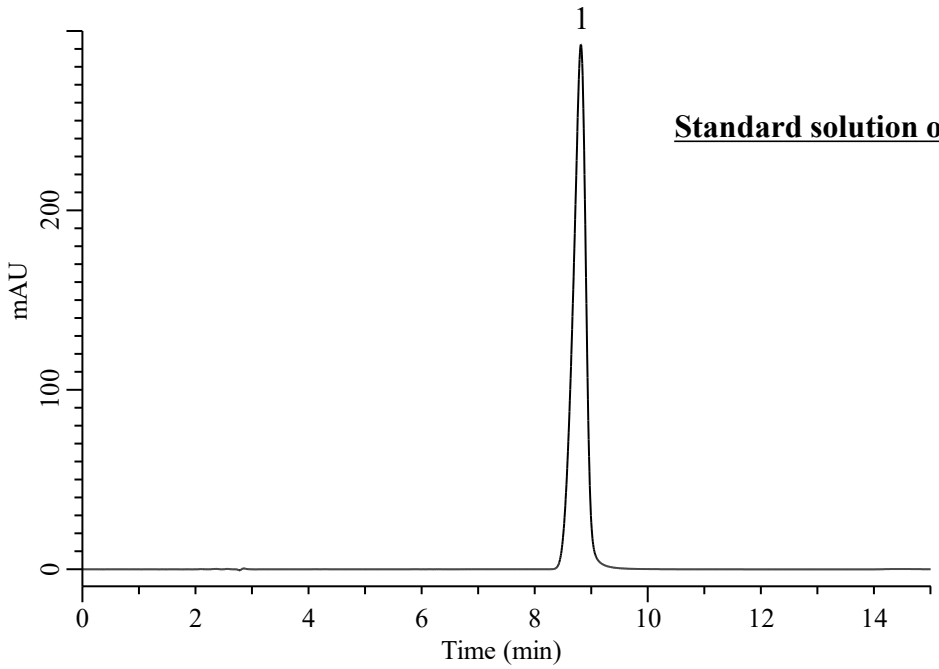
Analysis of Pregabalin

(Under the Condition of the draft for the Japanese Pharmacopoeia, Pregabalin)



Conditions

System	:	Chromaster PLUS HPLC system (HITACHI)
Column	:	InertSustain C18 (GL Sciences Inc.) (5 μm, 250 x 4.6 mm I.D.)
Column Cat. No.	:	5020-07346
Eluent	:	Solution*
Flow Rate	:	1.0 mL/min
Col. Temp.	:	30 ℃
Detection	:	UV 210 nm
Injection Vol.	:	20 μL
Sample	:	Standard

Analyte:

1. Pregabalin 10 mg/mL

Tailing factor	: 0.83 (≦ 1.1)
Number of theoretical plates	: 7,319 (≧ 6,600)
RSD of the peak area (%)(n=6)	: 0.64 (≦ 1.0)

*Dissolve 3.4 g potassium dihydrogen phosphate in 1000 mL water and add ammonia water (28) to adjust pH to 6.3. To 850 mL of this solution, add 150 mL of methanol.