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### Cationic nanostructured lipid carriers (cNLCs) as drug delivery systems for miRNA: investigations of formulation and process parameters

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Cationic NLCs represent lipid vesicles bearing cationic lipids on its surface, which leads to electrostatic interactions with negative charges of the nucleic acids such as miRNA and formation of a complex which protect the nucleic acids from the inevitable physicochemical biological impacts within the blood circulation [1]. This study aimed to develop cNLCs in order to obtain the most suitable formulation for further delivery of miRNAs.

cNLCs containing stearylamine, Precirol<sup>®</sup> ATO 5 and Miglyol<sup>®</sup> 812 in the lipid phase and different concentrations of Poloxamer<sup>®</sup> 188 and Tween<sup>®</sup> 80 in the aqueous phase were prepared by the high-pressure homogenization method. In order to evaluate appropriate process parameters for NLC preparation, different cycle numbers (1-5) and homogenization pressures (500 bar, 650 bar and 800 bar) were tested. Additionally, the influence of the cooling technique was investigated. cNLCs were characterized regarding particle size, particle size distribution, zeta potential, and crystallinity using photon correlation spectroscopy technique and laser diffraction, electrophoretic light scattering, and differential scanning calorimetry, respectively.

The obtained particle size of all formulations was between 80 and 180 nm, and it decreased significantly with the increase of non-ionic surfactant concentration. Furthermore, particle size decreased with the increase of the homogenization cycles. The surface charge value was highly positive in formulations (+32 to +41 mV), demonstrating the successful incorporation of stearylamine onto the nanoparticle surface. However, the cooling technique did not have a significant impact on the particle size of cNLCs.

#### References

1. Carrillo C. et al. Eur. J. Pharm. Sci. 49(2), 157-165 (2013)

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