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IMPROVING THE STABILITY OF BIOPHARMACEUTICALS BY APPLYING LYOPHILIZATION

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Abstract

Lyophilization in the pharmaceutical field continuously evolves and expands its applications, particularly in the design and formulation of biopharmaceutical products with critical stability during transport and long-term storage. This article aims to highlight the latest advancements and to explain the challenges in the lyophilization of the key groups of biological drugs.

This scientific paper is based on available scientific literature in the field of the application of lyophilization in biological drugs (Google Scholar, Science Direct, Scopus). Comparative and compilation methods were used. Understanding the fundamental theoretical postulates of lyophilization is crucial for comprehending the physicochemical changes occurring in the structure of biologically active substances, blood components and modern delivery systems for biologically active substances. This review summarizes the expanded scope of pharmaceutical applications based on lyophilization by discussing specific aspects of lyophilization formulations of antibodies, peptides, vaccines, other therapeutic proteins, nanoparticles and nanocapsules, liposomes, blood components and non-gene vectors. New formulation aspects and storage systems, as well as the importance of the freezing step, are also discussed. Formulation development that involves selection of appropriate excipients, understanding their physical properties, and determining the mechanisms of action for achieving a stable pharmaceutical product are essential for a successful lyophilization program. Additionally, the study provides insight into new stabilization concepts for biopharmaceutical products, process analytical technology (PAT), and quality by design (QbD), which are highly relevant and will contribute to future advancements and improvements in the lyophilization process.

The broad range of pharmaceutical applications based on lyophilization highlights the continuous importance and significance of this process in the pharmaceutical field. Developing a stable lyophilized biopharmaceutical

product can be challenging, as multiple factors must be considered to prevent its instability. By carefully evaluating and selecting key excipients and with optimization of the pH value, a stable lyophilized biopharmaceutical formulation with an acceptable shelf life can be designed successfully.

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