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Engineered Polymeric Excipients for Enhancing the Stability of Protein Biologics

Novel, biocompatible polymer excipients enhance the stability and extend the shelf-life of therapeutic protein biologics by effectively suppressing aggregation and denaturation.

Researchers at Purdue University have engineered novel polymeric excipients that enhance the stability of protein biologics. Monoclonal antibody-based therapies are increasingly being developed to treat cancer, autoimmune, and degenerative diseases. However, antibodies can be susceptible to denaturation and aggregation, and thus present challenges for manufacturing and storage. To combat these pitfalls, surfactants are used to mitigate protein aggregation, but are notoriously limited in polydispersity, purity, and stability. Improving therapeutic protein formulations is therefore crucial for reducing patient health risks and minimizing the economic burden on the healthcare industry.

Researchers at Purdue University have developed polymer excipients to help scientists and pharmaceutical companies bolster the stability of protein therapeutics by suppressing protein aggregation and denaturation. Not only are these alternative compositions based on FDA-approved and biocompatible chemistries, but the excipients also offer tailored thermodynamic properties. The engineered formulations will be monumental in advancing formulations, storage conditions, and product purity of therapeutic antibody solutions.

Technology Validation:

Accelerated dynamic light scattering experiments highlighted the excipient's exceptional efficacy in preserving antibody protein stability, surpassing conventional excipients such as polysorbates under high-temperature conditions. Complementary circular dichroism spectroscopy results revealed conformational alterations associated with aggregation, with the new polymer excipients consistently demonstrating a significant protective effect by mitigating negative shifts at the 220 nm wavelength, indicative of changes in secondary structure.

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Advantages:

-Applicable to a wide range of protein biologics

-Reduces health risks for patients

-Minimizes economic losses for pharmaceutical companies and healthcare systems

-Improves drug stability and lengthens shelf-life of antibody therapeutics

Applications:

-Poloxamers (a.k.a., pluronics)

-Surfactants, notably polysorbates

-Protein biologics products

TRL: 3

Intellectual Property:

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