Validation of the Resistive Pulse Sensing Method for Characterizing Nanoparticle Formulations for Drug Delivery
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Introduction
Precise characterization of nanomaterials is increasingly important as nanotechnology is deployed broadly across industry. However, accurate and rapid analysis of the size and concentration of nanoparticles has until now been lacking. Spectradyne’s nCS1 offers a new implementation of the resistive pulse sensing method and delivers:

- **True orthogonality to optical methods.**
- **High resolution size distributions.**
- **Sizing range: 40 nm - 2 µm diameter.**
- **Absolute concentration measurements.**
- **Concentration range: 10^6-10^{12} particles/mL.**
- **All particle materials.**
- **Arbitrary polydispersity.**
- **Total sample analysis in minutes.**

Superior Accuracy and Resolution.
A highly polydisperse mixture of particles with NIST-certified mean diameters of 52, 94, 122 & 150 nm is accurately measurable by the nCS1, as shown in Figure 1. In contrast, neither optical tracking nor DLS are able to measure the true composition of the sample.

Effective Formulation Stability Analysis.
Measurements of two different nanoparticle-based drug formulations clearly identified degradation of the formulation, as shown in Figure 3. Other measurement technology is unable to provide such high resolution size distribution information.

Conclusions
The resistive pulse sensing method as implemented in Spectradyne’s nCS1 is a proven high-precision technique for sizing and quantifying nanoparticle-containing drug formulations. The nCS1 demonstrates a highly linear response to varying particle concentration, and yields a precise, repeatable characterization of the distribution of mean 63 nm diameter nanoparticles in a commercial nanoparticle formulation. The nCS1 clearly distinguishes normal and degraded formulations by providing high-resolution particle size distributions, data unobtainable with other techniques. Finally, in a direct comparison with other leading particle analysis techniques, the nCS1 clearly demonstrates its superiority in measuring polydisperse samples.