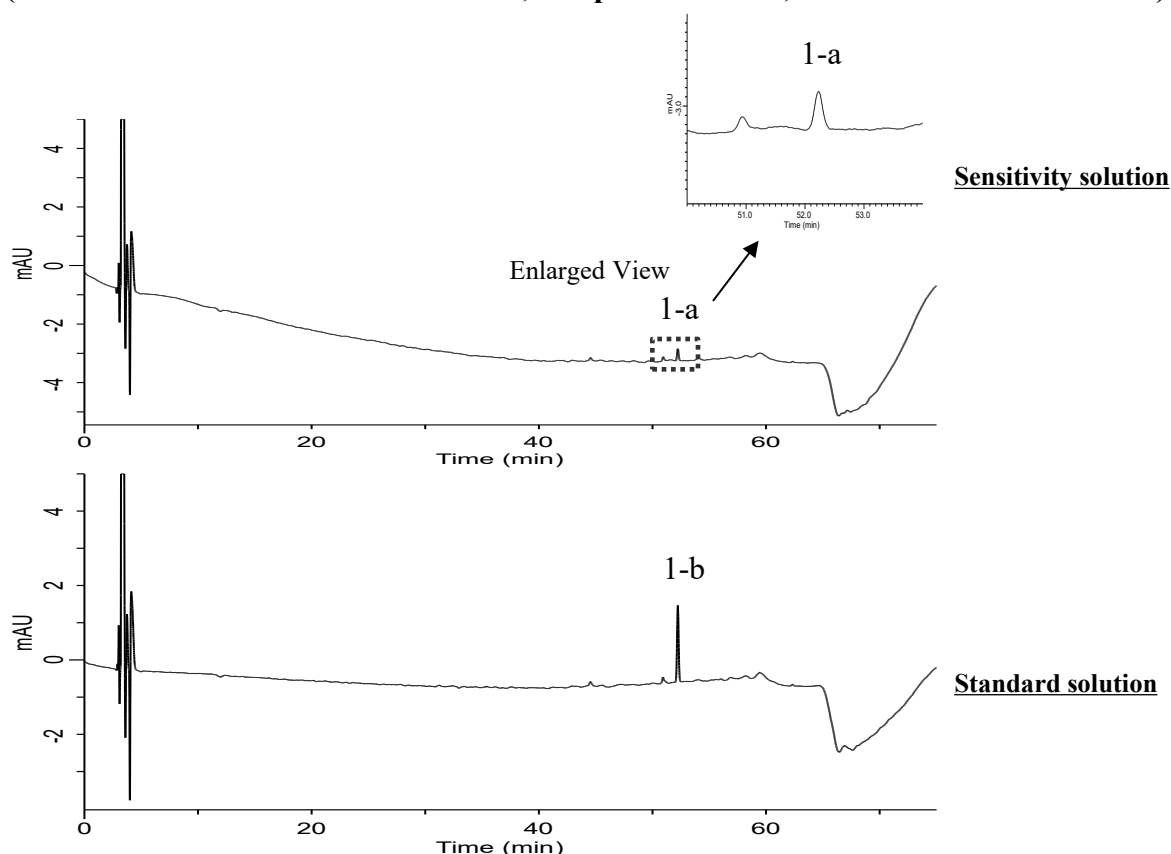


Analysis of Adapalene

(Under the Condition of draft for USP, Adapalene Cream, ORGANIC IMPURITIES)



Conditions

System : Primaide (HITACHI)
Column : InertSustainSwift C18 (GL Sciences Inc.)
(5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-88027
Eluent : A) CH₃OH
B) Solution*

Analyte:

1-a. Adapalene 0.04 μ g/mL
1-b. Adapalene 0.2 μ g/mL

Time (min)	A (vol %)	B (vol %)
0	50	50
3	50	50
55	100	0
60	100	0
70	50	50
75	50	50

Signal-to-noise ratio : 28.4 (≥ 10)

RSD of
the peak area of 1-b (%) (n=6) : 3.06 (≤ 5.0)

Flow Rate : 1.0 mL/min
Col. Temp. : 40 $^{\circ}$ C
Detection : UV 268 nm (Primaide 1435 DAD)
Injection Vol. : 20 μ L
Sample : Standard in Solution**/THF= 90/10, v/v

*: Add 1.7 mL of phosphoric acid to 1000 mL of water and adjust with 12 M sodium hydroxide to a pH of 2.5.

** : Ethanol/CH₃OH/2-Propanol = 90/5/5, v/v/v