Minimizing Health Care Professional's Exposure to Hazardous Drug Species

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TEVADAPTOR®
When Safety and Simplicity Click

Summary

Tevadaptor, a special device developed by Teva Medical Devices, to prevent the escape of hazardous drug species, including vapor, into the environment, was tested. Carboplatin, Etoposide, Cyclophosphamide and Doxorubicin HCl were used as the test compounds. Drug vials with attached Tevadaptor Vial Adaptor were connected to a system designed to capture any drug vapors leaking through Tevadaptor. Carboplatin, Etoposide, Cyclophosphamide, or Doxorubicin vapors escaping the adaptor were trapped at -70°C.

Sensitive LC/MS/MS methods were developed enabling the detection of Carboplatin, Etoposide, Cyclophosphamide, and Doxorubicin HCl at the nanogram (ng) level. The results showed that all

Tevadaptor units prevented analytes from escaping into the environment. When control TevadaptorTM units (devoid of filter system) were used, significant amounts of tested analytes were found.

Objective

To test the ability of the Tevadaptor closed system to prevent the escape of hazardous drug species.

Materials & Methods

Working standards of Carboplatin, Etoposide, Cyclophosphamide, and Doxorubicin HCl were prepared by dilution of a 100 pg/ml stock solution in methanol. The final calibration curve for all analytes contained 1, 2, 5, 10, 20 and 50 ng/ml in diluent (1:1 methanol:HPLC grade water).

The experimental set up included an original vial sealed with a rubber septum (supplied by the sponsor) containing the test material (Carboplatin, Cyclophosphamide, Etoposide or Doxorubicin HCl) with attached Tevadaptor Vial Adaptor. The vial - Tevadaptor assembly was placed in a 100 ml glass bottle and sealed with another rubber septum. A needle was introduced through both the bottle and the Tevadaptor septa, in a manner allowing an external stream of nitrogen to flow through the Tevadaptor into the vial, back to the bottle and from there through a second needle out into the collecting trap. The 100 ml glass bottle was kept in a water bath at 50°C in order to increase vapor pressure, and the collecting trap was immersed in a mixture of acetone and dry ice at -70°C.

Analyte vapors were collected at a stream of nitrogen of about 300 ml/min for 5 hours (-90L of nitrogen). At the end of the collecting time, the trapped analyte was dissolved in 10 mL of diluent (1:1 methanol:HPLC grade water) and analyzed by the LC/MS/MS method. The test was performed in one replicate (one control Tevadaptor unit, devoid of filters and one Tevadaptor unit) for Carboplatin, Etoposide, and Doxorubicin, and 12 replicates and 2 controls for Cyclophosphamide.

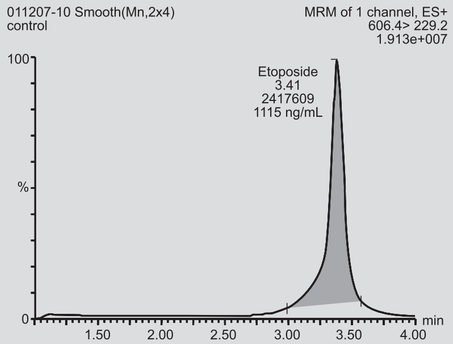
A recovery test was executed, employing the same vapor collection system using Naphthalene as a marker (because of its relatively high vapor-pressure). The test results demonstrated 90-100% recovery.

Conclusion

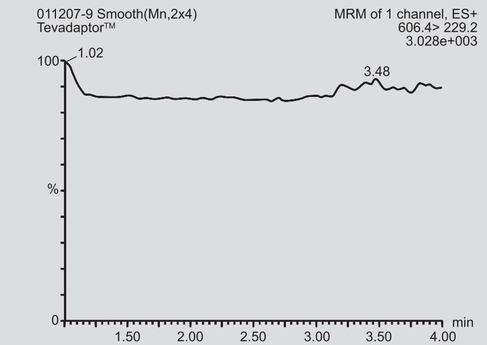
Tevadaptor prevents hazardous drugs species, including vapor, from escaping into the environment.

Tested analyte	Amount of tested analytes in control samples (ng)	Amount of tested analytes in Tevadaptor samples (ng)
Etoposide	11,50	Not detected
Doxorubicin HCl	460	Not detected
Carboplatin	53	Not detected
Cyclophosphamide	28-32	Not detected

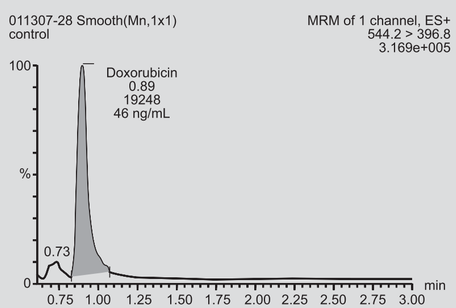
Etoposide Control Sample



Etoposide Tevadaptor Sample



Doxorubicin Control Sample



Doxorubicin HCl Tevadaptor Sample