



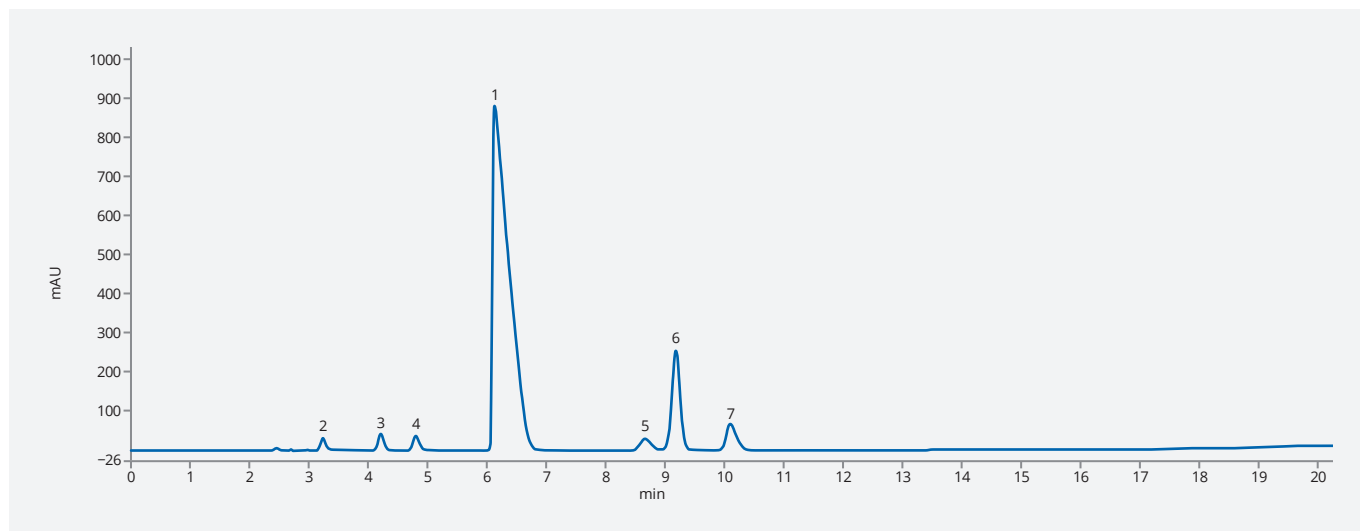
LISDEXAMFETAMINE ANALYSIS

ABSTRACT

This application offers an analytical technique for detection and quantification of lisdexamfetamine and its impurities profile. The method provides a perfect separation of isomers of lisdexamfetamine and d-amphetamine.

INTRODUCTION

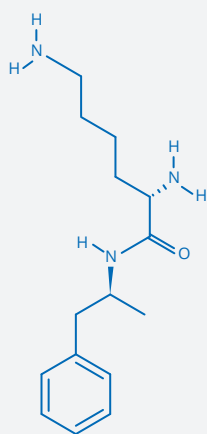
Lisdexamfetamine dimesylate is a long-acting central nervous system stimulating agent, a therapeutically inactive d-amphetamine prodrug, used in the treatment of attention-deficit/hyperactivity disorder and binge eating disorder. Impurities in the drug are closely related to the adverse reactions and can produce fatal immune response. Due to the strict regulatory requirements and lisdexamfetamine biotransformation in human body, the development of precise method for analysis is critical to ensuring the drug's quality and safety.

Lisdexamfetamine analysis

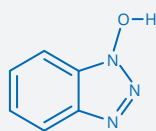
Test solution on ASTRA[®] Phenyl-Hexyl-HE column

Lisdexamfetamine analysis

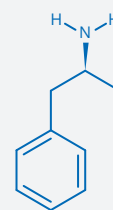
Column	ASTRA® Phenyl-Hexyl-HE, 5 µm
Dimensions	250 mm × 4.6 mm
Part number	AST-5891-LM46
Mobile phase	A: Water + 0.05% Methanesulfonic acid B: Methanol + 0.05% Methanesulfonic acid
Isocratic elution	A : B 70/30 (%/%)
Temperature	30 °C
Flow rate	1.0 mL/min
Injection volume	10 µL
Detection	UV @210 nm
Analytes	1. (S,S)-Lisdexamfetamine 2mg/mL, CAS: 608137-33-3 2. α,ε-Bislysyl-lisdexamfetamine 40µg/mL, CAS: 2243794-25-2 3. α-Lysyl-lisdexamfetamine 40µg/mL, CAS: 3082713-94-5 4. ε-Lysyl-lisdexamfetamine 40µg/mL, CAS: 3033059-94-5 5. (S,R)-Lisdexamfetamine 40µg/mL, CAS: 5002-60-8 6. 1-Hydroxybenztriazole 40µg/mL, CAS: 123333-53-9 7. d-Amfetamine 40µg/mL, CAS: 51-63-8



(S,S)-Lisdexamfetamine



1-Hydroxybenztriazole



d-Amfetamine



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