

Dissolution Tester



21 CFR Part 11 Compliant



Limited System Access



Authority Checks



Device Checks



Accurate and Complete Copies of Records



Audit Trail



Metadata Storage



Data Integrity Operating System



Infinity Test



Touch Screen



LAN



Fingerprint Authentication



Multi-Level Security



Print Report



Electronic Log Book

Benefits

- Consistent results with one dissolution water bath rather than variations possible with two separate dissolution water baths
- Incubation of replenishment media under same conditions to the dissolution media

Motorized Lift Mechanism

- Hands-free quiet operation
- Automatic stirrer height positioning for USP 1, 2, 5, 6 and intrinsic test methods

Auto Dropping System

- Simultaneous dropping of dosage in non-rotating media
- User defined test start (immediate or delayed) immediately after media temperature is attained
- AutoDropSyn can accommodate dosages and sinkers up to 24 mm

- Unibody construction (crevice-free) provides wobble free operation and accurate height adjustment
- Facilitates quick changeover between methods

Multi-stage Filtration

- 3 stage filtration ranging from 10 μ - 15 μ , 0.45 μ to 0.22 μ is possible
- Close proximity of filter manifold reduces variability caused by automation

Isolated Temperature Controller

- Isolated temperature controller for vibration-free and precise temperature control

Rinsing

- Programmable rinse volume purged to waste in multiple cycles to avoid carryover
- Circulate the rinse volume through the transfer tubings back to vessel to eliminate waste volume

QbD

Quality by Design

- International regulatory compliance (USP, Ph. Eur, JP)
- Easy access to all physical parameters for cleaning and mechanical qualification
- Designed to minimize routine validation
- Corrosion free sturdy bath top plate
- All sample contact parts are made of inert materials
- Versatility allows adaptation to USP 1, 2, 5, 6 intrinsic and special height (45 mm) apparatus
- Transparent and amber colored vessels-capacity ranging from 100 ml, 300 ml and 1000 ml
- Sampling manifold dives the individual cannulas and vessel temperature probes to the appropriate sampling zone based on the method
- Wake up and sleep mode for the temperature controller saves time and conserves energy
- High performance ZDV (Zero-Dead-Volume) syringe pump for precise and accurate sampling
- 2 axis movement of sample collector arm enables piercing of pre-cut septa for HPLC vials

18%
reduction in
variability

Dilution with Stirring

- Simultaneous purging and mixing of the aliquot and diluent for homogeneous sample preparation
- Automated dilution of aliquot is possible by using replenishment media or mobile phase

Specifications

| Model | Tester-08 |
|--------------------------------|---|
| No. of stations | n = 8 |
| Speed range | 20 RPM to 300 RPM |
| Speed accuracy | ± 0.5 RPM |
| Temperature range | 20°C to 45°C (extended range 10 to 40 and 20 to 55 optional) |
| Temperature accuracy (at 37°C) | ± 0.1°C |
| Display | 7" TFT touch screen display |
| Protocol storage | 1000 |
| Test report storage | 10000 |
| Sample interval | 1 min to 999 hrs, 59 min |
| No. of syringes | 8 |
| No of temperature probe | 8 |
| Interface port | Ethernet, Embedded thermal printer, RS 232, RS 485 |
| Stirrer drive | High performance BLDC drive (maintenance-free) |
| Vessel capacity | 150 ml, 250 ml, 1 L |
| Water bath | One piece moulded clear |
| Bath capacity | 22 L |
| Temperature controller | Heater : 1 kW, SS 316 with thermal protection |
| Electrical power | 220/230 VAC, 50/60 Hz, 1.3 kW/6 Amp 110 VAC, 50/60 Hz, 1.3 kW/10 Amp |
| Dimensions (L x W x H) : | |
| Basic | 67 cm x 51 cm x 71 cm |
| Offline Automation System | 101 cm x 51 cm x 71 cm |
| Weight : | |
| Basic | 84 kg |
| Offline Automation System | 141 kg |

Our Products

- Complete range of Dissolution Testers
- Dissolution Media Degasser



The information contained in this document is believed to be correct but **Pharma Alliance Group Inc** accepts no liability for any errors and reserves the right to alter specifications without notice
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