

Arisure[®] CSTD

Cyclophosphamide Wipe Study

Introduction

Arisure, a needle-free closed system transfer device (CSTD) prevents environmental contamination during the preparation, transfer, and administration of hazardous drugs. This paper presents an overview of the methods and testing used to demonstrate that Arisure prevents environmental contamination during the transfer of hazardous drugs after a typical use scenario with cyclophosphamide.

Procedure

Nine wipe samples were collected at the University of Findlay, College of Pharmacy in Findlay, Ohio. Arisure was evaluated for performance when preparing and transferring cyclophosphamide. A total of thirty transfers were performed inside a biological safety cabinet (BSC). After all transfers were completed, wipe samples were collected. Sample locations included the transfer area, IV bag prep area, airfoil, and technician's gloves.

ChemoGLO™ Wipe Kits were used to collect BSC surface and glove wipe samples. Control wipes were collected after cleaning with HDClean™ wipes, prior to beginning each Arisure transfer.

Arisure transfers were followed by a post-use wipe sampling.

ChemoGLO analyzed the wipe samples by liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS).

Results

Table 1. LC-MS/MS Cyclophosphamide Wipe Samples

| Cyclophosphamide Wipe Study Results | |
|-------------------------------------|--|
| Location | Cyclophosphamide Concentration (ng/cm ²) |
| Transfer Control 1 | ND |
| IV Bag Prep Control 1 | ND |
| Airfoil Control 1 | ND |
| Glove Arisure CSTD | ND |
| Transfer Arisure CSTD | ND |
| IV Bag Prep Arisure CSTD | ND |
| Airfoil Arisure CSTD | ND |

Table 1. Results of the LC-MS/MS analysis of wipe samples for cyclophosphamide. The lower limits of detection (LLQ) for these assays are 0.01 ng/cm². Concentrations that are less than the LLQ are defined as non-detectable (ND).

Conclusions

No detectable levels of cyclophosphamide were found in any wipe area after a typical use scenario. These results demonstrate that Arisure prevents environmental contamination during the transfer of chemotherapy drugs.

Data on file at Yukon Medical. Arisure Closed System Transfer Device Cyclophosphamide Wipe Study Whitepaper TSD 018.01.