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Cheng et al.

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(54) **METHODS FOR TREATING DIABETES VIA ADMINISTRATION OF CONTROLLED RELEASE METFORMIN**

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A61K 9/20; A61K 9/22; A61K 9/27

(52) **U.S. Cl.** **424/468**; 424/464; 424/465;
424/469; 424/470; 424/472; 424/474; 424/489;
424/490

(58) **Field of Search** 424/473, 469,
424/474, 475, 479, 480, 482; 514/635,
588, 591, 592, 593

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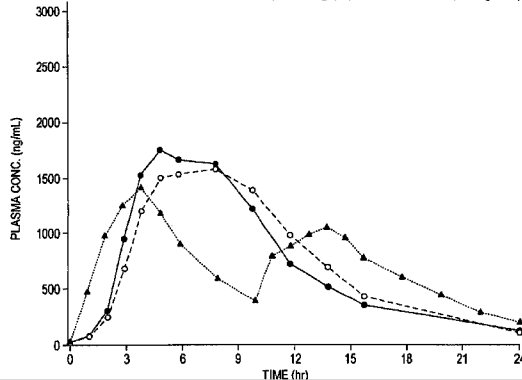
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(57) **ABSTRACT**

A method for treating patients having non-insulin-dependent diabetes mellitus (NIDDM) by administering a controlled release oral solid dosage form containing preferably a biguanide drug such as metformin, on a once-a-day basis. The dosage form provides a mean time to maximum plasma concentration (T_{max}) of the drug which occurs at a 5.5 to 7.5 hours after oral administration on a once-a-day basis to human patients. Preferably, the dose of drug is administered at dinnertime to a patient in the fed state.

21 Claims, 8 Drawing Sheets

MEAN PLASMA CONCENTRATION-TIME PROFILES OF METFORMIN IN ELEVEN SUBJECTS AFTER AN ORAL ADMINISTRATION OF METFORMIN XT (2 x 850 mg q.d.) OR GLUCOPHAGE (850 mg b.i.d.)



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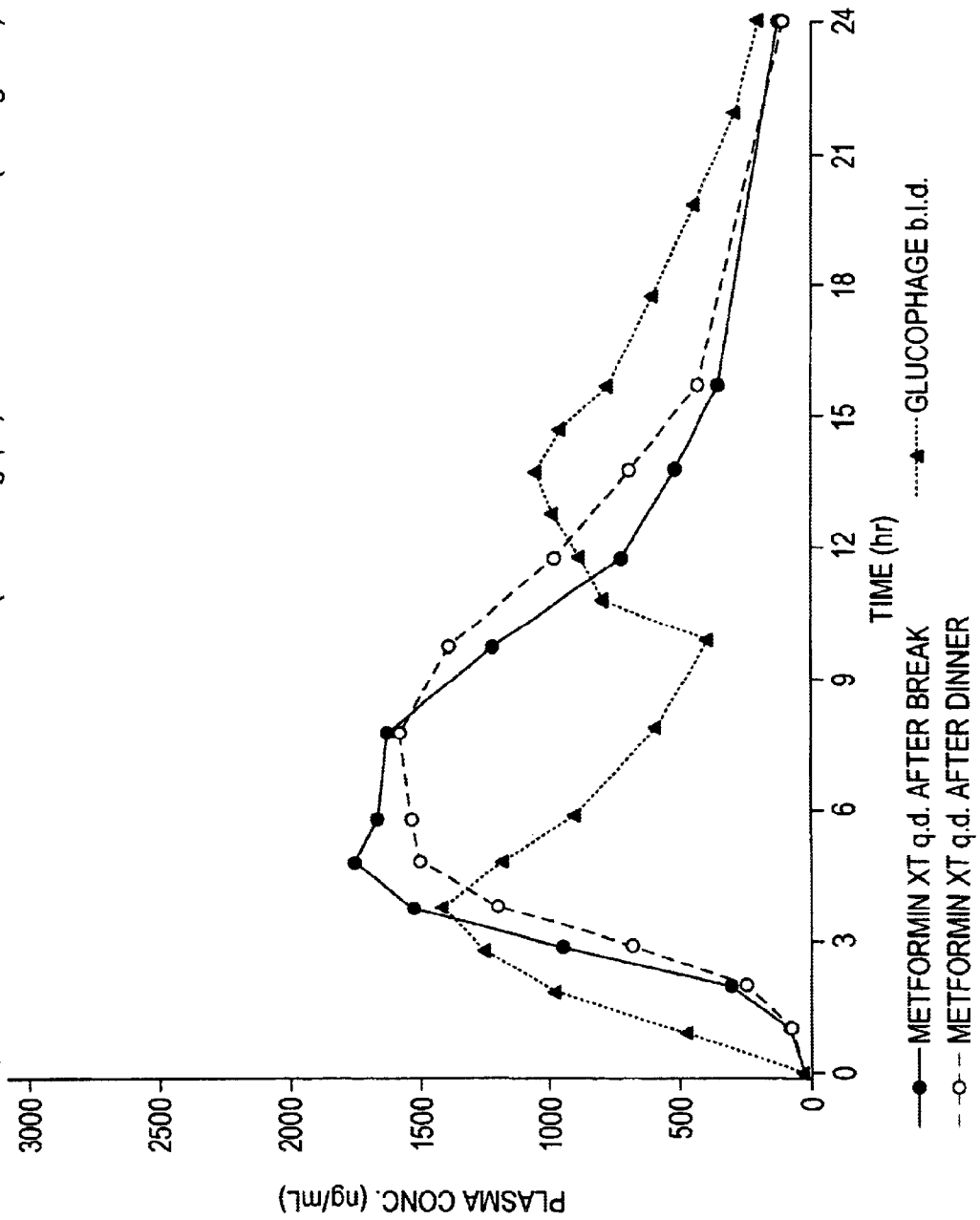


FIG. 1

MEAN PLASMA CONCENTRATION-TIME PROFILES OF METFORMIN IN TWELVE SUBJECTS AFTER AN ORAL ADMINISTRATION OF METFORMIN XT (4 x 500 mg q.d.) OR GLUCOPHAGE (2 x 500 mg b.i.d.)

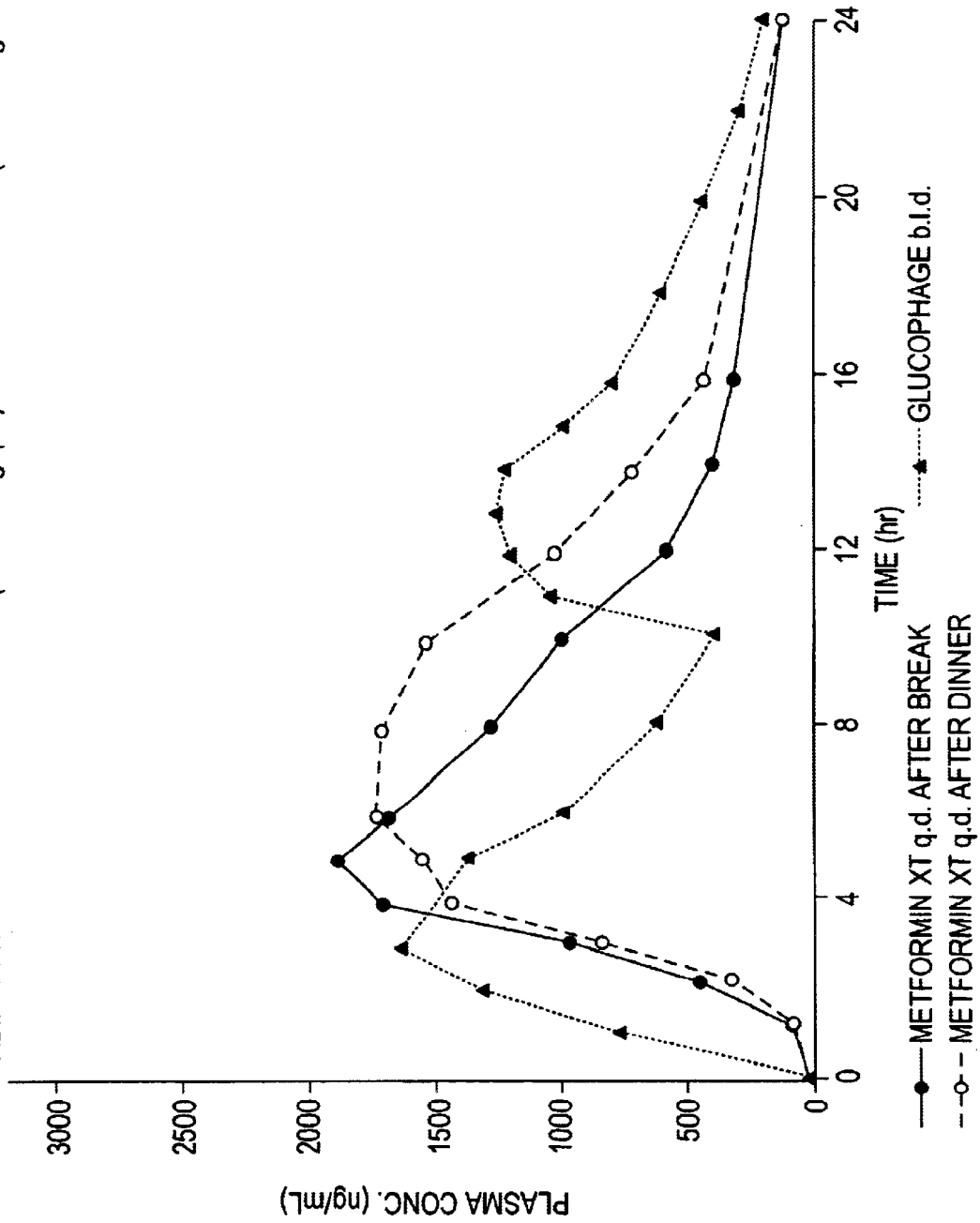


FIG. 2

MEAN PLASMA CONCENTRATION-TIME PROFILES OF METFORMIN IN EIGHT HEALTHY SUBJECTS AFTER MULTIPLE ORAL DOSES OF METFORMIN XT (4 x 500 mg q.d.)

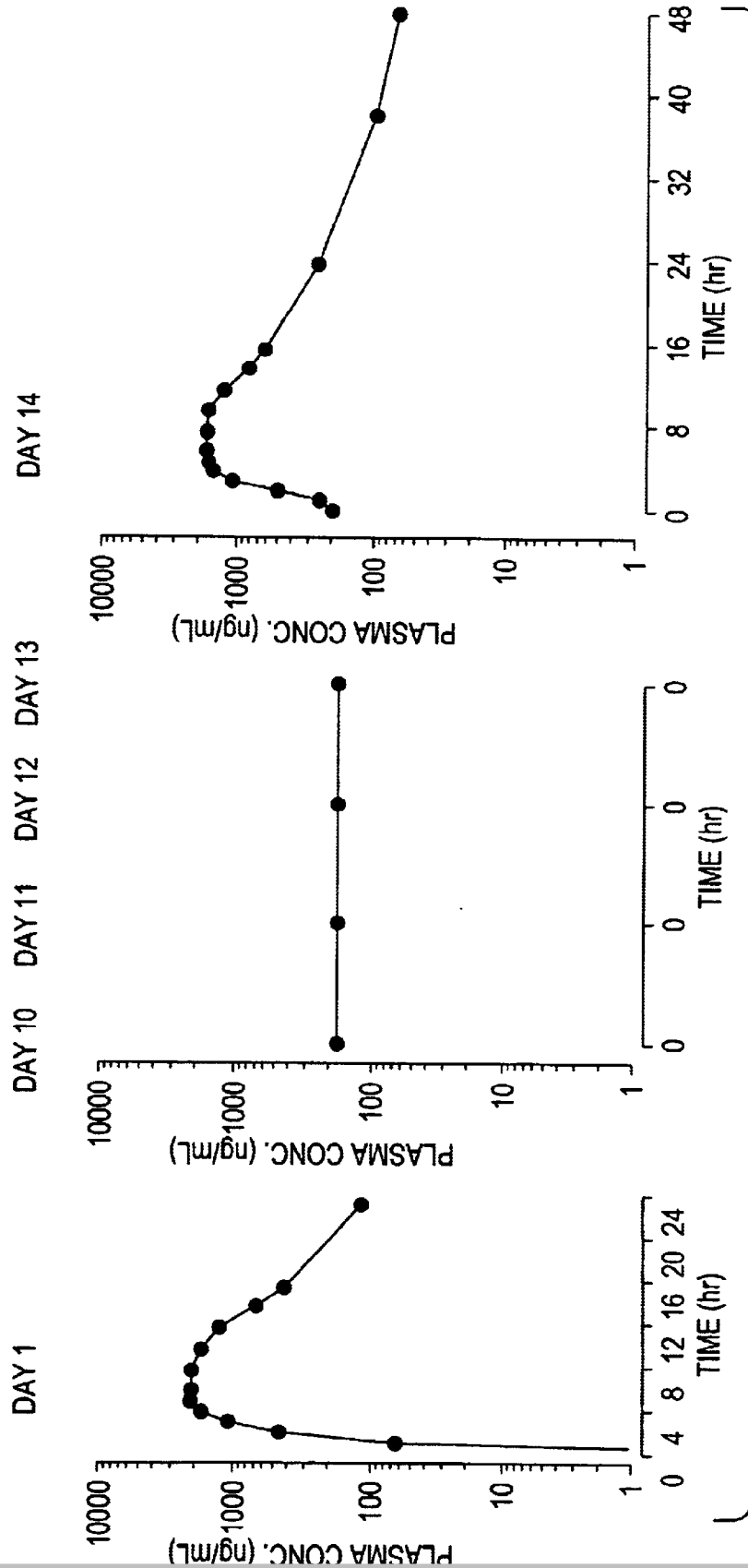


FIG. 3

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