

Friability Test Apparatus - Double Drum (21 CFR Part-11 Compliance)

Model: μ FTCal100 | Make: ANALAB | HSN Code: 90318000



Supplied with Roche Drum - 02 Nos., Drum Holding Knob with rubber bush, Removable Tablet Collecting SS Tray - 02 Nos., Acrylic Tablet Collecting Holder for SS Tray - 02 Nos., Power Cord, ANALABsafe software, USB Interface Cable, Operational & Instruction Manual with SOP, Calibration Test Certificate (Without Traceability Document) and Warranty Card.

Technical Specification:

Speed	:	Variable from 20 to 70/ 100 RPM
Accuracy	:	±0.5 RPM
Timer	:	Variable from 1 sec. to 9 hrs. 59 min 59 sec.
Counter	:	1 to 9999 revolutions
No. of drums	:	Two
Pharmacopeia Complies	:	As per USP, IP, Ph. Eur.
Method	:	40 analysis method for single friability test with View, Print & Delete facility.
Weight Transfer	:	Possible through RS-232 Port (From Balance to Instrument)
Tablet Discharge	:	Automatic in the Sample tray from drum after completion of analysis.
10° Tilt	:	With Audio Visual Alert message
Calculation of result	:	Friability in %
Calibration	:	RPM and Count (Automatic)
Verification	:	RPM, Count and Time
Power failure detection	:	Un-interrupted tablet testing after power resume.
Display	:	20 x 4 Line Alphanumeric Backlit LCD
Keypad	:	Membrane waterproof polycarbonate soft touch keypad compliance to UL/ROHS
Analysis Data Storage	:	More than 1500 data can be store in non-Volatile Memory which can print & view company name, print date and time, analysis date & time, record number, batch number / ID, sample name, username, pharmacopeia, assigned method number, RPM, tilt status, drum type, set and actual counts, initial and final weight, friability result, analysis done on, model number, drum ID, serial number, instrument ID etc. Secondly , analysis data can be print online.
Searching of data	:	With record number, batch number, date, date range and by scrolling.
Report Formation	:	As per GLP Compliance
21 CFR Part-11 Compliance	:	<ul style="list-style-type: none"> • In-built with system for ease of operation without PC. • 2 Admin, 10 Reviewers, 40 Users & 1 Manufacturer with individual Login ID & Passcode. • Audit trail can store more than 5000 lines in instrument. • Audit trail includes action taken, date & time, action taken by whom. • Audit trail can be transfer to PC through ANALABsafe software and can print on 40 / 80 column dot matrix printer for record.

- Admins can set up operation permission of each Users & Reviewers.
- Strict Admins control to audit and monitor usage and access.
- Audit trail record can be printed with Date, Date Range and by individual User's ID.
- Once Audit trail transfer to the PC or Printer, system will delete Audit trail records and before final deletion, the system will give warning twice.
- Data integrity with database capability to store Analysis Data, Audit trail and Passcode in instrument.
- No direct access to data from outside the instrument, thereby creating a closed system.
- Audit traceability to ensure that the device and results are appropriately handled.
- Auto User's logout after defined Logout time.
- Auto Users & Reviewers block when password is entered incorrectly 3 consecutive times.

Printer Interface	:	Centronics Parallel Port/ Serial (RS-232 C) Port
Printer	:	40/ 80 Column Dot Matrix Printer (Printer to be procure optionally)
PC Interface	:	USB Type - B
PC Connectivity	:	By USB Interface Cable with Driver, ANALABsafe software to transfer Analysis data in GLP format, Calibration data and Audit trail from Instrument to PC in non-editable format (Cannot be Deleted)
Power Supply	:	230VAC \pm 10%, 50 Hz

Optional

1. IQ / OQ / PQ / DQ Documents

Note: a) Please provide Customer's Name & Address prior to dispatch.

- b) To perform onsite documentation, visit charge will be extra depending upon place of Installation.
- c) Traceability documents along with installation report.
- d) Standards / Chemicals / Buffers required to perform documents are in customer's scope.
- e) We don't send documents by email.

2. GMP Enclosure made up of Stainless Steel

3. 40 / 80 Column dot matrix printer

4. Keypad Screen Guard

5. Traceability Documents

Available other Models of Friability Test Apparatus

- Friability Test Apparatus - Double Drum Model: μ FTCal10 with Fix RPM & Printing Facility as per Non-GLP Format
- Friability Test Apparatus - Double Drum Model: μ FTCal50 with Variable RPM & Printing Facility as per GLP Format
- Friability Test Apparatus - Double Drum Model: μ FTCal100 with 21 CFR Part-11 Compliance & Printing Facility as per GLP Format

Product Range

- pH/mV/°C/ORP Analyzer • Conductivity/TDS/Resistivity/Salinity/°C Analyzer
- Multiparameter Analyzer (pH/ORP/Conductivity/TDS/Resistivity/Salinity/°C)
- Karl Fischer Titrator • Auto Titrator • Automatic Melting Point Apparatus
- Flame Photometer • Friability Test Apparatus • Tablet Dis-integration Test Apparatus
- Tap Density Test Apparatus • Tablet Hardness Tester • Leak Test Apparatus
- Tablet Dissolution Test Apparatus • Electromagnetic Sieve Shaker • Ultrasonic Bath (Sonicator) • Analytical Electronics Balance • Halogen Based Moisture Analyzer
- Visible & UV-Vis. Spectrophotometer • Nitrogen Gas Generator • Zero Air Gas Generator • Combination Nitrogen / Zero Air Gas Generator • Air Drying Unit for TOC Analyzer • Dew Point Apparatus • Gas Handling & Purification System • Laboratory Furniture & Fume Hood • Exhaust Hood for AAS/ICP.

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