



When Clarity Counts.

SureCount™ PCS

(Particulate Contamination Standard)



INTRODUCTION

SureCount™ Particulate Contamination Standards (PCS) are specifically designed for testing liquid particle counting instruments to comply with global regulations and standards for

- USP<788> Particulate Matter in Injections
- EU Pharmacopoeia 2.9.19, and other pharmacopoeial compendia for subvisible particulate testing
- USP<787> Subvisible Particulate Matter in Therapeutic Protein Injections
- USP<789> Particulate Matter in Ophthalmic Solutions
- USP<1788> Methods for Determination of Subvisible Particulate Matter
- ASTM E3230-20 Extraction of Particulate Matter from Single-Use Components and Assemblies

GENERAL SPECIFICATIONS

Calibration standard for subvisible particulate detectors and liquid particle counters

- 15 µm polystyrene microparticles traceable to the NIST standard meter
- 3800 particles/mL ± 15% ascertained by Coulter method
- Available with and without Blanks that can be used for calibrations or measuring extractable particulates from single-use systems
- Supplied with a Certificate of Traceability for mean diameter

USED IN

- Pharmaceuticals
- Parenterals
- Ophthalmic Solutions
- Therapeutic Protein
- Single-Use Systems

Uniform diameter calibrated to the NIST standard meter

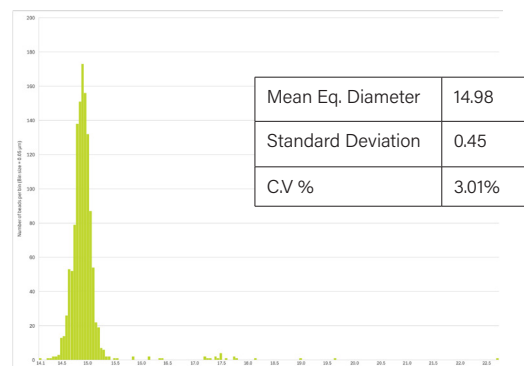


Figure 1: Example analysis showing size distribution based on optical microscopic examination with a NIST-calibrated stage micrometer and digital analysis. Each lot of SureCount™ PCS is supplied with certification of NIST traceability for diameter.

Uniform counts based on Coulter method

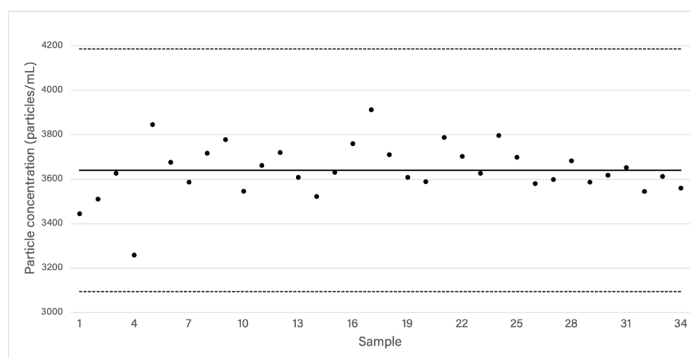


Figure 2: Count uniformity of SureCount™ PCS. Thirty-four samples of SureCount PCS were counted using the Coulter method to ascertain variation. The average count was 3640 particles/mL (solid line) with a CV of 3.32%. The upper and lower dotted lines represent the mean ± 15%.

Particulate Contamination Standards

Cost-Effective | Options for low- to high-throughput operations

Confidence | Test instrumentation for quality control

Compliance | With ISO, GMP/GLP, and global pharmacopoeia regulations

Ordering Information

Cat. #	Description
CC-6pk-01	SureCount™ PCS I: 3x25mL Particles & 3x25mL Blank
CC-24pk-01	SureCount™ PCS I: Case (12x25mL Particles & 12x25mL Blank)
CC-6pk-02	SureCount™ PCS II: 6x25mL Particles
CC-24pk-02	SureCount™ PCS II: Case (24x25mL Particles)

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