

KARL FISCHER TITRATOR WITH 21 CFR PART 11 COMPLIANCE

KAFI SMART



Automatic Karl Fischer Titrator & KAFI⁺

Karl Fischer titration is an accurate, rapid and efficient method for determining the water content in samples. When the sample is titrated in the presence of SO_2 , I_2 , and an organic base, moisture from the sample extracted in the solvent, can be quantitatively estimated. Dry methanol is used as a solvent in Karl Fischer titration.

The indicator-electrode is a two-pin platinum electrode across which a constant current is generated by a polarizing current source. For starting, very low volume of methanol as a solvent is needed in the specially designed vessel.

Background signal correction is done through an offset mode.

Calculated doses of Karl Fischer reagent are added to the solution in a hermetically sealed vessel as per stop criteria selected and the end-point volume is evaluated automatically. The instrument continuously monitors moisture leak in the vessel and neutralizes it automatically.

The built-in reagent standardization procedure by water (H_2O) or Sodium Tartrate ($\text{C}_4\text{H}_4\text{Na}_2\text{O}_6 \cdot 2\text{H}_2\text{O}$) for titre factor/concentration (F) is incorporated.

The liquid handling path comprises teflon tubing, teflon-lined valve, and a gastight syringe with teflon plunger. It creates a chemically inert system for this highly sensitive analysis.

The magnetic, adjustable-speed stirrer is a part of the system in which the sample is stirred vigorously to extract the moisture efficiently.

The result, including the leak rate, is printed in a tabulated form and is also displayed on back lighted liquid crystal display (LCD) screen.

MODES OF OPERATION

Karl Fischer titration is a dead stop titration process which monitors the mV drift to be lower than the stop band, and the end of the titration is detected when the leak rate is close to or less than stop band. The leak rate is displayed and also printed. There are two main modes of operation:

- (a) In minimum dose mode where the end dose is same as the minimum dose, the titration will be stopped when the mV does not rise above the stop band in specified delay time.
- (b) In drift mode, the titration will be stopped if the calculated drift value is less than or equal to entered drift value in $\mu\text{l}/\text{min}$.

APPLICATIONS

- Pharmaceutical
- Food and Beverages
- Petrochemicals
- Cosmetics
- Organic / Inorganic Chemicals etc.

FEATURES

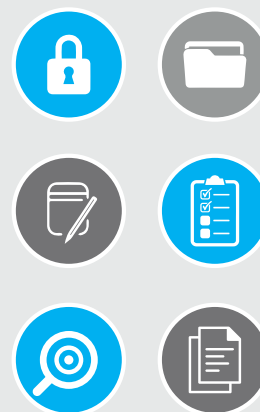
- Advanced Microcontroller based user-friendly, state-of-the-art product design with User interactive software for ease of operation with protection against invalid entries.
- Quick interchangeable imported burette assemblies with intelligent recognition for its volume size. Burette validation factor for dispensing correction is available for true end point volume.
- System recognizes proper connectivity of other peripherals like Burette, Stirrer, Electrode, Pen Drive etc. Gives indication incase of improper connectivity.
- Large memory capacity for method storage with suitable scientific parameters having GLP compliance.
- Sample Name & Identification Number with Date and Time for authentication. Daily Auto Incremented Run number and Factory entered CUSTOMER NAME & Instrument Sr. No. on report printouts make the system foolproof and GLP compliant.
- Quick monitoring, and automatic neutralization of moisture leak into vessel to keep it ready for next titration.
- End point delay up to 100 sec for slow moisture releasing samples.
- On line leak rate correction available.
- Microcontroller based variable speed, magnetic stirrer with digital indication.
- Calculation modes :
 - Weight /Weight
 - Volume/Volume
 - Volume/Density
- Selectable report format, complying with GLP requirements :
 - A) Report giving titration parameter and result.
 - B) Report of method parameters.
 - C) Condensed report of titration parameter and result.
 - D) Graph printout of reaction trend

Reports can be obtained even after resetting / power off / power failure conditions.

- Statistic function with run selectivity for finding Mean, S.D., R.S.D. and C.V. of last 10 repeat run results could be viewed or printed.
- ASTM standard compliant for analysis of oil samples.
- Date & Time display and report printout with run time indication.
- Balance interface to directly transfer the sample weight.

21 CFR PART 11 COMPLIANCE

- Audit Trail for all activities with search facility, report generation and printing
- 200 User ID's with alphanumeric entries of user name, password and role based privileges selection
- Multi-level roles with password protection
- User authentication is performed for each and every operation done by user
- Customizable PDF report file can be created through print
- USB Printing eliminates the need of serial port to connect with instrument
The user can take printout on printer via WiFi connectivity
- Electronic signature functionality
- Manual Archive and Data Backup facility available



Optional

- IQ, OQ, PQ, documents available
- Auto Fill & Drain Pump (i.e. for draining out waste from reaction vessel & to fill with fresh solvent)

SPECIFICATIONS

- **Principle** : Karl Fischer method of volumetric water determination.
- **mV range** : ± 3200 mV.
- **Accuracy** : ± 1 mV.
- **Polarized Measurement range** : 0 to ± 3200 mV
- **Polarized sensor Resolution** : 0.1 mV
- **End point detection** : Voltametric.
- **Polarising Current Range** : 1 μ A to 80 μ A in 8 steps.
- **Polarization Current Resolution** : 0.1 μ A
- **Polarization Current Accuracy**: 1.0 μ A
- **Cut-off criteria** : Delay or drift - user selectable.
- **Measuring Range** : 10 μ g to 500 mg (10 ppm - 100%)
- **Measuring Accuracy**: Better than 0.3% of respective Volume
- **Repeatability** : Better than 0.3% at > 10 mg H₂O
(at ideal analytical conditions)
- **Sensor** : Dual pin platinum electrode.
- **Sensor input** : Through special TNC connector.
- **Burette** : 5ml or 10ml capacity, interchangeable, with auto recognition.
- **Burette Resolution** : 1/5000 for 5 ml (i.e. 1 microlitre),
1/10000 for 10 ml (i.e. 1 microlitre)
- **Filling time** : < 20 sec.
- **Stirrer** : Magnetic capsule type, microcontroller based speed control with digital indication.
- **Display** : 7" TOUCH SCREEN
- **Method Storage** : 16 GB data storage capacity for 200 methods & results.
- **Results** : mg/ml, % , ppm, mg/g and on-line leak rate with cumulative titrant consumption.
- **Drift Measurement**: Online, $< 2 \mu$ g/min

REPORT FORMAT :

- a) **Method parameter.**
 - b) **Titration analysis report.**
 - c) **Titration analysis condensed report.**
 - d) **Statistics and on-line leak rate report.**
 - e) **Graph for reaction trend**
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- **Input/Output peripheral interface** :
 - a) **USB Port** : 1 No. for printer / pen drive
 - b) **Serial Port** : 1 No. for Balance.
 - **Power requirement** : 230 V AC ± 10 %, 50 Hz.
 - **Environmental Operating Conditions** :
 - a) **Operation** : Indoor
 - b) **Temperature** : Ambient to 45 °C
 - c) **Humidity** : 5 to 90% non-condensing.