CDER Standards Information Sheet

Recognition Category: ☐ Revision ☐ Reaffirmation ☑ New recognition

CDER Recognition Number: 2024-001

Standards Developing Organization (SDO) Name: ASTM

Standard Number: E3247-20

Title of Standard: ASTM Standard Test Method for Measuring the Size of Nanoparticles in Aqueous Media Using Dynamic Light Scattering

Scope/Abstract: 1.1 This test method addresses the determination of nanoparticle size (equivalent sphere hydrodynamic diameter) using batch-mode (off-line) dynamic light scattering (DLS) in aqueous suspensions and establishes general procedures that are applicable to many commercial DLS instruments. This test method specifies best practices, including sample preparation, performance verification, data analysis and interpretation, and reporting of results. The document includes additional general information for the analyst, such as recommended settings for specific media, potential interferences, and method limitations. Issues specific to the use of DLS data for regulatory submissions are addressed. 1.2 The procedures and practices described in this test method, in principle, may be applied to any particles that exhibit Brownian motion and are kinetically stable during the course of a typical experimental time frame. In practice, this includes particles up to about 1000 nm in diameter, subject to limitations as described in the test method. 1.3 This test method does not provide test specimen preparation procedures for all possible materials and applications, nor does it address synthesis or processing prior to sampling. The test specimen (suspension) preparation procedures should provide acceptable results for a wide range of materials and conditions. The analyst must validate the appropriateness for their particular application. 1.4 This test method is applicable to DLS instruments that implement correlation spectroscopy. Analysts using instruments based on frequency analysis may still find useful information relevant to many aspects of the measurement process, including limits of applicability and best practices. On-line (flow-mode) DLS measurements are not treated here specifically and may have additional limitations or issues relative to batch-mode operation.

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 Drug Products, Including Biological Products, that Contain Nanomaterials (April 2022)

Guidance for industry Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology (June 2014)

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