

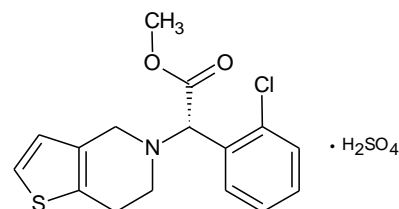
クロピドグレル硫酸塩（日本薬局方原案記載条件）

Clpidogrel Sulfate (The draft for the Japanese Pharmacopoeia) H130711G

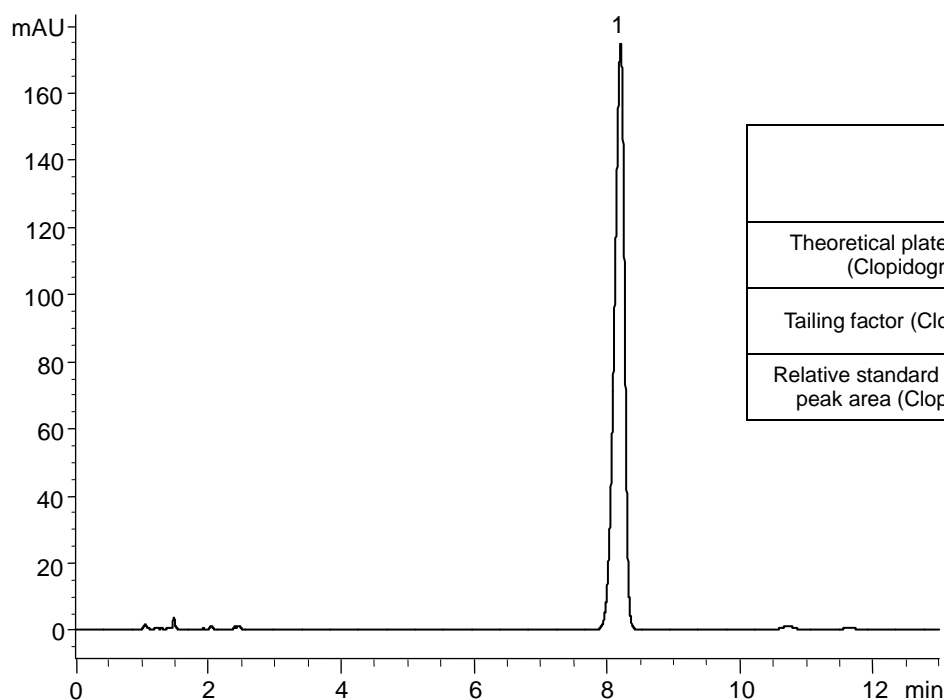
Standard solution*1

(0.126 mg/mL Clopidogrel sulfate)

1



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)	$\leq 1.0\%$	0.12%

Column : YMC-Pack Pro C18 (5 μ m, 12 nm)
150 X 4.0 mmI.D.

Eluent : A) buffer*2/methanol (19/1)
B) acetonitrile/methanol (19/1)
A/B (3/2)
*2 Dissolve 0.87 g of sodium 1-pentanesulfonate in 1000 mL water, adjust to pH 2.5 with H_3PO_4

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 μ L

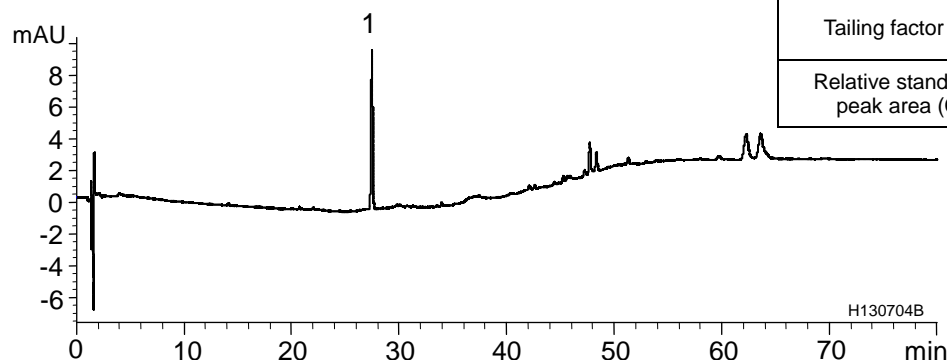
(The draft for the Japanese Pharmacopoeia; Assay)

*1 Standard solution was prepared from Clopidogrel Sulfate supplied as a reagent for laboratory use.

クロピドグレル硫酸塩（日本薬局方原案記載条件）

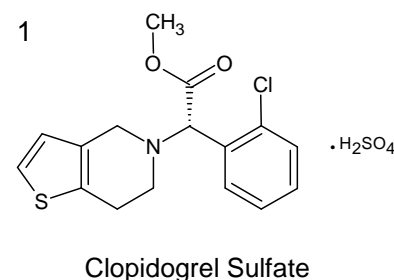
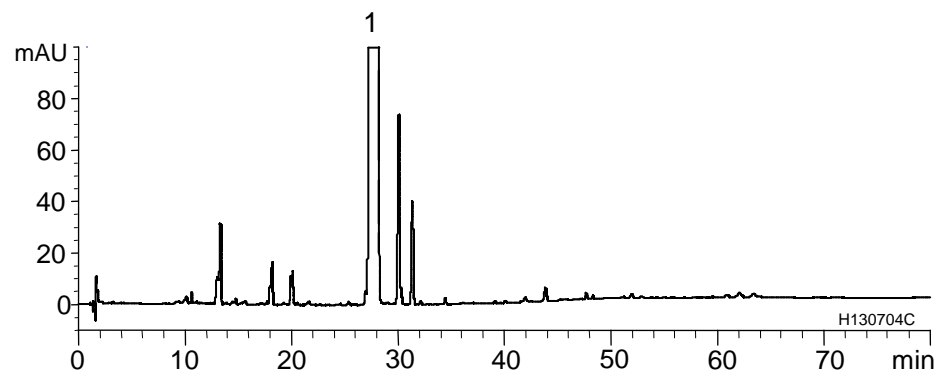
Clopidogrel Sulfate (The draft for the Japanese Pharmacopoeia) H130704D

A) Standard solution*¹
(6.5 µg/mL Clopidogrel sulfate)



	System suitability requirement	Result
Theoretical plate number (Clopidogrel)	≥60000	155300
Tailing factor (Clopidogrel)	≤2.0	0.97
Relative standard deviation of peak area (Clopidogrel)	≤2.0%	0.30

B) Sample solution*¹
(6.5 mg/mL Clopidogrel sulfate)



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

Eluent : A) buffer*²/methanol (19/1)
B) acetonitrile/methanol (19/1)
*² Dissolve 0.87 g of sodium 1-pentanesulfonate in 1000 mL water, adjust to pH 2.5 with H₃PO₄
10.5%B (0-3 min), 10.5-68.5%B (3-48 min), 68.5%B (48-68 min)

Flow rate : 1.0 mL/min

Temperature : 30°C

Detection : UV at 220 nm

Injection : 10 µL

(The draft for the Japanese Pharmacopoeia; Related substances)

*¹ All standard and samplesolutions were prepared from Clopidogrel sulfate supplied as a reagent for laboratory use.

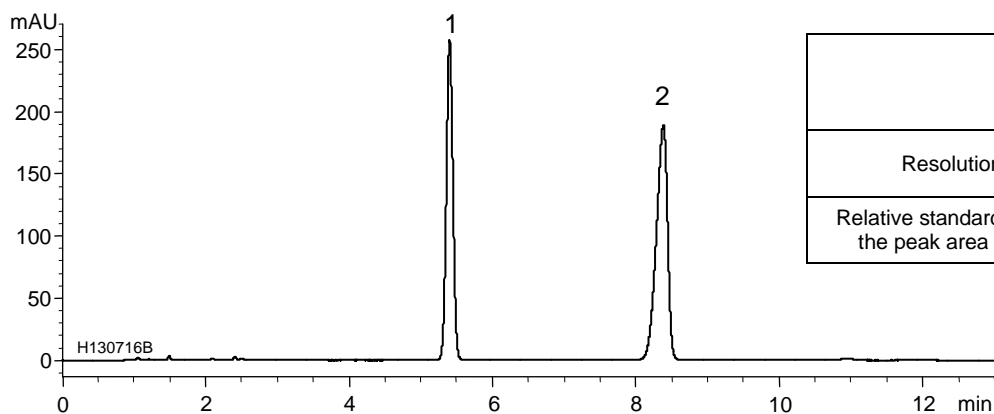
クロピドグレル硫酸塩錠（日本薬局方原案記載条件）

Clopidogrel Sulfate Tablets (The draft for the Japanese Pharmacopoeia)

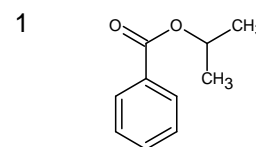
H130716G

A) Standard solution*¹

(0.133 mg/mL Isopropyl benzoate, 0.1 mg/mL Clopidogrel)



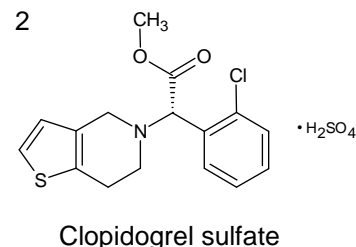
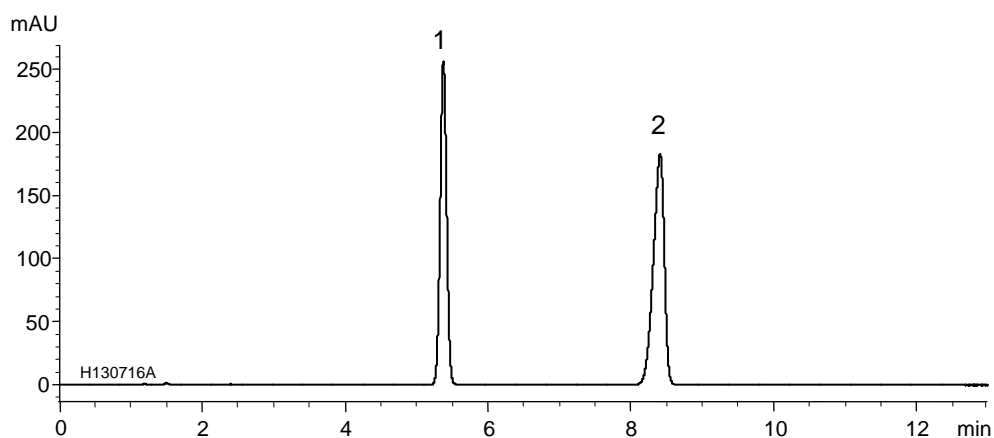
	System suitability requirement	Result
Resolution (1,2)	≥4	13.1
Relative standard deviation of the peak area ratio 1 to 2	≤1.0%	0.03%



Isopropyl benzoate (I.S.)

B) Sample solution*²

(0.133 mg/mL Isopropyl benzoate, 0.1 mg/mL Clopidogrel)



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

Eluent : A) buffer*³/methanol (19/1)
B) acetonitrile/methanol (19/1)
A/B (3/2)
*³ Dissolve 0.87 g of sodium 1-pentanesulfonate in 1000 mL water, adjust to pH 2.5 with H₃PO₄

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)

*¹ Standard solution was prepared from Clopidogrel sulfate supplied as a reagent for laboratory use.

*² Sample solution was prepared from Clopidogrel sulfate tablets.