Methods for the Determination of Particulate Matter in Injections and Ophthalmic Solutions

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Suggested audience: Drug product manufacturers that produce injectable drug products

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Background and objective(s): USP guidance for particulate matter content is comprehensively addressed in the following general chapters: <1> Injections; <787> Particulate Matter Determination for Therapeutic Proteins; <788> Particulate Matter Determination for Injections; <789> Particulate Matter Determination for Ophthalmic Solutions; and <1788> Methods for Determination of Particulate Matter in Injections.

General Chapter <1788> is being revised and reformatted to give detailed information on instrument standardization and calibration applicable to General Chapters <787>, <788>, and <789>. The revision will include recommendations for sample handling, laboratory environment, operator training, and general advice applicable to the light obscuration and membrane microscopic method, along with new guidance on the use of flow microscopy for the determination of particulate matter. The methods for analysis will be contained within their own General Chapters: <1788> Methods for the Determination of Particulate Matter in Injections and Ophthalmic Solutions; <1788.1> Light Obscuration Method for the Determination of Particulate Matter; <1788.2> Membrane Microscopic Method for the Determination of Particulate Matter; and <1788.3> Flow Imaging Method for the Determination of Particulate Matter.

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