



PhytoLab

SAFEGUARDING BOTANICAL QUALITY.

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<https://phyproof.phytolab.com>
Date: 20.06.23

Certificate of analysis

Batch: 136366009
Article: 89531 Arctiin
Manufacturing date: 11/2019
Expiry date: 06/2028

Test	Unit	Limit	Testresult
Appearance, SOP 100005		powder	Conform
Color, SOP 100006		white	Conform
Identification (UV spectrum from HPLC-DAD analysis) according to specification, SOP 204311		Conform	Conform
Identification (IR-spectroscopy, Ph.Eur. 10.3, 2.2.24)/USP 43 NF 37 <197>), SOP 206000		Conform	Conform
Identification (1H-NMR-spectroscopy), (outsourced), SOP 206010		Conform	Conform
Identification (13C-NMR-spectroscopy), (outsourced), SOP 206020		Conform	Conform
Water content, (micro determination, coulometric titration), Ph.Eur. 10.0., 2.5.32, SOP 304291 Vers. 2018-01: Mean value	%		2.6
Peakpurity, (HPLC), SOP 401367		Conform	Conform
Arctiin (HPLC), method 1 (% AU), SOP 440143	%	> = 98.00	99.18
Residual solvents, (headspace-GC), SOP 805765: Residual solvents	%		0.91

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Test	Unit	Limit	Testresult
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Inorganic impurities, (ICP-MS), for reference substances, SOP 811701:

	%		< 0.1
Sodium	%		< 0.1
Potassium	%		< 0.1
Magnesium	%		< 0.1
Calcium	%		< 0.1
Aluminium	%		< 0.1
Phosphorus	%		< 1.0
Sulfur	%		

Content, SOP 890000, calculated in (%):
(100 - water - residual solvents - inorganic impurities) x chromatographic purity / 100

%

96

This PhytoLab phyproof® reference standard is by definition a primary reference standard and does not need to be qualified against any other reference standard. The identity of the reference standard has been substantiated by at least two independent analytical methods such as IR, NMR, UV or MS analysis. A mass balance approach, which takes chromatographic purity into account, as well as the contents of water, residual solvents, inorganic impurities, and the counter ion (if the reference standard is present as a salt) is applied in the calculation of the absolute purity as given in this COA (see description of SOP 8900XX).

The absolute purity value (and not just the chromatographic purity result obtained by means of HPLC or GC) must be used in all quantitative calculations as the chromatographic techniques do not yet account for water, residual solvents and inorganic impurities.

Further information:

Shelf life/stability: The stated expiration date applies when the reference substance is stored in the original unopened container within the specified temperature range. PhytoLab does not guarantee the stability of the reference substance once the vial has been opened.

Long-term storage and handling: the reference standard should be stored in the original unopened vial, protected against light and humidity in an airtight container, within the temperature range given on the label and accompanying data sheet. If stored below room temperature, the vial should be warmed up to room temperature in a desiccator before it is opened in order to avoid condensation of humidity. The user assumes responsibility for deciding how previously opened reference standard vials should be used and the user must ensure that the contents of opened vials are still suitable for their intended use.

Exact weight: the exact weight of each vial is given on the label of the inner vial to two decimal places. This information may be used to produce stock solutions of a known concentration without having to weigh in the reference substance again. If used for this purpose, the content of the vial must be quantitatively transferred to a volumetric flask and filled up to the required level. Please note that PhytoLab is unable to guarantee the stability of the reference standard in solution.

Intended use: this reference standard is solely intended for laboratory analytical purposes, research & development, and scientific teaching and training purposes. It may not be used for any other purpose and particularly not for use in, or the production of, food, animal feed, human or veterinary drugs, cosmetics, medicinal products or diagnostic agents, including in-vitro diagnostic agents. PhytoLab is unable to guarantee the suitability of this reference standard for any particular application other than its qualitative and quantitative use in chromatography and identification testing.

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Test	Unit	Limit	Testresult
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Further information about this reference standard can be found on the accompanying data sheet or in our webshop. Spectral and chromatographic data, and a description of the applied chromatographic method, are provided in the attachments to this COA. A detailed explanation of all data given on the COA can be found in the guide that is available from the download area in our webshop, where you can also download all of the safety data sheets.

Vestenbergsreuth, 20.06.23


Dr. Jan Glaser.
Manager Reference Substances



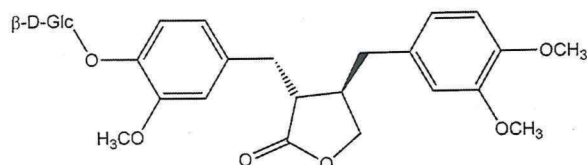
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Product Data Sheet

Arctiin

Product #: 89531



Physicochemical Data

CAS #: 20362-31-6
Molecular formula: C₂₇H₃₄O₁₁
Molecular weight [g/mol]: 534.56
Synonyms: Arctigenin 4-glucoside

Substance class: Phenylpropanes
Subgroup 1: Lignans
Solubility:

soluble in methanol. Please note that this solubility information is based on in-house experience or taken from published data. It is not meant to guarantee solubility up to a specific concentration, nor does it guarantee stability of the reference substance in solution.

Additional Information

Source: botanical origin

Long-term storage conditions: 15-25 °C

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Proof of Quality for Markers

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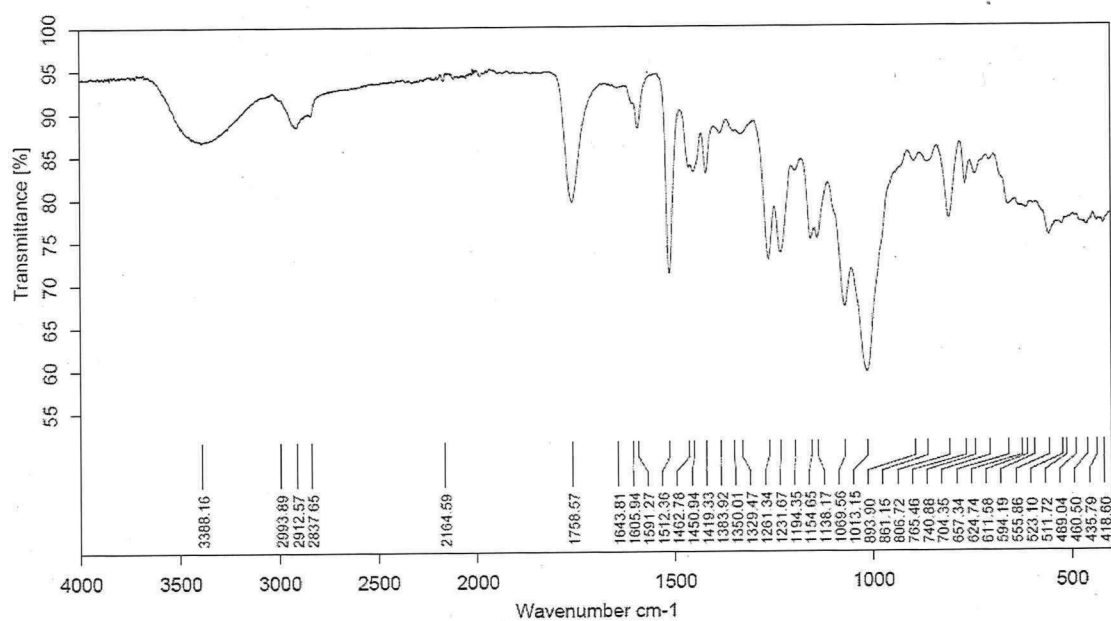
Supplements

Arctiin
Product # 89531

Batch # 12975

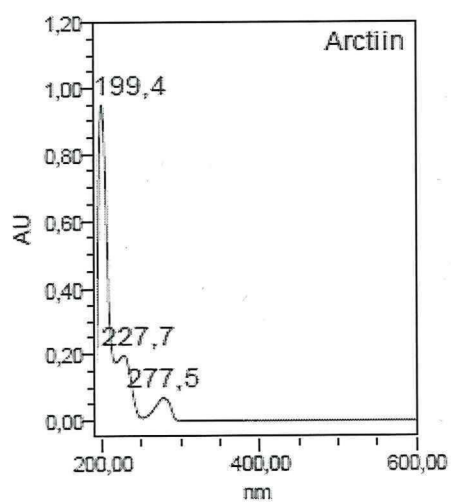
Identity tests:

IR spectrum



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UV spectrum (derived from HPLC/PDA)





NMR spectra

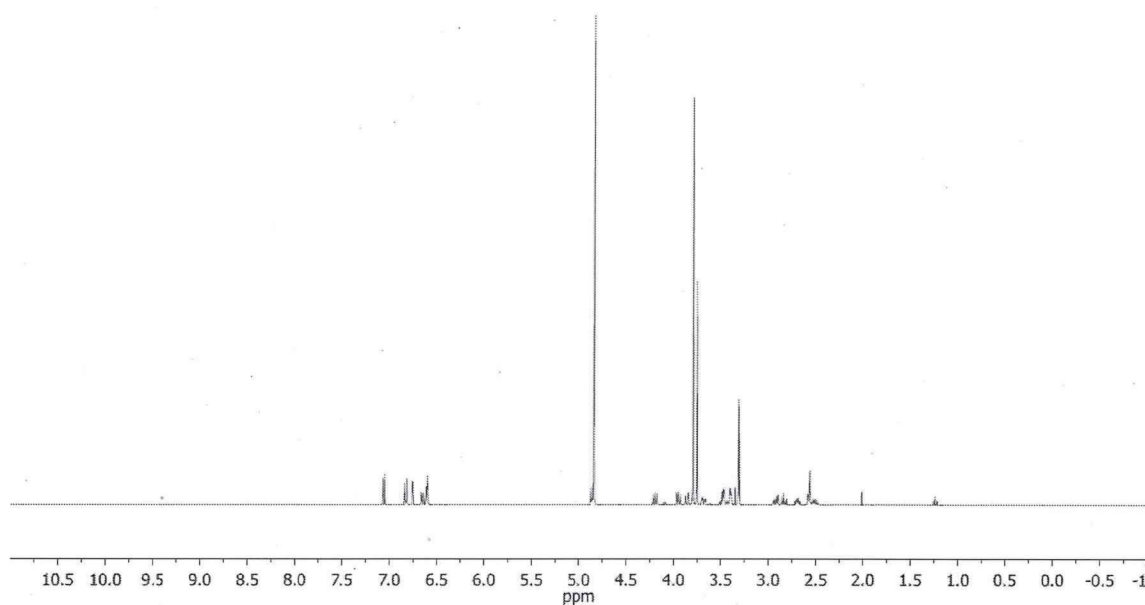
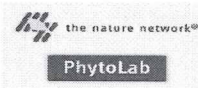
¹H-NMR

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Arctiin, Charge: 12975

15.6 mg ad 0.7 ml CD₃OD

400 MHz ¹H-NMR, Agilent MR400



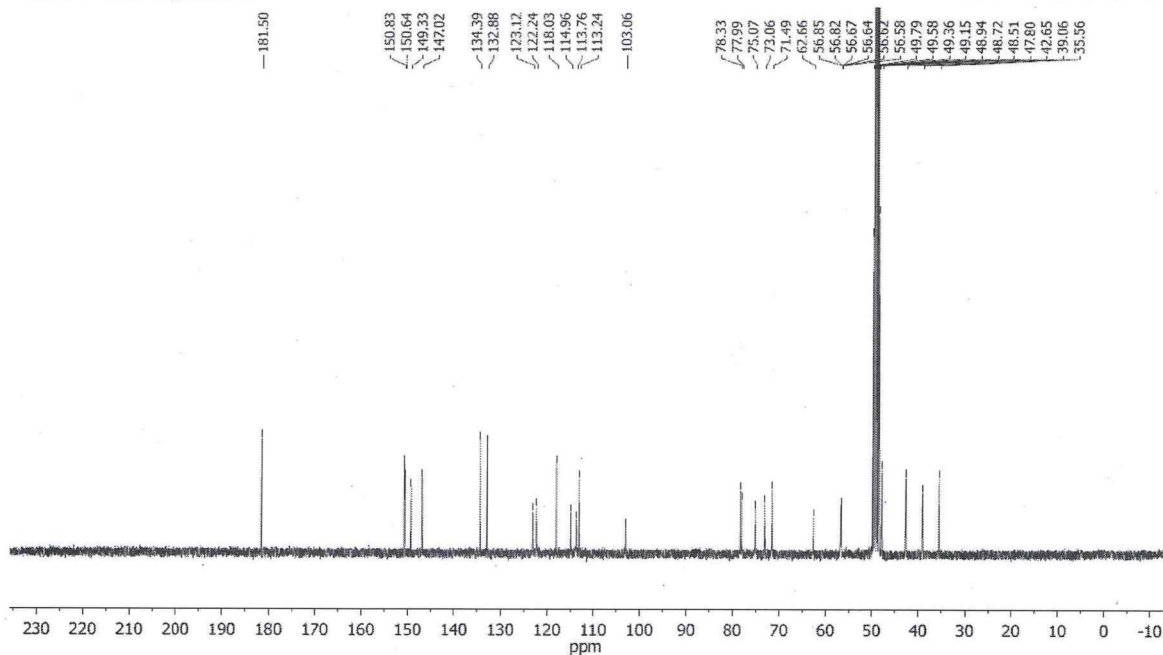
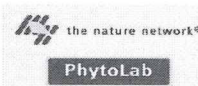
¹³C-NMR

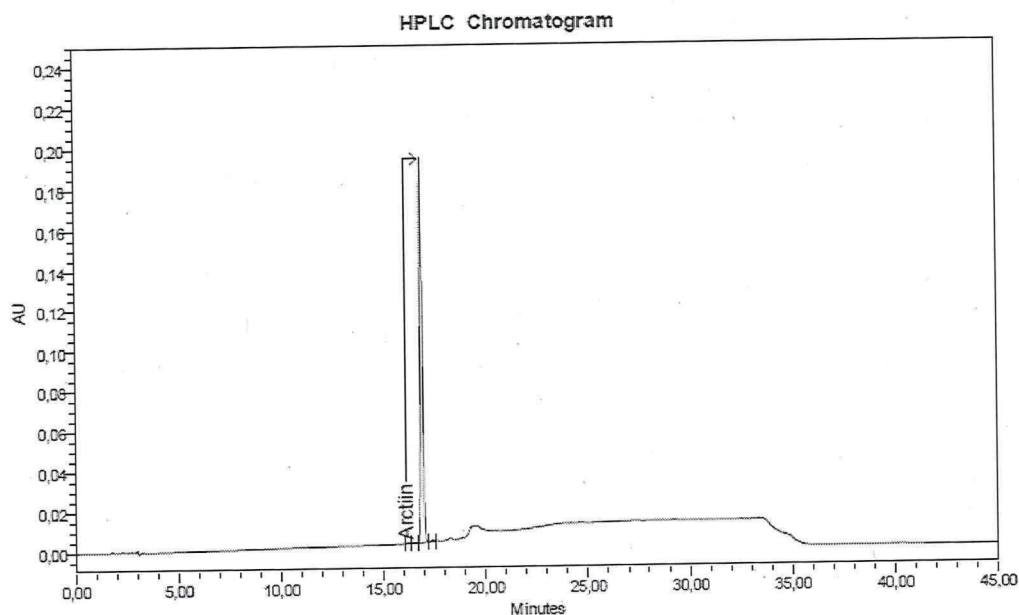
PhytoLab GmbH & Co. KG

Arctiin, Charge: 12975

15.6 mg ad 0.7 ml CD₃OD

100 MHz ¹³C-NMR, Agilent MR400



Chromatographic purity:

Peak Results

	Name	RT	Area	% Area
1		16,217	1949	0,12
2	Arctiin	16,914	1593929	99,20
3		17,409	10869	0,68
Sum				100,00

Analytical conditions

Column: Prodigy ODS 3 100A, 250 x 4.6 mm, 5 µm
Mobile Phase: eluent A: H₂O pH 2.0 (H₃PO₄)
eluent B: CH₃OH
Mode: gradient

Time [min]	Eluent A [%]	Eluent B [%]
0	90	10
20	20	80
30	20	80
32	90	10
45	90	10

Flow: 1.0 ml/min
Injection Volume: 20 µl
Column Temperature: 23°C
Sample concentration: approx. 5.2 mg/100 ml
Sample preparation: dissolved in 20% CH₃OH
Detection: UV, 230 nm
Special note: -

Please note: Values on the certificate of analysis may vary as these are average values of at least six injections while above chromatogram and report is only one example. Non-integrated peaks originate from the blank injection.