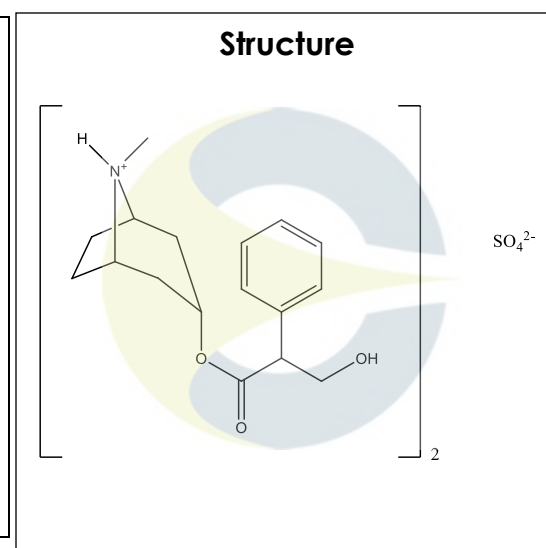


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PRODUCT NAME	Atropine sulfate
PART NUMBER	00011074
STANDARD TYPE	Primary (P)
LOT NUMBER	00011074-M01
REPORT NUMBER	CDXA-RSS-2050-02
SAMPLE NUMBER	CDXA-07-2192
DATE OF SAMPLE	09/11/2007
DATE OF RE-EVALUATION	12/22/2011 (1 st); 11/13/2015 (2 nd); 06/22/2020 (3 rd)
DATE OF REPORT	07/27/2020



CHEMICAL NAMES	α -(Hydroxymethyl)-(3-endo)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester benzeneacetic acid sulfate (2:1)
CHEMICAL FORMULA	(C ₁₇ H ₂₃ NO ₃) ₂ ·H ₂ SO ₄
MOLECULAR WEIGHT (MW)	676.82
CHEMICAL FAMILY	Alkaloids
CAS NUMBER	[55-48-1]
EC#(EINECS)	200-235-0
RTECS	CK2450000

ANALYTICAL RESULTS

TEST	METHOD	SPECIFICATION	RESULT
Adjusted Purity	NA	NA	95.3%
HPLC	0.700.10.2.METH22	NA	99.9%
NMR	NA	Conforms to structure	Conforms to structure
Mass Spectrum	Direct Infusion, ESI (+)	Conforms	Conforms
Residual Solvent	CDXA-AM-001-05	NA	Chloroform – 0.4% Dichloroethylene – 0.2% Dichloromethane – 0.2%
Water	0.700.12.37	NA	3.8%
Appearance	NA	NA	White powder

ADJUSTED PURITY: 95.3% IS BASED ON (100 - 0.8 SOLVENTS - 3.8 WATER) X 99.9% HPLC

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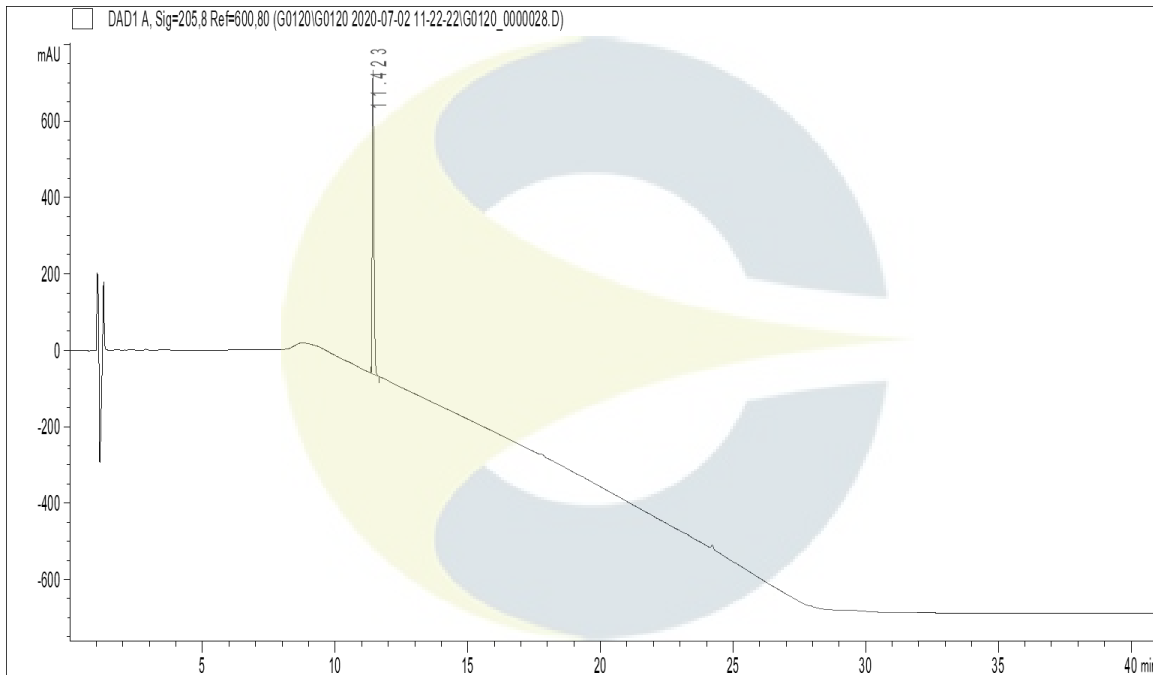
STORAGE CONDITIONS

STORAGE Room Temperature in a dry place.
EXPIRATION DATE 06/2025 under the above conditions.

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/minute
INJECTION VOL. 1.0 µL
INJECTION CONC. 0.98 mg/mL in Methanol
DETECTION 205 ± 4 nm

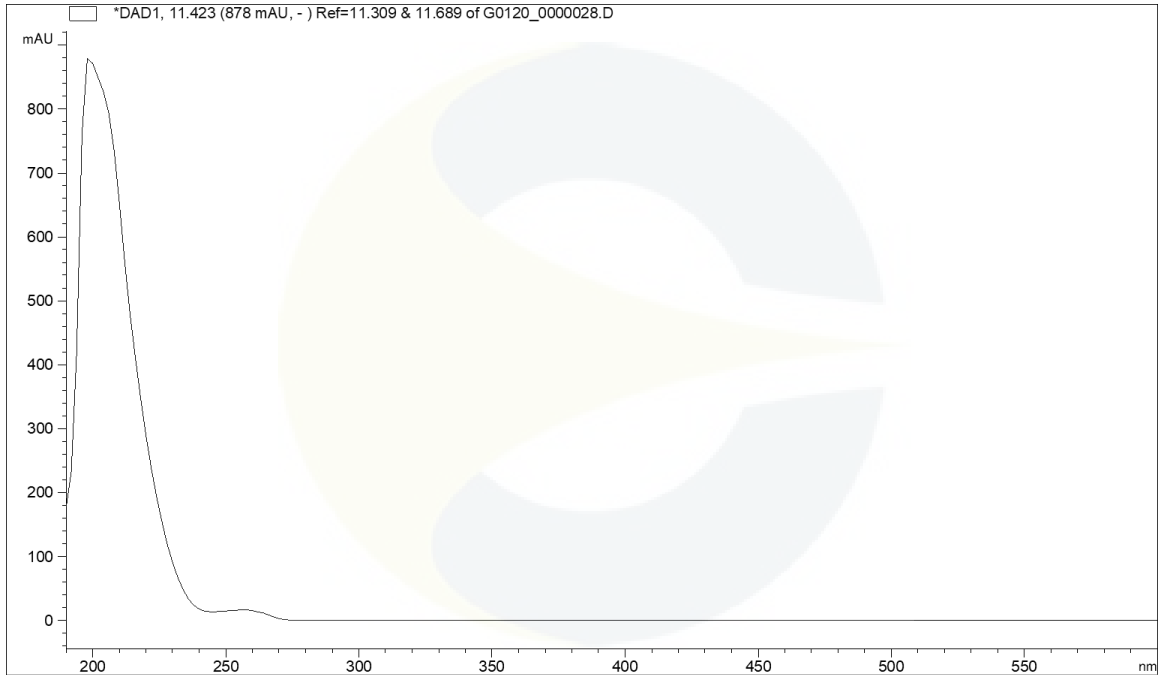
HPLC CHROMATOGRAM OF ATROPINE SULFATE (CDXA-07-2192)



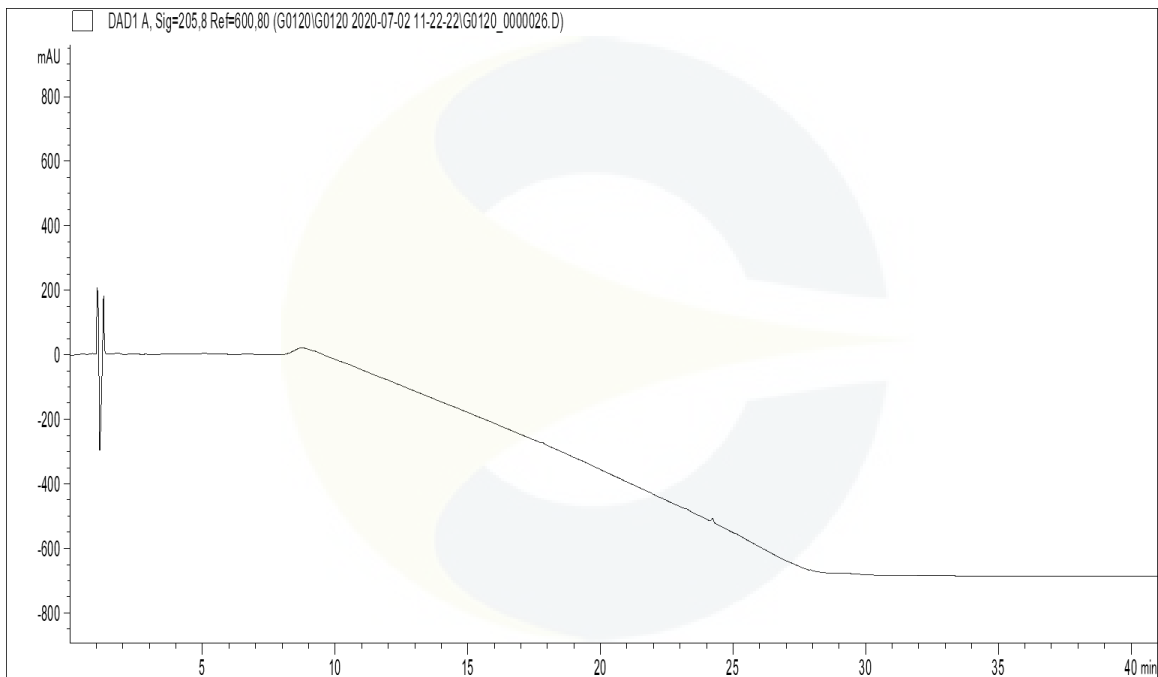
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UV SPECTRUM AT RT 11.4 MINUTES



HPLC CHROMATOGRAM OF DILUENT BLANK

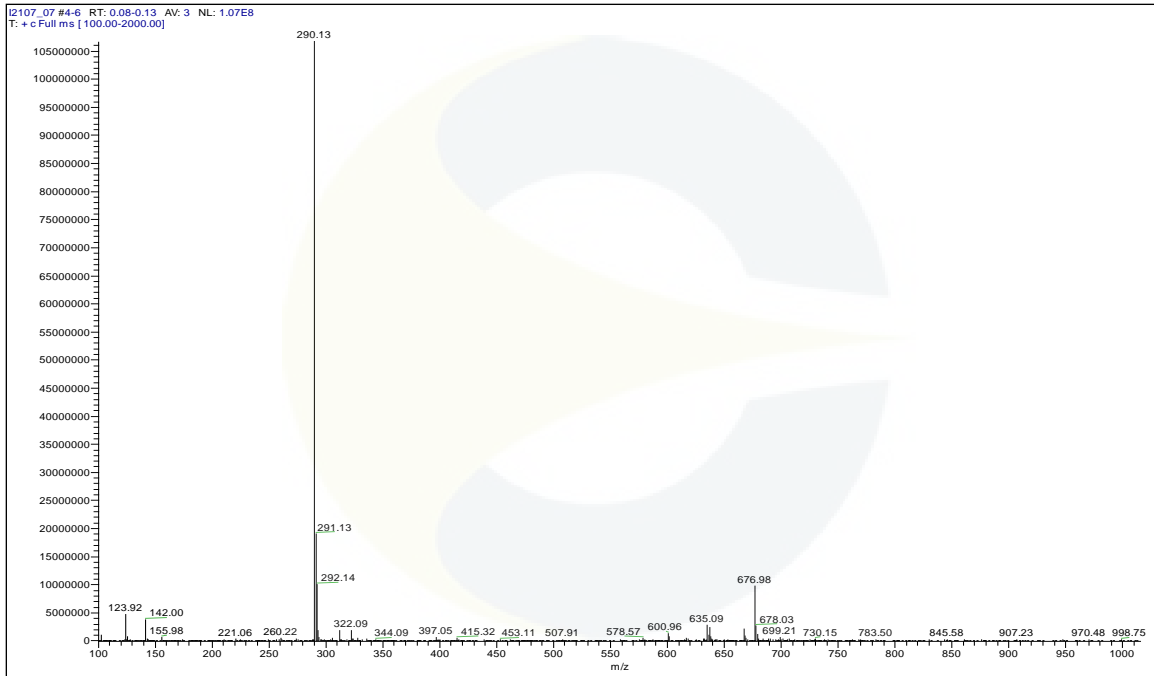


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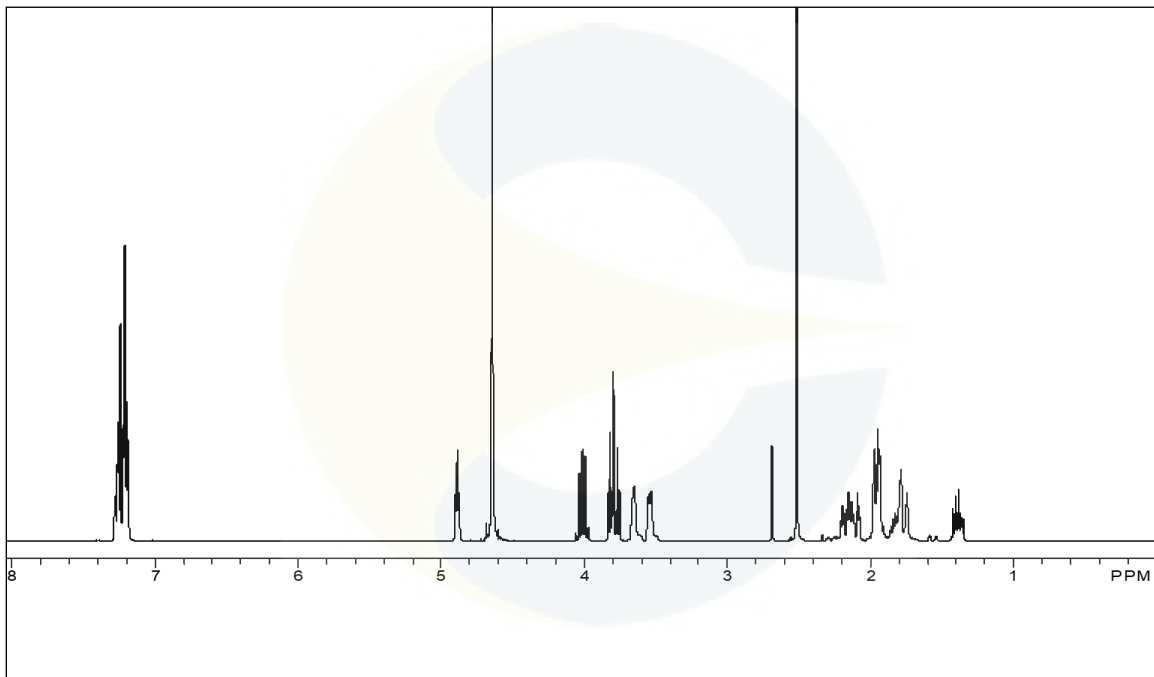
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Email: customerservice@lifetechindia.com Website: www.lifetechindia.com

MASS SPECTRUM OF ATROPINE SULFATE (CDXA-07-2192)



¹H-NMR SPECTRUM OF ATROPINE SULFATE (CDXA-07-2192) IN D₂O



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REVISION HISTORY

<u>Revision History</u>	<u>Date of Revision</u>	<u>Document/Changes</u>
00	02/07/2012	New report
01	12/08/2015	Passed second re-evaluation by HPLC, KF. Updated expiration date and chemical names.
02	07/27/2020	Passed third re-evaluation by HPLC and KF. Updated analytical results, expiration date, analytical conditions, and chromatograms. Removed melting point.

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