

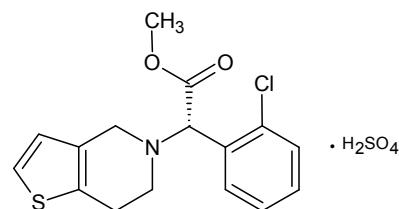
クロピドグレル硫酸塩（日本薬局方原案記載条件）

Clopidogrel Sulfate (The draft for the Japanese Pharmacopoeia) H130711G

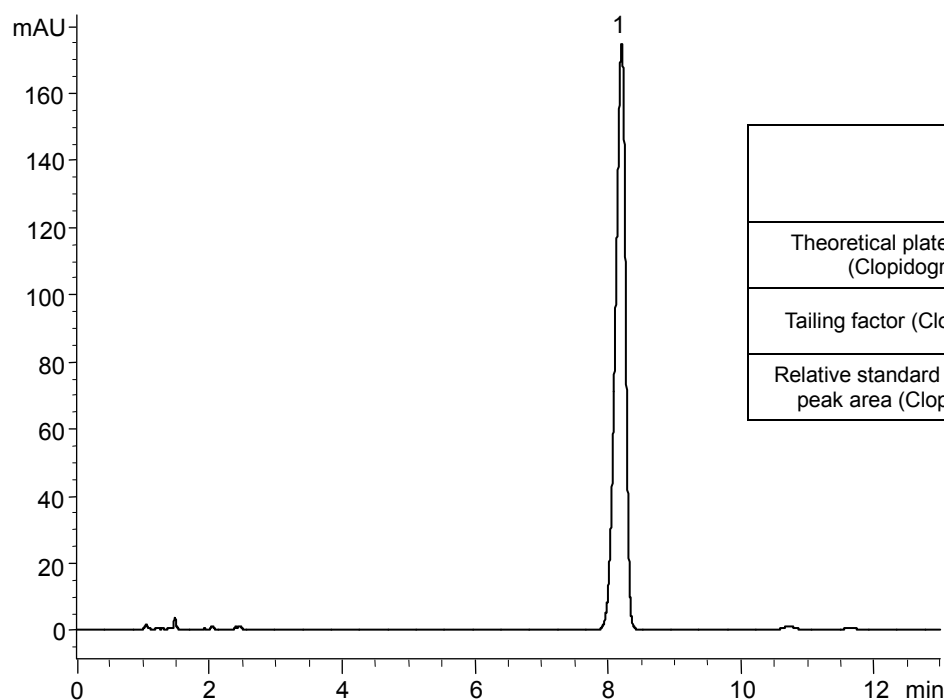
Standard solution\*<sup>1</sup>

(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 mmI.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.