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Quality by Design-based approach to liposomal development

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Quality by Design (QbD) is a new perspective to replace the traditional, "in-process study"-based quality control procedures of the Quality by Testing (QbT) method, which concept has been started to use in the pharmaceutical developments since the beginning of the 2000s.

The objective of our research project was to conduct a QbD-based development process to prepare liposomal formulations and thus investigate the effects of various production parameters (filtration, pressure, and temperature) and different compositions (phospholipid-cholesterol ratios, hydration media, and cryoprotectants).

The liposomal formulations were prepared by the thin-film hydration method [1]. The temperature and the pressure during the production were changed in addition to the filtration, as well as the ratio of the wall-forming agents. The products were investigated via dynamic light scattering technique to determine the vesicle size and the size distribution, and the zeta potential values were checked. The thermostability of the samples was analysed via differential scanning calorimetry (DSC) and thermogravimetric analysis (TGA) measurements. N_2 adsorption and desorption isotherms were measured to define the characteristics of the vesicular surface and the structure of the vesicles was verified via transmission electron microscopy (TEM).

The size of the prepared vesicles was under 200 nm, and the zeta potential values were slightly negative, except the API-containing formulations.

The results showed that the quality of the development process can be improved via the application of the QbD-based approach in the case of the liposomal formulations.

References

1. Pallagi E. et al. Int. J. Pharm. 562, 11-22 (2019)

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