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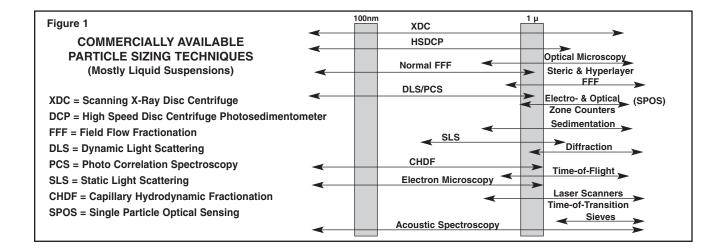
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Precision Particles: NIST Traceable Size Standards

Introduction

Measurement of microparticle size and size distributions is a critical and challenging task to anyone who is working with micron and sub-micron materials. Many different methods exist to complete this task (Fig. 1). As with all analytical techniques, the best choice is application specific. The most critical aspect of microparticle sizing is the use of microparticle size standards. In some cases the use of a standard is required to verify the correct operation of a sizing instrument, in others the instrument must be calibrated with a series of size standards before accurate measurements can be produced.

Polysciences provides Precision Particles, a series of NIST traceable polystyrene microparticle size standards that range in size from 40nm to 175µm. Because of the many different and acceptable sizing techniques used, it is important for the end user to know how Polysciences' determines particle size.



Questions and Answers

How does Polysciences determine the size and size distribution of Nanobeads, Microbeads and Megabeads?

For sizing the Nanobead (40 to 950 nanometers) and Microbead (1.0 to 9.0 microns) standards, Polysciences uses a Disc Centrifuge (DC) Instrument. This analyzer measures particle size distributions, using centrifugal sedimentation within an optically clear spinning disc. The principle involves the relationship between particle diameter size, and the rate of sedimentation. The instrument is calibrated with uniform NIST Standard Reference Materials of known diameters. For the Megabead (10 to 175 microns) standards, Polysciences uses single particle optical sensing (SPOS) a combination of light extinction and light scattering. Individual particles pass through a small optical sensing region one at a time and produce a detecting pulse. The magnitude of the pulse depends on the size of the particle. The particle size distribution plot of the sample is constructed one particle at a time by comparing the detected pulse heights with a standard calibration curve based on NIST traceable particles of known diameters.

For both methods, the mean diameter size is determined from the the major peak.

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Why does Polysciences measure particle size using these instruments?

All sizing methodologies have their advantages and disadvantages. There are many different considerations for choosing a sizing method and there is no single "right" method, only a best fit between the method and the application. Because the end users of our Precision Particles Size Standards will be using these methods and others, it is important to note some points about our current methodology:

- 1. These methods have high resolution while maintaining the ability to "see" a fairly wide size range. This enhances our ability to discriminate between two populations close in size and at the same time detect large aggregates and fines.
- 2. These methods allow statistically meaningful sampling with little user bias. The number of particles mea sured per sample is greater than 100,000.
- 3. The sizing measurements obtained are comparable to those obtained by the sizing instruments utilized by end users. While different methodologies will give slightly different answers, these methodologies will agree fairly closely with others.
- 4. Repeated measures on the same sample give consistent results.
- 5. Our measurements techniques are made with instruments calibrated and validated with NIST Standard Reference Materials.

How does Polysciences trace the size of their standards to the NIST Standard Reference Particles?

The calibrated mean diameter of Polysciences Precision Particle Size Standards are measured by Disc Centrifuge and Single Particles Optical Sensing instruments. Validation of the accuracy of the calibration method is performed using NIST Standard Reference Materials (1690,1692, and 1961). Traceability of the calibrated mean diameter to NIST Standard Reference Materials is provided through an unbroken chain of measurement using defined procedures and documented uncertainties.

How do the Polysciences NIST traceable Particle Size Standards compare to those of others?

Historically, very low %CVs (typically 1% or less), have been reported for particle size standards. This may be due to the fact that the particles were measured using electron microscopy techniques. Disadvantages of this method include sampling error due to a statistically small number of particles actually measured, and the possibility of user bias in taking the measurements. Polysciences has found that when these types of samples are measured, using our sizing techniques and equipment, the %CVs, are typically in the range of 2 to 4 %. As a primary manufacturer of monodisperse particles for FDA regulated industries, Polysciences must take into consideration the outlying peaks found in many "monodisperse" standards. We employ manufacturing methods to reduce the impact of these outliers. Our refined manufacturing methods enable Polysciences to produce calibration grade particle size standards with a narrower CV than many international standards.

The monodispersity of Polysciences' NIST Traceable Precision Particle Size Standards, as indicated by the coefficient of variation of the mean diameter of the particles in the sample, is comparable and often smaller than those offered by other vendors. In some cases Polysciences' Precision Particle Size Standards are more monodisperse than the NIST Standard Reference Materials to which they are traceable. Though % CV is not a NIST-traceable value, it is reported on product documents for informational purposes.

Size Comparison of Representative Lots of Polysciences' NIST Traceable Particles Size Standards With Competitive Products

<u>Source</u>	Nominal Size	Measured Size ¹	<u>%CV</u>
Polysciences	275 nm	274² nm	2.2
NIST	300 nm	266² nm	3.2
Polysciences	500 nm	512² nm	1.8
Competitor	500 nm	492² nm	2.2
Polysciences	1.0 micron	1.01 ³ micron	2.6
Competitor	1.0 micron	1.01 ³ micron	4.3
Polysciences	20.0 micron	19.47 ³ micron	2.6
Competitor	20.0 micron	19.14 ³ micron	3.6
Polysciences	30.0 micron	29.51 ³ micron	1.3
NIST	30.0 micron	28.41 ³ micron	3.2
Polysciences	50.0 micron	48.63 ³ micron	2.6
Competitor	50.0 micron	48.45 ³ micron	3.2
Polysciences	100.0 micron	102.77 ³ micron	2.1
Competitor	100.0 micron	98.70 ³ micron	2.8

¹ Number Weight Mean Diameter.

² Measured by Disc Centrifuge.

³ Measured by SPOS.

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NIST Traceable Precision Particle Size Standards Table

NANOBEADS

Catalog #	% Solids	Nominal Size	Size Range	Measurement Method ⁴
64004-15	1%	40nm	36.0-44.0nm	DC
64005-15	1%	50nm	45.0-55.0nm	DC
64006-15	1%	60nm	54.0-66.0nm	DC
64007-15	1%	70nm	63.0-77.0nm	DC
64008-15	1%	80nm	72.0-88.0nm	DC
64009-15	1%	90nm	81.0-99.0nm	DC
64010-15	1%	100nm	90.0-110.0nm	DC
64011-15	1%	125nm	119.0-131.0nm	DC
64012-15	1%	150nm	143.0-158.0nm	DC
64013-15	1%	200nm	190.0-210.0nm	DC
64014-15	1%	250nm	238.0-263.0nm	DC
64015-15	1%	300nm	285.0-315.0nm	DC
64016-15	1%	350nm	333.0-368.0nm	DC
64017-15	1%	400nm	380.0-420.0nm	DC
64018-15	1%	450nm	428.0-473.0nm	DC
64019-15	1%	500nm	475.0-525.0nm	DC
64020-15	1%	550nm	523.0-578.0nm	DC
64021-15	1%	600nm	570.0-630.0nm	DC
64022-15	1%	650nm	618.0-683.0nm	DC
64023-15	1%	700nm	665.0-735.0nm	DC
64024-15	1%	750nm	713.0-788.0nm	DC
64025-15	1%	800nm	760.0-840.0nm	DC
64026-15	1%	850nm	808.0-893.0nm	DC
64027-15	1%	900nm	855.0-945.0nm	DC
64028-15	1%	950nm	903.0-998.0nm	DC

4 CPS Disc Centrifuge, Model DC24000 (CPS Instruments, Inc.)

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Catalog #	% Solids	Nominal Size	Size Range	Measurement Method ⁵
64030-15	1%	1.00µm	0.95-1.05µm	DC
64035-15	1%	1.25µm	1.19-1.31μm	DC
64040-15	1%	1.50µm	1.43-1.58μm	DC
64045-15	1%	1.75µm	1.66-1.84µm	DC
64050-15	1%	2.00µm	1.90-2.10μm	DC
64055-15	1%	2.50µm	2.38-2.63µm	DC
64060-15	1%	3.00µm	2.85-3.15µm	DC
64065-15	1%	3.50µm	3.33-3.68µm	DC
64070-15	1%	4.00µm	3.80-4.20μm	DC
64080-15	1%	5.00µm	4.50-5.50μm	DC
64090-15	1%	6.00µm	5.40-6.60µm	DC
64100-15	1%	7.00µm	6.30-7.70μm	DC
64110-15	1%	8.00µm	7.20-8.80μm	DC
64120-15	1%	9.00µm	8.10-9.90μm	DC

MICROBEADS

⁵ BI-DCP Particle Sizer (Brookhaven Instruments)

MEGABEADS

Catalog #	% Solids	Nominal Size	Size Range	Measurement Method ⁶
64130-15	1%	10.0µm	9.00-11.00μm	SPOS
64140-15	1%	12.0µm	10.80-13.20µm	SPOS
64155-15	1%	15.0µm	13.50-16.50µm	SPOS
64160-15	1%	20.0µm	18.00-22.00µm	SPOS
64165-15	1%	25.0µm	22.50-27.50µm	SPOS
64170-15	1%	30.0µm	27.00-33.00µm	SPOS
64180-15	1%	40.0µm	36.00-44.00µm	SPOS
64190-15	1%	50.0µm	45.00-55.00μm	SPOS
64200-15	1%	60.0µm	54.00-66.00µm	SPOS
64210-15	1%	80.0µm	72.00-88.00µm	SPOS
64220-15	1%	100.0µm	90.00-110.00µm	SPOS
64225-15	1%	125.0µm	112.5-137.5μm	SPOS
64230-15	1%	150.0μm	135.0-165.0µm	SPOS
64235-15	1%	175.0μm	157.5-192.5µm	SPOS

6 Accusizer 780 Optical Particle Sizer (Particle Sizing Systems)

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