Aggregation of Therapeutic Proteins

Edited by Wei Wang & Christopher J. Roberts



Kirsty Ratanji

Aggregation of Therapeutic Proteins from Dilute Towards Concentrated Conditions Lucrèce Hélène Nicoud, 2016 Investigating the Immunogenicity of Therapeutic Proteins Kirsty Ratanji, 2017 Stress-induced Aggregation of Therapeutic Proteins Lu Liu, 2013 Therapeutic proteins are inherently unstable Stresses such as freeze thawing and agitation can induce protein aggregation and consequently reduce drug efficacy or cause adverse immunogenicity. The aims of this thesis were to better understand stress induced protein aggregation through novel findings in other disciplines such as biophysics and interfacial sciences We studied the effects of pH and additives on freezing induced perturbations of tertiary structure of a monoclonal antibody mAb by intrinsic tryptophan Trp fluorescence spectroscopy We found freezing induced protein aggregation may or may not first involve the perturbation of its native structure followed by the assembly processes to form aggregates Depending on the solution conditions either step can be rate limiting This study demonstrates the potential of fluorescence spectroscopy as a valuable tool for screening therapeutic protein formulations subjected to freeze thaw stress We investigated the effects of excipients on protein aggregation during agitation as well as the effects of same compounds on interfacial shear rheology of the protein at air liquid interface Heparin sucrose and Polysorbate 80 PS80 alone could not effectively inhibit a model protein keratinocyte growth factor 2 KGF2 FGF10 aggregation during non agitated and agitated incubation The combination of PS 80 and heparin or sucrose substantially inhibited aggregation during both protocols Interfacial shear rheology provides insight regarding the rate of gel formation and the role of non ionic surfactants at the interface There is a correspondence between formulations that exhibited interfacial gelation and formulations that exhibited agitation induced aggregation We also found filters used to remove particles from protein solutions actually shed particles which stimulated protein aggregation during stresses such as agitation Particles shedding from syringe filters varied greatly among the filters types from the manufacturers Furthermore particles shed from the filters may change the rate of protein aggregation during agitation Last but not least we found bevacizumab repackaged in plastic syringes could contain protein aggregates and was contaminated by silicone oil microdroplets Freeze thawing or other mishandling can further increase levels of particle contaminants This study may help to reduce mishandling of repackaged bevacizumab caused adverse effects in patients with eye diseases Prediction and Characterization of Therapeutic Protein Aggregation Lorenzo Gentiluomo, 2020 Formulation of Therapeutic Proteins Hristo Lyubomirov Svilenov, 2019

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