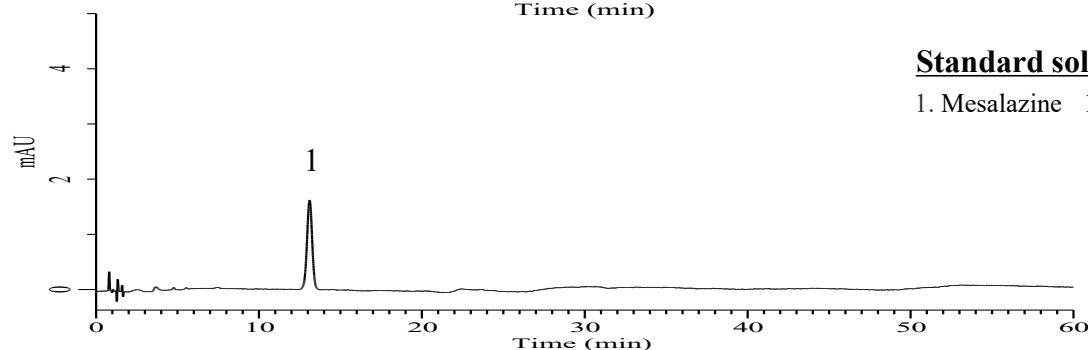
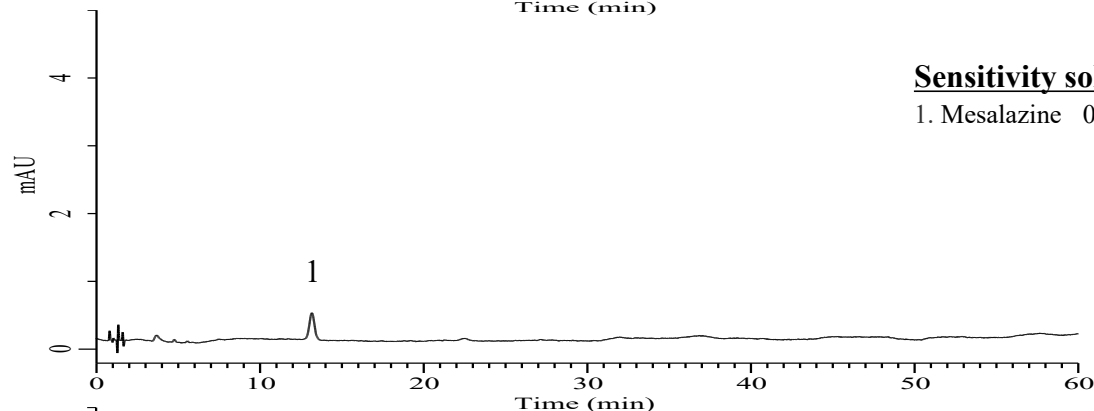
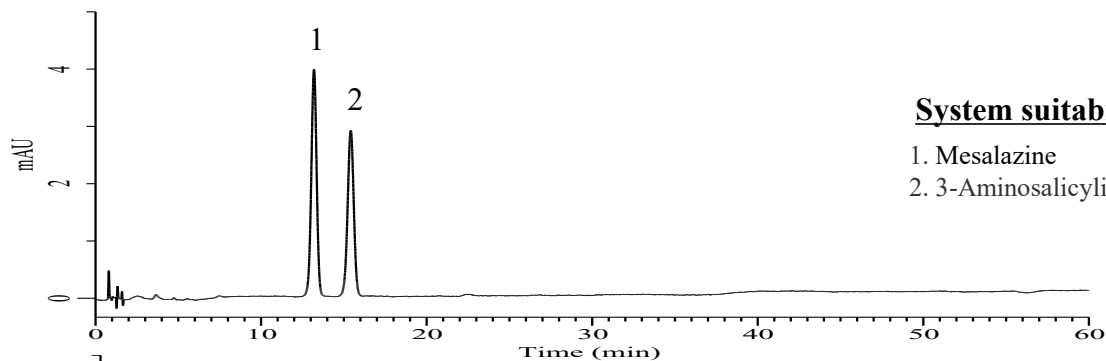


Analysis of Mesalazine

(Under the Condition of USP-NF, Mesalazine Suppositories, Organic Impurities)



Conditions

System : Chromaster PLUS HPLC system (HITACHI)
Column : InertSustain C8 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)

Column Cat. No. : 5020-16027

Eluent : A) CH₃OH
 B) CH₃CN
 C) Buffer*
 A/B/C = 90/35/1000, v/v/v

Flow Rate : 1.5 mL/min

Col. Temp. : 30 °C

Detection : UV 220 nm (5430 DAD)

Injection Vol. : 20 μ L

Sample : Standard

Analyte:

1. Mesalazine
 2. 3-Aminosalicylic acid

Resolution : 3.45 (≥ 1.5)

RSD of the peak area (%) (n=6) : 0.51 (≤ 5.0)

Signal-to-noise ratio : 23.3 (≥ 10)

*: Dissolve 1.39 g of potassium phosphate, monobasic and 2.24 g of octanesulfonic acid sodium salt, monohydrate in 1 L of water. Adjust with phosphoric acid to a pH of 2.2.