

CDER Standards Information Sheet

Recognition Category: Revision Reaffirmation New recognition

CDER Recognition Number: 2025-007

Standards Developing Organization (SDO) Name: ASTM

Standard Number: E3409-24

Title of Standard: Standard Test Method for Analysis of Liposomal Drug Formulations Using Multidetector Asymmetrical-Flow Field-Flow Fractionation

Scope/Abstract:

Parts 1.1 to 1.4 of the scope provided on the ASTM website:

1.1 This test method describes a measurement procedure to reproducibly separate component size populations present within liposomal drug formulations and to characterize their associated size and size distribution. The method can also yield information on the shape and physical stability of the liposomes and is applicable to measurements in the presence of serum proteins. Fractions can be collected for off-line analysis using various techniques not specified in this test method.

1.2 This test method applies to uni-lamellar and multi-lamellar liposomes that are designed for drug delivery and which are dispersed in a native solution that is aqueous in nature. The method is generally applicable over a particle size range (radius) of approximately 10 nm to 250 nm, and for injected lipid mass from 20 µg to 200 µg.

1.3 This test method is based on the multi-detector asymmetrical-flow field-flow fractionation (MD-AF4) technique as configured on a typical commercial instrument platform with online detectors such as multi-angle (static) light scattering (MALS), dynamic light scattering (DLS), ultraviolet-visible (UV-Vis) absorbance, and differential refractive index (dRI) (1).2

1.4 This method does not address liposome composition. Refer to Test Methods E3297, E3323, or E3324 for lipid quantification.

Extent of Recognition:

Complete Recognition

Rationale for Complete Recognition:

This standard is relevant to products regulated by CDER and is recognized based on its scientific and technical merit and/or because it supports existing regulatory policies.

Relevant Regulations, Guidance and/or Supporting Publications:

Guidance for Industry Liposome Drug Products Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation (April 2018)

In connection with ANDA submissions, product-specific guidance may be available for a particular liposome drug product. Refer to the FDA's Product-Specific Guidances for Generic Drug Development web page at <https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development>.

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