

## Microbial Ingress Through Breaches in Aseptic Manufacturing Systems: Experimental Investigation of Pressure-driven Leaks of Gases

Robert Stianchi Diego Vargas

By

Jun 23, 2014 1:28 pm EDT

The results indicate that microbial ingress did not occur under these extreme conditions. This indicates that a pressure-driven leak of a gas can provide an effective barrier against microbial ingress when the pressure drop across the breach ( $\Delta P$ ) exceeds 0.03 psi. This observation is attributed to the fact that when  $\Delta P$  exceeds 0.03 psi, the outward velocity of the air at the sterile boundary—which was estimated to be over 15 m/s—greatly exceeds the net translational velocity of an aerosolized microbe. The results of this investigation can be used to perform risk assessment analyses...

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