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QUALITY BY DESIGN APPROACH IN FORMULATION & OPTIMIZATION OF INSULIN LOADED LIPOSOMES BY DETERMINING ENCAPSULATION EFFICIENCY

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The purpose of this study was to extend Quality by Design (QbD) principles to develop insulin-loaded liposomes, to identify and control critical sources of variability in the process, and to understand the impact of formulation and process parameters on the liposomal formulation. Insulin was found to possess an excellent wound healing property. A desired property for a key liposome drug product quality, namely the drug encapsulation efficiency (EE%), was defined and evaluated, being an evaluation index for liposomal release rate and stability. Liposomal drug products containing insulin were prepared using thin film hydration method to produce topical controlled release systems. Liposomal formulation was optimized using a 2^{4-1} fractional factorial design to test some formulation and procedure variables. Solvent volumetric ratio, hydration time, sonication time and temperature of film and liposomes formation were all tested on the EE%. The optimized formula was further tested for morphology, particle size and zeta potential. The results showed insignificant effect of the temperature and significant effects of the other factors. The liposomes were spherical, smooth, and homogenous with particle size of 2.229 ± 0.065µm and zeta potential of -7.995 ± 0.0212. The optimized formula as obtained from the program was prepared with 1:1 choroform: methanol ratio, hydration time of one hour without sonication and had an EE% of 75.98%. These findings preliminary clarified the main factors depending on the EE%, and will provide important methodological references for further study of topical liposomes encapsulating insulin for wound healing, especially for diabetic patients.