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United States Patent [19]

Cheng et al.

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[45] Date of Patent: **Aug. 8, 2000**

- [54] **CONTROLLED RELEASE ORAL TABLET HAVING A UNITARY CORE**
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- [21] Appl. No.: **09/045,330**
- [22] Filed: **Mar. 20, 1998**
- [51] Int. Cl.⁷ **A61K 9/22**
- [52] U.S. Cl. **424/464; 424/469; 424/484; 424/468; 424/489**
- [58] Field of Search **424/464, 489, 424/450, 456**

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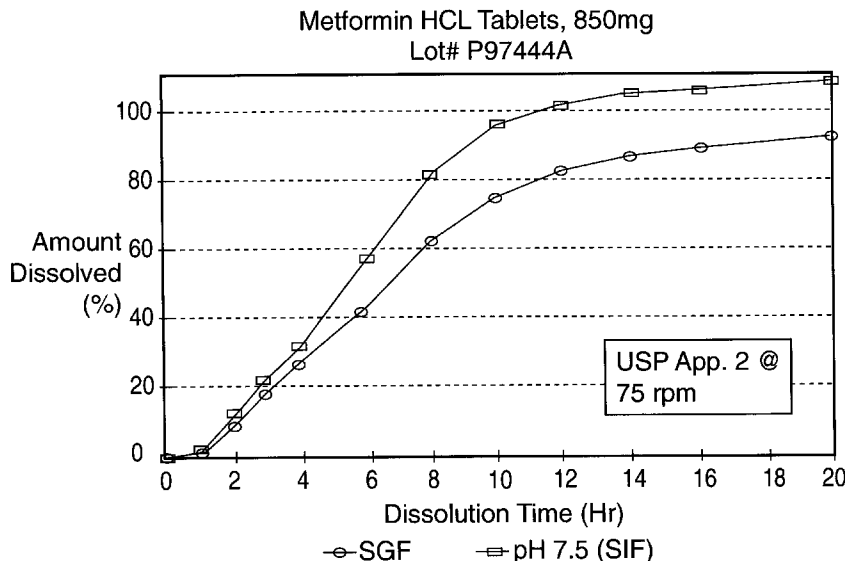
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[57] **ABSTRACT**

A controlled release antihyperglycemic tablet that does not contain an expanding polymer and comprising a core containing the antihyperglycemic drug, a semipermeable membrane coating the core and at least one passageway in the membrane.

29 Claims, 8 Drawing Sheets



Metformin HCL Tablets, 850mg
Lot# P97444A

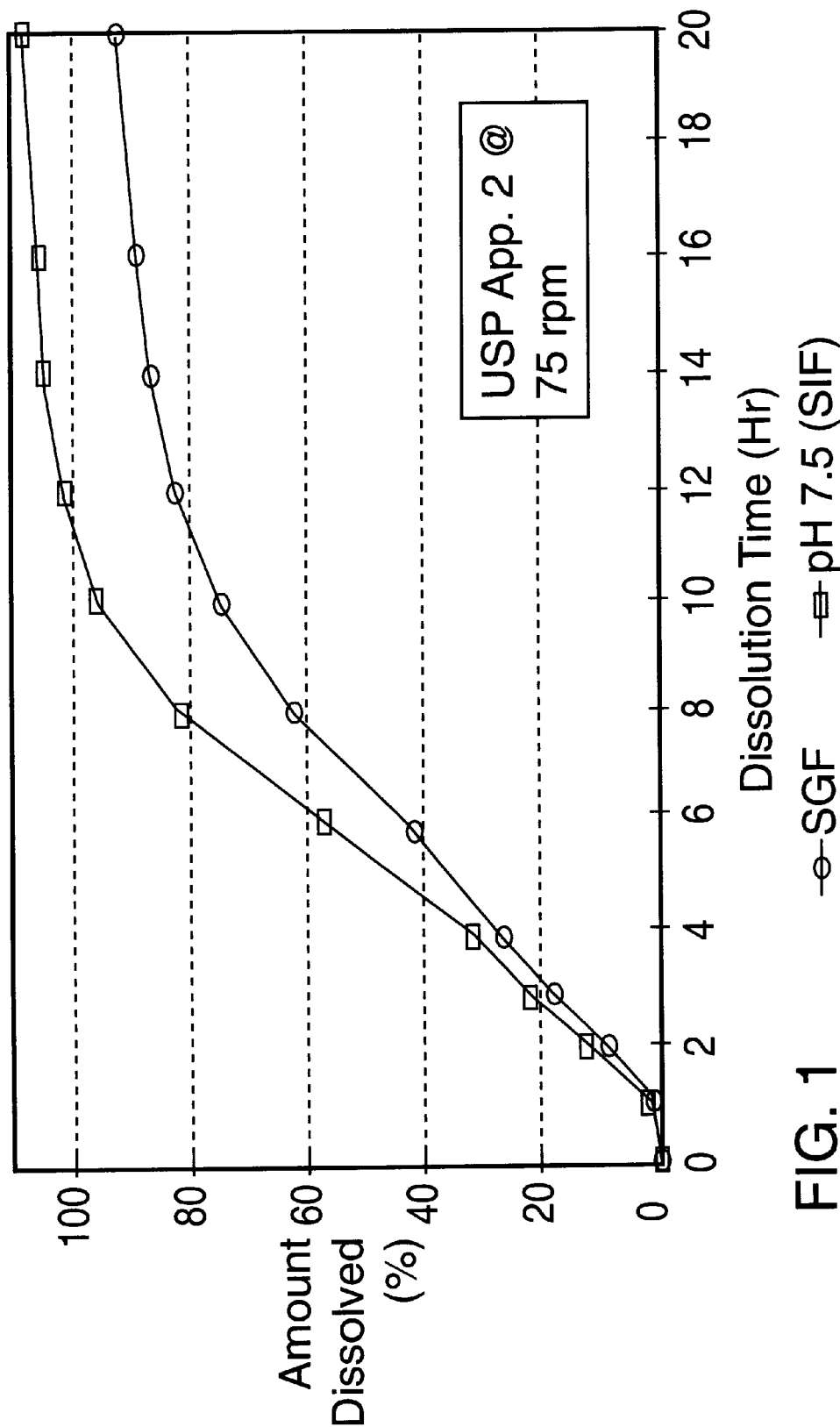


FIG. 1

Metformin HCL Tablets, 850mg
Lot# P97450A

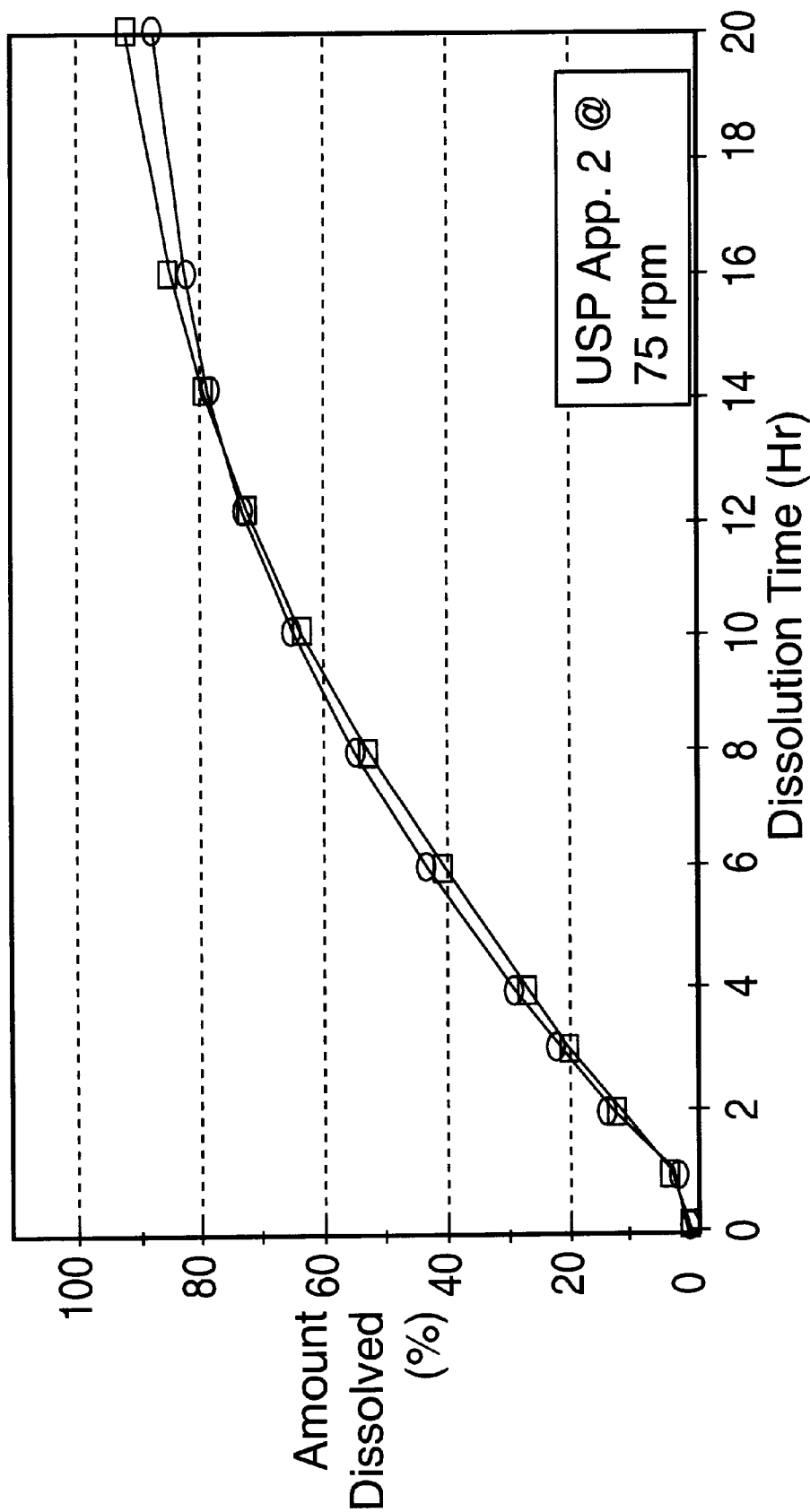


FIG. 2 ○—SGF □—pH 7.5 (SIF)

Metformin HCL Tablets, 850mg
Lot# P97450A-D

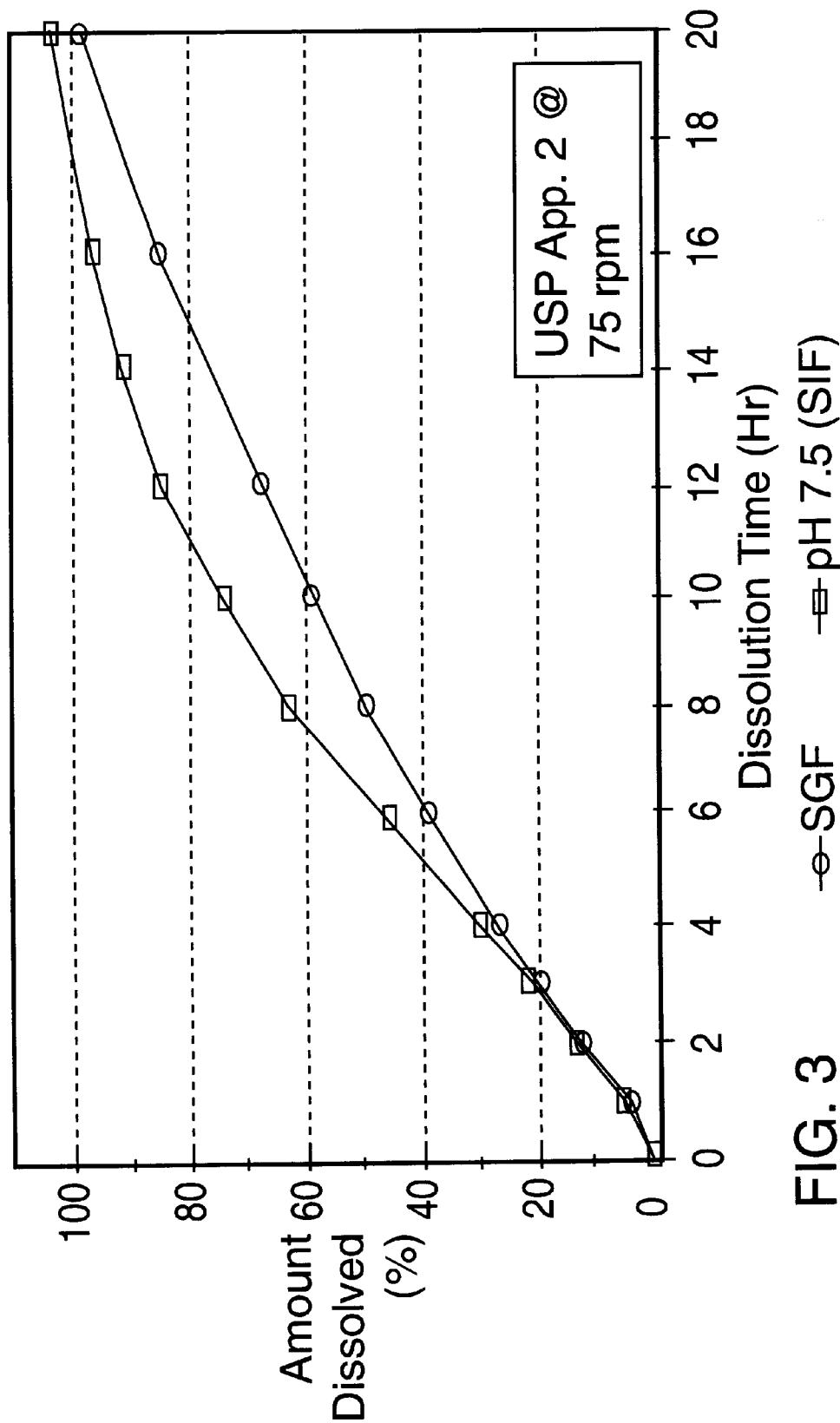


FIG. 3

Mean Metformin Conc. vs Time
Andrx Protocol P97-506 850mg. Fasting

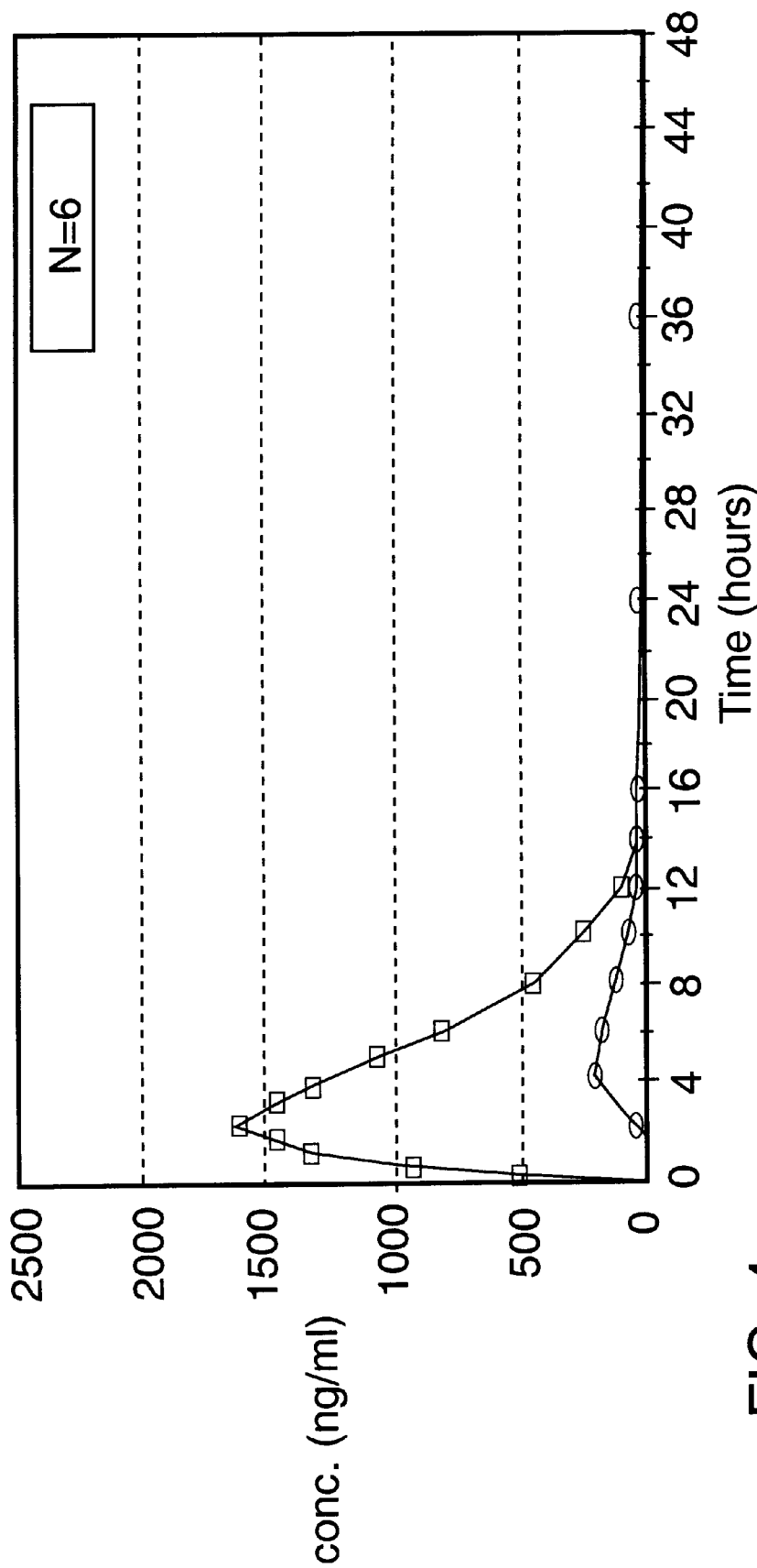


FIG. 4 —○— Andrx Metformin XL(P97444) —□— Glucophage (MAH82)

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