Determining Specific Gravity and Refractive Index of Triethyl Citrate according to the US Pharmacopeia

Anton Paar's Generation M density meters and Abbemat refractometers deliver accurate and repeatable measurement results while providing system security for 21 CFR Part 11 compliance.

Triethyl Citrate for pharmaceuticals

Triethyl Citrate ($C_{12}H_{20}O_7$) is a triester of citric acid and ethyl alcohol. Being a water soluble plasticizer, it is often used in the pharmaceutical industry as a coating for tablets to influence the rate and extent of drug release.

As a pharmaceutical additive, Triethyl Citrate is generally regarded as safe when used in normal quantities.

The U.S. Pharmacopeia monograph for Triethyl Citrate requires that specific gravity measure between 1.135 and 1.139, per physical test method <841>. In this physical test, the specific gravity determination is based on the ratio of the weight of the tested liquid in air at 25 °C to that of an equal volume of water at the same temperature. The monograph also requires refractive index measure between 1.439 and 1.441, per physical test method <831> performed at 25 °C with 589.3 nm wavelength light.

Testing for Conformance to the US Pharmacopeia Monograph with Anton Paar

Anton Paar's DMA Generation M series of density meters conform to the requirements of Physical Test <841>, Method II, using the oscillating U-Tube principle with industry leading sample temperature control. Instrument software automatically calculates specific gravity by weight, with the integrated apparent specific gravity output parameter.

Anton Paar's Abbemat Performance and Performance Plus refractometers measure refractive index with light at 589.3 nm wavelength and provide Peltier temperature control to 25 °C, conforming to the requirements of physical test method <831>.

These instruments have a standard software that meets 21 CFR Part 11 security requirements, including password protection, electronic signature and audit trail. Measurement, check and audit trail data can be exported locally, to network FTP sites or integrated into customers' LIMS.

Pharma Qualification Packages

- Available for DMA Generation M and Abbemat Performance and Performance Plus lines
- Fulfills all requirements of GMP, GAMP 5, 21 CFR Part 11 and USP<1058>

Modulyzer – Run DMA Generation M and Abbemat from one screen

- Simultaneous measurements of numerous parameters make lab work more efficient
- Custom connection kits and micro flow cells available to minimize required sample volume
- Filling in one step either by syringe or by automated sample changers, optionally with automatic cleaning procedures

Do you have any questions?

Contact Anton Paar directly:
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