

Certificate of Analysis
Primary reference standard



Substance:	Ginkgolic acid C15:1	Batch:	HWI02103-2
Article no.:	0258-05-85	Specification no.:	1803
Sample size:	10 mg in an amber glass vial		
Expiry date ¹⁾ :	04/2026		

Parameter	Method*	Requirement	Result
Characters			
Appearance	organoleptic	white to brown or faintly greenish powder, crystals, flakes or wax	complies
Identity			
¹ H-Nuclear magnetic resonance spectroscopy	M-0258-E, 2.2	¹ H-NMR spectrum corresponds to structure	complies ³⁾
Purity			
Liquid chromatography (CP)	M-0258-E, 3.1, HPLC TS 1	≥ 85.0%	97.2%
Residual solvents (RS)	M-0258-E, 3.3	≤ 2.0%	ND ^{3), 4)}
Water (W)	M-0258-E, 3.4	≤ 3.0%	0.37%
Assay²⁾			
Content 100% method	$\frac{(100\% - RS - W)}{100\%} \times CP$	≥ 85.0%	96.8%
Storage and handling:	The standard should be stored in the original amber glass vial at room temperature and protected from light. Shake before use. Do not dry, use on as is basis.		
Intended use:	Our HWI primary reference standard can be used e.g. for identification, assay and purity testing, method development and validation		

* valid version at time of testing, methods based on Ph. Eur.

¹⁾ storage in unopened, original container according to specified conditions.

²⁾ calculated "as is"

³⁾ test only performed when substance initially tested

⁴⁾ ND: not detectable

The definition for Primary reference standard to the WHO Technical Report 943 (2007) is:

„A designated primary chemical reference substance is one that is widely acknowledged to have the appropriate qualities within a specified context and whose assigned content when used as an assay standard is accepted without requiring comparison to another chemical substance.“

checked and approved	17. FEB. 2023 <i>S. Kempf</i> Stefanie Kempf Project Leader Laboratory Services	17. FEB. 2023 <i>F. Fischer</i> Ferdinand Fischer Project Leader Laboratory Services	
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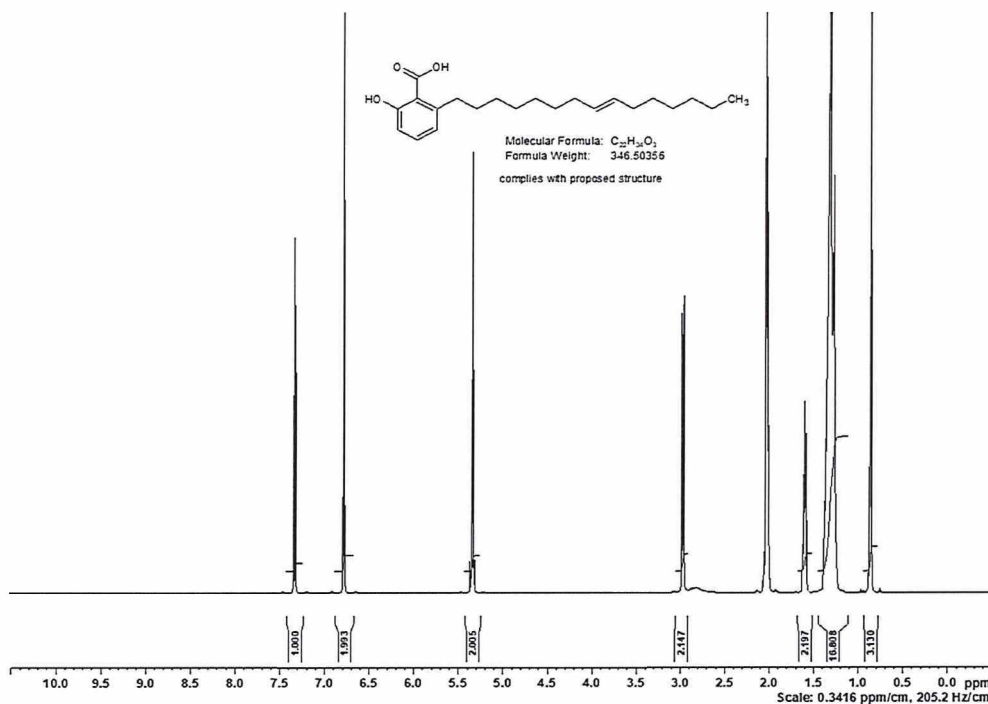
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NMR spectra

Ginkgolic acid C15:1, Charge HWI02103 (7,498mg) Schaefer, Fr. A180006548/1 H1/Aceton-d6 ms 184382



Current Data Parameters
NAME 6mal118.061
EXPNO 10
PROCNO 1

F2 - Acquisition Parameters
Date_ 20180508
Time_ 11.13
INSTRUM spect
PROBHD 5 mm CPPBBO BB
PULPROG zg30
TD 65536
SOLVENT Acetone
NS 32
DS 2
SWH 12019.230 Hz
FIDRES 0.183399 Hz
AQ 2.7262976 sec
RG 19.32
DW 41.600 usec
DE 10.00 usec
TE 300.2 K
D1 1.00000000 sec
TD0 1

----- CHANNEL f1 -----
SFO1 600.5536033 MHz
NUC1 1H
P1 12.00 usec
PLW1 25.00000000 W

F2 - Processing parameters
SI 65536
SF 600.5500222 MHz
WDW EM
SSB 0
LB 0.30 Hz
GB 0
PC 1.00
SR 22.25 Hz

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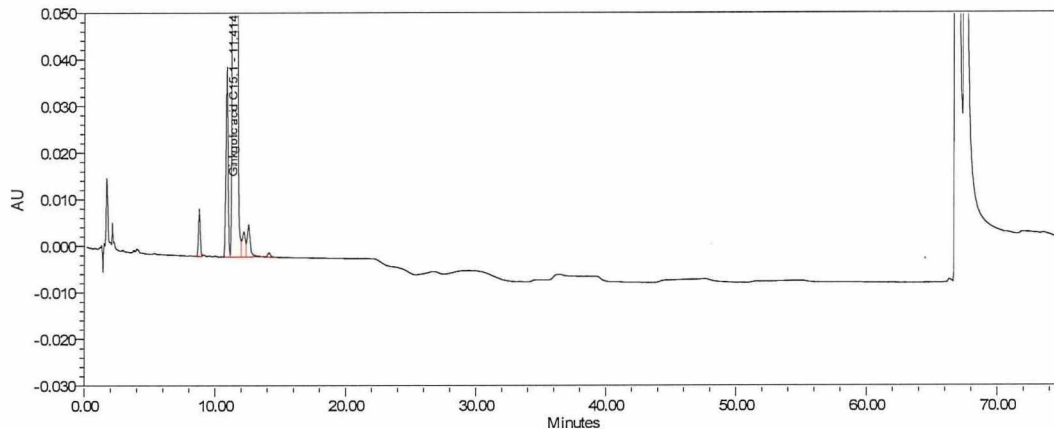
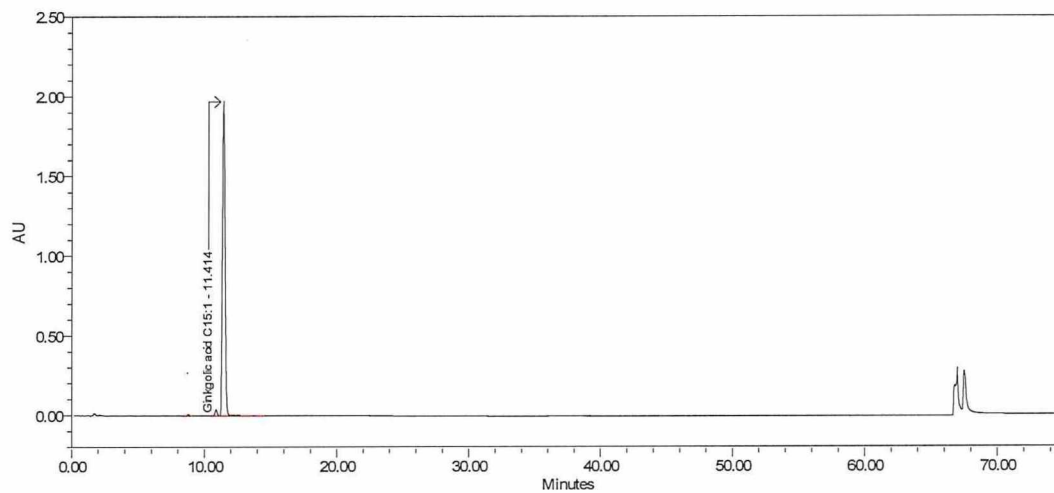


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HPLC chromatograms

Ginkgolic acid C15:1
HPLC separating system 1

Batch_No HWI02103



LUB23-00223-66; Ginkgolic acid C15:1; Batch_No HWI02103; Friday, January 27, 2023 7:45:43 PM CET;
Result Id 1234

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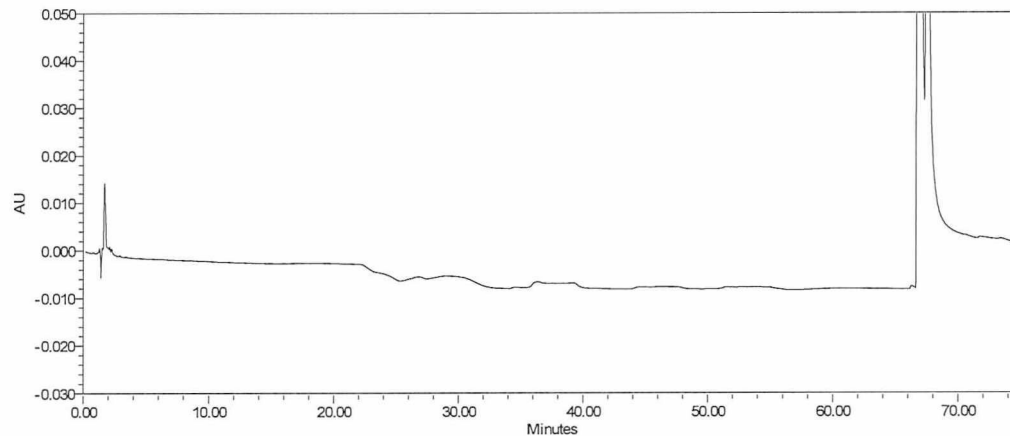
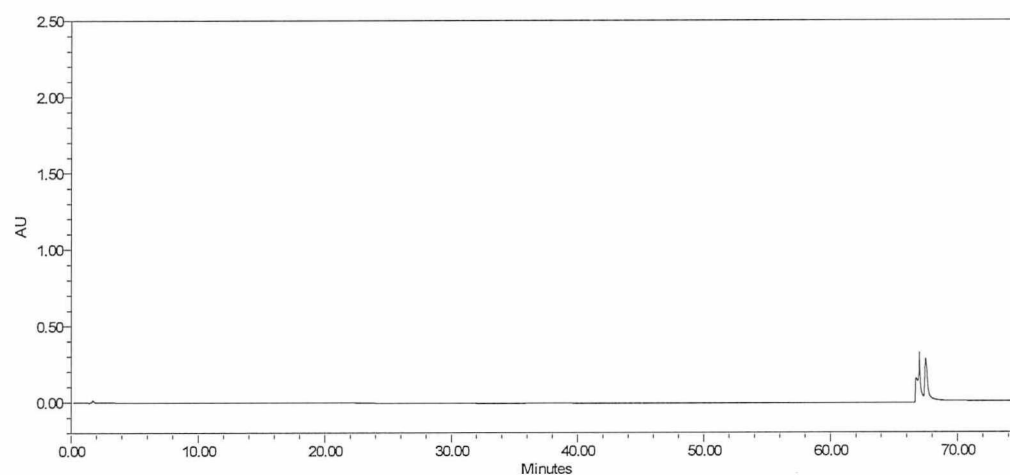
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Solvent
HPLC separating system 1

Batch_No



— LUB23-00223-3; Solvent; Batch_No ; Friday, January 27, 2023 5:13:41 PM CET; Result Id 1233

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