

Certificate of Analysis
Primary pharmaceutical reference standard



Substance: **Valerenic acid** Batch: **HWI01875**
Article no: **0201-05-95**
Storage: **airtight container, protected from light at ambient temperature**
Expiry date¹⁾: **02/2019**

Parameter	Method	Requirement	Result
Characters			
Appearance	organoleptic	colourless powder or crystals	complies
Identification			
¹ H-Nuclear magnetic resonance spectroscopy	M-0201-E, 2.2	¹ H-NMR spectrum corresponds to structure	complies
Assay			
Liquid chromatography (Method 1)	M-0201-E, 3.1, normalisation procedure	> 95.0 % ²⁾	99.20%
Quantitative NMR spectroscopy	M-0201-E, 3.2	> 95.0 % ²⁾	96.84%

¹⁾ storage in unopened, original container according to specified conditions.
²⁾ **Values for CP and qNMR may vary due to residual solvents and water content which can not be detected by chromatographic methods. For quantification purposes only qNMR value is valid.**

The definition for Primary pharmaceutical 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.“

01. MRZ. 2017

Katharina Hilsch
Project leader
Reference Standard Services

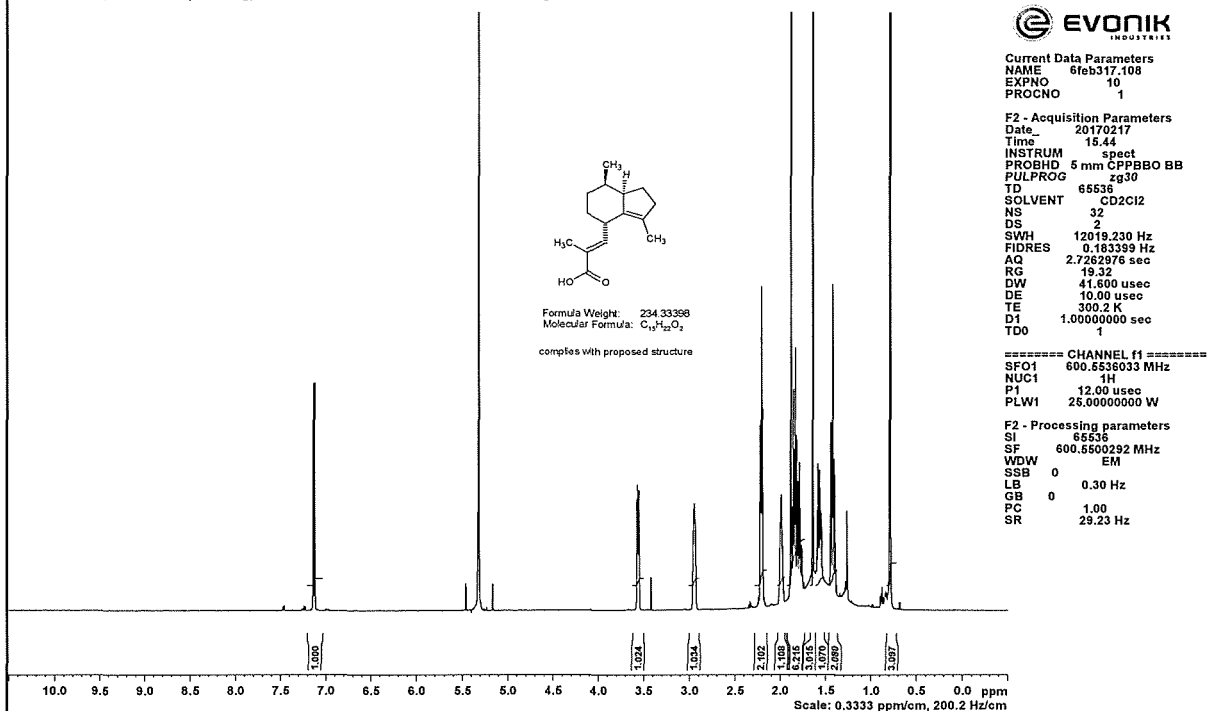
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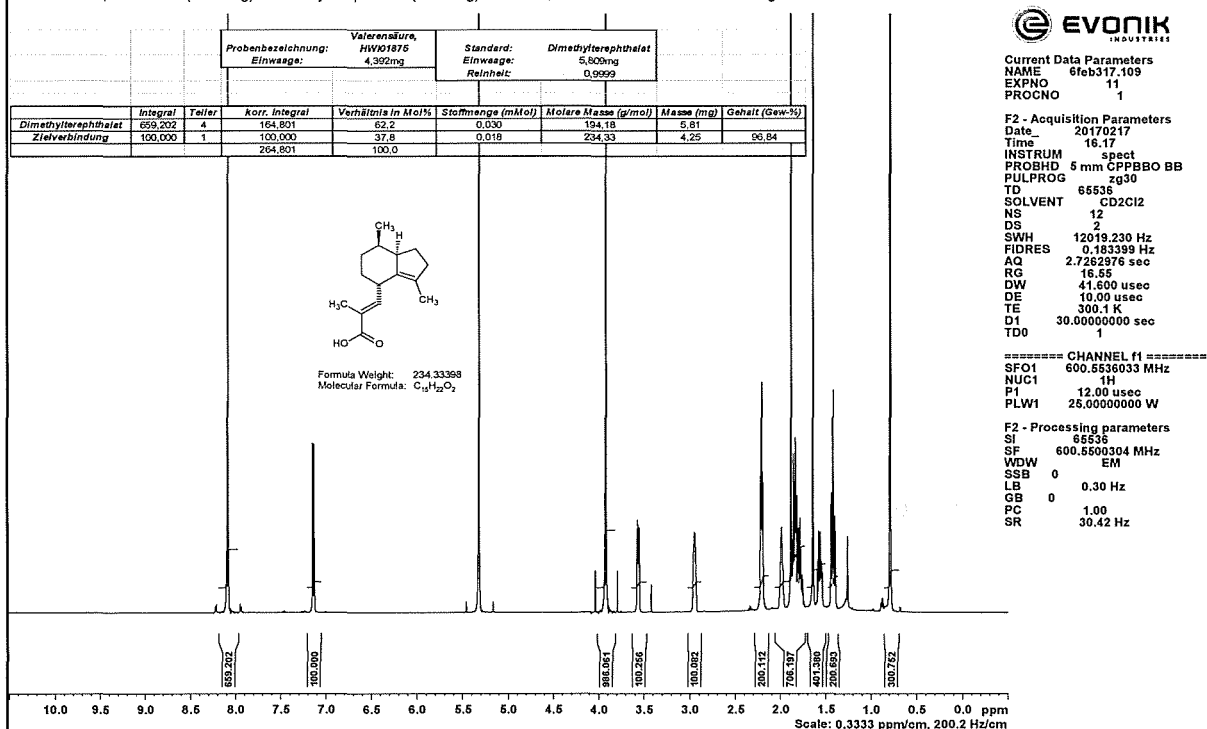
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NMR spectra

Valerensäure, HWI01875 (1.585mg) Schaefer, Fr. A170002613/1 H1/CD2Cl2 go 177170



Valerensäure, HWI01875 (4.392mg) + Dimethylterephthalat (5.809mg) Schaefer, Fr. A170002613/1 H1/CD2Cl2 go 177170-b



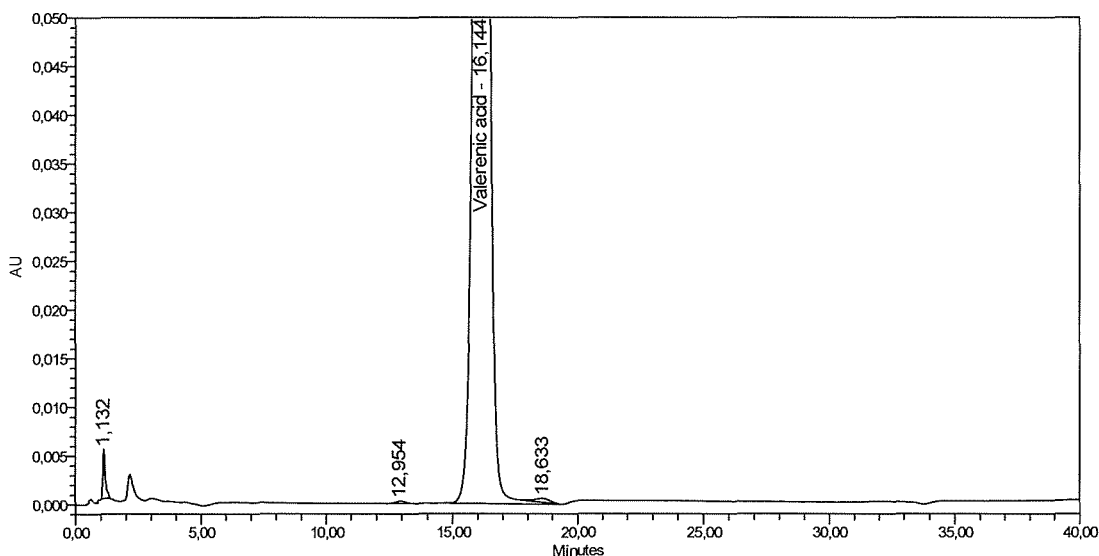
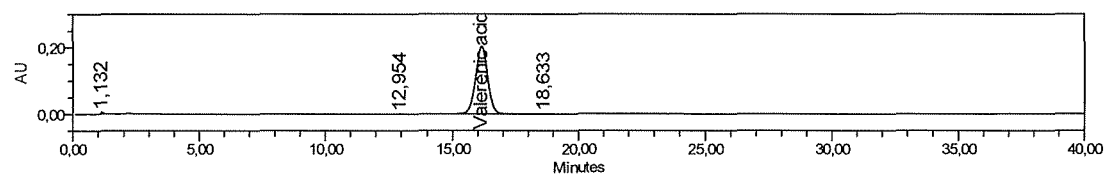
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Purity Determination of Valerenic acid
Valerenic acid, HWI01875
aus 20 mg Portion

Project Name	Referenzsubstanzen\Valerensäure_120829\HWI01875		
SampleName	wi17-00252/37	Date Acquired	15.02.2017 13:36:37 CET
Vial	2	Acq Method Set	TS1_2998_A_MS
Injection	1	Acquired By	wiegel
Injection Volume	40,00 ul	Date Processed	16.02.2017 14:11:08 CET
System Name	Alliance 08_2998	Processing Method	M0201_TS1_PM
Run Time	40,0 Minutes	Result Id	1141
Column_No	B1809	Processed By	Heiter
Processed Channel	Descr. 2998 Ch1 225nm@1.2nm	Channel	2998 Ch1 225nm@1.2nm



Peak Results

	Name	RT	Area	% Area	Height (µV)	Start Time (min)	Symmetry Factor	Resolution
1		1,132	35865	0,520	5046	1,033	1,8	
2		12,954	6795	0,099	262	12,400	1,0	28,1
3	Valerenic acid	16,144	6835834	99,139	203297	14,908	1,0	4,1
4		18,633	16735	0,243	406	17,842		

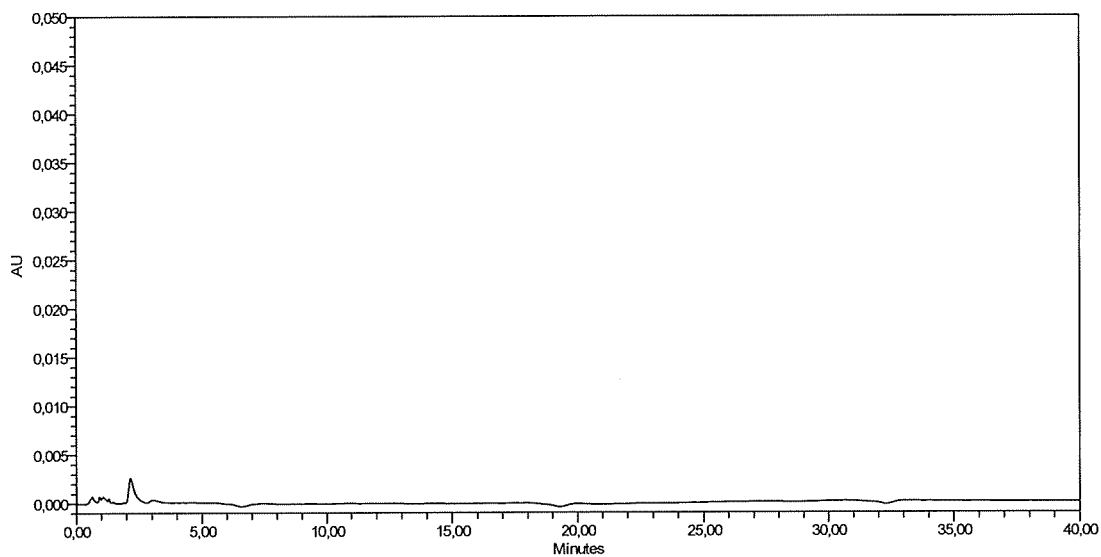
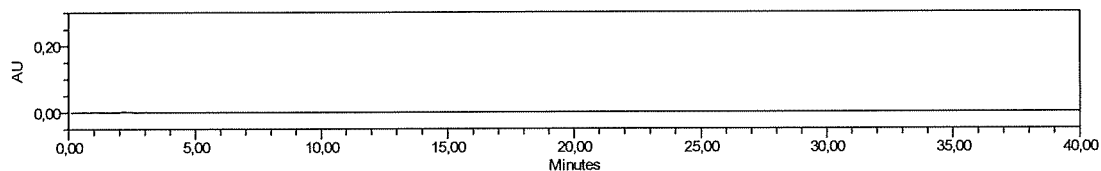
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Purity Determination of Valerenic acid
Solvent

Project Name	Referenzsubstanzen\Valerensäure_120829\HWI01875	Date Acquired	15.02.2017 12:55:28 CET
SampleName	wi17-00252/25	Acq Method Set	TS1_2998_A_MS
Vial	1	Acquired By	wiegel
Injection	1	Date Processed	16.02.2017 14:10:18 CET
Injection Volume	40,00 ul	Processing Method	M0201_TS1_PM
System Name	Alliance 08_2998	Result Id	1140
Run Time	40,0 Minutes	Processed By	Heiter
Column_No	B1809	Channel	2998 Ch1 225nm@1.2nm
Processed Channel Descr.	2998 Ch1 225nm@1.2nm		



Peak Results

	Name	RT	Area	% Area	Height (µV)	Start Time (min)	Symmetry Factor	Resolution
1								