Nano Drug Delivery: Integrated Visual and Chemical Confirmation

CytoViva® Illuminating the Future

For regulatory authorities tasked with approving new nano drug delivery vectors, integrated visual and chemical validation of the samples is becoming increasingly important. This integrated approach enables cross validation of chemical data from mass spectroscopy techniques along with nanoparticle concentration and size distribution data from light scattering measurement techniques.

CytoViva Enhanced Darkfield Hyperspectral Microscopy is viewed as an important tool to provide this integrated visual and chemical-spectral validation for these nano drug delivery vectors. Enhanced darkfield hyperspectral images provide spectral validation of the active pharmaceutical ingredient (API) loading within the nanoparticle vector, while also providing valuable visual observation regarding nanoparticle concentration and size consistency across the sample. Also, because hyperspectral validation of the API can be conducted at the individual nanoparticle level, it is possible to confirm the consistency of the drug loading process among nanoparticles in the sample batch.

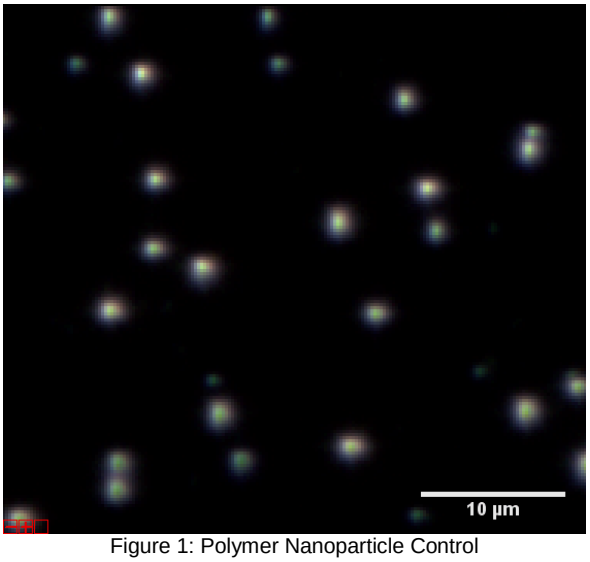

Figure 1: Polymer Nanoparticle Control

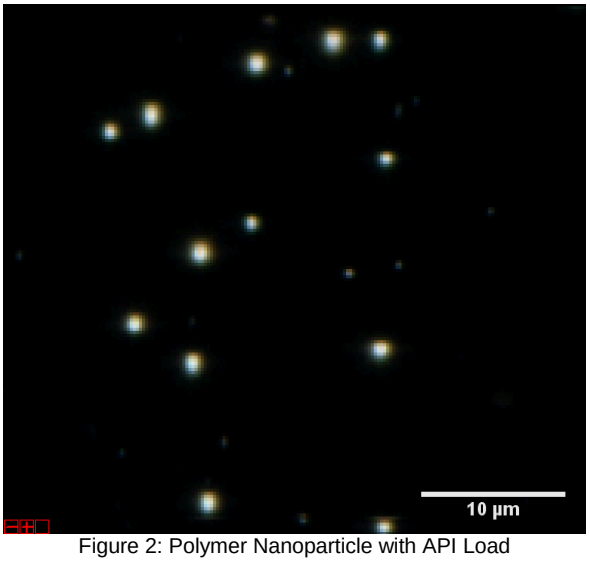

Figure 2: Polymer Nanoparticle with API Load

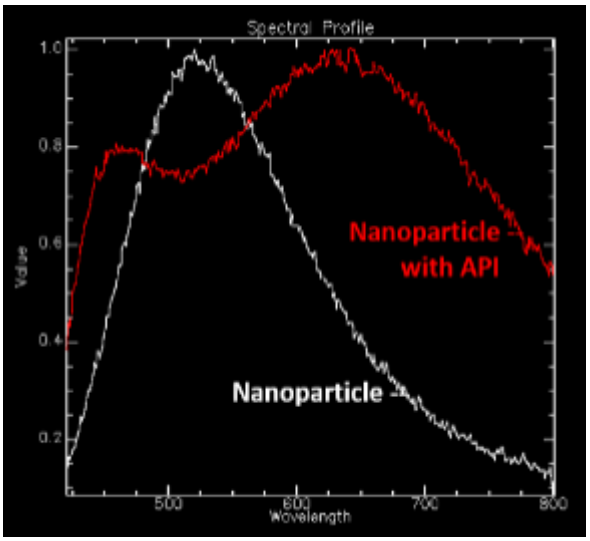

Figure 3: Spectral Response of Polymer Control (white) and Polymer API (red)

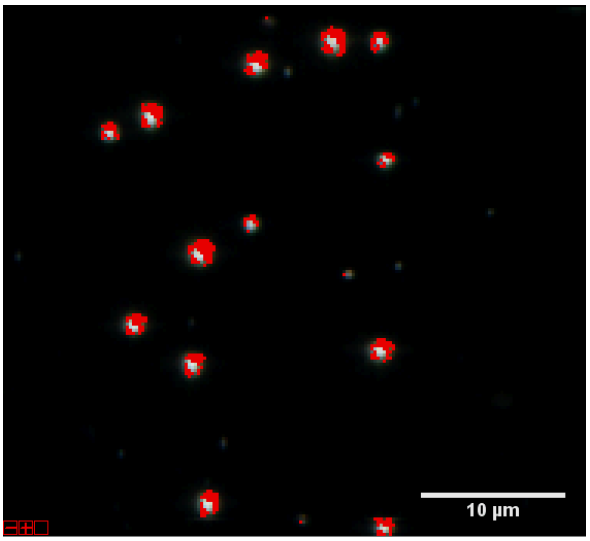

Figure 4: Spectral Mapping (in red) of the API Chemistry in the Nanoparticle

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To demonstrate how the system is typically used in this application, figure 1 above illustrates an enhanced darkfield hyperspectral image of a polymer based nano drug delivery construct. This is a control sample with no loading of an active pharmaceutical ingredient (API). Figure 2 illustrates the identical polymer sample with the API loading. While they look very similar optically, there is a distinct and highly repeatable difference in the spectral response of the API loaded sample versus the control as is illustrated in figure 3. To demonstrate the consistency of the presence of the API in the polymer nanoparticles, spectral mapping (in red) of the nanoparticle API spectrum was conducted in figure 4. You can see that the loading of the API in the nanoparticles is uniform across the sample based on the spectral mapping. It is also noteworthy that the API is consistently mapped in the same areas of each particle.

In addition, counts of these nanoparticles within the sample can be conducted along with size distribution consistency using simple imaging analysis tools such as Image J. These data points will help to cross validate counts and size homogeneity of the nanoparticles as measured with light scattering and related techniques.

The following link provides a copy of an FDA poster recently created that provides a more detailed example illustrating the potential for Enhanced Darkfield Hyperspectral Microscopy to be utilized for cross validation of nano drug delivery vectors, with respect to API loading, counts and size distribution. FDA Nano Drug Poster

Please contact CytoViva at info@cytoviva.com to learn more about Enhanced Darkfield Hyperspectral Microscopy and how it can help you cross validate your nano drug delivery construct and potentially expedite the regulatory approval process.