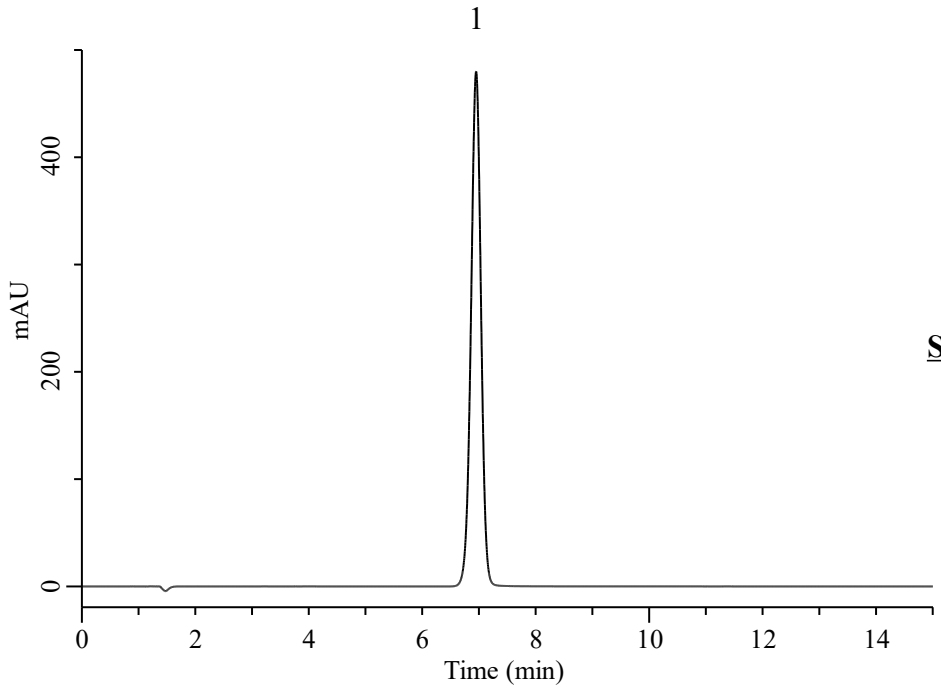
Analysis of Apremilast

(Under the Condition of draft for USP PF52(5), Apremilast, Assay)



Standard solution

Conditions

System	:	Chromaster PLUS (HITACHI)
Column	:	InertSustain C8 (GL Sciences Inc.) (5 µm, 150 x 4.6 mm I.D.)
Column Cat. No.	:	5020-16027
Eluent	:	CH_3CN/Solution*=40/60, v/v
Flow Rate	:	1.2 mL/min
Col. Temp.	:	40 ℃
Detection	:	UV 230 nm (Chromaster 5420 UV-VIS)
Injection Vol.	:	15 µL
Sample	:	Standard in CH_3CN/Solution**=50/50, v/v

Analyte:

1. Apremilast 0.1 mg/mL

Tailing factor : 0.97 (≦ 1.5)

RSD of
the peak area (%)(n=6) : 0.05 (≦ 1.0)

*: TFA/H_2O=0.6/600, v/v
**: 1 mL/L hydrochloric acid in H_2O/ H_2O=50/950, v/v