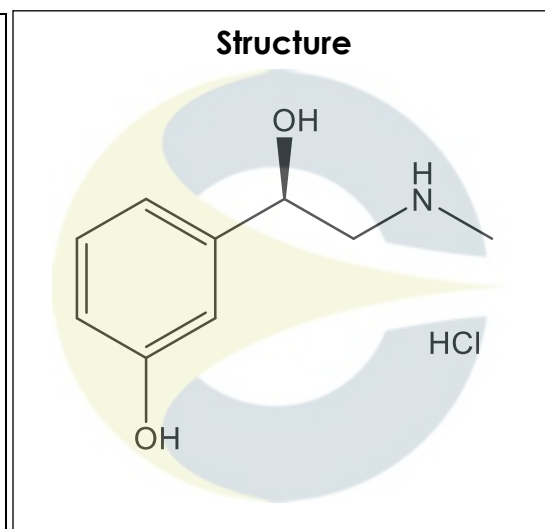


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<b>PRODUCT NAME</b>	Phenylephrine HCl
<b>PART NUMBER</b>	00016439
<b>STANDARD TYPE</b>	Primary (P)
<b>LOT NUMBER</b>	00016439-758
<b>REPORT NUMBER</b>	CDXA-RSS-288-03
<b>SAMPLE NUMBER</b>	CDXA-04-0758
<b>DATE OF SAMPLE</b>	12/10/2004
<b>DATE OF RE-EVALUATION</b>	07/29/2009 (1 <sup>st</sup> ); 10/07/2014 (2 <sup>nd</sup> ); 01/07/2019 (3 <sup>rd</sup> ); 12/06/2022 (4 <sup>th</sup> )
<b>DATE OF REPORT</b>	01/03/2023



<b>CHEMICAL NAMES</b>	Metasynephrine; Isophrin hydrochloride; Metaoxedrine chloride; Neo-Synephrine hydrochloride; Prefrin
<b>CHEMICAL FORMULA</b>	C <sub>9</sub> H <sub>13</sub> NO <sub>2</sub> • HCl
<b>MOLECULAR WEIGHT (MW)</b>	203.67
<b>CHEMICAL FAMILY</b>	Alkaloids
<b>CAS NUMBER</b>	[61-76-7]
<b>EC#(EINECS)</b>	200-517-3
<b>RTECS</b>	DO7525000

**ANALYTICAL RESULTS**

TEST	METHOD	SPECIFICATION	RESULT
Adjusted Purity	NA	≥ 85%	99.8%
HPLC	0.700.10.2.METH46	≥ 90%	99.8%
NMR	0.700.12.4	Conforms to structure	Conforms to structure
Mass Spectrum	Direct Infusion, ESI (+)	Conforms	Conforms
Residual Solvent*	CDXA-AM-001-00	NA	ND
Water	0.700.12.37	NA	ND
Appearance	NA	NA	White powder

\*Testing performed at an ISO 17025 accredited subcontracted laboratory.

ADJUSTED PURITY: 99.8% IS BASED ON (100 - 0.0 SOLVENTS - 0.0 WATER) X 99.8% HPLC

**STORAGE CONDITIONS**

<b>STORAGE</b>	+4 °C in a dry place.
<b>EXPIRATION DATE</b>	12/2027 under the above conditions.

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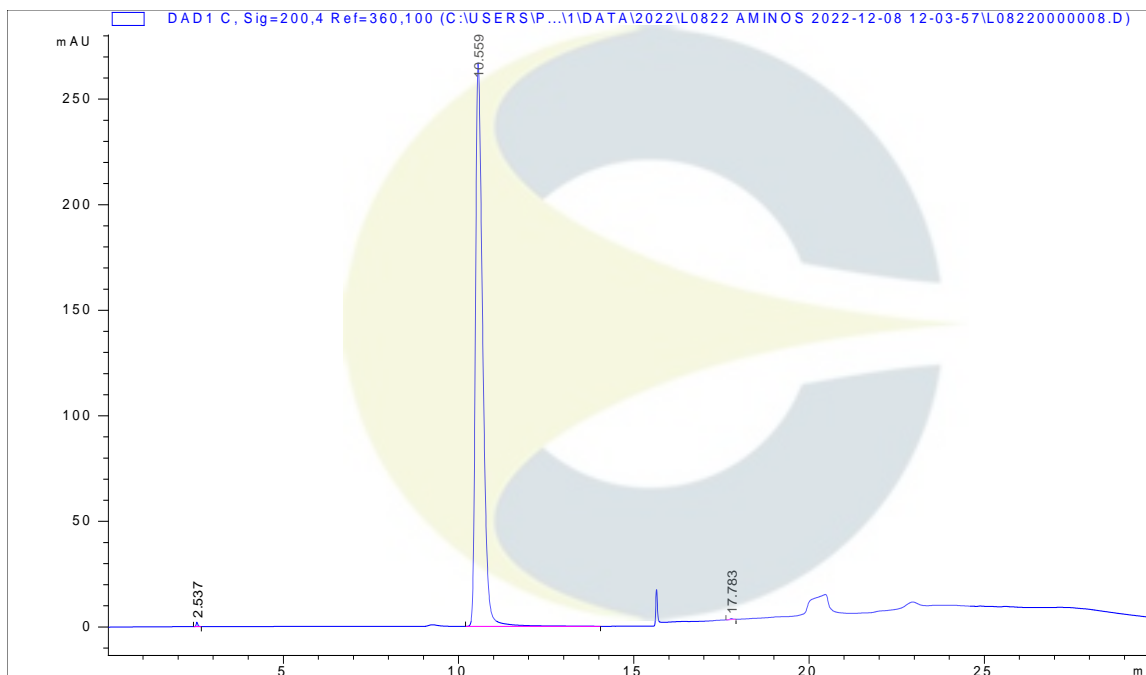
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### ANALYTICAL CONDITIONS

<b>INSTRUMENT</b>	AGILENT 1260 HPLC UV-VIS (DAD); FINNIGAN LCQ-DECA
<b>COLUMN</b>	Phenomenex Synergi Hydro-RP 80Å 250 x 4.6 mm, 4µm
<b>MOBILE PHASE</b>	A – 10 mM potassium phosphate monobasic, pH = 2.91 (aq), B - Acetonitrile; Isocratic 0% B for 10 minutes, then increasing to 30% B over 10 minutes. Hold at 30% B for 4 minutes. Decrease to 0% B over 5 minutes.
<b>COLUMN TEMP.</b>	22 °C
<b>FLOW RATE</b>	1.0 mL/minute
<b>INJECTION VOL.</b>	0.5 µL
<b>INJECTION CONC.</b>	1.2 mg/mL in high-purity water
<b>DETECTION</b>	200 ± 2 nm

### HPLC CHROMATOGRAM OF PHENYLEPHRINE HCL (CDXA-04-0758)

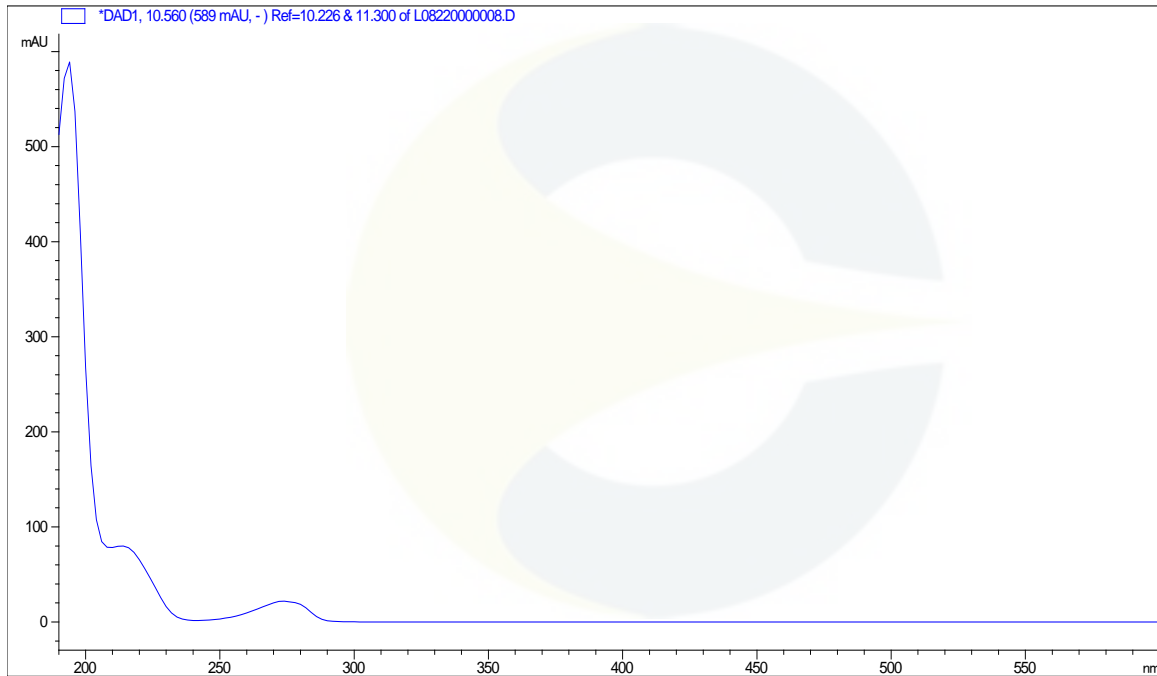


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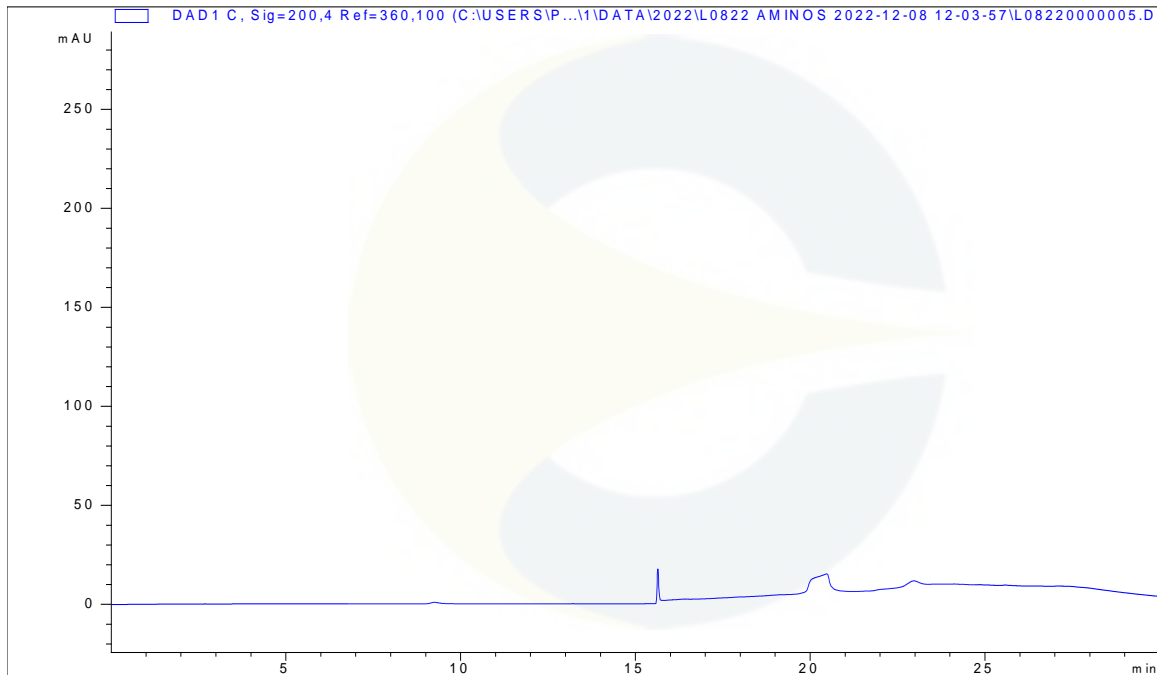
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## UV SPECTRUM AT RT = 10.6 MINUTES



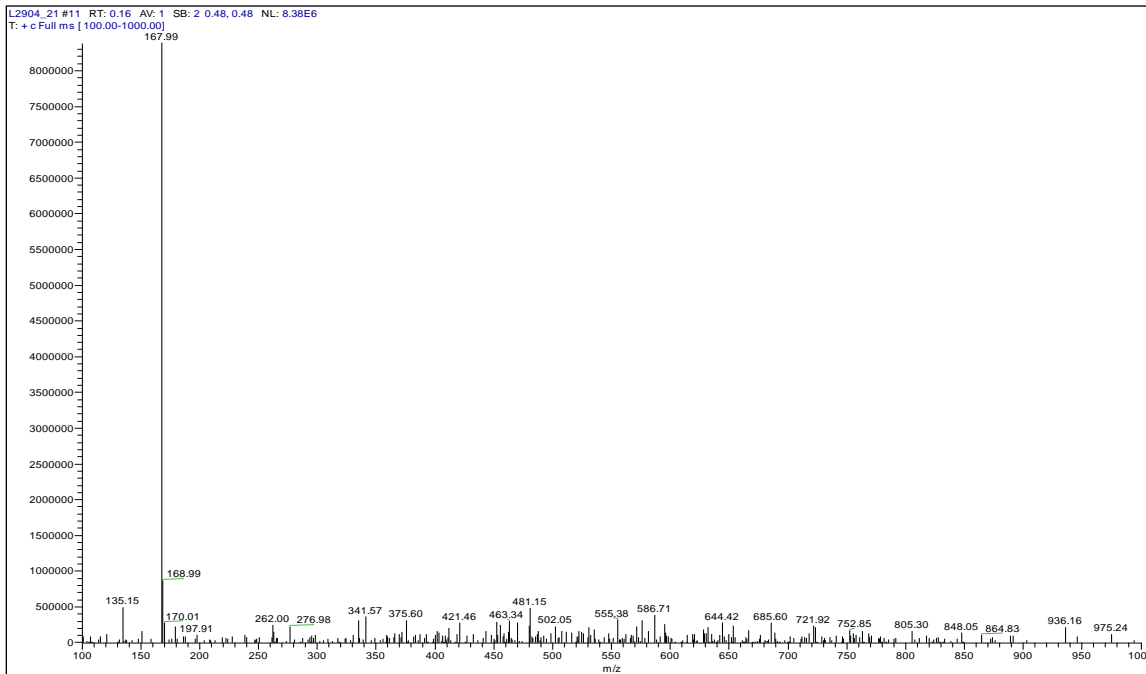
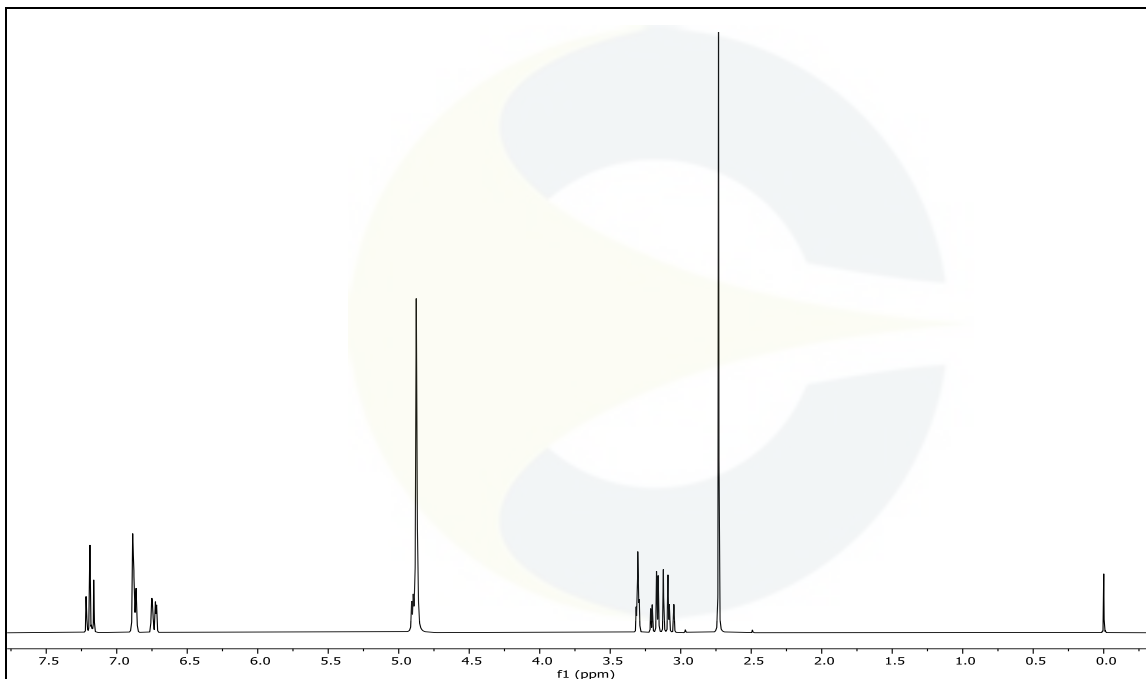
## HPLC CHROMATOGRAM OF DILUENT BLANK



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306, Aggarwal City Mall, Opposite M2K Pitampura, Delhi – 110034 (INDIA). Ph: +91-11-42208000, 42208111, 42208222, Mobile: +91-9810521400, Fax: +91-11-42208444  
Email: [customerservice@lifetechindia.com](mailto:customerservice@lifetechindia.com) Website: [www.lifetechindia.com](http://www.lifetechindia.com)

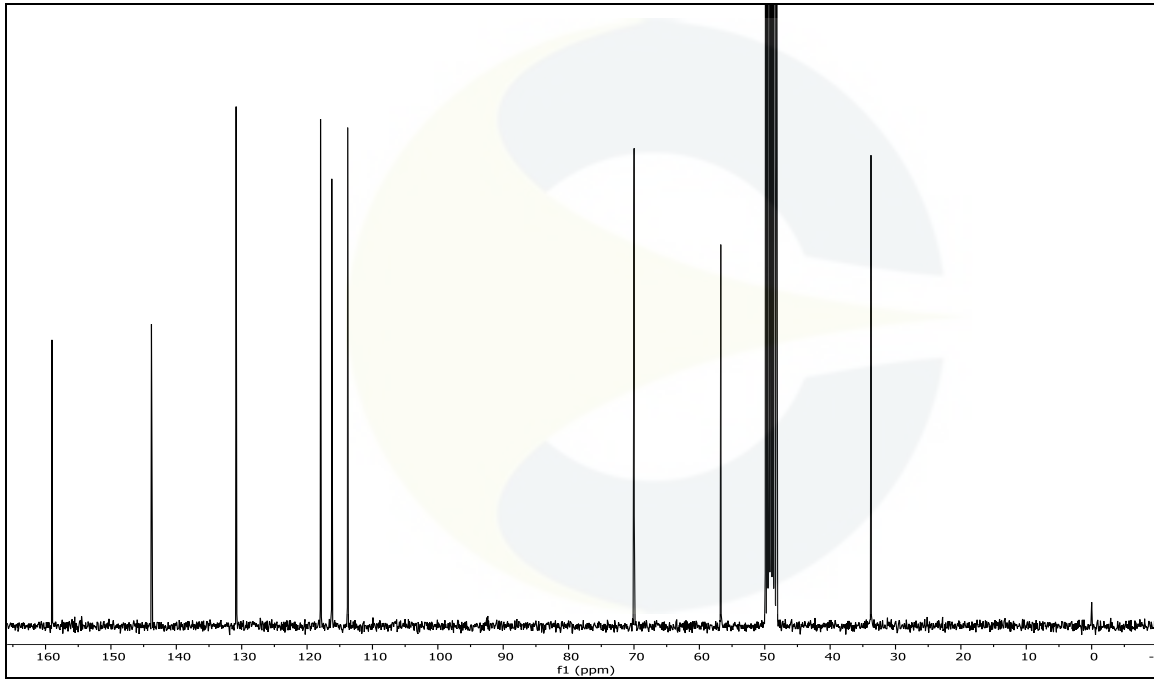
**MASS SPECTRUM OF PHENYLEPHRINE HCL (CDXA-04-0758)**

**<sup>1</sup>H-NMR SPECTRUM OF PHENYLEPHRINE HCL (CDXA-04-0758) IN CD<sub>3</sub>OD +TMS**


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 Email: [customerservice@lifetechindia.com](mailto:customerservice@lifetechindia.com) Website: [www.lifetechindia.com](http://www.lifetechindia.com)

**<sup>13</sup>C-NMR SPECTRUM OF PHENYLEPHRINE HCL (CDXA-04-0758) IN CD<sub>3</sub>OD +TMS**



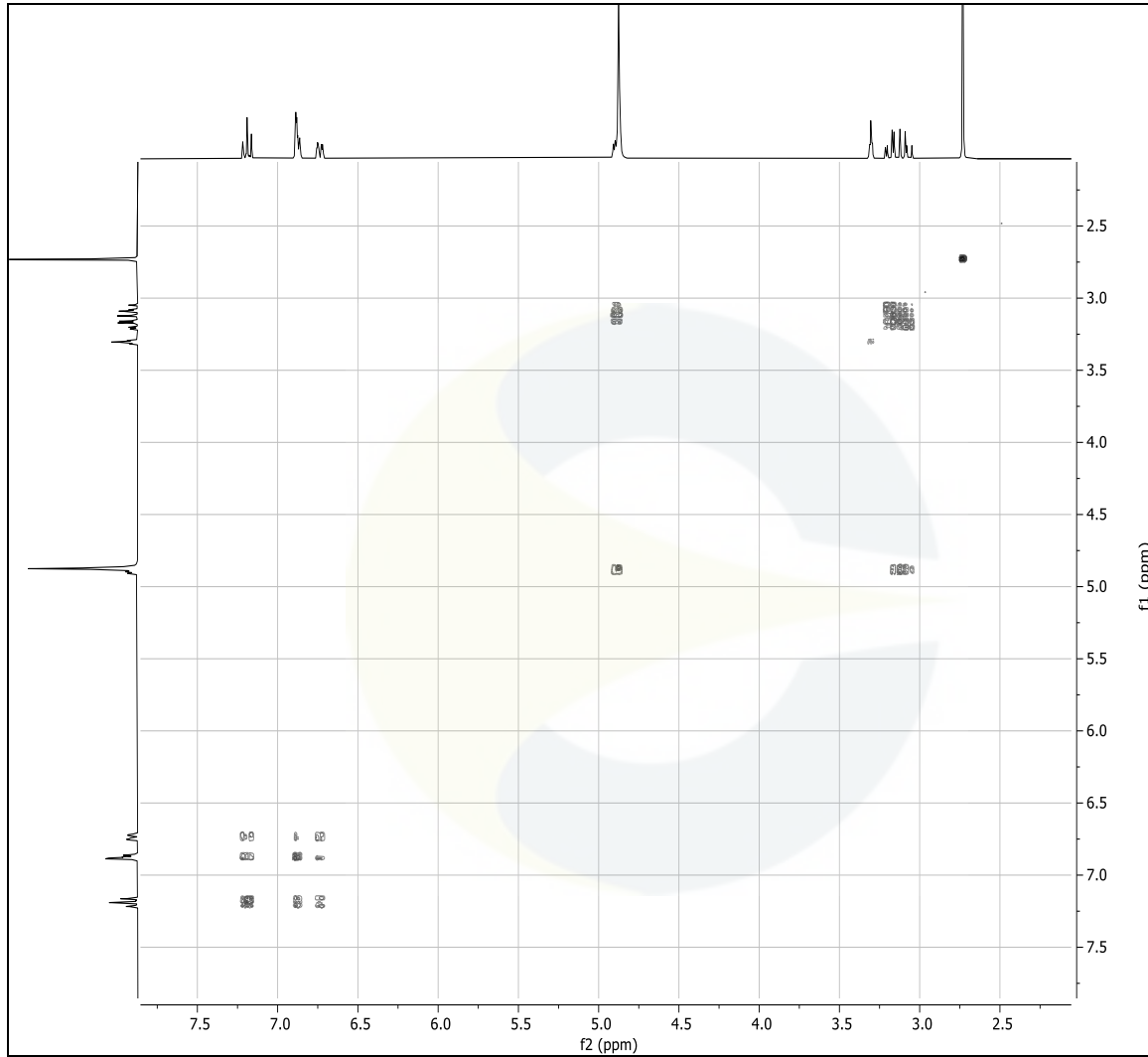
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COSY-NMR SPECTRUM OF PHENYLEPHRINE HCL (CDXA-04-0758) IN CD<sub>3</sub>OD +TMS

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## REVISION HISTORY

<u>Revision History</u>	<u>Date of Revision</u>	<u>Document/Changes</u>
00	07/29/2009	New report and first re-evaluation
01	12/23/2014	Passed second re-evaluation; updated expiration date, melting point and chemical names
02	01/16/2019	Material passed re-evaluation by HPLC and KF. Updated analytical method conditions, chromatograms, expiration date, and results. Removed melting point.
03	01/03/2023	Passed fourth re-evaluation by HPLC, KF and NMR. Updated analytical conditions, chromatograms, expiration date, and results.

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