

United States Patent [19]

Mehta et al.

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[54] **FORMULATIONS PROVIDING THREE DISTINCT RELEASES**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 731,175, May 6, 1985, abandoned.

[51] Int. Cl.⁴ **A61K 9/52; A61K 9/54; A61K 9/58**

[52] U.S. Cl. **424/458; 424/453; 424/457; 424/459; 424/461; 424/462**

[58] Field of Search **424/14, 16, 19-22, 424/37, 453, 457, 458, 459, 461, 462**

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[57] ABSTRACT

A therapeutic preparation consisting of three groups of spheroids containing an active medicinal substance. The first group of spheroids is uncoated and rapidly disintegrates upon ingestion to release an initial dose of medicinal substance a second group of spheroids is coated with a pH sensitive coat to provide a second dose and a third group of spheroids is coated with a pH independent coat to provide a third dose. A powder blend of active medicinal substance may be substituted for the first group of uncoated spheroids.

The therapeutic preparation may be utilized as a mixture of groups of spheroids in a capsule.

9 Claims, 6 Drawing Figures

FIG. 1

DISSOLUTION PROFILE OF COMPOSITE
CAPSULE PRODUCED IN EXAMPLE 3

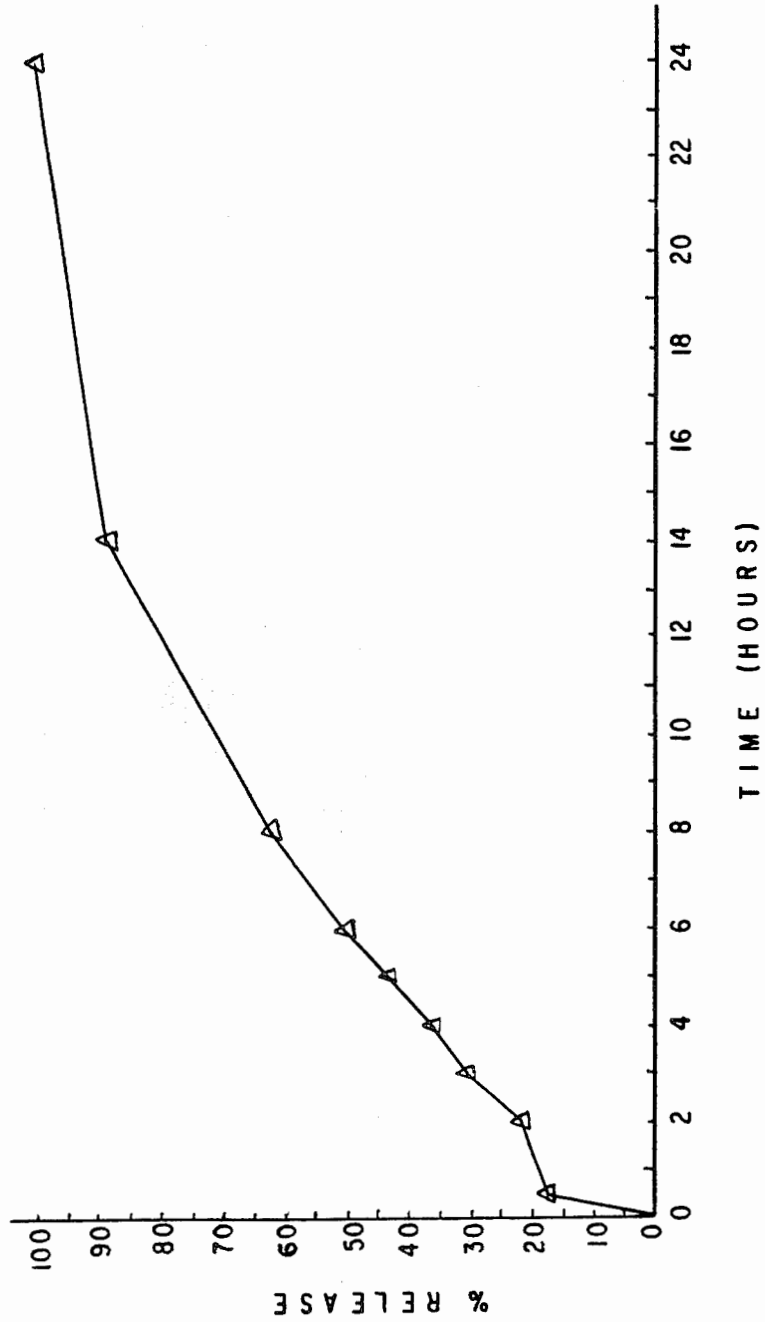


FIG. 2

PROPRANOLOL HCL DISSOLUTION PROFILE OF FIRST DOSE
IMMEDIATE RELEASE IN EXAMPLES 2,3 & 4 UNCOATED
SPHERES VS EXAMPLE 1 POWDER BLEND

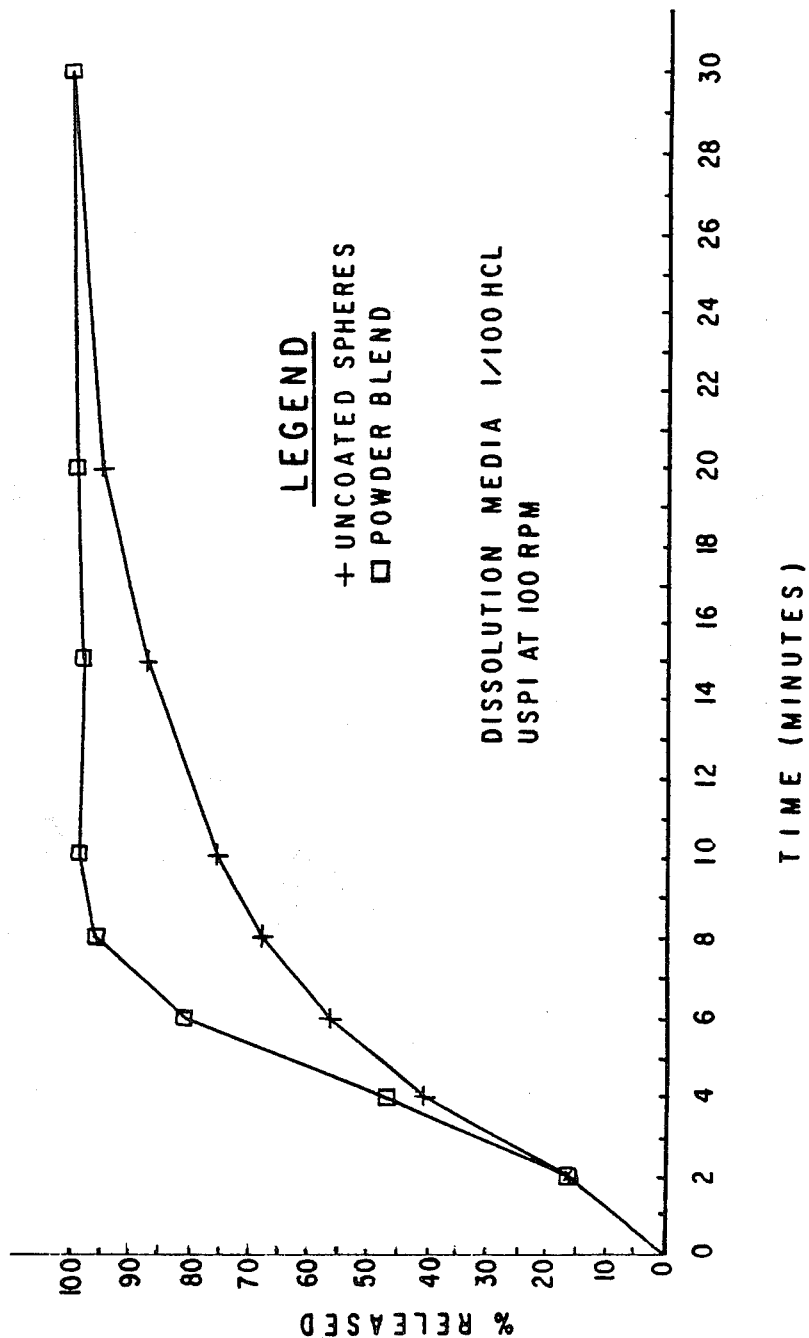


FIG. 3

DISSOLUTION PROFILE OF SECOND DOSE IN
EXAMPLE 1, 2, 3 & 4

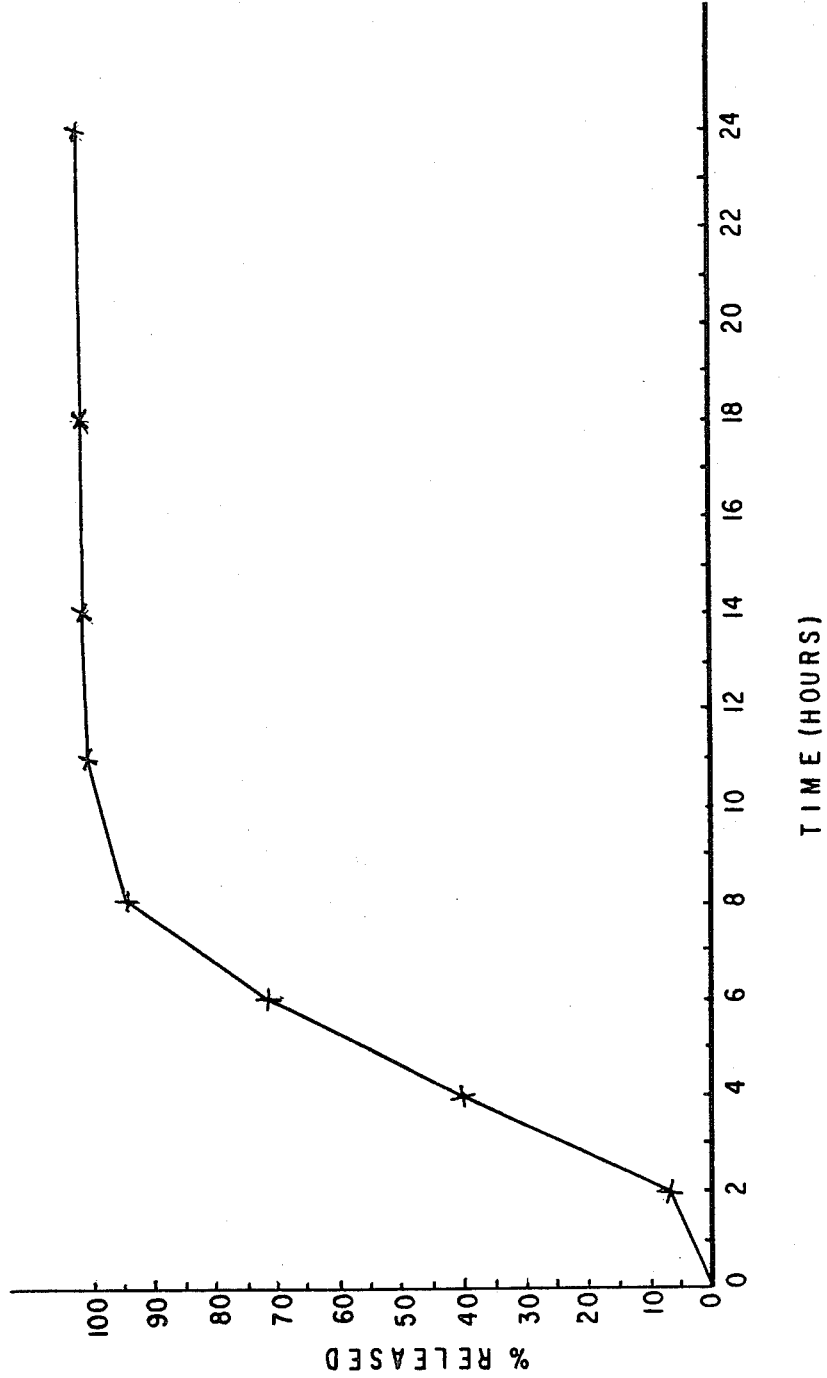
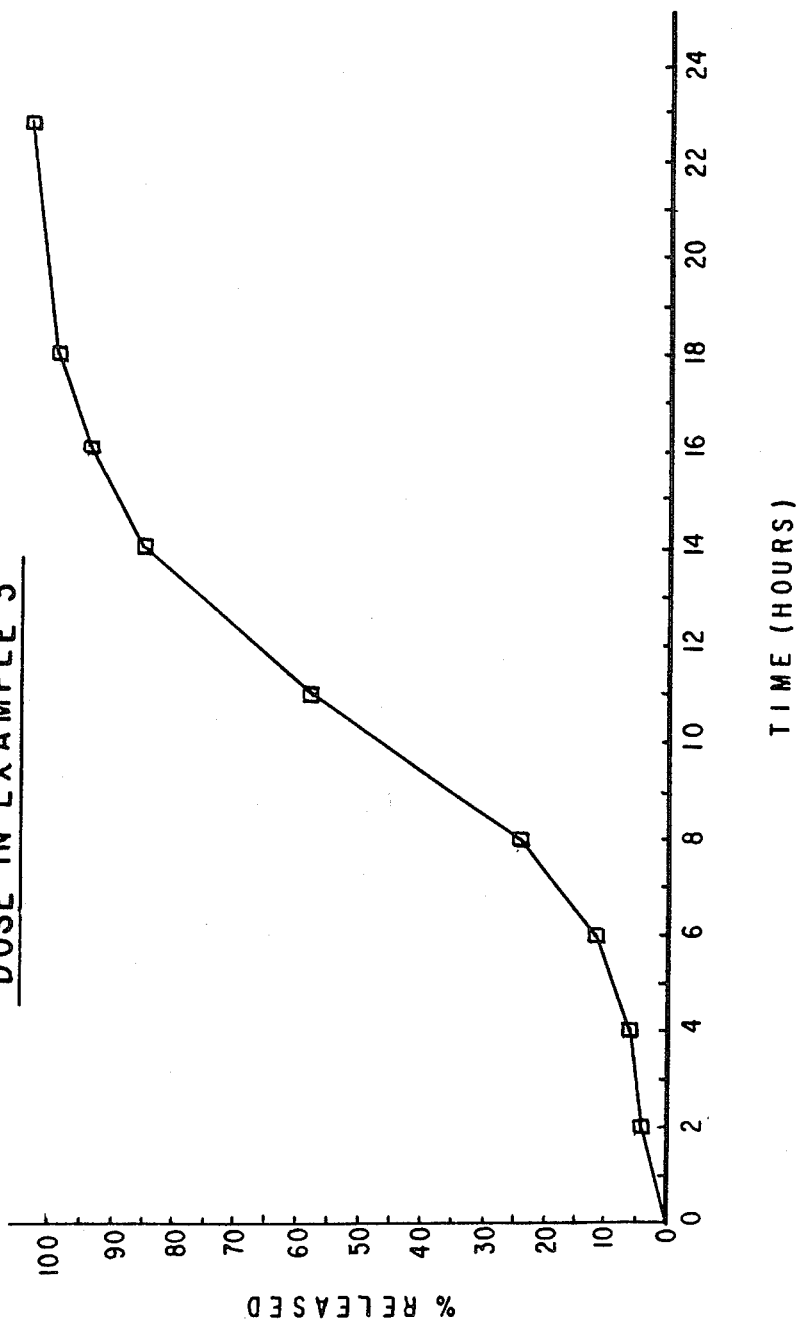


FIG. 4

DISSOLUTION PROFILE OF THIRD
DOSE IN EXAMPLE 3



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