PRODUCT SPECIFICATION

Thermo Scientific Count Controls PHARM-TROL, COUNT-CAL, Ezy-Cal, Validex

Maximize instrument repeatability, reproducibility, and performance accuracy

Thermo Scientific[™] Count Controls validate the results of laser particle counters regardless of brand to ensure they are accurately measuring for particulate matter in air, surface or liquid applications where contamination is a concern and requires diligent monitoring.

- Diameters are traceable to the standard meter through the National Institute of Standards and Technology (NIST), providing a simple, convenient method for calibrating particle counting instruments.
- Supplied as a low residue aqueous suspension that allows for minimal background interference and precise insight into the dynamic range and calibration of the instrument.
- Precisely diluted for immediate use in laser particle counters, minimizing any need for time-consuming adjustments of the concentration.



Count control concentrations are provided with a \pm tolerance to provide confidence in the results



PHARM-TROL[™] Count Precision Size Standards

PHARM-TROL has a 15 μm nominal diameter and is packaged in concentrations of 3800 particles/ mL \pm 15%. Used by manufacturers of parenteral drugs and ophthalmic solutions who are seeking interim verification of USP <788> and <789>.

COUNT-CAL[™] Count Precision Size Standards

COUNT-CAL products have a nominal range from 2 μ m to 70 μ m in concentrations of 3000 particles per mL ± 10%. COUNT-CAL can be used in similar applications as PHARM-TROL.

Ezy-Cal[™] Count Precision Size Standards

Ezy-Cal comes in ready-to-use concentrations of 2000 particles/ $mL \pm 10\%$. Typical applications include pharmaceutical, food, beverage, and wastewater.

Validex[™] Count Precision Size Standards

Validex is used for validating the performance of liquid particle counters used for testing drinking water. Each bottle contains a nominal concentration of 1000 particles/mL \pm 10% in ultrapure water.



Applications

- Calibration of particle counters using laser scatter, light scatter, light blockage, imaging microscopy, and electrical resistance.
- Verify instrument QC by checking for instrument problems, shifts in laser function, and calibration curve shape variations.

Specifications	PHARM-TROL	COUNT-CAL	Ezy-Cal	Validex			
Composition	Polystyrene	Polystyrene	Polystyrene	Polystyrene			
Diameter (nominal)	15 µm	2 μm to 70 μm 2 μm to 70 μm		5 μm and 10 μm			
Concentration	3800/mL ± 15%	3000/mL ± 10%	$2000/mL \pm 10\%$	1000/mL ± 10%			
Density	1.05 g/cm ³	1.05 g/cm ³	1.05 g/cm ³	1.05 g/cm ³			
Index of Refraction	1.59@589 nm (25°C)	1.59@589 nm (25°C)	1.59@589 nm (25°C)	1.59@589 nm (25°C)			
Fill Volume	25 mL	25 mL	100 mL	500 mL			
Additives	Trace amount of surfactant in each product						
Package Includes	Certificate of Calibration and Traceability to NIST.						
Storage and Handling	Unless otherwise stated, refrigerate (2-8°C) product when not in use, but do not freeze. Store upright and keep bottle tightly sealed. Mix product with gentle inversion by hand or vortex mixer.						

PHARM-TROL		COUNT-CAL	COUNT-CAL			Ezy-Cal	
Catalog Number	Nominal Diameter	Quantity	Catalog Number	Nominal Diameter	Quantity	Catalog Number	Nominal Diameter
CS-PK	15 µm	6 bottles	CC02-PK	2 µm	6 Bottles	6002	2 µm
CS-BX	15 µm	20 bottles	CC05-PK	5 µm	6 Bottles	6005	5 µm
			CC10-PK	10 µm	6 Bottles	6010	10 µm
Mallalan			CC15-PK	15 µm	6 Bottles	6015	15 µm
Catalog Nominal		CC20-PK	20 µm	6 Bottles	6020	20 µm	
		CC25-PK	25 µm	6 Bottles	6025	25 µm	
Number	Diameter		CC30-PK	30 µm	6 Bottles	6030	30 µm
CRS-05	5 µn	n	CC50-PK	50 µm	6 Bottles	6050	50 µm
CRS-10	10 µI	m	CC70-PK	70 µm	6 Bottles	6070	70 µm

PHARM-TROL and COUNT-CAL Beads Comply with Global Pharmacopoeia

- United States Pharmacopoeia (USP) <729>, <788>, and <789>
 - Globule Size Distribution in Intravenous Emulsions
 - Particulate Matter for Injections
 - Particulate Matter for Ophthalmic Solutions
- China Pharmacopoeia (Ch. P. 2010, Volume III, App. V)
- European Pharmacopoeia (Ph. Eur.) 2.9.19
 - Particluate Contamination: Sub-visible Particles
- Japan Pharmacopoeia (JP) 6.07
 - Insoluble Particulate Matter Test for Injections

Clinical Diagnostics Particle Technology 46500 Kato Road Fremont, California 94583 U.S.A. 1-800-232-3342 (USA) +1-510-979-5000 (International) info.microparticles@thermofisher.com

Find out more at thermofisher.com/particletechnology

© 2017 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **PS-10021646-0MTL-COUNT-CONTROLS-EN**

