United States Patent [19]

Lawrence et al.

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[54] **IRON DEXTRAN FORMULATIONS**

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[52] U.S. Cl. **424/78.17**; 424/647
[58] Field of Search 424/421, 647, 424/78.17

[56] **References Cited**

U.S. PATENT DOCUMENTS

Re. 24,642	4/1959	London et al. .
2,820,740	1/1958	London et al. .
2,885,393	5/1959	Herb .
3,686,397	8/1972	Muller .
3,697,502	10/1972	Christensen .
3,908,004	9/1975	Kitching .
4,101,435	7/1978	Hasegawa et al. .
4,180,567	12/1979	Herb .
4,452,773	6/1984	Molday 436/526
4,454,773	6/1984	Brunner et al. .
4,505,726	3/1985	Takeuchi et al. .
4,599,405	7/1986	Muekker et al. .
4,659,697	4/1987	Tanaka .
4,749,695	6/1988	Schwengers .
4,788,281	11/1988	Tosoni et al. .
4,927,756	5/1990	Schwengers .
5,102,652	4/1992	Groman et al. .
5,118,513	6/1992	Mehansho et al. .
5,248,492	9/1993	Groman et al. .
5,336,506	8/1994	Josephson et al. .
5,354,350	10/1994	Moore .

OTHER PUBLICATIONS

P. Carthew et al., *Hepatology*, vol. 13, No. 3, pp. 534–539 (1991): Rapid Induction of Hepatic Fibrosis in the Gerbil After the Parenteral Administration of Iron–Dextran Complex.

L.M. Fletcher, et al., *Gastroenterology*, vol. 97, pp. 1011–1018 (1989): Effects of Iron Loading on Free Radical Scavenging Enzymes and Lipid Peroxidation in Rat Liver.

R.D. Hamstra et al., *JAMA*, vol. 243, No. 17, pp. 1726–1731 (1980): Intravenous Iron Dextran in Clinical Medicine.

P.A. Henderson et al., *Blood*, vol. 34, No. 3, pp. 357–375 (1969): Characteristics of Iron Dextran Utilization in Man.

T. O. Pitts et al., *Nephron*, vol. 22, pp. 316–321 (1978): Hemosiderosis Secondary to Chronic Parenteral Iron Therapy in Maintenance Hemodialysis Patients.

L. R. Weintraub et al., *British Journal of Haemotology*, vol. 59, pp. 321–331 (1985): Pathogenesis of Hepatic Fibrosis in Experimental Iron Overload.
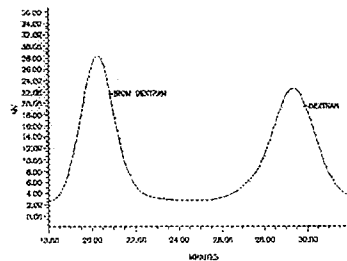
Package Insert for *INFeD* (Iron Dextran Injection, USP).

Package Insert for *Imferon* (Iron Dextran Injection, USP).

1994 ASH Abstract Reproduction Form, 36th Annual Meeting, Nashville, TN (1994): "Pharmacokinetics of Iron Dextran In Iron Deficient Dialysis Patients: Evaluation and Comparison of Two Agents", by D. Van Wyck et al.

1994 ASH Abstract Reproduction Form, 36th Annual Meeting, Nashville, TN (1994): "Iron Mobilization Early After Iron Dextran Infusion in Hemodialysis Patients: Evaluation and Comparison of 2 Agents", by D. Van Wyck et al.

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[57] **ABSTRACT**

Ferric oxyhydroxide-dextran compositions for treating iron deficiency having ellipsoidal particles with a preferred molecular weight range of about 250,000 to 300,000 daltons.
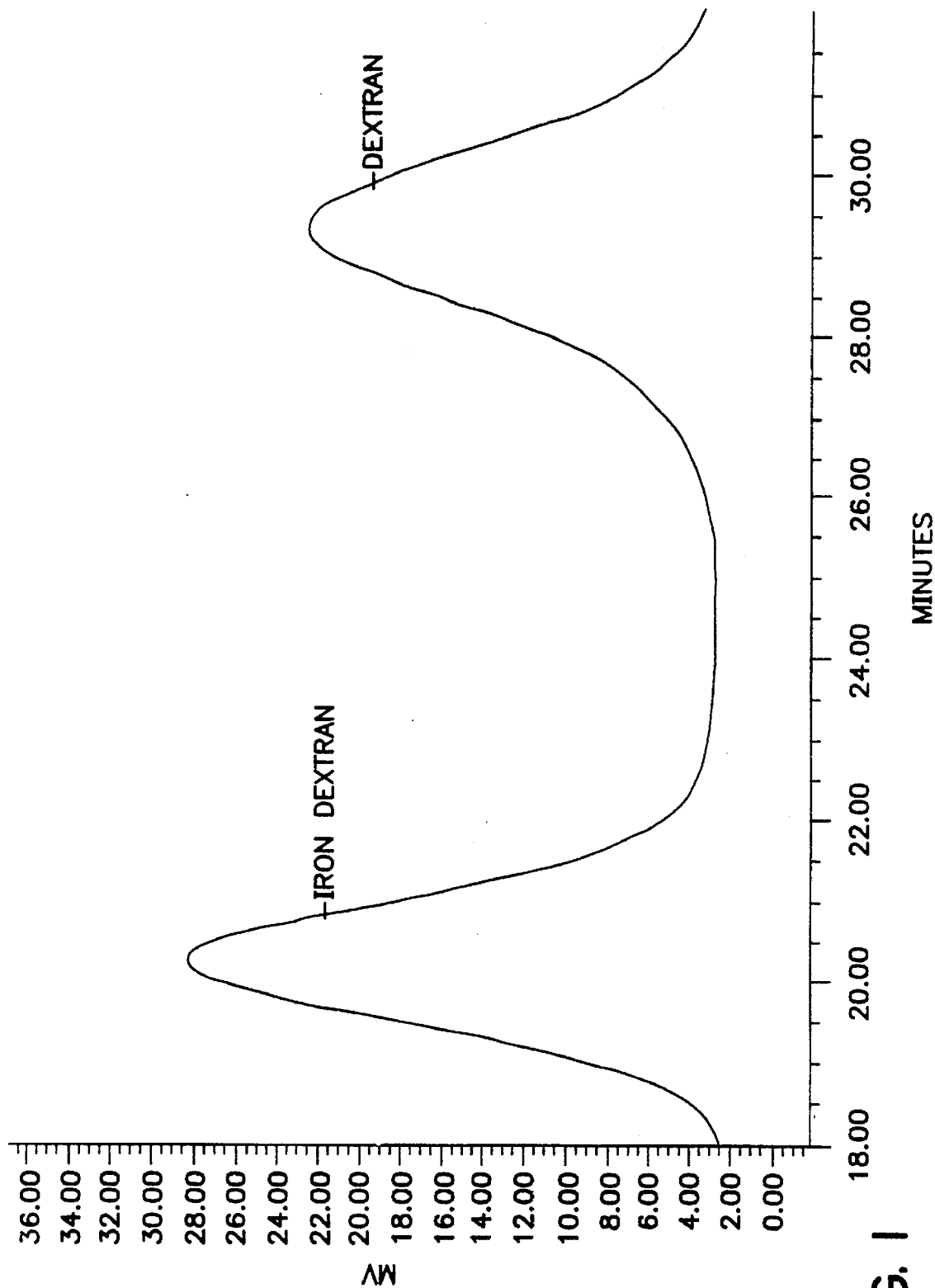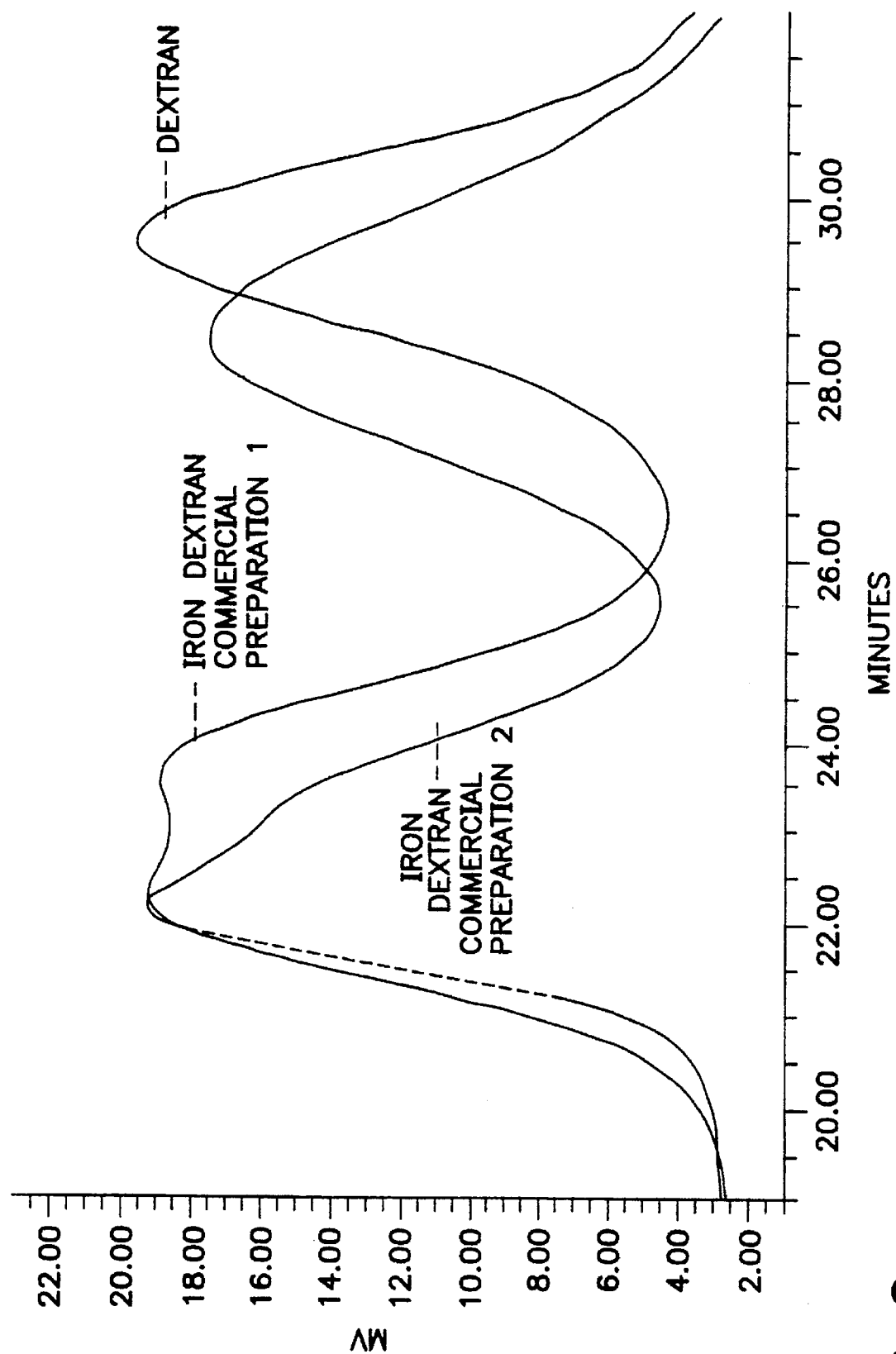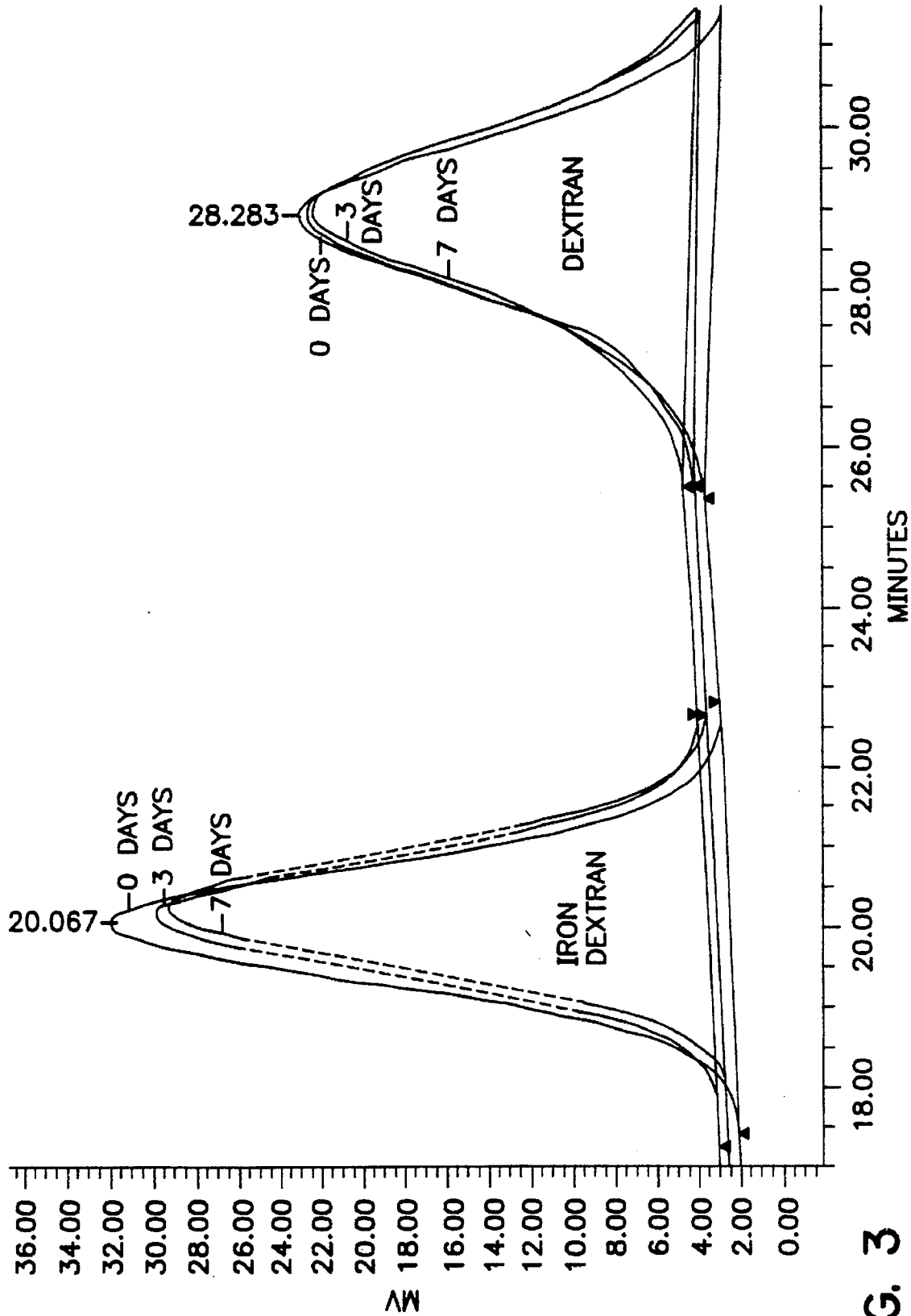
28 Claims, 6 Drawing Sheets

FIG. 1

FIG. 2

FIG. 3

FIG. 4

DOCKET ALARM
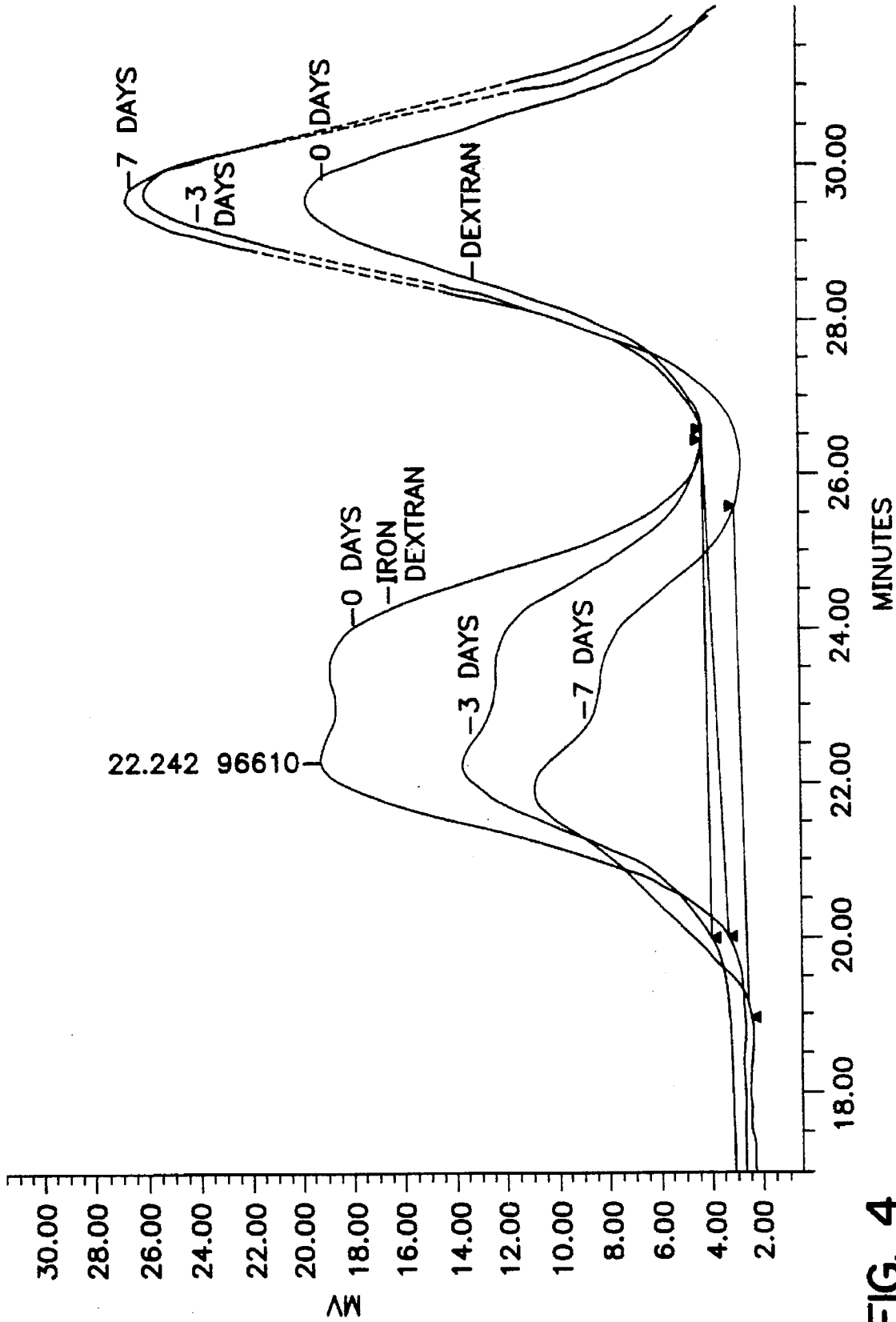
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