

Notice Inviting e-Tender

West Bengal Medical Services Corporation Limited Swasthya Sathi GN-29, Salt Lake, Sector-V Kolkata-700091

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Procurement, supply and installation of Hi Tech Analytical Instruments for State Drugs Control & Research Laboratory (SDCRL) of the Government of West Bengal (Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-101 /2025 Dated-06.02.2025

The following amendment have been made in the tender document,

<u> Amendment –I (Revision of Technical Specification)</u>

The revised technical specifications for the item is given below,

Eight Bowl Dissolution Apparatus with Auto-Sampler

We intend to procure an advance 8 bowl Dissolution Apparatus with Auto-Sampler, the instrument should have following specifications & features.

TYPICAL SPECIFICATIONS

- Dissolution Apparatus should have 7' TFT Touch Screen with user friendly iconic menu.
- > System should have built-in software to control all the system operations.
- > System should have auto tablet dropping mechanism to drop all tablets in media at same time.
- > System should be provided with mono shaft design for quick interchange from paddle to basket or vice versa. All vessels, shaft, paddles & basket should be laser marked for traceability.
- > System should have minimum capacity of storing 200 analysis methods with parameters.
- ➤ Temperature Range should be 20° C to 55° C
- \triangleright Temperature Accuracy should be $\pm 1^{\circ}$ C
- > Temperature Resolution should be 0.1°C
- System should have digital Temperature Sensor for perfect reading. PT-100 (RTD)
- > System should Print Interface with option of Deskjet, inkjet, laser jet printer connectivity & USB connectivity for data backup & system s/w up-gradation.

- \triangleright Paddle/Basket shaft speed should be minimum 20 to maximum 350 RPM with $\pm 1\%$ accuracy.
- > System should have a provision Sampling time selectivity i.e. Fixed time / programmable time intervals (Varying Intervals)
- System should have Time Interval Selectivity in steps of 1 Minute.
- > System should have auto-sampler with sampling volume range minimum 0.5 to 25.5ml.
- System should be supplied with 8 Glass Vessel with 1000ml Capacity.
- Dissolution system should be having moulded Water Bath with 17 litres capacity having builtin water level sensor having front loaded drain tap for easy draining of the water.
- > Dissolution system should have external water circulation with built-in heating provision.
- System should have Maximum number of Intervals up to 30.
- System should have Provision for selection of Dissolution Process Time from 1 min to 1200 hrs.
- > System should be compatible with USP Apparatus V, Apparatus VI, Enhancer Cell etc.

INTELLIGENT SAMPLING SYSTEM

- Automated sampling manifold should work as per USP Specifications. i.e. Sampling tubes should get lowered down in the media only at the time of sampling and withdrawn immediately after sampling, thus no part of the assembly contributes motion, agitation or vibration during Dissolution run
- Dissolution system's sampling tubes should be accurately moved to the USP sampling position only.
- > System should have 6 vessels temperature monitoring system with advanced Digital sensor which automatically measures and records the temperature of individual vessel at specified sample points.

SAMPLING PUMP

- ➤ 06 position High Pressure Piston Pump with Ceramic Rotor for inertness
- Microprocessor controlled & is ideal for sample withdrawal from 6 bowls.
- ➤ Should be compatible with SLS & other surfactants Medias.
- ➤ Programmable High flow rate maximum up to 25ml/min.
- > System Diagnostics function should be available to ensure proper working of system function.

SAMPLE COLLECTION

- ➤ Dissolution Apparatus should be supplied with 8 x 24 position sampling tray with test tubes.
- System should have optional provision to accommodate 1.5 ml & 2 ml HPLC vial tray.
- Sampling Tray should be having Sensor provision to locate proper position of tray with alarm facility for fail safe collection of sample.
- ➤ Option of sampling tray to accommodate wide mouth vial to minimise SLS media spill over problem due to foaming characteristics.
- Sampler collector's dispensing head should have x-y axis movement to collect the sample in vial thru septa.

ADDITIONAL FEATURES

- System should have Built-in Validation software for RPM, Temperature & sampling volume.
- ➤ It should have Facility to RINSE the entire sampling path in between sampling time-point to eliminate contamination & carry over
- It should be having cleaning software with cleaning tray to clean the entire sampling path after each run.
- > System software should have facilities to perform the dissolution test using two buffers (Buffer changing) to cater the application of enteric coating tablets.

- ➤ Software should have Recovery Test facility to study 100% Drug release pattern.
- > System should have Split time sample collection & on-time sample collection provision.

ANALYSIS RUN REPORT

- ➤ Report giving Run No., Set parameters and Actual parameters during the dissolution process.
- ➤ Diagnostic functionality report to ensure proper working of the system.
- Printout of each vessel temperature and paddle/ basket speed at every sampling interval for validation
- > Validation report for Temperature, RPM, Sample Volume and Replenishing Volume
- System software should have provision to take Selectable Report Format complying with GLP requirements.

Extra Key Features

- ➤ User authentication is performed for each and every operation done by user.
- PDF report file creation facility.
- Printer connectivity via Wifi & USB connection.
- Manual Archive and Auto Data Backup facility should available.

Warranty and support:

➤ The warranty should be 3 years and spares should be available for 7 years from the date of installation. The bidder/Manufacturer should have a service centre in Kolkata to render prompt support.