

Taylor dispersion analysis, a rapid, nanolitre method to monitor protein aggregation behaviour

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Biosimilar pharmaceuticals are complex biological molecules that have similar physicochemical properties to the originator therapeutic protein. They are produced by complex multi-stage processes and are not truly equivalent. Comparability studies between biosimilars are complex and difficult due to the further issues of immunogenicity. It is not currently possible to completely characterize every variation of a protein and therefore more analytical technologies need to be utilized given the increase in the number of biosimilars being produced as multiple patents expire. We explore the use of Taylor dispersion analysis (TDA) compared to dynamic light scattering to analyse a series of model proteins and commercially available biopharmaceutical formulations. BSA is known to exhibit the batch to batch variability and process induced physical changes that have been reported in biosimilar products. Inter and intra batch differences were evident in all grades of BSA analysed. Results for these samples indicated good correlation between the techniques for investigating aggregation behaviour. Analysis of formulated products including IgG1, IgG4, Mabthera, Enbrel, Oxytocin, Humira and Insulin showed that unlike conventional analytical methods, the complex excipient mixtures do not affect measurements. The reproducibility of TDA measurements enabled the stability and reversibility of aggregates to be more readily monitored than by using other techniques.

Biography

Wendy is a Lecturer in Biopharmaceutical Innovation within the School of Pharmacy at the University of Bradford, UK. She received her B.Sc. in Chemistry with Pharmaceutical and Forensic Science in 2001, before completing her PhD in Biopharmaceutics in 2005. Here she studied the effect of excipient combinations to stabilise both solid and liquid protein formulations for pulmonary delivery. From there Wendy moved to Glaxo Smithkline to take up a position as Physical Properties Scientist. However, it was her passion for biopharmaceutical research that led her back to academia in 2008 to undertake her Research Lectureship. In this role, Wendy has already successfully developed a novel sizing technology to determine low level aggregates for biopharmaceutical development. Here, BFG's expertise was evident as the only academic collaborator in the £1.2million Technology Strategy Board (TSB) award for this development.

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