

## Leak Test Apparatus (Without Vacuum Desiccator) (21 CFR Part-11 Compliance)

Model:  $\mu$ LTCal100 | Make: ANALAB | HSN Code: 90318000



Supplied with Vacuum Pump (Inbuilt with System), Silicon Tube, ANALABsafe software, USB Interface Cable, Operational & Instruction Manual with SOP, Calibration Test Certificate (Without Traceability Document) and Warranty Card.

## Technical Specification:

Vacuum Controller	: Microcontroller Based
Maximum Vacuum Level	: Greater than 650 mmHg
<b>Vacuum Stability</b>	: <b>Set Value Below 400 mmHg : ± 10 mmHg within 30 seconds</b> <b>Set Value Above 400 mmHg : ± 5 mmHg within 30 seconds</b>
Vacuum Hold Time	: Variable from 1 sec. to 99 min
Vacuum Release Time	: Variable from 1 sec. to 5 min
Vacuum Initial Delay Time	: Variable from 1 to 60 second to achieve 100 mmHg <b>(Run will be aborted if 100 mmHg is not achieved in 60 seconds)</b>
Vacuum Release	: Auto - after completion of Vacuum Hold Time
Vacuum Measurement	: Digital
<b>Vacuum Measurement Units</b>	: <b>mmHg, bar, kPa, inHg, atm, psi, cmH2O, kg/cm2</b>
Number of Sample	: 1 to 99
Calibration	: With NABL Certified Standard Digital Vacuum Gauge
Method	: 40 methods with View, Print & Delete facility.
Pharmacopeia Complies	: As per USP, IP, Ph. Eur.
<b>Material of Construction</b>	: <b>Stainless Steel</b>
Display	: 20 x 4 Line Alphanumeric Backlit LCD
Keypad	: Membrane waterproof polycarbonate soft touch keypad compliance to UL/ROHS
Calibration Data Storage	: Non-Volatile Memory which can store, print & view calibration date & time, company name, Username, set and actual reading of Vacuum, calibration done by, instrument serial number, instrument ID, model number etc.
Analysis Data Storage	: <b>More than 1500</b> analysis data can be stored with company name, analysis date & time, record number, batch number / ID, sample name, username, assigned method number, numbers of samples, set vacuum, vacuum hold time, vacuum release time, vacuum calibration date, Instrument model number, serial number, instrument ID etc. <b>Secondly</b> , analysis data can print online.
Searching of data	: With record number, batch number, date, date range and by scrolling.
<b>Report Formation</b>	: <b>As per GLP Compliance</b>

- 21 CFR Part-11 Compliance :**
- 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, Calibration Data, Method 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%, 50Hz

## 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. 300 mm Vacuum Desiccator Made up of Polycarbonate

### 3. 40 / 80 Column dot matrix printer

### 4. Keypad Screen Guard

### 5. Traceability Documents

#### Available other Models of Leak Test Apparatus

- Leak Test Apparatus Model:  $\mu$ LTCal10 - Up to 525 mm of Hg Vacuum with Printing Facility as per Non-GLP Format
- Leak Test Apparatus Model:  $\mu$ LTCal50 - Up to 625 mm of Hg Vacuum with Printing Facility as per GLP Format
- Leak Test Apparatus Model:  $\mu$ LTCal100 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.

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