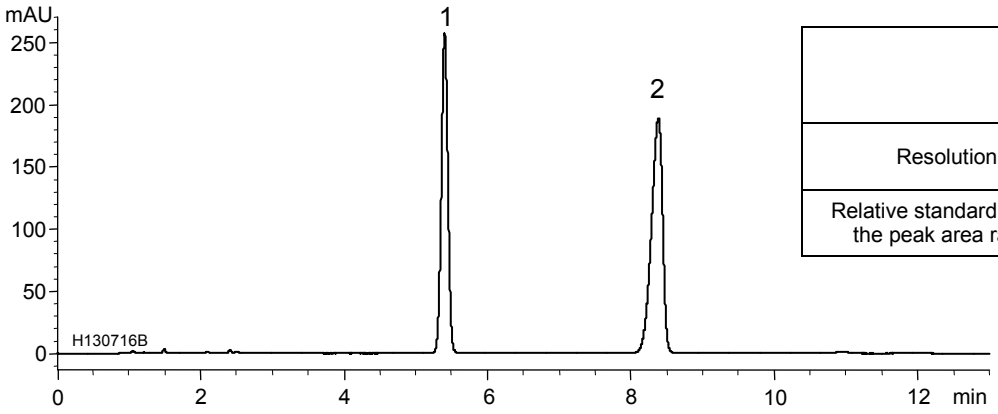
HPLC DATA SHEET

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

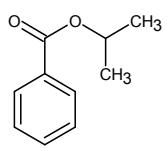
(A) Standard solution*[1]

(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%

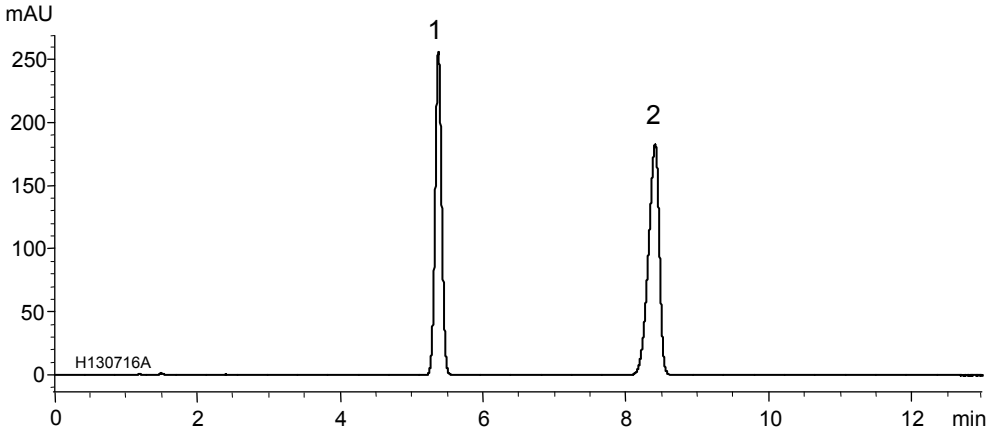
1



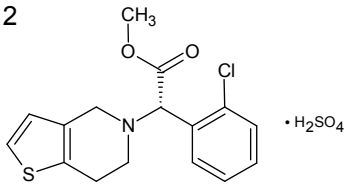
Isopropyl benzoate (I.S.)

(B) Sample solution*[2]

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



2



Clopidogrel sulfate

Column	: YMC-Pack Pro C18 (5 μm, 12 nm) 150 X 4.0 mmI.D.
Eluent	: A) buffer*[3]/methanol (19/1) B) acetonitrile/methanol (19/1) A/B (3/2)
Flow rate	: 1.1 mL/min *(adjust the flow rate so that the retention time of Clopidogrel is about 8 min)*
Temperature	: 30℃
Detection	: UV at 220 nm
Injection	: 10 μL

*[3] *Dissolve 0.87 g of sodium 1-pentanesulfonate in 1000 mL water, adjust pH 2.5 with H_3PO_4*

(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.