

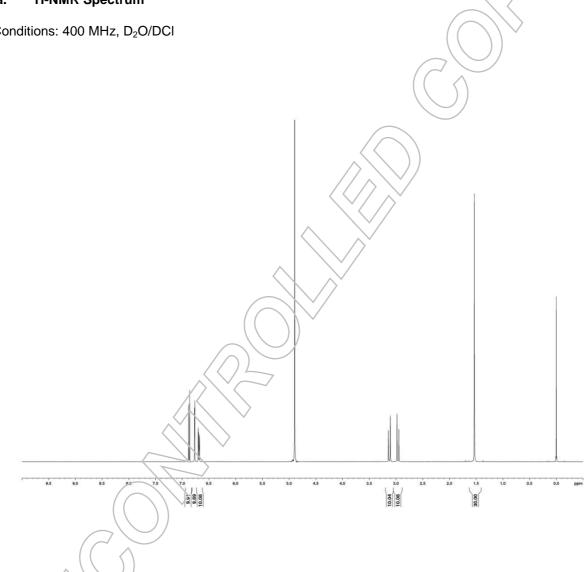
LGC GmbH. Im Biotechnologiepark. TGZ II. D-14943 Luckenwalde. Germany



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

¹H-NMR Spectrum la.

Conditions: 400 MHz, D₂O/DCI

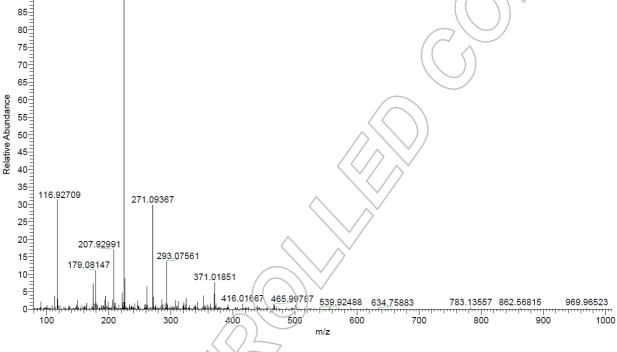


The structure is confirmed by the signals of the spectrum and their interpretation.





Method: 3.2 kV ESI-; capillary temperature: 269 °C

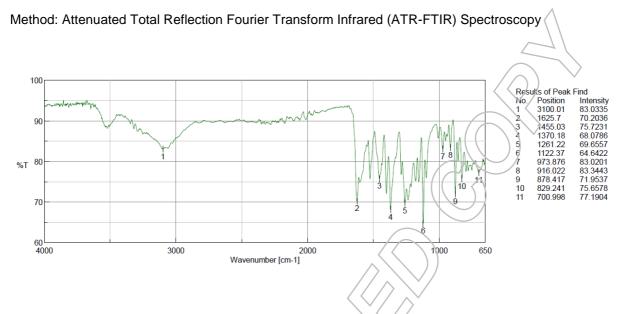


Theoretical value: 225.08808

The signal of the MS spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.







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

II. Purity

IIa. Water Content

Method: Karl Fischer titration

Determined value	7.48 %
Theoretical value	- 7.38 %
Content of excessive water	0.10 %

IIb. Residual Solvents

Method: ¹H-NMR

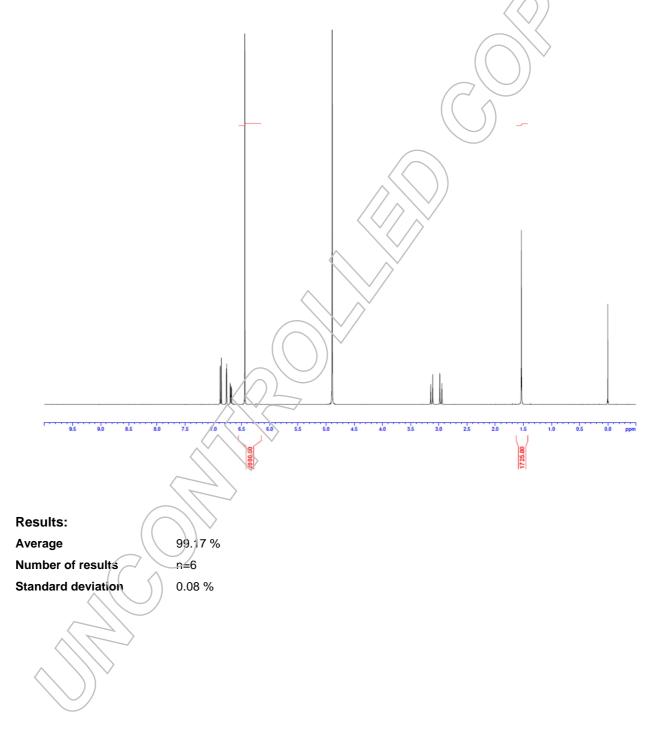
No significant amounts of residual solvents were detected (< 0.05 %).





III. Assay by Quantitative NMR Spectroscopy

The assay of the reference substance was established by quantitative NMR spectroscopy using D_2O/DCI as the solvent and with Maleic acid (certified reference material, signal 6.15 – 6.56 ppm, 2 H) as internal standard.







Water content Residual solvents Assay (quantitative NMR spectroscopy) 0.10 % No significant amounts of residual solvents were detected (< 0.05 %). 99.17 %

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.

Release Date: Luckenwalde, 2015-06-04

Dr. Sabine Schröder Product Release



LGCFOR1501.00 lot number 61111 LGC GmbH. Im Biotechnologiepark. TGZ II. D-14943 Luckenwalde. Germany