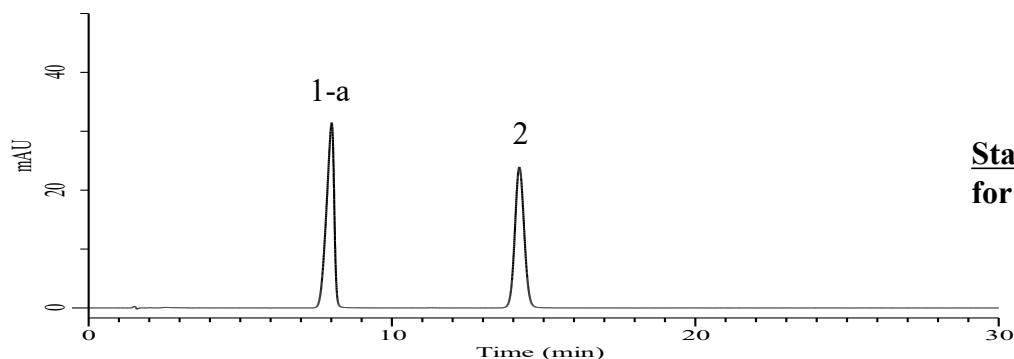
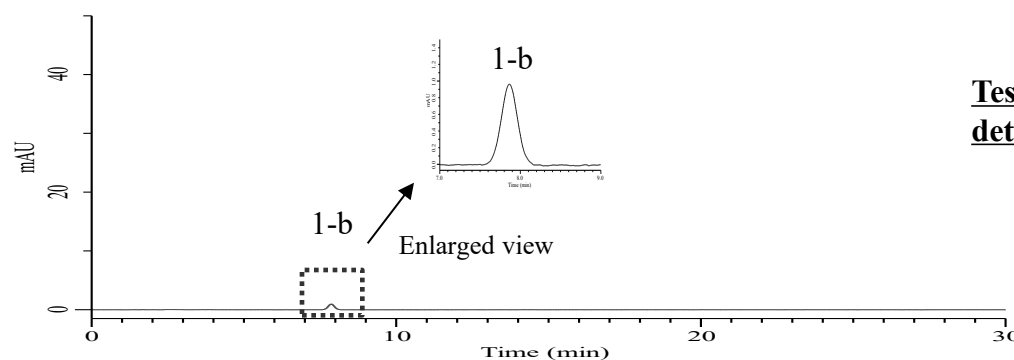


Analysis Nicardipine hydrochloride

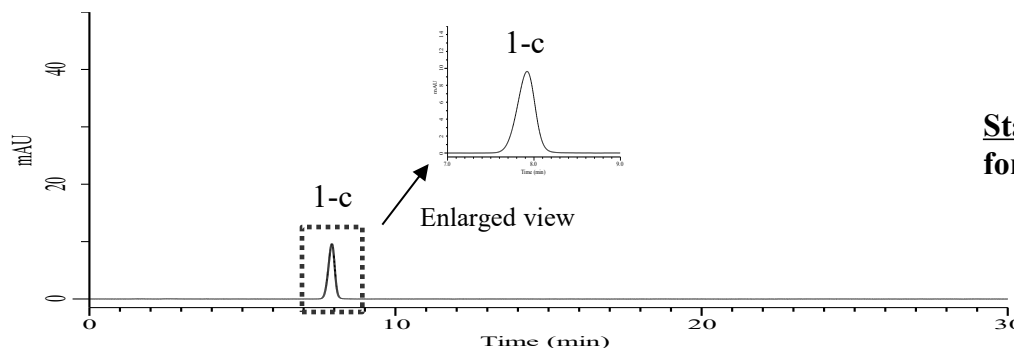
(Under the Condition of the Japanese Pharmacopoeia 19th, Nicardipine Hydrochloride Injection, Related substances)



**Standard solution
for Assay**



**Test for required
detectability solution**



**Standard solution
for Related substances**

Conditions

System : Chromaster PLUS (HITACHI)
Column : Inertsil Hybrid-C18 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-076016
Eluent : 0.01 mol/L KH_2PO_4 in $\text{H}_2\text{O}/\text{CH}_3\text{OH}=320/680$, v/v
Flow Rate : 1.1 mL/min
Col. Temp. : 40 $^\circ\text{C}$
Detection : UV 254 nm (Chromaster 5420 UV-VIS)
Injection Vol. : 10 μL
Sample : Standard in CH_3OH

Analyte:

1-a. Nicardipine hydrochloride 40 $\mu\text{g/mL}$
 1-b. Nicardipine hydrochloride 1 $\mu\text{g/mL}$
 1-c. Nicardipine hydrochloride 10 $\mu\text{g/mL}$
 2. Dibutyl phthalate 160 $\mu\text{g/mL}$

Resolution (1-a,2) : 12.0 (≥ 6)

Test for required detectability (1-b)(%)
 : (8 $\leq$) 9.7 (≤ 12)

RSD of
 the peak area (%) (1-c)(n=5) : 0.32 (≤ 1.0)