A Single-Dose, Two-Way Crossover, Open-Label Bioequivalence Study of an Amphetamine Extended-Release Oral Suspension in Healthy Adults

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Abstract

Objective:
The purpose of this study was to compare the pharmacokinetics of a new extended-release amphetamine oral suspension (AMP XR-OS) with a standard extended-release mixed amphetamine salts product, Adderall XR®.

Method:
In this single-dose, open-label, randomized, two-period, two-treatment crossover study, 42 healthy adult volunteers received 15 mL of AMP XR-OS in one period and a 30 mg Adderall XR capsule in another period (both containing 18.8 mg of amphetamine base) under fasted conditions. Blood samples were analyzed for d- and l-amphetamine concentrations, and pharmacokinetic parameters Cmax, AUC0-5, AUC5-last, and AUCinf were calculated to determine bioequivalence. Safety was monitored throughout the study.

Results:
The 90% confidence intervals (CIs) for the log-transformed Cmax, AUC0-5, AUC5-last, and AUCinf fell within the accepted 80% to 125% range for establishing bioequivalence for d- and l-amphetamine. The most common adverse events were nausea and decreased appetite.

Conclusion:
AMP XR-OS is bioequivalent to Adderall XR in healthy adult participants.