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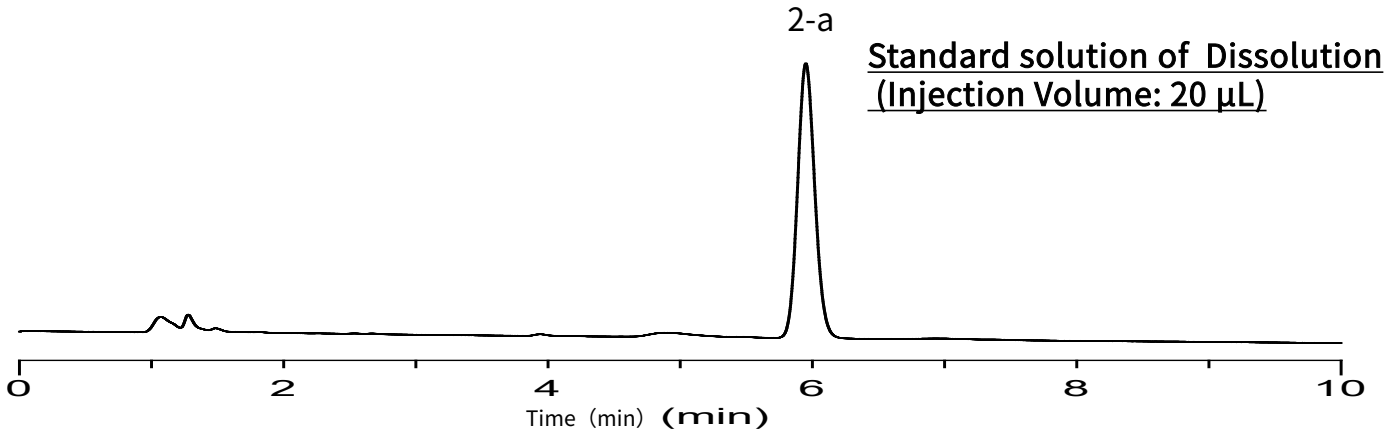
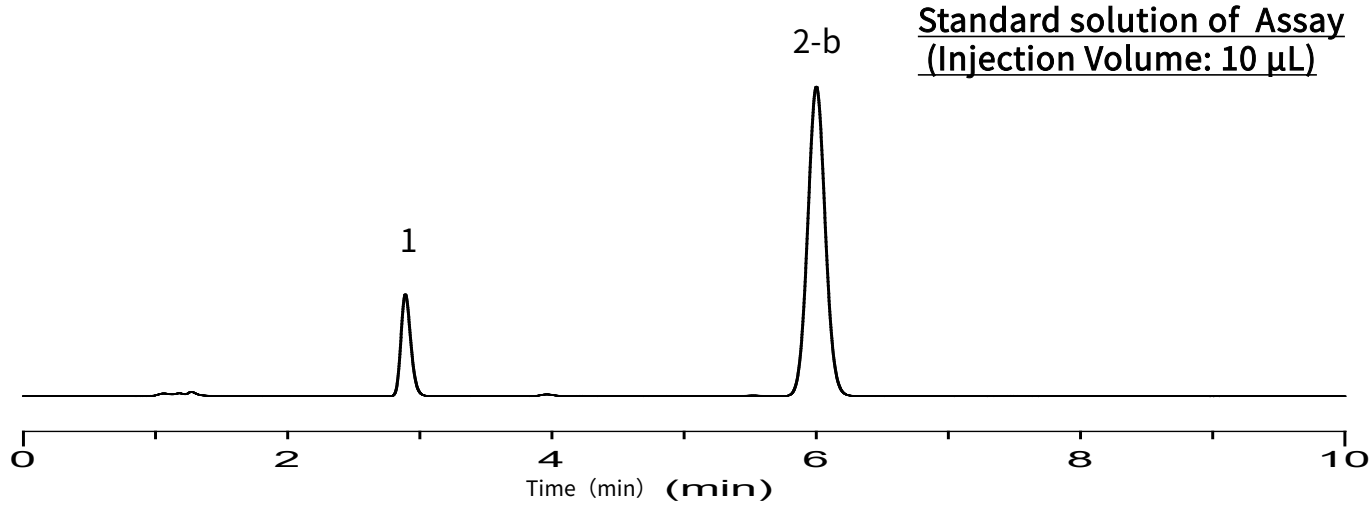
Analysis of Sodium Valproate

(Under the Condition of the draft for the Japanese Pharmacopoeia, Sodium Valproate Extended-release Tablets B)

Data No. LB532-0812





Conditions

System	:	GL7700 HPLC system
Column	:	InertSustain C18 (5 µm, 150 x 4.6 mm I.D.)
Column Cat. No.	:	5020-07345
Eluent	:	A) CH_3CN B) 50 mM NaH_2PO_4 (pH 3.0, H_3PO_4) A/B = 50/50, v/v
Flow rate	:	1.0 mL/min
Col. Temp.	:	25 °C
Detection	:	UV 210 nm (UV7750 UV Detector)
Sample	:	Standard

Analyte:

1. Methyl *p*-hydroxybenzoate	4 mg/L
2. Valproic acid	220 mg/L (2-a) or 800 mg/L (2-b)

Theoretical plates (2-a)	: 9,617 (≧ 3,000)
Symmetry factor (2-a)	: 1.10 (≦ 2.0)
RSD of the peak area of 2-a (%)(n=6)	: 0.23 (≦ 1.0)
Resolution (1, 2-b)	: 16.4 (≧ 7)
RSD of the relative peak area of 2-b to 1 (%)(n=6)	: 0.07 (≦ 1.0)