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Change to read:

**<789>[▲]SUBVISIBLE[▲] (USP 1-May-2024) PARTICULATE MATTER IN
[▲]INTRAOCULAR[▲] (USP 1-May-2024) SOLUTIONS**

Change to read:

[▲]All intraocular solutions should be essentially free from particles that can be observed on visual inspection using [Visible Particulates in Injections \(790\)](#), as directed by [Ophthalmic Products—Quality Tests \(771\)](#). Additionally, certain injection products require subvisible particulate matter testing by [Particulate Matter in Injections \(788\)](#) or [\(771\)](#). The tests described in this chapter are physical tests performed for the purpose of enumerating subvisible particles within specific size ranges.

Particulate matter for intraocular solutions is defined as mobile, randomly sourced, unintended, insoluble substances. Every intraocular solution is subject to the particulate matter limits referenced in [\(771\)](#), unless otherwise specified in the individual monograph. When higher limits are appropriate, they will be specified in the individual monograph. Refer to [\(771\)](#) and the specific monograph when a question of test applicability occurs.

Light obscuration and microscopic procedures for the determination of particulate matter in intraocular solutions are identical to those for parenteral injections; therefore, where appropriate, [\(788\)](#) is cross-referenced. This chapter provides two test procedures. The intraocular solution may be tested by either the light obscuration method (LO) or the microscopic method, depending on which one is most appropriate for the product being tested. Many stakeholders choose LO as the first choice, especially when silicone oil may be present. For certain products, which are limited by volume, viscosity, or color, the membrane microscopic method may be preferred. Limits are the same for either method. In some instances, the viscosity of a material to be tested may be sufficiently high so as to preclude its analysis by either test method. In this event, a quantitative dilution with an appropriate diluent may be made to decrease viscosity, as necessary, to allow the analysis to be performed, following the guidance in [Methods for the Determination of Subvisible Particulate Matter \(1788\)](#) with appropriate documentation. Issues that arise with either method may be resolved by consulting [Measurement of Subvisible Particulate Matter in Therapeutic Protein Injections \(1787\)](#) and [\(1788\)](#).[▲] (USP 1-May-2024)

In the tests described below, the results obtained by examining a discrete unit or group of units for particulate matter cannot be extrapolated with certainty to other units that remain untested. Thus, sampling plans based on known operational factors must be developed if valid inferences are to be drawn from observed data to characterize the level of particulate matter in a large group of units. Sampling plans need to be based on consideration of product volume, particle numbers historically found to be present in comparison to limits, size distribution of particles present, and variability of particle counts between units.

Change to read:

LIGHT OBSCURATION PARTICLE COUNT TEST

This test applies to [▲]intraocular solutions[▲] (USP 1-May-2024) including solutions constituted from sterile solids, for which a test for *Particulate Matter* is specified in the individual monograph.[▲] (USP 1-May-2024)

Test Apparatus, Instrument Standardization, Test Environment, Test Procedure, and Calculations

Proceed as directed in [\(788\)](#), [Method 1 Light Obscuration Particle Count Test](#).

Interpretation

The [▲]intraocular solutions[▲] (USP 1-May-2024) meet the requirements of the test if the average number of particles present in the units tested does not exceed the appropriate value listed in [Table 1](#).[▲] (USP 1-May-2024)

Table 1. Light Obscuration Particle Test Limits

	Diameter		
	≥10 μm	≥25 μm	≥50 μm
Number of particles	50/mL	5/mL	2/mL

Change to read:

MICROSCOPIC PARTICLE COUNT TEST

Some articles cannot be tested meaningfully by light obscuration. In such cases, individual monographs clearly specify that only a microscopic particle count is to be performed. The microscopic particle count test enumerates subvisible, essentially solid, particulate matter in ▲intraocular solutions▲ (USP 1-May-2024) after collection on a microporous membrane filter. Some ▲intraocular solutions (e.g., high viscosity solutions that do not filter readily)▲ (USP 1-May-2024) may be ▲effectively analyzed using▲ (USP 1-May-2024) the microscopic test▲, with appropriate dilution and proper selection of the filtration membrane.▲ (USP 1-May-2024)

When performing the microscopic test, do not attempt to size or enumerate amorphous, semiliquid, or otherwise morphologically indistinct materials that have the appearance of a stain or discoloration on the membrane surface. These materials show little or no surface relief▲, do not cast a shadow▲ (USP 1-May-2024) and present a gelatinous or film-like appearance▲ (See (1788)).▲ (USP 1-May-2024)

Test Apparatus, Test Environment, Test Procedure, and Enumeration of Particles

Proceed as directed in (788), [Method 2 Microscopic Particle Count Test](#).

Interpretation

The ▲intraocular solutions▲ (USP 1-May-2024) meet the requirements of the test if the average number of particles present in the units tested does not exceed the appropriate value listed in [Table 2](#).

Table 2. Microscopic Particle Test Limits

	Diameter		
	≥10 μm	≥25 μm	≥50 μm
Number of particles	50/mL	5/mL	2/mL

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
<789> SUBVISIBLE PARTICULATE MATTER IN INTRAOCULAR SOLUTIONS	Desmond G. Hunt Principal Scientific Liaison	GCDF2020 General Chapters - Dosage Forms 2020

Most Recently Appeared In:

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