

## PAMAS USP

# Software programme for pharmaceutical applications

**Particle measurements in compliance with the pharmaceutical standards USP <787>, USP <788>, USP <789>, EP, BP, JP, KP and IP or according to customer specific standards**

- Software for the measurement of infusion solutions, parenterals and similar fluids according to pharmaceutical standards
- Can be used together with the laboratory particle counters PAMAS SBSS and PAMAS SVSS
- Numerical and graphical report of cumulative particle counts in compliance with the pharmaceutical standards USP <787> (Subvisible Particulate Matter in Therapeutic Protein Injections), USP <788> (Particulate Matter in Injections) and USP <789> (Particulate Matter in Ophthalmic Solutions) as well as further national pharmacopoeias including EP, JP, KP, BP and IP
- Additional function: Sensor calibration
- Support package for IQ (installation qualification) and OQ (operation qualification) for the validation of particle counters
- Compatible with Microsoft Windows® 7, 8 and 10

## Software for particle measurements according to pharmaceutical standards

Together with the software **PAMAS USP**, the laboratory particle counters PAMAS SVSS and PAMAS SBSS perform particle measurements in compliance with the pharmaceutical standards USP <787>, USP <788>, USP <789> and other pharmacopoeias including EP, BP, JP, KP and IP.

### Validation of particle counters according to USP <788>

With the help of the software PAMAS USP, the particle counters PAMAS SVSS and PAMAS SBSS can also be validated for pharmaceutical applications.



*The analysing system PAMAS SVSS is a standard laboratory particle counter for pharmaceutical applications and other low viscous liquids.*



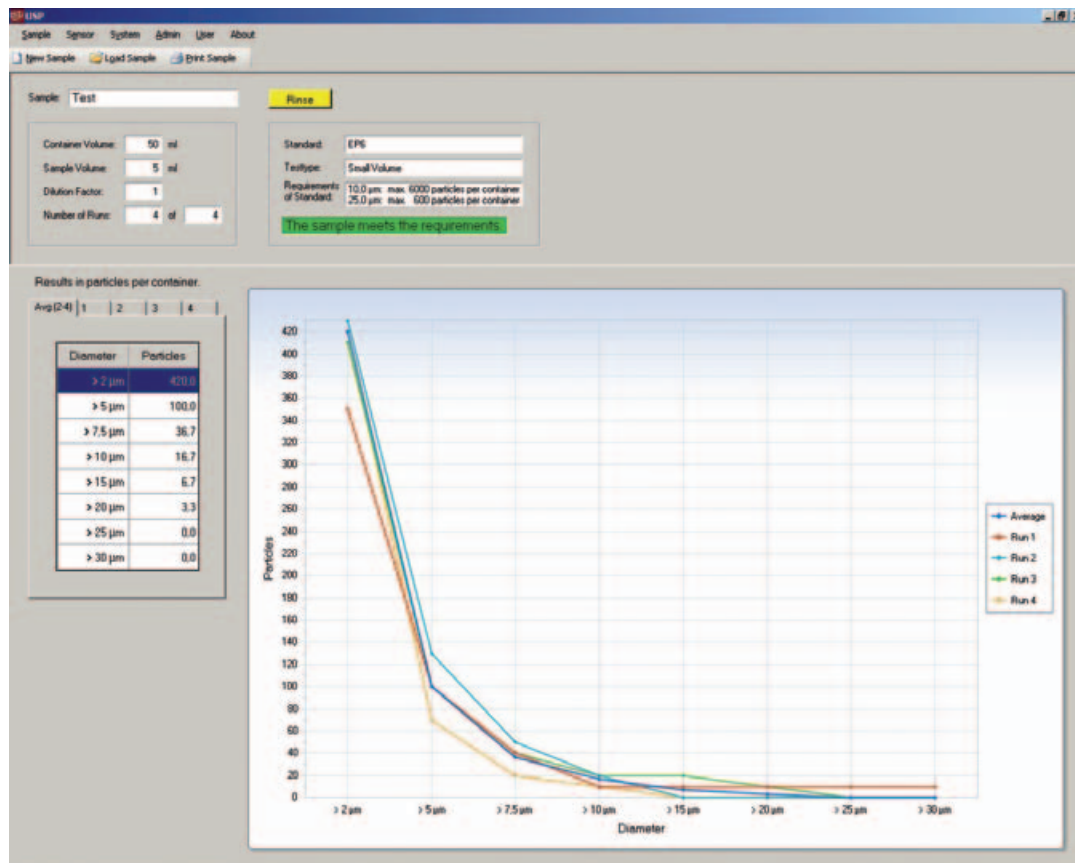
*The measuring instrument PAMAS SBSS is a standard laboratory particle counter for high viscous bottle samples.*

### Technical details:

- Simple data input of new pharmaceutical standards
- Customer specific standards can be defined
- Data storage and printing of all measuring parameters, including operator, measurement settings, single measuring results and mean value
- Optional definition of diluting factor
- Automatic data storage on a free selectable (network) path
- Data export of measuring results into Microsoft excel

### Conformity to 21 CFR Part 11 through:

- Access control via password
- Measurements can be reviewed and approved (electronic signature).
- Data storage in encrypted data base



*If the sample meets the cleanliness requirements of the selected standard, the measuring result will be marked in green.*

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