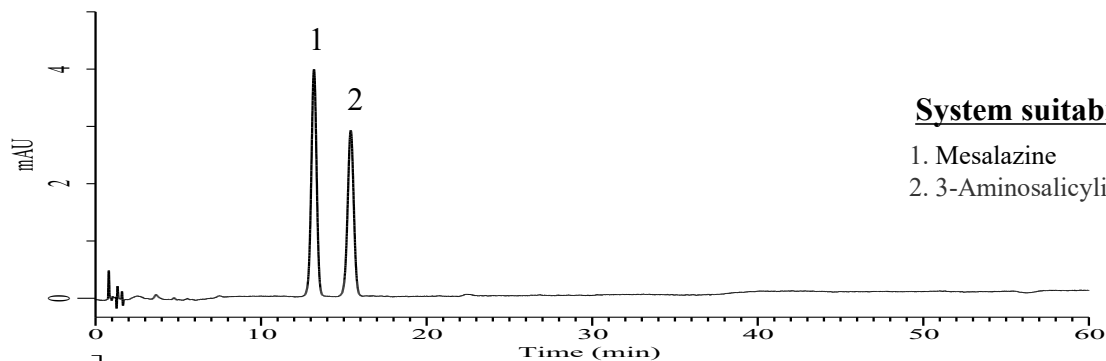


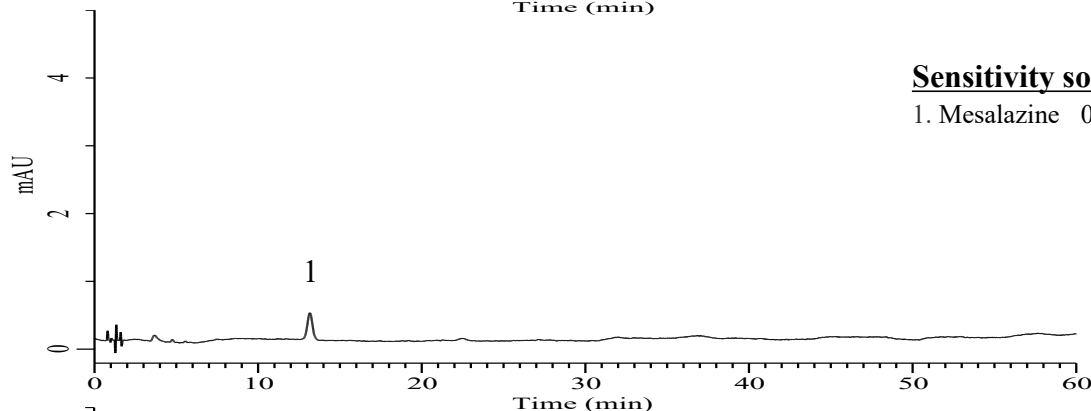
Analysis of Mesalazine

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



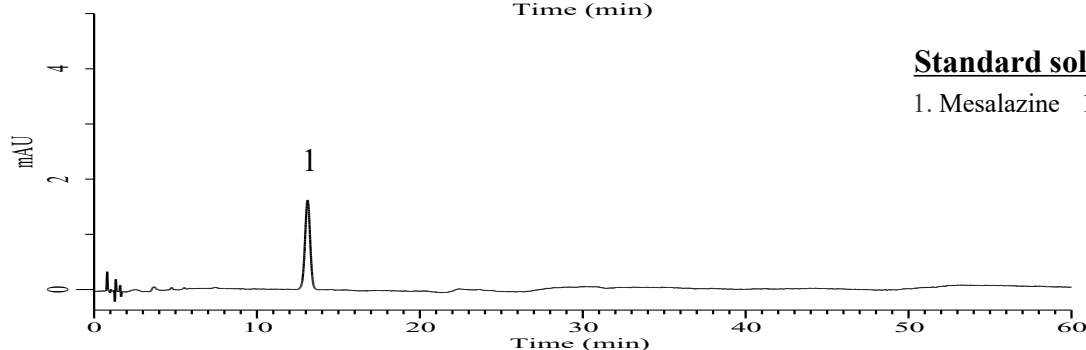
System suitability solution

1. Mesalazine 2.5 μ g/mL
2. 3-Aminosalicylic acid 2.5 μ g/mL



Sensitivity solution

1. Mesalazine 0.25 μ g/mL



Standard solution

1. Mesalazine 1.0 μ g/mL

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.