

Technical specification required for testing of intrinsic dissolution rates of pharmaceutical materials

Item	Technical Requirement
The instrument	Automatic micro-controller based intrinsic dissolution rate testing apparatus (Should comply with current USP, IP and EP specifications or better) is required with automatic withdrawal of sample in vials for testing in UV-Vis or using HPLC.
Water bath	Transparent, Moulded Acrylic or glass water bath, capacity – 17ltrs to 30ltrs, with built-in water level sensor, temperature sensor, preferably amber colour. There should be 6 +2 amber coloured vessels for dissolution of the tablets. Easy water drain and clean up option should be available.
Bath temperature	30-40 °C with temperature accuracy ± 0.1 °C and temperature resolution 0.1 °C. Stabilization time less than 30 minutes.
Automatic heater	The heater should be possible to be turned on automatically at a specified time
Bath Circulation	There should be a suitable arrangement for efficient water circulation to maintain same temperature in the entire volume of water without serious turbulence.
Alarm	There should be alarm form any error in the system (preferred)
Dissolution Vessels, Paddles & Baskets	As per USP/BP/IP selection between Polycarbonate or amber coloured. Monoshaft Design with easy changeover between paddle and basket mode of operation to eliminate routine height validation as per USP.
Tablet dispenser	Should have facility to drop 6 tablets at a time.
Display	Suitable LED or LCD display
Speed of paddles	Suitable motor driven paddles with 20-250RPM speed, with 1RPM step and accuracy $\pm 1\%$.
Dissolution process time	1 min to 720hrs or better
Time interval sensitivity	1 minute or better
Sampling Time Selectivity	Fixed / Programmable intervals. Total process time is automatically calculated.
Maximum number of intervals	30 or better
Method storage	15 programmes or better
Report Format	A] GLP compliant –Dissolution process report consist of: Customer Name. Instrument Sl. No. Auto Incremental Run No. Sample Name. Identification No. Date / Time Type of USP Apparatus [baskets or paddles] Stirrer depth. Buffer volume. Set / actual process parameters. [Temp., RPM, Interval No. and total elapsed time] B] Programme parameter report. C] Data Evaluation software [optional] :- Evaluation programme parameter. Evaluation report. Dissolution Profile with passing limits marks.
Printer output	A suitable printer port should be available and a suitable printer should also be provided.
Auto Sampler for	Micro-controller sample collector with [6 X 24 rows] position sample collector

OFF line measurement	tray with 10 ml vial capacity with caps and 12 channels peristaltic pump [ISMATECH-SWISS Make with built-in calibration facility] with Silicon /Tigon tubing's. & also include HPLC vials tray with 2 ml vial capacity in the quote. There should be rinsing facility for the entire sampling path after each sampling. The auto-sampler should have either peristaltic pump or a syringe pump (preferred) with a facility for replenishing the dissolution jar for smooth operation.
Sampling System	Intelligent sample probe positioning – complies with USP requirement.
Sampling Volume	2ml - 15 ml / min, programmable.
Pump Flow rate	Selectable.
Tubing Cleaning	Built-in cleaning function with cleaning tray.
Environmental Operating Conditions	Operation : Indoor Temperature : Ambient to 45 Relative Humidity : 5 to 90% non-condensing.
Power Supply	230 V AC \pm 10% , 50 Hz
Software	Data evaluation, Rinsing & complete validation software must be provided. Special software programme for calculating % drug dissolved vs time using individual tablet weight should also be included. The software should come with perpetual license and update and upgradation of software should be provided till the updated/upgraded version of the software is compatible with the supplied system.
Tablet dispenser	Drops 6 dosage form at single instance
Tablet mater	A suitable Tablet making press should also be included
UPS	A suitable UPS (2KVA) with 1 hr backup on full load should be included in the price.
PC	A branded (Dell/HP/IBM) PC with i5 processor, Windows 7 OS, 1TB HDD, 8GB ram, DVD R/W, wireless network card should be included in the quote of the instrument.
Users in India	A list of users in India with the contact details of all the end user should be provided.
Warranty	A 2 years of warranty should be included
CAMC	An additional 3 years CAMC should also be quoted separately
Various accessories	All possible accessories (paddles, baskets, should be quoted separately
Installation and user training	Installation at customer site and required user training must be give after installation.

The vendors should quote two different systems, one using Syringe Pump (referred) and the other using peristaltic pump. The indenter reserves the right to select one based on the quoted price and available fund for the purchase.