DRUG STABILITY IN TEVADAPTOR® EQUIPPED VIALS

Analyst laboratories

Israel, June 2010

TEVADAPTOR®

When Safety and Simplicity Click

Summary

Tevadaptor® is a closed drug reconstitution system developed by Teva Medical Ltd. Maintaining sterility of drug solution was tested during a period of 14 days in order to assess its effect on drug concentration. The test was applied using two drugs - Etoposide and Paclitaxel. Vials containing drugs mounted with Tevadaptor®, as well as the control vials, were kept in room temperature and analyzed using HPLC on time zero and on days 1, 7 and 14. No effect on drug concentration was found for each drug, stability of concentration was proved to be maintained.

Objective

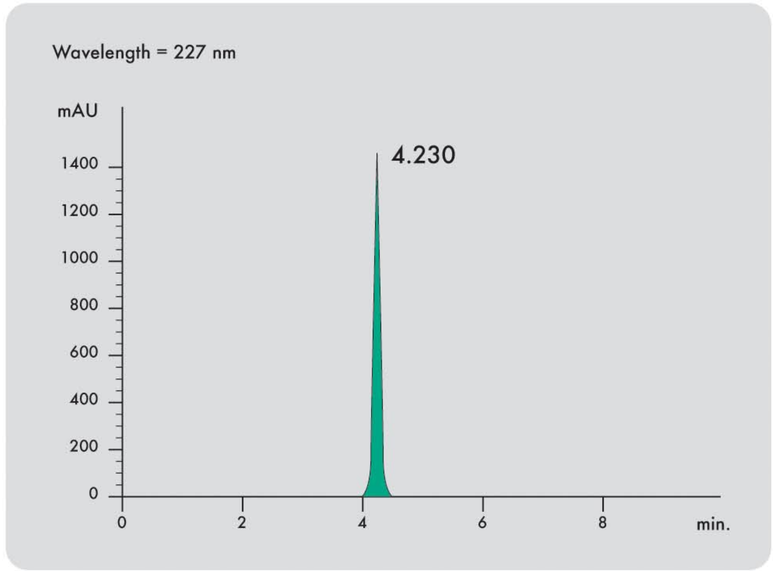
To ascertain the ability of Tevadaptor® system in maintaining drugs stability of concentration, and to assess the effect of Tevadaptor® on drug concentration.

Materials and Methods

Five vials containing Etoposide and 5 vials containing Paclitaxel were mounted with Tevadaptor® Vial Adaptor. Two additional vials of each drug lacking the Tevadaptor® were used as control vials. All vials were kept at ambient temperature. One gram of each sample was aspirated from the test vials at time zero and on days 1, 7 and 14.

All samples were analyzed using HPLC and assayed against standard solutions.

A HPLC typical chromatogram of paclitaxel standard solution (0.6mg/mL).



Test results are summarized in the following table

Drug Concentration vs Time

DRUG	Sample average (mg/g)		Control average (mg/g)	
	t_0	D14	t_0	D14
Etoposide	19.64	19.51	19.70	19.57
Paclitaxel	6.03	6.14	6.05	6.11

Conclusion

Almost no difference was observed between vials with Tevadaptor® and control vials. Thus Tevadaptor® had no effect on drug concentration.

(Teva Medical does not take any responsibility for drug stability beyond manufacturers' recommendations)