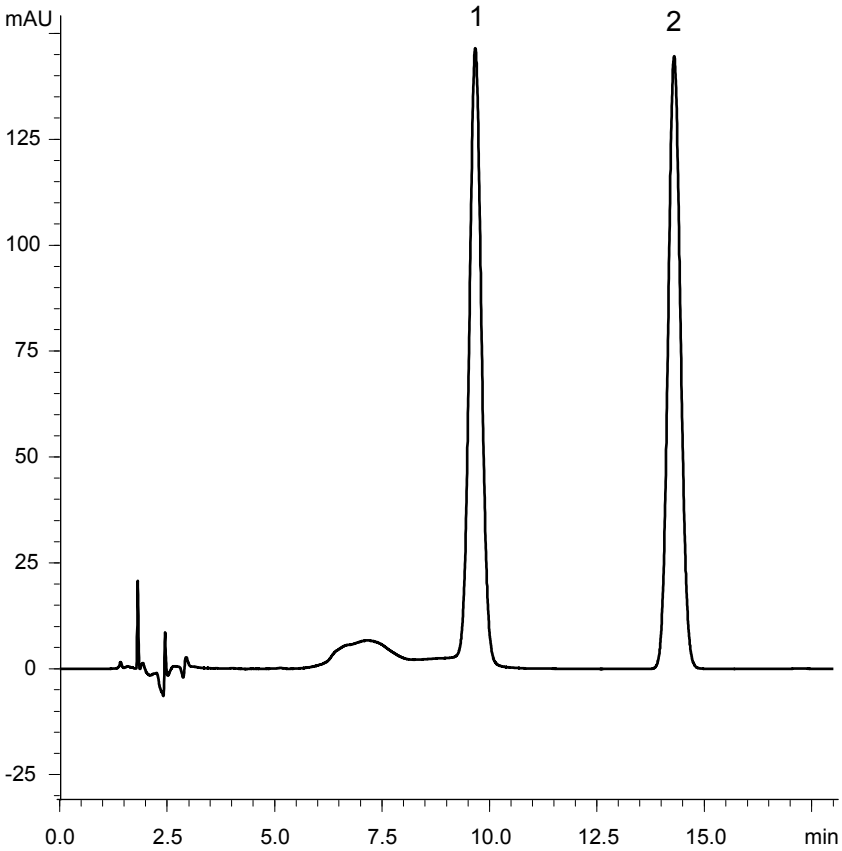
HPLC DATA SHEET

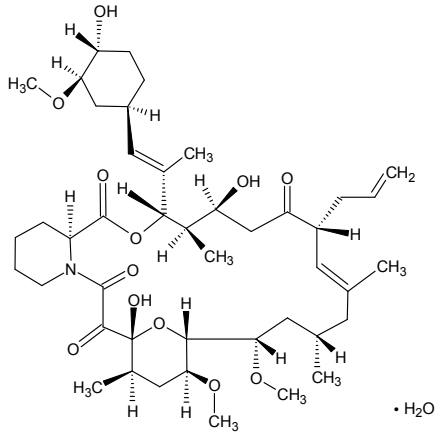
タクロリムス水和物（日本薬局方記載条件）
Tacrolimus hydrate (The Japanese Pharmacopoeia)

U120322D

Sample solution*
(0.5 mg/mL Tacrolimus, 0.15 mg/mL Heptyl *p*-hydroxybenzoate)

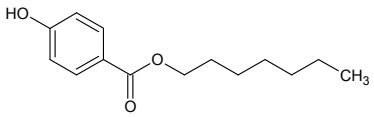


1



Tacrolimus hydrate

2



Heptyl *p*-hydroxybenzoate (I.S.)

	System suitability requirement	Result
Resolution (1, 2)	≧6	8.8
Relative standard deviation of the peak area ratio of 1 to 2	≦1.0%	0.93%

Column : YMC-Triart C18 (5 μm, 12 nm)
150 X 4.6 mmI.D.
Eluent : 2-propanol/THF/water (2/2/5)
Flow rate : 0.7 mL/min *(adjust the flow rate so that the retention time of tacrolimus is about 10 min)*
Temperature : 50℃
Detection : UV at 220 nm
Injection : 10 μL
(The Japanese Pharmacopoeia 16th; Assay)

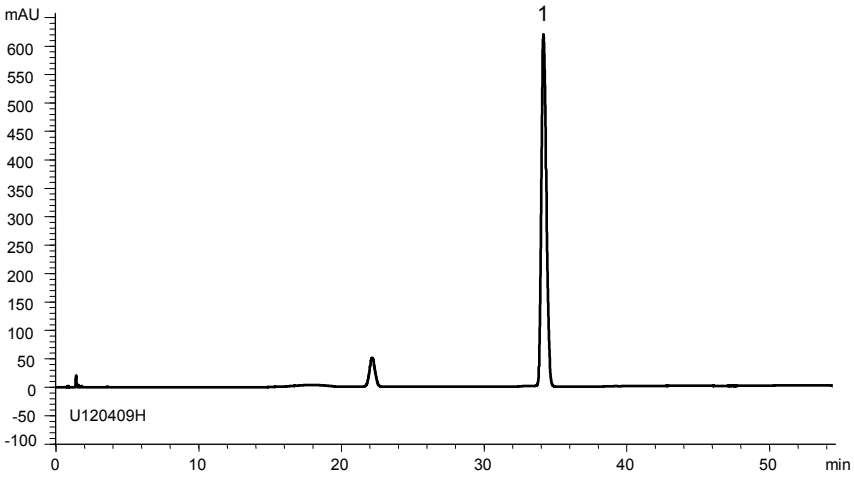
*Sample solution was prepared from Tacrolimus supplied as a reagent for laboratory use.

HPLC DATA SHEET

タクロリムス
Tacrolimus

U120413A

A) Assay: Standard solution*1, Sample solution*1 / Organic Impurities Procedure 2: Sample solution*1
(3 mg/mL Tacrolimus)



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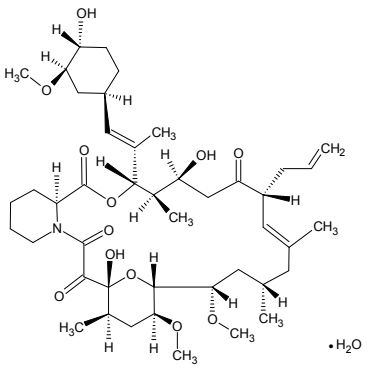
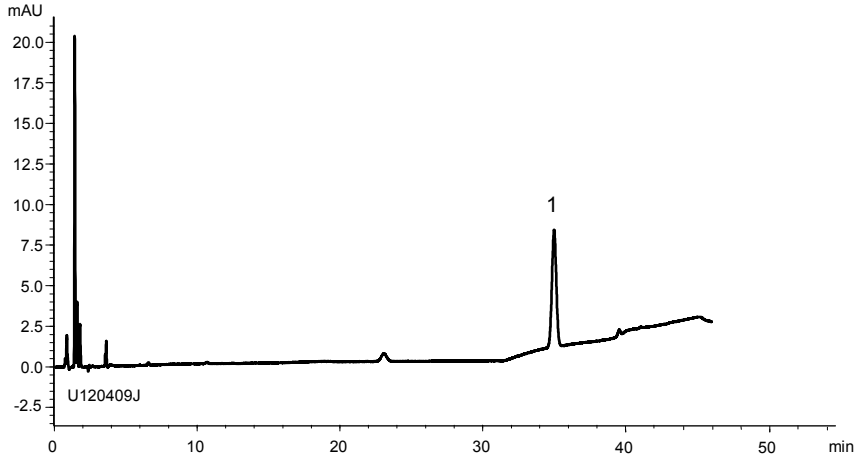


Tacrolimus

B) Organic Impurities Procedure 2: Standard solution*1
(30 μg/mL Tacrolimus)



Column	: YMC-Triart C18 (3 μm, 12 nm)
	150 X 4.6 mmI.D.
Eluent	: A) 6 mM phosphoric acid/solution*2 (4/1)
	B) 6 mM phosphoric acid/solution*2 (1/4)
	28%B (0-30 min), 28-85%B (30-53 min)
	*2 acetonitrile/*tert*-butyl methyl ether (81/19)
Flow rate	: 1.5 mL/min
Temperature	: 60℃
Detection	: UV at 220 nm
Injection	: 20 μL

(The United States Pharmacopeial Forum 36(6); Assay, Organic Impurities Procedure 2)

*1 All standard and sample solutions were prepared from Tacrolimus supplied as a reagent for laboratory use.

YMC SEPARATION TECHNOLOGY

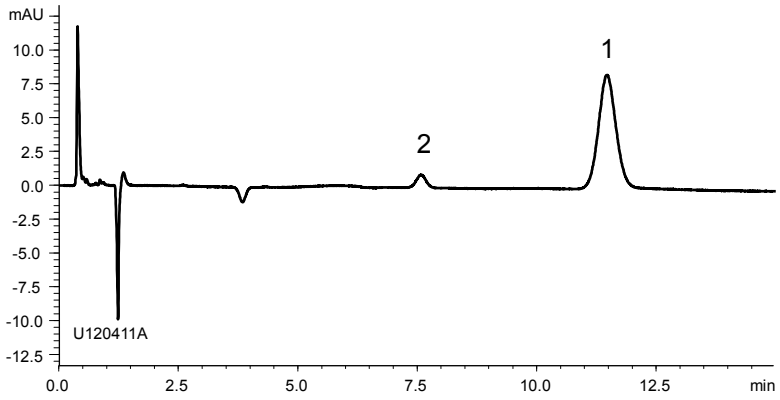
HPLC DATA SHEET

タクロリムスカプセル
Tacrolimus capsules

U120413B

	System suitability requirement	Result
Tailing factor (Tacrolimus)	≦2.0	1.06
Sum of relative standard deviation of the 1 and 2	≦3.0%	2.5%

A) Standard solution*
(50 μg/mL Tacrolimus)



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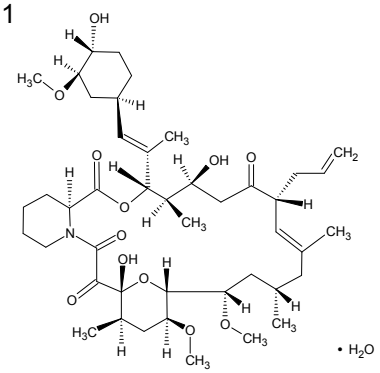
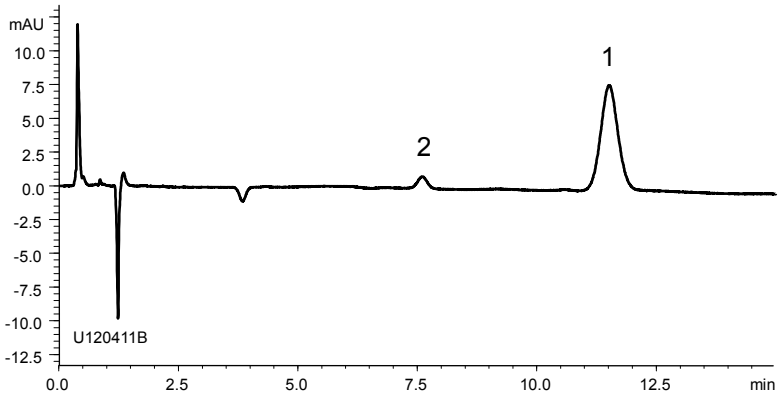


Tacrolimus

B) Sample solution*
(50 μg/mL Tacrolimus)



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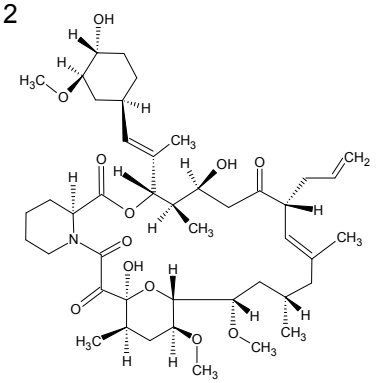


Tacrolimus 19-epimer

Column	: YMC-Triart C18 (3 μm, 12 nm) 50 X 4.6 mmI.D.
Eluent	: acetonitrile/*tert*-butyl methyl ether/6 mM phosphoric acid (335/55/600)
Flow rate	: 1.3 mL/min
Temperature	: 60℃
Detection	: UV at 205 nm
Injection	: 5 μL

(Modified conditions of The United States Pharmacopeial Forum 36(6); Assay)

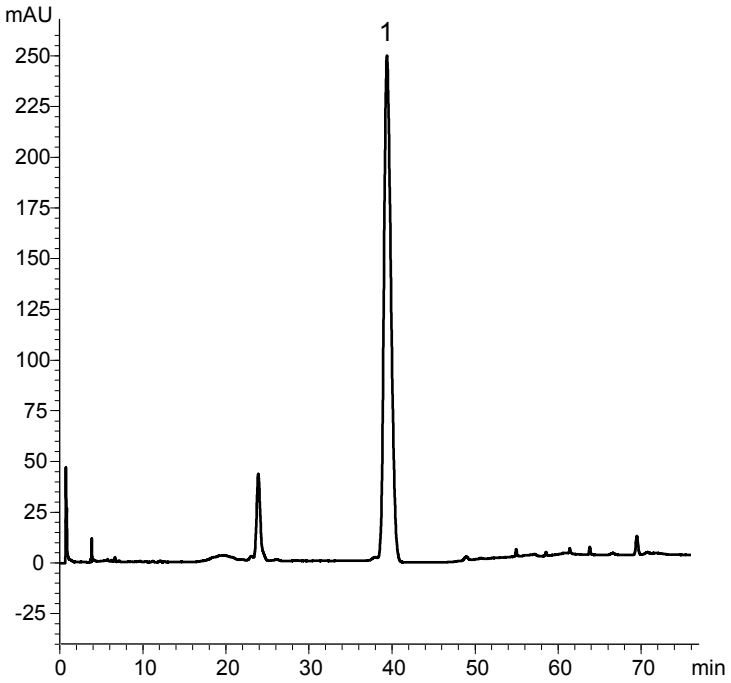
*Standard solution was prepared from Tacrolimus supplied as a reagent for laboratory use.
Sample solution was prepared from Tacrolimus capsules.

HPLC DATA SHEET

タクロリムスカプセル
Tacrolimus capsules

U120410C

Sample solution*1
(1.5 mg/mL Tacrolimus)



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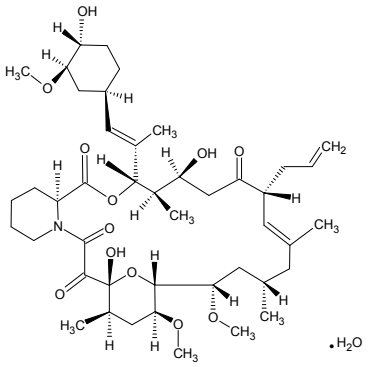

Tacrolimus

Column	: YMC-Triart C18 (3 μm, 12 nm)
	150 X 4.6 mmI.D.
Eluent	: A) 6 mM phospholic acid/solution*2 (4/1)
	B) 6 mM phospholic acid/solution*2 (1/4)
	26%B (0-45 min), 26-85%B (45-60 min), 85%B (60-75 min)
	*2 acetonitrile/*tert*-butyl methyl ether (81/19)
Flow rate	: 1.5 mL/min
Temperature	: 60℃
Detection	: UV at 220 nm
Injection	: 40 μL

(The United States Pharmacopeial Forum 36(6); Organic Impurities Procedure 2)

*1 Sample solution was prepared from Tacrolimus capsules.