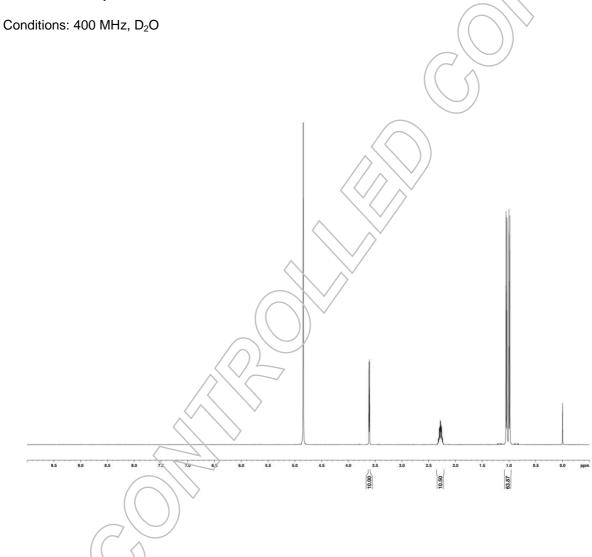


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The identity of the reference substance was established by following analyses.

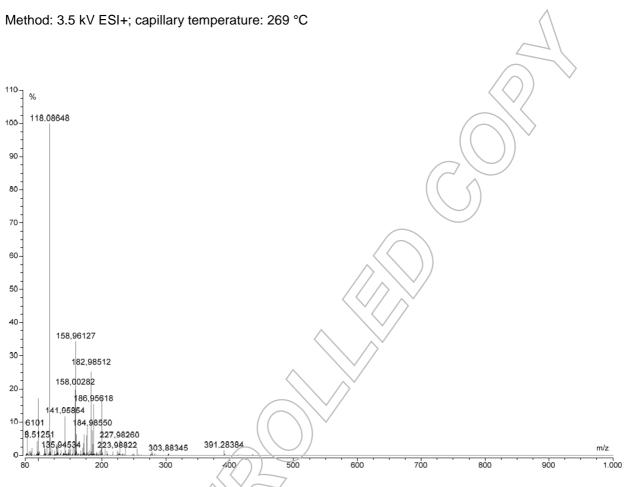
Ia. ¹H-NMR Spectrum



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





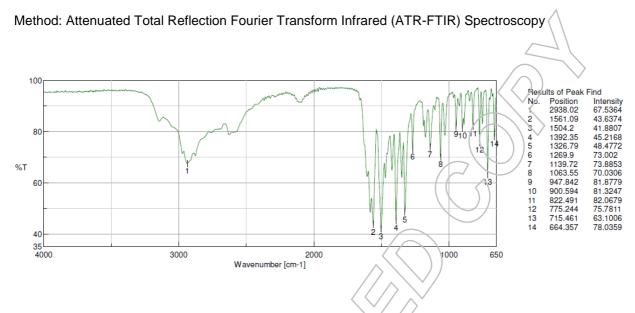


Theoretical value: 118.08626

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

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

IIb. Residual Solvents

Method: ¹H-NMR

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

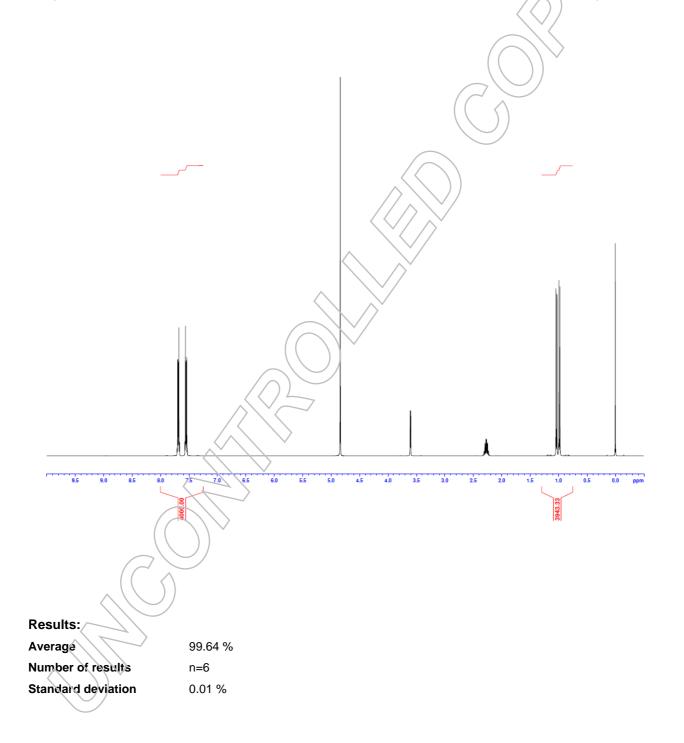


Method: Karl Fischer titration



III. Assay by Quantitative NMR Spectroscopy

The assay of the reference substance was established by quantitative NMR spectroscopy using D_2O as the solvent and with Potassium hydrogen phthalate (certified reference material, signal 7.25 – 8.00 ppm, 4 H) as internal standard.





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Water content Residual solvents Assay (quantitative NMR spectroscopy) No significant amounts of water were detected (< 0.05 %). No significant amounts of residual solvents were detected (< 0.05 %). 99.64 %

The assay is assessed to be 99.6 % 'as is'

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

Release Date: Luckenwalde, 2015-06-08

Dr. Sabine Schröder Product Release



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