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Technical Regulatory Topic

New ASTM Standard Practice for Extraction of Particulate Matter from the Single-Use Systems

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Introduction

In May 2020, ASTM♦ International published a new standard practice on a method to extract particles from single-use systems (SUS). This document, "E3230-20: Standard Practice for Extraction of Particulate Matter from the Surfaces of Single-Use Components and Assemblies Designed for Use in Biopharmaceutical Manufacturing"[1], is the outcome of several years of collaboration inside the ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products.

Scope of the ASTM Standard Practice

This standard practice provides useful recommendations on validating the effectiveness of an extraction method used to collect loose particles from the surface of single-use components and assemblies. The approach was inspired by an automotive industry standard[2] used for parts which require critical cleanliness. The guidance on the method for counting the particles is not provided.

1 Can be bought on ASTM International website: https://www.astm.org/Standards/E3230.htm (accessed December 7, 2020).

2 ISO 16232:2018

Content of the ASTM Standard Practice

The ASTM practice contains useful guidance on the following:

- types of extraction method;
- the key elements to consider when defining a liquid extraction method to collect particles from SUS;
- different parameters that can potentially impact the effectiveness of the extraction method;
- tests required to verify that the extraction is done in adequate conditions, for example a background control test;
- qualifying the effectiveness of the liquid extraction method;
- acceptance criteria based on a declining criterion, in which the extraction procedure must achieve a minimum 90% particle removal effectiveness during qualification;
- troubleshooting and optimization of the extraction method during the development and qualification steps.

This standard provides excellent guidance to verify that the extraction method applied is actually effective.

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