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Improved Storage Stability for Protein-Based PharmaceuticalsÂ

A novel excipient formulation is designed to enhance the storage stability of dried protein-based pharmaceuticals by reducing crystallization and utilizing FDA-approved components.

Researchers at Purdue University have developed a novel excipient formulation for addition to dried protein-based pharmaceuticals to improve storage stability. From 2019 to 2023, approximately 25â€“30% of drugs approved by the U.S. Food and Drug Administration (FDA) were biologics, the majority of which comprised protein-based formulations or protein components. For stable storage, these protein-based formulas are often dried, either through lyophilization (or freeze-drying) or spray drying. However, both lyophilization and spray drying expose proteins to stressors that can lead to degradation. To mitigate these effects, protective excipients are commonly incorporated into formulations. These researchers have designed a novel formulation that improves storage stability relative to the current standard, with reduced incidences of crystallization, which can severely impact long-term stability.

Technology Validation:

The proposed formulation was spray dried to remove the water, and the resulting residual moisture content was analyzed using Karl Fischer coulometric titration. Particle size analysis showed that using the novel excipient formulation did not impact the particle size for any spray-dried formulations. The study found that, upon spray drying, the proposed formula showed enhanced protein storage stability compared to traditionally used trehalose or mannitol.

Advantages:

-Improved storage stability

-Comprised of components with pre-existing FDA approval as excipients

-Reduced crystallization

Technology ID

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Category

Pharmaceuticals/Drug Delivery & Formulations

Pharmaceuticals/Pharmaceutical Manufacturing & Methods

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Applications:

-Dried, protein-based pharmaceuticals

-Mid- to long-term storage of dried, protein-based pharmaceuticals

-Hospital, clinic, and home administration of injectable protein-based pharmaceuticals

TRL: 2

Intellectual Property:

Provisional-Patent, 2025-05-19, United States