

EVALUATION OF ALTERNATIVE SURFACTANTS AS STABILIZERS FOR THERAPEUTICAL PROTEIN FORMULATIONS

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Key Words: surfactants, monoclonal antibody, formulation development, interface phenomena

Surfactants are potent stabilizers of proteins, preventing protein unfolding and aggregation presumably by competitive adsorption to interfaces. Due to limited data on e.g. performance and safety, only three surfactants are routinely found within marketed formulations of parenteral protein products: polysorbate 20 (PS20), polysorbate 80 (PS80), or poloxamer 188 (Px188).

These molecules are well-established and safe for parenteral administration but possess liabilities such as degradation of the surfactant itself and/or chemical inhomogeneity (PS) or show decreased stabilizing effects at silicone oil-water interfaces (Px188). Thus, there is a need to evaluate alternative surfactants to expand the toolbox for product development and to ensure optimal drug product stability and quality.

In our studies, potential alternative surfactants were evaluated and compared to PS20 and Px188 (e.g. during real-time and stress stability studies using a model mAb). Data from these efforts will be presented.