Measuring physical properties of liposomes and of lipid-based nanoparticles for RNA delivery: from method development to standardization

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Nanotechnology-based health products nanoparticles are providing innovative solutions in health technologies and the pharmaceutical field, responding to unmet clinical needs. However, suitable standardized methods need to be available for quality and safety assessments of these innovative products to support their translation into the clinic and for monitoring their performance when manufacturing processes are changed. The question arises which technological solutions are currently available within the scientific community to support the requested characterisation of nanotechnology-based products, and which methodological developments should be prioritized to support product developers in their regulatory assessment. In this work we will present the state-of-the-art methods to identify methodological gaps associated with the preclinical characterization of liposomes and lipid-based nanoparticles in line with regulatory needs. The regulatory information needs, and available standard methods will be presented. Efforts of the community toward the development of standard test methods will be discussed. As an example of a success story, the development of SOP and standards focusing on the use of asymmetric-flow field-flow fractionation (AF4) for the physical-chemical characterization of liposomes and lipid-based nanoparticles for mRNA delivery will be discussed.