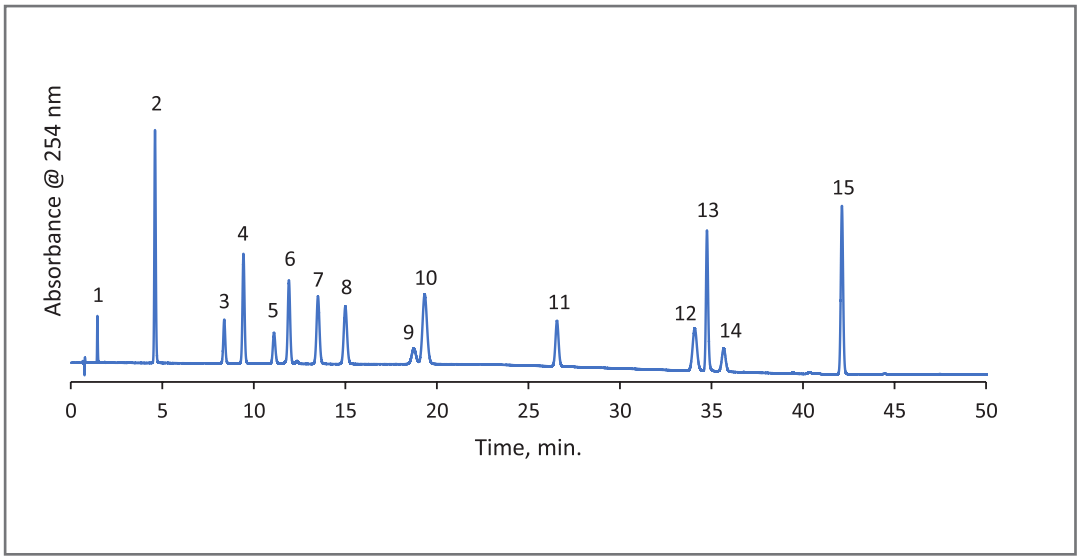
HALO®

PHARMACEUTICALS

Paracetamol Impurities: European Pharmacopoeia 9.4 Method

Application Note 211-EP



PEAK IDENTITIES:

1. Impurity K
2. Paracetamol
3. Impurity A
4. Impurity B
5. Impurity F
6. Impurity C
7. Impurity D
8. Impurity E
9. Impurity M
10. Impurity G
11. Impurity H
12. Impurity I
13. Impurity L
14. Impurity J
15. Impurity N

TEST CONDITIONS:

Column: HALO 90 Å C18, 2.7 µm, 2.1 x 100 mm
Part Number: 92812-602
Guard Column: HALO 90 Å C18, 2.7 µm, 2.1 x 5 mm
Part Number: 92812-102
Guard Column Holder: Part Number: 94900-001
Mobile Phase A: Phosphate Buffer (1.7g. potassium dihydrogen phosphate and 1.8g. dipotassium hydrogen in 1000mL)
Mobile Phase B: Methanol
Gradient:

Time	% B
0.0	5
1.0	5
10.0	10
20.0	10
40.0	34
50.0	34

Flow Rate: 0.3 mL/min
Initial Pressure: 246 bar
Temperature: 30 °C
Detection: 254 nm, PDA
Injection Volume: 1 µL
Sample Solvent: 85/15 Water/ MeOH
Data Rate: 40 Hz
Response Time: 0.025 sec.
Flow Cell: 1 µL
LC System: Shimadzu Nexera X2

Paracetamol (acetaminophen) is a common pain relief and fever medication taken individually, or in combination with other medications. An analysis of paracetamol and 14 of its impurities are separated on a HALO 90 Å C18 column following the official European Pharmacopoeia 9.4 method. Baseline resolution is obtained for all compounds including critical pairs of impurity M/G and impurities I/L/J. A HALO 90 Å C18 guard column is also used in order to provide optimum protection for your HALO® HPLC column without sacrificing the column's efficiency.