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Risk-based optimization of liposome-based nano-carrier systems

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The number of requirements for pharmaceuticals is growing dynamically; thus, conscious design and analysis is needed to incorporate these needs into development plans. It can be ensured by a risk assessment-based approach as part of the Quality by Design method [1]. Liposomal formulations are innovative forms of drug delivery systems; however, their development is a challenging process. Certain factors decisively influence the vesicles, while the relevant properties of the product vary depending on the development goals. Different production methods require different material characteristics and production settings. Identifying the product profile of the formulation, the critical quality attributes of the liposomes, and the manufacturing parameters that have a critical effect on the result will help in the development process. This work determined the requirements of liposomal formulations prepared by the thin-film hydration method and the factors influencing the final product. The formulations were optimized for vesicle size, size distribution, and surface charge, and the relationships describing the results obtained by changing the production settings were investigated [2]. The tested critical factors included the type, amount, and ratio of the wall-forming agents, the hydration medium and cryoprotectant, the working temperature, and additional physical parameters of the production technique. After determining the appropriate manufacturing conditions, the surface charge of the formulations was optimized by adding dicetylphosphate or stearylamine to the formulations following a factorial design. Liposomes have been characterized via morphological, thermodynamical, and structural studies.

References

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