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Optimizing Freeze-Dried Drug Nanosuspensions: Role of Freezing Rate and Excipients

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Poor aqueous solubility remains a major barrier in oral drug development, with approximately 80% of new drug candidates classified as BCS Class II or IV compounds [1]. These poorly soluble drugs often suffer from limited bioavailability, necessitating the development of advanced formulation strategies to improve their therapeutic performance. One such compound, indomethacin, a widely studied BCS Class II drug, was selected as a model in this study. To address its solubility and stability challenges, indomethacin was formulated as a nanosuspension and subsequently freeze-dried to produce a stable, easy-to-handle powder.

This study investigated the effects of formulation components, specifically surfactants and polymers, and freeze-drying process parameters on the redispersion of nanosuspensions. Stabilizer combinations were screened to identify optimal formulations, which were then freeze-dried under controlled conditions. Particular attention was given to the freezing step, where cooling rates were varied to optimize nanoparticle stabilization and minimize aggregation.

The lyophilized powders were characterized for particle size after redispersion, morphology, solid-state properties, and dissolution behavior. Results showed that both the choice of stabilizers and the freezing protocol significantly influenced the redispersion efficiency and dissolution performance. Cryoprotectants and faster freezing rates played pivotal roles in preserving nanoparticle integrity during the freeze-drying process.

Overall, this study demonstrates the importance of excipient selection and freezing conditions in maintaining nanosuspension quality after freeze-drying. Optimizing these parameters offers a promising approach to enhance the stability and bioavailability of poorly soluble drugs.

[1] Hall, D. Trends and Challenges in the Evolving Small Molecule Development Pipeline. 2023 01 May 2023 12 November 2024]; Available from: <https://www.lonza.com/knowledge-center/smallmolecules/a/small-molecule-trends-and-challenges>