AMSINO
Advancing Healthcare Worldwide®

Statement

VAC-GARD® Bacterial Filter Efficiency (BFE) of Receptal® and EZE-Vac® Suction Systems

Amsino's Suction Systems all utilize an internal filter and fluid shut-off mechanism: VAC-GARD®. This filter is also available as an independent external filter/shut-off product. This mechanism is designed to shut off the air flow once it contacts fluid (i.e., when the canister or liner is full). It also acts as a bacterial filter to help prevent any microorganisms contaminating the facility's vacuum system. This filter has been tested by an independent laboratory to evaluate its bacterial filter efficiency as summarized below.

Test Method

This procedure was performed to evaluate the BFE at an increased challenge level of the filter mechanism. The test was performed against a suspension of *Staphylococcus aureus* (ATCC #6538), to determine filtration efficiency.

The test was conducted in accordance with the US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211, and 820. The test method was adapted from ASTM F2101, standard BFE procedure to employ a more severe challenge than would be experienced in normal use. It was sponsored by Amsino and performed by Nelson Laboratories, Inc. (NLI)[1].

Challenge Flow Rate	30 Liters per Minute (L/min)
Area Tested	Entire Test Article (filter portion)
Side Tested	Filter Side
Challenge Level	1.1×10^7 CFU
Mean Particle Size (MPS):	~3.1 µm

Results Summary

The filter efficiency was found to be effective at >99.99% against particles greater than or equal to approximately 3.1 µm.

Total Colony Forming Units (CFU) Recovered	Filter Efficiency (%)
7.4×10^2	99.9935
1.8×10^2	99.9984
1.6×10^2	99.9986

[1] Nelson Laboratories, LLC (NL), ANSI National Accreditation Board Certificate #AT-1382; Laboratory Number 805135; NL Study Number 02162015NL, 19 Feb 2015. The actual study is on file with Amsino and is considered proprietary and confidential. Contact Amsino for further information.

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