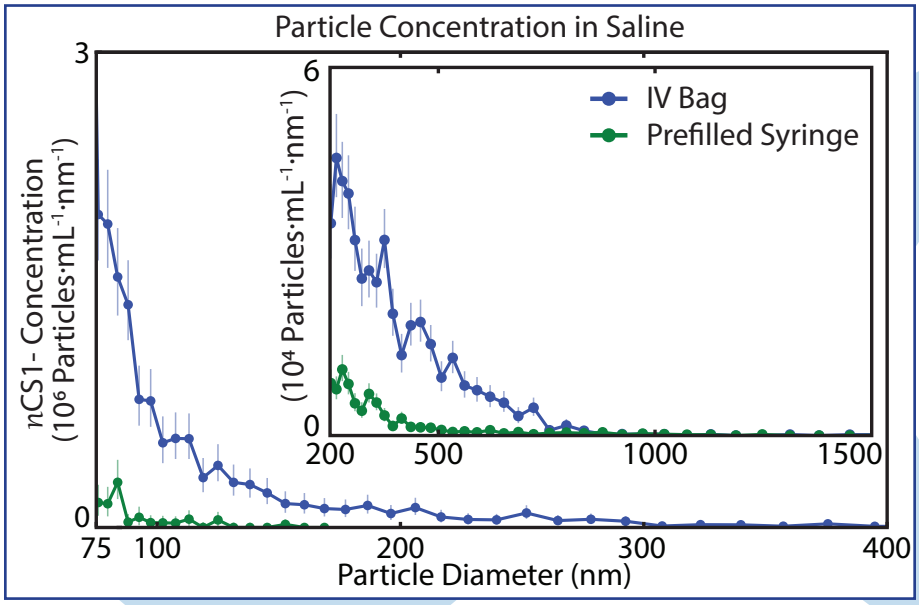
Spectradyne®
Particle Analysis

Measuring Cleanliness of Fluids Using the nCS1™

Cleanliness of any fluid, but in particular those put into the human circulatory system, can be of paramount importance. In the case of these fluids, particulates present must be physically small enough to easily pass through the circulatory system, be processed and released as waste, in addition to being non-toxic. Submicron filtration may be used on these fluids to remove particulates. Stringent regulatory requirements already exist for both visible (>100µm) and sub-visible (1-100µm) particulates in parenteral liquids.

As reliable measurement techniques for nanometer (<100nm) and sub-micron (100-1,000nm) particles become available, we can expect closer scrutiny of these particulates as well. While much attention is spent on looking at these particulates in drug formulations themselves, parenteral fluids such as IV saline also need to be checked for particulates. Spectradyne's innovative nCS1™ nanoparticle analyzer is ideally suited for accurate quantification of these particulates.



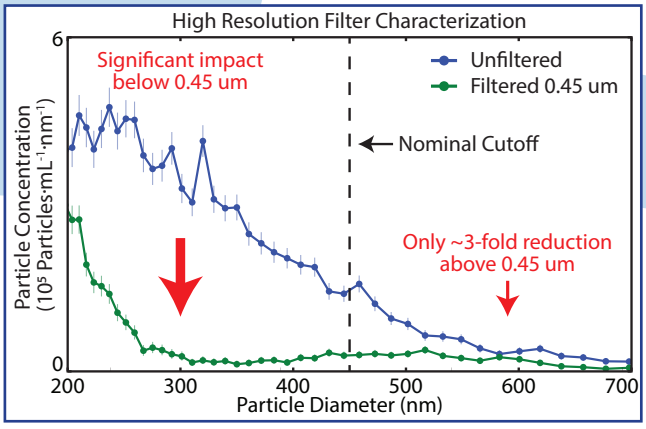
To demonstrate the efficacy of the nCS1 in looking at IV saline, two sources of 0.9% saline were compared for particulate content. One source was an IV bag, the second was a pre-filled flush syringe. The figure to the right shows the results for two size ranges, 75-400nm and 250-1600nm (inset). The table below summarizes the absolute concentration results for two different ranges:

Particle Concentration (1/mL)		
Source	75-250nm	250-500nm
IV Bag	6.27E+07	8.92E+06
Syringe	4.12E+06	1.37E+06

The results clearly show that the saline in the pre-filled flush syringe (green) is cleaner than the bagged IV saline (blue). These measurements highlight the broad size range of the nCS1 (in this case 75-2,000nm) over a concentration range of nearly six orders of magnitude.

In a related study, the effect of filtering a nanomedicine component was recorded using the high resolution of the nCS1. A sample containing a broad distribution of ferromagnetic particles used for cell isolation was analyzed before and after filtration through a cellulose acetate membrane with a 0.45µm nominal pore size. As a positive control, 794nm polystyrene beads were added to both samples at a final concentration of $2x10^7$ particles/ml (the control was added to the filtered sample after filtration).

The results of the filter study are shown at right, with the unfiltered sample in blue and the filtered one in green. What was surprising was that the filter removed a significant number of particles well below its rated size of 0.45µm. In addition, the filter showed relatively poor (only ~ 3-fold) particle rejection in the 450-750nm size range. This indicates relatively poor filter performance versus what would be expected.



No other nanoparticle analysis technology can make the measurements shown above with the resolution, reliability and ease of the nCS1. For more information or to arrange a demonstration of the technology, please visit our website or contact us by email.