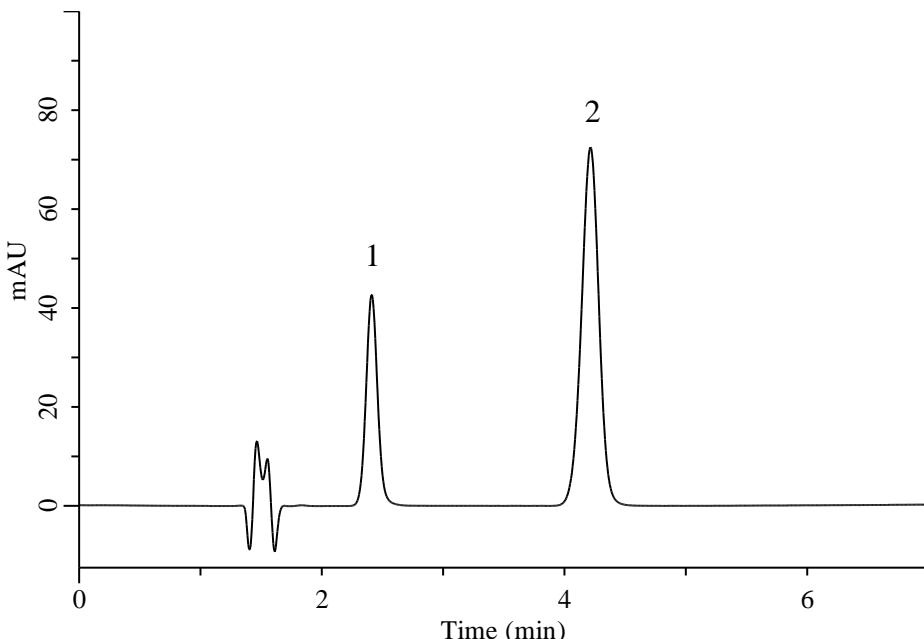


Analysis of Sulfamethoxazole and Trimethoprim

(Under the Condition of USP43-NF38, Sulfamethoxazole and Trimethoprim Oral Suspension)



Conditions

System : Chromaster HPLC system (HITACHI)
Column : Inertsil WP300 C18 (GL Sciences Inc.)
(10 μ m, 300 x 3.9 mm I.D.)
Column Cat. No. : 5020-90660
Eluent : Solution*
Flow Rate : 2.0 mL/min
Col. Temp. : 40 °C
Detection : UV 254 nm
Injection Vol. : 20 μ L
Sample : Standard

Analyte:

1.Trimethoprim 0.032 mg/mL
2.Sulfamethoxazole 0.032 mg/mL

Relative retention times

Trimethoprim : 2.41/2.41 (1.0)
Sulfamethoxazole : 4.20/2.41 (1.7)

Resolution : 8.17 (\geq 5.0)

Tailing factor

peak area of 1 : 1.05 (\leq 2.0)
peak area of 2 : 0.97 (\leq 2.0)

RSD of the

peak area of 1 (%)(n=6) : 0.33 (\leq 2.0)
peak area of 2 (%)(n=6) : 0.42 (\leq 2.0)

* Mix 1400 mL of water, 400 mL of acetonitrile, and 2.0 mL of triethylamine in a 2000-mL volumetric flask. Allow to equilibrate to room temperature, and adjust with 0.2 N sodium hydroxide or dilute glacial acetic acid (1 in 100) to a pH of 5.9 \pm 0.1. Dilute with water to volume.