

CDER Standards Information Sheet

Recognition Category: ☐ Revision ☐ Reaffirmation ☒ New recognition

CDER Recognition Number: 2025-009

Standards Developing Organization (SDO) Name: ISO

Standard Number: TS 4958:2024

Title of Standard: Nanotechnologies - Vocabulary - Liposomes

Scope/Abstract:

Abstract from ISO:

This document defines terms related to liposomes in nanotechnologies, within the context of biological systems and biomedical applications. In this context, liposomes are one form of lipid-based nanomaterials. This document does not address terms that can be relevant to other types of lipid-based particles (e.g. solid lipid nanoparticles).

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:

As described in the scope section of the April 2022 guidance referenced below, FDA has not established regulatory definitions of “nanotechnology,” “nanomaterial,” “nanoscale,” or other related terms.

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

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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