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Quality-focused formulation - QbD-based liposome design and development

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Formulations should carry the quality designed into the products to meet the pharmaceutical requirements. The Quality by Design (QbD) approach ensures the quality of medicines by developing and manufacturing products following statistics-, analytics- and risk-management-based methodologies [1].

This research aims to systematise the characteristics of the components (material attributes, MAs) and the preparation settings (process parameters, PPs) in case of the thin-film hydration liposome preparation technique. Furthermore, the study specifies the quality target product profile of a liposomal formulation and the critical quality attributes of the liposomes. Also, it identifies those MAs and PPs that influence the characteristics of the vesicles [2].

The theory was supported with practical research; the effect of the working temperature, the phosphatidylcholine-cholesterol ratios, the PEGylated phospholipid concentration, the type of the hydration media and the cryoprotectants were studied in different formulations. The results present the key points of a Risk Assessment (RA)-based experimental design, and the impacts of the critical factors mentioned above based on the investigation of the liposomal characteristics (size, surface charge, thermodynamic behaviours and structural investigations).

The study revealed the relevance of the QbD-based RA in the thin-film hydration-based liposome preparation process and shown the main effects of the tested critical factors. The results ensure that the understanding and the application of the QbD elements in the pharmaceutical developments help to influence and to reach the aimed quality of the formulated product.

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