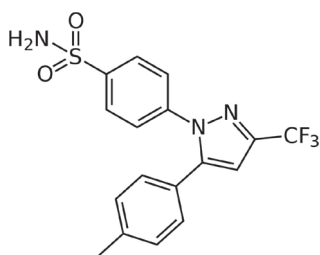
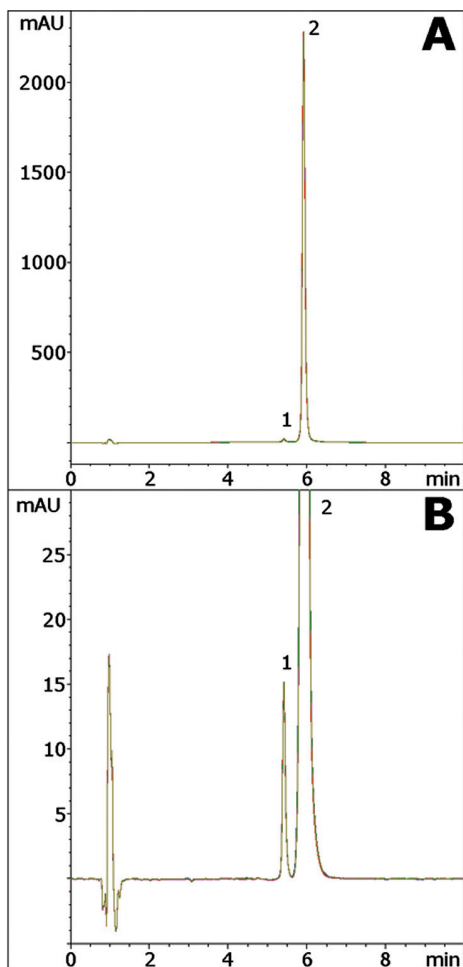


Celecoxib

Impurities method with improved peak shape



Note: Celecoxib is a selective COX-2 inhibitor used for treatment of acute pain and inflammation due to conditions such as arthritis. It is marketed by Pfizer under the trade name Celebrex, which is under patent protection until 2014.

Method Conditions

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

Catalog No.: 69020-7.5P

Dimensions: 4.6 x 75 mm

Mobile Phase: A: DI H₂O / 0.1% formic acid

B: 97% acetonitrile / 3% DI H₂O / 0.1% formic acid

Gradient:	time (min.)	%B
	0	30
	5	60
	6	30

Temperature: 35°C

Post time: 4 min

Injection vol.: 5µL

Flow rate: 1.0 mL/min

Detection: UV 254 nm

Sample: A 200 mg strength Celebrex® capsule was ground and added to a 100 mL volumetric flask. 50 mL MeOH was added and the solution was sonicated. The flask was diluted to mark with solvent A and a portion was filtered with a 0.45µm nylon syringe filter (MicroSolv Tech Corp.).

Peaks: 1. Impurity
2. Celecoxib

t₀: 0.9 min

Discussion

Celecoxib is separated from an impurity in this simple gradient method. The peak shape obtained for the API is excellent and shows good peak symmetry. In addition, the method shows good repeatability from run to run. The API retention time %RSD from five runs was 0.025%. The five run overlay chromatogram is shown in Figure A. Figure B shows a zoom-in view so that the impurity peak can be seen clearly. Another benefit of the method is that the mobile phase is MS-compatible.