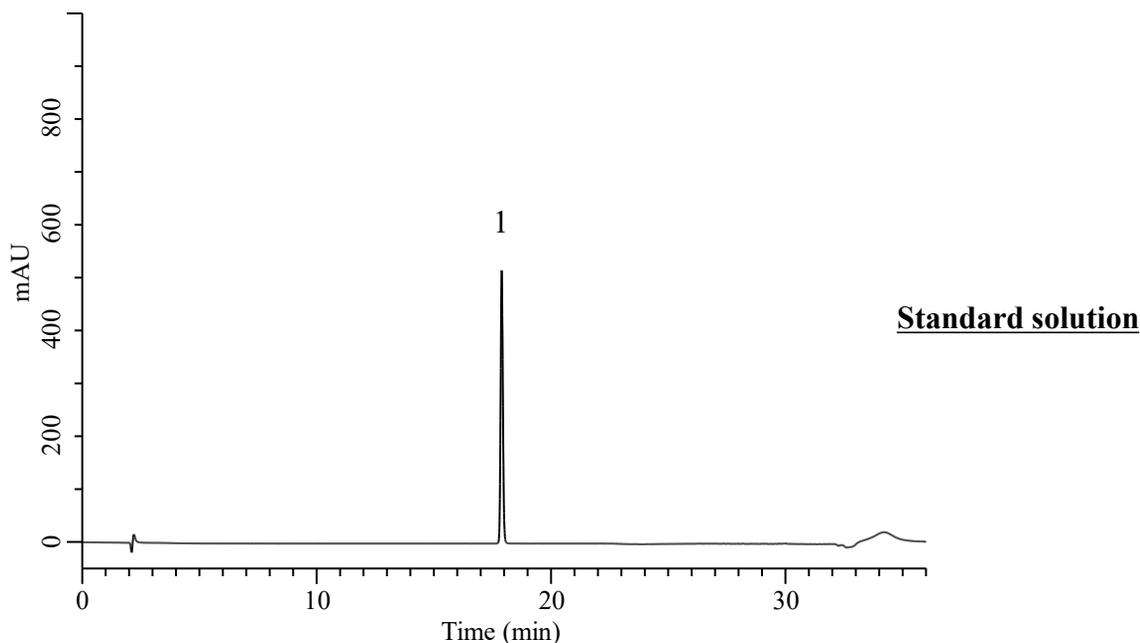


Analysis of Olaparib

(Under the Condition of draft for USP, Olaparib Tablets , Assay)



Conditions

System : Chromaster PLUS (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
 (3.5 μm, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-89996
Eluent : A) CH₃CN/TFA = 1000/0.5 , v/v
 B) H₂O/TFA = 1000/0.5 , v/v

Analyte:

1. Olaparib 0.4 mg/mL

Tailing factor : (0.8 ≤) 1.09 (≤ 1.8)

RSD of the peak area of 1 (%) (n=6) : 0.17 (≤ 1.0)

Time (min)	A (vol %)	B (vol %)
0.0	10	90
20.0	40	60
28.0	95	5
30.0	95	5
30.1	10	90
36.0	10	90

Flow Rate : 1.0 mL/min
Col. Temp. : 30 °C
Detection : UV 276 nm (Chromaster 5430 DAD)
Injection Vol. : 10 μL
Sample : Standard in CH₃CN/H₂O = 50/50, v/v