

June 1st 2011

THE PARTICLE COUNTER. USEFUL FOR FORMULATION AND PROCESS DEVELOPEMENT OF PARENTERALS.

Comments by major pharmaceutical company research scientist.

We've found the Spectrex to be a very useful tool in formulation and process development for parenteral products in cases where the volume of solution available is limited, and we are primarily interested either in 1) differences in relative numbers and sizes of particles when comparing various formulations or processing treatments, or 2) changes in relative numbers of particles with time. By being able to count particles non-destructively, we are able to perform counts on the same vial over arbitrarily long periods of time. By using the small vial attachment, we are able to limit the volume of sample to about 3 ml in a 5 ml glass vial. The USP method, by contrast, requires about 25 ml.