

Sterility of nüm™ Vapocoolant Device

Overview

Nüm vapocoolant is a sterile device provided with a patented barrier system that maintains sterility of the contents for the life of the product. When nüm is manufactured, a Tyvek lid is applied at the nozzle and a cap is applied to the base. The lid is peelable for easy removal. The cap is press fit for easy removal and secured with a tamper evident seal. Together these features ensure that after sterilization, the vapocoolant and the vapocoolant fluid pathway remain sterile. Several different tests have been employed to ensure sterility is established and maintained.

Overall Sterility

Nüm is radiation sterilized to provide a sterility assurance level (SAL) of 10⁻⁶. Quarterly dose audits are conducted to ensure that the sterilization dose continues to remain valid. Gas chromatography-mass spectrometry (GC/MS) was used to analyze the vapocoolant to verify that it's composition did not change after sterilization or throughout the labeled three year shelf life.

Lid Sterile Barrier

The lid prevents microbes in the outside environment from contaminating the spray nozzle or allowing microbes into nüm's fluid path. The lid sterile barrier for nüm devices was evaluated for devices which had undergone worst-case simulated shipping and devices which had been accelerated heat aged up to a three year equivalence. Three industry standard evaluations were conducted which together verified the performance of this microbial barrier.



The strength of the lid seal was evaluated through ASTM F88M, which assessed the strength and consistency of the seal to the nüm nozzle.

ASTM F1886 was used to visually inspect the seal to ensure that no defects which could compromise its integrity existed or occurred over the device shelf life. ASTM F2096 (bubble leak) testing was conducted to make sure that no defects occurred in the Tyvek which could compromise its ability to prevent microbial intrusion.

Cap Sterile Barrier

The cap is applied at the base of the device and forms a seal with the main body of the device, similar to seals used on bottled water.



To assess that the seal maintained a microbial barrier over nüm's shelf life, the device was directly challenged with aerosolized bacteria spores. For this testing, sample media was placed inside the cap during manufacturing and the device was sterilized. After simulated shipping and accelerated aging, devices were placed in a sealed chamber and exposed to a microbial aerosol of *Bacillus atrophaeus* spores. After exposure, the sample media was aseptically removed from each device and plated for incubation. No device at any time point showed microbial intrusion, demonstrating that the cap provides a reliable seal against contamination for the shelf life of the product.

Summary

Nüm is a sterile vapocoolant which has been validated to remain sterile throughout the shelf life of the product. The barrier system employed to ensure sterility have been evaluated to make sure they are effective for the three year shelf life of the product.