
[New Proposed Chapter <1153> Drug Products Containing Nanomaterials](#)

Type of Posting: General Announcement

Posting Date: 26–Apr–2019

Expert Committee: General Chapters Dosage Forms

Proposed New Title: <1153> Drug Products Containing Nanomaterials

Input Deadline: 10–Jun–2019

Estimated proposal PF: *Pharmacopeial Forum* 45(5) [Sept – Oct 2019]

Description of scope and application: There are large numbers of formulations containing nanomaterials that are currently under development, under review, or have already received approval from the US FDA requiring the need to identify important properties of these formulations. This new informational general chapter describes materials that have features or structures that exist on the nanoscale in any of the three spatial dimensions. This chapter provides guidance on the composition and attributes of these nanomaterials because they may impact the quality and performance of drug product.

Preliminary outline:

1. Introduction
2. Names and Definitions
3. General Quality Tests of Drug Products Containing Nanomaterials
4. General Quality Tests
5. Description of Product Quality Tests

Anticipated implementation timing: routine

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