Polysorbate identity and quantity dictates the extensional flow properties of protein-excipient solutions

Kathleen Lauser[1], Amy Rueter[1], and Michelle Calabrese[1]

[1]University of Minnesota Twin Cities

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Abstract

While protein medications are promising for treatment of cancer and autoimmune diseases, challenges persist in terms of development and injection stability of high-concentration formulations. Here, the extensional flow properties of protein-excipient solutions are examined via dripping-onto-substrate (DoS) extensional rheology, using a model ovalbumin protein (OVA) and biocompatible excipients polysorbate 20 (PS20) and 80 (PS80). Despite similar PS structures, differences in extensional flow are observed based on PS identity in two regimes: at moderate total solution concentrations where surface tension differences drive changes in extensional flow behavior, and at small PS:OVA ratios, which impacts the onset of weakly elastic behavior. Undesirable elasticity is observed in ultra-concentrated formulations, independent of PS identity; higher PS contents are required to observe these effects than with analogous polymeric excipient solutions. These studies reveal novel extensional flow behaviors in protein-excipient solutions, and provide a straightforward methodology for assessing the extensional flow stability of new protein-excipient formulations.

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