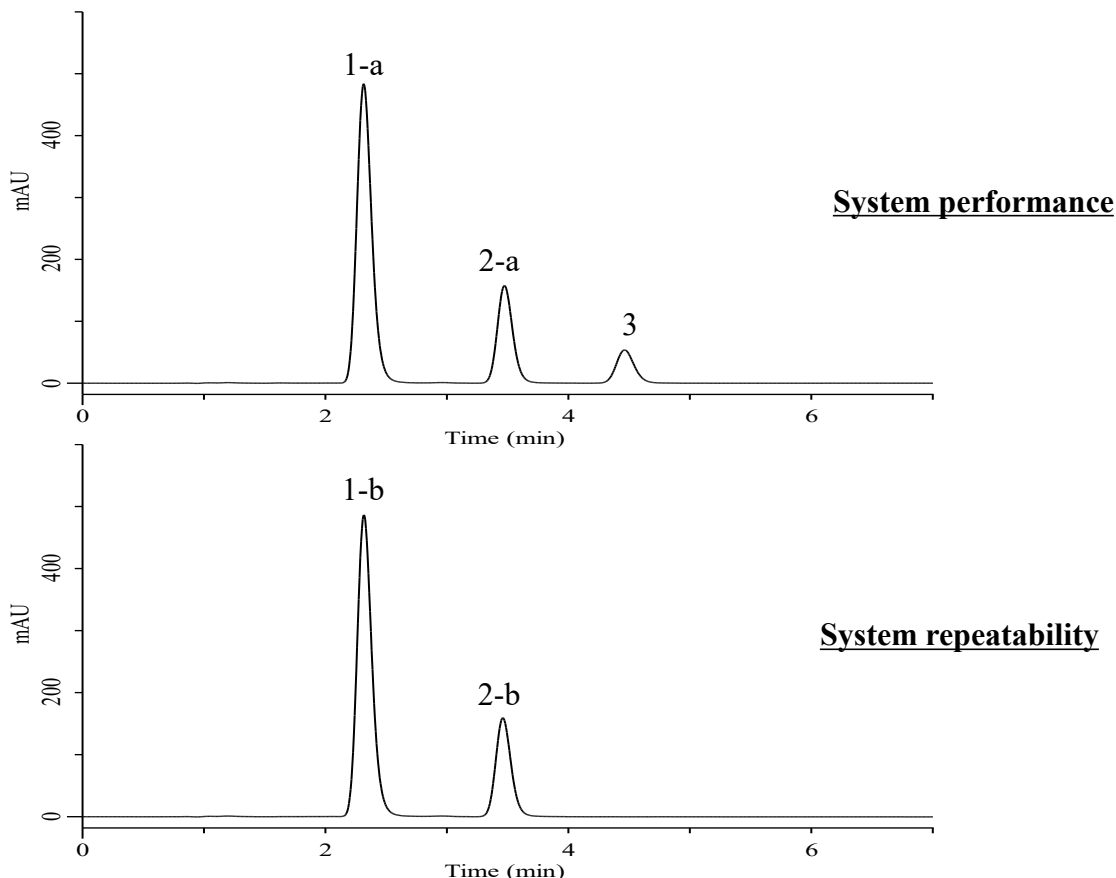


Analysis of Pioglitazone Hydrochloride and Glimepiride

(Under the Condition of the Japanese Pharmacopoeia 18th, Pioglitazone Hydrochloride and Glimepiride Tablets, ASSAY(1)Pioglitazone Hydrochloride)



Conditions

System : Chromaster (HITACHI)
Column : InertSustainSwift C18 (GL Sciences Inc.)
 (HP 3 μ m, 50 x 4.6 mm I.D.)
Column Cat. No. : 5020-88222
Eluent : A) CH₃CN
 B) Buffer*
 A/B = 50/50, v/v
Flow Rate : 0.68 mL/min
Col. Temp. : 40 °C
Detection : UV 228 nm (Chromaster 5430 DAD)
Injection Vol. : 20 μ L
Sample : Standard in Eluent

Analyte:

1-a. Pioglitazone Hydrochloride : 66 mg/L
 1-b. Pioglitazone Hydrochloride : 66 mg/L
 2-a. Ethyl benzoate : 10 μ L/L
 2-b. Ethyl benzoate : 10 μ L/L
 3. Glimepiride : 6 mg/L

Resolution (1-a, 2-a) : 5.1 (≥ 4)

Resolution (2-a, 3) : 4.0 (≥ 3)

RSD of the peak ratio of

1-b to 2-b (%) (n=6) : 0.02 (≤ 1.0)

* Dissolve 7.80 g of sodium dihydrogen phosphate dihydrate in water to make 1000 mL, and adjust to pH 4.0 with diluted phosphoric acid (1 in 10).