

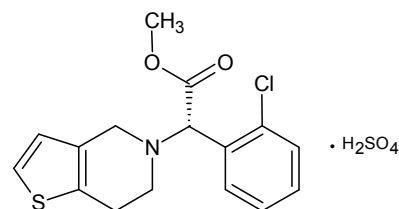
クロピドグレル硫酸塩（日本薬局方原案記載条件）

Clopidogrel Sulfate (The draft for the Japanese Pharmacopoeia) H130711G

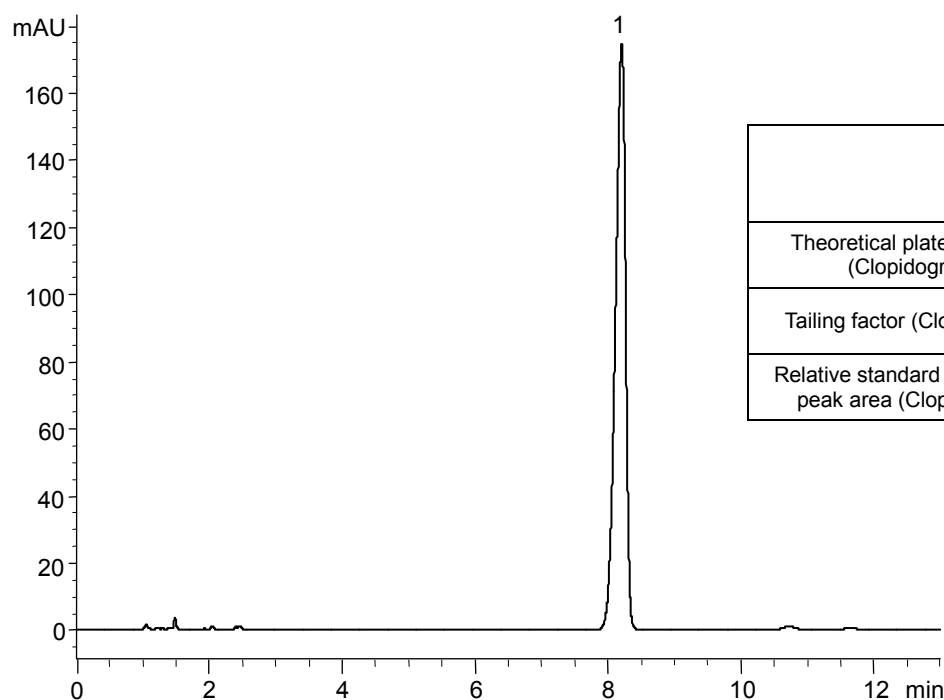
Standard solution\*<sup>1</sup>

(0.126 mg/mL Clopidogrel sulfate)

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Clopidogrel sulfate



|  | System suitability requirement | Result |
|--|--------------------------------|--------|
| Theoretical plate number (Clopidogrel)                 | ≥4500                          | 13900  |
| Tailing factor (Clopidogrel)                           | ≤2.0                           | 0.80   |
| Relative standard deviation of peak area (Clopidogrel) | ≤1.0%                          | 0.12%  |

Column : YMC-Pack Pro C18 (5 μm, 12 nm)  
150 X 4.0 mm I.D.

Eluent : A) buffer\*<sup>2</sup>/methanol (19/1)  
B) acetonitrile/methanol (19/1)  
A/B (3/2)  
*\*<sup>2</sup> Dissolve 0.87 g of sodium 1-pentanesulfonate in 1000 mL water, adjust pH 2.5 with H<sub>3</sub>PO<sub>4</sub>*

Flow rate : 1.1 mL/min (adjust the flow rate so that the retention time of Clopidogrel is about 8 min)

Temperature : 30°C

Detection : UV at 220 nm

Injection : 10 μL

(The draft for the Japanese Pharmacopoeia; Assay)

\*<sup>1</sup> Standard solution was prepared from Clopidogrel sulfate supplied as a reagent for laboratory use.