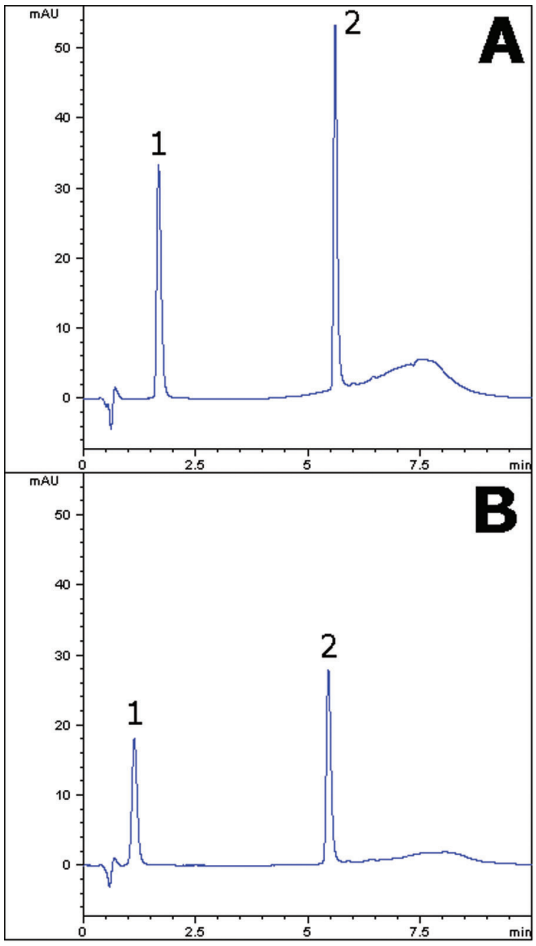
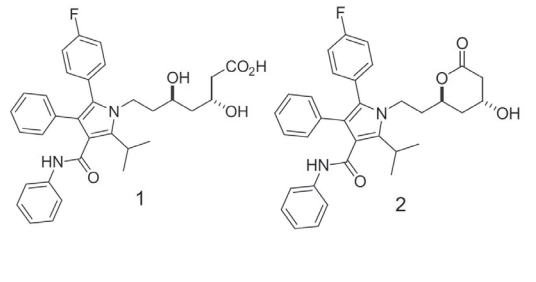
Atorvastatin Method Transfer

Use of near-UHPLC 2.2µm column





Peak:	Efficiency (N/m)	
	4µm	2.2µm
1	88420	143780
2	206920	481460

Method Conditions

Column: Fig. A: Cogent Bidentate C18 2.0̄™, 2.2µm, 120Å
Fig. B: Cogent Bidentate C18™, 4µm, 100Å

Catalog No.: Fig. A: 40218-05P-2; **Fig. B:** 40018-05P-2

Dimensions: 2.1 x 50 mm

Mobile Phase: A: DI H_2O / 10 mM ammonium acetate
B: 90% acetonitrile / 10% DI H_2O / 10 mM ammonium acetate

Gradient:

time (min.)	%B
0	40
1	100
6	100
7	40

Flow rate: 0.3mL/min

Detection: UV 248 nm

Sample: 40 mg strength Lipitor® tablet was ground and added to a 50 mL volumetric flask with a portion of solvent B diluent. The solution was sonicated 10 min and diluted to mark with solvent B. It was then filtered through a 0.45µm nylon membrane (MicroSolv Tech Corp.). The filtrate was diluted 4x in a diluent of 50/50 solvent B/ 1N HCl. It was heated in a dry bath for 10 min at 85°C.

Peaks: 1. Atorvastatin
2. Atorvastatin lactone

Discussion

This application note demonstrates how data obtained on a 4µm Cogent Bidentate C18 column (Fig. B) can be adapted for a 2.2µm phase (Fig. A). The retention times of both analytes are very comparable. The method produces excellent separation of the API and its main acid degradant. It is also LC-MS compatible and so could be used in clinical applications involving plasma samples.

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