Assessment of the containment performance of closed system drug transfer devices (CSTDs) that either employ a mechanically closed physical barrier or air filtration technology – a Universal Test Protocol for assessment of all CSTD technologies.

Introduction

January 19th 2016, the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control (CDC) Department of Health and Human Services (HHS) published a request for information notice in the Federal Register entitled “Request for Information on Development of a Performance Test Protocol for Closed System Transfer Devices that Incorporate Air-Cleaning Technology To Provide Worker Protection During Pharmacy Compounding and Administration of Hazardous Drugs”.

In collaboration with the Health and Safety Laboratory UK, BSTL submitted a detailed approach to NIOSH with supporting data for consideration as a Universal Vapour Performance Test for CSTDs.

Data is presented here from a larger study of the containment performance of CSTDs that employ both physical barrier (PhaSeal® and ChemoClave™) and air filtration (OnGuard®) technology. See table 1 below.

Scientific Approach

Air was sampled for 30 minutes at a flow of 100 mL/minute on to Tenax TA™ from the chamber during manipulation of CSTDs, according to Task 1 and Task 2. Tubes were then analysed using ATD-GC-MS. Negative controls were performed on each day of test using water as surrogate.

Results

Figure 6. Figure showing a typical GC signature for 2-Phenoxyethanol (POE), detection by MS employing selected ion mode (SIM).

“The liquid release is seen easily by eye and this correlates with the chemical vapour detection values for POE release.”

Conclusions from BSTL/HSL Universal CSTD Performance Test Protocol

IFU conditions must be used for all manipulations of CSTD systems. The original NIOSH draft protocol compromised CSTD function.

- 2-Phenoxyethanol is a more realistic surrogate for hazardous drugs (HDs) given its vapour pressure of 1 Pascal.
- Using a Time Weighted Average (TWA) approach allows both air filtration and physical barrier containment to be assessed using the same Universal Containment Performance Test Protocol. This represents a paradigm shift from the original draft NIOSH vapour containment test protocol.

Using the developed BSTL/HSL Universal Performance Test Protocol for CSTDs we have demonstrated that, by appropriate selection of surrogate, CSTDs that employ air filtration technology are able to prevent both vapour and liquid release of hazardous drugs during manipulations performed in Pharmacy for compounding and administration.

“Vapour contamination values for PhaSeal® and OnGuard® (Tevador®) were >LLOQ for both tests (n=10). ChemoClave® however, produced higher release values of between 5 and 25 x LOD and one release of 120 x LOD.

References


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