

## PharmaCounts™ Traceable Particle Count Controls



meets international Pharmacopeia requirements

optimized concentrations for direct use

particle diameters traceable to SI units

long shelf life at room temperature

### Traceable particle count controls designed to comply with requirements of the pharmaceutical industry

The PharmaCount™ series by Applied Microspheres product line consists of polystyrene particle suspensions with precisely defined numbers of particles. It is designed for pharmaceutical quality control laboratories to facilitate calibration and validation processes for liquid particle counters. PharmaCount™ series are not suitable for replacing the official standards supplied by the US, Japanese or Korean Pharmacopeia organisations but the products mimic the specifications to a particle standard as defined in the pharmaceutical standards. As such, they are ideally suited to perform regular tests to ensure compliance of the analytical instruments applied in GMP environments. PharmaCounts™ products consist of particle size standards traceable to the International System of Units (SI). The Certificates of Traceability supplied with each product meet requirements of GMP-compliant records of instrument validations.

#### PharmaCount™ JPKP

PharmaCount™ JPKP meets the requirements of Japanese and Korean Pharmacopeia Insoluble Particulate Matter Test for Injections. It is designed for use as instrument control for the test prescribed by the Japanese and Korean Pharmacopeia. It is supplied in a pack of two 50 mL bottles. Each bottle contains 763 to 1155 particles per ml of monodisperse polystyrene microspheres with calibrated mean diameter of 10 µm. A magnetic stir bar is included in each bottle to ensure optimal dispersion and uniformity during sampling.



#### PharmaCount™ US

PharmaCount™ US meets the requirements of the U.S. Pharmacopeia <1788.1>: Light obscuration method for the determination of visible particulate matter in Injections and Ophthalmic solutions. It is designed for use as intermediate instrument control. Each bottle contains monodisperse polymer microspheres with 15 µm nominal diameters. The counts range of acceptance and the ratio of counts between the population fractions with size  $\geq 10 \mu\text{m}$  and  $\geq 15 \mu\text{m}$  comply with the official standard as provided by the USP. It is supplied in a pack of six 25 mL bottles with a magnetic stir bar included in each bottle to ensure optimal dispersion and uniformity during sampling.

#### PharmaCount™ TC

PharmaCount™ TC is a particle size and count reference standard designed for easy calibration of single particle optical sizing (SPOS) instruments using light extinction and/or scattering. It is supplied in a pack of six 25 mL bottles. Each bottle contains three different size populations monodisperse polymer microspheres with nominal diameters of 0,8 µm, 2 µm and 5 µm, with approximate counts of 1.200.000, 800.000 and 400.000 per ml, respectively. Particle diameters are traceable to SI, which includes NIST-traceability. A magnetic stir bar is included in each bottle for optimal dispersion and uniformity during sampling.

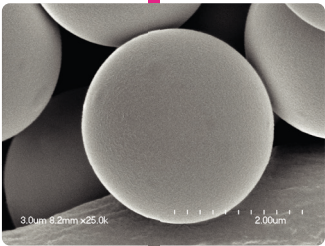
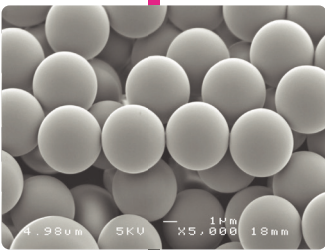
#### PharmaCount™ BC

PharmaCount™ BC is a particle size and count reference standard ideally suited for performing insoluble particulate matter tests for lipid injectable emulsions as prescribed by the United States Pharmacopeia <729>. It is designed for use as instrument control and supplied in packs of six 25 mL bottles. Each bottle contains two different size populations of monodisperse polymer microspheres with nominal diameters of 5 µm and 10 µm, with approximate counts of 400.000 and 200.000 per ml, respectively. Particle diameters are traceable to SI, which includes NIST-traceability. A magnetic stir bar is included in each bottle to ensure optimal dispersion and uniformity during sampling.

## Particle Count Control Sets Complying with Pharmaceutical Guidelines - Ph Series

	PharmaCount™ US	PharmaCount™ JP	PharmaCount™ BC	PharmaCount™ TC
PIN	20015-25	20010-50	20510-25	20825-25
Nominal diameter	15 µm	10 µm	5 µm, 10 µm	0,8 µm, 2 µm, 5 µm
Particle counts	in accordance to USP count standard	1000/ml	per diameter*	per diameter*
Ratio N10µ / N15µ	in accordance to USP count standard	n.a.	n.a.	n.a.
Package	6x 25 mL	2x 50 mL	6x 25 mL	6x 25 mL
Set content	6 particle suspensions and certificate	2 particle suspensions and certificate	6 particle suspensions and certificate	6 particle suspensions and certificate
Volumes	25 mL each	50 mL each	25 mL each	25 mL each

\*see product description



## Particle Count Control Sets - 3M Series / 1D Series Traceable to NIST and the International System of Units (SI)

PIN	Nom. Diameter	Nom. Counts
3M002-25	2 µm	3.000 Part. / mL
3M005-25	5 µm	3.000 Part. / mL
3M010-25	10 µm	3.000 Part. / mL
3M015-25	15 µm	3.000 Part. / mL
3M020-25	20 µm	3.000 Part. / mL
3M025-25	25 µm	3.000 Part. / mL
3M030-25	30 µm	3.000 Part. / mL
3M040-25	40 µm	3.000 Part. / mL
3M070-25	70 µm	3.000 Part. / mL
3M100-25	100 µm	3.000 Part. / mL
1D025-25	25 µm	500 Part. / mL
1D040-25	40 µm	500 Part. / mL
1D070-25	70 µm	500 Part. / mL