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MFI™ for Analysis of Dissolution, Precipitation, Agglomeration and Contamination in Biological Solutions

Analysis of dissolution, precipitation, agglomeration and contamination is important in the formulation, handling and stability assessment of biological solutions such as buffers (e.g. PBS) and growth media (e.g. MEM, MLM, GG). Existing analysis techniques involving manual microscopy can be subjective, labor intensive, and limited in terms of statistics. Automated techniques using light scattering or light obscuration are indirect measurements which assume a homogenous particle population, and are often incompatible with colored or viscous solutions.

MFI™ is a new technique which employs digital imaging of a flowing sample stream in order to analyze and quantify the particulate content in these solutions. MFI™ instruments provide sensitive detection, counting, and sizing of each individual particle combined with an automatic image capture and shape analysis capability valuable for diagnosing particle origin. This unique combination of quantitative analysis combined with visual insight can contribute to product quality and process yield enhancement both through more rigorous incoming and in-process inspection and, through the additional insight gained for process development and troubleshooting.

The MFI™ Advantage

Material and Shape Independence: Unlike many indirect particle size measurement technologies, the direct, pixel based imaging technique employed in MFI makes no assumptions of particle size or shape. MFI™ is well suited for heterogeneous outlier populations commonly found in biological solutions.

Concentration Measurement: MFI™ instruments provide highly sensitive detection, counting, and sizing of each individual particle present in each image frame. Each frame represents an accurately known volume of sample, permitting direct measurement of particle concentration.

Selective Image Capture: The selective image capture feature in MFI™ allows a user to store images of any particles detected during the run. These images serve to confirm numerical results and are invaluable for process control, quality control and diagnosis and troubleshooting.

Comprehensive Morphological Analysis: Stored images can be analyzed using the MFI™ morphological analysis module, providing measurement of ECD, Feret's diameter, area, perimeter, circularity and transparency. These additional parameters can be conveniently presented in the form of histograms or scatterplots. This analysis provides further insight into the particle nature and origin.

Speed and Convenience: MFI™ analyzers are easy to operate and analyze multiple image frames per second providing a full population analysis in less than 5 minutes.

Direct Observation: During analysis, image frames are displayed providing immediate visual feedback on the nature of a particle population.

Time-Resolved Sampling: MFI™ systems will time-stamp each image, and produce trend charts of particles size distribution parameters (mean, mode, count, and concentration). The integration interval can be adjusted to accommodate the rate of change to the particle population, and the run duration can extend to 24hrs.

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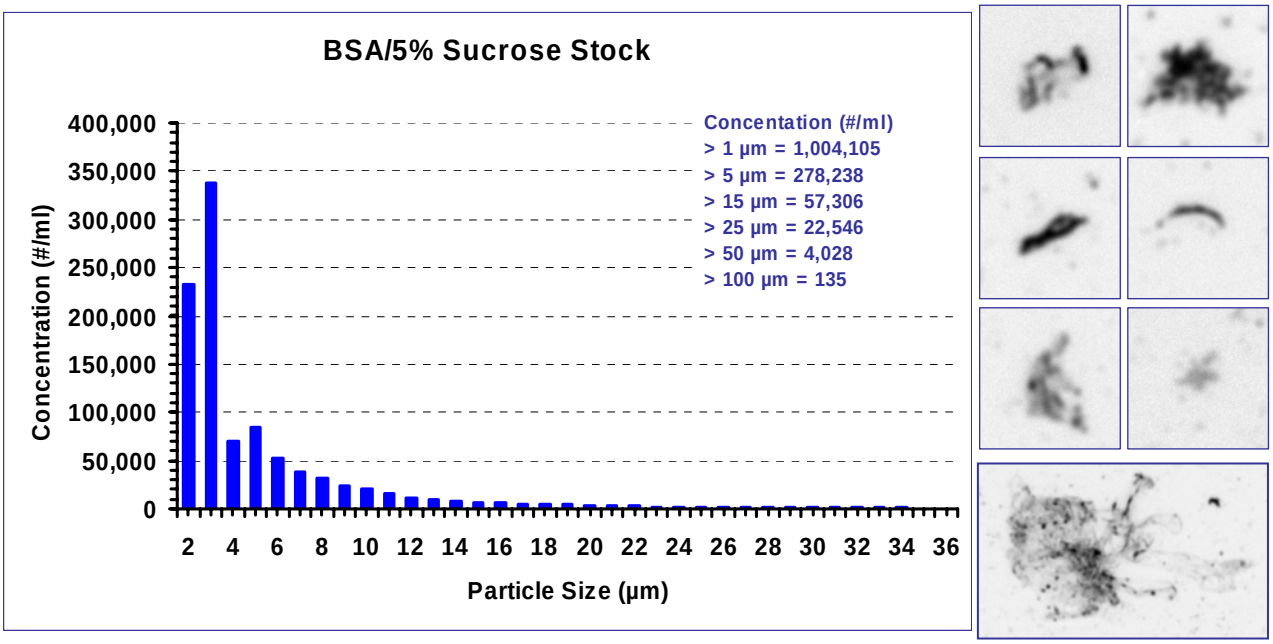
MFI™ Sizing, Counting, Image Capture

The DPA4100 MFI™ system supports operation at two different magnification set points depending on the size range of interest (0.75-100µm or 2.25-400µm). Images can be stored selectively based on detection of particles falling into user-specified size ranges, or sequentially as a function of time. The results below are an example of the DPA4100 analysis of a BSA/Sucrose solution.



MFI™ Morphology Analysis

In addition to measuring the size and concentration of outlier particles, MFI™ can measure the morphological characteristics of the suspended particulate (equivalent circular diameter, Feret's diameter, area, perimeter, circularity, and transparency) using the captured images. Powerful software tools including variable thresholding, histograms, scatter plots, and fully exportable data sets permit comprehensive comparisons across samples and more advanced particulate diagnostics.

Summary

MFI™ instruments provide highly sensitive detection, counting, and sizing of each individual particle combined with an automatic image capture and shape analysis capability. These features provide further insight into the nature and origin of the suspended particulates, and can contribute to product quality and process yield enhancement both through more rigorous incoming and in-process inspection and, through the additional insight gained for process development and troubleshooting.