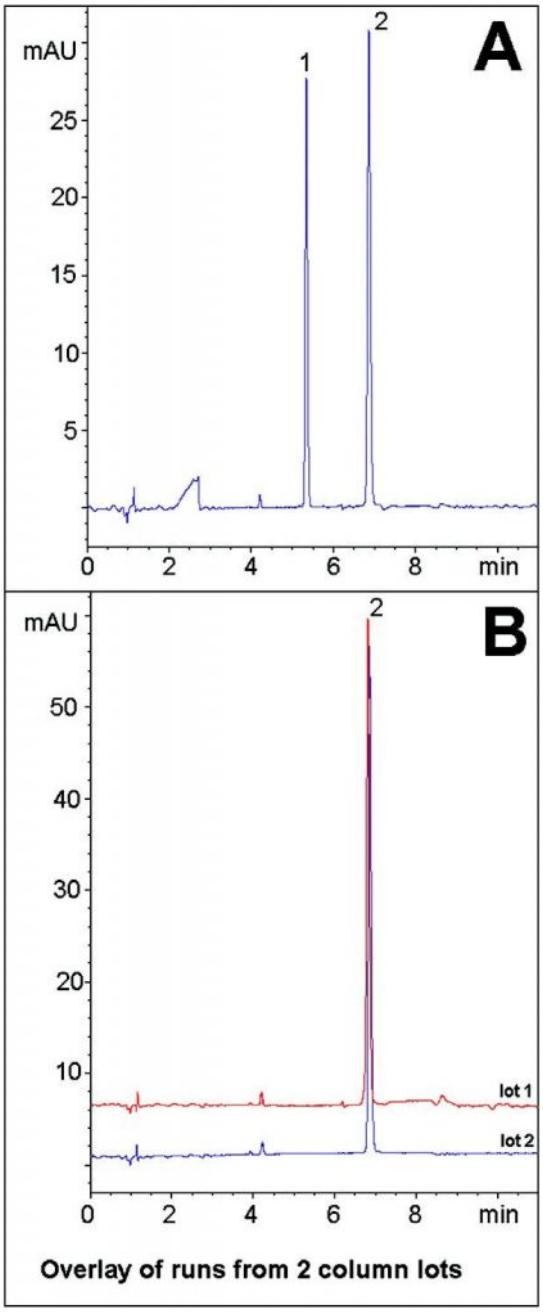
Valaciclovir Analyzed with HPLC – AppNote

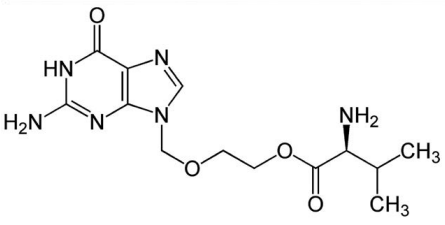
Separation of Prodrug from a Degradant in Forced Degradation of Valtrex® Tablets

In this Application Note, the anti-viral Herpes drug Valaciclovir and its main acid degradant are well separated *(Figure A)*. Valaciclovir is a prodrug and the degradant observed here is believed to be the active form, Acyclovir. Both compounds did not retain very strongly in Reversed Phase and the USP Method calls for a lengthy 40 minute Gradient with high water content for the Assay. The eight minute gradient provides sufficient Separation.

Data from two Column lots is shown below in the non-degraded extract *(Figure B)* to demonstrate the Method Reproducibility.

MicroSolv Technology Corporation
9158 Industrial Blvd. NE, Leland, NC 28451
tel. (732) 380-8900, fax (910) 769-9435
Email: customers@mtc-usa.com
Website: www.mtc-usa.com





Peaks:

1. Degradant
2. Valaciclovir

Method Conditions

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

Catalog No.: 70000-7.5P

MicroSolv Technology Corporation
9158 Industrial Blvd. NE, Leland, NC 28451
tel. (732) 380-8900, fax (910) 769-9435
Email: customers@mtc-usa.com
Website: www.mtc-usa.com

Dimensions: 4.6 x 75mm

Mobile Phase:

A: DI Water with 0.1% Formic Acid (v/v)

B: Acetonitrile with 0.1% Formic Acid (v/v)

Gradient:

Time *(minutes)*	%B
0	95
1	95
6	40
7	40
8	95

Post Time: 3 minutes

Injection vol.: 1µL

Flow rate: 1.0mL / minute

Detection: UV @ 254nm

Sample Preparation: Stock Solution: 1000mg strength Valtrex Tablet was ground and added to 100mL volumetric flask containing 50mL 50:50 DI Water / Acetonitrile diluent. The solution was sonicated 10 minutes, diluted to mark, and mixed. A portion was filtered through a 0.45µm Nylon Syringe Filter (MicroSolv Tech Corp.).

Figure A: Acid Degradation Extract: The Stock Solution was diluted 1:100 with 50:50 1N HCL / Acetonitrile mixture and heated at 85°C for 30 minutes.

Figure B: Non-Degraded Extract: The Stock Solution was diluted 1:100 with 50:50 Acetonitrile / DI Water.

Attachment

No 254 Valaciclovir Analyzed with HPLC pdf 0.6 Mb Download File

MicroSolv Technology Corporation
9158 Industrial Blvd. NE, Leland, NC 28451
tel. (732) 380-8900, fax (910) 769-9435
Email: customers@mtc-usa.com
Website: www.mtc-usa.com