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Certificate

Catalog No.:
Ph1510-25
Ph1510a25

PharmaCount1510 - Kit

Lot Number:	Ph360.161
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 mL/min
Calibration:	To generate the calibration curve NIST ¹⁾ traceable reference size standards have been applied. ¹⁾ NIST: Institute of Standards and Technology, Gaithersburg - USA Calibration Curve: 160114.cal

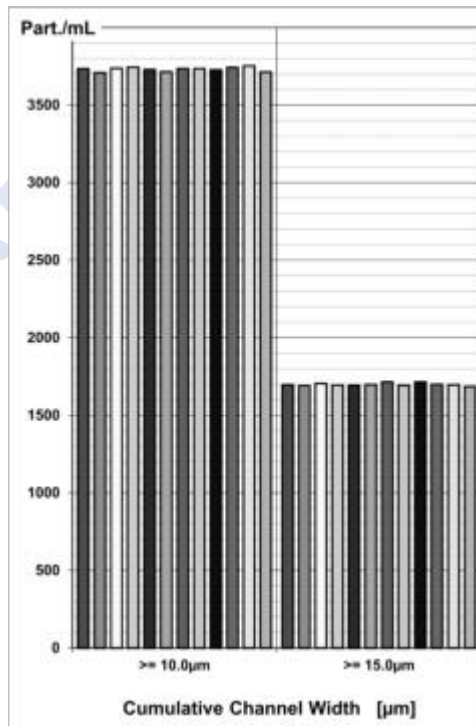
Number of Particles $\geq 10,0\mu\text{m}$ ($N_{10\mu}$): 3330 - 4110 Part./mL

$N_{10\mu} / N_{15\mu}$ (Ratio): 1.78 - 2.57

To determine these data 12 PharmaCount1510-Kits with a total of 36 single measurements of 5 mL each have been performed during filling of this lot

Number of Particles $\geq 10,0\mu\text{m}$ (Blank):	< 10 Part./mL
Most frequent Particle Size x_N :	12.2 μm and 20.0 μm
Precision of Volume:	1.5%

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



Wiesbaden - 29.03.2016

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Dr. Bernd Schied



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How to Apply

Referring to USP <788>: Particulate Matter of Injections, Sect. Light Obscuration Particle Count Test

1. Preparation of the Particle Counting System

It should be size calibrated and a volume precision test should have been conducted.

The particle counting system should be free of particles inside of the sensor and the sample injection part. Assign two channels für cumulative countings. The following channel widths have to be adjusted:

Channel 1: $\geq 10.00\mu\text{m}$ and Channel 2: $\geq 15.00\mu\text{m}$

1. Counting of the Blank:

Treat the Blank with an ultra sonic bath for 30 seconds first. Perform 4 countings of 5.0mL each without any further pre-treatment. The first one is necessary for purging only. The last three of them will be used for calculating the average values and will be written into the "Result Entry Form" of this certificate.

2. The Main Counting Test:

The PharmaCount1510 bottle has to be homogenized for 15 seconds with a magnetic stirrer first. The stir bar should hit the inner wall of the bottle frequently. Treat the bottle for 30 seconds with an ultrasonic bath. Place the injection needle approx. 1mm above the bottom of the bottle and keep gentle stirring during all further measurements.

Conduct four consecutive countings of 5.0mL each. The first one is necessary for purging only. The last three will be used to calculate the average values and will be written into the "Result Entry Form" of this certificate. The difference of the average of particle sample and Blank is the average number of particles per mL ($N_{10\mu}$). The count test is passed if $N_{10\mu}$ and $N_{10\mu} / N_{15\mu}$ will be within the certified reference values of this certificate.

Storage, Shelf Life

PharmaCount1510 bottles should be stored in **vertical position** at 4°C - 15°C together with other chemical reference materials only. Any vigorous shaking should be avoided.

This PharmaCount1510 kit can be applied without any quality loss for 2 years from shipping date.

Freezing, solar radiation or any contamination can result in wrong count results.

Shipping Date:



Particle Counting Instrument <i>Partikelzählgerät</i>		Department / Operator <i>Abteilung / Prüfer</i>		Date <i>Datum</i>
Particle Suspension <i>Partikelprobe</i>		Blank <i>Blankprobe</i>		Comments <i>Bemerkungen</i>
① $N_{10\mu}$	① $N_{10\mu}$	① $N_{15\mu}$	① $N_{15\mu}$	
② $N_{10\mu}$	② $N_{10\mu}$	② $N_{15\mu}$	② $N_{15\mu}$	
③ $N_{10\mu}$	③ $N_{10\mu}$	③ $N_{15\mu}$	③ $N_{15\mu}$	
Average <i>Mittelwert</i>	=	Average <i>Mittelwert</i>	=	
$N_{10\mu}$		$N_{15\mu}$		$N_{10\mu} / N_{15\mu}$
Certified $N_{10\mu}$ <i>Zertifiz.</i>	3330 - 4110 <i>Part./mL</i>	Certified $N_{10\mu} / N_{15\mu}$ <i>Zertifiz.</i>	1,78 - 2,57 <i>1,78 - 2,57</i>	
Test passed? <i>Test bestanden?</i>		<input type="checkbox"/> yes <i>ja</i>	<input type="checkbox"/> no <i>nein</i>	Sign <i>Unterschrift</i>