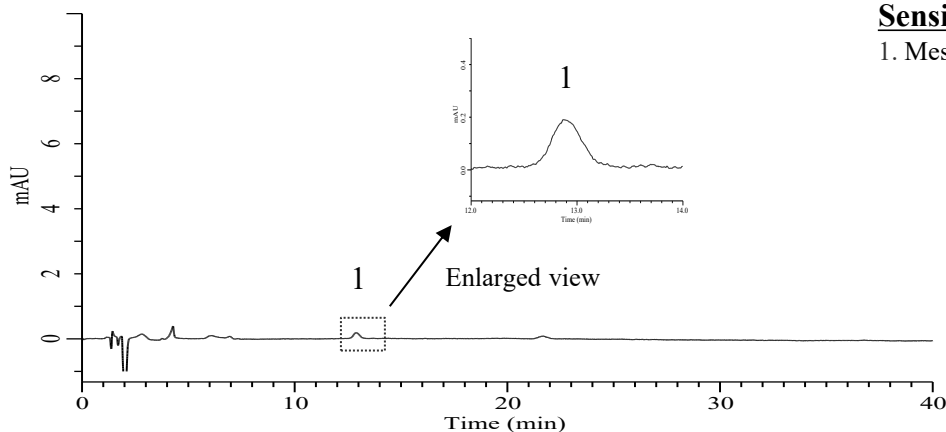


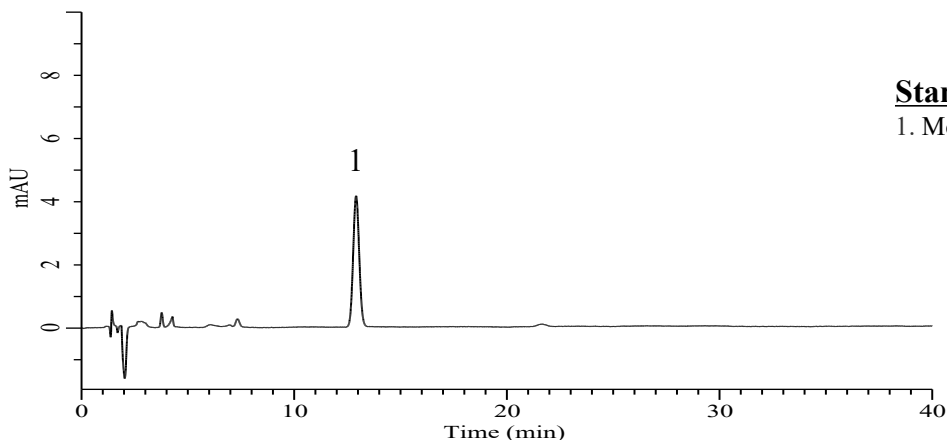
Analysis of Mesalazine

(Under the Condition of USP-NF, Mesalamine Delayed-Release Tablets,
ORGANIC IMPURITIES)



Sensitivity solution

1. Mesalazine 0.1 μ g/mL



Standard solution

1. Mesalazine 0.002 mg/mL

Conditions

System : Primaide HPLC system (HITACHI)
Column : InertSustain C8 (GL Sciences Inc.)
 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-16028
Eluent : A) CH₃OH
 B) Buffer*
 A/B = 25/75, v/v
Flow Rate : 1.5 mL/min
Col. Temp. : 30 °C
Detection : UV 220 nm
Injection Vol. : 30 μ L
Sample : Standard

Analyte:

1. Mesalazine

RSD of the peak area (%) (n=6) : 0.61 ($\leq$ 5.0)

Signal-to-noise ratio : 10.9 ($\geq$ 10)

*: Dissolve 1.8 g of monobasic potassium phosphate and 4.7 g of sodium 1-octanesulfonate in 1 L of water. Adjust with phosphoric acid to a pH of 2.1.