

Certificate of Analysis
Primary reference standard



Substance:	Orientin	Batch:	HWI03244
Article no.:	0381-05-85	Specification no.:	1983
Sample size:	10 mg in an amber glass vial		
Expiry date ¹⁾ :	07/2025		

Parameter	Method*	Requirement	Result
Characters			
Appearance	organoleptic	white to yellow powder	complies
Identity			
¹ H-Nuclear magnetic resonance spectroscopy	M-0381-E, 2.2	¹ H-NMR spectrum corresponds to structure	complies
Assay ²⁾			
Liquid chromatography (CP)	M-0381-E, 3.1, HPLC TS 1	≥ 85.0%	99.2 %
Quantitative NMR spectroscopy	M-0381-E, 3.2	≥ 70.0%	97.5%
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⁾ 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 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

19. JAN. 2022 *S. Kempf*

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21. JAN. 2022 *O. Revermann*

Dr. Ole Revermann
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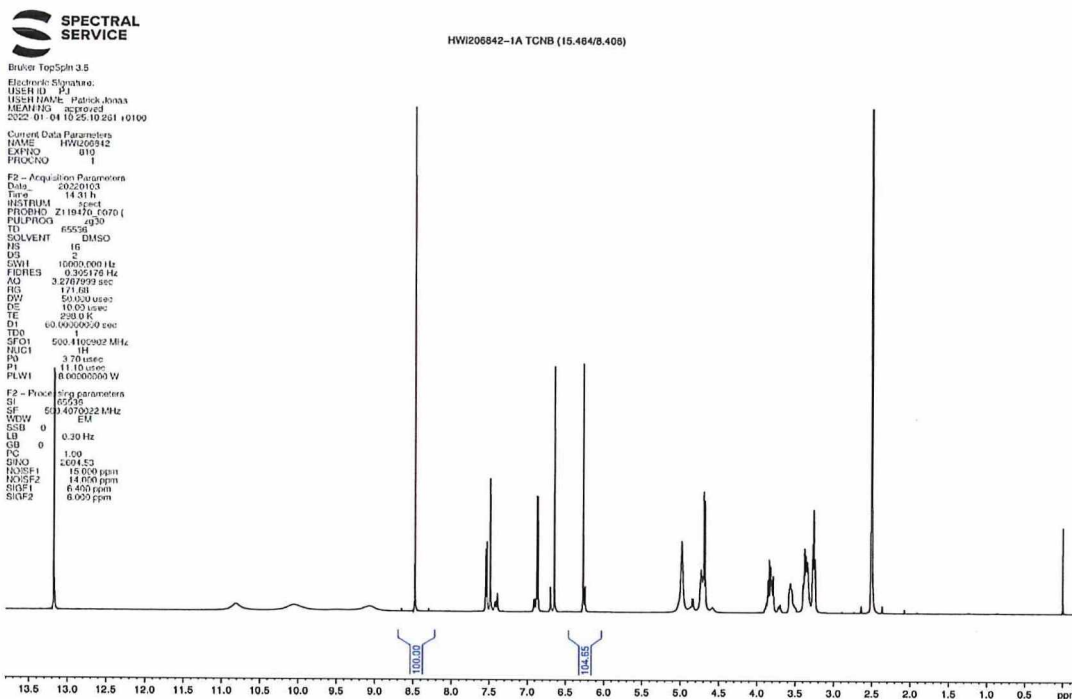
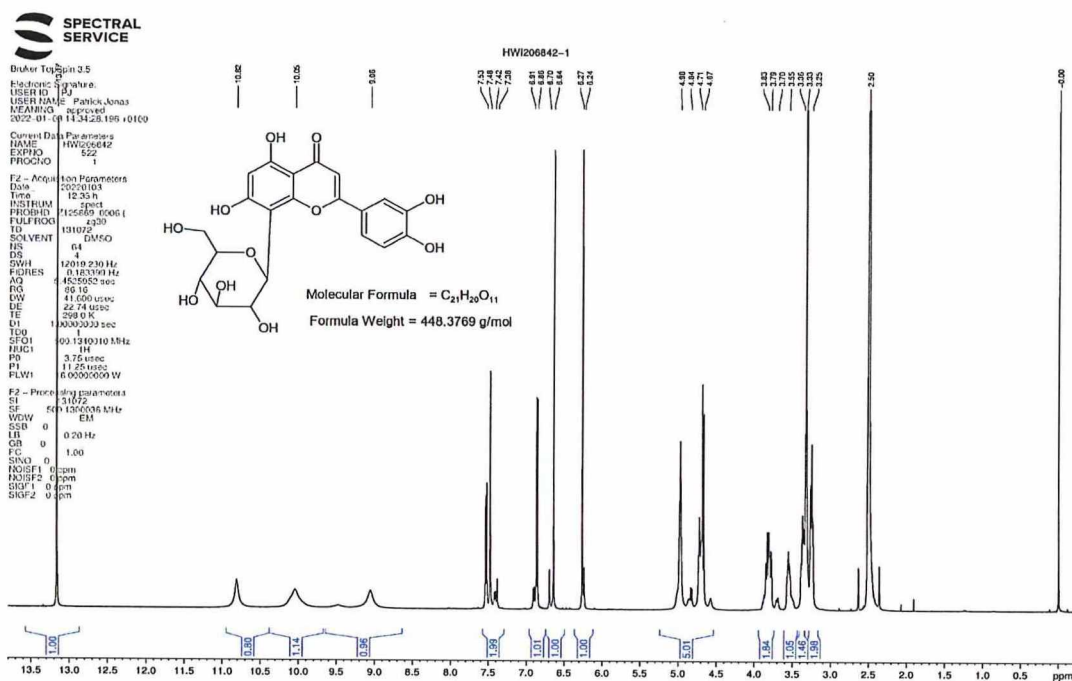
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HWI group

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NMR spectra



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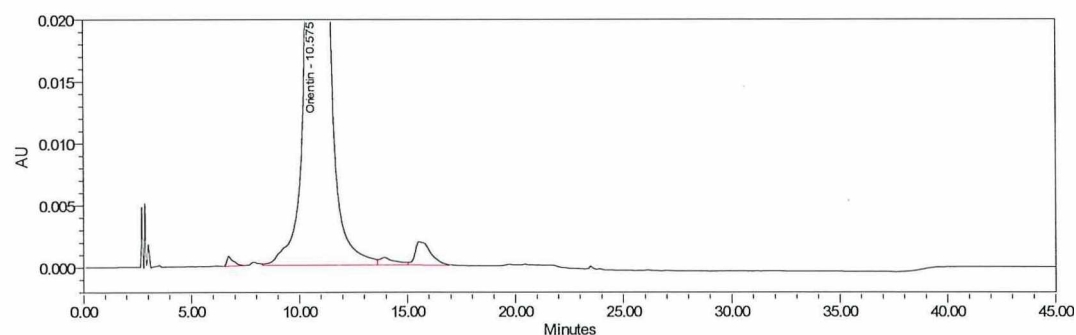
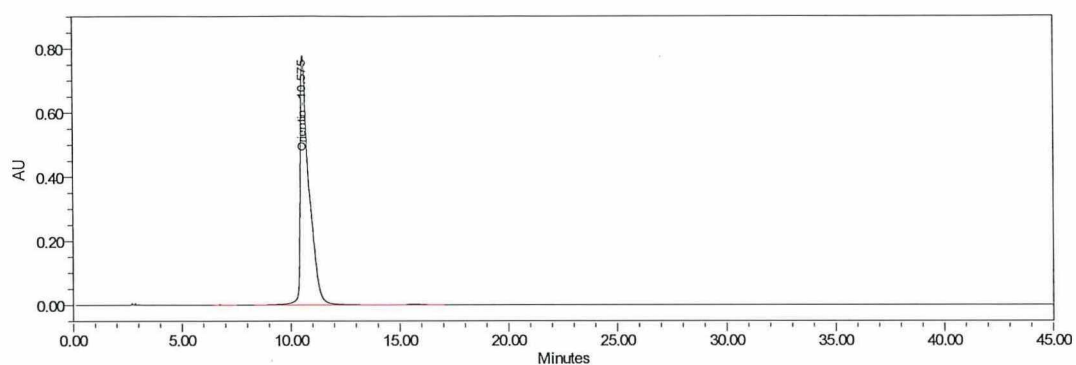


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HPLC chromatograms

Orientin
HPLC separating system 1

Batch_No HWI03244



Bu22-00118-40; Orientin; Batch_No HWI03244; Tuesday, January 11, 2022 12:50:25 PM CET; Result Id 1093

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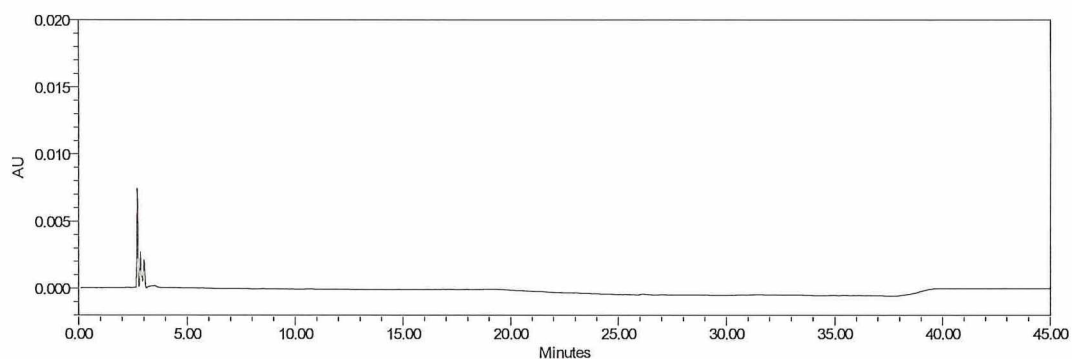
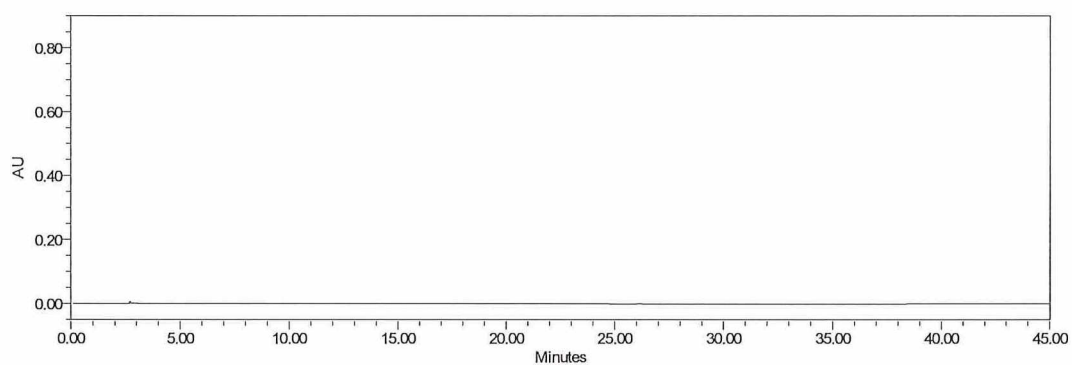
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Solvent
HPLC separating system 1

Batch_No



— Bu22-00118-6; Solvent; Batch_No ; Tuesday, January 11, 2022 11:18:17 AM CET; Result Id 109;

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