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Couch et al.

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- (54) **SUSTAINED RELEASE DELIVERY OF AMPHETAMINE SALTS**
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- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 115 days.

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Related U.S. Application Data

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- (52) **U.S. Cl.** **424/490**; 424/489; 424/494; 424/495; 424/484; 424/486; 424/464; 424/468; 424/451; 424/457

- (58) **Field of Search** 424/490, 489, 424/494, 495, 484, 486, 464, 468, 451, 457

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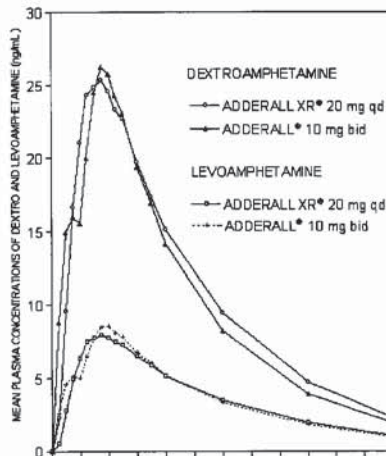
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- (57) **ABSTRACT**

A pharmaceutical composition comprises a once-a-day sustained release formulation of at least one amphetamine salt which provides mean plasma concentration profile aspects in human ADHD patients which are substantially the same as that provided by ADDERALL XR® type pulsatile formulations.

37 Claims, 13 Drawing Sheets



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Figure 1

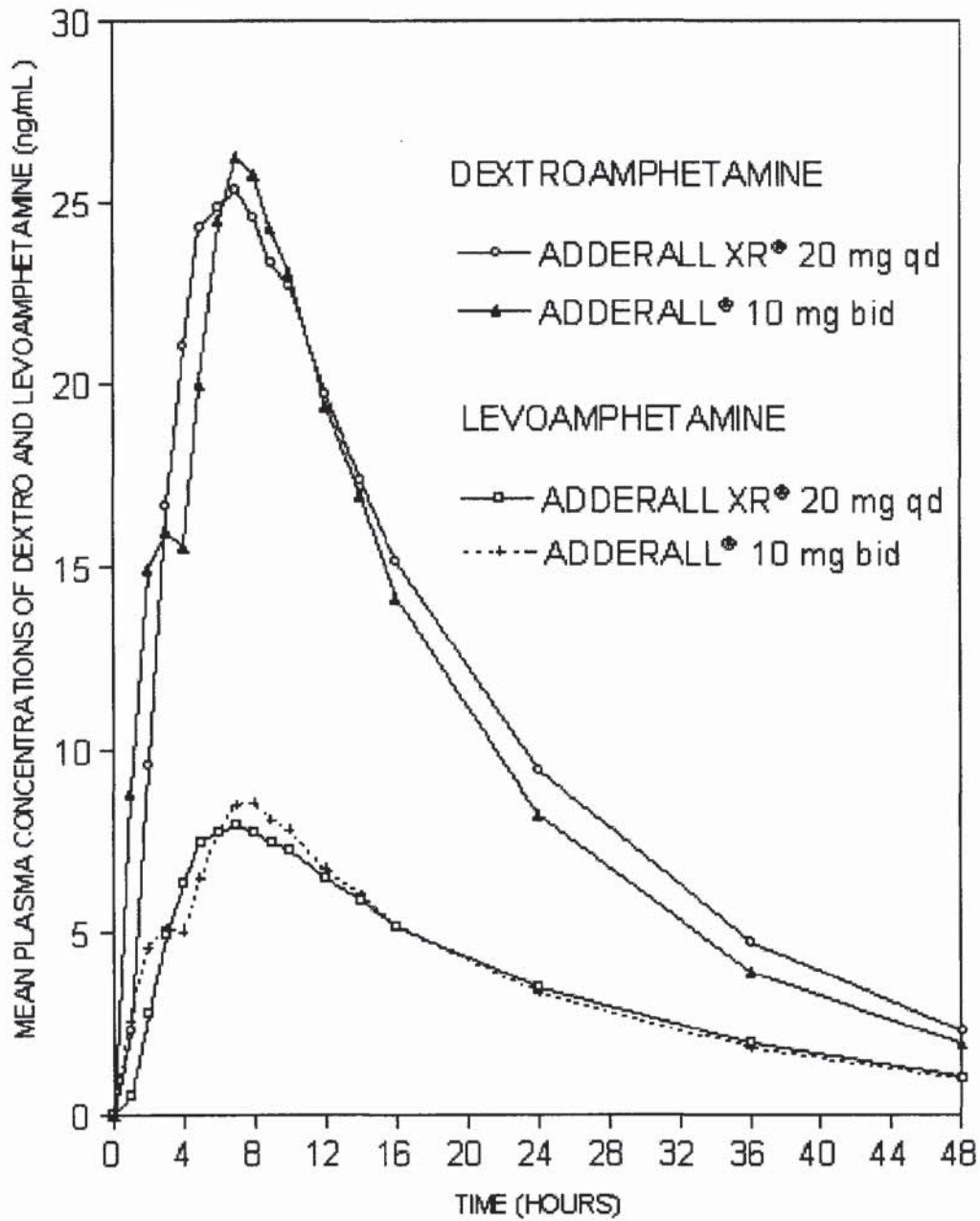


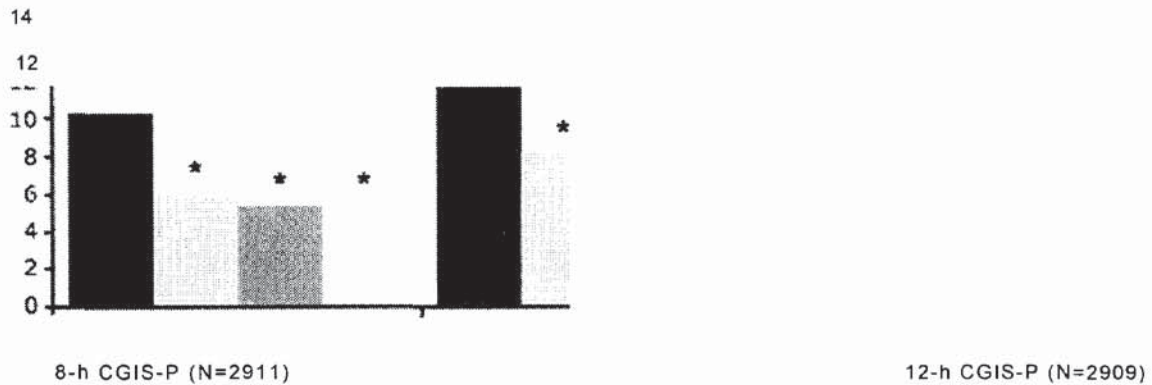
Figure 2. Mean CGIS-P total scores for ITT population.

• *Baseline (previous med)

Week 1 (Adderall XR™)

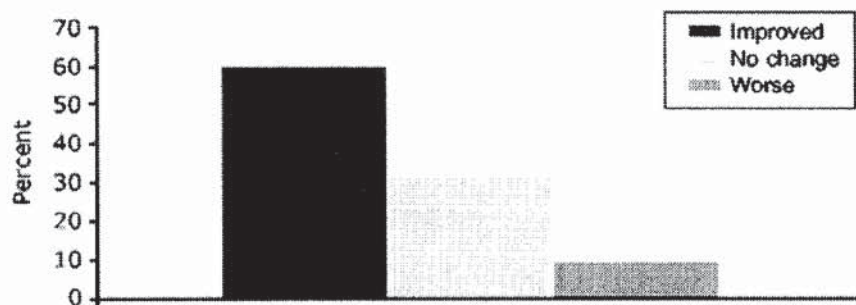
Week 3 (Adderall XR™)

Week 7 (Adderall XR™)



*P<0.0001 vs baseline. Note: a lower score indicates better response to treatment

Figure 3. CGI Improvement scores at week 7.



Improved = very much improved and much improved; No change = minimally improved and no change; Worse = minimally worse and very much worse.

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