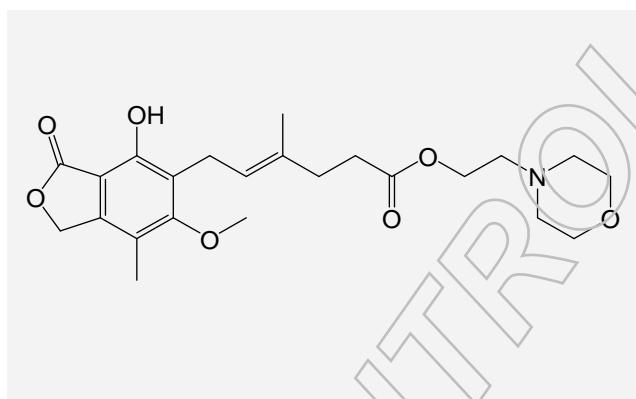


Certificate of Analysis

Reference Substance

Mycophenolate Mofetil

Catalogue Number:	LGCFOR1001.00	Long-term Storage:	2 to 8 °C, dark
Lot Number:	9901	Appearance:	white solid
Molecular Formula:	C ₂₃ H ₃₁ NO ₇	Melting Point:	95 °C
Molecular Weight:	433.49	Assay 'as is':	99.2 %
CAS Number:	[128794-94-5]		



Date of shipment: **2016-May-20**

This certificate is valid for two years from the date of shipment provided the substance is stored under the recommended conditions.

Release Date: 2011-09-22

LGC GmbH



Dr. Sabine Schröder
Product Release

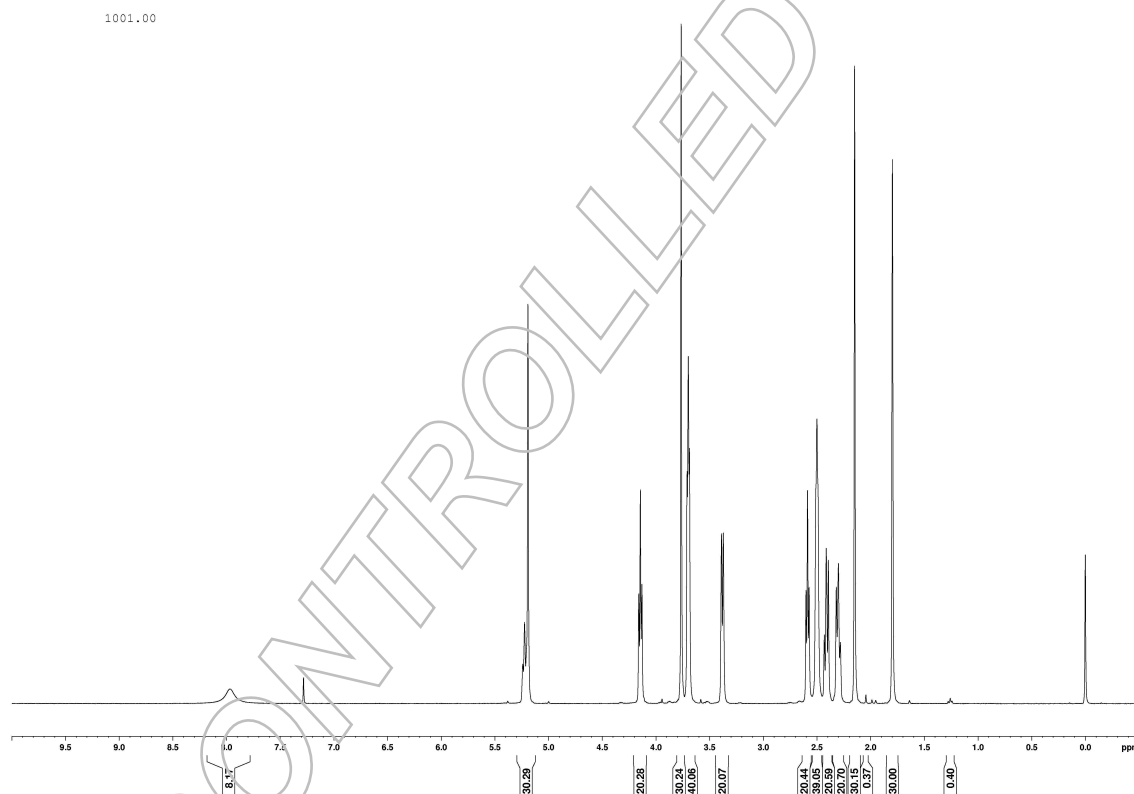
I. Identity

The identity of the reference substance was established by following analyses.

Ia. ¹H-NMR Spectrum

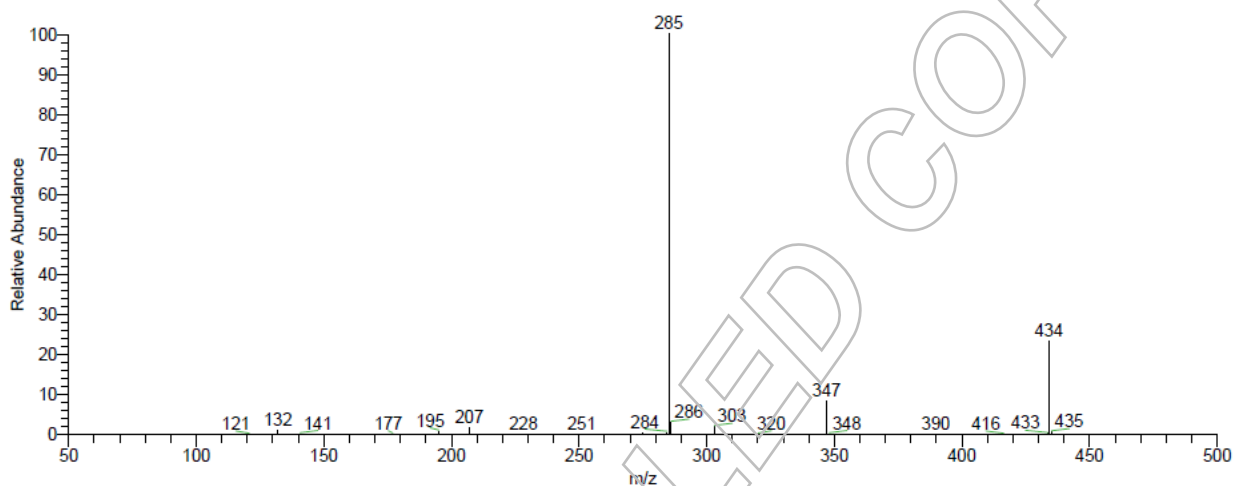
Conditions: 400 MHz, CDCl₃

The structure is confirmed with the signals of the spectrum and their interpretation.



Ib. Mass Spectrum

Method: 4.5 kV ESI; vaporization temperature: 200 °C, direct inlet

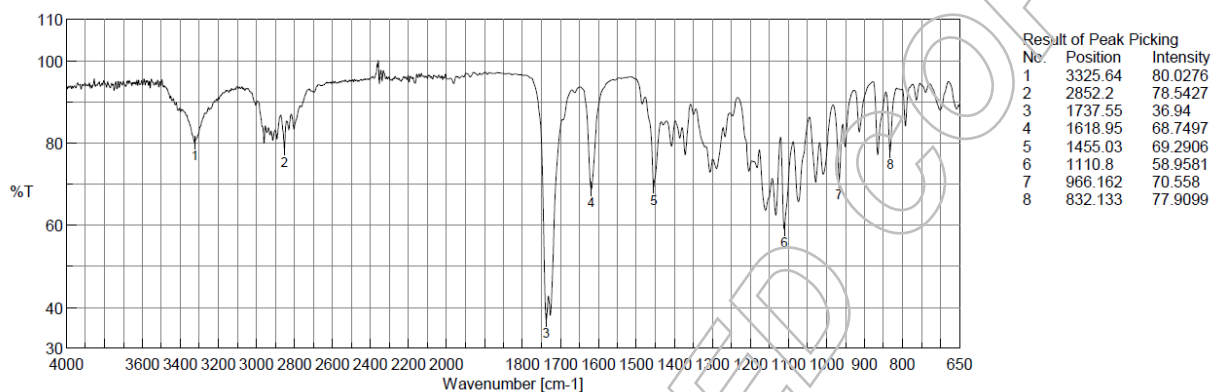


m/z	fragments
434	[MH]
433	[M]
347	[C ₁₉ H ₂₃ O ₆]
285	[C ₁₇ H ₁₇ O ₄]

The signals of the mass spectrum and their interpretation are consistent with the structural formula.

Ic. IR Spectrum

Method: Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) Spectroscopy



The signals of the IR spectrum and their interpretation are consistent with the structural formula.

II. Purity

The purity of the reference substance was analysed by high performance liquid chromatography (HPLC).

HPLC Conditions:

Column:

Hypersil Gold (C18)
5 µm, 150 x 4.6 mm

Conditions:

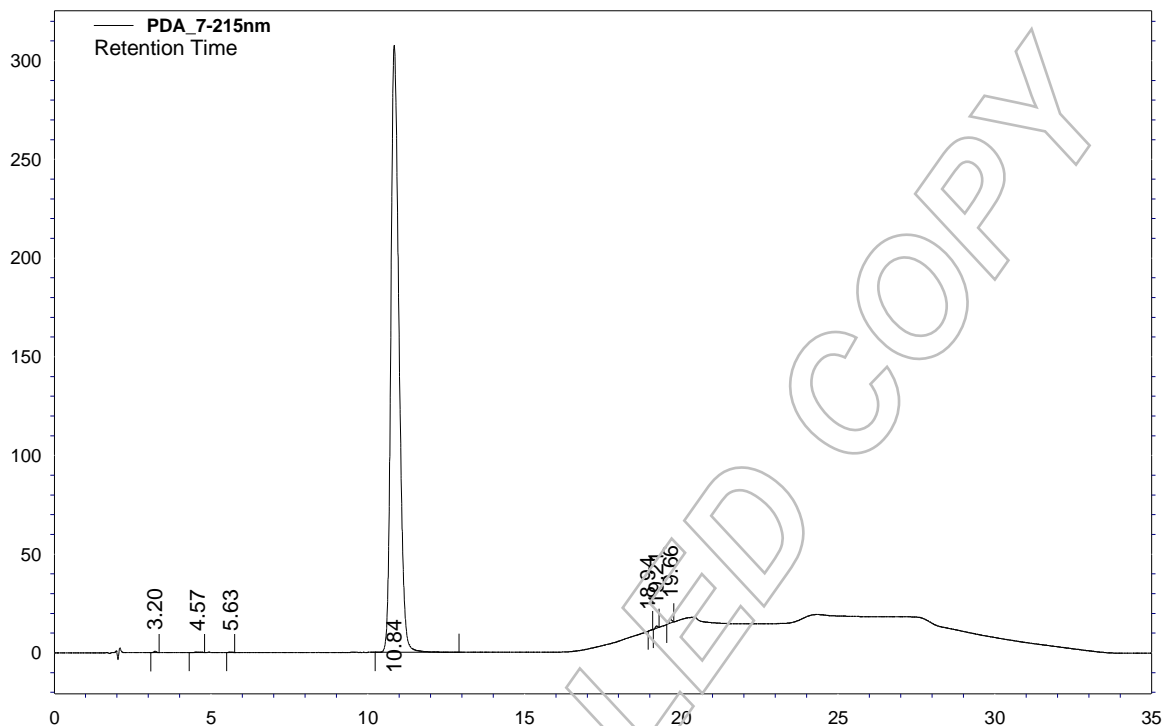
1.0 ml/min, 40 °C
0-13 min Water/Acetonitrile 75/25
13-17 min Water/Acetonitrile to 50/50
17-25 min Water/Acetonitrile 50/50
25-30 min Water/Acetonitrile to 75/25
30-35 min Water/Acetonitrile 75/25 (v/v);
0.1 % H₃PO₄

Detector:

DAD
215 nm

Injector:

Auto
4 µl; 0.05646 mg/ml in
Water/Acetonitrile 50/50 (v/v)



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	3.20	4020	0.07
2	4.57	1547	0.03
3	5.63	1334	0.02
4	10.84	5526139	99.58
5	18.94	683	0.01
6	19.21	5272	0.10
7	19.66	10447	0.19
Totals		5549442	100.00

For the calculation the system peaks were ignored. The content of the analyte was determined as ratio of the peak area of the analyte and the cumulative areas of the purities, added up to 100 %.

Results:

Average 99.55 %
Number of results n=6
Standard deviation 0.02 %



Excellence through measurement

LGCFOR1001.00 Lot Number 9901

III. Water Content

Method: Karl Fischer titration

Results:

Average 0.07 %
Number of results n=2

IV. Residual Solvents

Method: ¹H-NMR

Result: 0.24 % Ethyl acetate

V. Final Result

Total impurities (HPLC) 0.45 %
Water content 0.07 %
Residual solvents 0.24 %
Assay (100 % method)¹ 99.24 %

The assay is assessed to be 99.2 % 'as is'

The assay 'as is' is equivalent to the assay based on the not anhydrous and not dried substance respectively.

¹ The calculation of the 100 % method follows the formula:

$$\text{Assay (\%)} = (100 \% - \text{KF} - \text{RES}) * \frac{\text{Purity HPLC (\%)}}{100 \%}$$

Water (KF) and Residual solvents (RES) are considered as absolute contributions, HPLC purity is considered as relative contribution.

LGCFOR1001.00 Lot Number 9901

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