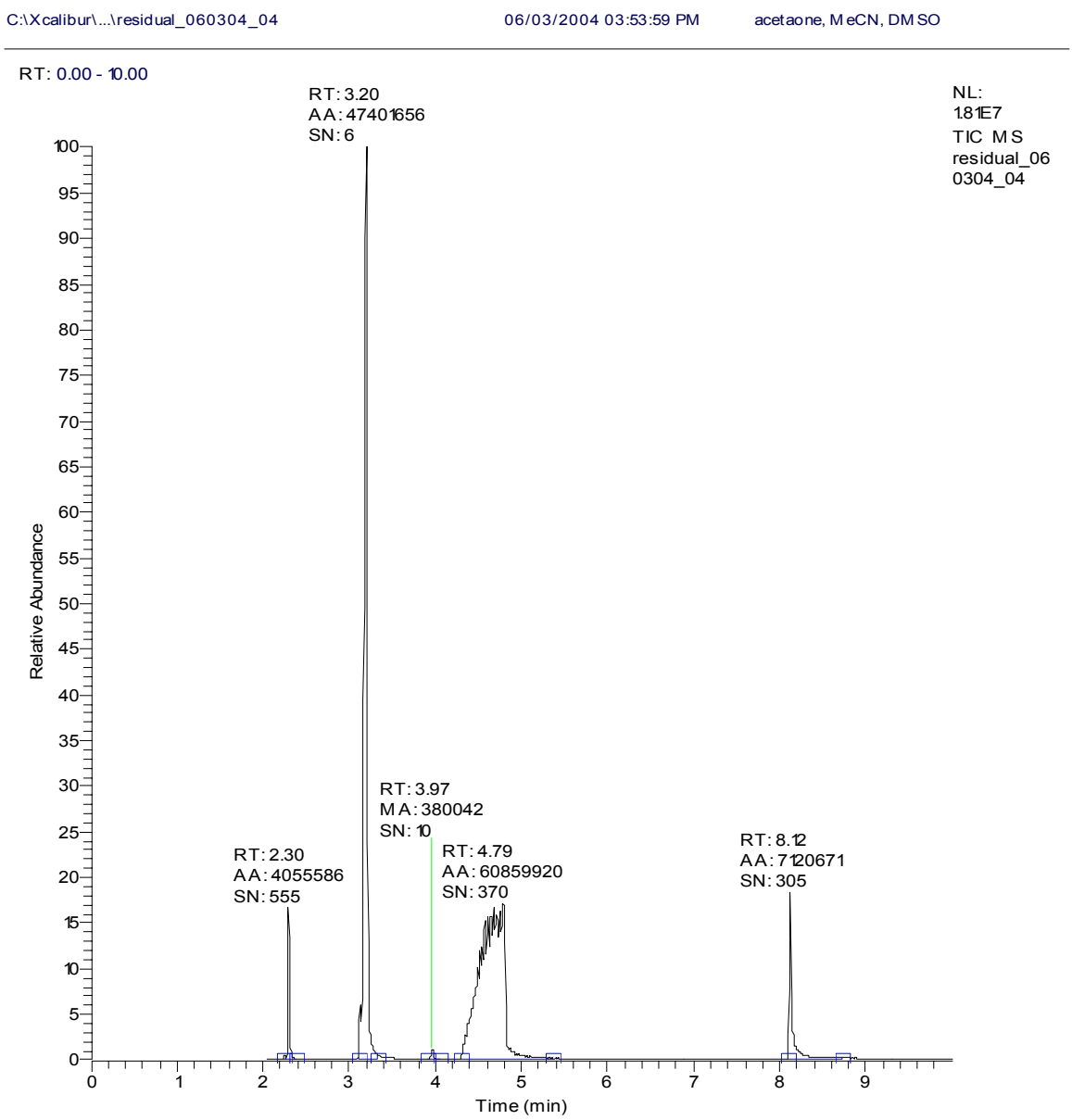

Appendix Q112 This figure shows a typical mass chromatogram of the solvent standards in preparative mobile phase for the residual solvent analysis. The peaks are baseline separated, but the signals for acetone and for acetonitrile are difficult to see on the same scale. Acetone (5,000 ppm) elutes at 2.3 minutes, ethanol (8%) at 3.2 minutes, acetonitrile (400 ppm) at 4.0 minutes, water (92%) at 4.8 minutes and dimethylsulfoxide (5,000 ppm) at 8.12 minutes.

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Experimental Conditions:

Chemicals for External Standards
Acetonitrile, Acetone and Dimethylsulfoxide were high purity from Aldrich.
The external standard mixture was Acetone 5000 ppm, DMSO 5000 ppm, and MeCN 400 ppm in FLT mobile phase (92:8 PBS: ethanol).

Instrument:
ThermoFinnigan Trace GC equipped with a mass detector Polaris Q as detector
AT-WAX column, 30m, 0.25mm ID, 0.32 µm df
AS 2000 Autosampler
0ven Temperature
Initial: 40°C hold 1min holding for 1min
Ramp 1: 40° to 81°C @ 15°C/min (hold 1 min)
Ramp 2: 56° to 190°C @ 20°C/min, hold for 1.5 min

Injector Temperature: 225°C
Injection Volume: 0.5 µL
Carrier Gas: He
Column Flow Rate: 1 mL/min, constant flow, holding for 4.5 min
Ramp 1: 2.0 mL/min holding for 4 min

Split Ratio: 100:1, split flow: 100 mL/min
Ion Source Temperature: 200°C
Transfer Line Temperature: 275°C
Scan Range: 15 – 100

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