Minimizing the Risk of Exposure to Potentially Hazardous Drugs

Souraski Medical Center, Tel Aviv, Israel, February 5, 2009

Introduction

One of the requirements of closed system drug reconstitution devices is prevention of liquid spills onto the working surface (NIOSH Alert, September 2004). Elastomer septa in the device should remain dry upon component connections and disconnections.

Objective

This test is designed to examine Tevadaptor septa for dryness upon repeated use. Drug solutions are simulated by acidic water, and examination is done by wiping the septa surfaces with litmus paper.

Materials & Methods

The test materials were Tevadaptor Syringe Adaptors and Vial Adaptors, vials with test solution, empty luer lock syringes, litmus paper, distilled water at pH 1.
The procedure consisted of repeated withdrawal of 1 ml of water from the vials, followed by wiping the septa with litmus paper.

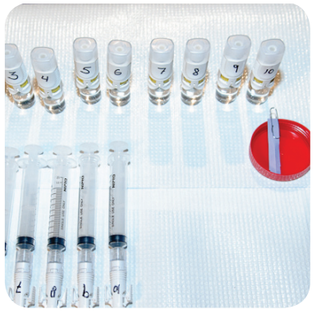
Results

In none of the Tevadaptor devices tested was any litmus paper color change observed.

Conclusion

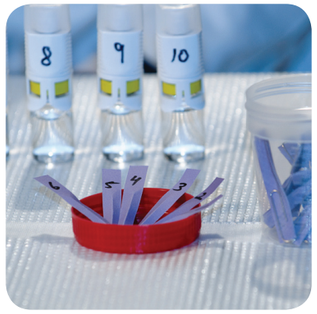
Tevadaptor provides dry component disconnections and thus minimizes the risk of exposure to potentially hazardous substances.

TEVADAPTOR®
When Safety and Simplicity Click



Step 1

Ten vials were prepared, each contained 10 ml of distilled water at pH 1. A Tevadaptor Vial Adaptor was mounted onto each vial. Ten luer lock syringes were connected to Tevadaptor Syringe Adaptors.



Step 2

Ten groups of litmus paper were prepared, six numbered strips in each group.

Step 3

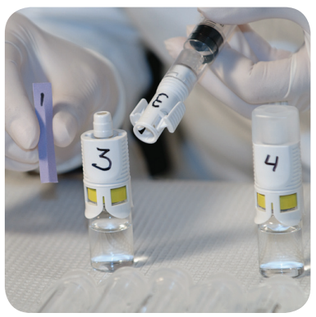
Each syringe assembly was connected to a vial assembly and about 1 ml of acidified water was drawn into the syringe.

Step 4

The Syringe Adaptor was disconnected from the Vial Adaptor according to the product's Instructions For Use.

Step 5

One litmus paper strip was used to wipe the surfaces of the Vial Adaptor and Syringe Adaptor septa.

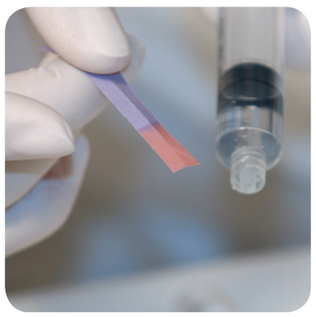


Step 6

The litmus paper was observed carefully and any color change, indicating solution leakage, was recorded.

Step 7

The above procedure was repeated, using the same syringe assembly and vial assembly 5 more times.



Step 8

As control for proper function of the litmus paper, the syringe was disconnected from the Syringe Adaptor and a drop of solution applied onto a strip of litmus paper. A color change from blue to red was confirmed. The whole of the above procedure was repeated on another 9 vials and 9 syringes successfully.