

Impact of filter variability on industrial hygiene sample results

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ABSTRACT

Introduction The quality of a filter, used for industrial hygiene (IH) sampling of airborne pharmaceutical compounds may have an impact on IH sample results. In order to evaluate this impact, **different unique lot numbers of one same filtertype, provided by the supplier**, have been verified. The research question is as follows: “Is there any difference between three different studied lot numbers of the same filtertype, regarding sample stability during simulated air sampling and desorption efficiency ?”

Methods In order to study the filter variability, three different lot numbers of a filtertype were evaluated for different test substances. Tests were performed at three concentration levels, generally corresponding to 0.1 x; 1 x and 10 x the Occupational Exposure Limit (OEL) of the active compound. The four studied filtertypes are glass fiber, teflon, nylon and acid coated glass fiber. Following compounds were selected as test substances : Fentanyl, TMC-125, Acetaminophen, Abiraterone Acetate, Nebivolol, Risperidone and Domperidone. For the analysis of these compounds, analytical methods were used that have been developed and extensively validated in the past.

Results Validation criteria for sample stability during simulated sampling are a 90 - 110% recovery of spiked material and a **relative standard deviation (RSD) \leq 10%**. Validation criteria for desorption efficiency are a 90 - 110 % desorption efficiency and a **RSD \leq 10%**. For all test substances, these validation criteria were met for three different lot numbers, at three different concentration levels. A two-factor ANOVA-data-analysis revealed that for the four studied filtertypes, there was no significant difference between three different lot numbers, for both recovery after simulated air sampling and desorption efficiency.

Conclusion In order to study the possible impact that filter variability has on IH measurements, different lot numbers for different filtertypes were evaluated. It can be concluded that for the same filtertype, there seems no difference for three different studied lot numbers, regarding sample stability during simulated air sampling and desorption efficiency.
