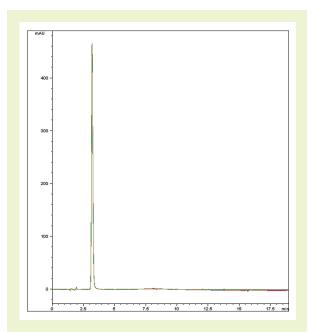


Lamotrigine, a Very Polar Compound

USP assay method



Note: Lamotrigine is a phenyltriazine anticonvulsant used to treat epilepsy and type I bipolar disorder. It is believed to act as a sodium channel blocker.

Method Conditions

Column: Cogent Bidentate C18™, 4µm, 100Å

Catalog No.: 40018-15P

Dimensions: 4.6 x 150 mm

Solvents: A: 2.7 g/L KH₂PO₄: triethylamine 150:1, adjusted to pH 2.0

with H₃PO₄ B: Acetonitrile

Gradient:

time (min.)	%B
0	23.5
4	23.5
14	80
15	23.5
19	23.5

Injection vol.: 10µL

Detection: UV 270 nm

Sample: 25 mg strength tablet was ground and dissolved in 5 mL MeOH in a 100 mL volumetric flask. The flask was diluted to mark with 0.10 M HCl. It was sonicated and filtered with a 0.45µm nylon filter (MicroSolv Tech Corp.).

Peak: Lamotrigine

t₀: 1.9 min

Discussion

The USP assay method for lamotrigine uses a relatively low pH of 2.0. These conditions may promote hydrolysis of the bonded phase in conventional L1 columns, but the unique chemistry of the Cogent Bidentate C18 column is very rugged and shows no loss of retention for the API, as the five run overlay in the figure shows. The retention time %RSD for the five runs was 0.15%. In addition the peak shape was highly symmetrical.