subject equipment :**

* Sufficient area for the instrument is available in the quality control area.

06. **Discussing/Review/Comments:**

* The user requirement specification is prepared for communicating the user expectation from the subject equipment manufacturer/supplier with respect to the subject equipment. The requirements specified are the basic requirements based on the available information for the process, operation and GMP requirements. The vendor is encouraged to quote for the latest product with quality, process control, safety etc. Final techno-commercial offers/quotation and /or any kind of queries should be directed to the following authorised person;

9. Centrifuge Table Top

Base unit:

1. Table-top high speed centrifuge with option of fixed angle as well as swing out rotors
2. Should give minimum Speed of 14,000 rpm or above with fixed angle rotor
3. Should give minimum 16,000xg rcf or above with fixed angle rotor
4. Speed setting should be possible in both rpm and rcf.
5. System should have store programs with quick access programs key.
6. Should meet international safety certification standards of operation.
7. LCD digital display for RPM/RCF, timer and temperature setting and actual run conditions should be displayed
8. Should be programmable with easy preset programs for short spin.
9. Soft-touch lid closure
10. Quickly opening and closing the rotor lid
11. Warranty: 3 years
12. If a voltage stabilizer/UPS is required, it should be supplied along with the unit
13. Power requirement: 220 v to 240 v – 50 Hz power

Rotors

1. Certified aerosol-tight rotor
2. Rotor for 18-24 nose 1.5/2.0 mL tubes
3. Adaptors for PCR tubes (0.2 ml)

10.

DEEP Freezer (-20) capacity- 250liter

Deep freezer is double walled cooled units. Outer body are constructed out of thick PCRC, pre coated corrosion resistant GI sheet duly pre-treated with primers and rust proofing and painted with long lasting stove enamel or elegantly powder coated. The inner construction is made of stainless steel sheet-304. The 80 mm gap between the walls is filled high grade polyurethane insulation, which ensures maximum thermal efficiency.

1. Cooling: An energy efficient cooling unit is installed in our freezer. We use high end CFC free compressors of Emerson / Kirloskar/ Tecumseh / Bitzer/ Danfoss make, conforming to latest international standards and guidelines.

Features:

Capacity modulation and precision cooling
High Energy Efficiency
Compact
Proven Technology
Wide Voltage Range
Superior quality wear resistant part

Improved SEER (**Seasonal Energy Efficiency Ratio**) - improved SEER gives more efficiency.

2. Cooling medium: air cooled CFC free refrigerants.

3. Temperature Range: Temperature range is Ambient to -20oC controlled by nanotechnology based microprocessor temperature controller. **Temperature accuracy is +/- 2oC or better**

4. Doors:

Heavy-duty counterbalanced lid with integrated keyed lock and independent sub lids
Double-seal lid gaskets minimize frost buildup
Right hand side hinged door in upright models

5. Motor: ½ HP externally mounted motor provides maximum and efficient airflow throughout the cabinet.

6. Capacity: 250 Liters

7. Alarm System:

Power failure or temperature deviation triggers audible and visual warning. System includes adjustable safety alarm with automatic, continuous charge battery backup and digital battery indicator.

System includes touchpad alarm test function RS-232 data port with system software.

Exterior alarm contacts for connection to remote monitoring system.

8. Monitoring System:

Extreme Ambient Alert that warns if room temperature can affect performance

On-board power monitoring with digital readout of incoming line voltage

Built-in surge suppressor

SPECIAL FEATURE:

1. Safety interlock for alarm on high temperature to avoid any mistake.
2. Alarm for timer function for work time completion.
3. Easy door closing and locking.
4. Easy control panel access for effective maintenance.
5. Door open alarm and indicator
6. Compressor running indicator for easy equipment function monitoring.
7. LCD Display with new PID based Nano technology feature.

11. ULTRA LOW TEMPERATURE FREEZER- (-86) Capacity: 250 Liters

Special Features

1. High-tech construction combines vacuum panel insulation with environmentally-friendly, water-blown foam insulation for maximum sample-to-vial footprint storage.
2. Environmentally-friendly, CFC/HCFC free refrigerants
3. Power management system protects against a wide range of voltage variation and is easily accessible through the touch-screen display.
4. Microprocessor based control system.
5. Defrost cycle can be initiated to shut down the compressor and keep the cabinet defrost free.
6. Ergonomic and easy to use.
7. CFC/HCFC-free refrigerants maximize cooling and minimize environmental impact
8. Corrosion resistant interior and exterior
9. Incident monitor provides visual and audible warnings of system abnormalities for increased sample protection.
10. Digital display and direct settings for maintaining desired operations.
11. Castors for ease of movement
12. Lockable hinged doors

Construction Details

Ultra-low temperature freezer is double walled cooled units. Outer body are constructed out of thick PCRC, pre coated corrosion resistant GI sheet duly pre-treated with primers and rust proofing and painted with long lasting stove enamel or elegantly powder coated. The inner construction is made of stainless steel sheet-

304. The 100 mm gap between the walls is filled high grade polyurethane insulation, which ensures maximum thermal efficiency.

1. **Cooling:** An energy efficient cooling unit is installed in our freezer. We use high end CFC free compressors of Kirloskar/ Tecumseh / Bitzer/ Danfoss make, conforming to latest international standards and guidelines.

Features:

Capacity modulation and precision cooling

High Energy Efficiency

Compact

Proven Technology

Wide Voltage Range

Superior quality wear resistant part

Improved SEER (**Seasonal Energy Efficiency Ratio**) - improved SEER gives more efficiency.

2. **Capacity:** 250 Liters

3. **Cooling medium:** air cooled CFC free refrigerants.

4. **Temperature Range:** Temperature range is -10oC to -86oC controlled by nanotechnology based microprocessor temperature controller.

Temperature accuracy is +/- 1oC or better

9. Alarm System:

Power failure or temperature deviation triggers audible and visual warning.

System includes adjustable safety alarm with automatic, continuous charge battery backup and digital battery indicator.

System includes touchpad alarm test function RS-232 data port with system software.

Exterior alarm contacts for connection to remote monitoring system.

10. Monitoring System:

Extreme Ambient Alert that warns if room temperature can affect performance

On-board power monitoring with digital readout of incoming line voltage

Built-in surge suppressor

5. Freezers are equipped with an internal voltage regulator and voltage compensation system to ensure a longer compressor life.

SPECIAL FEATURE:

1. Safety interlock for alarm on high temperature to avoid any mistake.
2. Alarm for timer function for work time completion.
3. Easy door closing and locking.
4. Easy control panel access for effective maintenance.
5. Door open alarm and indicator
6. Compressor running indicator for easy equipment function monitoring.
7. LCD Display with new PID based Nano technology feature.

Tender Specification

12. Desiccators cabinet

| | |
|---------------------------|-------------------------|
| • Chamber Volume (cu ft) | Not less than 0.6 – 0.7 |
| • Chamber Volume (Liters) | Not less than 19.0 |
| • Material | Polystyrene EPDM |
| • Orientation | Horizontal |
| • Color | No color/ clear visible |

TENDER SPECIFICATION

13 Tablet Dissolution Tester with Piston Pump Auto Sampler

01. **Purpose :** To analyze Dissolution percentage of the drug substance in Tablet or Capsule as per USP/EP/IP/BP monographs .

02. **Specific Requirement:**

➤ **Basic Dissolution Bath**

- The system should be 08 Bowl Dissolution System with (6+2 Vessel Configuration) enable to perform comparative studies.
- The dissolution system should have Complies with current USP, IP, EP & ASTM 2503-13 specifications.
- The system should Supports USP 1, 2, 5, 6 & Intrinsic Test Methods, Small volume and stationary baskets.
- The bath should have alphanumeric keyboard with 40*2 Lines back lighted liquid crystal display. (LCD)
- The bath should have Mono shaft design for easy change over from USP 1 to USP 2, eliminates routine height check as per USP.
- It should have vibration free external water circulating cum heating pump for precise temperature control in Dissolution Bath & Media Bowl.
- All Accessories should be laser mark with serial number for authentication and traceability.
- The bath should have Special chuck housing for Wobble free operation.
- The system should have Non-Volatile memory storage of 15 methods with parameters.
- The system should have facility of on time interval & split function for sample withdrawal to have USP sampling requirements.
- The bath top plate should be PVDF Coated with numbering for identification.
- The software should have Multi level pass-word facility.
- The software should have built-in clean function for media change over and cleaning.
- The system should have Recovery Test for R & D
- The bath should have Front drain tap for easy cleaning of water bath.
- The system should have RS 232 Interface for data downloading and parallel port for printer.
- The software should have the Auto start in case of power failure.
- The system should have Validation software to validate RPM temperature, sampling and replenishment.
- The system should have the programmable rinsing volume capability to eliminate the carry over.

➤ **Sampling Manifold:**

- The system should have intelligent sampling manifold to have the compliance with USP sampling zone requirements.
- The sampling manifold should have the sampling and media replacement as single probe.
- Carrier tubing's should be SLS Compatible.
- The manifold should have the individual temperature probes to measure and record the temperature of each vessel.
- The manifold should be able to measure the temperature and record the temperature of each vessel at zero time before the dissolution run initiated.

➤ **Sample collector:**

- Over Head Design for electronic safety and fail safe operation.
- Single sampler collector to cater more sampling intervals.(24x6)
- Sensor to locate proper position of tray with alarm facility for proper collection of sample.
- Collection pins closed to the vials, minimum exposed to surrounding environment.
- Wide mouth vial to minimized SLS over spillage problem due to bubble formation.
- Easy positioning with respect to vials or test tube tray for easy change over.
- HPLC vials tray accommodation provision should be available.

➤ **Piston Pump:**

- 06 position High Pressure Piston Pump with Ceramic Rotor Model [PP 06]
- Microprocessor controlled & is ideal for sample withdrawal from 6 vessels.
- Valve less design
- Compatible with SLS & other surfactants Medias.
- Programmable High flow rate up to 25ml/min.
- System Diagnostics function to ensure proper working of all the components.

➤ **Specifications:**

- Temperature Range: 20°C to 55 °C.
- Temperature Accuracy +/- 0.1°C accuracy up to 45°C & +/- 0.2°C accuracy between 45°C to 55°C.
- Paddle/ Baskets Speed: 20 to 350 RPM.
- Dissolution Process time: 1 min to 720 Hours.
- Sampling Volume Range : 0.5 ml to 25.5 ml
- Maximum number of sampling Intervals – 24 intervals
- Sampling time selectivity: Fixed/ Programmable

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04. **Training:**

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05. **Available size/Area for the subject equipment :**

- * Sufficient area for the instrument is available in the quality control area.

06. **Discussing/Review/Comments:**

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14. Electrophoresis unit with Power Pack

| | | |
|----------------------------|---|----------------------------|
| VOLTAGE | : | 0...600V |
| CURRENT | : | 0...500mA |
| POWER | : | 0...150W |
| PARAMETER RANGE | : | 1...100% of full scale |
| TIMER | : | 0...99:59h |
| VOLT-HOURS | : | 0...99.99kVh |
| DISPLAY LCD, | : | 2x16 characters |
| RESOLUTION | : | 1V, 1mA, 1W |
| PROGRAMS | : | 9x9 set of parameters |
| OUTPUTS | : | 4 in parallel, 4mm sockets |
| MINIMUM LOAD RESISTANCE | : | 30Ω |
| BUFFER DEPLETION DETECTION | : | on/off, programmable |
| NO LOAD DETECTION | : | on/off, programmable |
| GROUND LEAKAGE DETECTION | : | |
| OVERLOAD DETECTION | : | |
| COMPUTER CONTROL | : | |
| AMBIENT TEMPERATURE | : | 0...40°C |
| RELATIVE HUMIDITY | : | 0...95%, non condensing |
| POWER REQUIREMENTS | : | 50/60Hz, |

1. Mini horizontal gel unit
 - A. Gel size (W x L): 6 x 7.5cm
 - B. Removable casting tray
 - C. 2 x 1mm thick, 8-sample combs
 - D. Colored loading strips
 - E. Buffer Volume: 300-350 ml
 - F. Maximum Sample Capacity: 30-35

2. Mini-plus horizontal gel unit
 - A. Gel size (W x L): 10 x 11.5cm
 - B. removable casting tray
 - C. 2 x 1mm thick, 16-sample combs
 - D. coloured loading strips.
 - E. Buffer Volume: 400-500 ml
 - F. Maximum Sample Capacity: 75-80

15. Muffle furnace

Furnace construction: (i) Double shell steel case with cooling fan to keep outside case cool
(ii) High purity alumina fiber insulation for max. energy saving

Heating element: The chamber section should be heated by six to eight Super Kanthal Molybdenum disilicide heating elements.

Std. Working Temperature: 1600° C (continuous)

Max Working Temperature: 1700° C (< 3 hours)

Temperature Control: The temperature controller should be a PID automatic control power control and programmable with necessary safety features.

Heating Rate The furnace should be of fast heating type with the maximum attainable temperature should reach as a ramp function in less than one hour.

Temperature Accuracy : +/- 1.0 °C

Thermocouple : Pt. Pt. Rh. Thyristor controller will be provided along with the Furnace to measure the temperature with recrystallized alumina sheath & connecting holder complete set.

Cooling Fan/ Air Circulation: Attached with Furnace, Provided inside the control unit to Protect Costly component

Max. Power Up to 8 KW

16 Hot Air Oven

Hot Air Oven

- Should have Chamber capacity of 90-250 ltrs.
- It should have interior & exterior construction of SS 304
- Should be provided with air ventilation and air circulating fan.
- It should option for auto cut off when door opens during operation.
- It should have fitted with stainless steel vertical channels for height adjustment of trays.
- It should have Digital PID temperature controller with PT100 sensor for precise monitoring & control
- Controller should be Equipped with timer (timer bypass option should be available), auto tuning and alarms.
- Controller should have LED/LCD display.
- Oven Temperature range: ambient +10°C to 250°C
- Control accuracy $\pm 1.0^\circ\text{C}$
- It should have independent over temperature safety protection and should be user settable.
- It should have over current protection.
- Oven should be CE or equivalent Indian standard certified.
- Supply Voltage: 230 V AC, 50 HZ, Single phase.
- Local Service Setup for prompt and efficient post sales support.
- Should have RS 485 port for communication.

❖ Installation and Documents and certification:

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- To be supplied certificate of compliance for each modules
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❖ Training:

- To be provided as required by the supplier's certified person at our site.

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17. Incubator-cum-Shaker

Construction: These are very sturdy double walled units with outer chamber is made of mild steel & inner chamber is made of high grade stainless steel sheet-304. The 3” gap between each walls, is filled with high-grade glass wool or PUF insulation for minimum thermal loss. Perfect System: The heaters are placed between the first and the second wall of the orbital shaker, which avoids the direct contact of heaters from the third (Stainless Steel inside chamber) walls. The heat to the inside chamber is given indirectly through forced air circulation, provided by the heavy-duty blower placed between the walls of the incubator. This system helps to control the temperature with higher sensitivity (+/- 0.5oC or less). Temperature Range: Temperature Range: 5oC above ambient to 70oC.

Shaking speed: 250 RPM. Platform Size: 450mm x 450 mm. The shaking platform should be designed to accommodate 250ml to 500ml flasks.

SPECIAL FEATURE:

1. Safety interlock for alarm on high temperature to avoid any mistake.
2. Alarm for timer function for work time completion.
3. Digital shaking speed indicator.
4. Shaking platform easy speed regulation option for lower value upto 20 + 5 RPM.
5. Easy door closing and locking.
6. Easy control panel access for effective maintenance.
7. Door open alarm and indicator
8. Compressor running indicator for easy equipment function monitoring.
9. LCD Display with new PID based Nano technology feature.

18. Karl Fischer Titrator

01. **Purpose** : To analyze water content in percentage/ppm level of the drug substance, API, Bulk Drug as per IP/USP/BP/EP monograph .

02. Specific Requirement:

- 8 Advanced Microprocessor based system with easy interchangeable burette assemblies
- 9 Imported Burette assemblies with Auto recognition thru advance sensor technology & Burette validation factor for dispensing correction.
- 10 Software should be in dialog mode, Alpha-numeric entries of Sample Name, Titrant Name, Identification No. & Date for report printout.
- 11 50 method storage capacity with 2 tier password (**Admin & User**) protection facility
- 12 Four standardized modes of operation such as :
 - * Neutralization * Concentration
 - * Percentage * PPM
- 13 **Serial port for balance**, parallel port for printer & **RS232 port for PC** connectivity.
- 14 **Automatic Monitoring of moisture leaks** with on line as well as offline Correction Facility.
This should help in keeping the instrument always ready for next analysis.
- 8 **Results should be in mg/ml, %, ppm, mg/g etc. Complete result data storage for last 10 analysis.**
- 9 Report Formats such as; (**compliance to GLP norms**)
 - a) Parameters and Result.
 - b) Program parameters.
 - c) **Condensed report of titration parameter and result.**
 - d) **Statistics report for last 10 run results i.e. Mean, Standard Deviation (S.D), Relative Standard Deviation (RSD) & Coefficient of Variance (CV).**
- 10 **In-built –Standardization procedures for Water / Sodium Tartrate; compliant to USP 23/921.**
- 11 User selectable polarizing current range helps to use various grades of solvents.
- 12 Micro controller based Magnetic Stirrer with digital speed settings.
- 13 Option of Auto drain and filling accessory should be available.

14 Error indication for wrong value / parameter entry, improper connection of electrode, printer, balance, PC etc.

System Should Have following Specifications:

- 1. mV Range: +/- 3200 mV, Accuracy : +/- 1mV**
- 2. Measuring Range: 10 µg to 500 mg. (20ppm to 100%)**
- 3. Burette Resolution: 1/ 10000 for 10 ml.**
- 4. End point Detection: Voltametric.**
- 5. Sensor: Dual pin platinum electrode.**
- 6. Polarizing Current : 1uA – 80uA in 8 steps.**

03. Installation and Documents and certification:

- * Installation should be done by the supplier's certified person.
- * To be supplied certificate of compliance for each modules
- * To be supplied IQ/OQ Documents.

04. Training:

- * To be provided by the supplier's certified person at our site.

05. Available size/Area for the subject equipment :

- * Sufficient area for the instrument is available in the quality control area.

06. Discussing/Review/Comments:

- * The user requirement specification is prepared for communicating the user expectation from the subject equipment manufacturer/supplier with respect to the subject equipment. The requirements specified are the basic requirements based on the available information for the process, operation and GMP requirements. The vendor is encouraged to quote for the latest product with quality, process control, safety etc. Final techno-commercial offers/quotation and /or any kind of queries should be directed to the following.

19. Magnetic stirrer with Hot plate

Features

- Digital temperature control with max. Temperature up to 280°C
- Digital speed control with max. Speed up to 1500rpm
- Stainless steel work plate with ceramic coating provides good chemical resistant performance
- External temperature control is possible by connecting the temperature sensor (PT1000) with an accuracy at $\pm 0.5^{\circ}\text{C}$
- LED display shows temperature and speed
- The “HOT” warning will flash when the work plate temperature is above 50°C even if the hotplate is turned off.

Specifications –

Work plate Dimension- $\phi 135\text{mm}$ (5 inch)

Work plate material -stainless steel cover with ceramic

Motor type- Brushless DC motor

Motor rating input- 5W (Not less than)

Motor rating output- 3W (Not less than)

Power -515W

Heating output- 500W

Voltage- 100-120/200-240V 50/60Hz

Stirring positions -1

Max. stirring quantity- 3L

Max. magnetic bar[length]- 50mm

Speed range- 200-1500rpm

Speed display- LED

Temperature display -LED

Speed display resolution- $\pm 1\text{rpm}$

Heating temperature range- Room temp.-280, increment 1°C

Control accuracy of work plate- $\pm 1^{\circ}\text{C}$ ($<100^{\circ}\text{C}$) $\pm 1\%$ ($>100^{\circ}\text{C}$)

Overheating protection - 320°C

Temperature display accuracy - $\pm 1^{\circ}\text{C}$

External temperature sensor - PT1000 (accuracy $\pm 0.5^{\circ}\text{C}$)

"Hot" warning - 50°C

Protection class - IP21

Dimension[WxDxH] -150×260×100mm

Weight – approx 1.8kg

Permissible ambient temperature and humidity - $5\text{-}40^{\circ}\text{C}$, 80%RH

20. PCR Thermal Cycler (Gradient)

1. Gradient Thermal Cycler with peltier heating and cooling based system. Power Supply: 220 -230 volt, 50–60 Hz.
2. Should have 48x2 blocks for 0.2ml/0.5ml tubes, which can be independently controllable for both the blocks.
3. Should have a maximum ramp rate of 5 0C /second and average ramp rate of 3 0C /sec or more.
4. Should have adjustable heating option of the lid for each block
5. Should have a temperature range of 0-100 0C with accuracy of ± 0.2 0C and uniformity of ± 0.4 0C in each well with a gradient range between 30-100 0C.
6. Should have a LCD display and have USB ports with a memory of not less than 500 programs.
7. Should be programmable, power-saving auto standby option when instrument is idle
8. Machine should be FDA / IVD / IEC / UN or UL and IEC certified.
9. Should be supplied with suitable online UPS with minimum one hour power back-up.
10. Equipment will be selected only after proper demonstration at AIIMS Bhopal.
11. **3 years on-site warranty and CMC for subsequent 2 years warranty.**
12. Free upgradation of software, if applicable.
13. Instrument shall be supplied with all the accessories required to function.

❖ Installation and Documents and certification:

- Installation should be done by the supplier's certified person.
- To be supplied certificate of compliance for each modules
- To be supplied IQ/OQ Documents.

❖ Training:

- To be provided by the supplier's certified person at our site.

❖ Available size/Area for the subject equipment :

- Sufficient area for the instrument is available in the quality control area.

❖ Discussing/Review/Comments:

- The user requirement specification is prepared for communicating the user expectation from the subject equipment manufacturer/supplier with respect to the subject equipment. The requirements specified are the basic requirements based on the available information for the process, operation and GMP requirements. The vendor is encouraged to quote for the latest product with quality, process control, safety etc.

21. pH Meter

01. **Purpose :** To analyze pH range of any aqueous solution & conductivity of various liquid samples as per USP/EP/IP/BP monographs.

02. **Specific Requirement:**

pH Meter should have following specifications:

1. PH Range: -2.00 to 19.999.
2. Accuracy: 0.002 PH
3. MV Range: 0 to 1999.9 mv
4. Resolution : 0.1mv.
5. Slope Range : 80 to 120 %.

It should have following features;

1. Three point/Five Point Calibration (User entered Buffer Values) with auto buffer recognition facility with password protection
2. It should be advance micro controller based user friendly system with reading storage of 40 or more pH/mV readings
3. Automatic and manual temperature compensation facility.
4. Provision for Alpha- numeric entries of Sample name, Identification Number, customers name on report printouts.
5. Reading resolution selection i.e. 0.1 or 0.01 or 0.001 pH
6. Instrument should have printer & PC connectivity.
7. System should have date & time locking facility by password.
8. System should have at-least two level password provision.

It should also be capable of measuring pH of semi-solid samples by using Flat Surface Probe / Electrode. Also determination of pH of small volume (i.e. 500ul) sample should be possible.

22. Tablet Hardness Tester

01. **Purpose** : To analyze Tablet Hardness & Physical dimensions as IP/USP/BP/EP monograph .

02. **Specific Requirement:**

1. System should have Automatic measurement of tablet parameters- Length/Diameter & Hardness. It should have provision for external balance connectivity.
2. It should have easy alignment of all shaped tablets for perfect measurement (i.e.round, oval, oblong shape tablets etc.)
3. Should work for a Test sample up to 40.0mm diameter or length. Should have optional provision up to 60mm.
4. Measuring range of Hardness should be 2 - 500 N (Optional up to 600N) with Accuracy - +/- 1N
5. Measuring range of Diameter : 0.10 to 40.00mm with Accuracy +/- 0.06mm. Optional provision for extending length measurement up to 60mm
6. Should have User selectable measurement units like mm & inch for diameter, for Hardness – units like N (Newton's) / Kp (Kilo Ponds) / Sc (Strong Cobb) / Pound & for Weight - mg or gm.
7. System should have alpha-numeric Keypad for easy entry of Test Parameters, Product name, Batch no., Process stage, Compression / Press No., etc.
8. Built-in Calibration menu with GLP print out. For Hardness - 3 point Load cell as per USP. For Diameter & Thickness - 3 point with standard gauges.
9. Method Storage : up to 99 Programs with all parameters.
10. System should be able to performed testing continuously for up to 99 tablets.
11. It should give complete GLP compliant report with all details of Tablet batch, including complete statistic of all measurements.

03. **Installation and Documents and certification:**

- * Installation should be done by the supplier's certified person.
- * To be supplied certificate of compliance for each modules
- * To be supplied IQ/OQ Documents.

04. **Training:**

- * To be provided as required by the supplier's certified person at our site.

05. **Available size/Area for the subject equipment :**

- * Sufficient area for the instrument is available in the quality control area.

06. **Discussing/Review/Comments:**

- * The user requirement specification is prepared for communicating the user expectation from the subject equipment manufacturer/supplier with respect to the subject equipment. The requirements specified are the basic requirements based on the available information for the process, operation and GMP requirements. The vendor is encouraged to quote for the latest product with quality, process control, safety etc. Final techno-commercial offers/quotation and /or any kind of queries should be directed to the following.

23. VISCOMETER

Instrument should with features –

No calculations required:

- Direct reading of viscosity in cP or mPa.s *Displayed Info:*
 - Viscosity (cP or mPa•s)
 - % Torque
 - Speed/Spindle *Easy-to-Use:*
 - Flip a switch
 - Turn a knob *Spindle/Speed selection Flip to “Speed”*
 - Turn the knob
 - Choose RPM *Flip to “Spindle”*
 - Turn the knob
 - Choose spindle *Auto Range* push for determining full scale range (FSR) viscosity *18 Speeds* for complete range capability *Accuracy: 1.0% of range* *Repeatability: 0.2%* **WITH** Viscosity range cp (mPa.s) minimum required is 100 & maximum 13M, RPM .3-100 and number of
 - increments must be 18.
- ❖ **Installation and Documents and certification:**
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 - To be supplied certificate of compliance for each modules
 - To be supplied IQ/OQ Documents.
- ❖ **Training:**
 - To be provided as required by the supplier’s certified person at our site.
- ❖ **Available size/Area for the subject equipment :**
 - Sufficient area for the instrument is available in the quality control area.
- ❖ **Discussing/Review/Comments:**
 - The user requirement specification is prepared for communicating the user expectation from the subject equipment manufacturer/supplier with respect to the subject equipment. The requirements specified are the basic requirements based on the available information for the process, operation and GMP requirements. The vendor is encouraged to quote for the latest product with quality, process control, safety etc.

24. Vortex Shaker

| S.No. | Specifications |
|-------|---|
| 1. | Should have heavy metal base and rubber feet to prevent movement of shaker during use |
| 2. | Should have choice of continuous and touch mode |
| 3. | Variable Speed Control, maximum speed 3000 rpm |
| 4. | Should have a hand insert, microtube insert and cup attachment |

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❖ Training:

- To be provided as required by the supplier's certified person at our site.

❖ Available size/Area for the subject equipment :

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25. Water Bath

Temperature Control Temperature Sensitivity $\pm 0.5^{\circ}\text{C}$ or better Spatial Deviation In Temperature $\pm 0.5^{\circ}\text{C}$ or better Readability 0.1°C Temperature Range 5°C above ambient to 90°C . Temperature Sensor PT-100 Temperature Controller PID Display LED/LCD Adjustable alarm limits Optional Safety thermostats Temperature Sensors PT-100 Automatic temperature setting Yes Adjustable limits Yes Accessories Timer (999 mins) optional Program (Real Time) optional Data Acquisition Program optional Serial Port (Printer) RS232 optional Inspection window in door optional Printer Report Program optional 2 x 24 characters LCD Display optional Access Port 30 mm optional Internal Dimensions 350 x 250 x 150 mm, No. of Rows 2, No. of Holes 6 Power Consumption Nominal Power 500 - 650W Nominal Voltage 220-230 Volts, 50 Hz Single Phase Frequency 50 Hz

SPECIAL FEATURE:

1. Safety interlock on high temperature.
2. Alarm for timer function for work time completion.
3. Easy closing and lid locking.
4. Flask holder SS 304 tray inside the water bath
5. Easy control panel access for effective maintenance.
6. Low water safety

26. Water Bath Shaker

| S.No. | Specifications |
|-------|--|
| 1. | Temperature setting range °C: Ambient +5°C to 100°C |
| 2. | Temperature Uniformity $\pm 0.05^\circ\text{C}$ |
| 3. | Temperature Stability $\pm 0.1^\circ\text{C}$ or better |
| 4. | Capacity should be around 25 L or more |
| 5. | Should have a digital display |
| 6. | Water bath chamber should be made of 304 stainless steel |
| 7. | Should have a coil free design for easy cleaning |
| 8. | Water bath cabinet should be epoxy powder coated cold rolled steel or similar material. |
| 9. | Should include stainless steel cover and shaking tray |
| 10. | Should have FDA class I certifications |
| 11. | Drain tap should be in-built within the system, preferentially at the bottom and should be properly welded to prevent leakage. |
| 12. | Three programmable temperature and shaking presets - allows commonly used temperatures and shaking to be quickly selected. |
| 13. | It should have countdown timer with audible buzzer for accurate reaction timing. |
| 14. | It should have fixed thermal cut-out which protects the bath to accidentally run without water. |
| 15. | Adaptors for 50 ml (10) , 100 ml (10) , 250 (10) ml beakers and flasks |

❖ **Installation and Documents and certification:**

- Installation should be done by the supplier's certified person.
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