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Straub et al.(10) **Patent No.:** US 6,395,300 B1
(45) **Date of Patent:** *May 28, 2002(54) **POROUS DRUG MATRICES AND METHODS OF MANUFACTURE THEREOF**

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(51) **Int. Cl.⁷** A61K 9/14; A61K 47/02;
B29B 9/00(52) **U.S. Cl.** 424/489; 264/5(58) **Field of Search** 424/405, 400,
424/484, 489; 428/402; 264/5, 9, 11-13,

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Primary Examiner—Edward J. Webman(74) *Attorney, Agent, or Firm*—Holland & Knight LLP**ABSTRACT**

Drugs, especially low aqueous solubility drugs, are provided in a porous matrix form, preferably microparticles, which enhances dissolution of the drug in aqueous media. The drug matrices preferably are made using a process that includes (i) dissolving a drug, preferably a drug having low aqueous solubility, in a volatile solvent to form a drug solution, (ii) combining at least one pore forming agent with the drug solution to form an emulsion, suspension, or second solution, and (iii) removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous matrix of drug. The pore forming agent can be either a volatile liquid that is immiscible with the drug solvent or a volatile solid compound, preferably a volatile salt. In a preferred embodiment, spray drying is used to remove the solvents and the pore forming agent. The resulting porous matrix has a faster rate of dissolution following administration to a patient, as compared to non-porous matrix forms of the drug. In a preferred embodiment, microparticles of the porous drug matrix are reconstituted with an aqueous medium and administered parenterally, or processed using standard techniques into tablets or capsules for oral administration.

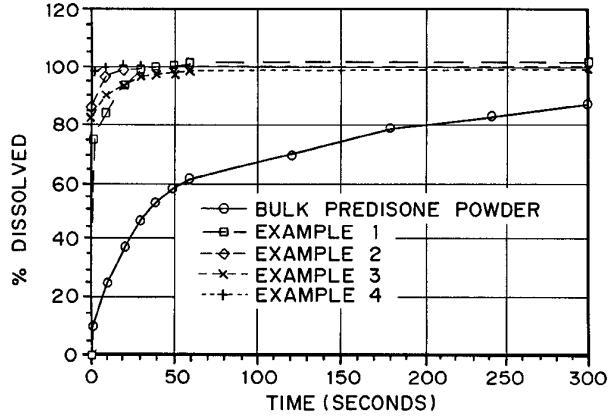
7 Claims, 4 Drawing Sheets

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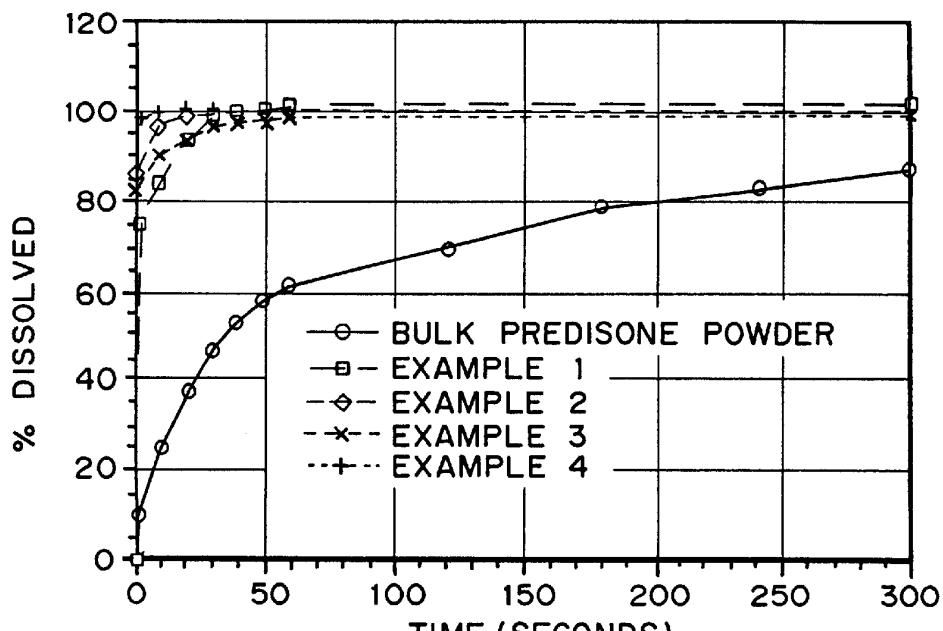
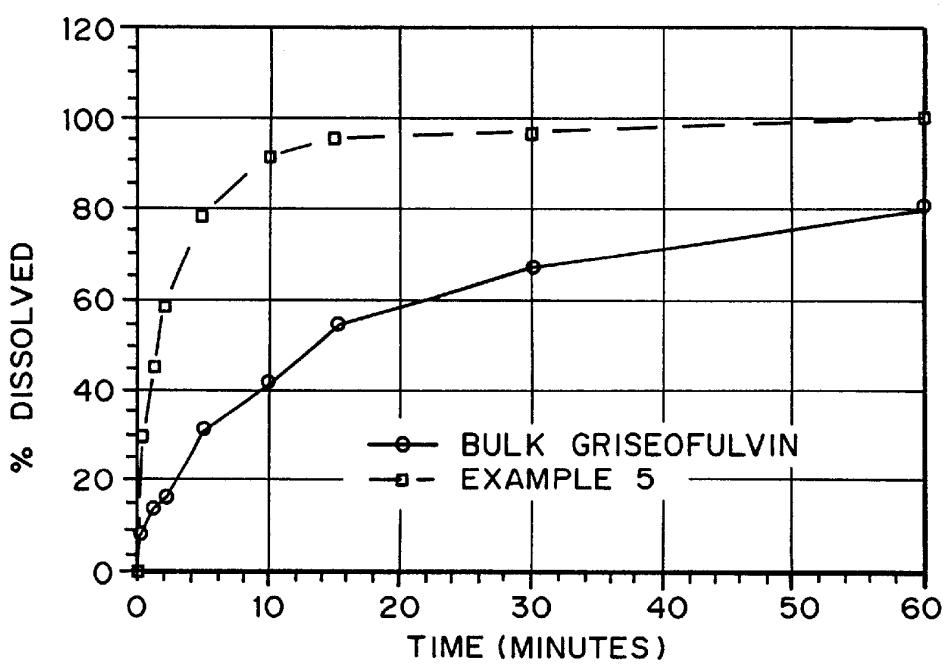
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**FIG. 1****FIG. 2**

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