



Solvents

Analysis of residual solvents in drug substances

Application Note

BioPharma

Authors

Agilent Technologies, Inc.

Introduction

Gas chromatography using an Agilent CP-Select 624 CB column separates seven residual solvents in a drug in ten minutes.



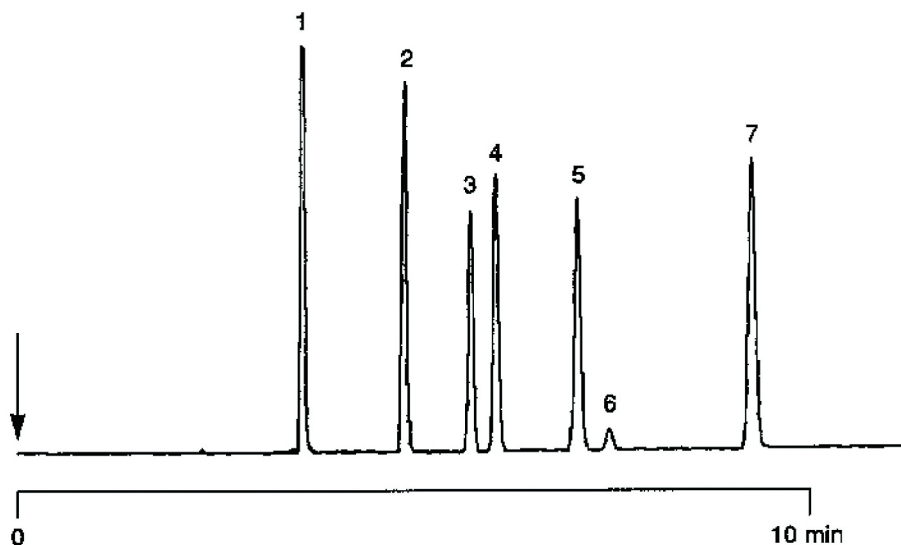
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Conditions

Technique : GC-capillary
Column : Agilent CP-Select 624 CB, 0.32 mm x 30 m,
fused silica WCOT CP-Select 624 CB
(df = 1.8 μ m) (Part no. CP7414)
Temperature : 40 °C (10 min) \rightarrow 180 °C, 15 °C/min
Carrier Gas : He, 50 kPa (0.5 bar, 7 psi)
Injector : Split, 60 mL/min
T = 140 °C
Detector : FID
T = 250 °C
Sample Size : 2 μ L
Concentration Range : 100 ppm
Solvent Sample : water

Peak identification

1. methanol
2. ethanol
3. acetone
4. 2-propanol (isopropanol)
5. 2-methyl-2-propanol (tert.-butanol)
6. methyl tert.butyl ether (MTBE)
7. propanol



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