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(12) **United States Patent**
Groman et al.

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(54) **POLYOL AND POLYETHER IRON OXIDE COMPLEXES AS PHARMACOLOGICAL AND/OR MRI CONTRAST AGENTS**

6,165,378 A 12/2000 Maruno et al. 252/62.53

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(73) Assignee: **AMAG Pharmaceuticals, Inc.**, Lexington, MA (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 933 days.

This patent is subject to a terminal disclaimer.

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(21) Appl. No.: **10/410,527**

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(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 09/521,264, filed on Mar. 8, 2000, now Pat. No. 6,599,498.

(60) Provisional application No. 60/128,579, filed on Apr. 9, 1999.

(51) **Int. Cl.**

A61B 5/055 (2006.01)

A01N 43/04 (2006.01)

A61K 31/715 (2006.01)

(52) **U.S. Cl.** **424/9.3; 424/9.351; 514/23; 514/54; 514/59**

(58) **Field of Classification Search** 424/646, 424/9.3; 514/23, 54, 59
See application file for complete search history.

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(57) **ABSTRACT**

Pharmacological compositions, and methods for administration, of the type employing an iron oxide complex with a polyol or polyether. The methods of administration may comprise parenteral administration of an effective dose of the complex formulated in a biocompatible liquid delivered at a rate of from about 1 mL/sec to less than 1 mL/min and wherein upon administration the complex provides minimal detectable free iron in a subject, and minimal incidence of anaphylaxis. The pharmacological compositions are of the type employing a polyol or polyether iron oxide complex, which, upon parenteral administration to a subject, are substantially immunosilent, provide minimal anaphylaxis and minimal free iron, and undergo minimal dissolution in vivo.

8 Claims, 13 Drawing Sheets

Percent Cross-Reactivity to α -Dextran for C-7228 versus INFeD® Using ELISA

ELISA Results Using Rat Serum Raised to Dextran-BSA

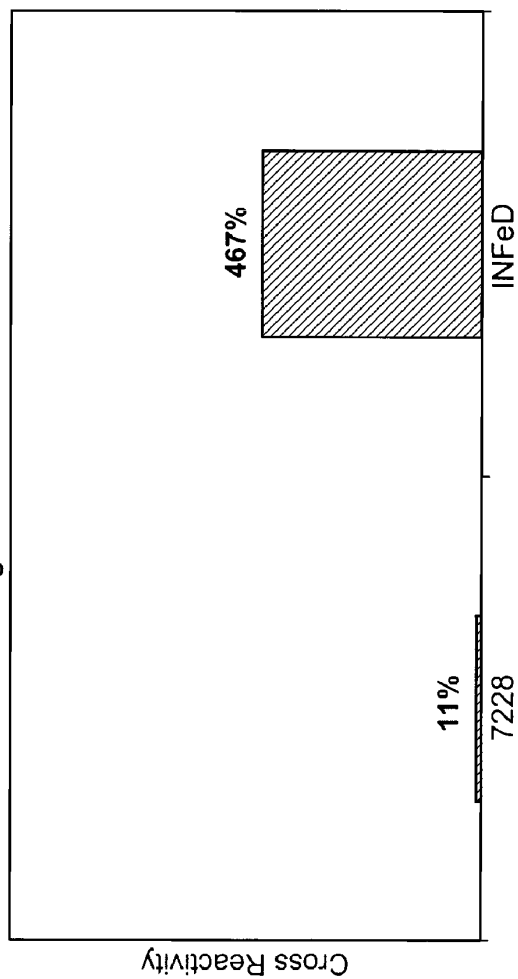


FIG. 1

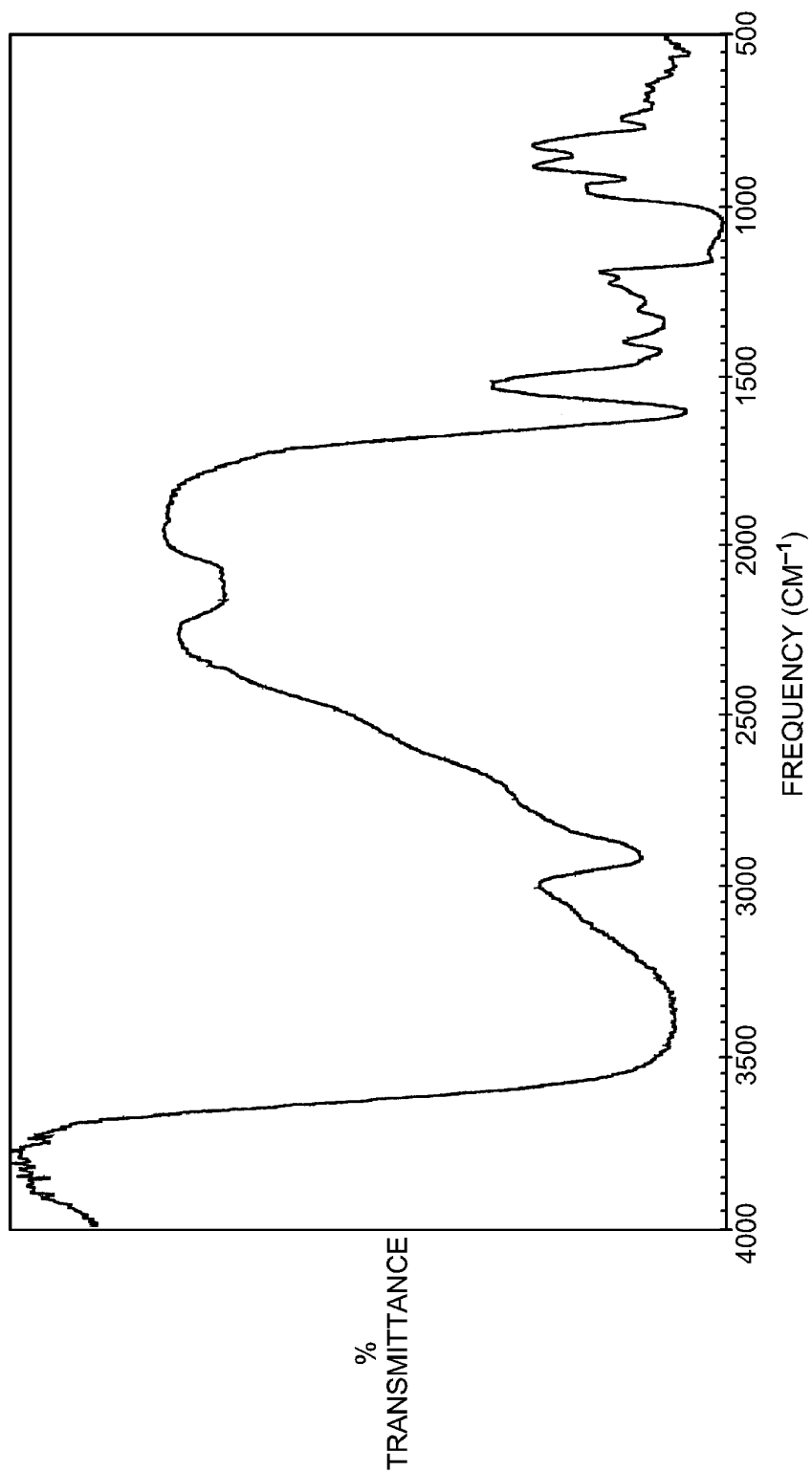


FIG. 2

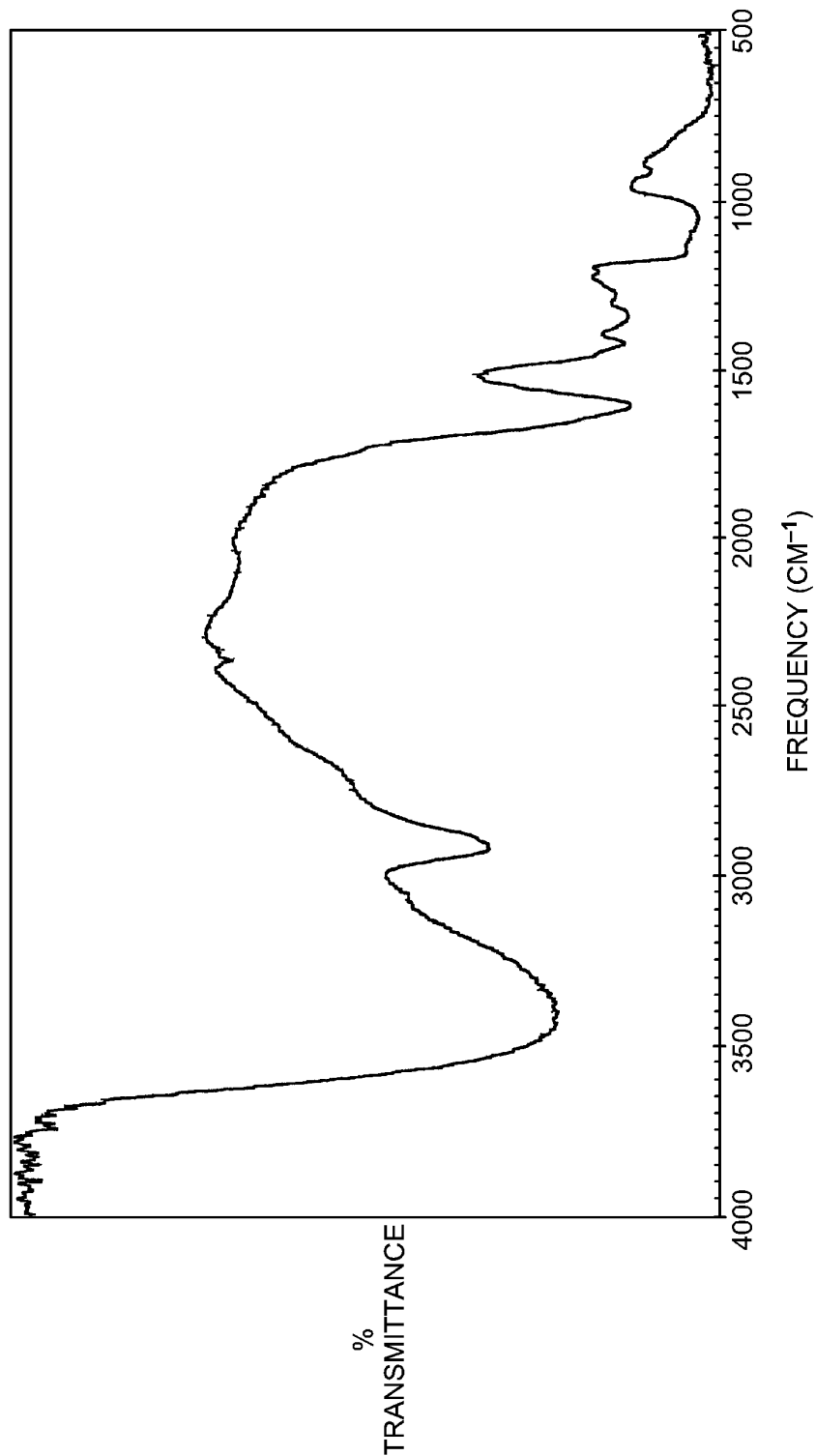


FIG. 3

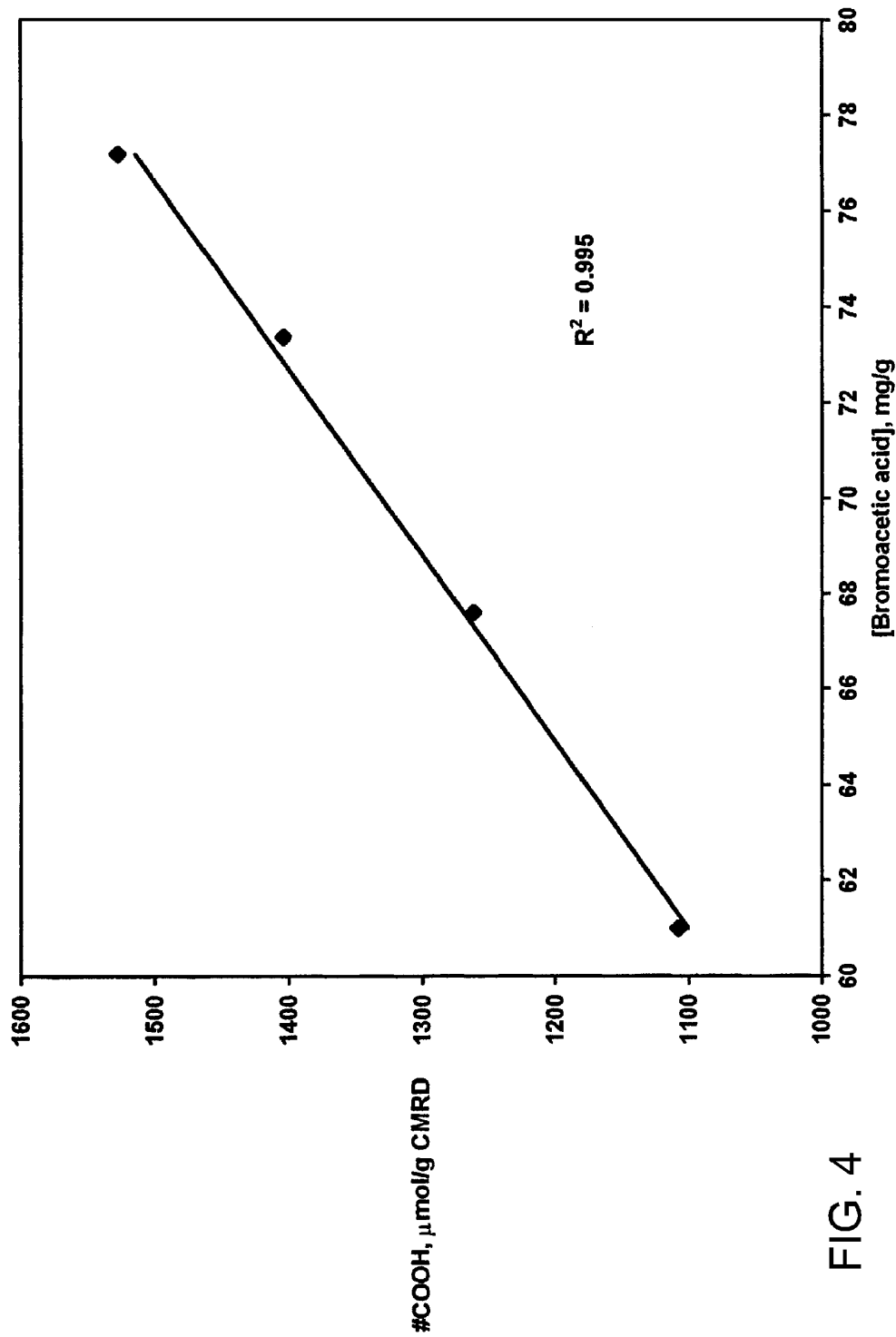


FIG. 4

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