

Tap Density Test Apparatus (21 CFR Part-11 Compliance)

Model: μ TDCal100 | Make: ANALAB | HSN Code: 90318000



Supplied with 100 ml & 250 ml Cylinder, Holder for 100 ml & 250 ml Cylinder, Power Cord, ANALABsafe software, USB Interface Cable, Operational & Instruction Manual with SOP, Calibration Test Certificate (Without Traceability Document) and Warranty Card.

Technical Specification:

No. of Station	: Two
USP Compliance	: 1) USP1 (300 taps per min.) 2) USP2 (250 taps per min.) 3) USP3 (55 taps per min.) – Available Optionally
Stroke Height	: 14mm ± 2mm / 3mm ± 0.2mm
Stroke / Minute	: 300 ± 5, 250 ± 5, 55 ± 5
No. of taps	: 1-9999
Platform Rotation	: 5 – 15 rotation / minutes
Rotating and tapping motion	: Simultaneous
Display of Strokes/min	: Simultaneously - Set & Actual
Cylinder Supports	: 100ml and 250 ml
Pharmacopeia Complies	: As per USP, IP, Ph. Eur.
Method	: 41 analysis method with View, Print & Delete facility
Calculation of result	: Bulk Density, Tapped density, Compressibility index and Hausner ratio
Weight Transfer	: Possible through RS-232 Port (From Balance to Instrument)
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 analysis data with Batch No., username, sample name, Bath Number/ID Tap/minute, Tap Hight, Tap Count 1, Tap Count 2, Tap Count 3, Tap Count Final,Weight of Sample, Total Number of taps, Initial Volume(Vo), Final Volume (Vf), Tap Density, Bulk Density, Compressibility Index, & Hausner Ratio, instrument serial number, Instrument Make & Model & Signature etc. Secondly, analysis data can be print online without saving analysis data in Instrument.
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, Analysis Method, 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, 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. Keypad Screen Guard

Available other Models of Tap Density Test Apparatus

- Tap Density Test Apparatus Model: μ TDCal10 with Printing Facility as per Non-GLP Format
- Tap Density Test Apparatus Model: μ TDCal50 with Printing Facility as per GLP Format
- Tap Density Test Apparatus Model: μ TDCal100 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.

ANALAB SCIENTIFIC INSTRUMENTS PVT. LTD.

AN ISO 9001 : 2015 CERTIFIED CO.
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