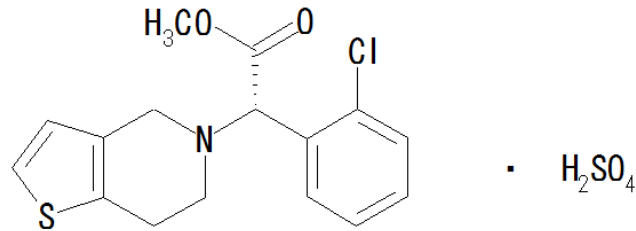


U.S. Pharmacopeia method



Clopidogrel Bisulfate :Limit of Clopidogrel Related Compound C

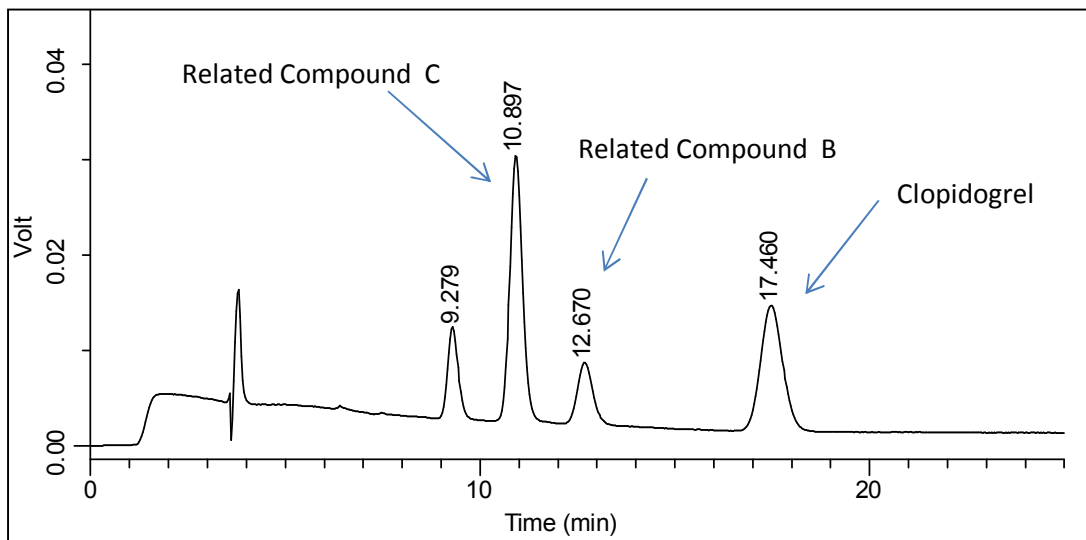


Column	: CHIRALCEL® OJ 0.46cmΦ × 25cmL (L80)
Mobile phase	: Heptane / dehydrated alcohol = 85 / 15 (v / v)
Flow rate	: 0.8mL/min.
Injection volume	: 10μL
UV detection	: 220nm

System suitability

Sample: 0.02 mg/mL each of USP Clopidogrel Bisulfate RS, USP Clopidogrel Related Compound B RS, and USP Clopidogrel Related Compound C RS prepared as follows. Dissolve a quantity of USP Clopidogrel Bisulfate RS, USP Clopidogrel Related Compound B RS, and USP Clopidogrel Related Compound C RS in dehydrated alcohol (about 50% of the volume of the flask), and dilute with heptane to volume.

Relative retention time: clopidogrel related compound B, clopidogrel, and clopidogrel related compound C are 0.7, 1.0, and 0.6, respectively.



	Requirement	Result
Resolution between Compound B and Compound C	≥ 2.0	2.5
Signal-to-noise ratio for clopidogrel related compound C	≥ 20	688