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Investigating the influence of Polysorbate 20/80 and Polaxamer P188 on bovine serum albumin and lysozyme aggregation, rheology and interfacial properties

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This study for the first time details the effect of the PS 20, 80 and Poloxamer P188 on the interfacial and bulk rheological properties through novel advanced characterization techniques. The current challenges faced in the formulation of high concentration protein-based therapeutics include protein stability/ aggregation and high viscosity. Although there has been significant progress in developing a mechanistic understanding of the protein systems themselves, the impact of the other formulation components has been very limited. Excipients like surfactants such as Polysorbate, or Polaxamers which are commonly utilized in biotherapeutic formulations may potentially impact many of these aspects. However, a detailed and systematic study of the effect of these excipients on protein aggregation and corresponding effects on bulk rheology evolution has not been carried out. Additionally, the impact on interfacial and surface properties has been limited in the range of formulation conditions and an impact on interfacial rheology has not been investigated in detail. In this study, we utilize a range of advanced characterization techniques such as optical and microfluidic rheometry, interfacial rheometry, DLS and tensiometry as well as thermal aggregation studies to develop new insights into the impact of Polysorbate 20, Polysorbate 80 and Poloxamer P188 surfactants on the aggregation behavior, rheology and interfacial and surface properties of Bovine Serum Albumin (BSA) and Lysozyme.

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