

PharmaCount™

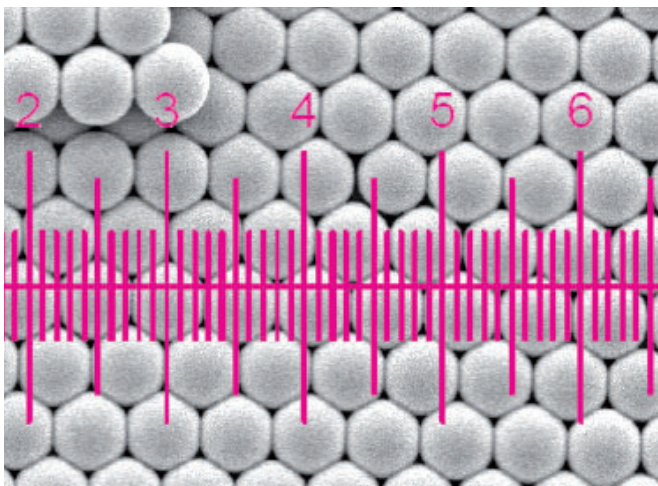
Particle count and size reference standards

The PharmaCount™ series by Applied Microspheres is a product line consisting 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. Laboratories observing QC protocols meeting the US, Japanese and Korean Pharmacopeia requirements, are obliged to use standards supplied or defined by the US, Japanese or Korean Pharmacopeia organisations to perform mandatory (6 monthly) tests. PharmaCount™ US, PharmaCount™ JP and PharmaCount™ Bi-Cal meet the specifications of these standards and are therefore ideally suited to perform (intermediate) tests to ensure that their instruments are always correctly calibrated, thereby safeguarding USP, JP and KP compliancy.

PharmaCount™ Bi-Cal and PharmaCount™ Tri-Cal are particle count control products that simplify the calibration of single particle optical sizing (SPOS) instruments using light extinction and/or scattering. These instruments are commonly used in pharmaceutical



quality control laboratories and calibration can be troublesome. NIST traceable particle size standards are used for all PharmaCount™ products and all particle sizing and counting instruments used are calibrated with NIST traceable size standards.



PharmaCount™ US

PharmaCount™ US meets the requirements of U.S. Pharmacopeia, USP 1788 for the determination of Particulate Matter in Injections and Ophthalmic solutions light obscuration particle count test. It is designed for use as intermediate instrument control. It is supplied in a pack of six 25mL bottles. Each bottle contains monodisperse polymer microspheres with 15 µm nominal diameters for the purpose of obtaining a ratio between the population fractions with size $\geq 10 \mu\text{m}$ and $\geq 15 \mu\text{m}$. The provided ratio falls in the range stipulated by USP 1788. A magnetic stir bar is included in each bottle to ensure optimal dispersion and uniformity during sampling.

PharmaCount™ JP

PharmaCount™ JP meets the requirements of Japanese and Korean Pharmacopeia for the determination of Particulate Matter in Injections and Ophthalmic solutions light obscuration particle count test. It is designed for use as instrument control. It is also suitable as intermediate 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 1000 particles per ml (+ 10%), of monodisperse polymer 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™ 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 of NIST traceable monodisperse polymer microspheres with nominal diameters of 0,8 µm, 2 µm and 5 µm, with approximate counts per ml of 1.2 mio, 800k and 400k respectively. 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 USP 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 NIST traceable monodisperse polymer microspheres with nominal diameters of 5 µm and 10 µm, with approximate counts of 400k and 200k particles per ml respectively. A magnetic stir bar is included in each bottle to ensure optimal dispersion and uniformity during sampling.



Ordering information

| | PharmaCount™ US | PharmaCount™ JP | PharmaCount™ BC | PharmaCount™ TC |
|-------------------|-----------------|-----------------|-----------------|--------------------|
| PIN | 21015 | 20010 | 20510 | 20825 |
| Nominal diameter | 15 µm | 10 µm | 5 µm, 10 µm | 0,8 µm, 2 µm, 5 µm |
| Particle counts | 3365-3940/ml | 1000/ml | per diameter* | per diameter* |
| Ratio N10µ / N15µ | as per USP 1788 | n.a. | n.a. | n.a. |
| Package | 6x 25 ml | 2x 50 ml | 6x 25 ml | 6x 25 ml |

* see product description