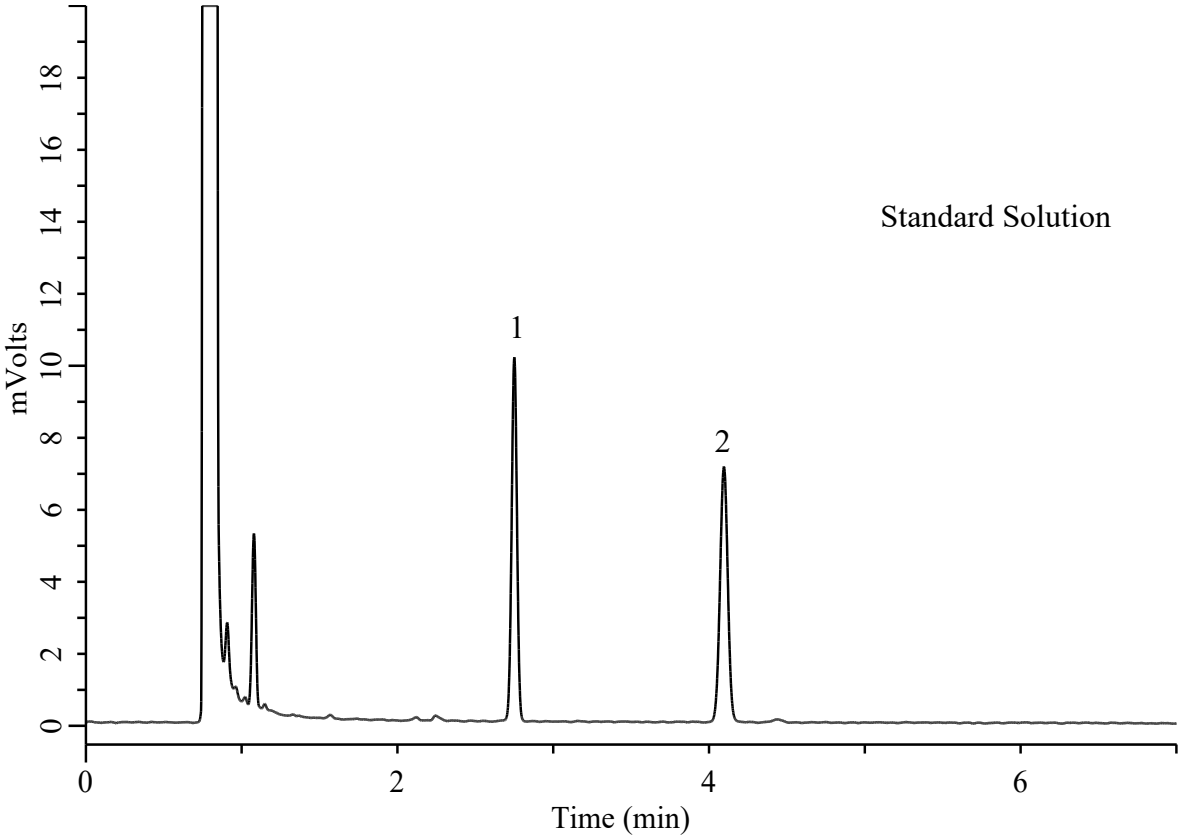
Analysis of Busulfan

(Under the Condition of USP-PF, Busulfan Tablets, ASSAY)



Conditions

System : GC-4000 Plus system
Column : InertCap 5 (GL Sciences Inc.)
0.53 mm I.D. x 30 m df = 1.5 µm
Column Cat. No. : 1010-18446
Column Temp. : 160 ℃
Run time : NLT 2.2 times the retention time of 1,4-diiodobutane (Busulfan [Deriv.])
Carrier Gas : He 68.9 kPa (≒ 10 psi), Constant press.
Injection : Split 56.8 mL/min
200 ℃
Inlet liner : Focus Liner (Cat. No. 3001-35353)
Detection : FID Auto Range
280 ℃
Injection Vol. : 1.0 µL
Sample : Standard

Analyte :
1. Busulfan [Deriv.] 50 µg/mL
2. 1,5-diiodopentane 50 µg/mL
Analyte in n-Hexane

Relative retention times
1 : 1.00 (RT = 2.75 min)
2 : 1.49 (RT = 4.10 min)

Tailing Factor
Tailing factor of 1 : 0.98 (0.8-1.8)

RSD
RSD of the peak ratio of 1 to 2 (%) (n=5) : 0.79 (≦ 1.0)