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Study of early stages of protein aggregation/denaturation following mechanical agitation

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In recent years, polypeptides and proteins used in therapeutic applications have increased dramatically and as a result have driven the development of a variety of pharmaceutical formulation and manufacturing approaches. One core process in all macromolecules-based formulation is the process of mixing (agitation). Different methods of agitation is currently employed in the biopharmaceutical industry, each depending on its efficacy and anti-disruptive nature. The sensitive native structure of protein can easily be disrupted during the application of this critical process which could result in poor therapeutic efficacy and production efficiencies. In this study, the early stages of protein aggregation/denaturation following mechanical agitation was analysed using three independent technologies. The particle size of the protein macromolecules was analysed with Dynamic Light Scattering (DLS) (Zetasizer Omni, Brookhaven). Protein aggregation/denaturation was also measured with turbidimetry (UV/Vis 360 nm) and fluorescence spectroscopy (Thioflavin T assay). Three types of mechanical stresses were applied for Bovine Serum Albumin (BSA) in aqueous solution: low shear stress (magnetic stirring), high shear stress (passage through syringe and an ocular needle) and mechanical vibrations (sonication). The study has shown that there was some degree of protein unfolding/denaturation for all agitation approaches. The order in degree of unfolding and aggregation based on our data is magnetic stirring process, (i.e., filling vials through the small diameter pipe lines) and can lead to protein degradation resulting in lost therapeutic effect.

Biography

I Ermolina has completed her PhD from Kazan Institute of Biochemistry and Biophysics, Russian Academy of Sciences in 1995, following by Postdoctoral studies from Hebrew University of Jerusalem, Glasgow University and Southhampton University. Currently, she is a Senior Lecturer at De Montfort University, Leicester UK, teaching the pharmaceutical technology, pharmaceutical material sciences and analytical techniques. She has published 45 papers in peer reviewed journals and has been serving as a Reviewer for few sceintific journals.

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