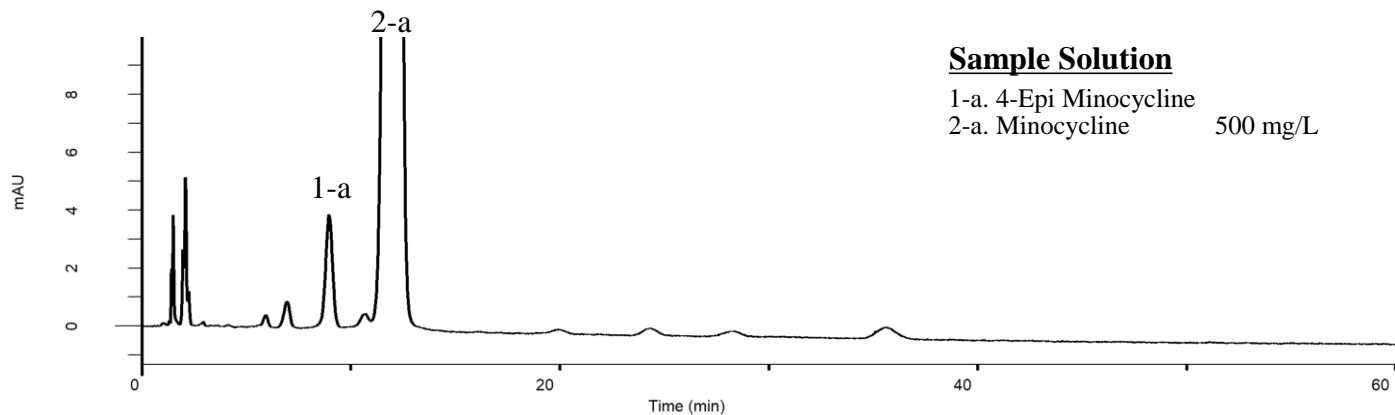


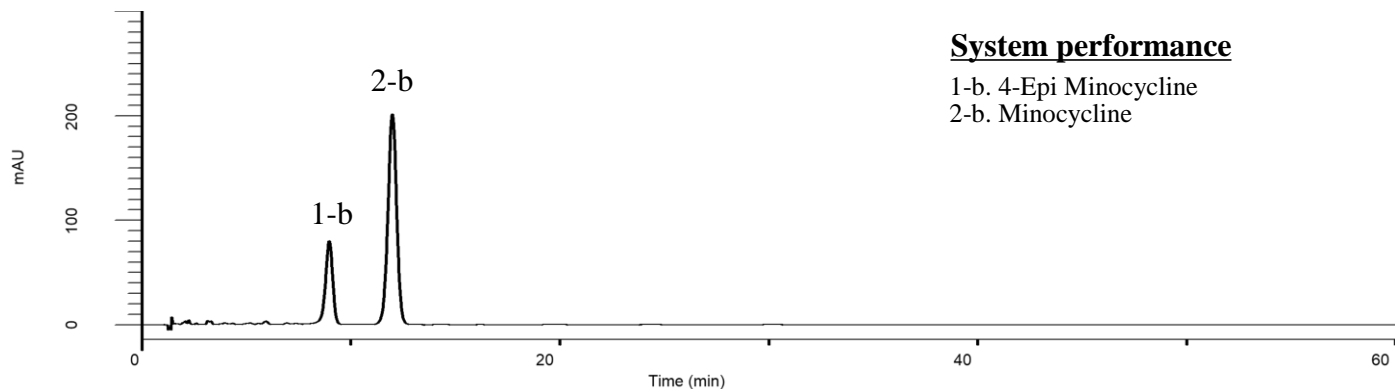
Analysis of Minocycline Hydrochloride

(Under the Condition of the Japanese Pharmacopoeia 17th edition)



Sample Solution

1-a. 4-Epi Minocycline
2-a. Minocycline 500 mg/L



System performance

1-b. 4-Epi Minocycline
2-b. Minocycline

Conditions

System : GL7700 HPLC system
Column : InertSustainSwift C8
 (5 μ m, 150 x 4.6 mmI.D.)
Column Cat. No. : 5020-88331
Eluent : Buffer*
Flow Rate : 1.4 mL/min
Col. Temp. : 25 °C
Detection : UV 280 nm (PD7752 PDA Detector)
Injection Vol. : 20 μ L
Sample : Standard

Analyte:

1. 4-Epi Minocycline
2. Minocycline

Resolution (1, 2) : 4.38 (\geq 2.0)

Pressure: about 18 MPa

*Adjust to pH 6.5 of a mixture of a solution of ammonium oxalate monohydrate (7 in 250), N,N-dimethylformamide and 0.1 mol/L disodium dihydrogen ethylenediamine tetraacetate TS (11:5:4) with tetrabutylammonium hydroxide TS.

0.1 mol/L disodium dihydrogen ethylenediamine tetraacetate TS:

Dissolve 37.2 g of disodium dihydrogen ethylenediamine tetraacetate dihydrate in water to make 1000 mL.

Tetrabutylammonium hydroxide TS:

A solution containing 13 g/dL of tetrabutylammonium hydroxide.