

APSS-2000

Automated Parenteral Sampling System



The APSS-2000 syringe sampling system sizes and counts suspended particulate matter in a wide range of liquids and meets or exceeds all current USP, EP, and JP requirements. Recipe functions allow the APSS-2000 to adapt to future regulatory changes.

The APSS-2000 system consists of an SLS-2000 syringe sampler, a LiQuilaz® II E Series light obscuration spectrometer, and SamplerSight-Pharma software, allowing reports to meet 21 CFR 11 “Electronic Records and Signatures” rulings.

BENEFITS

Defect Reduction

- 100% sample volume for greater accuracy
- A precise sample volume within 0.2 ml is achieved with the syringe sampler, producing repeatable results
- SamplerSight-Pharma software comes with a Validation Information Notebook, providing comprehensive software development documentation and full IQ, OQ, and PQ protocols
- SamplerSight-Pharma complies with FDA 21 CFR 11

User-Friendly

- Reduce operator error and ensure process accuracy with recipes for repeat sample processing to USP, EP, or JP standards
- Automated particle counter calibration wizard for full calibration or routine verification
- Alarm levels for pass/fail criteria ensure quality control
- Automated backup scheduling ensures enhanced data integrity

Comprehensive System

- Easy-to-use, pull-down menus
- Active Directory security password maintains system integrity
- Particle measurements are reported per ml or per container values
- Small sample volume minimizes waste of expensive product
- Various custom report formats are available
- Electronic report approval

FEATURES

- Particle size capability from 1.5 to 125 μm
- Fifteen user-selectable sizing channels
- Meets and exceeds all USP, EP and JP requirements
- Sample volumes from 0.2 ml to 1 liter
- Adapters for SVI and IV bag testing
- Automated sensor calibration
- Plug and play ultrasonic bath and magnetic stirrer options available

APPLICATIONS

- Pharmaceutical parenteral monitoring to USP, EP, JP and FDA standards
- Parts/medical device cleanliness testing
- Laboratory water sampling
- Water for Injection (WFI) and Purified Water (PW) testing
- Filter efficiency testing

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Specifications

Liquid Sensor	LiQuilaz® II E-20P	LiQuilaz® II E-15P
Size Range	2 – 125 µm	1.5 – 125 µm
Location	Internal to SLS-2000	
Size Channels	15	
Flow Rates	10 or 20 ml/min	
Volume Sampled	100%	
Maximum Concentration	10,000 per ml ¹	
Sample Temperature	50 – 122 °F (10 – 50 °C)	
Zero-count Level	< 1 count per 10 ml	
Capillary Size	0.5 x 0.7 mm	
Maximum Pressure	25 psi	
Maximum Sample Viscosity	35 centipoise @ 20 ml/min 50 centipoise @ 10 ml/min	
Laser Source	Laser diode	
Wetted Surface Materials	Fused Silica, Black Quartz, Teflon, Kel-F®, Kalrez®	

¹ Greater than 90% accuracy (less than 10% coincidence loss) at maximum recommended concentration.

Liquid Sampler	SLS-2000
Syringe Size	1, 5, 10, and 25 ml (10 ml is standard and included)
Sampling Mode	Vacuum
Minimum Sample Volume ²	0.4 ml @ 20 ml/min, 0.2 ml @ 10 ml/min
Wetted Surface Materials	Glass, Teflon
Dimensions (H x W x L)	17.1 x 9 x 15 in (43.4 x 22.9 x 38.1 cm) Including particle counter
Weight (Particle Counter)	30 lb (13.6 kg) Including particle counter
Power	100 – 240 V, 50 – 60 Hz
Environment Temperature	Temperature 50 – 86 °F (10 – 30 °C)
Humidity	0 – 98% non-condensing

² Minimum sample volume depends on the sample syringe used.

Software	SamplerSight Pharma
Operating System	Windows® 7, Windows 10 (64 bit)
Developer	Particle Measuring Systems
Test Procedure	Software Validation Information Notebook

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