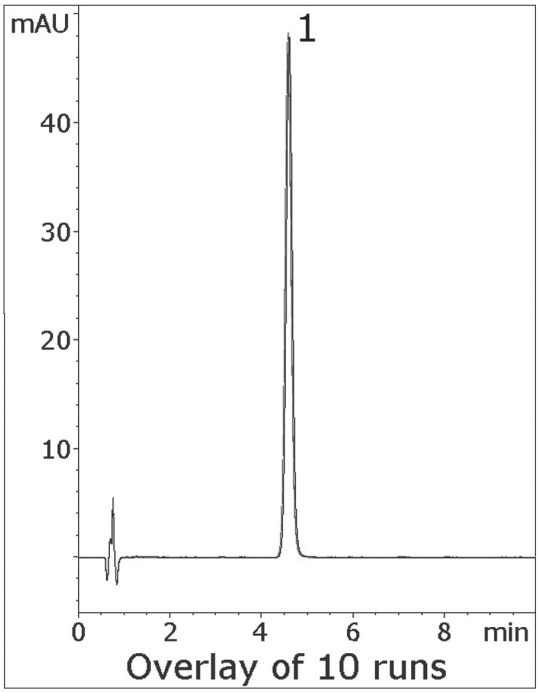
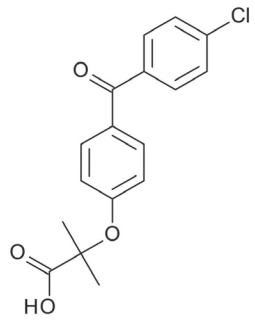
Fenofibric Acid Capsule (Trilipix®)

Simple isocratic LC-MS compatible assay method





Fenofibric Acid

Note: Fenofibric acid is used to moderate cholesterol levels for patients at risk for cardiovascular diseases. It lowers the amount of triglycerides and low-density lipoprotein (LDL) cholesterol, as well as increases the amount of highdensity lipoprotein (HDL) cholesterol. It is often used in combination with statins.

Method Conditions

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

Catalog No.: 40018-75P

Dimensions: 4.6 x 75 mm

Mobile Phase: 50% DI H_2O / 50% acetonitrile / 0.1% formic acid (v/v)

Injection vol.: 1µL

Flow rate: 1.0 mL/min

Detection: UV 285 nm

Sample: 135 mg strength Trilipix delayed release capsule contents were ground with a mortar and pestle. The contents were added to a 100 mL volumetric flask containing 50 mL methanol. The flask was sonicated 10 min and diluted to mark with methanol. Then a portion was filtered with a 0.45µm nylon filter (MicroSolv Tech Corp.). 100µL of filtrate was diluted with 900µL of methanol.

Peak: 1. Fenofibric acid

Discussion

The USP assay method for fenofibric acid uses a phosphate buffer which is incompatible with MS detection. In this isocratic method, only formic acid is needed in the mobile phase. The peak efficiency and symmetry are excellent in this method. In addition, the run-to-run precision is reliable and robust, as shown in the 10-run overlay in the figure.

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