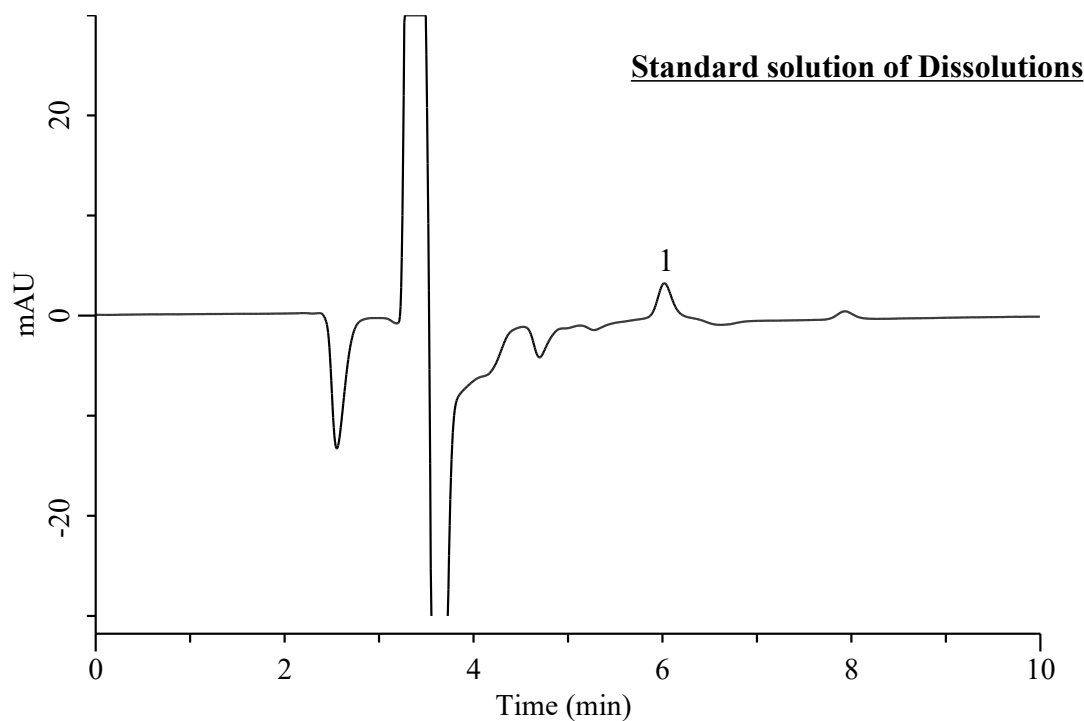


Analysis of Pregabalin

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



Conditions

System	: Chromaster PLUS HPLC system (HITACHI)	Analyte:	
Column	: InertSuatain Cyano (GL Sciences Inc.) (5 μ m, 150 x 4.6 mm I.D.)	1. Pregabalin	28 μ g/mL
Column Cat. No.	: 5020-89276		
Eluent	: Solution*		
Flow Rate	: 0.66 mL/min	Tailing factor	: 1.19 (≤ 2.0)
Col. Temp.	: 35 $^{\circ}$ C	Number of theoretical plates	: 7,489 ($\geq 5,000$)
Detection	: UV 210 nm		
Injection Vol.	: 50 μ L	RSD of the peak area (%) (n=6)	: 1.86 (≤ 2.0)
Sample	: Standard		

*Dissolve 9.41g of sodium 1-hexanesulfonate and 2 mL of trimethylamine in 880 mL of water, add phosphoric acid, and adjust to pH 3.1. To this solution, add 130 mL of acetonitrile.