

LC Laboratories®

CERTIFICATE OF ANALYSIS

Temsirolimus, >99%

LC LABS CAT. NO. T-8040

CHEMICAL NAME Temsirolimus

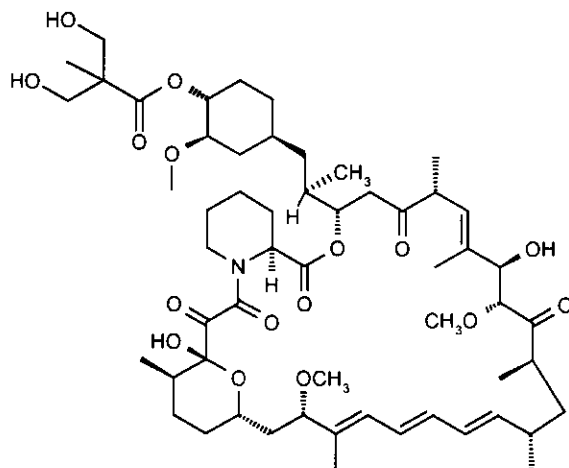
FORMULA C₅₆H₈₇NO₁₆

M.W. 1030.29

CAS NO. 162635-04-3

STORAGE Store at or below -20 °C***

SOLUBILITY Soluble in DMSO at 200 mg/mL; soluble in ethanol at 200 mg/mL; very poorly soluble in water; maximum solubility in plain water is estimated to be about 10-20 µM; buffers, serum or other additives may increase or decrease the aqueous solubility.



ANALYTICAL DATA

LOT NUMBER BTM-111

FORM Granular solid or powder

COLOR White to off-white

HPLC PURITY >99% (see attached chromatogram)

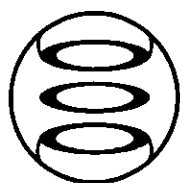
TLC PURITY >99% (see attached chromatogram)

<u>ELEMENTAL ANALYSIS</u>	For C ₅₆ H ₈₇ NO ₁₆ :	<u>Calculated</u>	<u>Found</u>
		C 65.28%	65.01%
		H 8.51%	8.59%
		N 1.36%	1.39%

***This product is stable at ambient temperature for several weeks during ordinary shipping and time spent in Customs or other delay. We recommend storage at -20 °C for long-term storage.

May 20, 2019

D:\COFA-BIZ\B-B-COFA\BTM-111F.WPD



LC Laboratories®

Cat. No. T-8040

Temsirolimus

Lot BTM-111

RUN# 1913

MAY 19, 2019

15:26:39

>99% (sum of all equilibrating peaks;
~87%trans)

AREA#

RT	AREA	TYPE	WIDTH	AREA%
1.185	2557	UU	.079	.07290
4.218	5896	BU	.301	.16810
7.200	9008	PU	.336	.25682
8.620	3490062	UU	.737	99.50221

TOTAL AREA=3507523

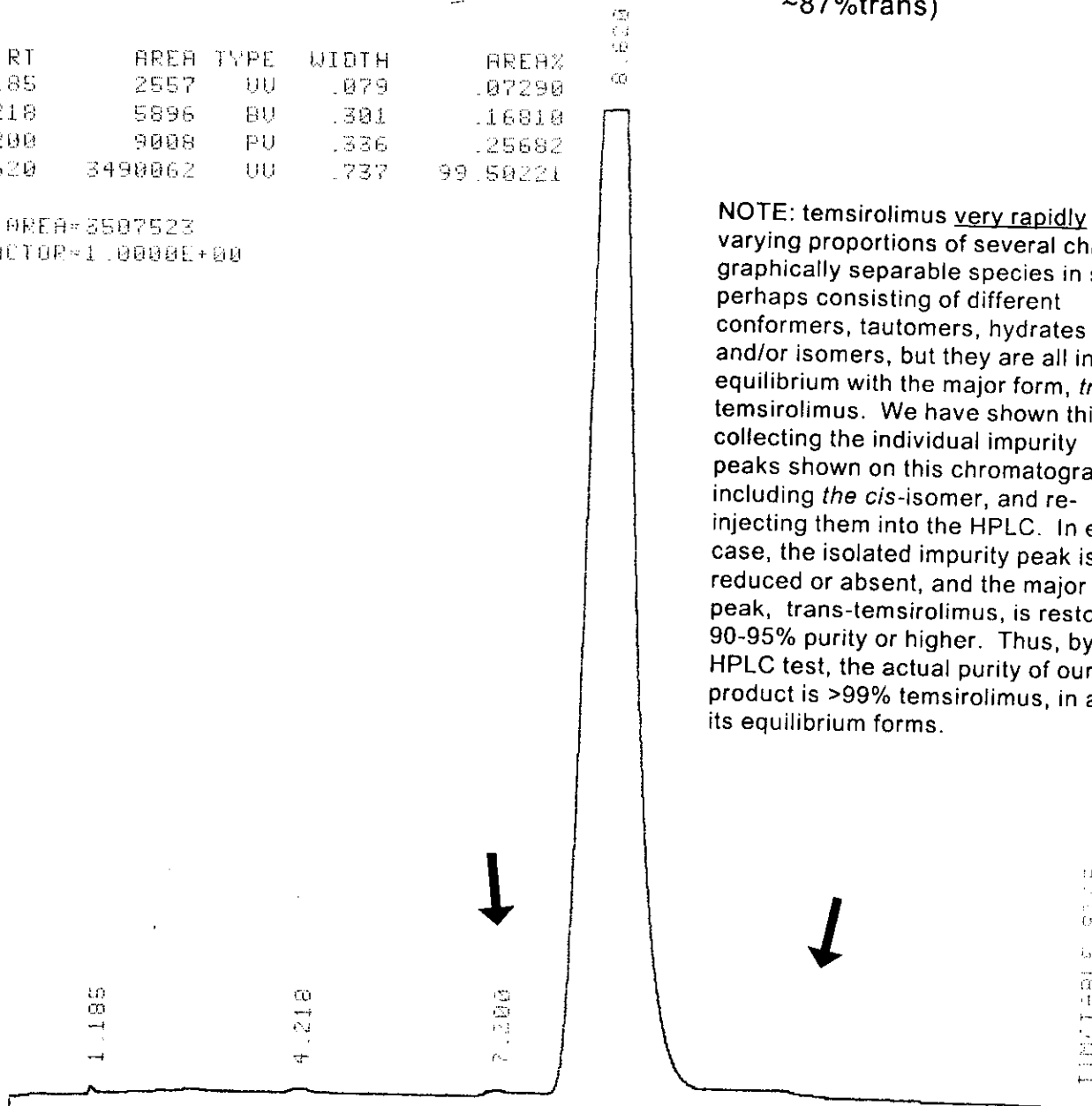
MUL FACTOR=1.00000E+00

NOTE: temsirolimus very rapidly forms varying proportions of several chromatographically separable species in solution, perhaps consisting of different conformers, tautomers, hydrates and/or isomers, but they are all in equilibrium with the major form, *trans*-temsirolimus. We have shown this by collecting the individual impurity peaks shown on this chromatogram, including the *cis*-isomer, and re-injecting them into the HPLC. In each case, the isolated impurity peak is reduced or absent, and the major peak, *trans*-temsirolimus, is restored, at 90-95% purity or higher. Thus, by the HPLC test, the actual purity of our product is >99% temsirolimus, in all of its equilibrium forms.

*CAT. No. T-8040 TEMSIROLIMUS LOT No. BTM-111

* RUN # 1913 MAY 19, 2019 15:26:39

START



HPLC: C₁₈ Column, 4.6 mm x 30 cm
Methanol/Water/Acetic Acid 96/4/0.08
2 mL/min
UV Detection at 254 nm



Cat. No. T-8040
Temsirolimus
Lot BTM-111
>99%



- TLC: 60 Å silica gel plates with fluorescent indicator
- Develop with Chloroform/Methanol 90/10
- Visualize via short wave UV fluorescence quenching
- Also visualize by exposure to iodine vapor