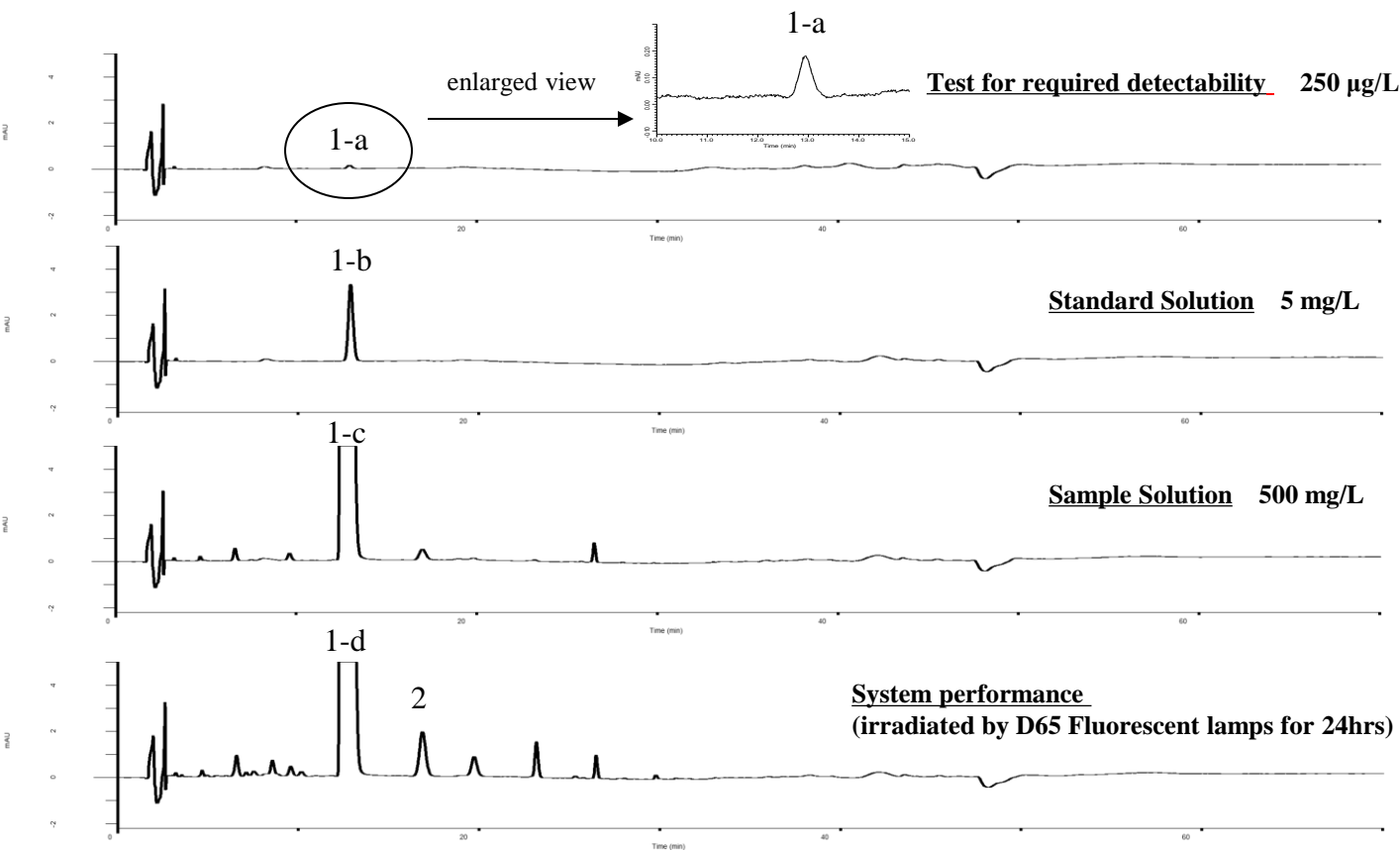


Analysis of Silodosin

(Under the Condition of the Japanese Pharmacopoeia)



Conditions

System : GL7700 HPLC system
Column : InertSustain C18
 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-07346
Eluent : A) CH₃CN
 B) Buffer*

Analyte:

1. Silodosin
 2. Impurity

Resolution (1-d, 2) : 6.7 (\geq 6)
 RSD of the peak
 area (1-b)(%)(n=6) : 0.66 (\leq 2.5)

Time(min)	A(vol%)	B(vol%)
0.0	25	75
15.0	25	75
35.0	50	50
45.0	50	50
45.1	25	75
70.0	25	75

Flow Rate : 1.35 mL/min
Col. Temp. : 40 °C
Detection : UV 225 nm (PD7752 PDA Detector)
Injection Vol. : 10 μ L
Sample : Standard

*Dissolve 3.9 g of sodium dihydrogenphosphate dihydrate in 1000 mL of water.
 Adjust pH 3.4 by diluted phosphoric acid.