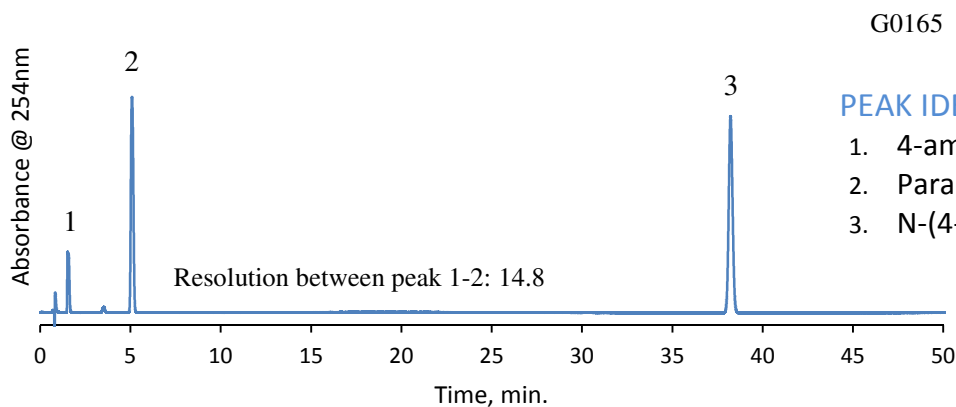


Application Note: 171-EP

Separation of Paracetamol and Impurities According to EP 9.4



PEAK IDENTITIES:

1. 4-aminophenol (impurity K)
2. Paracetamol
3. N-(4-chlorophenyl) acetamide (impurity J)

TEST CONDITIONS:

Column: HALO 90Å C18, 2.7 µm, 2.1 x 100mm

Part Number: 92812-602

Mobile Phase A: 20mM Potassium Phosphate Buffer

Mobile Phase B: Methanol

Gradient: 0-1 min. hold at 5%

1-10 min. 5-10% B

10-20 min. hold at 10% B

20-40 min. 10-34% B

40-50 min. hold at 34% B

Flow Rate: 0.3 mL/min

Initial Pressure: 171 bar

Temperature: 30°C

Detection: UV 254 nm, PDA

Injection Volume: 5 µL

Sample Solvent: methanol:water, 5:95

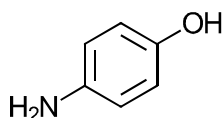
Data Rate: 40 Hz

Response Time: 0.005 sec

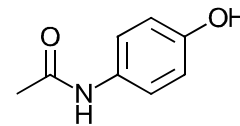
Flow Cell: 2 µL

LC System: Agilent 1200 SL

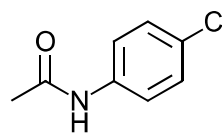
STRUCTURES:



4-aminophenol



Paracetamol



N-(4-chlorophenyl) acetamide

A HALO C18 column is used to separate paracetamol and two of its impurities following the European Pharmacopoeia 9.4 monograph for paracetamol. This method is used to examine several paracetamol impurities providing high resolution between peaks while leaving sufficient separation in the baseline for any other impurity or degradant peaks that may be present in a sample.