



PhytoLab GmbH & Co. KG Dutendorfer Str. 5-7 91487 Vestenbergsgreuth

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 Date: 2.09.20

Certificate of analysis

Batch: 112053328
 Article: 84104 Aposcopolamine

Test	Unit	Limit	Testresult
Appearance, SOP 100005		powder	Conform
Color, SOP 100006		white	Conform
Solubility, SOP 105001:			Conform
Methanol		soluble	Conform
n-Hexane		soluble	Conform
DMSO		soluble	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: Mean value	%		< 0.2
Peakpurity, (HPLC), SOP 401367		Conform	Conform
Aposcopolamine (HPLC), method 1 (% AU), SOP 441776	%	> = 90.00	99.12



Certificate of analysis

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Test	Unit	Limit	Testresult
Residual solvents, (headspace-GC), SOP 805765:			
Residual solvents	%		0.35
Inorganic impurities, (ICP-MS), for reference substances, SOP 811701:			
Sodium	%		< 0.1
Potassium	%		< 0.1
Magnesium	%		< 0.1
Calcium	%		< 0.1
Aluminium	%		< 0.1
Phosphorus	%		< 0.1
Sulfur	%		< 1.0
Content*, SOP 890000	%		99

Assessment:

The above mentioned reference substance meets the specification.

*The absolute content is calculated considering the chromatographic purity, and if available, the content of water, residual solvents and inorganic impurities according to the following formula:
 Content = (100% - water content (%) - residual solvents (%) - inorganic impurities (%)) x chromatographic purity (%) / 100.

The chromatographic purity is checked regularly: the last analysis has been performed in May 2017.

The reference substance cannot be documented with an expiry date. The pack is closed and is recommended to be stored as indicated. The unopened product is guaranteed to fulfill the specifications of this analytical report for a period of 60 months. Once opened we can no longer guarantee the stability of the material.

Vestenbergsgreuth, 2.09.20

Dr. Jan Glaser
 Manager Reference Substances

Product Data Sheet

Aposcopolamine

Product #: 84104

Physicochemical Data

CAS #: 535-26-2
Molecular formula: C₁₇H₁₉NO₃
Molecular weight [g/mol]: 285.34
Synonyms: Apohyoscine

Substance class: Nitrogen-containing Compounds
Subgroup 1: Alkaloids
Subgroup 2: Tropane alkaloids

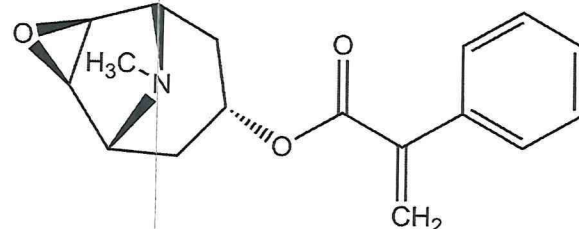
Solubility: Soluble in DMSO, n-hexane and methanol. Please note that this solubility information is based on in-house experience or taken from published data. It is not meant to guarantee solubility up to a specific concentration, nor does it guarantee stability of the reference substance in solution.

Additional Information

Source: synthetic

Long-term storage conditions: 15-25 °C

Manufacturer: PhytoLab GmbH & Co.KG
Dutendorfer Straße 5-7
91487 Vestenbergsgreuth
Germany



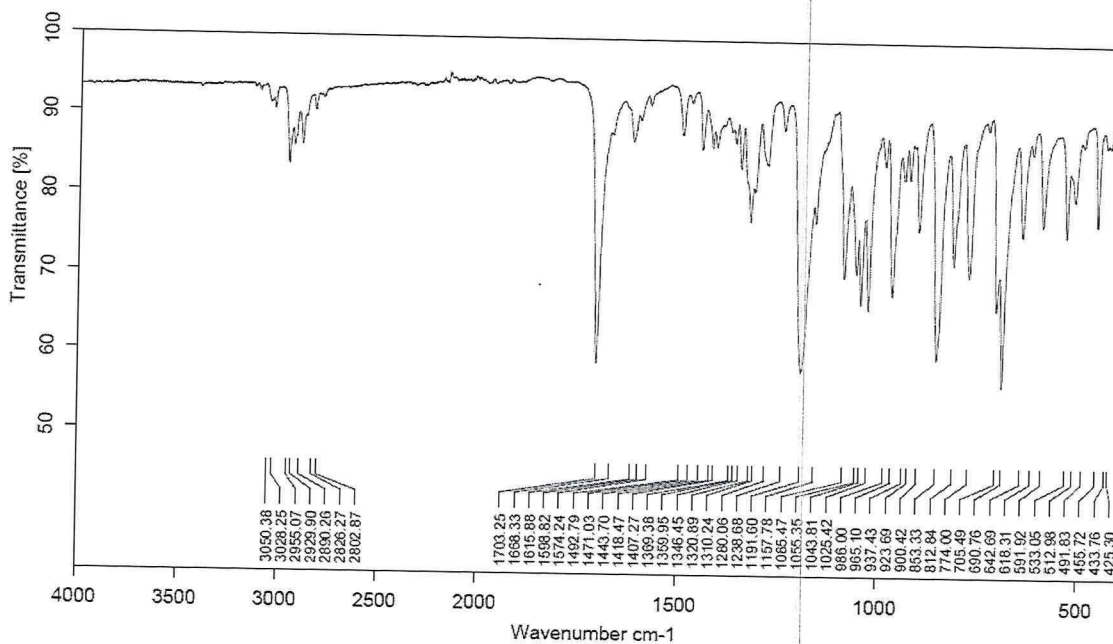
Supplements

Aposcopolamine
Product # 84104

Batch # 12207

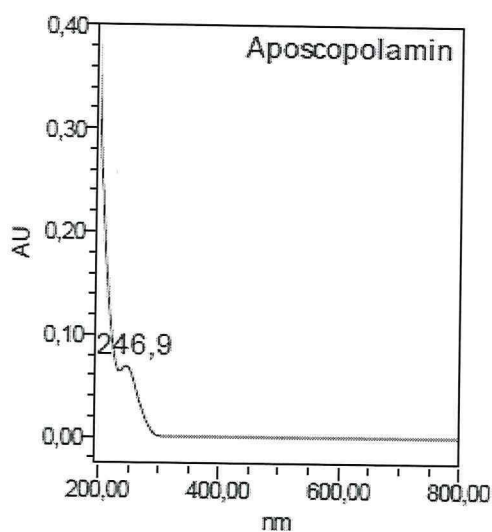
Identity tests:

IR spectrum



C:\Bruker\DATA\84104_Aposcopolamin_12207_0.0

UV spectrum (derived from HPLC/PDA)

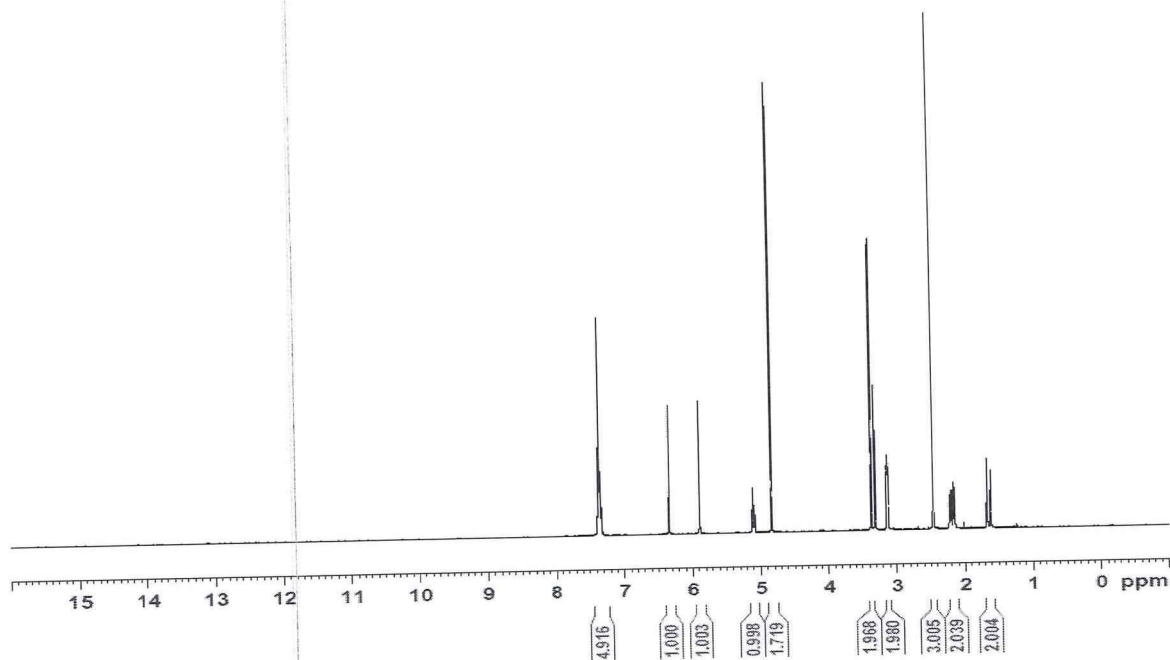




NMR spectra

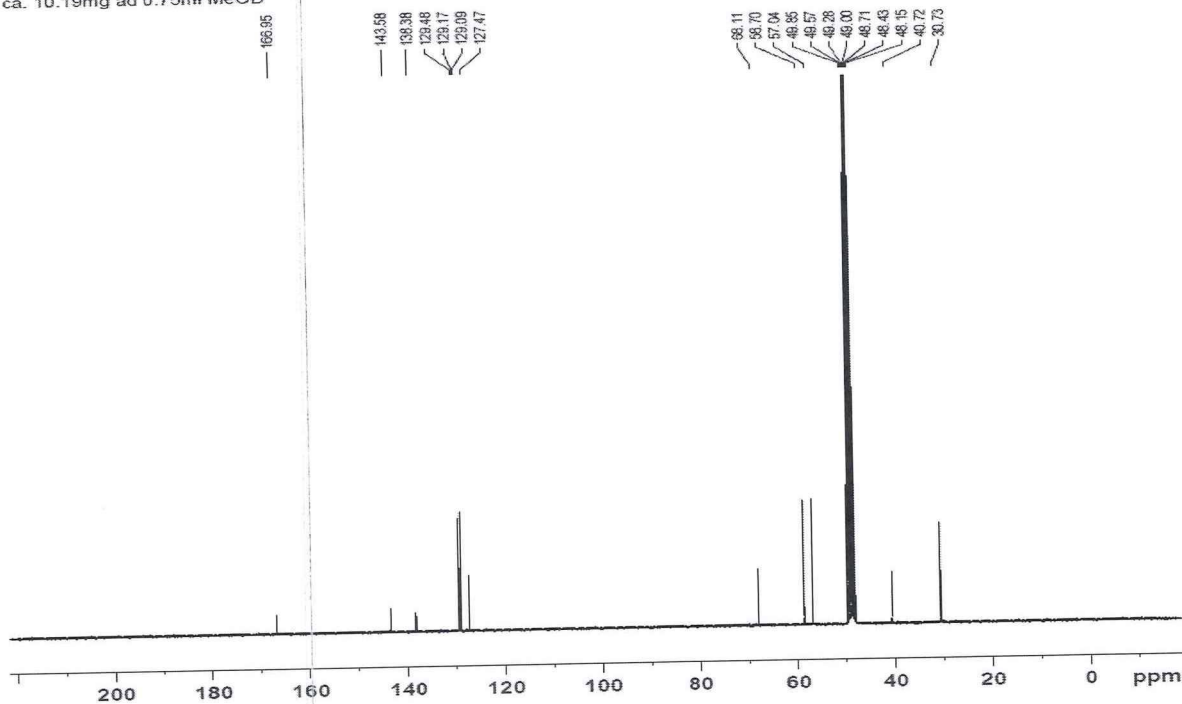
¹H-NMR

PhytoLab GmbH & Co. KG
Aposcopolamin, Charge 12207
ca. 10.19mg ad 0.75ml MeOD

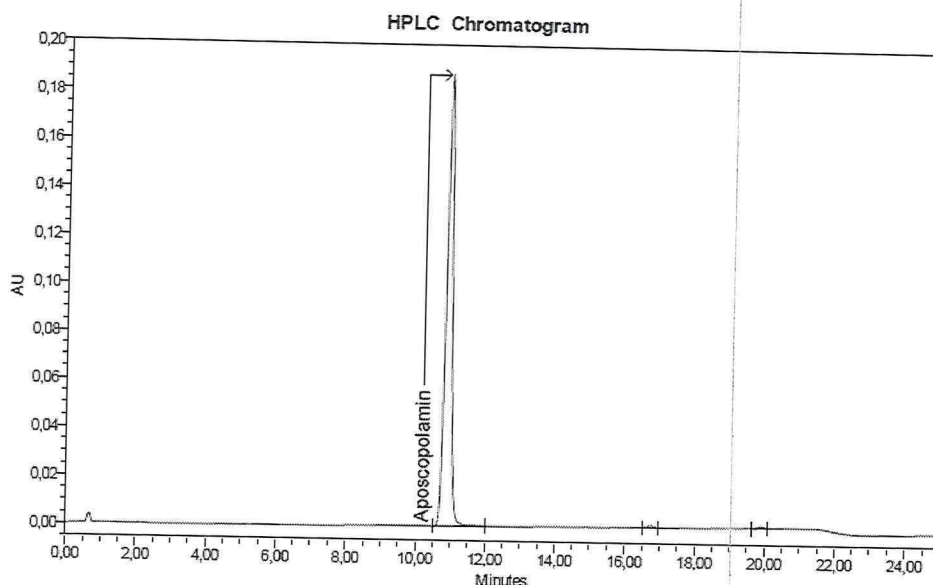


¹³C-NMR

PhytoLab GmbH & Co. KG
Aposcopolamin, Charge 12207
ca. 10.19mg ad 0.75ml MeOD



Chromatographic purity:



Peak Results

	Name	RT	Area	% Area
1	Aposcopolamin	10,902	2318341	99,17
2		16,752	11264	0,48
3		19,915	8154	0,35
Sum:				100,00

Analytical conditions

Column: Luna C18, 75 x 4.6 mm, 3 µm
 Mobile Phase: eluent A: KH₂PO₄ buffer (7g/1l) pH 3.3/ CH₃CN (606/320 V/V) + 3.5g Sodiumdodecylsulfate
 eluent B: CH₃CN
 Mode: gradient

Time [min]	Eluent A [%]	Eluent B [%]
0	95	5
2	95	5
20	70	30
21	95	5
25	95	5

Flow: 1.0 ml/min
 Injection Volume: 20 µl
 Column Temperature: 23 °C
 Sample concentration: approx. 5.4 mg/100 ml
 Sample preparation: dissolved in eluent A
 Detection: UV, 210 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.