

CDER Standards Information Sheet

Recognition Category: Revision Reaffirmation New recognition

CDER Recognition Number: 2025-008

Standards Developing Organization (SDO) Name: ASTM

Standard Number: E2503-13 (Reapproved 2020)

Title of Standard: Standard Practice for Qualification of Basket and Paddle Dissolution Apparatus

Scope/Abstract:

- 1.1 This practice covers the set-up and calibration of the paddle and basket dissolution apparatus.
- 1.2 Use of this practice may be applied to apparatus that have been modified to enable automatic dissolution testing (that is, a valve in the bottom of the vessel or sampling through the shaft).

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:

This standard is limited in scope and should be used in conjunction with the FDA CGMP guidance listed below. Please see the guidance for additional considerations.

Guidance for industry The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 - Current Good Manufacturing Practice (CGMP) (January 2010)

Additional supporting publications:

USP General Chapter <711> Dissolution

USP Dissolution Toolkit, Procedures for Mechanical Calibration and Performance Verification Test, Apparatus 1 and Apparatus 2, Version 2.0, March 22, 2010

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