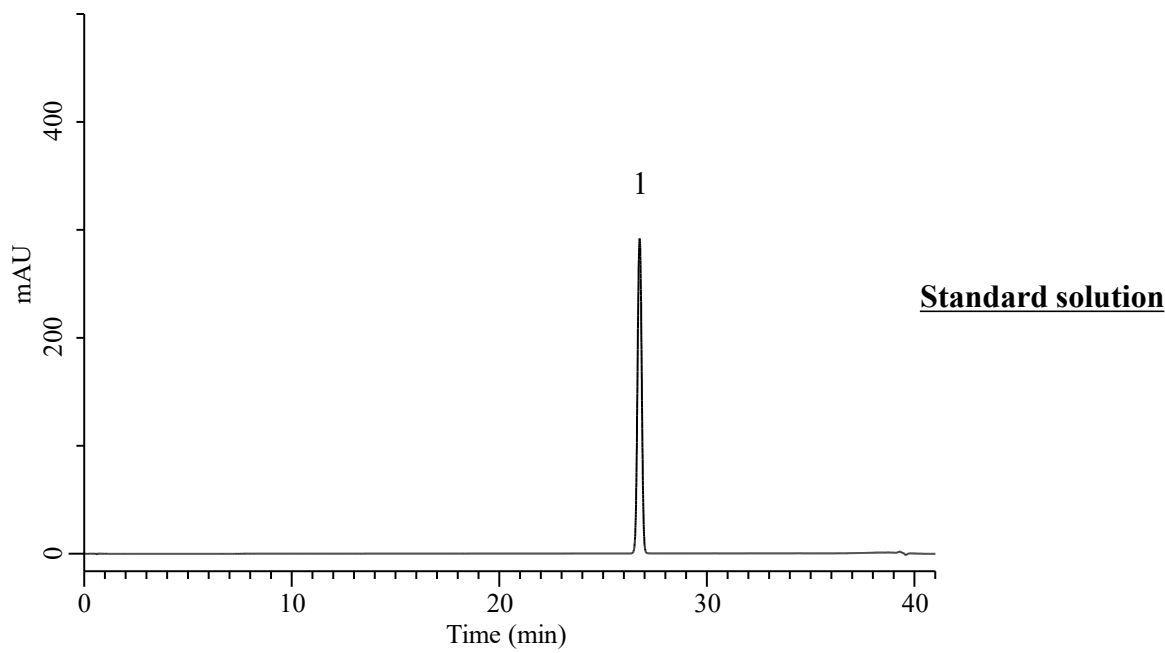


Analysis of Olaparib  
(Under the Condition of draft for USP, Olaparib , Assay)



Conditions

System : Chromaster PLUS (HITACHI)  
Column : Inertsil Hybrid-C18 (GL Sciences Inc.)  
(3.5 μm, 100 x 4.6 mm I.D.)  
Column Cat. No. : 5020-76041  
Eluent : A) 0.06% TFA in CH<sub>3</sub>OH/H<sub>2</sub>O = 95/5 , v/v  
B) 0.06% TFA in CH<sub>3</sub>OH/H<sub>2</sub>O = 5/95 , v/v

Analyte:  
1. Olaparib 0.8 mg/mL  
  
Tailing factor : 0.98 (≦ 2.0)  
  
RSD of  
the peak area of 1 (%) (n=6) : 0.261 (≦ 0.73)

| Time (min) | A (vol %) | B (vol %) |
|------------|-----------|-----------|
| 0.0        | 0         | 100       |
| 35.0       | 55        | 45        |
| 37.0       | 90        | 10        |
| 38.0       | 90        | 10        |
| 38.1       | 0         | 100       |
| 41.0       | 0         | 100       |

Flow Rate : 2.0 mL/min  
Col. Temp. : 50 °C  
Detection : UV 276 nm (Chromaster 5430 DAD )  
Injection Vol. : 10 μL  
Sample : Standard in CH<sub>3</sub>OH/H<sub>2</sub>O = 50/50, v/v