Headspace Gas Chromatography (HS-GC)

How Safe is Your Mask?

Ethylene Oxide

Surgical masks are typically sterilized with ethylene oxide at room temperature. However, ethylene oxide is a carcinogen. There are strict requirements on the ethylene oxide residue in single-use sterile medical device products. Both ISO 10993.7-2008 (Biological evaluation of medical devices) and China’s National standard “Biological Evaluation of Medical Devices Part VII: Ethylene Oxide Sterilization Residues” (GB / T16886.7-2015) specify the maximum allowable residual amount of ethylene oxide. Shimadzu HS-GC is most suited for measurement of ethylene oxide in safety masks.

Methodology involves simple sample preparation of transferring 1 g of sample into headspace bottle followed by sealing for testing. Excellent linearity was achieved for calibration curve ranging from 0.2-10 ug standard, along with reproducibility of 2.64% for 6 injections of 0.4 ug ethylene oxide.

Chromatogram showing ethylene oxide measurement in standard sample, with calibration curve of 0.2 – 10 ug in the insert.
Shimadzu GC column (SH-Rxi™-624Sil MS)

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Shimadzu (Asia Pacific) Pte Ltd, February 2020
Revised: April 2020

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