

Rapid characterization of formulations: Protein size, aggregate levels and viscosity

David M Goodall
Paraytec Limited, UK

The aim of this presentation is to introduce the principles and practice of instrumentation for characterizing protein formulations without the need for any treatment such as filtration or dilution. Generic methods will be illustrated for measurement of protein size, aggregate levels and viscosity of the formulation. The methodology is well suited for rapid characterization to investigate developability of formulated proteins and biopharmaceuticals, including biosimilars. The Viscosizer 200, now commercially available from Malvern Instruments, is designed to determine the size of molecules and particles with hydrodynamic radii in the range 0.05 – 150 nm, and to provide information on the relative viscosity of their solutions and formulations. The technique is based on UV imaging of a sample during pressure driven flow through a looped capillary. Taylor dispersion analysis gives high precision values of diffusion coefficient and hydrodynamic radius, and also quantifies sub-visible protein particles. Relative viscosity is obtained from comparison of timing between the two imaging windows to that of a dilute reference standard. Benefits of this methodology include: applicability to protein formulations over a wide concentration range; extended run sequences through system automation; and small volumes of materials required per run, typically 5 microliters. Viscosity measurements will be illustrated by work on protein solutions with concentrations up to 350 mg/mL, and studies of test proteins including BSA carried out by Malvern Instruments in collaboration with Paraytec.

Biography

David Goodall is CSO and founder of Paraytec Limited, based in York, UK. Paraytec's main customer focus is to provide early insights for those working in analytical and preformulations R&D and assessing developability of biopharmaceuticals and pharmaceuticals. David is also Emeritus Professor of Chemistry at the University of York, where his speciality was analytical science and instrumentation. He is the author of over 150 papers and has received awards from the Chromatographic Society and the Royal Society of Chemistry. Collaborative work with industrial and academic partners includes a project characterising protein aggregation during which prototypes of the instruments were developed.

david.goodall@paraytec.com