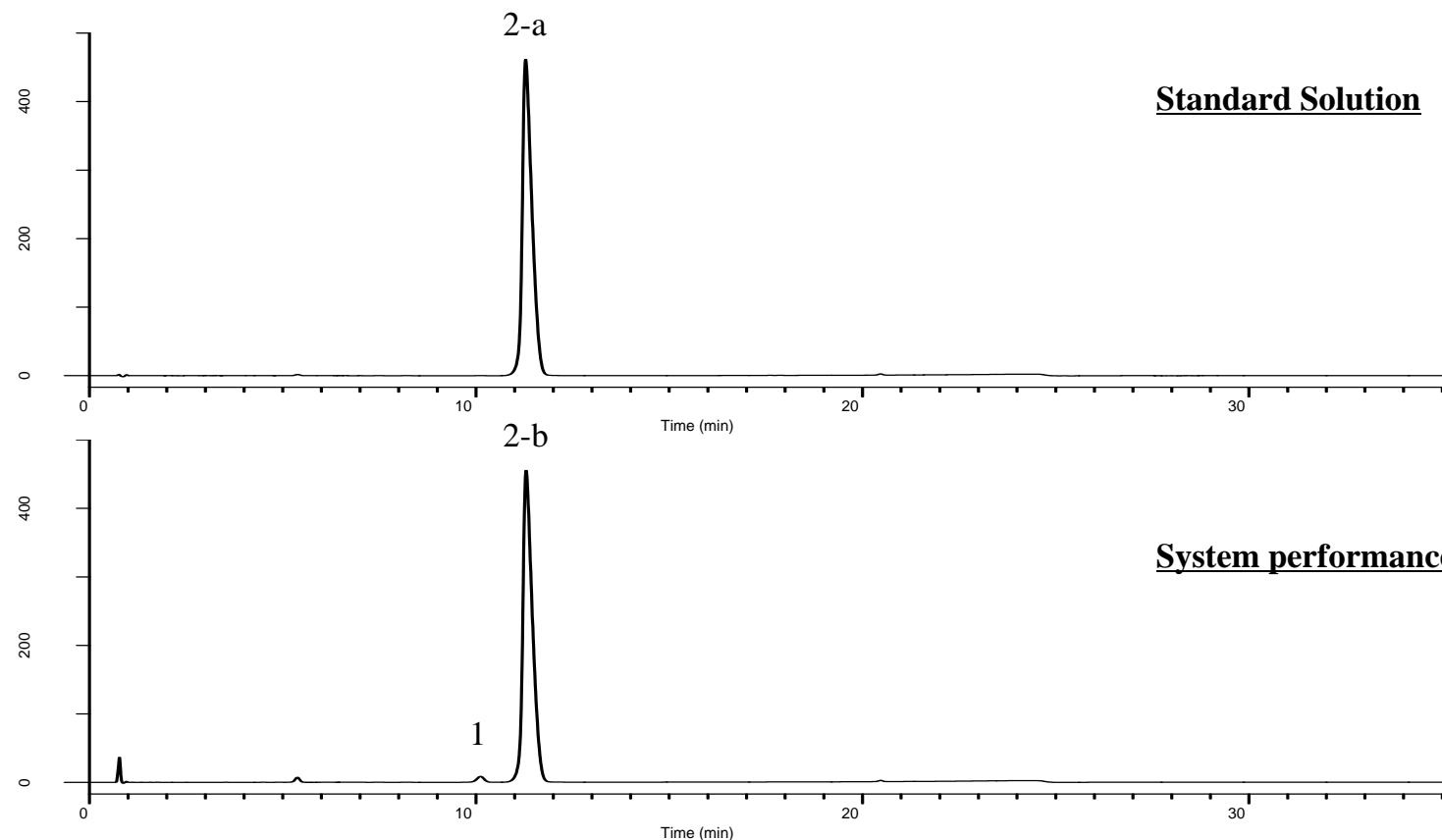


Analysis of Montelukast sodium

Data No. LB294-0894

Standard Solution

System performance



Conditions

System : GL7700 HPLC system
Column : InertSustain Phenylhexyl
(3 μ m, 100 x 4.6 mm I.D.)
Column Cat. No. : 5020-89148
Eluent : A) 0.2 % TFA in H₂O
B) CH₃OH/CH₃CN = 3/2 ,v/v

Analyte:

1. Impurity
2. Montelukast sodium

Time (min)	A (vol%)	B (vol%)
0	48	52
5	45	55
12	45	55
22	25	75
23	25	75
23.1	48	52
35	48	52

Relative retention time (1 to 2-b) : 0.90
Resolution (1, 2-b) : 2.77 (\geq 1.5)
Theoretical plates : 10,183 (\geq 5,000)
Tailing factor : 1.41 (\leq 2.5)
RSD of the peak area (%) (n=5) : 0.20 (\leq 1.0)

Flow Rate : 1.5 mL/min
Col. Temp. : 50 °C
Detection : UV 255 nm (PD7752 PDA Detector)
Injection Vol. : 20 μ L