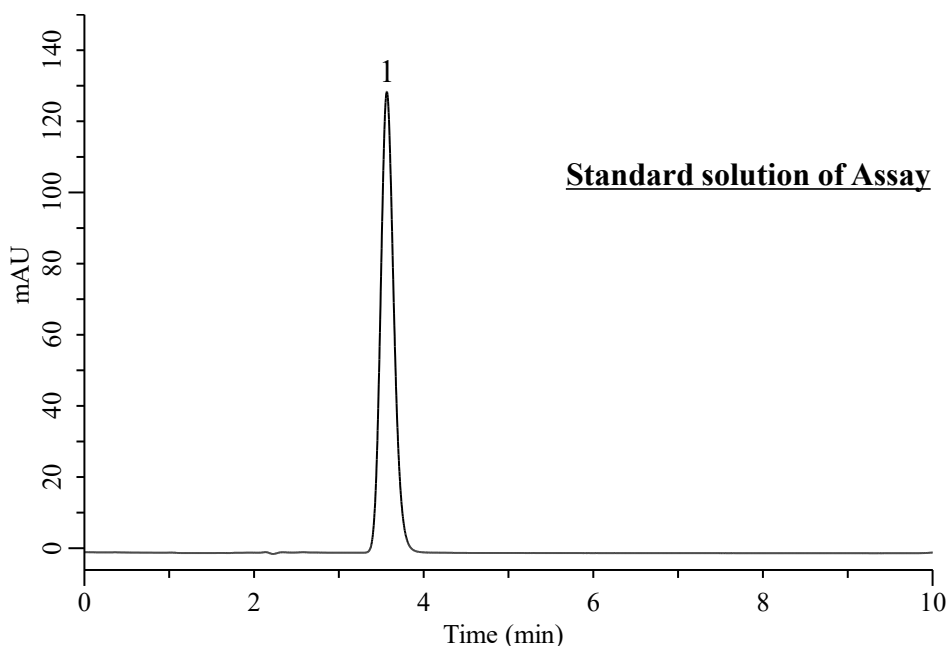


Analysis of Pregabalin

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



Conditions

System	: Chromaster PLUS HPLC system (HITACHI)1.	Analyte:	Pregabalin
Column	: InertSustain C18 (GL Sciences Inc.) (10 μ m, 300 x 3.9 mm I.D.)		1 mg/mL
Column Cat. No.	: 5020-90556		
Eluent	: Solution*	Tailing factor	: 1.15 ($\leq$ 2.0)
Flow Rate	: 0.88 mL/min	Number of theoretical plates	: 2,540 ($\geq$ 1,800)
Col. Temp.	: 20 °C	RSD of the peak area (%) (n=6)	: 0.01 ($\leq$ 1.0)
Detection	: UV 210 nm		
Injection Vol.	: 50 μ L		
Sample	: Standard		

* Dissolve 5.79 g anhydrous disodium phosphate and 3.52 g potassium dihydrogen phosphate in 1000 mL water, and adjust pH to 7.0 by adding phosphoric acid or potassium hydroxide solution. To 1mL of this solution, add 550mL of water, 350mL of methanol, and 100mL of acetonitrile.