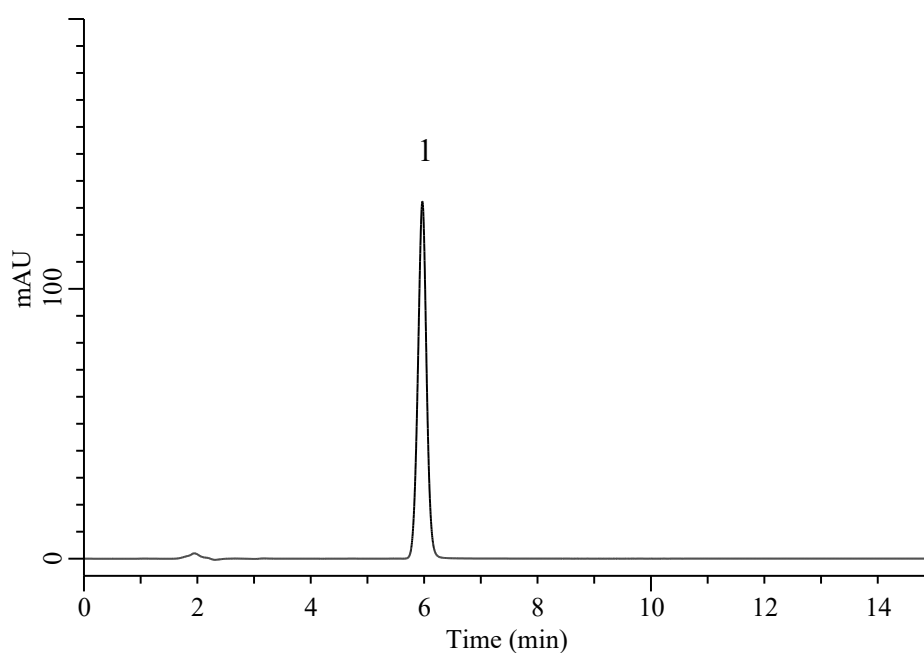


Analysis of Gliclazide

(Under the Condition of the draft for Japanese Pharmacopoeia, Gliclazide Tablets, ASSAY)



Conditions

System : Chromaster PLUS (HITACHI)
Column : Inertsil WP300 C18 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-05845
Eluent : A) CH₃CN
 B) H₂O
 A/B = 9/11, v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 35 °C
Detection : UV 228 nm (Chromaster 5420 UV-VIS)
Injection Vol. : 10 μ L
Sample : Standard in CH₃OH

Analyte:

1. Gliclazide 0.06 mg/mL

Theoretical plates number : 7598 (≥ 3500)

Symmetry factor : ($0.7 \leq$) 1.05 (≤ 1.2)

RSD of the peak area (%) (n=6) : 0.06 (≤ 1.0)