

ISOA16 Sterile IPA

Integrated Filtration Sprayer System 90 Day Sterility



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Sterile spray bottles operate with a 0.2 micron vented trigger sprayer. Sterile 70 % IPA is filled inside HDPE bottle. Sprayer has a “sandwich” of 0.2-micron nylon filter supported by two silicone rings. Since air is aspirated through 0.2 micron filter only.

Sterility Testing at 90 Days

The current USP <71> Sterility Test method was used to test the alcohol. Each of the twenty test bottles were pooled and filtered by vacuum filtration through a 0.45 µm filter. Three rinses were made with 100 mL of USP Fluid D each. Fluid D was chosen to neutralize the antimicrobial nature of the IPA. After filtration, half of the filter was applied to FTM (Fluid Thioglycollate Medium) and half to SCDM (Soybean Casein Digest Medium).

The samples were incubated for 14 days, the FTM at 30 - 35°C and the SCDM at 20 - 25°C for 14 days. The sample passed the sterility test confirming its sterility.

Conclusion:

The testing data establishes the integrity of contents of the filtered sprayer system over a period of its use for 90 days in a non-controlled environment. Extend your 7 day protocol to 90 days...

	<u>Product Number</u>	
CH-ISOA16	16 oz Spray	12 btl / case

