02 Protein Aggregation in Disease: The Next Phase

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Protein Aggregation in Disease: The Next Phase Protein Fibrillation Associated to Shear Stress During Low Volume Aseptic Filling of Injectable Pharmaceuticals.

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The formation of intrinsic protein particles (IPPs) within injectable pharmaceutical formulations has been reported during the low volume aseptic filling process in several studies. While this occurrence is specific to the protein and its formulation, there exists evidence hinting at a potential correlation between these events and the application of shear stress forces during the filling unit operation.

Consequently, we have developed a microfluidics-based method to induce shear stress in a controlled manner, reproducing the formation of IPPs. To gain deeper insights in the molecular mechanism of the particle formation, we have explored different variables. These investigations aim to elucidate the primary factor driving particle formation, determining whether it indeed arises from the applied mechanical force or if it is intricately linked to potential surface or interface interactions among the molecules.

After identifying the principal factors contributing to the formation of IPPs under shear stress, the next objective is to establish a platform capable of assessing the protein and/or formulation sensitivity to form aggregates during the low volume filling process. This endeavour holds the potential to facilitate the development of more resilient biopharmaceutical products.