Process optimization for quality-oriented manufacturing of lipid nanocarriers

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Introduction. Lipid nanoparticles (LNPs) have gained great attention in research as nanocarriers for targeted drug delivery mainly due to their unique properties, such as high bioavailability, enhanced drug solubilization and protection, and biocompatibility. Here we focused on developing optimal LNPs as advanced drug delivery systems for improving the encapsulation of hydrophobic drugs.

Methods. We used "Design of Experiments" approach for screening of main formulation parameters influencing responses, this way, we elaborated several LNPs according to DOE by using the solvent injection technique (Figure 1). We evaluated mean particle size, polydispersity index (PDI) and zeta potential (ZP) by dynamic light scattering and electrophoretic mobility. One optimal composition computationally predicted was then prepared and its stability was studied upon storage at different temperatures (4ºC/RT).

Results. Most of the formulations engineered resulted in appropriate physical properties, with small hydrodynamic sizes and narrow size distribution. In addition, optimized LNPs were stable over time at both temperatures tested. From the initial batch volume, we were able to scale-up the reaction leading to the formation of optimal LNPs without observing changes in the physicochemical characteristics of LNPs obtained, thus confirming their high stability and scalability of the process.

Conclusions. We have successfully engineered optimal LNPs in a first panel of formulations with different characteristics ready to be used as drug delivery systems. The efficacy of these optimized LNPs as nanocarriers will be tested soon.

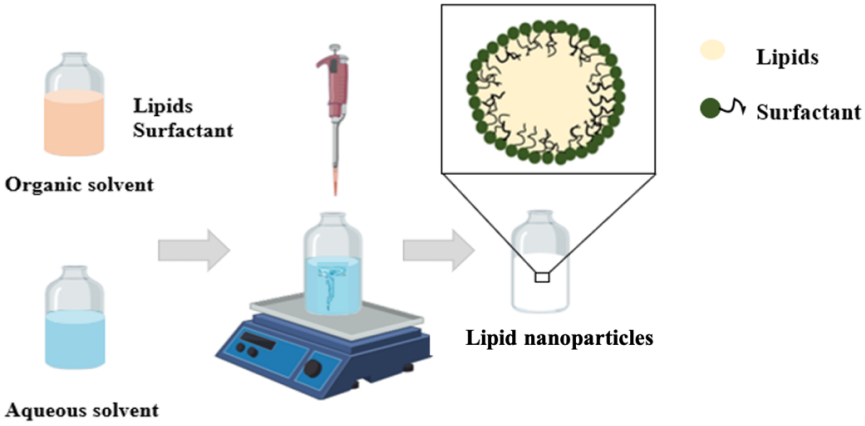

Figure 1. Lipid nanoparticles production by solvent injection technique.