Water Technologies & Solutions
application note

low level linearity conductivity study on the Sievers M9 TOC Analyzer

introduction

Per USP <645> the United States Pharmacopeia requires reporting of conductivity of water for pharmaceutical purposes. Water conductivity must be measured accurately using instrumentation that has been calibrated and meets the specifications and operating parameters set forth in USP <645>.

The Sievers* M9 Total Organic Carbon (TOC) Analyzer with sample conductivity can be used for simultaneous Stage 1 conductivity and TOC reporting. The M9 Analyzer is fully compliant with USP <643> and <645>. A detailed analysis of the M9 and how it complies with both regulations can be found in the white paper, "Electrical Conductivity, Temperature Dependence, and the Sievers M9 Analyzer" and the application note, "Sievers Lean Lab: Simultaneous Stage 1 Conductivity and TOC Lab Testing of Pharmaceutical Water".[1,2]

The Stage 1 conductivity limit stated in USP <645> at 25 °C is 1.3 µS/cm. At these low levels, verifying performance of a conductivity meter and probe or an online cell can be challenging. Low-conductivity samples and standards can be easily contaminated by their container or exposure to carbon dioxide in air as it diffuses into the sample and dissociates.

To help eliminate unnecessary investigations related to contamination of low-level standards while still ensuring the integrity and accuracy of the conductivity measurement, the study presented in this application note demonstrates linearity of the M9 Analyzer at low conductivity levels. Performance at higher conductivity levels can be verified during routine analysis.

linearity of the M9 Analyzer at low conductivity levels

To demonstrate the linearity and accuracy of the Sievers M9 TOC Analyzer for sample conductivity, especially at low conductivity levels, a study was performed by SUEZ.

A commercially available 100 µS/cm sodium chloride (NaCl) standard was carefully diluted to nine different concentrations using high-purity DI water in Sievers Dual Use Conductivity & TOC (DUCT) vials. Sievers DUCT vials have a proprietary coating and do not contribute to either conductivity or TOC through leaching or absorption.

Results of this study are illustrated in **Figures 1** and **2**. All data are blank adjusted and temperature compensated to 25 °C. **Figure 2** specifically demonstrates conductivity measurements below 10 µS/cm to support the low-level linearity and accuracy specifications of the M9 Analyzer.

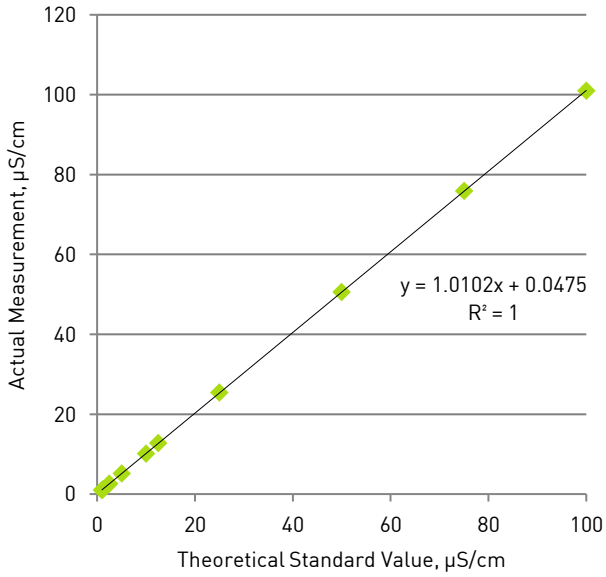

Figure 1: Measured versus expected conductivity for 1 to 100 µS/cm

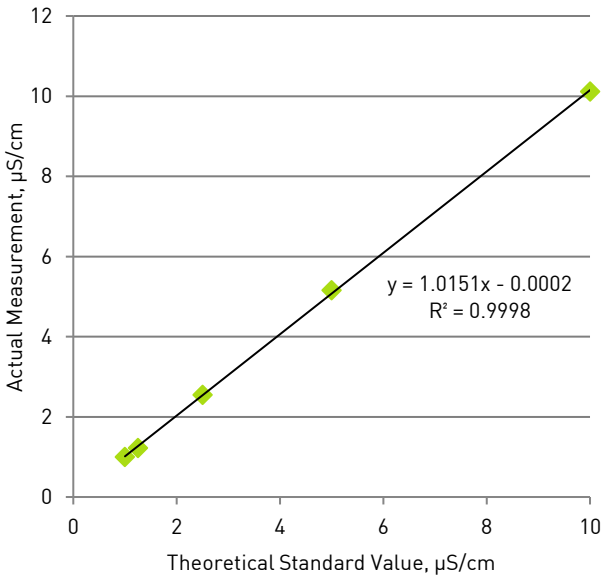

Figure 2: Measured versus expected conductivity for 1 to 10 µS/cm

conclusion

The results of this study demonstrate high accuracy and linearity of the Sievers M9 TOC Analyzer for sample conductivity across a wide dynamic range of conductivity levels. Customers can therefore have confidence, even at low conductivity levels, when using the M9 Analyzer to measure Stage 1 sample conductivity for USP <645> requirements.

With the high degree of linearity and accuracy for sample conductivity demonstrated below 10 µS/cm in this study, routine verification of M9 conductivity accuracy can occur at higher conductivity levels (e.g., 25 µS/cm) to minimize the effect of any contamination of the verification standard.

Using the Sievers M9 Analyzer for simultaneous measurement of TOC and conductivity can streamline lab processes and enable companies to increase efficiency.

References

1. Electrical Conductivity, Temperature Dependence, and M9 Analyzer, 300 00322, 2016. Retrieved Dec. 20, 2016, from https://geinstruments.com/down-media?f_id=42654
2. Sievers Lean Lab: Simultaneous Stage 1 Conductivity and TOC Lab Testing of Pharmaceutical Water, 300 40030, 2018. Retrieved Mar. 14, 2018, from https://geinstruments.com/down-media?f_id=43067