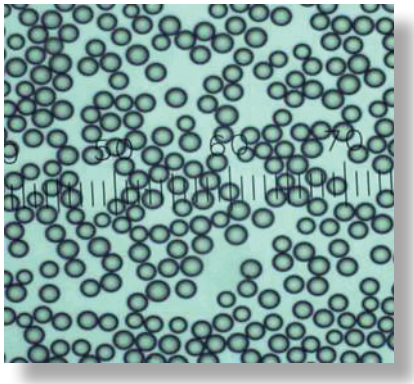
Thermo Scientific 4D Series Duke Standards Dry Microsphere Size Standards

Calibrate air particle counters for pharma, healthcare, biotech and electronics

- Mean size standard uncertainty of ≤ 2.5% enables calibration of air particle counters to ISO 21501-4 regulations
- Superior uniformity provides exact calibration point when setting the calibration curve
- Diameter traceable to NIST, a known government standard
- Certificate of Traceability provides objective evidence for QC compliance



The 4D Series is the first dry bead specifically designed to meet the ISO 21501-4 international standard for improving the repeatability and reproducibility of air particle counters.

Thermo Scientific 4D Series Duke Standards™ Dry Microsphere Size Standards are designed with a calibration uncertainty that is less than or equal to 2.5% of the mean diameter, enabling them to be used to calibrate airborne optical particle counters (OPC) in compliance with ISO 21501-4.

These beads come with a Certificate of Calibration and Traceability to the National Institute of Standards and Technology (NIST), providing the documentation needed for QC/regulatory programs and audits.

Available in 3 µm, 5 µm, 7 µm and 10 µm diameters, these dry polymer beads are ideal for OPC instrument manufacturers and service providers working to the ISO standard, as well as pharmaceutical, healthcare, and biotech companies manufacturing products with ISO 21501-4 certified OPCs in a ISO 14644 classified cleanroom.

The ISO 21501 standard delivers a calibration method designed to improve the repeatability and reproducibility of air particle counters. It deals comprehensively with statistical uncertainty and defines limits to a set of performance parameters which must be covered in routine periodic calibration.

Conformance to ISO 21501-4 ensures that air particle counter instruments 1) size particles correctly to an acceptable uncertainty level, and 2) count particles accurately to a defined counting efficiency level.

ISO 14644 is a widely used standard for cleanroom classification using OPCs.

The 4D Series comes conveniently packaged in dropper-tipped bottles to enable direct dispensing of the beads into the sampling chamber of the OPC

Thermo SCIENTIFIC

Authorized Distributor in your area

Distrilab microsphere technology

Wapenrustlaan 11-31
7321 DL Apeldoorn
The Netherlands

www.distrilab.nl
info@distrilab.nl
+31 (0) 85 040 9913

4D Series Duke Standards Dry Microsphere Size Standards

With the potential to impact the health of bilions of people, pharmaceutical manufacturing is one of the more regulated industries in the world. Calibration requirements are governed by the U.S. Food and Drug Administration (FDA) while the corresponding standards in Europe are administered by the European Medicines Administration (EMEA) and local legislation. Since process measurements are critical to ensure product quality, calibrating instruments precisely and in a timely manner is an important step toward ensuring pharmaceutical products are manufactured correctly.

FDA and EMEA regulations require manufacturers to maintain calibration records and perform calibration according to written, approved procedures. In addition to specifically addressing the calibration needs of pharmaceutical manufacturers seeking compliance to ISO 21501-4, the 4D Series beads come with a Certificate of Calibration and Traceability to the National Institute of Standards and Technology (NIST) which includes a description of the calibration method and its uncertainty, and a table of chemical and physical properties.

Specifications

Composition	Polystyrene
Format	Dry
Index of refraction	1.59 @ 589 nm (25°C)
Additives	Trace flow agent might be present
Expiration date	≥ 24 months (from date of shipment)
Documentation	Certificate of Calibration and Traceability to NIST, and Material Safety Data Sheet (MSDS)
Storage and Handling	Unless otherwise stated, store at ambient room temperature. Store upright, keep bottle tightly sealed. Mix product with gentle inversion by hand or vortex mixer.

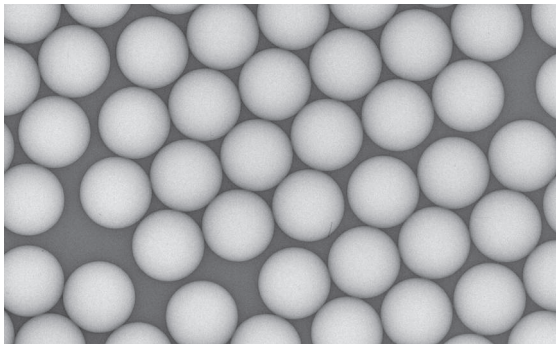
Nominal Diameter	Mean Size Uncertainty	Bottle Size	Approximate Count Per Gram	Catalog Number
Uniform PS-DVB Dry Spheres - Calibrated by Optical Microscopy				
3 µm	≤ 2.5 %	1 gram	1.4×10^{10}	4D-03
5 µm	≤ 2.5 %	1 gram	8.4×10^{10}	4D-05
7 µm	≤ 2.5 %	1 gram	5.5×10^{9}	4D-07
10 µm	≤ 2.5 %	1 gram	4.3×10^{9}	4D-10

Over 35 years of particle technology expertise

With a depth and breadth of innovative particle technology design and manufacturing experience that spans over 35 years, we are your proven, reliable source for world class diagnostic, dyed, undyed, fluorescent, flow cytometry, size standard, and count control bead solutions.

All Thermo Scientific beads are manufactured in our proprietary ISO 13485 certified facilities under rigorous quality control procedures. By manufacturing our own beads, we can provide customers with comprehensive data about the characteristics and functionality of the beads they purchase.

Customers can also count on our responsive, technical support backed by years of particle applications training and research.



thermoscientific.com/particletechnology

© 2013 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries. Specifications, terms and pricing are subject to change. Not all products are available in all countries. Please consult your local sales representative for details.

Clinical Diagnostics
Particle Technology

46360 Fremont Boulevard
Fremont, California 94583
U.S.A.

1-800-232-3342 (USA)
+1-510-979-5000 (International)
thermoscientific.com/particletechnology

Thermo SCIENTIFIC
Part of Thermo Fisher Scientific

PS4003.1-11/13

Authorized Distributor in your area

Distrilab microsphere technology

Wapenrustlaan 11-31
7321 DL Apeldoorn
The Netherlands

www.distrilab.nl
info@distrilab.nl
+31 (0) 85 040 9913