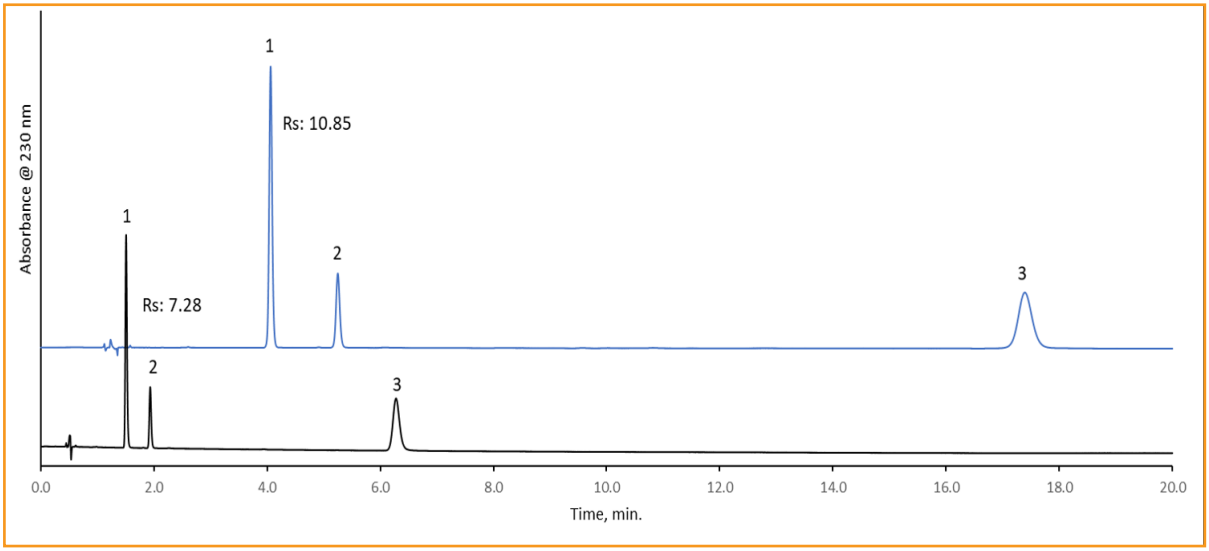
HALO®

PHARMACEUTICALS

Separation of Lidocaine and Related Impurities - USP Method Modernization

382



TEST CONDITIONS:

Column: HALO 120 Å Elevate C18, 2.7 µm, 4.6 x 150 mm (USP: L1)
Part Number: 92274-702
Column: HALO 120 Å Elevate C18, 2.7 µm, 2.1 x 100 mm (USP: L1)
Part Number: 92272-602
Mobile Phase A: Potassium Phosphate Buffer, pH: 8.0
Mobile Phase B: Acetonitrile
Isocratic: 30% B
Flow Rate: 1.0, 0.4 mL/min
Back Pressure: 255 bar
Temperature: 30 ºC
Injection: 20.0, 3.4 µL
Sample Solvent: Mobile Phase
Wavelength: PDA, 230 nm
Flow Cell: 1 µL
Data Rate: 100 Hz
Response Time: 0.05 sec.
LC System: Shimadzu Nexera X2

PEAK IDENTITIES:

1. 2-Cl-N(2-6-dimethylphenyl) Acetamine (Imp. H)
2. 2-6-Dimethylaniline Hydrochloride (Imp. A)
3. Lidocaine

Lidocaine is a local anesthetic which prevents pain by blocking the signals at the nerve endings in the skin. A USP organic impurities test method is performed using a HALO® Elevate C18 column (L1) allowing for excellent performance with a high pH mobile phase (blue trace). The method runtime is then reduced by >50% along with a significant decrease in mobile phase consumption while still meeting the impurity resolution requirments of no less than 1.5 (black trace).

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