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Development of lysozyme-loaded self-emulsifying drug delivery systems using hydrophobic ion pairing

Martin Deák[1], Nur Aslan[2], Katalin Kristó[1], Tamás Sovány[1]

[1]Institute of Pharmaceutical Technology and Regulatory Affairs, University of Szeged, Szeged, Hungary
[2]Department of Pharmaceutical Technology, Faculty of Pharmacy, Ege University, Izmir, Turkey

Introduction: Oral administration of protein-based therapeutics is limited by gastrointestinal pH, enzymatic degradation and the intestinal barrier. Therefore, developing stable oral formulations with improved bioavailability is a major challenge as an alternative to currently available invasive delivery routes. In this study, lysozyme-loaded, lipid-based self-emulsifying drug delivery systems (SEDDS) were developed and converted into solid dosage form via adsorption onto mesoporous silica to enable tableting.

Methods: Lysozyme was formulated as a hydrophobic ion pair with sodium lauryl sulfate to improve stability and solubility. Liquid SEDDS were prepared using a three-factor constrained mixture design and the emulsifiers (Tween 20/80, Span 20/80) were combined based on a 2^2 factorial design and Miglyol 810 as the oil phase. The stability parameters of the resulting emulsions were evaluated. Solid SEDDS were obtained by adsorbing the liquid systems onto mesoporous silica (Neusilin UFL2), and compressibility was investigated as a function of liquid load. Artificial neural networks (ANN) were used to analyze the correlations.

Results: A design space enabling the preparation of SEDDS with optimal properties was established. A 1:1 SEDDS-to-silica ratio proved optimal and formulations containing Tween 20 exhibited the most favorable compressibility. ANN modeling identified surface tension as the most influential factor affecting compressibility, allowing reliable prediction of tableting performance.

Conclusion: This systematic investigation of these innovative drug delivery systems can contribute to improving the oral bioavailability of proteins by providing deeper insight into the role of individual formulation components.

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