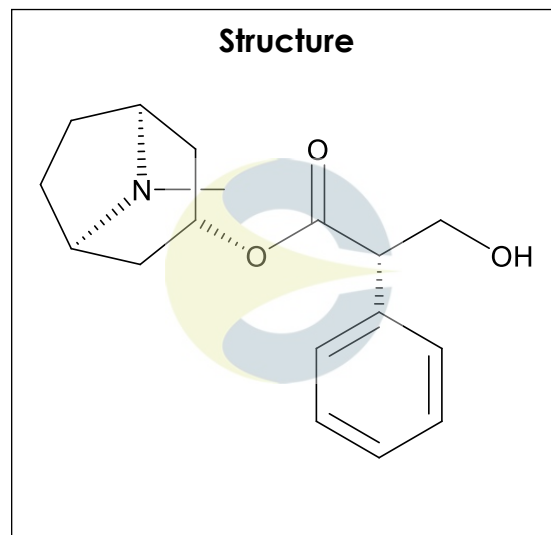


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PRODUCT NAME	L-Hyoscyamine
PART NUMBER	00008875
STANDARD TYPE	Primary (P)
LOT NUMBER	00008875-197
REPORT NUMBER	CDXA-RSS-853-02
SAMPLE NUMBER	CDXA-06-0461
DATE OF SAMPLE	04/21/2006
DATE OF RE-EVALUATION	10/06/2010 (1 st); 02/13/2015 (2 nd); 06/13/2019 (3 rd)
DATE OF REPORT	07/01/2019



CHEMICAL NAMES	1 α H,5 α H-Tropan-3 α -ol (-)-tropate; (-)-Atropine; (S)-Atropine; Cystospaz; Daturine; Duboisine; (-)-Hyoscyamine; L-Hyoscyamin; l-Tropine tropate
CHEMICAL FORMULA	C ₁₇ H ₂₃ NO ₃
MOLECULAR WEIGHT (MW)	289.37
CHEMICAL FAMILY	Alkaloids
CAS NUMBER	[101-31-5]
EC#(EINECS)	202-933-0
RTECS	NH0875000

ANALYTICAL RESULTS

TEST	METHOD	SPECIFICATION	RESULT
Adjusted Purity	NA	NA	97.6%
HPLC	99.1-04-1.0-000684	NA	99.3%
NMR	NA	Conforms to structure	Conforms to structure
Mass Spectrum	Direct Infusion, ESI (+)	Conforms	Conforms
Residual Solvent	CDXA-AM-001-00	NA	ND
Water	99.1-04-10.0-000094	NA	1.7%
Appearance	NA	NA	White powder

ADJUSTED PURITY: 97.6% IS BASED ON (100 - 0.0 SOLVENTS - 1.7 WATER) X 99.3% GC

STORAGE CONDITIONS

STORAGE	Room Temperature in a dry place.
EXPIRATION DATE	06/2024 under the above conditions.

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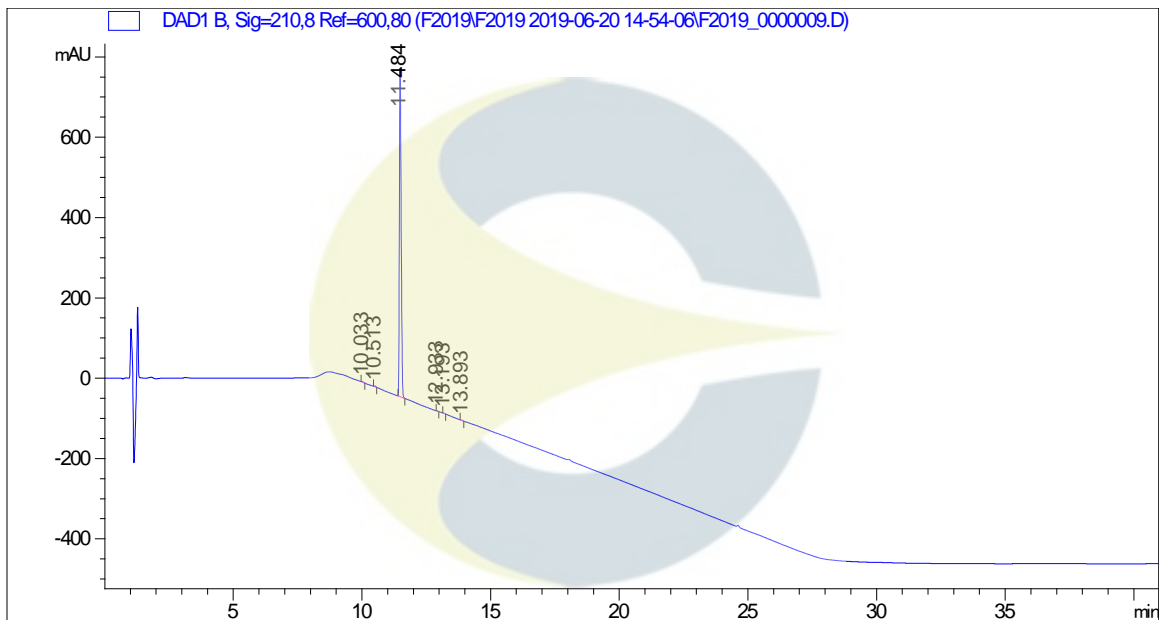
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ANALYTICAL CONDITIONS

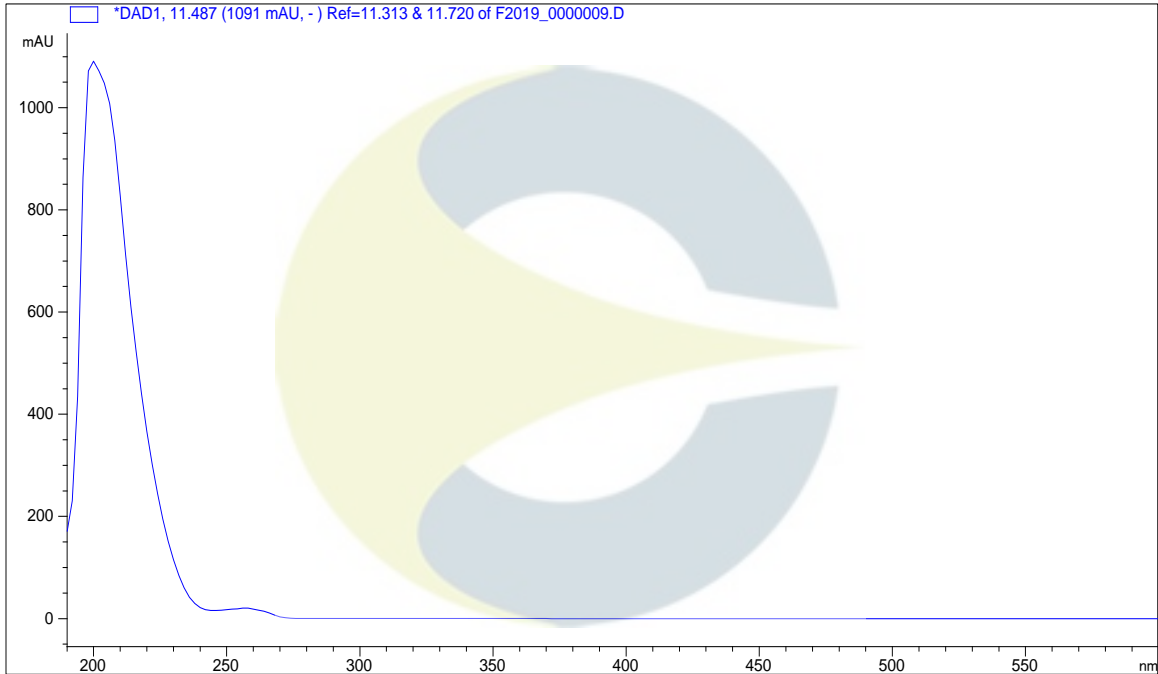
INSTRUMENT	AGILENT 1260 HPLC UV-VIS (DAD); FINNIGAN LCQ-DECA
COLUMN	Phenomenex Luna C18(2) 150 x 2.00 mm, 5 µm particle size
MOBILE PHASE	A - 0.1% Trifluoroacetic acid in Ultrapure water, B - Acetonitrile; Isocratic 5% B for 5 minutes, then increasing to 95% B over 20 minutes. Hold at 95% B for 15 minutes.
COLUMN TEMP.	60 °C
FLOW RATE	0.4 mL/min
INJECTION VOL.	1.0 µL
INJECTION CONC.	1.1 mg/mL in methanol
DETECTION	210 ± 4 nm

HPLC CHROMATOGRAM OF L-HYOSCYAMINE (CDXA-06-0461)

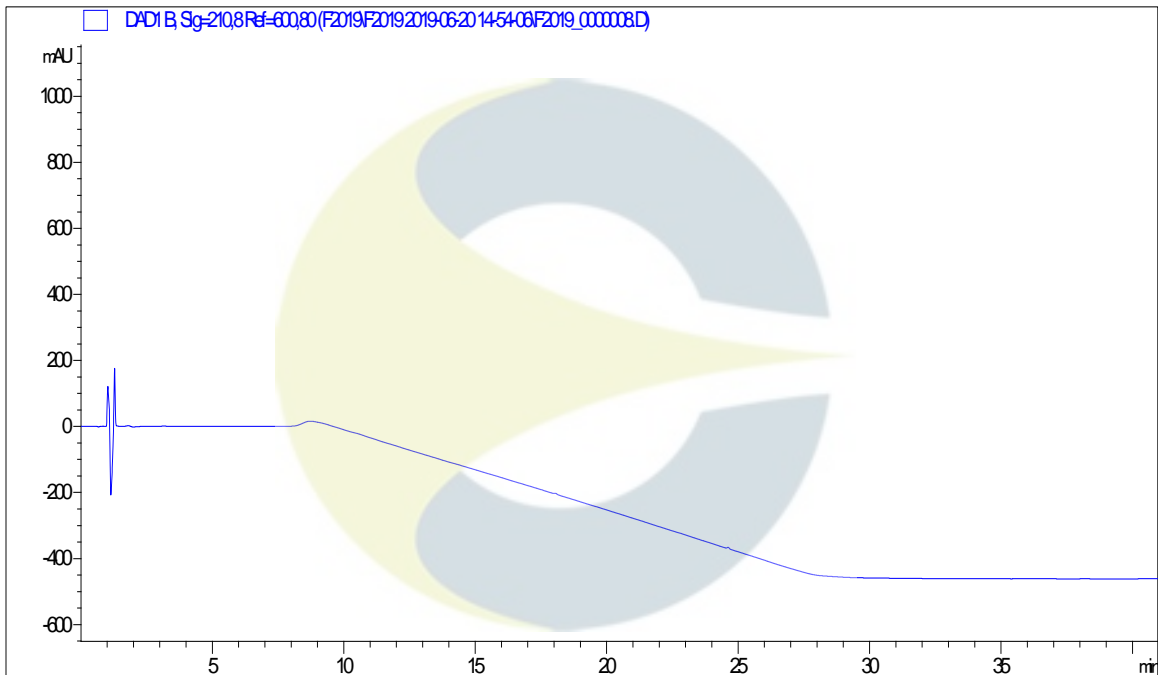


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UV SPECTRUM AT RT = 11.5 MINUTES

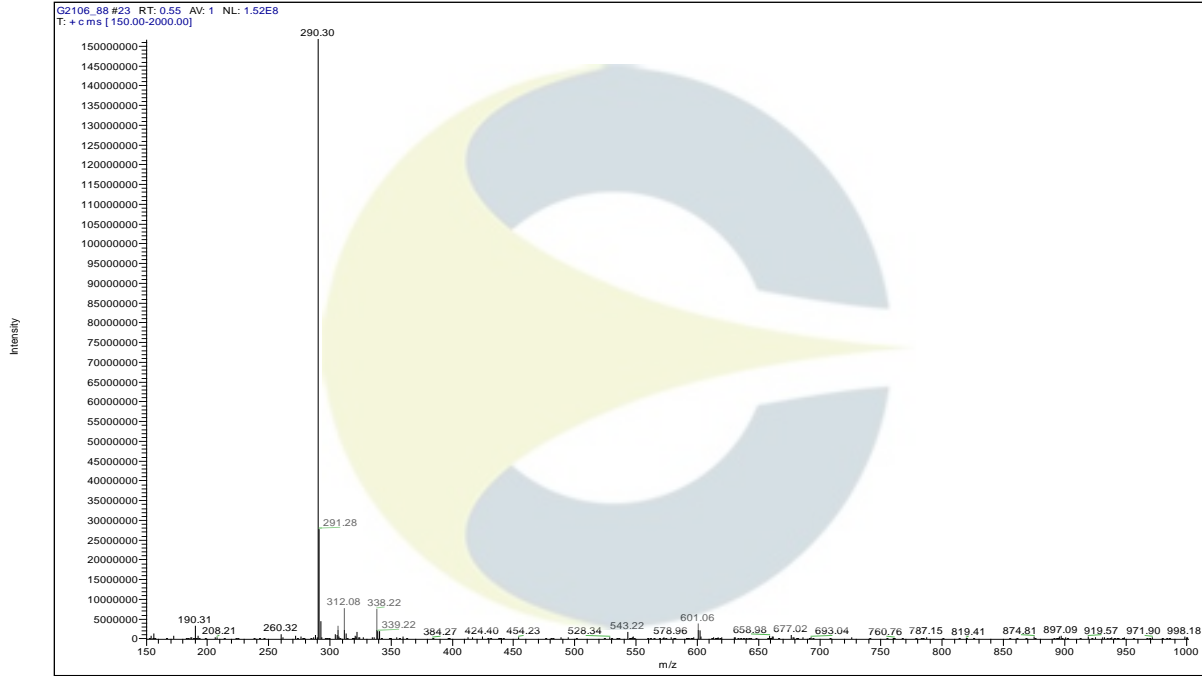


HPLC CHROMATOGRAM OF DILUENT BLANK

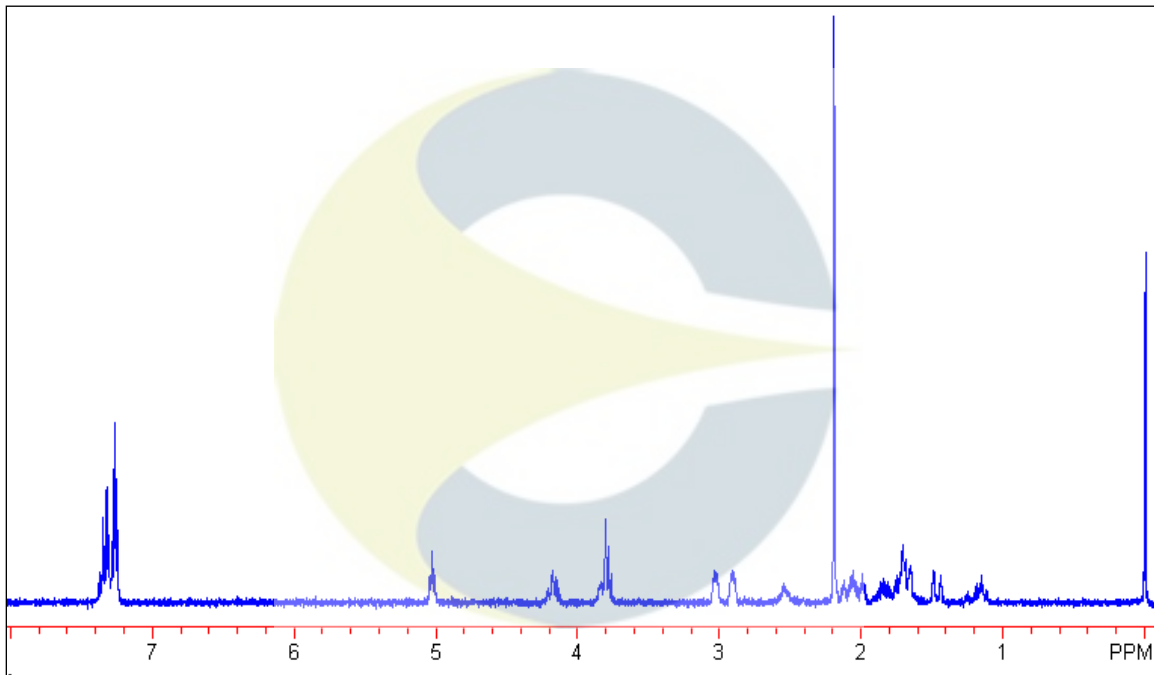


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MASS SPECTRUM OF L-HYOSCYAMINE (CDXA-06-0461)



¹H-NMR SPECTRUM OF L-HYOSCYAMINE (CDXA-06-0461) IN CDCl₃



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REVISION HISTORY

<u>Revision History</u>	<u>Date of Revision</u>	<u>Document/Changes</u>
00	10/12/2010	New report
01	03/12/2015	Passed second re-evaluation by HPLC. Updated expiration date, chemical structure, chemical names and melting point
02	07/01/2019	Material passed third reevaluation by HPLC and water determination. Updated "Analytical Results, Analytical Conditions, chromatograms, chemical structure, and expiration date. Removed melting point.

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