Lipid Nanoparticles (LNPs) Characterization

Lipid nanoparticles (LNPs) have shown great success in the pharmaceutical industry, leading to 23 approved products in the U.S. and Europe over the past 30 years. They offer promising formulation options for drugs limited by low therapeutic indexes in traditional dosage forms and current "undruggable" targets. Analytical characterization of LNPs is critical to drug design, formulation development, understanding *in vivo* performance, as well as quality control [1]. To address these challenges and facilitate future applications of LNPs in drug development, Alfa Chemistry offers a variety of available analytical approaches for physicochemical characterizations of LNPs-based pharmaceutical modalities. The characterization items include identification and quantification of lipid, drug encapsulation efficiency, nanoparticle characteristics, product stability, drug release and others.

Guidance for LNPs Drug Products

In 2018, a guidance for industry on the development of liposome drug products was published by the U.S. FDA, and several critical quality attributes (CQAs) that have to be addressed were pointed out [1]. The CQAs are:

(1) Identification and quantification of lipid species;
(2) Quantification of the encapsulated, free, and total API;
(3) Nanoparticle characterization including morphology, structure, particle size distribution, and surface charge;

(4) Physical (fusion and aggregation) and chemical (lipid and API degradation) stability of the product;
(5) *In vitro* drug release kinetics.

Reference

1. Fan Y., et al. Analytical characterization of liposomes and other lipid nanoparticles for drug delivery[J]. *Journal of pharmaceutical and biomedical analysis*, 2021, 192: 113642.

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