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Certificate

Catalog No.:
PC2503-25
PC2503a25

Particle Count Standard - Kit 25µm

Lot Number: **PC300.712**

Components of the Product: Each kit consists of:
Particle Count Standard: 1x 25mL Blank Sample: 1x 25mL
Magnetic Stir Bar: 1x Certificate: 1x

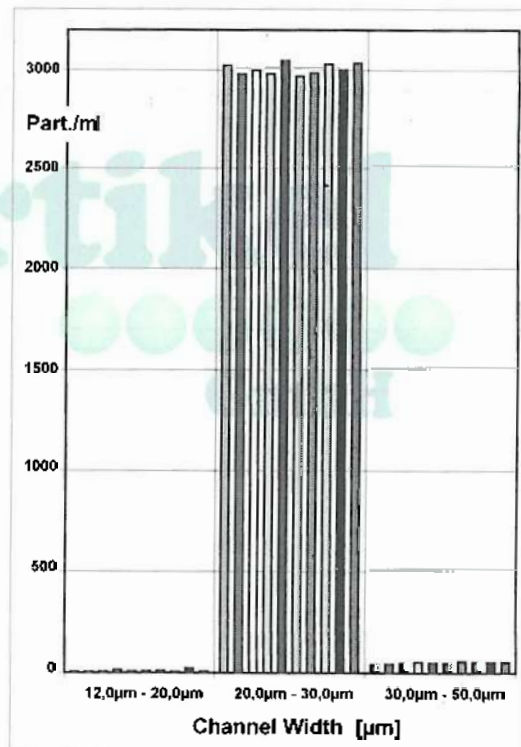
Particle Counting System: Type "Syringe", Fa. Markus Klotz GmbH - Bad Liebenzell, Germany
Sensor: 8032 Flow Rate: 16,0 mL/min

Calibration: To generate the calibration curve NIST[®] traceable reference size standards have been applied. [®] NIST: Institute of Standards and Technology, Gaithersburg - USA
Calibration Curve: 120606.cal

Mean Particle Diameter x_{μ} : 26,9µm
Size Range of Measurement: 20,0µm - 30,0µm
Particle Concentration: 3020 Part./mL
Deviation in Measurements: ±50 Part./ml (±1.7%)
Error in Volume: 0.9%

To determine these count data 10 bottles of the particle count standard with a total of 30 measurements of ## mL each had been performed

Polymer Density: 1.05 g/mL
Refractive Index: 1.59 (25° C, 589nm)
Chemical Composition: Aqueous Suspension consisting of:
Poly-(styrene-codivinyllbenzene)
Surfactants (<0.05%)
Preservatives (<0.03%)



Wiesbaden - 24.07.2012

Dr. Bernd Schied

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Each Particle Count Standard Kit has been designed to singularly check count accuracy of one particle counting system. The kit is not optimized for size calibrations. Please conduct with each bottle four consecutive measurements of 5mL each. The first one is for rinsing and equilibration only and may not be used for evaluation.

How to Apply the Particle Count Standard Kit

Preparation of the Particle Counting System

- * First the particle counting instrument has to be size-calibrated, the volume accuracy has to be checked and the sensor as well as the sample injection part has to be particle-free.
- * Assign the channel widths. The following channel widths have to be adjusted:

Channel	1	Main Channel	3
Size Range	12.0µm - 20.0µm	20.0µm - 30.0µm	30.0µm - 50.0µm

Verification using the Blank Sample

- * The first 5mL should be used without measurement (rinse only).
- * Measurement: Perform 3 particle count measurements of 5mL each
If the last two measurements will show a total particle concentration of <50 part./mL each and a particle concentration of <10 part./mL in the main channel then the real particle counting can be started. If this assumption is not fulfilled the particle counting device has to be cleaned and the procedure with the Blank sample has to be repeated completely.

Verification using the Particle Count Standard

- * Do not shake! During the entire preparation and measurement input of air or generation of foam has to be avoided necessarily! Allow 15 seconds of stirring with the magnetic stir bar thereby the stir bar should hit the inner wall occasionally.
- * Open the bottle and place the injection needle of the counting instrument approximately 5mm above the bottom of the bottle.
- * Please take care that even during the last measurement no air can be sucked into the sensor.
The magnetic stir bar should rotate monotonously slow and should hit the wall once in a while only.
- * Rinsing/equilibration: Use the first 5mL to clean the sensor.
- * Measurement: Perform 3 measurements of 5mL each and calculate the average count result. If the counted particle number in channel 1 or 3 is more than 10% of the counted particle number of the main channel then too many air bubbles had been generated and counted. In this case the complete measurement has to be repeated after allowing the closed particle count standard to stay untouched for a few days.

Storage, Shelf Live

Particle Count Standard bottles should be stored in **vertical position** at 4°C - 15°C together with other chemical reference materials. Do not store with chemicals of daily use. Do not freeze!

This PharmaCount1510-Kit can be applied without any quality loss until: **20. NOV. 2016**

Product Lot (Blank): **BI320.812**

Product Lot: (Suspension): **PC300.712**

Shipping Lot

13519

Result Record Form

Prüfpaß

Measured Counts <i>Meßwerte</i> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Average <i>Mittelwert</i>	Certified Counts <i>Zertifikatswert</i> 3020 Part./ml Company Specif. <i>Firmenspezifikation</i> Deviat. fr. Comp. Specif. [Part./mL] <i>Abweich. v. Firmenspezif. [Part./mL]</i>	Comments <i>Bemerkungen</i> Particle Counting Instrument <i>Partikelzählgerät</i> Operator / Department <i>Prüfer / Abteilung</i>
Test passed? Test bestanden? <input type="checkbox"/> yes ja <input type="checkbox"/> no nein		Sign+Date <i>Unterschrift+Datum</i>