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News

Biochemistry broadens service options with two new instruments: Micro-Flow Imaging (MFI™) and SoloVPE

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MFI™

Subvisible particles are the class of particles that are less than 100 µm in size. They may be proteinaceous or non-proteinaceous in nature and are under ever-increasing scrutiny by regulators due to the fact that they may pose immunogenicity risks. Current subvisible particulate standards are harmonized across the various compendia (USP, Ph.Eur., JP) and involve monitoring and counting of particles that are ≥ 10 µm and ≥ 25 µm. However, since the primary focus of USP is on extrinsic/foreign particulates in small molecule parenteral drugs, USP is a new chapter that was developed to address therapeutic proteins. In addition, USP is a guidance chapter addressing the task of characterization of particles with the emphasis on proteinaceous particles. FDA expects that now in addition to measuring particulates that are ≥10 µm in size, subvisible particulates in the 2-10 µm range should also be characterized and quantified using technique(s) that can accurately estimate the amount of subvisible protein particulates present. One of these techniques is flow imaging microscopy.



Eurofins Lancaster Labs has purchased the Protein Simple Micro-Flow Imaging™ (MFI™) 5200 system to support our clients with aggregate and particle analysis. The MFI™ is capable of measuring and characterizing protein aggregates and other particulates such as, air bubbles, silicone oil droplets and contaminants in the sub-visible and visible ranges. This technique is a critical tool for characterizing subvisible particles in stress studies, in-use studies, and pharmaceutical manual studies. Further, the instrument is validated for cGMP purposes.

SoloVPE

One of the most critical measurements of a biopharmaceutical product is the protein concentration or A280. This is typically determined by UV-VIS spectroscopy. One of the challenges associated with this technique is the sample preparation, in particular the ability to perform extremely accurate dilutions. Many proteins tend to “stick” to plastic and glass and also can be quite viscous. This can be exacerbated by high concentration protein solutions, which may require the dispensing of small aliquots and/or serial dilutions. Therefore, a relatively simple assay can become highly dependent on analyst technique and expertise and yield results with greater than desired error. In order to compensate for this error, multiple replicates are usually performed in order to monitor precision.



The C Technologies, Inc. SoloVPE System is an alternative approach to the traditional UV-Vis

spectroscopy for determining protein concentration. While still utilizing the measurement principles based on the Beer-Lambert Law, the pathlength is varied dynamically; whereas conventional instruments use a single fixed pathlength. This technique is known as slope spectroscopy. The ability of the SoloVPE System to take direct measurements of this slope value allows for rapid determination (less than one minute) of protein concentration when the Extinction Coefficient is known. This instrument has been shown to perform better than traditional A280 methods for high concentration protein samples over a range of 0.01 mg/ml to 300 mg/ml. However, one of the biggest advantages of this technology is the fact that samples can be run without dilutions, thus eliminating the human error discussed above. Further, this technique requires no baseline correction. The software is 21CFR11 compliant so the instrument can be utilized for cGMP analyses (stability and release testing).