

Savillex Technical Note

Particle Testing of 5L Purillex® Bag Assemblies

Particle cleanliness is a critical quality attribute for single-use containers used in bioprocessing and pharmaceutical applications, including drug and media filling, storage, and transport. Potential sources of particulate contamination include the materials of construction, manufacturing processes, personnel, and environmental factors. Any particles introduced by the container system could compromise the safety, efficacy, or quality of the final drug product.

To mitigate these risks, it is essential to routinely test single-use systems for particle load in accordance with regulatory standards. One such standard is United States Pharmacopeia (USP) <788>, which outlines acceptable particulate levels for injectable products. This tech note details baseline particle testing and corresponding results for Savillex 5L Purillex® Bag Assemblies performed using Method 1 (Light Obscuration) per USP <788>.

Test Objective

Evaluate the particulate cleanliness of Savillex 5L Purillex bag assemblies using USP <788>, Method 1.

Test Methodology

Particle testing was conducted by Nelson Labs (Salt Lake City, UT, USA). Nelson Labs study number 1769485-S01 (available upon request). Three (3) Savillex 5L Purillex bag assemblies (Figure 1) were filled to a nominal volume (range: 1000.70 mL to 1004.99 mL) with deionized water, inverted 20 times (ensuring that water contacted all wetted surfaces (bag, tubing, and luer connectors)), and sampled in quadruplicate. The first draw was discarded, and the remaining three samples were averaged to produce a single result for each bag.

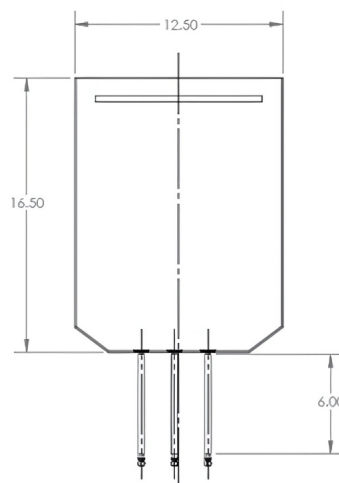


Figure 1: 5L Purillex Bag Assembly Tested



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Results and Discussion

Results of the particle test are shown in Table 1 and presented graphically in Figure 2.

Table 1: Particle Counts From 5L Purillex Bag Assemblies

Test Article	Analyte	Specification	Result	Conclusion
Sample 1	Particles $\geq 10\mu\text{m}$	≤ 25 particles/mL	0 particles/mL	Conforms
	Particles $\geq 25\mu\text{m}$	≤ 3 particles/mL	0 particles/mL	
Sample 2	Particles $\geq 10\mu\text{m}$	≤ 25 particles/mL	1 particles/mL	Conforms
	Particles $\geq 25\mu\text{m}$	≤ 3 particles/mL	0 particles/mL	
Sample 3	Particles $\geq 10\mu\text{m}$	≤ 25 particles/mL	0 particles/mL	Conforms
	Particles $\geq 25\mu\text{m}$	≤ 3 particles/mL	0 particles/mL	

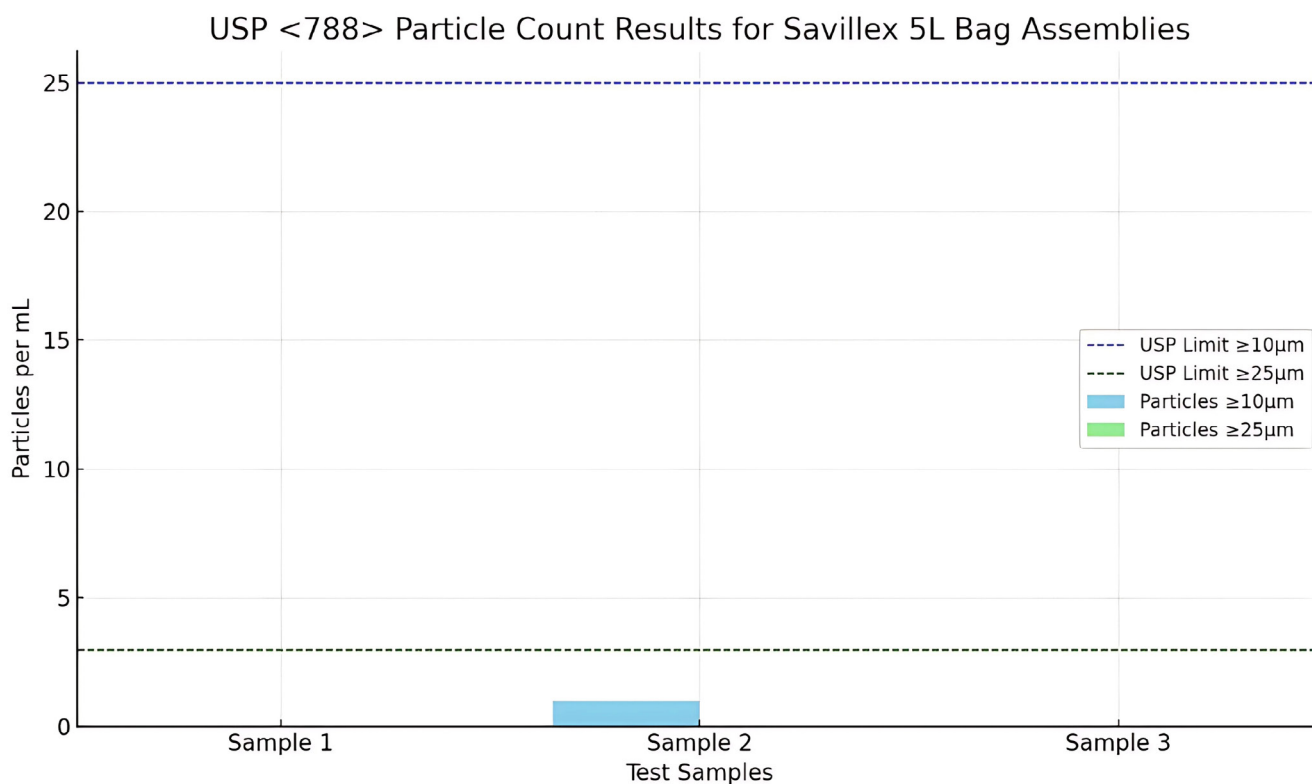


Figure 2: 5L Purillex Bag Assembly Particle Test Results



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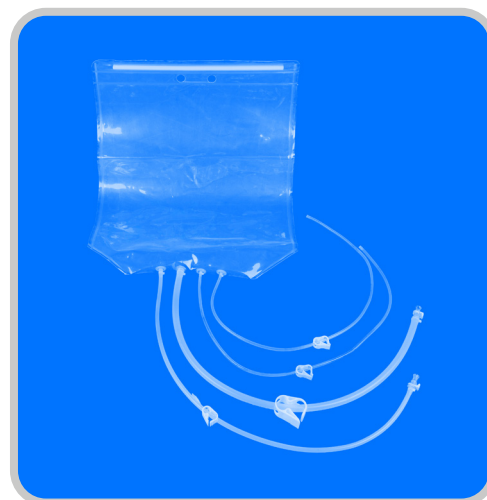
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Instrumentation and Materials

Equipment	Model/Part Number	Manufacturer	Calibration	Calibration Due	Lot
Bag Assembly	052D3-3	OPI (for Savillex)	N/A	N/A	052D3-3
Liquid Particle Counter	HIAC 9703+ Pharmaceutical Particle Counter	Beckman Coulter	03 Jan 2025	31 Jul 2025	N/A

Conclusion

Savillex 5L Purillex Bag Assemblies were shown to meet stringent particle cleanliness requirements under USP <788>, Method 1, confirming their suitability for critical bioprocessing applications where particulate control is essential.



5L Purillex Bag Assembly

**Contact us today at info@savillex.com to learn more about
Purillex Bag Assemblies.**



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10321 West 70th St. | Eden Prairie, MN 55344-3446 USA | Phone: 952.935.4100
Email: info@savillex.com | www.savillex.com

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