FINISHED PRODUCT SPECIFICATIONS

TEST	SPECIFICATION
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 Ion Content	NMT 0.20% (w/v)
Free Ferric Ion Content	NMT 0.30% (w/v)
Non-Volatile Residue	Minimum 24.0% (w/v)
Phenol Content	NMT 0.5% (w/v)
Relative Viscosity at 25°C	NMT 20
Endotoxins	NMT 0.50 EU/mg
Absorption from Injection Site	Passes (In-House Method)
Acute Toxicity	Passes (Acute Toxicity for Iron Dextran Injection, USP)
Total Aerobic Microbial Count	NMT 50 CFU/mL

Written By:		Title: Analytical Chemist	Date: April 27, 2021
Revised By:		Title: QC Manager	Date: April 27, 2021
Approved By:		Title QA Manager	Date: April 27, 2021