

FINISHED PRODUCT SPECIFICATIONS

Iron Dextran 5 % Powder

<u>TEST</u>	<u>SPECIFICATION</u>
Appearance	Light brown to Dark Brown Powder
Iron Concentration	14.0 % - 18.0 % (w/w)
Chloride Concentration	NMT 2.0 % (w/w)
Loss on Drying:	NMT 10.0 %

FINISHED PRODUCT SPECIFICATIONS

Iron Dextran 10% Powder

<u>TEST</u>	<u>SPECIFICATION</u>
Appearance	Dark Brown Powder
Iron Concentration	28.0% - 33.0% (w/w)
Chloride Concentration	2.4% - 3.3% (w/w)
Loss on Drying	NMT 10.0%

FINISHED PRODUCT SPECIFICATIONS

Liquid Iron Dextran 10%

<u>TEST</u>	<u>SPECIFICATION</u>
Appearance	Dark brown slightly viscous liquid
Identification	Passes (Identification for Iron Dextran Injection, USP)
pH:	4.5 to 7.0
Iron Content	9.5% to 10.5% (w/v)
Chloride Content	0.8% to 1.1% (w/v)
Dextran Content	8.0% to 15.0% (w/v)
Total Free Iron Content	NMT 0.30% (w/v)
Free Ferrous Iron Content	NMT 0.20% (w/v)
Free Ferric Iron Content	NMT 0.30% (w/v)
Non-Volatile Residue	Minimum 24.0% (w/v)
Phenol Content	NMT 0.5% (w/v)
Relative Viscosity	NMT 20 at 25°C
Endotoxins	NMT 0.50 EU/mg
Absorption from Injection Site	Passes (In-House Method)
Acute Toxicity USP)	Passes (Acute Toxicity for Iron Dextran Injection, USP)
Total Aerobic Microbial Count	Less Than 50 CFU/mL