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Burnside et al.

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(54) **ORAL PULSED DOSE DRUG DELIVERY SYSTEM**
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Barr's Paragraph IV Certification against Parent U S Patent 6,322,819 on Jan. 14, 2003.

(73) Assignee: **Shire Laboratories, Inc.**, Rockville, MD (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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§ 371 (c)(1),
(2), (4) Date: **Jul. 19, 2001**

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Related U.S. Application Data

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(51) **Int. Cl.**⁷ **A61K 33/22**; A61K 33/24; A61K 33/36; A61K 31/135

(52) **U.S. Cl.** **424/452**; 424/458; 424/468; 424/469; 424/470; 424/471; 424/472; 424/514; 424/649

(58) **Field of Search** 424/457, 458, 424/468, 469, 470, 471, 472; 514/649

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(57) **ABSTRACT**

A multiple pulsed dose drug delivery system for pharmaceutically active amphetamine salts, comprising an immediate-release component and an enteric delayed-release component wherein (1) the enteric release coating has a defined minimum thickness and/or (2) there is a protective layer between the pharmaceutically active amphetamine salt and the enteric release coating and/or (3) there is a protective layer over the enteric release coating. The product can be composed of either one or a number of beads in a dosage form, including either capsule, tablet, or sachet method for administering the beads.



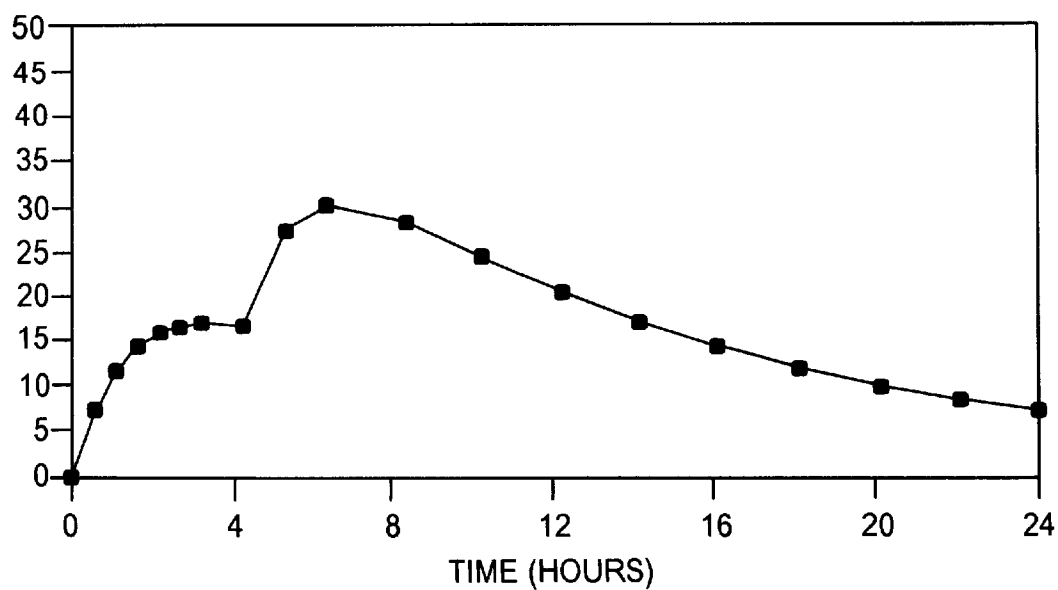


FIG. 1

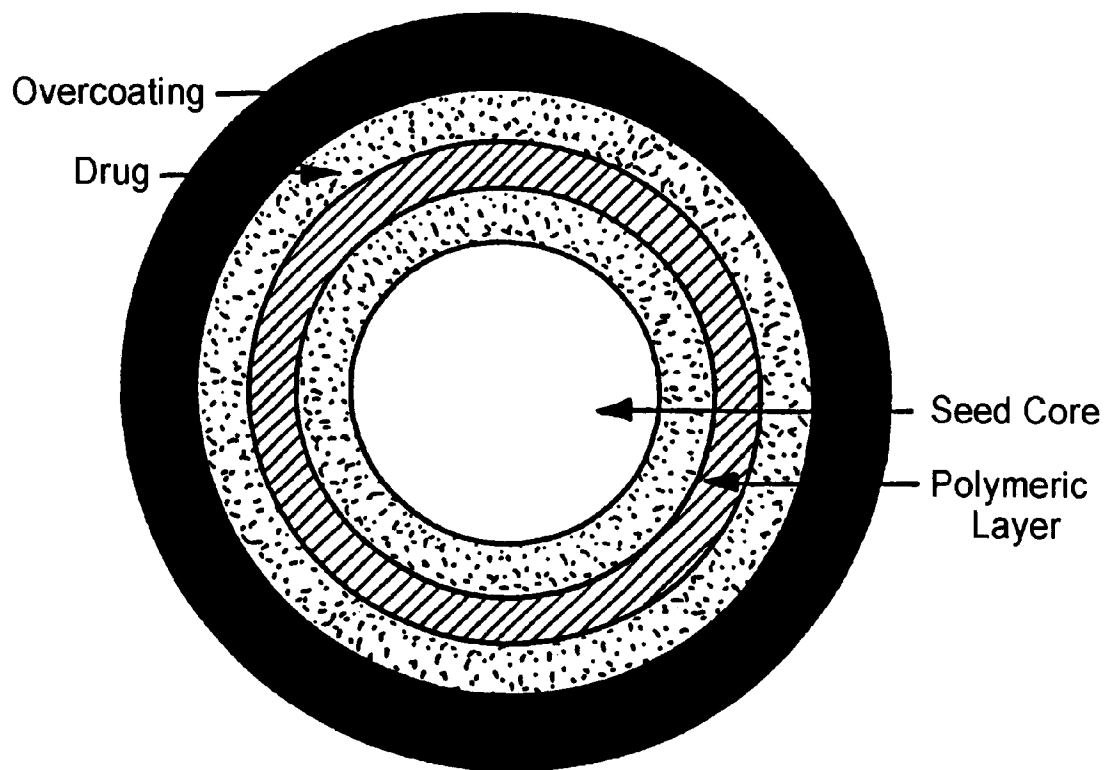


FIG. 2A

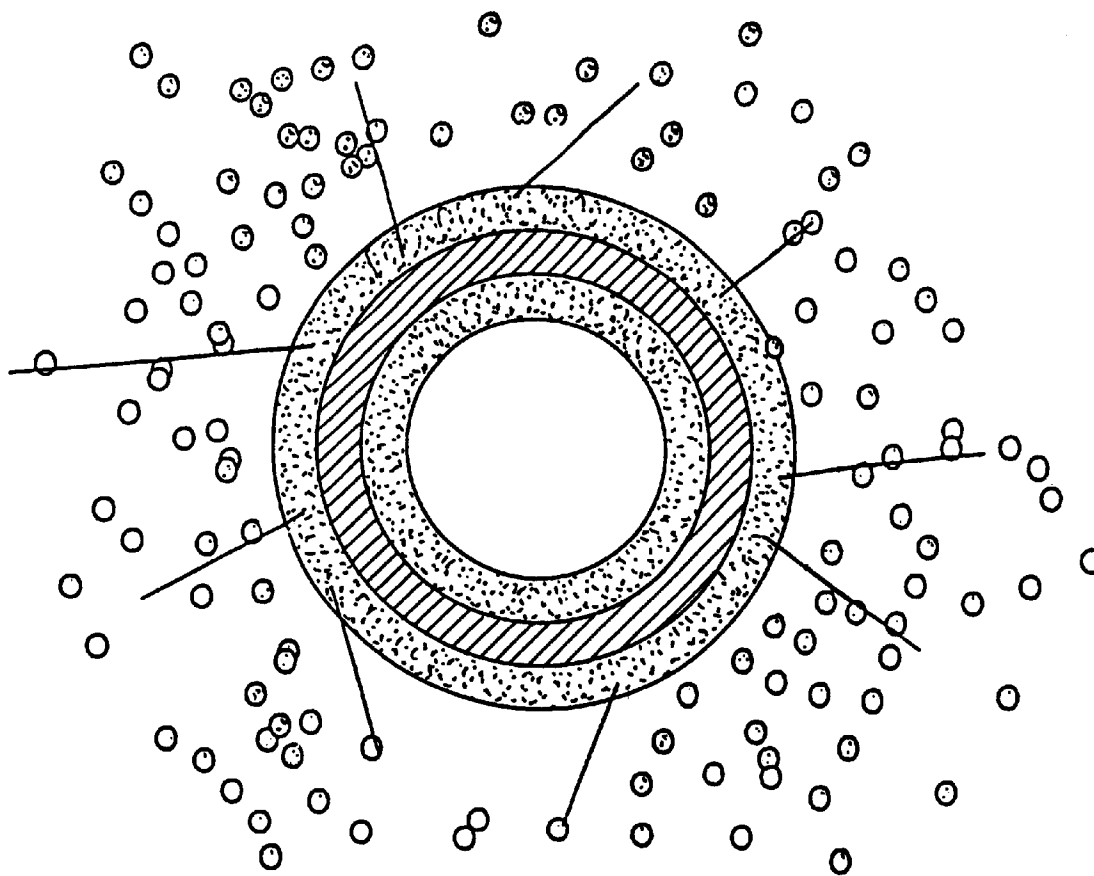


FIG. 2B

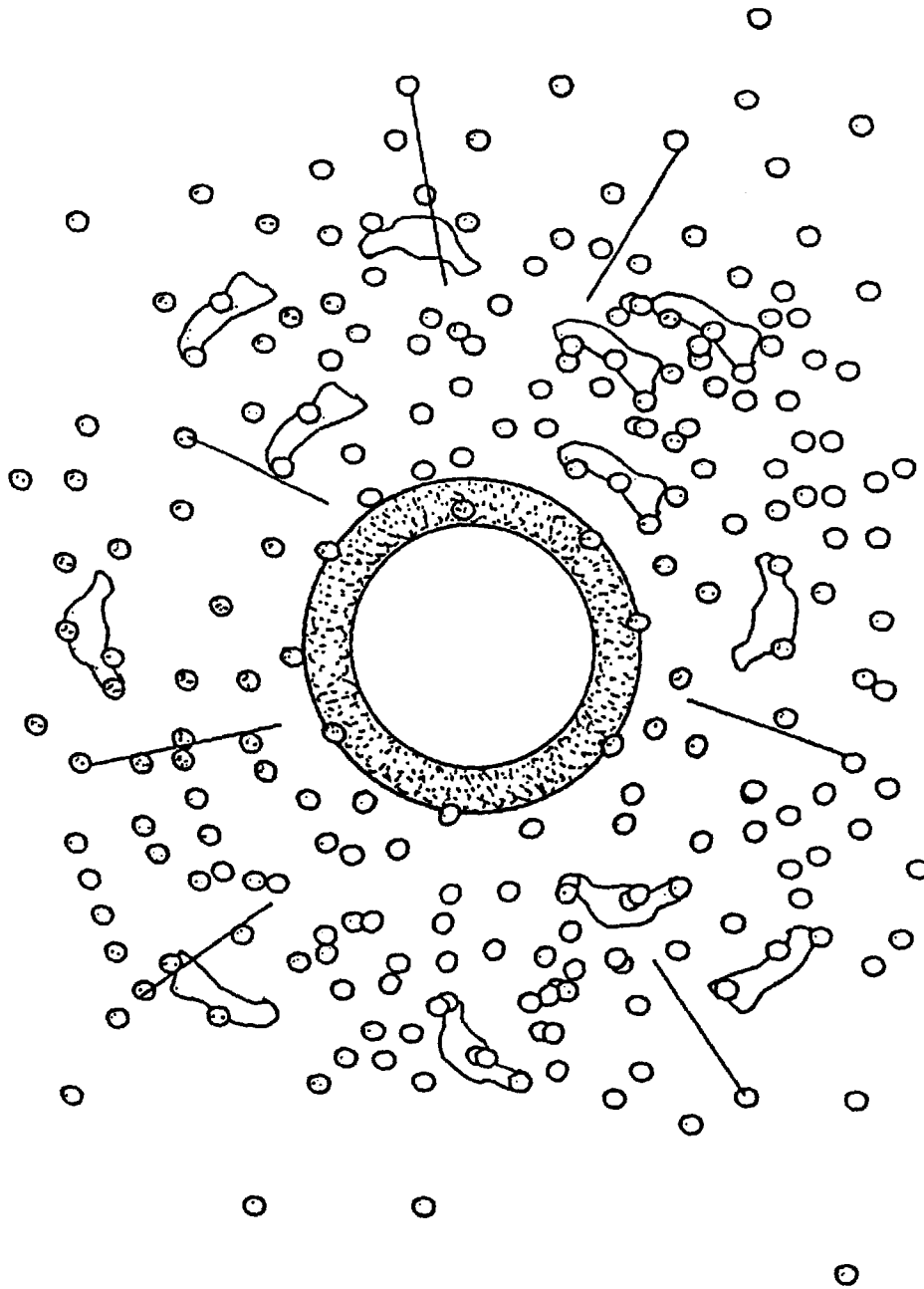


FIG. 2C

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