

On Site Testing Report

Water for Injection
Pfizer
Kalamazoo, MI

Testing Overview:

JM Canty's InFlow™ Particle sizing instrumentation was set up to sample a continuous stream of WFI within the Pfizer Kalamazoo MI plant. The testing began on August 8, 2013 and ended on August 12, 2013 encompassing four days of continuous testing. Concentration (PPM), gas, & solid size distribution were analyzed during the testing period. Outputs for PPM were set for every 3 minutes, while outputs for gas and particle size distribution were set for every 4 hours.

Data:

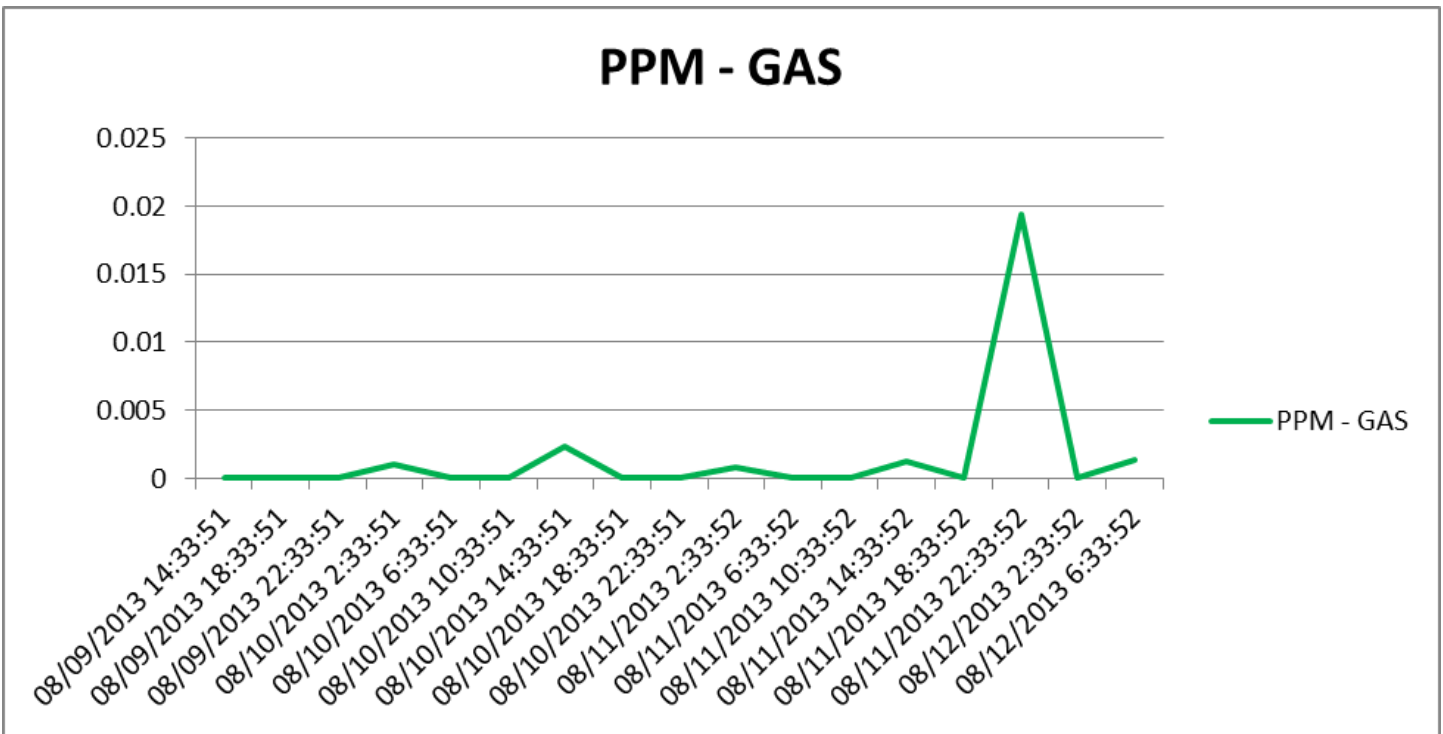


Figure 1 – PPM Gas – Droplets measured with aspect ratio < 1.15

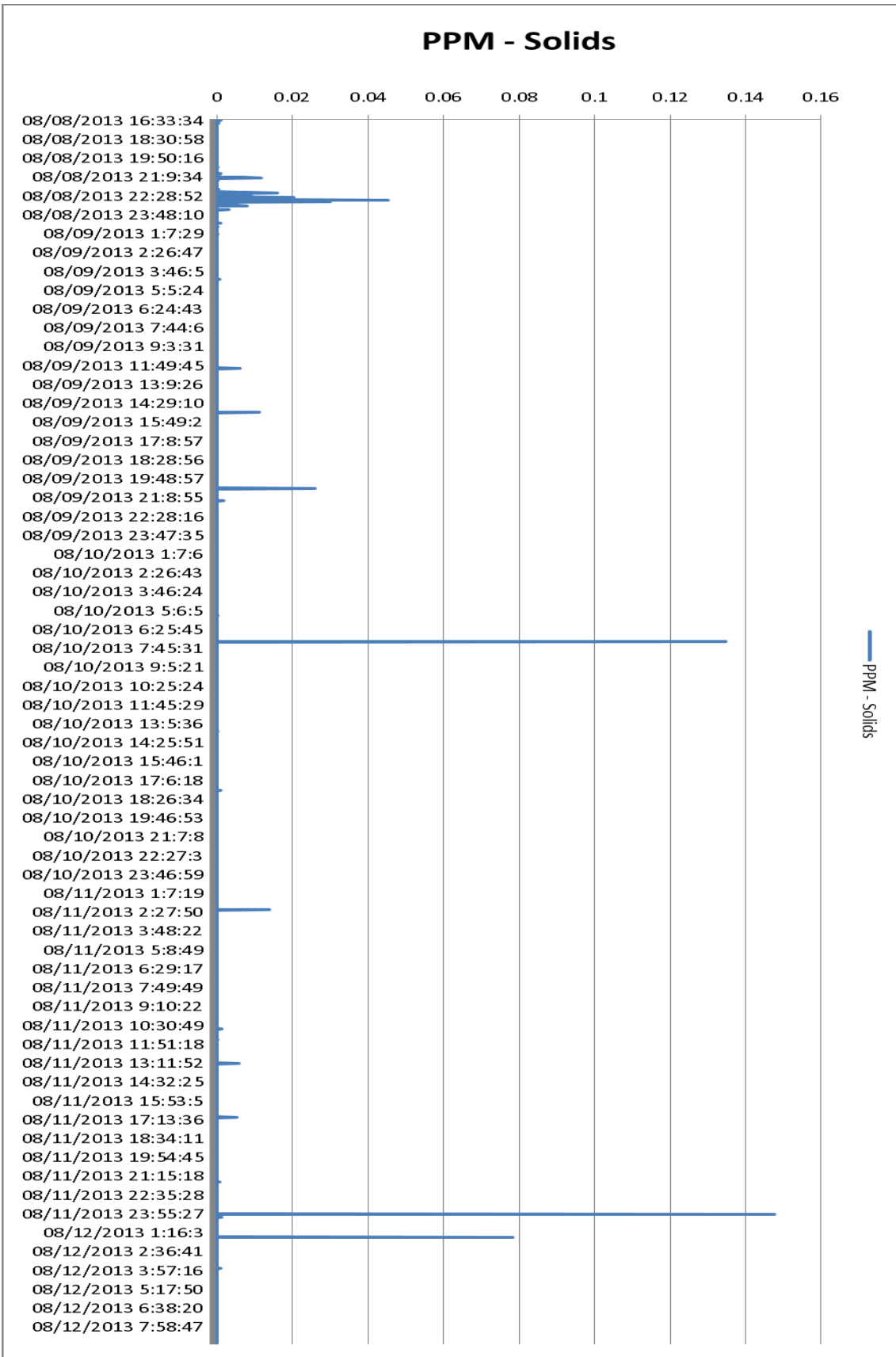


Figure 2 – PPM Solids – Particulate measured with aspect ratio >1.15

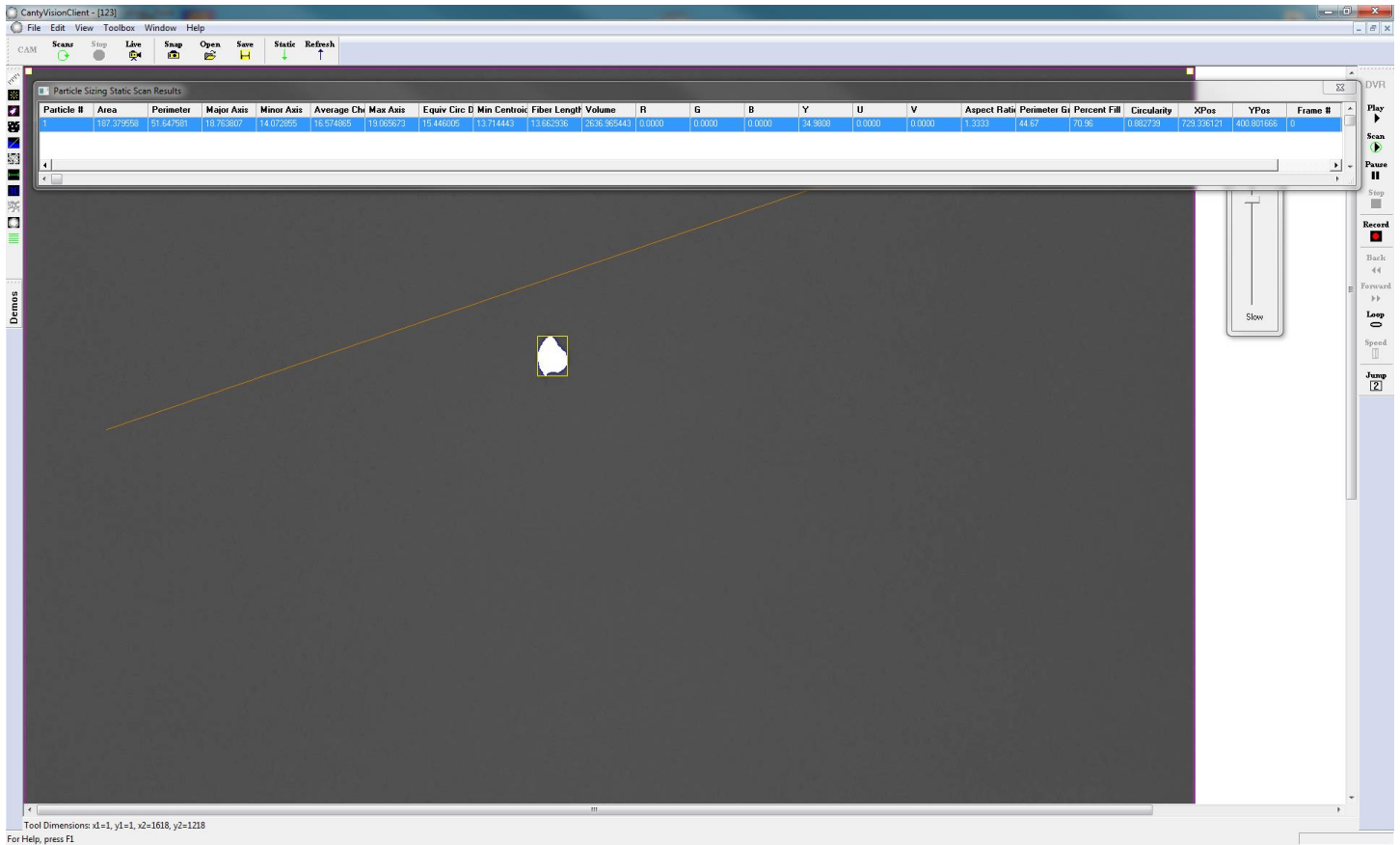


Figure 3 – Image of Particle detected within software - 13µm particle

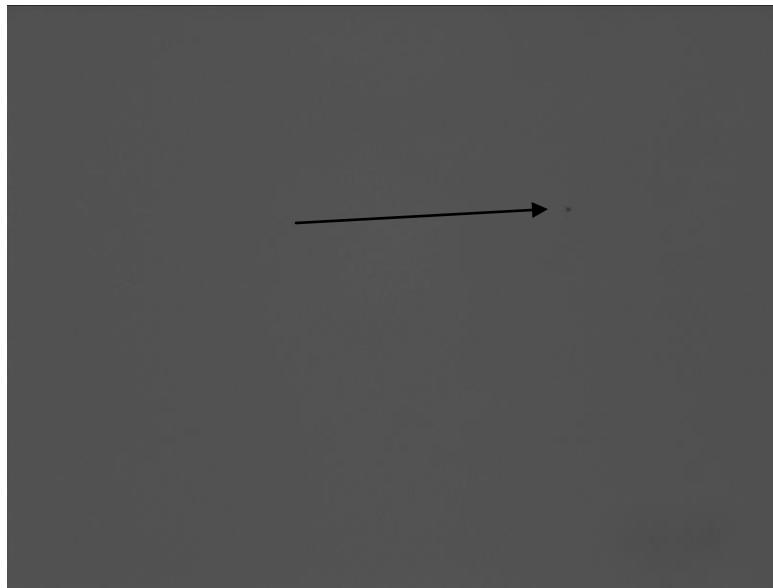


Figure 4 – Image of Particle – 3µm particle

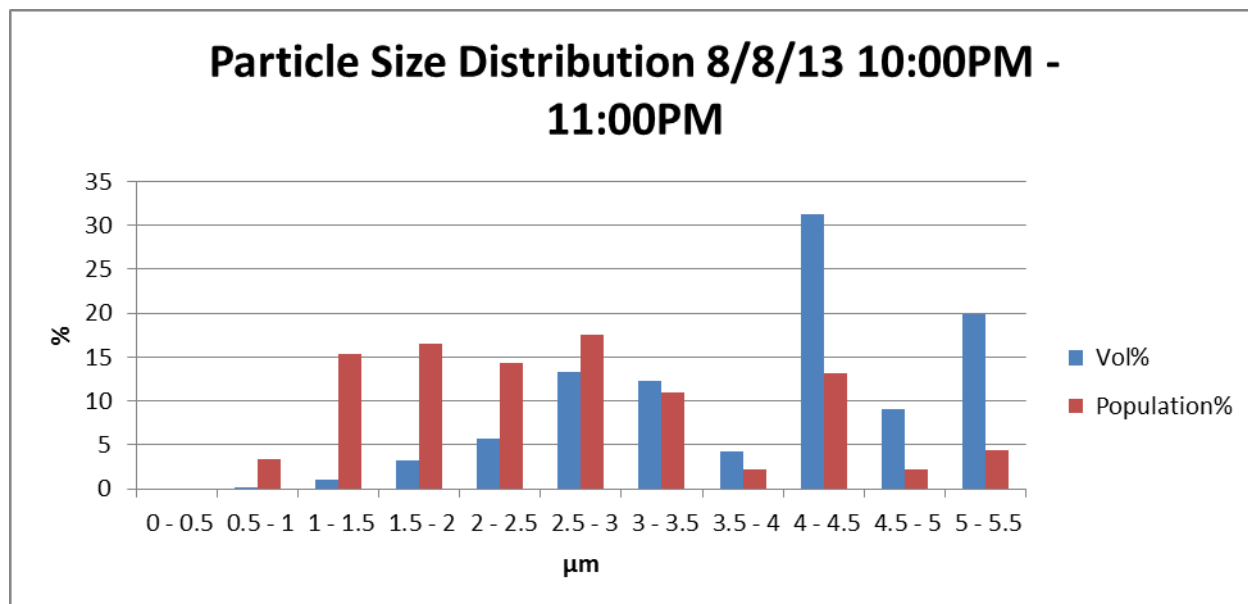


Figure 5 – Particle Size Distribution by Volume & Population

Conclusion:

JM Canty’s particle analysis equipment was able to see and analyze particulate within the WFI stream supplied. Gas concentration detected was very low. Particle concentration detected was also low during the majority of the analysis time; however spikes in this concentration were detected during the analysis period. Most spikes were consistently detected during 8PM & 12AM on all days except 8/10/13. The majority of particles analyzed had an aspect ratio < 2; implying those particles detected were solids. Canty software was able to give visual verification of detected particles proving their presence.