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Particulate Matter in Oral Dosage Forms



Authors and Contributors

Anil Sawant, PhD, Merck & Co/ Merck Sharpe & Dohm (*Chair*)

Girish Agashe, Merck & Co.

Joseph DeVito, PharmD, Teva Pharmaceuticals

Katrina Elia, SPI Pharma Inc.

David Exline, Gateway Analytical, LLC

Dennis E. Guilfoyle, PhD, Johnson & Johnson Inc.

Cindy Gulian, PhD, Johnson & Johnson Consumer Inc.

Sonia Khawaja, Johnson & Johnson Inc.

Wendy Luo, PhD, Bristol-Myers Squibb

Dirk Overroedder, PhD, Johnson & Johnson Inc.

Leslie Shur, Johnson & Johnson Consumer Inc.

Myriam Sosa, Novartis

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1.0 Introduction

Particulate matter in oral dosage forms has been the subject of customer complaints, recalls, and regulatory actions; yet, no industry standard or guidance exists addressing mitigation, acceptance criteria, clinical relevance, inspection, sampling, testing, or acceptable complaint levels. This lack of a consensus standard, along with subjective decision-making, makes it difficult to compare quality metrics (e.g., rejection rate, complaint rate, recall rate, etc.) between products, manufacturing sites, or companies. To better understand industry's perspective on the root causes, challenges, and current practices, the Parenteral Drug Association launched the *PDA Survey: 2015 Particulate Matter in Oral Dosage Forms (1)*. Responses clearly indicated that the majority of the respondent facilities had been inspected by the U.S. Food and Drug Administration and that of these, a few had already received particulate observations from the FDA, European Medicines Agency, or local/national healthcare agencies. Although particulate matter recalls are predominantly associated with parenteral products, several oral products have also been recalled for the presence of foreign particles (2–6).

1.1 Purpose

This technical report documents the current practices used by manufacturers of drug products, active pharmaceutical ingredients, excipients, and packaging/primary containers to control, inspect, sample, and test intrinsic and extrinsic particulate matter in oral dosage forms.

1.2 Scope

The scope of this technical report includes current practices and guidelines for monitoring of particulates, as well as recent quality, clinical relevance, and regulatory experience.

This document is limited to discussion of visible particulate matter in oral dosage forms. Other dosage forms that are administered by a non-oral route and sterile dosage forms are out of scope.



Bethesda Towers
4350 East West Highway
Suite 600
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
E-mail: info@pda.org
Web site: www.pda.org