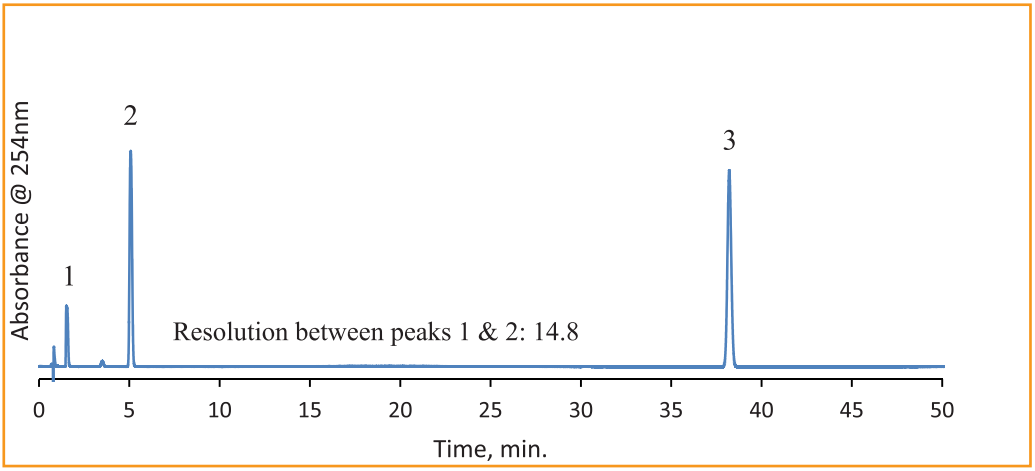
HALO®

PHARMACEUTICALS

Separation of Paracetamol and Impurities According to EP 9.4

Application Note 171-EP



PEAK IDENTITIES:

1. 4-Aminophenol (Impurity K)
2. Paracetamol
3. N-(4-Chlorophenyl) acetamide (Impurity J)

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.

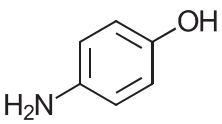
TEST CONDITIONS:

Column: HALO 90 Å C18, 2.7 µm, 2.1 x 100 mm
Part Number: 92812-602
Mobile Phase:
A: 20 mM potassium phosphate buffer
B: Methanol
Gradient:

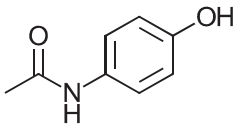
Time (min)	% B
0-1	5
1-10	5-10
10-20	10
20-40	10-34
40-50	34

Flow Rate: 0.3 mL/min
Pressure: 171 bar
Temperature: 30 °C
Detection: UV 254 nm, PDA
Injection Volume: 5.0 µL
Sample Solvent: 5/95 methanol/water
Data Rate: 40 Hz
Response Time: 0.005 sec
Flow Cell: 2.0 µL
LC System: Agilent 1200 SL

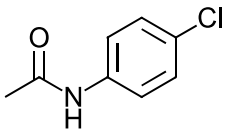
STRUCTURES:



4-aminophenol



Paracetamol



N-(4-chlorophenyl) acetamide