

EFFECT OF AGITATION ON PROTEIN AGGREGATION IN VIALS MADE FROM GLASS OR PLASTIC

Birgit Mueller-Chorus, West Pharmaceutical Services
birgit.mueller-chorus@westpharma.com
Erica Tullo, West Pharmaceutical Services
Vinod Vilivalam, West Pharmaceutical Services
Lloyd Waxman, West Pharmaceutical Services

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The increasing use of proteins as therapeutics including monoclonal antibodies has focused attention on the need to maintain the stability of these labile molecules during both storage and shipment. The degradation of therapeutic proteins can arise from aggregation and adsorption in primary containers, as well as from exposure to leachables, and chemical damage due to exposure to oxygen or light. Since vials continue to be used as primary containers for multiple-use applications, including vaccines and lyophilized drug products, we have compared the effect of mechanical stress on protein aggregation in vials made of glass versus vials made of the plastic cyclic olefin polymer (COP). The goal of the study was to first develop and characterize a simple stress model consisting of rotating vials placed horizontally on an orbital shaker. The second goal was to use this method to compare aggregation in vials made from COP or glass. It was shown that proteins have a reduced tendency to aggregate in COP, and that the level of aggregation was protein-dependent