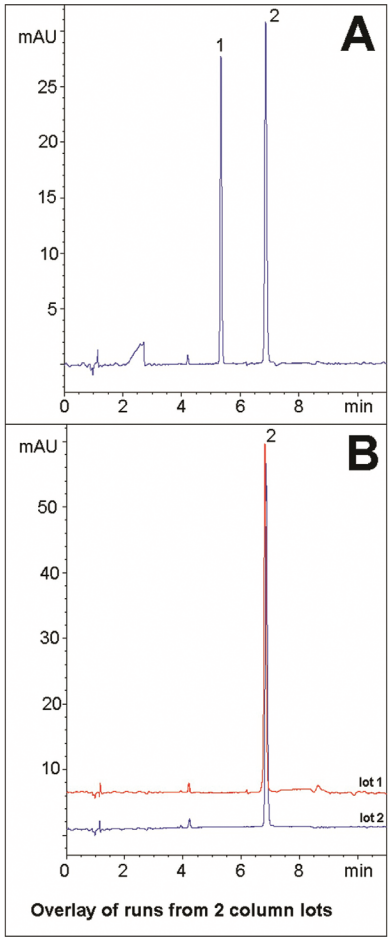
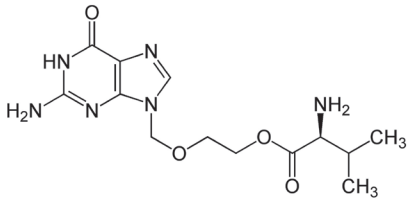
Forced Degradation of Valaciclovir (Valtrex®)

Easy separation of prodrug from degradant



Overlay of runs from 2 column lots



Valaciclovir

Figures:
A: Acid degradation extract: The stock solution was diluted 1:100 with 50/50 1N HCl / acetonitrile mixture. It was heated at 85°C for 30 min.
B: Non-degraded extract: The stock solution was diluted 1:100 with 50/50 acetonitrile / DI H_2O.

Method Conditions

Column: Cogent Diamond Hydride™, 4µm, 100Å

Catalog No.: 70000-7.5P

Dimensions: 4.6 x 75 mm

Solvents: A: DI H_2O / 0.1% formic acid (v/v)
B: Acetonitrile / 0.1% formic acid (v/v)

Gradient:

time (min.)	%B
0	95
1	95
6	40
7	40
8	95

Post Time: 3 min

Injection vol.: 1µL

Flow rate: 1.0 mL/min

Detection: UV 254 nm

Sample: Stock Solution: 1000 mg strength Valtrex tablet was ground and added to 100mL volumetric flask containing 50mL 50/50 DI H_2O / acetonitrile diluent. The solution was sonicated 10 min, diluted to mark, and mixed. A portion was filtered through a 0.45µm nylon syringe filter (MicroSolv Tech Corp.).

Peaks: 1. Degradant
2. Valaciclovir

t_0: 0.9 min

Discussion

In this application note, the anti-viral herpes drug valaciclovir and its main acid degradant are well separated (Fig. A). Valaciclovir is a prodrug and the degradant observed here is believed to be the active form, aciclovir. Both compounds did not retain very strongly in reversed phase. In fact, the USP method calls for a lengthy 40 min gradient with high water content for the assay.

Data from two column lots is shown in the non-degraded extract (Fig. B) to demonstrate the stationary phase reproducibility.

MANUFACTURED BY:
MICROSOLV TECHNOLOGY CORPORATION
9158 Industrial Blvd NE
Leland, NC 28451
p: 1.732.380.8900
f: 1.910.769.9435
customers@mtc-usa.com
www.Cogent-HPLC.com